

changes must be filed. The new sheets of drawings must be filed with the amended figures being identified as "amended" and with added figures identified as "new" for each sheet that has changed. In the event that a figure is canceled, the figure must be surrounded by brackets and identified as "Canceled." See also MPEP § 1413 for a further discussion as to the drawings.

Form paragraph 14.20.01 may be used to advise applicant of the proper manner of making amendments in a reissue application.

¶ 14.20.01 *Amendments To Reissue-37 CFR 1.173(b)*

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

Examiner Note:

This form paragraph may be used in the first Office action to advise applicant of the proper manner of making amendments.

Form paragraph 14.21.01 may be used to notify applicant that proposed amendments **filed prior to final rejection** in the reissue application do not comply with 37 CFR 1.173(b).

¶ 14.21.01 *Improper Amendment To Reissue - 37 CFR 1.173(b)*

The amendment filed [1] proposes amendments to [2] that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

A shortened statutory period for reply to this letter is set to expire ONE MONTH or THIRTY DAYS, whichever is longer, from the mailing date of this letter.

Examiner Note:

This form paragraph may be used for any 37 CFR 1.173(b) informality as to an amendment submitted in a reissue application prior to final rejection. After final rejection, applicant should be informed that the amendment will not be entered in an Advisory Office action.

Note that if an informal amendment is submitted **after final rejection**, form paragraph 14.21.01 should not be used. Rather, an advisory Office action should be issued using Form PTO-303 indicating that the amendment was not entered because it does not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications.

ALL CHANGES ARE MADE VIS-À-VIS THE PATENT TO BE REISSUED

When a reissue patent is printed, all underlined matter is printed in *italics* and all brackets are printed

as inserted in the application, in order to show exactly which additions and deletions have been made to the patent being reissued. Therefore, all underlining and bracketing in the reissue application should be made relative to the text of the patent, as follows. In accordance with 37 CFR 1.173(g), all amendments in the reissue application must be made relative to (i.e., *vis-à-vis*) the patent specification in effect as of the date of the filing of the reissue application. The patent specification includes the claims and drawings. If there was a prior change to the patent (made via a prior concluded reexamination certificate, reissue of the patent, certificate of correction, etc.), the first amendment of the subject reissue application must be made relative to the patent specification as changed by the prior proceeding or other mechanism for changing the patent. All amendments subsequent to the first amendment must also be made relative to the patent specification in effect as of the date of the filing of the reissue application, and **not** relative to the prior amendment.

The Subject Patent Already Has Underlining or Bracketing

If the original (or previously changed) patent includes a formula or equation already having underlining or bracketing therein as part of the formula or equation, any amendment of such formula or equation should be made by bracketing the entire formula and rewriting and totally underlining the amended formula in the re-presented paragraph of the specification or rewritten claim in which the changed formula or equation appears. Amendments of segments of a formula or equation should not be made. If the original patent includes bracketing and underlining from an earlier reexamination or reissue, double brackets and double underlining should be used in the subject reissue application to identify and distinguish the present changes being made. The subject reissue, when printed, would include double brackets (indicating deletions made in the subject reissue) and boldface type (indicating material added in the subject reissue).

EXAMPLES OF PROPER AMENDMENTS

A substantial number of problems arise in the Office because of improper submission of amendments in reissue applications. The following examples

are provided to assist in preparation of proper amendments to reissue applications.

Original Patent Description or Patent Claim Amended

Example (1)

If it is desired to change the specification at column 4 line 23, to replace "is" with --are--, submit a copy of the entire paragraph of specification of the patent being amended with underlining and bracketing, and point out where the paragraph is located, e.g.,

Replace the paragraph beginning at column 4, line 23 with the following:

Scanning [is] are controlled by clocks which are, in turn, controlled from the display tube line synchronization. The signals resulting from scanning the scope of the character are delivered in parallel, then converted into serial mode through a shift register wherein the shift signal frequency is controlled by a clock that is, in turn, controlled from the display tube line synchronization.

Example (2)

For changes to the claims, one must submit a copy of the entire patent claim with the amendments shown by underlining and bracketing, e.g.,

Amend claim 6 as follows:

Claim 6 (Amended). The apparatus of claim [5]] wherein the [first] second piezoelectric element is parallel to the [second] third piezoelectric element.

If the dependency of any original patent claim is to be changed by amendment, it is proper to make that original patent claim dependent upon a later filed higher numbered claim.

Cancellation of Claim(s)

Example (3)

To cancel an original patent claim, in writing, direct cancellation of the patent claim, e.g.,

Cancel claim 6.

Example (4)

To cancel a new claim (previously added in the reissue), in writing, direct cancellation of the new claim, e.g.,

Cancel claim 15.

Presentation of New Claims

Example (5)

Each new claim (i.e., a claim not found in the patent, that is newly presented in the reissue application) should be presented with underlining throughout the claim, e.g.,

Add claim 7 as follows:

Claim 7. The apparatus of claim 5 further comprising electrodes attaching to said opposite faces of the first and second piezoelectric elements.

Even though original claims may have been canceled, the numbering of the original claims does not change. Accordingly, any added claims are numbered beginning with the number next higher than the number of claims in the original patent. If new claims have been added to the reissue application which are later canceled prior to issuance of the reissue patent, the examiner will renumber any remaining new claims in numerical order to follow the number of claims in the original patent.

Amendment of New Claims

An amendment of a "new claim" (i.e., a claim not found in the patent, that was previously presented in the reissue application) must be done by presenting the amended "new claim" containing the amendatory material, and completely underlining the claim. The presentation cannot contain any bracketing or other indication of what was in the previous version of the claim. This is because all changes in the reissue are made *vis-à-vis* the original patent, and not in comparison to the prior amendment. Although the presentation of the amended claim does not contain any indication of what is changed from the previous version of the claim, applicant must point out what is changed in the "Remarks" portion of the amendment. Also, per 37 CFR 1.173(c), each change made in the claim must be accompanied by an explanation of the support in the disclosure of the patent for the change.

Amendment of Original Patent Claims More Than Once

The following illustrates proper claim amendment of original patent claims in reissue applications:

A. Patent claim.

Claim 1. A cutting means having a handle portion and a blade portion.

B. Proper first amendment format.

Claim 1 (Amended). A [cutting means] knife having a bone handle portion and a notched blade portion.

C. Proper second amendment format.

Claim 1 (Twice Amended). A [cutting means] knife having a handle portion and a serrated blade portion.

Note that the second amendment must include the changes previously presented in the first amendment, i.e., [cutting means] knife, as well as the new changes presented in the second amendment, i.e., serrated.

The word bone was presented in the first amendment and is now to be deleted in the second amendment. The word "bone" is NOT to be shown in brackets in the second amendment. Rather, the word "bone" is simply omitted from the claim, since "bone" never appeared in the patent. An explanation of the deletion should appear in the remarks.

The word notched which was presented in the first amendment is replaced by the word serrated in the second amendment. The word notched is being deleted in the second amendment and did not appear in the patent; accordingly, "notched" is not shown in any form in the claim. The word serrated is being added in the second amendment, and accordingly "serrated" is added to the claim and is underlined.

In the second amendment, the deletions of "notched" and "bone" are not changes from the original patent claim text and therefore are not shown in brackets in the second amendment. In both the first and the second amendments, the entire claim is presented only with the changes from the original patent text.

1454 Appeal Brief

The requirements for an appeal brief are set forth in 37 CFR 1.192 and MPEP § 1206, and they apply to a reissue application in the same manner that they apply to a non-reissue application. There is, however, a difference in practice as to presentation of the copy of the claims in the appeal brief for a reissue application. The claims on appeal presented in an appeal brief for a reissue application should include all underlining and bracketing necessary to reflect the changes made

to the patent claims during the prosecution of the reissue application. In addition, any new claims added in the reissue application should be completely underlined.

1455 Allowance and Issue

"BLUE SLIP"

In all reissue applications prepared for issue where a blue slip is needed (i.e., 08/ and earlier series), the patent number of the original patent which is being reissued should be placed in the box provided therefor below the box for the applicant's name on the blue Issue Classification Slip (form PTO-270) or design Issue Classification Slip (form PTO-328). Otherwise, the Issue Classification Slip is prepared in the same manner as for a non-reissue application.

For 09/ and later series applications, the patent number of the original patent which is being reissued should be placed on the face of the file wrapper above the box "PREPARED AND APPROVED FOR ISSUE" just after "(Exr. Initials)" in the line reading "SURRENDER OF ORIGINAL PATENT _____ (Exr. Initials)."

CHANGES TO THE ORIGINAL PATENT

The specifications of reissue patents will be printed in such a manner as to show the changes over the original patent text by enclosing any material omitted by the reissue in heavy brackets [] and printing material added by the reissue in *italics*. 37 CFR 1.173 (see MPEP § 1411) requires the specification of a reissue application to be presented in a specified form, specifically designed to facilitate this different manner of printing, as well as for other reasons.

The printed reissue patent specification will carry the following heading, which will be added by the Publishing Division of the Office of Patent Publication:

"Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue."

The examiners should see that the specification is in proper form for printing. Examiners should carefully check the entry of all amendments to ensure that the changes directed by applicant will be accurately printed in any reissue patent that may ultimately issue.

Matter appearing in the original patent which is omitted by reissue should be enclosed in brackets, while matter added by reissue should be underlined.

Any material added by amendment in the reissue application (as underlined text) which is later canceled should be crossed through, *and not bracketed*. Material cancelled from the original patent should be enclosed in brackets, *and not lined through*.

All the claims of the original patent should appear in the reissue patent, with canceled patent claims being enclosed in brackets.

CLAIM NUMBERING

No renumbering of the original patent claims is permitted, even if the dependency of a dependent patent claim is changed by reissue so that it is to be dependent on a subsequent higher numbered claim.

When a dependent claim in a reissue application depends upon a claim which has been canceled, and the dependent claim is not thereafter made dependent upon a pending claim, such a dependent claim must be rewritten in independent form.

New claims added during the prosecution of the reissue application should follow the number of the highest numbered patent claim and should be completely underlined to indicate they are to be printed in italics. Often, as a result of the prosecution and examination, some new claims are canceled while other new claims remain. When the reissue is allowed, any claims remaining which are additional to the patent claims (i.e., claims added via the reissue) should be renumbered in sequence starting with the number next higher than the number of claims in the original patent. Therefore, the number of claims allowed will not necessarily correspond to the number of the last claim in the reissue application, as allowed.

CLAIM DESIGNATED FOR PRINTING

At least one claim of an allowable reissue application must be designated for printing in the *Official Gazette*. Whenever at least one claim has been amended or added in the reissue, the claim (claims) designated for printing must be (or include) a claim which has been changed or added by the reissue. A canceled claim is not to be designated as the claim for the *Official Gazette*.

If there is no change in the claims of the allowable reissue application (i.e., when they are the same as the

claims of the original patent) or, if the only change in the claims is the cancellation of claims, then the most representative pending *allowed* claim is designated for printing in the *Official Gazette*.

PROVIDING PROPER FORMAT

Where a reissue application has not been prepared in the above-indicated manner, the examiner may obtain from the applicant a clean copy of the reissue specification prepared in the indicated form, or a proper submission of a previously improperly submitted amendment. However, if the deletions from the original patent are small, the reissue application can be prepared for issue by putting the bracketed inserts at the appropriate places and suitably numbering the added claims.

When applicant submits a clean copy of the reissue specification, or a proper submission of a previous improper amendment, a supplemental reissue declaration should **not** be provided to address this submission, because the correction of format does not correct a 35 U.S.C. 251 error in the patent.

PARENT APPLICATION DATA

All parent application data on the front face of the original patent file wrapper should be placed on the bibliographic data sheet reprint for 09/ and later series applications or on the front face of the reissue file wrapper for 08/ and earlier series applications, if it is still proper.

It sometimes happens that the reissue is a continuation of another reissue application, and there is also original-patent parent application data. The examiner should ensure that the parent application data on the original patent is properly combined with the parent application data of the reissue, in the text of the specification and on the bibliographic data sheet reprint for 09/ and later series applications or on the front face of the reissue file wrapper for 08/ and earlier series applications. The combined statement as to parent application data should be checked carefully for proper bracketing and underlining.

REFERENCES CITED AND PRINTED

The list of references to be printed in the reissue patent should include both the references cited during the original prosecution and the references cited during the prosecution of the reissue application. A

patent cannot be reissued solely for the purpose of adding citations of additional prior art.

EXAMINER'S AMENDMENT AND SUPPLEMENTAL DECLARATION

When it is necessary to amend the reissue application in order to place the application in condition for allowance, the examiner may:

(A) request that applicant provide the amendments (e.g., by facsimile transmission or by hand-carry); or

(B) make the amendments, with the applicant's approval, by a formal examiner's amendment.

If the changes are made by a formal examiner's amendment, the *entire* paragraph(s) or claim(s) being amended need not be presented in rewritten form for any deletions or additions. Changes to the specification including the claims of an application made by the Office in an examiner's amendment may be made by specific instructions to insert or delete subject matter set forth in the examiner's amendment by identifying the precise point in the specification or the claim(s) where the insertion or deletion is to be made. 37 CFR 1.121(g).

If it is necessary to amend a claim or the specification in order to correct an "error" under 35 U.S.C. 251 and thereby place the application in condition for allowance, then a supplemental oath or declaration will be required. See MPEP § 1444. The examiner should telephone applicant and request the supplemental oath or declaration, which must be filed before the application can be counted as an allowance.

FINAL REVIEW OF THE REISSUE APPLICATION BY THE EXAMINER

Prior to forwarding a reissue application to the Technology Center (TC) Special Program Examiner (SPRE) for final review, the examiner should complete and initial an Examiner Review Checklist. A copy of the checklist should be available from the SPRE or from the Paralegal Specialist of the TC.

1456 Reissue Review

All reissue applications are monitored and reviewed in the Technology Centers (TCs) by the Office of TC Special Program Examiner (which includes SPRE, paralegal or other technical support

who might be assigned as backup) at several stages during the prosecution. In order to ensure that SPREs are aware of the reissue applications in their TCs, a pair of terminal-specific PALM flags have been created which must be set by the SPRE before certain PALM transactions can be completed. First, when a new reissue application enters the TC, a PALM flag must be set at a SPRE PALM terminal before a docketing transaction will be accepted. By having to set this first flag, the SPRE is made aware of the assignment of the reissue application to the TC and can take steps, as may be appropriate, to instruct the examiner on reissue-specific procedures before the examination process begins, as well as throughout the period that the examiner is handling the reissue application. Further, a second PALM flag must be set at a SPRE PALM terminal before a Notice of Allowance can be generated or the PALM transaction for an issue revision can be entered, thereby ensuring that the SPRE is made aware of when the reissue application is being allowed so that the SPRE may be able to conduct a final review of the reissue application, if appropriate.

When the reissue application has been reviewed and is ready to be released to issue, the TC SPRE should initial the face of the file wrapper, and forward the reissue file to the Office of Patent Legal Administration (OPLA). Along with the reissue file, the file for the original patent should be forwarded to OPLA.

After leaving the TC, all reissue applications go through a screening process which is currently performed in OPLA. The screening process which includes review of the reissue oath or declaration for compliance with 37 CFR 1.175, review of the presentation and entry of reissue amendments for compliance with 37 CFR 1.173(b), and review of other matters to ensure adherence to current reissue practices. A patentability review is made in a sample of reissue applications by the Office of Patent Quality Review. The screening process and the patentability review are appropriate vehicles for correcting errors, identifying problem areas and recognizing trends, providing information on the uniformity of practice, and providing feedback to the TCs.

1460 Effect of Reissue

35 U.S.C. 252. Effect of reissue.

The surrender of the original patent shall take effect upon the issue of the reissued patent, and every reissued patent shall have the same effect and operation in law, on the trial of actions for

causes thereafter arising, as if the same had been originally granted in such amended form, but in so far as the claims of the original and reissued patents are substantially identical, such surrender shall not affect any action then pending nor abate any cause of action then existing, and the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent.

A reissued patent shall not abridge or affect the right of any person or that person's successors in business who, prior to the grant of a reissue, made, purchased, offered to sell, or used within the United States, or imported into the United States, anything patented by the reissued patent, to continue the use of, to offer to sell, or to sell to others to be used, offered for sale, or sold, the specific thing so made, purchased, offered for sale, used, or imported unless the making, using, offering for sale, or selling of such thing infringes a valid claim of the reissued patent which was in the original patent. The court before which such matter is in question may provide for the continued manufacture, use, offer for sale, or sale of the thing made, purchased, offered for sale, used, or imported as specified, or for the manufacture, use, offer for sale, or sale in the United States of which substantial preparation was made before the grant of the reissue, and the court may also provide for the continued practice of any process patented by the reissue that is practiced, or for the practice of which substantial preparation was made, before the grant of the reissue, to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced before the grant of the reissue.

The effect of the reissue of a patent is stated in 35 U.S.C. 252. With respect to the Office treatment of the reissued patent, the reissued patent will be viewed as if the original patent had been originally granted in the amended form provided by the reissue.

1470 Public Access of Reissue Applications

37 CFR 1.11(b) opens all reissue applications filed after March 1, 1977, to inspection by the general public. 37 CFR 1.11(b) also provides for announcement of the filings of reissue applications in the *Official Gazette* (except for continued prosecution applications filed under 37 CFR 1.53(d)). This announcement will give interested members of the public an opportunity to submit to the examiner information pertinent to patentability of the reissue application.

The filing of a continued prosecution application under 37 CFR 1.53(d) of a reissue application will not be announced in the *Official Gazette*. Although the filing of a continued prosecution application of a reissue application constitutes the filing of a reissue application, the announcement of the filing of such continued prosecution application would be redundant

in view of the announcement of the filing of the prior reissue application in the *Official Gazette*.

37 CFR 1.11(b) is applicable only to those reissue applications filed on or after March 1, 1977. Those reissue applications previously on file will not be automatically open to inspection but a liberal policy will be followed in granting petitions for access to such applications.

For those reissue applications filed on or after March 1, 1977, the following procedure will be observed:

(A) The filing of reissue applications will be announced in the *Official Gazette* (except for continued prosecution applications filed under 37 CFR 1.53(d)) and will include certain identifying data as specified in 37 CFR 1.11(b). Any member of the general public may request access to a particular reissue application filed after March 1, 1977. Since no record of such request is intended to be kept, an oral request will suffice. In the File Information Unit (Record Room), only the regular application charge card need be completed and submitted. The charge card will not be made part of a pending or abandoned reissue application;

(B) The pending reissue application files will be maintained in the Technology Centers (TCs) and inspection thereof will be supervised by TC personnel. Although no general limit is placed on the amount of time spent reviewing the files, the Office may impose limitations, if necessary. No access will be permitted while the application is actively being processed;

(C) After a reissue application has left the TC for administrative processing, requests for access should be directed to the appropriate supervisory personnel in the division or branch where the application is currently located;

(D) A reissue application file is not available to the public once the reissue application file has been released and forwarded by the TC for publication of the reissue patent. This would include any reissue application files which have been selected for a quality review check at the Office of Patent Quality Review. Unless prosecution is reopened pursuant to a quality review check, the reissue application files are not available to the public until the reissue patent issues. This is because the reissue application file has been put into a special format for printing purposes

and public access at this stage would disrupt the publication process;

(E) Requests for copies of papers in the reissue application file must be in writing addressed to Box 10, Commissioner of Patents and Trademarks, Washington, DC 20231 and may be either mailed or delivered to the Customer Service Window. The price for a copy of an application as filed is set forth in 37 CFR 1.19(b)(1). Since no useful purpose is seen for retaining such written requests for copies of papers in reissue applications, the request(s) should be destroyed after the order has been completed.

See also MPEP § 103.

1480 Certificates of Correction — Office Mistake

35 U.S.C. 254. Certificate of correction of Patent and Trademark Office mistake.

Whenever a mistake in a patent, incurred through the fault of the Patent and Trademark Office, is clearly disclosed by the records of the Office, the Director may issue a certificate of correction stating the fact and nature of such mistake, under seal, without charge, to be recorded in the records of patents. A printed copy thereof shall be attached to each printed copy of the patent, and such certificate shall be considered as part of the original patent. Every such patent, together with such certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form. The Director may issue a corrected patent without charge in lieu of and with like effect as a certificate of correction.

37 CFR 1.322. Certificate of correction of Office mistake.

(a)(1) The Commissioner may issue a certificate of correction pursuant to 35 U.S.C. 254 to correct a mistake in a patent, incurred through the fault of the Office, which mistake is clearly disclosed in the records of the Office:

- (i) At the request of the patentee or the patentee's assignee;
- (ii) Acting *sua sponte* for mistakes that the Office discovers; or
- (iii) Acting on information about a mistake supplied by a third party.

(2)(i) There is no obligation on the Office to act on or respond to a submission of information or request to issue a certificate of correction by a third party under paragraph (a)(1)(iii) of this section.

(ii) Papers submitted by a third party under this section will not be made of record in the file that they relate to nor be retained by the Office.

(3) If the request relates to a patent involved in an interference, the request must comply with the requirements of this section and be accompanied by a motion under § 1.635.

(4) The Office will not issue a certificate of correction under this section without first notifying the patentee (including any assignee of record) at the correspondence address of record as specified in § 1.33(a) and affording the patentee or an assignee an opportunity to be heard.

(b) If the nature of the mistake on the part of the Office is such that a certificate of correction is deemed inappropriate in form, the Commissioner may issue a corrected patent in lieu thereof as a more appropriate form for certificate of correction, without expense to the patentee.

Mistakes incurred through the fault of the Office may be the subject of Certificates of Correction under 37 CFR 1.322. The Office, however, has discretion under 35 U.S.C. 254 to decline to issue a Certificate of Correction even though an Office mistake exists. If Office mistakes are of such a nature that the meaning intended is obvious from the context, the Office may decline to issue a certificate and merely place the correspondence in the patented file, where it serves to call attention to the matter in case any question as to it subsequently arises. Such is the case, even where a correction is requested by the patentee or patentee's assignee.

In order to expedite all proper requests, a Certificate of Correction should be requested only for errors of consequence. Instead of a request for a Certificate of Correction, letters making errors of record should be utilized whenever possible.

THIRD PARTY INFORMATION ON MISTAKES IN PATENT

Third parties do not have standing to demand that the Office issue, or refuse to issue, a Certificate of Correction. *See Hallmark Cards, Inc. v. Lehman*, 959 F. Supp. 539, 543-44, 42 USPQ2d 1134, 1138 (D.D.C. 1997). 37 CFR 1.322(a)(2) makes it clear that third parties do not have standing to demand that the Office act on, respond to, issue, or refuse to issue a Certificate of Correction. The Office is, however, cognizant of the need for the public to have correct information about published patents and may therefore accept information about mistakes in patents from third parties. 37 CFR 1.322(a)(1)(iii). Where appropriate, the Office may issue certificates of correction based on information supplied by third parties, whether or not such information is accompanied by a specific request for issuance of a Certificate of Correction.

While third parties are permitted to submit information about mistakes in patents which information

will be reviewed, the Office need not act on that information nor deny any accompanying request for issuance of a Certificate of Correction. Accordingly, a fee for submission of the information by a third party has not been imposed. The Office may, however, choose to issue a Certificate of Correction on its own initiative based on the information supplied by a third party, if it desires to do so. Regardless of whether the third party information is acted upon, the information will not be made of record in the file that it relates to, nor be retained by the Office. 37 CFR 1.322(a)(2)(ii).

When such third party information (about mistakes in patents) is received by the Office, the Office will not correspond with third parties about the information they submitted either (1) to inform the third parties of whether it intends to issue a Certificate of Correction, or (2) to issue a denial of any request for issuance of a Certificate of Correction that may accompany the information. The Office will confirm to the party submitting such information that the Office has in fact received the information if a stamped, self-addressed post card has been submitted. See MPEP § 503.

PUBLICATION IN THE *OFFICIAL GAZETTE*

Each issue of the *Official Gazette* (patents section) numerically lists all United States patents having Certificates of Correction. The list appears under the heading "Certificates of Correction for the week of (date)."

1481 Applicant's Mistake

35 U.S.C. 255. Certificate of correction of applicant's mistake.

Whenever a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require reexamination. Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.

37 CFR 1.323. Certificate of correction of applicant's mistake.

The Office may issue a certificate of correction under the conditions specified in 35 U.S.C. 255 at the request of the patentee or the patentee's assignee, upon payment of the fee set forth in § 1.20(a). If the request relates to a patent involved in an interfer-

ence, the request must comply with the requirements of this section and be accompanied by a motion under § 1.635.

37 CFR 1.323 relates to the issuance of Certificates of Correction for the correction of errors which were not the fault of the Office. Mistakes in a patent which are not correctable by Certificate of Correction may be correctable via filing a reissue application (see MPEP § 1401 - § 1460).

In re Arnott, 19 USPQ2d 1049, 1052 (Comm'r Pat. 1991) specifies the criteria of 35 U.S.C. 255 (for a Certificate of Correction) as follows:

Two separate statutory requirements must be met before a Certificate of Correction for an applicant's mistake may issue. The first statutory requirement concerns the nature, i.e., type, of the mistake for which a correction is sought. The mistake must be:

- (1) of a clerical nature,
- (2) of a typographical nature, or
- (3) a mistake of minor character.

The second statutory requirement concerns the nature of the proposed correction. The correction must not involve changes which would:

- (1) constitute new matter or
- (2) require reexamination.

If the above criteria are not satisfied, then a Certificate of Correction for an applicant's mistake will not issue, and reissue must be employed as the vehicle to "correct" the patent. Usually, any mistake affecting claim scope must be corrected by reissue.

A mistake is not considered to be of the "minor" character required for the issuance of a Certificate of Correction if the requested change would materially affect the scope or meaning of the patent. See also MPEP § 1412.04 as to correction of inventorship via certificate of correction or reissue.

The fee for providing a correction of applicant's mistake, other than inventorship, is set forth in 37 CFR 1.20(a). The fee for correction of inventorship in a patent is set forth in 37 CFR 1.20(b).

CORRECTION OF ASSIGNEES' NAMES

The Issue Fee Transmittal Form portion (PTOL-85B) of the Notice of Allowance provides a space (item 3) for assignment data which should be completed in order to comply with 37 CFR 3.81. Unless an assignee's name and address are identified in the appropriate space for specifying the assignee, (i.e., item 3 of the Issue Fee Transmittal Form PTOL-85B),

the patent will issue to the applicant. Assignment data printed on the patent will be based solely on the information so supplied.

A request for a Certificate of Correction under 37 CFR 1.323 arising from incomplete or erroneous assignee's name furnished in item 3 of PTOL-85B will not be granted unless a petition under 37 CFR 1.183 has been granted. Any such petition under 37 CFR 1.183 should be directed to the Office of Petitions and should include:

(A) the petition fee required by 37 CFR 1.17(h);

(B) a request that 37 CFR 3.81(a) be waived to permit the correct name of the assignee to be provided after issuance of the patent;

(C) a statement that the failure to include the correct assignee name on the PTOL-85B was inadvertent; and

(D) a copy of the Notice of Recordation of Assignment Document.

CORRECTION OF INVENTORS' NAMES

35 U.S.C. 256. Correction of named inventor.

Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.

The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

In requesting the Office to effectuate a court order correcting inventorship in a patent pursuant to 35 U.S.C. 256, a copy of the court order and a Certificate of Correction under 37 CFR 1.323 should be submitted to the Certificates of Corrections Branch.

37 CFR 1.324. Correction of inventorship in patent, pursuant to 35 U.S.C. 256.

(a) Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his or her part, the Commissioner may, on petition, or on order of a court before which such matter is called in question, issue a certificate naming only the actual inventor or inventors. A petition to correct inventorship of a patent involved in an interference must comply with the requirements of this section and must be accompanied by a motion under § 1.634.

(b) Any petition pursuant to paragraph (a) of this section must be accompanied by:

(1) Where one or more persons are being added, a statement from each person who is being added as an inventor that the inventorship error occurred without any deceptive intention on his or her part;

(2) A statement from the current named inventors who have not submitted a statement under paragraph (b)(1) of this section either agreeing to the change of inventorship or stating that they have no disagreement in regard to the requested change;

(3) A statement from all assignees of the parties submitting a statement under paragraphs (b)(1) and (b)(2) of this section agreeing to the change of inventorship in the patent, which statement must comply with the requirements of § 3.73(b) of this chapter; and

(4) The fee set forth in § 1.20(b).

(c) For correction of inventorship in an application see §§ 1.48 and 1.497, and in an interference see § 1.634.

The petition to correct inventorship under 37 CFR 1.324 must include the statements and fee required by 37 CFR 1.324(b).

Under 37 CFR 1.324(b)(1), a statement is required from each person who is being added as an inventor that the inventorship error occurred without any deceptive intention on their part. In order to satisfy this, a statement such as the following is sufficient:

"The inventorship error of failing to include John Smith as an inventor of the patent occurred without any deceptive intention on the part of John Smith."

Nothing more is required. The examiner will determine only whether the statement contains the required language; the examiner will not make any comment as to whether or not it appears that there was in fact deceptive intention (see MPEP § 2022.05).

Under 37 CFR 1.324(b)(2), all current inventors who did not submit a statement under 37 CFR 1.324(b)(1) must submit a statement either agreeing to the change of inventorship, or stating that they have no disagreement with regard to the requested change. "Current inventors" include the inventor(s) being retained as such and the inventor(s) to be deleted. These current inventors need not make a statement as to whether the inventorship error occurred without deceptive intention.

If an inventor is not available, or refuses, to submit a statement, the assignee of the patent may wish to consider filing a reissue application to correct inventorship, since the inventor's statement is not required for a non-broadening reissue application to correct inventorship. See MPEP § 1412.04.

Under 37 CFR 1.324(b)(3), a statement is required from the assignee(s) of the patent agreeing to the change of inventorship in the patent. The assignee statement agreeing to the change of inventorship must be accompanied by a proper statement under 37 CFR 3.73(b) establishing ownership, unless a proper 37 CFR 3.73(b) statement is already in the file. See MPEP § 324 as to the requirements of a statement under 37 CFR 3.73(b).

While a request under 37 CFR 1.48(a) is appropriate to correct inventorship in a nonprovisional *application*, a petition under 37 CFR 1.324 is the appropriate vehicle to correct inventorship in a *patent*. If a request under 37 CFR 1.48(a) is inadvertently filed in a patent, the request may be treated as a petition under 37 CFR 1.324, and if it is grantable, form paragraph 10.14 set forth below should be used.

Similarly, if a request under 37 CFR 1.48(a) is filed in a pending application but not acted upon until after the application becomes a patent, the request may be treated as a petition under 37 CFR 1.324, and if it is grantable, form paragraph 10.14 set forth below should be used.

The statutory basis for correction of inventorship in a patent under 37 CFR 1.324 is 35 U.S.C. 256. It is important to recognize that 35 U.S.C. 256 is stricter than 35 U.S.C. 116, the statutory basis for corrections of inventorship in applications under 37 CFR 1.48. 35 U.S.C. 256 requires "on application of all the parties and assignees," while 35 U.S.C. 116 does not have the same requirement. Under 35 U.S.C. 116 and 37 CFR 1.48, waiver requests under 37 CFR 1.183 may be submitted (see, e.g., MPEP § 201.03, under the heading "Statement of Lack of Deceptive Intention"). This is not possible under 35 U.S.C. 256 and 37 CFR 1.324. In correction of inventorship in a nonprovisional application under 37 CFR 1.48(a), the requirement for a statement by each originally named inventor may be waived pursuant to 37 CFR 1.183; however, correction of inventorship in a patent under 37 CFR 1.324 requires petition of all the parties, i.e., originally named inventors and assignees, in accordance with statute (35 U.S.C. 256) and thus the requirement cannot be waived. Correction of inventorship requests under 37 CFR 1.324 should be directed to the Supervisory Patent Examiner whose unit handles the subject matter of the patent. Form paragraphs 10.13 through 10.18 may be used.

¶ 10.13 Petition Under 37 CFR 1.324, Granted

Paper No. [1]

In re Patent No. [2] :
 Issue Date: [3] : **DECISION**
 Appl. No.: [4] : **GRANTING**
 Filed: [5] : **PETITION**
 For: [6] : 37 CFR 1.324

This is a decision on the petition filed [7] to correct inventorship under 37 CFR 1.324.

The petition is granted.

The patented file is being forwarded to Certificate of Corrections Branch for issuance of a certificate naming only the actual inventor or inventors.

[8]
 Supervisory Patent Examiner,
 Art Unit [9],
 Patent Examining Group [10]
 [11]

Examiner Note:

1. Petitions to correct inventorship of an issued patent are decided by the Supervisory Patent Examiner, as set forth in the Commissioner's memorandum dated June 2, 1989.
2. In bracket 11, insert the correspondence address of record.
3. This form paragraph is printed with the USPTO letterhead.
4. Prepare Certificate using form paragraph 10.15.

¶ 10.14 Treatment of Request Under 37 CFR 1.48 Petition Under 37 CFR 1.324, Petition Granted

Paper No. [1]

In re Patent No. [2] :
 Issue Date: [3] : **DECISION**
 Appl. No.: [4] : **GRANTING**
 Filed: [5] : **PETITION**
 For: [6] : 37 CFR 1.324

This is a decision on the request under 37 CFR 1.48, filed [7]. In view of the fact that the patent has already issued, the request under 37 CFR 1.48 has been treated as a petition to correct inventorship under 37 CFR 1.324.

The petition is granted.

The patented file is being forwarded to Certificate of Corrections Branch for issuance of a certificate naming only the actual inventor or inventors.

[8]
 Supervisory Patent Examiner,
 Art Unit [9],
 Patent Examining Group [10]
 [11]

Examiner Note:

1. Petitions to correct inventorship of an issued patent are decided by the Supervisory Patent Examiner, as set forth in the Commissioner's memorandum dated June 2, 1989.
2. This form paragraph is printed with the USPTO letterhead.

- 3. Prepare Certificate using form paragraph 10.15.
- 4. In bracket 11, insert the correspondence address of record.

¶ 10.15 Memorandum - Certificate of Correction (Inventorship)

DATE: [1]
 TO: Certificates of Correction Branch
 FROM: [2], SPE, Art Unit [3]
 SUBJECT: Request for Certificate of Correction

Please issue a Certificate of Correction in U. S. Letters Patent No. [4] as specified on the attached Certificate.

[5], SPE
 Art Unit [6]

UNITED STATES PATENT AND TRADEMARK OFFICE
 CERTIFICATE

Patent No. [7]
 Patented: [8]

On petition requesting issuance of a certificate for correction of inventorship pursuant to 35 U.S.C. 256, it has been found that the above identified patent, through error and without deceptive intent, improperly sets forth the inventorship. Accordingly, it is hereby certified that the correct inventorship of this patent is:

[9]

[10], Supervisory Patent Examiner
 Art Unit [11]

Examiner Note:

- 1. In bracket 9, insert the full name and residence (City, State) of each actual inventor.
- 2. This is an internal memo, not to be mailed to applicant, which accompanies the patented file to Certificates of Correction Branch as noted in form paragraphs 10.13 and 10.14.
- 3. In brackets 5 and 10, insert name of SPE; in brackets 6 and 11 the Art Unit and sign above each line.
- 4. Two separate pages of USPTO letterhead will be printed when using this form paragraph.

¶ 10.16 Petition Under 37 CFR 1.324, Dismissed

Paper No. [1]

In re Patent No. [2] :
 Issue Date: [3] : **DECISION**
 Appl. No.: [4] : **DISMISSING**
 Filed: [5] : **PETITION**
 For: [6] : 37 CFR 1.324

This is a decision on the petition filed [7] to correct inventorship under 37 CFR 1.324.

The petition is dismissed.

A petition to correct inventorship as provided by 37 CFR 1.324 requires (1) a statement from each person who is being added as an inventor that the inventorship error occurred without any deceptive intention on their part, (2) a statement from the current named inventors (including any "inventor" being deleted) who

have not submitted a statement as per "(1)" either agreeing to the change of inventorship or stating that they have no disagreement in regard to the requested change, (3) a statement from all assignees of the parties submitting a statement under "(1)" and "(2)" agreeing to the change of inventorship in the patent; such statement must comply with the requirements of 37 CFR 3.73(b); and (4) the fee set forth in 37 CFR 1.20(b). This petition lacks item(s) [8].

[9]
 Supervisory Patent Examiner,
 Art Unit [10],
 Patent Examining Group [11]
 [12]

Examiner Note:

- 1. If each of the four specified items has been submitted but one or more is insufficient, the petition should be denied. See paragraph 10.17. However, if the above noted deficiency can be cured by the submission of a renewed petition, a dismissal would be appropriate.
- 2. If the petition includes a request for suspension of the rules (37 CFR 1.183) of one or more provisions of 37 CFR 1.324 that are required by the statute (35 U.S.C. 256), form paragraph 10.18 should follow this form paragraph.
- 3. In bracket 8, pluralize as necessary and insert the item number(s) which are missing.
- 4. In bracket 12, insert correspondence address of record.
- 5. This form paragraph is printed with the USPTO letterhead.

¶ 10.17 Petition Under 37 CFR 1.324, Denied

Paper No. [1]

In re Patent No. [2] :
 Issue Date: [3] : **DECISION DENYING PETITION**
 Appl. No.: [4] : 37 CFR 1.324
 Filed: [5] :
 For: [6] :

This is a decision on the petition filed [7] to correct inventorship under 37 CFR 1.324.

The petition is denied.

[8]

[9]
 Supervisory Patent Examiner,
 Art Unit [10],
 Patent Examining Group [11]
 [12]

Examiner Note:

- 1. In bracket 8, a full explanation of the deficiency must be provided.
- 2. If the petition lacks one or more of the required parts set forth in 37 CFR 1.324, it should be dismissed using paragraph 10.14 or 7.99, rather than being denied.
- 3. In bracket 12, insert correspondence address of record.
- 4. This form paragraph is printed with the USPTO letterhead.

¶ 10.18 Waiver of Requirements of 37 CFR 1.324 Under 37 CFR 1.183, Dismissed

Suspension of the rules under 37 CFR 1.183 may be granted for any requirement of the regulations which is not a requirement of the statutes. In this instance, 35 U.S.C. 256 requires [1]. Accordingly, the petition under 37 CFR 1.183 is dismissed as moot.

Examiner Note:

1. This form paragraph should follow form paragraph 10.16 whenever the petition requests waiver of one or more of the provisions of 37 CFR 1.324 that are also requirements of 35 U.S.C. 256.

2. If the petition requests waiver of requirements of 37 CFR 1.324 that are not specific requirements of the statute (i.e., the fee or the oath or declaration by all inventors), the application must be forwarded to a petitions attorney in the Office of the Deputy Commissioner for Patent Examination Policy for decision.

CORRECTION TO PERFECT CLAIM FOR 35 U.S.C. 119 (a)-(d) BENEFITS

See MPEP § 201.16 for a discussion of when 35 U.S.C. 119 (a)-(d) benefits can be perfected by certificate of correction.

CORRECTION AS TO 35 U.S.C. 120 AND 35 U.S.C. 119(e) BENEFITS

For Applications Filed Prior to November 29, 2000

For applications filed prior to November 29, 2000, it is the version of 37 CFR 1.78, which was in effect prior to November 29, 2000, that applies. The pre-November 29, 2000 version reads as follows:

37 CFR 1.78. Claiming benefit of earlier filing date and cross-references to other applications.

(a)(1) A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior application must be:

- (i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or
- (ii) Complete as set forth in § 1.51(b); or
- (iii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and include the basic filing fee set forth in § 1.16; or

(iv) Entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(l) within the time period set forth in § 1.53(f).

(2) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Unless the reference required by this paragraph is included in an application data sheet (§ 1.76), the specification must contain or be amended to contain such reference in the first sentence following any title. The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior application. The identification of an application by application number under this section is the specific reference required by 35 U.S.C. 120 to every application assigned that application number. Cross-references to other related applications may be made when appropriate (see § 1.14(a)).

(3) A nonprovisional application other than for a design patent may claim an invention disclosed in one or more prior filed copending provisional applications. In order for a nonprovisional application to claim the benefit of one or more prior filed copending provisional applications, each prior provisional application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior provisional application must be entitled to a filing date as set forth in § 1.53(c), have any required English-language translation filed therein within the time period set forth in § 1.52(d), and have paid therein the basic filing fee set forth in § 1.16(k) within the time period set forth in § 1.53(g).

(4) Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number). Unless the reference required by this paragraph is included in an application data sheet (§ 1.76), the specification must contain or be amended to contain such reference in the first sentence following any title.

Under certain conditions specified below, a Certificate of Correction can be used, with respect to 35 U.S.C. 120 and 119(e) priority, to correct:

(A) the failure to make reference to a prior copending application pursuant to 37 CFR 1.78(a)(2) and (a)(4); or

(B) an incorrect reference to a prior copending application pursuant to 37 CFR 1.78(a)(2) and (a)(4).

For all situations other than where priority is based upon 35 U.S.C. 365(c), the conditions are as follows:

(A) for 35 U.S.C. 120 priority, all requirements set forth in 37 CFR 1.78(a)(1) must have been met in the application which became the patent to be corrected;

(B) for 35 U.S.C. 119(e) priority, all requirements set forth in 37 CFR 1.78(a)(3) must have been met in the application which became the patent to be corrected;

(C) the prior copending application to be added via the Certificate of Correction must be identified elsewhere (other than the first sentence of the specification following the title or in an application data sheet) in the application papers; and

(D) it must be clear from the record of the patent and the parent application(s) that priority is appropriate.

Where 35 U.S.C. 120 and 365(c) priority based on an international application is to be asserted or corrected in a patent via a Certificate of Correction, the following conditions must be satisfied:

(A) all requirements set forth in 37 CFR 1.78(a)(1) must have been met in the application which became the patent to be corrected;

(B) the prior copending application to be added via the Certificate of Correction must be identified in the application papers other than in the first sentence of the specification following the title or in an application data sheet and other than in a claim under 35 U.S.C. 119(a)-(d);

(C) it must be clear from the record of the patent and the parent application(s) that priority is appropriate; and

(D) the patentee must submit with the request for the certificate copies of documentation showing designation of states and any other information needed to make it clear from the record that the 35 U.S.C. 120 priority is appropriate. See MPEP § 201.13(b) as to the requirements for 35 U.S.C. 120 priority based on an international application.

If all the above-stated conditions are satisfied, a Certificate of Correction can be used to amend the patent to make reference to a prior copending applica-

tion, or to correct an incorrect reference to the prior copending application. Note *In re Schuurs*, 218 USPQ 443 (Comm'r Pat. 1983) which suggests that a Certificate of Correction is an appropriate remedy for correcting, in a patent, reference to a prior copending application. Also, note *In re Lambrecht*, 202 USPQ 620 (Comm'r Pat. 1976), citing *In re Van Esdonk*, 187 USPQ 671 (Comm'r Pat. 1975).

If any of the above-stated conditions is not satisfied, the filing of a reissue application (see MPEP § 1401 - § 1460) would be appropriate to pursue the desired correction of the patent.

For Applications Filed On or After November 29, 2000

For applications filed on or after November 29, 2000, it is the version of 37 CFR 1.78, which is in effect as of November 29, 2000, that applies. 37 CFR 1.78 reads as follows:

37 CFR 1.78. Claiming benefit of earlier filing date and cross-references to other applications.

(a)(1) A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior application must be:

- (i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or
- (ii) Complete as set forth in § 1.51(b); or
- (iii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and include the basic filing fee set forth in § 1.16; or
- (iv) Entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(l) within the time period set forth in § 1.53(f).

(2) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. This reference must be submitted during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date

of the prior application. This time period is not extendable. Unless the reference required by this paragraph is included in an application data sheet (§ 1.76), the specification must contain or be amended to contain such reference in the first sentence following the title. If the application claims the benefit of an international application, the first sentence of the specification must include an indication of whether the international application was published under PCT Article 21(2) in English (regardless of whether benefit for such application is claimed in the application data sheet). The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior application. The identification of an application by application number under this section is the specific reference required by 35 U.S.C. 120 to every application assigned that application number. Cross references to other related applications may be made when appropriate (see § 1.14). Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and this paragraph is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior application. The time period set forth in this paragraph does not apply to an application for a design patent.

(3) If the reference required by 35 U.S.C. 120 and paragraph (a)(2) of this section is presented in a nonprovisional application after the time period provided by paragraph (a)(2) of this section, the claim under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior filed copending nonprovisional application or international application designating the United States of America may be accepted if the reference identifying the prior application by application number or international application number and international filing date was unintentionally delayed. A petition to accept an unintentionally delayed claim under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior filed application must be accompanied by:

- (i) The surcharge set forth in § 1.17(t); and
- (ii) A statement that the entire delay between the date the claim was due under paragraph (a)(2) of this section and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional.

(4) A nonprovisional application other than for a design patent may claim an invention disclosed in one or more prior filed provisional applications. In order for a nonprovisional application to claim the benefit of one or more prior filed provisional applications, each prior provisional application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior provisional application must be entitled to a filing date as set forth in § 1.53(c), and the basic filing fee set forth in § 1.16(k) must be paid within the time period set forth in § 1.53(g).

(5) Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number), and, if the provisional application is filed in a language

other than English, an English language translation of the non-English language provisional application and a statement that the translation is accurate. This reference and English language translation of a non-English language provisional application must be submitted during the pendency of the nonprovisional application, and within the later of four months from the actual filing date of the nonprovisional application or sixteen months from the filing date of the prior provisional application. This time period is not extendable. Unless the reference required by this paragraph is included in an application data sheet (§ 1.76), the specification must contain or be amended to contain such reference in the first sentence following the title. Except as provided in paragraph (a)(6) of this section, the failure to timely submit the reference and English language translation of a non-English language provisional application required by 35 U.S.C. 119(e) and this paragraph is considered a waiver of any benefit under 35 U.S.C. 119(e) to such prior provisional application.

(6) If the reference or English language translation of a non-English language provisional application required by 35 U.S.C. 119(e) and paragraph (a)(5) of this section is presented in a nonprovisional application after the time period provided by paragraph (a)(5) of this section, the claim under 35 U.S.C. 119(e) for the benefit of a prior filed provisional application may be accepted during the pendency of the nonprovisional application if the reference identifying the prior application by provisional application number and any English language translation of a non-English language provisional application were unintentionally delayed. A petition to accept an unintentionally delayed claim under 35 U.S.C. 119(e) for the benefit of a prior filed provisional application must be accompanied by:

- (i) The surcharge set forth in § 1.17(t); and
- (ii) A statement that the entire delay between the date the claim was due under paragraph (a)(5) of this section and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional.

Under no circumstances can a Certificate of Correction be employed to correct an applicant's mistake by adding or correcting a priority claim under 35 U.S.C. 119(e) for an application filed on or after November 29, 2000.

Section 4503 of the American Inventor's Protection Act of 1999 (AIPA) amended 35 U.S.C. 119(e)(1) to state that:

No application shall be entitled to the benefit of an earlier filed provisional application under this subsection unless an amendment containing the specific reference to the earlier filed provisional application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this subsection. The Director may establish procedures, including the payment of a surcharge,

to accept an unintentionally delayed submission of an amendment under this section *during the pendency of the application*. (emphasis added)

35 U.S.C. 119(e)(1), as amended by the AIPA, clearly prohibits the addition or correction of priority claims under 35 U.S.C. 119(e) when the application is not pending, e.g., an issued patent. Therefore, a Certificate of Correction is no longer a valid mechanism for adding or correcting a priority claim under 35 U.S.C. 119(e) after a patent has been granted on an application filed on or after November 29, 2000.

Under certain conditions as specified below, however, a Certificate of Correction can still be used, with respect to 35 U.S.C. 120 priority, to correct:

(A) the failure to make reference to a prior copending application pursuant to 37 CFR 1.78(a)(2); or

(B) an incorrect reference to a prior copending application pursuant to 37 CFR 1.78(a)(2).

Where priority is based upon 35 U.S.C. 120 to a **national application**, the following conditions must be satisfied:

(A) all requirements set forth in 37 CFR 1.78(a)(1) must have been met in the application which became the patent to be corrected;

(B) the prior copending application to be added via the Certificate of Correction must be identified elsewhere (other than the first sentence of the specification following the title or in an application data sheet) in the application papers;

(C) it must be clear from the record of the patent and the parent application(s) that priority is appropriate; and

(D) a grantable petition to accept an unintentionally delayed claim for the benefit of a prior application must be filed, including a surcharge as set forth in 37 CFR 1.17(t), as required by 37 CFR 1.78(a)(3).

Where 35 U.S.C. 120 and 365(c) priority based on an **international application** is to be asserted or corrected in a patent via a Certificate of Correction, the following conditions must be satisfied:

(A) all requirements set forth in 37 CFR 1.78(a)(1) must have been met in the application which became the patent to be corrected;

(B) the prior copending application to be added via the Certificate of Correction must be identified in the application papers other than in the first sentence of the specification following the title or in an application data sheet and other than in a claim under 35 U.S.C. 119(a)-(d);

(C) it must be clear from the record of the patent and the parent application(s) that priority is appropriate;

(D) the patentee must submit with the request for the certificate copies of documentation showing designation of states and any other information needed to make it clear from the record that the 35 U.S.C. 120 priority is appropriate (see MPEP § 201.13(b) as to the requirements for 35 U.S.C. 120 priority based on an international application);

(E) the first sentence of the specification must be amended to indicate whether the international application was published under PCT Article 21(2) in English as required by 37 CFR 1.78(a)(2); and

(F) a grantable petition to accept an unintentionally delayed claim for the benefit of a prior application must be filed, including a surcharge as set forth in 37 CFR 1.17(t), as required by 37 CFR 1.78(a)(3).

If all the above-stated conditions are satisfied, a Certificate of Correction can be used to amend the patent to make reference to a prior copending application, or to correct an incorrect reference to the prior copending application, for benefit claims under 35 U.S.C. 120 and 365(c).

If any of the above-stated conditions is not satisfied, the filing of a reissue application (see MPEP § 1401 - § 1460) may be appropriate to pursue the desired correction of the patent for benefit claims under 35 U.S.C. 120 and 365(c).

1485 Handling of Request for Certificates of Correction

A request for a Certificate of Correction should be addressed to the attention of the Certificate of Correction Branch, Commissioner for Patents, Washington, DC 20231. Requests for Certificates of Correction will be forwarded to the Certificate of Correction Branch of the Office of Patent Publication, where they will be listed in a permanent record book.

If the patent is involved in an interference, a Certificate of Correction under 37 CFR 1.324 will not be issued unless a corresponding motion under 37 CFR 1.634 has been granted by the administrative patent judge. Otherwise, determination as to whether an error has been made, the responsibility for the error, if any, and whether the error is of such a nature as to justify the issuance of a Certificate of Correction will be made by the Certificate of Correction Branch. If a report is necessary in making such determination, the case will be forwarded to the appropriate group with a request that the report be furnished. If no certificate is to issue, the party making the request is so notified and the request, report, if any, and copy of the communication to the person making the request are placed in the file and entered thereon under "Contents" by the Certificate of Correction Branch. The case is then returned to the patented files. If a certificate is to issue, it will be prepared and forwarded to the person making the request by the Office of Patent Publication. In that case, the request, the report, if any, and a copy of the letter transmitting the Certificate of Correction to the person making the request will be placed in the file and entered thereon under "Contents".

Applicants, or their attorneys or agents, are urged to submit the text of the correction on a special Certificate of Correction form, PTO/SB/44 (also referred to as Form PTO-1050), which can serve as the camera copy for use in direct offset printing of the Certificate of Correction.

Where only a part of a request can be approved, or where the Office discovers and includes additional corrections, the appropriate alterations are made on the form PTO/SB/44 by the Office. The patentee is notified of the changes on the Notification of Approval-in-part form PTOL-404. The certificate is issued approximately 6 weeks thereafter.

Form PTO/SB/44 should be used exclusively regardless of the length or complexity of the subject matter. Intricate chemical formulas or page of specification or drawings may be reproduced and mounted on a blank copy of PTO/SB/44. Failure to use the form has frequently delayed issuance since the text must be retyped by the Office onto a PTO/SB/44.

The exact page and line number where the errors occur in the application file should be identified on

the request. However, on form PTO/SB/44, only the column and line number in the printed patent should be used.

The patent grant should be retained by the patentee. The Office does not attach the Certificate of Correction to patentee's copy of the patent. The patent grant will be returned to the patentee if submitted.

Below is a sample form illustrating a variety of corrections and the suggested manner of setting out the format. Particular attention is directed to:

(A) Identification of the exact point of error by reference to column and line number of the printed patent or to claim number and line where a claim is involved.

(B) Conservation of space on the form by typing single space, beginning two lines down from the printed message.

(C) Starting the correction to each separate column as a sentence, and using semicolons to separate corrections within said column, where possible.

(D) Two-inch space left blank at bottom of the last sheet for signature of attesting officer.

(E) Use of quotation marks to enclose the exact subject matter to be deleted or corrected; use of double hyphens (-- --) to enclose subject matter to be added, except for formulas.

(F) Where a formula is involved, setting out only that portion thereof which is to be corrected or, if necessary, pasting a photocopy onto form PTO/SB/44.

UNITED STATES PATENT AND TRADEMARK
OFFICE CERTIFICATE OF CORRECTION

Patent No. ————

Dated April 1, 1969

James W. Worth

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the drawings, Sheet 3, Fig. 3, the reference numeral 225 should be applied to the plate element attached to the support member 207. Column 7, lines 45 to 49, the left-hand formula should appear as follows:

Rg
CX^oZ
CFz

Column 10, formula XXXV, that portion of the formula reading

CH		CN
	should read	
-C-		-C-

Formula XXXVII, that portion of the formula reading “-CH2CH-” should read —CHCH—.

Column 2, line 68 and column 3, lines 3, 8 and 13, for the claim reference numeral “2”, each occurrence, should read —1—.

Column 10, line 16, cancel beginning with “12. A sensor device” to and including “tixe strips.” in column 11, line 8, and insert the following claim:

12. A control circuit of the character set forth in claim 1 and for an automobile having a convertible top, and including; means for moving said top between raised and lowered retracted position; and control means responsive to said sensor relay for energizing the top moving means for moving said top from retracted position to raised position.

ELECTRONIC PUBLICATION OF CERTIFICATES OF CORRECTION WITH LATER LISTING IN THE OFFICIAL GAZETTE

Beginning in August of 2001, the U.S. Patent and Trademark Office (USPTO) will begin to publish on the USPTO web site at <http://www.uspto.gov/web/patents/certofcorrect> a listing by patent number of the patents for which certificates of correction are being issued.

The USPTO is now automating the publication process for certificates of correction. This new process will result in certificates of correction being published quicker electronically on the USPTO's web site as compared to their paper publication and the listing of the certificates of correction in the *Official Gazette*. Under the newly automated process, each issue of cer-

tificates of correction will be electronically published on the USPTO web site at <http://www.uspto.gov/web/patents/certofcorrect>, and will also subsequently be listed in the *Official Gazette* (and in the *Official Gazette Notices* posted at <http://www.uspto.gov/web/offices/com/sol/og>) approximately three weeks thereafter. The listing of certificates of correction in the *Official Gazette* will include the certificate's date of issuance.

On the date on which the listing of certificates of correction is electronically published on the USPTO web site: (A) the certificate of correction will be entered into the file wrapper of the patent and will be available to the public; (B) a printed copy of the certificate of correction will be mailed to the patentee or the patent's assignee; and (C) an image of the printed certificate of correction will be added to the image of the patent on the patent database at <http://www.uspto.gov.patft>. Dissemination of all other paper copies of the certificate of correction will occur shortly thereafter.

The date on which the USPTO makes the certificate of correction available to the public (e.g., by adding the certificate of correction to the file wrapper) will be regarded as the date of issuance of the certificate of correction, not the date of the certificate of correction appearing in the *Official Gazette*. Certificates of correction published in the above-described manner will provide the public with prompt notice and access and is consistent with the legislative intent behind the American Inventors Protection Act of 1999. See 35 U.S.C. 10(a) (authorizing the USPTO to publish in electronic form).

The listing of certificates of correction can be electronically accessed on the day of issuance at <http://www.uspto.gov/web/patents/certofcorrect>. The electronic image of the printed certificate of correction can be accessed on the patent database at <http://www.uspto.gov/patft> and the listing of the certificates of correction, as published in the *Official Gazette* three weeks later, will be electronically accessible at <http://www.uspto.gov/web/offices/com/sol/og>.

PTO/SB/44 (02-01)

Approved for use through 01/31/2004. OMB 0651-0033

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.
(Also Form PTO-1050)

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

PATENT NO :

DATED :

INVENTOR(S) :

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

[Large empty rectangular box for providing details of the correction]

MAILING ADDRESS OF SENDER:

PATENT NO. _____

No. of additional copies



Burden Hour Statement: This form is estimated to take 1.0 hour to complete. Time will vary depending upon the needs of the individual case. Any comment on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

1490 Disclaimers

35 U.S.C. 253. Disclaimer.

Whenever, without any deceptive intention, a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid. A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing, and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent to the extent of the interest possessed by the disclaimant and by those claiming under him.

In like manner any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.

37 CFR 1.321. Statutory disclaimers, including terminal disclaimers.

(a) A patentee owning the whole or any sectional interest in a patent may disclaim any complete claim or claims in a patent. In like manner any patentee may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted. Such disclaimer is binding upon the grantee and its successors or assigns. A notice of the disclaimer is published in the *Official Gazette* and attached to the printed copies of the specification. The disclaimer, to be recorded in the Patent and Trademark Office, must:

(1) be signed by the patentee, or an attorney or agent of record;

(2) identify the patent and complete claim or claims, or term being disclaimed. A disclaimer which is not a disclaimer of a complete claim or claims, or term, will be refused recordation;

(3) state the present extent of patentee's ownership interest in the patent; and

(4) be accompanied by the fee set forth in § 1.20(d).

(b) An applicant or assignee may disclaim or dedicate to the public the entire term, or any terminal part of the term, of a patent to be granted. Such terminal disclaimer is binding upon the grantee and its successors or assigns. The terminal disclaimer, to be recorded in the Patent and Trademark Office, must:

(1) be signed:

(i) by the applicant, or

(ii) if there is an assignee of record of an undivided part interest, by the applicant and such assignee, or

(iii) if there is an assignee of record of the entire interest, by such assignee, or

(iv) by an attorney or agent of record;

(2) specify the portion of the term of the patent being disclaimed;

(3) state the present extent of applicant's or assignee's ownership interest in the patent to be granted; and

(4) be accompanied by the fee set forth in § 1.20(d).

(c) A terminal disclaimer, when filed to obviate a judicially created double patenting rejection in a patent application or in a reexamination proceeding, must:

order to comply with 37 CFR 3.73(b), the assignee's

(1) Comply with the provisions of paragraphs (b)(2) through (b)(4) of this section;

(2) Be signed in accordance with paragraph (b)(1) of this section if filed in a patent application or in accordance with paragraph (a)(1) of this section if filed in a reexamination proceeding; and

(3) Include a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the rejection.

A disclaimer is a statement filed by an owner (in part or in entirety) of a patent or of a patent to be granted (i.e., an application), in which said owner relinquishes certain legal rights to the patent. There are two types of disclaimers: a statutory disclaimer and a terminal disclaimer. The owner of a patent or an application is the original inventor(s) or the assignee of the original inventor(s). The patent or application is assigned by one assignment or by multiple assignments which establish a chain of title from the inventor(s) to the assignee(s). The owner of the patent or application can sign a disclaimer, and a person empowered by the owner to sign the disclaimer can also sign it. Per 37 CFR 1.321(b)(1)(iv), an attorney or agent of record is permitted to sign the disclaimer. For a disclaimer to be accepted, it must be signed by the proper party as follows:

(A) A disclaimer filed in an application must be signed by

(1) the applicant where the application has not been assigned,

(2) the applicant and the assignee where each owns a part interest in the application,

(3) the assignee where assignee owns the entire interest in the application, or

(4) an attorney or agent of record.

(B) A disclaimer filed in a patent or a reexamination proceeding must be signed by either

(1) the patentee (the assignee, the inventor(s) if the patent is not assigned, or the assignee and the inventors if the patent is assigned-in-part), or

(2) an attorney or agent of record.

(C) Where the assignee (of an application or of a patent being reexamined or to be reissued) signs the disclaimer, there is a requirement to comply with 37 CFR 3.73(b) in order to satisfy 37 CFR 1.321, unless an attorney or agent of record signs the disclaimer. In ownership interest must be established by:

(1) filing in the application or patent evidence of a chain of title from the original owner to the assignee, or

(2) specifying in the record of the application or patent where such evidence is recorded in the Office (e.g., reel and frame number, etc.).

The submission with respect to 37 CFR 3.73(b) to establish ownership must be signed by a party authorized to act on behalf of the assignee. See also MPEP § 324 as to compliance with 37 CFR 3.73(b). A copy of the "Statement Under 37 CFR 3.73 (b)," which is reproduced in MPEP § 324, may be sent by the examiner to applicant to provide an acceptable way to comply with the requirements of 37 CFR 3.73 (b).

(D) Where the attorney or agent of record signs the disclaimer, **there is no need** to comply with 37 CFR 3.73(b).

(E) The signature on the disclaimer need not be an original signature. Pursuant to 37 CFR 1.4(d)(2), the submitted disclaimer can be a copy, such as a photocopy or facsimile transmission of an original disclaimer.

STATUTORY DISCLAIMERS

Under 37 CFR 1.321(a) the owner of a patent may disclaim a complete claim or claims of his or her patent. This may result from a lawsuit or because he or she has reason to believe that the claim or claims are too broad or otherwise invalid. If the patent is involved in an interference, see 37 CFR 1.662(c).

TERMINAL DISCLAIMERS

37 CFR 1.321(a) also provides for the filing by an applicant or patentee of a terminal disclaimer which disclaims or dedicates to the public the entire term or any portion of the term of a patent or patent to be granted.

37 CFR 1.321(c) specifically provides for the filing of a terminal disclaimer in an application or a reexamination proceeding for the purpose of overcoming a judicially created double patenting rejection. See MPEP § 804.02.

PROCESSING

The Certificate of Correction Branch is responsible for the handling of all statutory disclaimers filed under the first paragraph of 35 U.S.C. 253, whether

the case is pending or patented, and all terminal disclaimers (filed under the second paragraph of 35 U.S.C. 253) except for those filed in an application pending in a Technology Center (TC). This involves:

(A) Determining compliance with 35 U.S.C. 253 and 37 CFR 1.321 and 3.73;

(B) Notifying applicant or patentee when the disclaimer is informal and thus not acceptable;

(C) Recording the disclaimers; and

(D) Providing the disclaimer data for printing.

TERMINAL DISCLAIMER IN PENDING APPLICATION PRACTICE

Where a terminal disclaimer is filed in an application pending in a TC, it will be processed by the paralegal of the Office of the Special Program Examiner of the TC having responsibility for the application. The paralegal will:

(A) Determine compliance with 35 U.S.C. 253 and 37 CFR 1.321 and 3.73, and ensure that the appropriate terminal disclaimer fee set forth in 37 CFR 1.20(d) was applied by the legal instruments examiner;

(B) Notify the examiner having charge of the application whether the terminal disclaimer is acceptable or not;

(C) Where the terminal disclaimer is not acceptable, indicate the nature of the informalities so that the examiner can inform applicant in the next Office action;

(D) Where the terminal disclaimer is acceptable, record the terminal disclaimer; and

(E) Where the terminal disclaimer is acceptable, provide the appropriate terminal disclaimer data for printing.

The paralegal will identify a terminal disclaimer as being present in an application by:

For applications with 08/ and earlier series code

(A) Attaching a green label to the file wrapper;

(B) Stamping a notice on the file of the term which has been disclaimed;

(C) Endorsing the paper containing the terminal disclaimer submission on the "Contents" flap of the application file; and

(D) Entering the terminal disclaimer into the PALM system records, for the application.

For applications with 09/ and later series code

(A) Checking a box on the file wrapper which states that the terminal disclaimer has been filed;

(B) Endorsing the paper containing the terminal disclaimer submission on the "Contents" flap of the application file; and

(C) Entering the terminal disclaimer into the PALM system records, for the application.

The paralegal completes a Terminal Disclaimer Informal Memo to notify the examiner of the nature

of any informalities in the terminal disclaimer. The examiner should notify the applicant of the informalities in the next Office action, or by interview with applicant if such will expedite prosecution of the application. Further, the examiner should initial and date the Terminal Disclaimer Informal Memo and return it to the paralegal to indicate that the examiner has appropriately notified applicant about the terminal disclaimer. The paralegal will then discard the Terminal Disclaimer Informal Memo.

T. D. INFORMAL MEMO: DO NOT MAIL THIS MEMO TO APPLICANT

DATE: _____

TO: EXAMINER _____

APPL. S.N.: _____

FROM: _____
PARALEGAL SPECIALIST

ART UNIT: _____

SUBJECT: Decision on Terminal Disclaimer (T.D.) filed: _____

INSTRUCTIONS: I have reviewed the submitted T.D. with the results as set forth below. If you agree, please use the appropriate form paragraphs identified by this informal memo in your next Office action to notify applicant of the T.D. If you disagree or have any questions, please see me or the Special Program Examiner. THIS IS AN INFORMAL, INTERNAL MEMO ONLY. IT MUST NOT BE (1) MAILED TO APPLICANT OR (2) PLACED OF RECORD IN THE APPLICATION FILE. When your action is complete, please initial, date and return this memo to me. THANK YOU.

- The T.D. is PROPER and has been recorded (see ¶14.23).
- The T.D. is NOT PROPER and has not been accepted for the reason(s) checked below (see ¶14.24):
- The recording fee of \$ _____ has not been submitted nor is there any authorization in the application file for the use of a deposit account (see ¶14.26.07).
- The T.D. does not satisfy Rule 321 in that the person who has signed the T.D. has not stated the extent of his/her interest (and/or the extent of the interest of the business entity represented by the signature) in the application/patent (see ¶¶14.26 & 14.26.01).
- The T.D. lacks the enforceable only during common ownership clause - needed to overcome a double patenting rejection, Rule 321(b) (see ¶14.27.01)
- The T.D. is directed to a particular claim(s), which is not acceptable since "the disclaimer must be a terminal portion of the term of the entire patent to be granted." (MPEP 1490) (see ¶¶14.26 & 14.26.02).
- The person who signed the T.D.:
- is not an attorney "of record" (see ¶¶14.29 and 14.29.01).
- has failed to state his/her capacity to sign for the business entity (see ¶14.28),
- is not recognized as an officer of the assignee (see ¶¶14.29 & possibly 14.29.02).
- No documentary evidence of a chain of title from the original inventor(s) to assignee has been submitted, nor is the reel and frame number specified as to where such evidence is recorded in the Office (see 37 CFR 3.73(b) and 1140 O.G. 72). NOTE: This documentary evidence or the specifying of the reel and frame number may be found in the T.D. or in a separate paper of record in the application (see ¶14.30).
- The T.D. is not signed (see ¶¶14.26 & 14.26.03).
- The serial number of the application (or the number of the patent) which forms the basis for the double patenting rejection is missing or incorrect (see ¶14.32).
- The serial number of this application (or the number of the patent in reexam or reissue cases being disclaimed is missing or incorrect (see ¶¶14.26, 14.26.04 or 14.26.05).
- The period disclaimed is incorrect or not specified (see ¶¶14.26, 14.27.02 or 14.27.03).
- Other:
- Suggestion to request refund (see ¶14.36). NOTE: If already authorized, credit refund to deposit account and do not check this item.

I have appropriately notified applicant(s) of the status of the Terminal Disclaimer filed in this case.

Ex. Initials: _____ Date: _____

RETURN THIS MEMO TO CPK2-2D25.

(Rev. 5/98)

OTHER MATTERS DIRECTED TO TERMINAL DISCLAIMERS

Requirements of Terminal Disclaimers

A proper terminal disclaimer must disclaim the terminal part of the statutory term of any patent granted on the application being examined which would extend beyond the expiration date of the full statutory term, shortened by any terminal disclaimer, of the patent (or of any patent granted on the application) to which the disclaimer is directed. Note the exculpatory language in the second paragraph of the sample terminal disclaimer forms, PTO/SB/25 and PTO/SB/26, provided at the end of this Chapter. That language ("In making the above disclaimer, the owner does not disclaim...") is permissible in a terminal disclaimer.

The terminal disclaimer must state that any patent granted on the application being examined will be enforceable only for and during the period that it and the patent to which the disclaimer is directed or the patent granted on the application to which the disclaimer is directed are commonly owned. See MPEP § 706.02(1)(2) for examples of common ownership, or lack thereof.

The terminal disclaimer must state that the agreement is to run with any patent granted on the application being examined and to be binding upon the grantee, its successors, or assigns.

The appropriate one of form paragraphs 14.27.04 and 14.27.06 (reproduced below) may be used to provide applicant or patent owner with an example of acceptable terminal disclaimer language. Additionally, copies of forms PTO/SB/25 and PTO/SB/26 (provided at the end of this Chapter) may be attached to the Office action to provide sample terminal disclaimers.

Since the claims of pending applications are subject to cancellation, amendment, or renumbering, a terminal disclaimer directed to a particular claim or claims will not be accepted; the disclaimer must be of a terminal portion of the term of the entire patent to be granted. The statute does not provide for conditional disclaimers and accordingly, a proposed disclaimer which is made contingent on the allowance of certain claims cannot be accepted. The disclaimer should identify the disclaimant and his or her interest in the application and should specify the date when the disclaimer is to become effective.

Effect of Disclaimers in Continuing Applications

A terminal disclaimer filed to obviate a double patenting rejection is effective only with respect to the application identified in the disclaimer unless by its terms it extends to continuing applications. For example, a terminal disclaimer filed in a parent application normally has no effect on a continuing application claiming filing date benefits of the parent application under 35 U.S.C. 120. A terminal disclaimer filed in a parent application to obviate a double patenting rejection *does, however, carry over* to a continued prosecution application (CPA) filed under 37 CFR 1.53(d). The terminal disclaimer filed in the parent application carries over because the CPA retains the *same application number* as the parent application, i.e., the application number to which the previously filed terminal disclaimer is directed. If applicant does not want the terminal disclaimer to carry over to the CPA, applicant must file a petition under 37 CFR 1.182, along with the required petition fee, requesting the terminal disclaimer filed in the parent application not be carried over to the CPA; see below "Withdrawing a Terminal Disclaimer" (paragraph "A. Before Issuance of Patent"). If applicant files a Request for Continued Examination (RCE) of an application under 37 CFR 1.114 (which can be filed on or after May 29, 2000 for an application filed on or after June 8, 1995), any terminal disclaimer present will continue to operate, since a new application has not been filed, but rather prosecution has been continued in the existing application. A petition under 37 CFR 1.182, along with the required petition fee, may be filed, if withdrawal of the terminal disclaimer is to be requested.

Two or More Copending Applications

If two (or more) pending applications are filed in *each* of which a rejection of one claimed invention over the other on the ground of obviousness-type double patenting is proper, the rejection will be made in each application. An appropriate terminal disclaimer must be filed in *each* application. This is because a terminal disclaimer filed to obviate a double patenting rejection is effective only with respect to the application identified in the disclaimer. Moreover, the filing of an appropriate terminal disclaimer in each application will prevent a potential improper timewise extension of patent rights in the last application to be issued.

FORM PARAGRAPHS

The following form paragraphs may be used to inform the applicant (or patent owner) of the status of a submitted terminal disclaimer.

¶ 14.23 Terminal Disclaimer Proper

The terminal disclaimer filed on [1] disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of [2] has been reviewed and is accepted. The terminal disclaimer has been recorded.

Examiner Note:

1. In bracket 1, insert the date the terminal disclaimer was filed.
2. In bracket 2, list the Patent Number and/or Application Number (including series code and serial no.) preceded by the phrase --any patent granted on Application Number--.
3. If an assignment is submitted to support the terminal disclaimer, also use form paragraph 14.34 to suggest that the assignment be separately submitted for recording in the Office.
4. See MPEP § 1490 for discussion of requirements for a proper terminal disclaimer.
5. Use form paragraph 14.23.01 for reexamination proceedings.
6. For improper terminal disclaimers, see the form paragraphs which follow.

¶ 14.23.01 Terminal Disclaimer Proper (Reexamination Only)

The terminal disclaimer filed on [1] disclaiming the terminal portion of the patent being reexamined which would extend beyond the expiration date of [2] has been reviewed and is accepted. The terminal disclaimer has been recorded.

Examiner Note:

1. In bracket 1, insert the date the terminal disclaimer was filed.
2. In bracket 2, list the Patent Number and/or Application Number (including series code and serial no.) preceded by the phrase --any patent granted on Application Number--.
3. If an assignment is submitted to support the terminal disclaimer, also use 14.34 to suggest that the assignment be separately submitted for recording in the Office.
4. See MPEP § 1490 for discussion of requirements for a proper terminal disclaimer.
5. For improper terminal disclaimers, see the form paragraphs which follow.

¶ 14.24 Terminal Disclaimer Not Proper - Introductory Paragraph

The terminal disclaimer filed on [1] disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of [2] has been reviewed and is NOT accepted.

Examiner Note:

1. In bracket 1, insert the date the terminal disclaimer was filed.
2. In bracket 2, list the Patent Number and/or Application Number (including series code and serial no.) preceded by the phrase --any patent granted on Application Number--.

3. One or more of the appropriate form paragraphs 14.26 to 14.32 MUST follow this form paragraph to indicate why the terminal disclaimer is not accepted.

4. Form paragraph 14.33 includes the full text of rule 37 CFR 3.73 and may be included in the Office action when deemed appropriate.

5. Form paragraph 14.35 may be used to inform applicant that an additional disclaimer fee will not be required for the submission of a replacement or supplemental terminal disclaimer.

6. Do not use in reexamination proceedings, use form paragraph 14.25 instead.

¶ 14.25 Terminal Disclaimer Not Proper - Introductory Paragraph (Reexamination Only)

The terminal disclaimer filed on [1] disclaiming the terminal portion of the patent being reexamined which would extend beyond the expiration date of [2] has been reviewed and is NOT accepted.

Examiner Note:

1. In bracket 1, insert the date the terminal disclaimer was filed.
2. In bracket 2, list the Patent Number and/or the Application Number (including series code and serial no.) preceded by the phrase --any patent granted on Application Number--.
3. One or more of the appropriate form paragraphs 14.26 to 14.32 MUST follow this form paragraph to indicate why the terminal disclaimer is not accepted.
4. Form paragraph 14.33 includes the full text of rule 37 CFR 3.73 and may be included in the Office action when deemed appropriate.
5. Form paragraph 14.35 may be used to inform applicant that an additional disclaimer fee will not be required for the submission of a replacement or supplemental terminal disclaimer.

¶ 14.26 Does Not Comply With 37 CFR 1.321(b) and/or (c) "Sub-Heading" Only

The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because:

Examiner Note:

1. This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25 and followed by one or more of the appropriate form paragraphs 14.26.01 to 14.27.03.

¶ 14.26.01 Extent of Interest Not Stated

The person who has signed the disclaimer has not stated the extent of his/her interest, or the business entity's interest, in the application/patent. See 37 CFR 1.321(b)(3).

Examiner Note:

This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25 AND 14.26.

¶ 14.26.02 Directed to Particular Claim(s)

It is directed to a particular claim or claims, which is not acceptable, since "the disclaimer must be of a terminal portion of the term of the entire [patent or] patent to be granted." See MPEP § 1490.

Examiner Note:

This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25 AND 14.26.

¶ 14.26.03 Not Signed

The terminal disclaimer was not signed.

Examiner Note:

1. This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25 AND 14.26.

¶ 14.26.04 Application/Patent Not Identified

The application/patent being disclaimed has not been identified.

Examiner Note:

1. This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25 AND 14.26.

¶ 14.26.05 Application/Patent Improperly Identified

The application/patent being disclaimed has been improperly identified since the number used to identify the [1] being disclaimed is incorrect. The correct number is [2].

Examiner Note:

1. This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25 AND 14.26.

2. In bracket 1, insert --application-- or --patent--.

3. In bracket 2, insert the correct Application Number (including series code and serial no.) or the correct Patent Number being disclaimed.

4. A terminal disclaimer is acceptable if it includes the correct Patent Number or the correct Application Number or the serial number together with the proper filing date or the proper series code.

¶ 14.26.06 Not Signed by All Owners

It was not signed by all owners and; therefore, supplemental terminal disclaimers are required from the remaining owners.

Examiner Note:

1. This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25 AND 14.26.

¶ 14.26.07 No Disclaimer Fee Submitted

The disclaimer fee of \$ [1] in accordance with 37 CFR 1.20(d) has not been submitted, nor is there any authorization in the application file to charge a specified Deposit Account or credit card.

Examiner Note:

1. In bracket 1, insert the fee for a disclaimer.

2. This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25 AND 14.26. If the disclaimer fee was paid for a terminal disclaimer which was not accepted, applicant does not have to pay another disclaimer fee when submitting a replacement or supplemental terminal disclaimer, and this form paragraph should not be used.

¶ 14.27.01 Lacks Clause of Enforceable Only During Period of Common Ownership

It does not include a recitation that any patent granted shall be enforceable only for and during such period that said patent is commonly owned with the application(s) or patent(s) which formed the basis for the double patenting rejection. See 37 CFR 1.321(c)(3).

Examiner Note:

This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25 AND 14.26.

¶ 14.27.02 Fails To Disclaim Terminal Portion of Any Patent Granted On Subject Application

It fails to disclaim the terminal portion of any patent granted on the subject application.

Examiner Note:

1. This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25 AND 14.26.

2. Use this form paragraph when the period disclaimed is not the correct period or when no period is specified at all.

3. When using this form paragraph, give an example of proper terminal disclaimer language using form paragraph 14.27.04 following this or the series of statements concerning the defective terminal disclaimer.

¶ 14.27.03 Fails To Disclaim Terminal Portion of Subject Patent

It fails to disclaim the terminal portion of the subject patent.

Examiner Note:

1. This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25 AND 14.26.

2. Use this form paragraph in a reissue application or reexamination proceeding when the period disclaimed is not the correct period or when no period is specified at all.

3. When using this form paragraph, give an example of proper terminal disclaimer language using form paragraph 14.27.05 (for reissue) or form paragraph 14.27.06 (for reexamination proceeding) following this or the series of statements concerning the defective terminal disclaimer.

¶ 14.27.04 Examples of Acceptable Terminal Disclaimer Language in Patent To Be Granted

Examples of acceptable language for making the disclaimer of the terminal portion of any patent granted on the subject application follow:

I. If a Provisional Obviousness-Type Double Patenting Rejection Over A Pending Application was made, use:

Petitioner hereby disclaims, except as provided below, the terminal part of any patent granted on the instant application, which would extend beyond the expiration date of any patent granted on Application No. _____, filed on _____, as shortened by any terminal disclaimer. Petitioner hereby agrees that any patent so granted on the instant application shall be enforceable only for and

during such period that it and any patent granted on the above-listed application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors, or assigns.

II. If an Obviousness-Type Double Patenting Rejection Over A Prior Patent was made, use:

Petitioner hereby disclaims, except as provided below, the terminal part of any patent granted on the instant application, which would extend beyond the expiration date of Patent No. _____, as presently shortened by any terminal disclaimer. Petitioner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the above listed patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors, or assigns.

Alternatively, Form PTO/SB/25 may be used for situation I, and Form PTO/SB/26 may be used for situation II; a copy of each form may be found at the end MPEP Chapter 1400.

¶ 14.27.06 *Examples of Acceptable Terminal Disclaimer Language in Patent (Reexamination Situation)*

Examples of acceptable language for making the disclaimer of the terminal portion of the patent being reexamined follow:

I. If a Provisional Obviousness-Type Double Patenting Rejection Over A Pending Application was made, use:

Petitioner hereby disclaims, except as provided below, the terminal part of the patent being reexamined, which would extend beyond the expiration date of any patent granted on Application No. ____/_____, filed on _____, as shortened by any terminal disclaimer. Petitioner hereby agrees that the patent being reexamined shall be enforceable only for and during such period that it and any patent granted on the above-listed application are commonly owned. This agreement is binding upon the patent owner, its successors, or assigns.

II. If an Obviousness-Type Double Patenting Rejection Over A Prior Patent was made, use:

Petitioner hereby disclaims, except as provided below, the terminal part of the patent being reexamined, which would extend beyond the expiration date of Patent No. _____, as presently shortened by any terminal disclaimer. Petitioner hereby agrees that the patent for which a reexamination certificate is issued as a result of this proceeding shall be enforceable only for and during such period that it and the above listed patent are commonly owned. This agreement is binding upon the patent owner, its successors, or assigns.

¶ 14.28 *Failure To State Capacity To Sign*

The person who signed the terminal disclaimer has failed to state his/her capacity to sign for the corporation or other business

entity, and he/she has not been established as being authorized to act on behalf of the assignee.

Examiner Note:

1. This form paragraph **MUST** be preceded by form paragraphs 14.24 OR 14.25 and 14.26.

¶ 14.29 *Not Recognized as Officer of Assignee - "Sub-Heading" Only*

The person who signed the terminal disclaimer is not recognized as an officer of the assignee, and he/she has not been established as being authorized to act on behalf of the assignee. See MPEP § 324.

Examiner Note:

1. This form paragraph is to be used when the person signing the terminal disclaimer is not an authorized officer as defined in MPEP § 324.

2. This form paragraph **MUST** be preceded by form paragraphs 14.24 or 14.25 and followed by form paragraphs 14.29.01 and/or 14.29.02 when appropriate. An attorney or agent of record is always authorized to sign the terminal disclaimer, even though there is no indication that he or she is an officer of the assignee.

3. Use form paragraph 14.29.02 to explain how an official, other than a recognized officer, may properly execute a terminal disclaimer.

¶ 14.29.01 *Attorney/Agent Not of Record*

An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

Examiner Note:

1. This form paragraph **MUST** be preceded by form paragraphs 14.24 or 14.25 AND 14.29.

2. An attorney or agent, however, may sign a terminal disclaimer provided he/she is an attorney or agent of record or is established as an appropriate official of the assignee. To suggest to the attorney or agent, not of record, how he/she may establish status as an appropriate official of the assignee to execute a terminal disclaimer, use form paragraph 14.29.02.

¶ 14.29.02 *Criteria To Accept Terminal Disclaimer When Signed by a Non-Recognized Officer*

It would be acceptable for a person, other than a recognized officer, to execute a terminal disclaimer, provided the record for the application includes a statement that the person is empowered to sign terminal disclaimers and/or act on behalf of the organization.

Accordingly, a new terminal disclaimer which includes the above empowerment statement will be considered to be executed by an appropriate official of the assignee. A separately filed paper referencing the previously filed terminal disclaimer and containing a proper empowerment statement would also be acceptable.

Examiner Note:

1. This form paragraph **MUST** be preceded by form paragraphs 14.24 or 14.25 AND 14.29.

2. When form paragraph 14.29 is used to indicate that a terminal disclaimer is denied because it was not signed by a recognized officer nor by an attorney or agent of record, this form paragraph should be used to point out one way to correct the problem.
3. While an indication of the person's title is desirable, its inclusion is not mandatory when this option is employed.
4. A sample terminal disclaimer should be sent with the Office action.

¶ 14.30 No Evidence of Chain of Title to Assignee - Application

The assignee has not established its ownership interest in the application, in order to support the terminal disclaimer. There is no submission in the record establishing the ownership interest by either (a) providing documentary evidence of a chain of title from the original inventor(s) to the assignee, or (b) specifying (by reel and frame number) where such documentary evidence is recorded in the Office (37 CFR 3.73(b)).

Examiner Note:

1. This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25.
2. Where an attorney or agent of record signs a terminal disclaimer, there is no need to provide a statement under 37 CFR 3.73(b). Thus, this form paragraph should not be used.
3. It should be noted that the documentary evidence or the specifying of reel and frame number may be found in the terminal disclaimer itself or in a separate paper.

¶ 14.30.01 No Evidence of Chain of Title to Assignee - Patent

The assignee has not established its ownership interest in the patent, in order to support the terminal disclaimer. There is no submission in the record establishing the ownership interest by either (a) providing documentary evidence of a chain of title from the original inventor(s) to the assignee, or (b) specifying (by reel and frame number) where such documentary evidence is recorded in the Office (37 CFR 3.73(b)).

Examiner Note:

1. This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25.
2. Where an attorney or agent of record signs a terminal disclaimer, there is no need to provide a statement under 37 CFR 3.73(b). Thus, this form paragraph should not be used.
3. It should be noted that the documentary evidence or the specifying of reel and frame number may be found in the terminal disclaimer itself or in a separate paper in the application.

¶ 14.30.02 Evidence of Chain of Title to Assignee - Submission Not Signed by Appropriate Party - Terminal Disclaimer Is Thus Not Entered

The submission establishing the ownership interest of the assignee is informal. There is no indication of record that the party who signed the submission establishing the ownership interest is authorized to sign the submission (37 CFR 3.73(b)).

Examiner Note:

1. This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25.
2. Where an attorney or agent of record signs a terminal disclaimer, there is no need to provide any statement under 37 CFR 3.73(b). Thus, this form paragraph should not be used.
3. This form paragraph should be followed by one of form paragraphs 14.16.02 or 14.16.03. In rare situations where BOTH form paragraphs 14.16.02 and 14.16.03 do not apply and thus cannot be used, the examiner should instead follow this form paragraph with a detailed statement of why there is no authorization to sign.
4. Use form paragraph 14.16.06 to point out one way to correct the problem.

¶ 14.32 Application/Patent Which Forms Basis for Rejection Not Identified

The application/patent which forms the basis for the double patenting rejection is not identified in the terminal disclaimer.

Examiner Note:

1. This form paragraph MUST be preceded by form paragraphs 14.24 or 14.25.
2. Use this form paragraph when no information is presented. If incorrect information is contained in the terminal disclaimer, use form paragraphs 14.26 and 14.26.05.

¶ 14.33 37 CFR 3.73 - Establishing Right of Assignee To Take Action

The following is a statement of 37 CFR 3.73:

37 CFR 3.73 Establishing right of assignee to take action.

(a) The inventor is presumed to be the owner of a patent application, and any patent that may issue therefrom, unless there is an assignment. The original applicant is presumed to be the owner of a trademark application or registration, unless there is an assignment.

(b)(1) In order to request or take action in a patent or trademark matter, the assignee must establish its ownership of the patent or trademark property of paragraph (a) of this section to the satisfaction of the Commissioner. The establishment of ownership by the assignee may be combined with the paper that requests or takes the action. Ownership is established by submitting to the Office a signed statement identifying the assignee, accompanied by either:

(i) Documentary evidence of a chain of title from the original owner to the assignee (e.g., copy of an executed assignment). The documents submitted to establish ownership may be required to be recorded pursuant to § 3.11 in the assignment records of the Office as a condition to permitting the assignee to take action in a matter pending before the Office; or

(ii) A statement specifying where documentary evidence of a chain of title from the original owner to the assignee is recorded in the assignment records of the Office (e.g., reel and frame number).

(2) The submission establishing ownership must show that the person signing the submission is a person authorized to act on behalf of the assignee by:

(i) Including a statement that the person signing the submission is authorized to act on behalf of the assignee; or

(ii) Being signed by a person having apparent authority to sign on behalf of the assignee, e.g., an officer of the assignee.

(c) For patent matters only:

(1) Establishment of ownership by the assignee must be submitted prior to, or at the same time as, the paper requesting or taking action is submitted.

(2) If the submission under this section is by an assignee of less than the entire right, title and interest, such assignee must indicate the extent (by percentage) of its ownership interest, or the Office may refuse to accept the submission as an establishment of ownership.

¶ 14.34 Suggestion To Record Assignment Submitted With Terminal Disclaimer

The assignment document filed on [1] is acceptable as the documentary evidence required by 37 CFR 3.73. If the assignment document is not already recorded with the United States Patent and Trademark Office, it is suggested that the assignment document be submitted for recording among the Office assignment records. See 37 CFR 3.11 and MPEP § 302.

Examiner Note:

1. In bracket 1, insert the date the assignment document was filed.
2. This form paragraph should be used when an assignment document (an original, facsimile, or copy) is submitted for recording among the assignment records of the Office.

¶ 14.35 Disclaimer Fee Not Required Twice - Applicant

It should be noted that applicant is not required to pay another disclaimer fee as set forth in 37 CFR 1.20(d) when submitting a replacement or supplemental terminal disclaimer.

Examiner Note:

1. This form paragraph can be used to notify an applicant that another disclaimer fee will not be required when a replacement or supplemental terminal disclaimer is submitted.
2. Use form paragraph 14.35.01 for providing notification to patent owner, rather than an applicant.

¶ 14.35.01 Disclaimer Fee Not Required Twice - Patent Owner

It should be noted that patent owner is not required to pay another disclaimer fee as set forth in 37 CFR 1.20(d) when submitting a replacement or supplemental terminal disclaimer.

Examiner Note:

This form paragraph can be used to notify a patent owner that another disclaimer fee will not be required when a replacement or supplemental terminal disclaimer is submitted.

¶ 14.36 Suggestion That "Applicant" Request a Refund

Since the required fee for the terminal disclaimer was previously paid, applicant's payment of an additional terminal disclaimer fee is not required. Applicant may request a refund of this additional terminal disclaimer fee by submitting a written request for a refund and a copy of this Office action to: Commissioner of Patents and Trademarks, Office of Finance, Washington, DC 20231.

Examiner Note:

1. This form paragraph should be used to notify applicant that a refund can be obtained if another terminal disclaimer fee was paid when a replacement or supplemental terminal disclaimer was submitted.
2. Note - If applicant has authorized or requested a fee refund to be credited to a specific Deposit Account or credit card, then an appropriate credit should be made to that Deposit Account or credit card and this paragraph should NOT be used.
3. Use form paragraph 14.36.01 for providing notification to patent owner, rather than an applicant.

¶ 14.36.01 Suggestion That "Patent Owner" Request a Refund

Since the required fee for the terminal disclaimer was previously paid, patent owner's payment of an additional terminal disclaimer fee is not required. Patent owner may request a refund of this additional terminal disclaimer fee by submitting a written request for a refund and a copy of this Office action to: Commissioner of Patents and Trademarks, Office of Finance, Washington, DC 20231.

Examiner Note:

1. This form paragraph should be used to notify patent owner that a refund can be obtained if another terminal disclaimer fee was paid when a replacement or supplemental terminal disclaimer was submitted.
2. Note - If patent owner has authorized or requested a fee refund to be credited to a specific Deposit Account or credit card, then an appropriate credit should be made to that Deposit Account or credit card and this form paragraph should NOT be used.

¶ 14.37 Samples of a Terminal Disclaimer Over a Pending Application and Assignee Statement Enclosed

Enclosed with this Office action is a sample terminal disclaimer which is effective to overcome a provisional obviousness-type double patenting rejection over a pending application (37 CFR 1.321(b) and (c)).

Also enclosed is a sample Statement Under 37 CFR 3.73(b) (Form PTO/SB/96) which an assignee may use in order to ensure compliance with the rule. Part A of the Statement is used when there is a single assignment from the inventor(s). Part B of the Statement is used when there is a chain of title. The "Copies of assignments..." box should be checked when the assignment document(s) (set forth in part A or part B) is/are not recorded in the

Office, and a copy of the assignment document(s) is/are attached. When the "Copies of assignments..." box is checked, either the part A box or the part B box, as appropriate, must be checked, and the "Reel____, Frame____" entries should be left blank. If the part B box is checked, and copies of assignments are not included, the "From:____ To:____" blank(s) must be filled in. This statement should be used the first time an assignee seeks to take action in an application under 37 CFR 3.73(b), e.g., when signing a terminal disclaimer or a power of attorney.

Examiner Note:

1. This form paragraph can be used to provide applicant samples of a terminal disclaimer which contains the necessary clauses to overcome a provisional obviousness-type double patenting rejection over a pending application and a Statement to be signed by an assignee to ensure compliance with 37 CFR 3.73(b).

2. Note that the requirements for compliance with 37 CFR 3.73(b) have been made more liberal, such that certain specifics of the sample statement are no longer required. At present, in order to comply with 37 CFR 3.73(b), the assignee's ownership interest must be established by (a) filing in the application or patent evidence of a chain of title from the original owner to the assignee, or (b) specifying in the record of the application or patent where such evidence is recorded in the Office (e.g., reel and frame number, etc.). The submission with respect to (a) and (b) to establish ownership must be signed by a party authorized to act on behalf of the assignee.

(See your Group Paralegal or Special Program Examiner for copies of the sample terminal disclaimer and Statement Under 37 CFR 3.73(b) to enclose with the Office action. Alternatively, it is permissible to copy the sample terminal disclaimer found after MPEP § 1490 and the Sample Statement Under 37 CFR 3.73(b) found after MPEP § 324.)

¶ 14.38 Samples of a Terminal Disclaimer Over a Prior Patent and Assignee Statement Enclosed

Enclosed with this Office action is a sample terminal disclaimer which is effective to overcome an obviousness-type double patenting rejection over a prior patent (37 CFR 1.321(b) and (c)).

Also enclosed is a sample Statement Under 37 CFR 3.73(b) (Form PTO/SB/96) which an assignee may use in order to ensure compliance with the rule. Part A of the Statement is used when there is a single assignment from the inventor(s). Part B of the Certificate is used when there is a chain of title. The "Copies of assignments..." box should be checked when the assignment document(s) (set forth in part A or part B) is/are not recorded in the Office, and a copy of the assignment document(s) is/are attached. When the "Copies of assignments..." box is checked, either the part A box or the part B box, as appropriate, must be checked, and the "Reel____, Frame____" entries should be left blank. If the part B box is checked, and copies of assignments are not included, the "From:____ To:____" blank(s) must be filled in. This statement should be used the first time an assignee seeks to take action in an application under 37 CFR 3.73(b), e.g., when signing a terminal disclaimer or a power of attorney.

Examiner Note:

1. This form paragraph can be used to provide applicant samples of a terminal disclaimer which contains the necessary clauses to overcome an obviousness-type double patenting rejection over a prior patent and a Statement to be signed by an assignee to ensure compliance with 37 CFR 3.73(b).

2. Note that the requirements for compliance with 37 CFR 3.73(b) have been made more liberal, such that certain specifics of the sample statement are no longer required. At present, in order to comply with 37 CFR 3.73(b), the assignee's ownership interest must be established by (a) filing in the application or patent evidence of a chain of title from the original owner to the assignee, or (b) specifying in the record of the application or patent where such evidence is recorded in the Office (e.g., reel and frame number, etc.). The submission with respect to (a) and (b) to establish ownership must be signed by a party authorized to act on behalf of the assignee.

(See your Group Paralegal or Special Program Examiner for copies of the sample terminal disclaimer and Statement Under 37 CFR 3.73(b) to enclose with the Office action. Alternatively, it is permissible to copy the sample terminal disclaimer found after MPEP § 1490 and the Sample Statement Under 37 CFR 3.73(b) found after MPEP § 324.)

¶ 14.39 Sample Assignee Statement Under 37 CFR 3.73(b) Enclosed

Enclosed with this Office action is a sample Statement under 37 CFR 3.73(b) which an assignee may use in order to ensure compliance with the Rule. Part A of the Statement is used when there is a single assignment from the inventor(s). Part B of the Statement is used when there is a chain of title. The "Copies of assignments..." box should be checked when the assignment document(s) (set forth in part A or part B) is/are not recorded in the Office, and a copy of the assignment document(s) is/are attached. When the "Copies of assignments..." box is checked, either the part A box or the part B box, as appropriate, must be checked, and the "Reel____, Frame____" entries should be left blank. If the part B box is checked, and copies of assignments are not included, the "From:____ To:____" blank(s) must be filled in. This statement should be used the first time an assignee seeks to take action in an application under 37 CFR 3.73(b).

Examiner Note:

1. This form paragraph can be used to provide applicant a sample of a Statement to be signed by an assignee to ensure compliance with 37 CFR 3.73(b).

2. Note that the requirements for compliance with 37 CFR 3.73(b) have been made more liberal, such that certain specifics of the sample statement are no longer required. At present, in order to comply with 37 CFR 3.73(b), the assignee's ownership interest must be established by (a) filing in the application or patent evidence of a chain of title from the original owner to the assignee, or (b) specifying in the record of the application or patent where such evidence is recorded in the Office (e.g., reel and frame number, etc.). The submission with respect to (a) and (b) to establish ownership must be signed by a party authorized to act on behalf of the assignee.

(See your Group Paralegal or Special Program Examiner for a copy of the sample Statement Under 37 CFR 3.73(b) to enclose

with the Office action. Alternatively, it is permissible to copy the sample Statement Under 37 CFR 3.73(b) found after MPEP § 324.)

WITHDRAWING A RECORDED TERMINAL DISCLAIMER

If timely requested, a recorded terminal disclaimer may be withdrawn before the application in which it is filed issues as a patent, or in a reexamination proceeding, before the reexamination certificate issues. After a patent or reexamination certificate issues, it is unlikely that a recorded terminal disclaimer will be nullified.

A. Before Issuance Of Patent

While the filing and recordation of an unnecessary terminal disclaimer has been characterized as an “unhappy circumstance” in *In re Jentoft*, 392 F.2d 633, 157 USPQ 363 (CCPA 1968), there is no statutory prohibition against nullifying or otherwise canceling the effect of a recorded terminal disclaimer which was erroneously filed before the patent issues. Since the terminal disclaimer would not take effect until the patent is granted, and the public has not had the opportunity to rely on the terminal disclaimer, relief from this unhappy circumstance may be available by way of petition or by refiling the application (other than by refiling it as a CPA).

Under appropriate circumstances, consistent with the orderly administration of the examination process, the nullification of a recorded terminal disclaimer may be addressed by filing a petition under 37 CFR 1.182 requesting withdrawal of the recorded terminal disclaimer. Petitions seeking to reopen the question of the propriety of the double patenting rejection that prompted the filing of the terminal disclaimer have not been favorably considered. The filing of a continuing application other than a CPA, while abandoning the application in which the terminal disclaimer has been filed, will typically nullify the effect of a terminal disclaimer. The filing of a Request for Continued Examination (RCE) of an application under 37 CFR 1.114 will not nullify the effect of a terminal disclaimer, since a new application has not been filed, but rather prosecution has been continued in the existing application.

B. After Issuance Of Patent

The mechanisms to correct a patent — Certificate of Correction (35 U.S.C. 255), reissue (35 U.S.C. 251), and reexamination (35 U.S.C. 305) — are not available to withdraw or otherwise nullify the effect of a recorded terminal disclaimer. As a general principle, public policy does not favor the restoration to the patent owner of something that has been freely dedicated to the public, particularly where the public interest is not protected in some manner — e.g., intervening rights in the case of a reissue patent. See, e.g., *Altoona Publix Theatres v. American Tri-Ergon Corp.*, 294 U.S. 477, 24 USPQ 308 (1935).

Certificates of Correction (35 U.S.C. 255) are available for the correction of an applicant’s mistake. The scope of this remedial provision is limited in two ways — by the nature of the mistake for which correction is sought and the nature of the proposed correction. *In re Arnott*, 19 USPQ2d 1049 (Comm’r Pat. 1991). The nature of the mistake for which correction is sought is limited to those mistakes that are:

- (A) of a clerical nature,
- (B) of a typographical nature, or
- (C) of a minor character.

The nature of the proposed correction is limited to those situations where the correction does not involve changes which would:

- (A) constitute new matter, or
- (B) require reexamination.

A mistake in filing a terminal disclaimer does not fall within any of the categories of mistake for which a certificate of correction of applicant’s mistake is permissible, and any attempt to remove or nullify the effect of the terminal disclaimer would typically require reexamination of the circumstances under which it was filed.

Although the remedial nature of reissue (35 U.S.C. 251) is well recognized, reissue is not available to correct all errors. It has been the Office position that reissue is not available to withdraw or otherwise nullify the effect of a terminal disclaimer recorded in an issued patent. First, the reissue statute only authorizes the Commissioner to reissue a patent “for the unexpired part of the term of the original patent.” Since the granting of a reissue patent without the effect of a recorded terminal disclaimer would result in

extending the term of the original patent, reissue under these circumstances would be contrary to the statute. Second, the principle against recapturing something that has been intentionally dedicated to the public dates back to *Leggett v. Avery*, 101 U.S. 256 (1879). The attempt to restore that portion of the patent term that was dedicated to the public to secure the grant of the original patent would be contrary to this recapture principle. Finally, applicants have the opportunity to challenge the need for a terminal disclaimer during the prosecution of the application that issues as a patent. "Reissue is not a substitute for Patent Office appeal procedures." *Ball Corp. v. United States*, 729 F.2d 1429, 1435, 221 USPQ 289, 293 (Fed. Cir. 1984). Where applicants did not challenge the propriety of the examiner's obvious-type double patenting rejection, but filed a terminal disclaimer to

avoid the rejection, the filing of the terminal disclaimer did not constitute error within the meaning of 35 U.S.C. 251. *Ex parte Anthony*, 230 USPQ 467 (Bd. App. 1982), *aff'd*, No. 84-1357 (Fed. Cir. June 14, 1985).

Finally, the nullification of a recorded terminal disclaimer would not be appropriate in a reexamination proceeding. There is a prohibition (35 U.S.C. 305) against enlarging the scope of a claim during a reexamination proceeding. As noted by the Board in *Anthony, supra*, if a terminal disclaimer was nullified, "claims would be able to be sued upon for a longer period than would the claims of the original patent. Therefore, the vertical scope, as opposed to the horizontal scope (where the subject matter is enlarged), would be enlarged."

PTO/SB/43 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

DISCLAIMER IN PATENT UNDER 37 CFR 1.321(a)	
Name of Patentee	Docket Number (Optional)
Patent Number	Date Patent Issued
Title of Invention	
<p>I hereby disclaim the following complete claims in the above identified patent: _____</p> <p>_____</p>	
<p>The extent of my interest in said patent is (if assignee of record, state liber and page, or reel and frame, where assignment is recorded): _____</p>	
<p>The fee for this disclaimer is set forth in 37 CFR 1.20(d).</p>	
<p><input type="checkbox"/> Patentee claims small entity status. See 37 CFR 1.27.</p> <p><input type="checkbox"/> Small entity status has already been established in this case, and is still proper.</p> <p><input type="checkbox"/> A check in the amount of the fee is enclosed.</p> <p><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input type="checkbox"/> The Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. _____. I have enclosed a duplicate copy of this sheet.</p>	
<p>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p>	
<p>Signed at _____, State of _____ this _____ day of _____, 20_____.</p>	
<p>_____ Signature</p>	
<p>_____ Typed or printed name of patentee/attorney or agent of record</p>	
<p>_____ Address</p>	
<p>_____ City, State, Zip Code or Foreign Country as applicable</p>	

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PTO/SB/26 (10-00)
 Approved for use 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT	Docket Number (Optional)
<p>In re Application of: Application No.: Filed: For:</p> <p>The owner*, _____, of _____ percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior Patent No. _____. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.</p> <p>In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patent, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.</p> <p>Check either box 1 or 2 below, if appropriate.</p> <p>1. <input type="checkbox"/> For submissions on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.</p> <p>I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p> <p>2. <input type="checkbox"/> The undersigned is an attorney or agent of record.</p> <p style="text-align: right; margin-right: 100px;">_____ Signature</p> <p style="text-align: right; margin-right: 100px;">_____ Date</p> <p style="text-align: center; margin-top: 10px;">_____ Typed or printed name</p> <p><input type="checkbox"/> Terminal disclaimer fee under 37 CFR 1.20(d) included.</p> <p style="text-align: center;">WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p style="text-align: center;"><small>*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP § 324.</small></p>	

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Chapter 1500 Design Patents

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1501 Statutes and Rules Applicable

The right to a patent for a design stems from:

35 U.S.C. 171. Patents for designs.

Whoever invents any new, original and ornamental design for an article of manufacture may obtain a patent therefor, subject to the conditions and requirements of this title.

The provisions of this title relating to patents for inventions shall apply to patents for designs, except as otherwise provided.

37 CFR 1.151. Rules applicable.

The rules relating to applications for patents for other inventions or discoveries are also applicable to applications for patents for designs except as otherwise provided.

37 CFR 1.152-1.155, which relate only to design patents, are reproduced in the sections of this chapter.

It is noted that design patent applications are not included in the Patent Cooperation Treaty (PCT), and the procedures followed for PCT international appli-

cations are not to be followed for design patent applications.

The practices set forth in other chapters of this *Manual of Patent Examining Procedure* (MPEP) are to be followed in examining applications for design patents, except as particularly pointed out in the chapter.

1502 Definition of a Design

In a design patent application, the subject matter which is claimed is the design embodied in or applied to an article of manufacture (or portion thereof) and not the article itself. *Ex parte Cady*, 1916 C.D. 62, 232 O.G. 621 (Comm'r Pat. 1916). “[35 U.S.C.] 171 refers, not to the design of an article, but to the design for an article, and is inclusive of ornamental designs of all kinds including surface ornamentation as well as configuration of goods.” *In re Zahn*, 617 F.2d 261, 204 USPQ 988 (CCPA 1980).

The design for an article consists of the visual characteristics embodied in or applied to an article.

Since a design is manifested in appearance, the subject matter of a design patent application may relate to the configuration or shape of an article, to the surface ornamentation applied to an article, or to the combination of configuration and surface ornamentation.

Design is inseparable from the article to which it is applied and cannot exist alone merely as a scheme of surface ornamentation. It must be a definite, preconceived thing, capable of reproduction and not merely the chance result of a method.

¶ 15.42 Visual Characteristics

The design for an article consists of the visual characteristics or aspect displayed by the article. It is the appearance presented by the article which creates an impression through the eye upon the mind of the observer.

¶ 15.43 Subject Matter of Design Patent

Since a design is manifested in appearance, the subject matter of a Design Patent may relate to the configuration or shape of an article, to the surface ornamentation on an article, or to both.

1502.01 Distinction Between Design and Utility Patents

In general terms, a “utility patent” protects the way an article is used and works (35 U.S.C. 101), while a “design patent” protects the way an article looks (35 U.S.C. 171). The ornamental appearance for an article includes its shape/configuration or surface

ornamentation upon the article, or both. Both design and utility patents may be obtained on an article if invention resides both in its utility and ornamental appearance.

While utility and design patents afford legally separate protection, the utility and ornamentality of an article may not be easily separable. An invention may have a blend of functional aspect and ornamental design.

Some of the more common differences between design and utility patents are summarized below:

(A) The term of a utility patent on an application filed on or after June 8, 1995 is 20 years measured from the U.S. filing date; or if the application contains a specific reference to an earlier application under 35 U.S.C. 120, 121, or 365(c), 20 years from the earliest effective U.S. filing date, while the term of a design patent is 14 years measured from the date of grant (see 35 U.S.C. 173).

(B) Maintenance fees are required for utility patents (see 37 CFR 1.20), while no maintenance fees are required for design patents.

(C) Design patent applications include only a single claim, while utility patent applications can have multiple claims.

(D) Restriction between plural, distinct inventions is discretionary on the part of the examiner in utility patent applications (see MPEP § 803), while it is mandatory in design patent applications (see MPEP § 1504.05).

(E) An international application naming various countries may be filed for utility patents under the Patent Cooperation Treaty (PCT), while no such provision exists for design patents.

(F) Foreign priority under 35 U.S.C. 119(a)-(d) can be obtained for the filing of utility patent applications up to 1 year after the first filing in any country subscribing to the Paris Convention, while this period is only 6 months for design patent applications (see 35 U.S.C. 172).

(G) Utility patent applications may claim the benefit of a provisional application under 35 U.S.C. 119(e) whereas design patent applications may not. See 35 U.S.C. 172 and 37 CFR 1.78 (a)(4).

(H) A Request for Continued Examination (RCE) under 37 CFR 1.114 may only be filed in utility and plant applications filed under 35 U.S.C. 111(a) on or

after June 8, 1995, while RCE is not available for design applications (see 37 CFR 1.114(e)).

(I) Continued prosecution application (CPA) practice under 37 CFR 1.53(d) is available for design applications regardless of the filing date of the prior application, but is available for utility and plant applications only where the prior application has a filing date prior to May 29, 2000 (see 37 CFR 1.53(d)(1)(i)).

(J) Utility patent applications filed on or after November 29, 2000 are subject to application publication under 35 U.S.C. 122(b)(1)(A), whereas design applications are not subject to application publication (see 35 U.S.C. 122(b)(2)).

Other distinctions between design and utility patent practice are detailed in this chapter. Unless otherwise provided, the rules for applications for utility patents are equally applicable to applications for design patents (35 U.S.C. 171 and 37 CFR 1.151).

1503 Elements of a Design Patent Application

A design patent application has essentially the elements required of an application for a utility patent filed under 35 U.S.C. 101 (see Chapter 600). The arrangement of the elements of a design patent application and the sections of the specification are as specified in 37 CFR 1.154.

A claim in a specific form is a necessary element of a design patent application. See MPEP § 1503.03.

A drawing is an essential element of a design patent application. See MPEP § 1503.02 for requirements for drawings.

1503.01 Specification

37 CFR 1.153. Title, description and claim, oath or declaration.

(a) The title of the design must designate the particular article. No description, other than a reference to the drawing, is ordinarily required. The claim shall be in formal terms to the ornamental design for the article (specifying name) as shown, or as shown and described. More than one claim is neither required nor permitted.

(b) The oath or declaration required of the applicant must comply with § 1.63.

37 CFR 1.154. Arrangement of application elements in a design application.

(a) The elements of the design application, if applicable, should appear in the following order:

- (1) Design application transmittal form.
- (2) Fee transmittal form.
- (3) Application data sheet (see § 1.76).
- (4) Specification.
- (5) Drawings or photographs.
- (6) Executed oath or declaration (see § 1.153(b)).

(b) The specification should include the following sections in order:

(1) Preamble, stating the name of the applicant, title of the design, and a brief description of the nature and intended use of the article in which the design is embodied.

(2) Cross-reference to related applications (unless included in the application data sheet).

(3) Statement regarding federally sponsored research or development.

(4) Description of the figure or figures of the drawing.

(5) Feature description.

(6) A single claim.

(c) The text of the specification sections defined in paragraph (b) of this section, if applicable, should be preceded by a section heading in uppercase letters without underlining or bold type.

¶ 15.05 Design Patent Specification Arrangement

The following order or arrangement should be observed in framing a design patent specification:

(1) Preamble, stating name of the applicant, title of the design, and a brief description of the nature and intended use of the article in which the design is embodied.

(2) Cross-reference to related applications unless included in the application data sheet.

(3) Statement regarding federally sponsored research or development.

(4) Description of the figure or figures of the drawing.

(5) Feature Description, if any.

(6) A single claim.

I. PREAMBLE AND TITLE

A preamble, if included, should state the name of the applicant, the title of the design, and a brief description of the nature and intended use of the article in which the design is embodied (37 CFR 1.154).

The title of the design identifies the article in which the design is embodied by the name generally known and used by the public but it does not define the scope of the claim. See MPEP § 1504.04, subsection I.A. The title may be directed to the entire article embodying the design while the claimed design shown in full lines in the drawings may be directed to only a portion of the article. However, the title may not be directed to less than the claimed design shown in full lines in the drawings. A title descriptive of the actual article aids the examiner in developing a complete field of search of the prior art and further aids in the proper

assignment of new applications to the appropriate class, subclass, and patent examiner, and the proper classification of the patent upon allowance of the application. It also helps the public in understanding the nature and use of the article embodying the design after the patent has been issued. For example, a broad title such as "Adapter Ring" provides little or no information as to the nature and intended use of the article embodying the design. If a broad title is used, the description of the nature and intended use of the design may be incorporated into the preamble. Absent an amendment requesting deletion of the description, it would be printed on any patent that would issue.

When a design is embodied in an article having multiple functions or comprises multiple independent parts or articles that interact with each other, the title must clearly define them as a single entity, for example, combined or combination, set, pair, unit assembly.

Since 37 CFR 1.153 requires that the title must designate the particular article, and since the claim must be in formal terms to the "ornamental design for the article (specifying name) as shown, or as shown and described," the title and claim must correspond. When the title and claim do not correspond, the title should be objected to under 37 CFR 1.153 as not corresponding to the claim.

However, it is emphasized that, under the second paragraph of 35 U.S.C. 112, the claim defines "the subject matter which the applicant regards as his invention" (emphasis added); that is, the ornamental design to be embodied in or applied to an article. Thus, the examiner should afford the applicant substantial latitude in the language of the title/claim. The examiner should only require amendment of the title/claim if the language is clearly misdescriptive, inaccurate, or unclear (i.e., the language would result in a rejection of the claim under 35 U.S.C. 112, second paragraph; see MPEP § 1504.04, subsection II). The use of language such as "or the like" or "or similar article" in the title when directed to the environment of the article embodying the design will not be the basis for a rejection of the claim under 35 U.S.C. 112; second paragraph. Such language is improper only when used to broaden the article, *per se*, which embodies the design. An acceptable title would be "door for cabinets, houses, or the like," while the title "door or the like" would be unacceptable and the

claim will be rejected under 35 U.S.C. 112, second paragraph. *Ex parte Pappas*, 23 USPQ2d 1636 (Bd. Pat. App. & Inter. 1992). See also MPEP § 1504.04; subsection II.

Amendments to the title, whether directed to the article in which the design is embodied or its environment, must have antecedent basis in the original disclosure and may not introduce new matter. *Ex parte Strijland*, 26 USPQ2d 1259 (Bd. Pat. App. & Inter. 1992). If an amendment to the title is directed to the environment in which the design is used and the amendment would introduce new matter, the amendment to the title must be objected to under 35 U.S.C. 132. If an amendment to the title is directed to the article in which the design is embodied and the amendment would introduce new matter, in addition to the objection under 35 U.S.C. 132, the claim must be rejected under 35 U.S.C. 112, first paragraph.

Any amendment to the language of the title should also be made at each occurrence thereof throughout the application, except in the oath or declaration. If the title of the article is not present in the original figure descriptions, it is not necessary to incorporate the title into the descriptions as part of any amendment to the language of the title.

¶ 15.05.01 Title of Design Invention

The title of a design being claimed must correspond to the name of the article in which the design is embodied or applied to. See MPEP § 1503.01.

¶ 15.59 Amend Title

For [1], the title [2] amended throughout the application, original oath or declaration excepted, to read: [3]

Examiner Note:

1. In bracket 1, insert reason.
2. In bracket 2, insert --should be-- or --has been--.

II. DESCRIPTION

No description of the design in the specification beyond a brief description of the drawing is generally necessary, since as a rule the illustration in the drawing views is its own best description. However, while not required, such a description is not prohibited and may be incorporated, at applicant's option, into the specification or may be provided in a separate paper. Descriptions of the figures are not required to be written in any particular format, however, if they do not describe the views of the drawing clearly and accurately, the examiner should object to the unclear and/

or inaccurate descriptions and suggest language which is more clearly descriptive of the views.

In addition to the figure descriptions, the following types of statements are permissible in the specification:

(A) Description of the appearance of portions of the claimed design which are not illustrated in the drawing disclosure. Such a description, if provided, must be in the design application as originally filed, and may not be added by way of amendment after the filing of the application as it would be considered new matter.

(B) Description disclaiming portions of the article not shown in the drawing as forming no part of the claimed design.

(C) Statement indicating the purpose of broken lines in the drawing, for example, environmental structure or boundaries that form no part of the design to be patented.

(D) Description denoting the nature and environmental use of the claimed design, if not included in the preamble pursuant to 37 CFR 1.154 and MPEP § 1503.01, subsection I.

It is the policy of the Office to attempt to resolve questions about the nature and intended use of the claimed design prior to examination by making a telephone inquiry at the time of initial docketing of the application. This will enable the application to be properly classified and docketed to the appropriate examiner and to be searched when the application comes up for examination in its normal course without the need for a rejection under 35 U.S.C. 112 prior to a search of the prior art. Explanation of the nature and intended use of the article may be added to the specification provided it does not constitute new matter. It may alternately, at applicant's option, be submitted in a separate paper without amendment of the specification.

(E) A "characteristic features" statement describing a particular feature of the design that is considered by applicant to be a feature of novelty or nonobviousness over the prior art (37 CFR 1.71(c)).

This type of statement may not serve as a basis for determining patentability by an examiner. In determining the patentability of a design, it is the overall appearance of the claimed design which must be

taken into consideration. *In re Rosen*, 673 F.2d 388, 213 USPQ 347 (CCPA 1982); *In re Leslie*, 547 F.2d 116, 192 USPQ 427 (CCPA 1977). Furthermore, the inclusion of such a statement in the specification is at the option of applicant and will not be suggested by the examiner.

¶ 15.47 Characteristic Feature Statement

A "characteristic features" statement describing a particular feature of novelty or unobviousness in the claimed design may be permissible in the specification. Such a statement should be in terms such as "The characteristic feature of the design resides in [1]," or if combined with one of the Figure descriptions, in terms such as "the characteristic feature of which resides in [2]." While consideration of the claim goes to the total or overall appearance, the use of a "characteristic feature" statement may serve later to limit the claim (*McGrady v. Aspenglas Corp.*, 487 F. Supp. 859, 208 USPQ 242 (S.D.N.Y. 1980)).

Examiner Note:

In brackets 1 and 2, insert brief but accurate description of the design.

¶ 15.47.01 Feature Statement Caution

The inclusion of a feature statement in the specification is noted. However, the patentability of the claimed design is not based on the specified feature but rather on a comparison of the overall appearance of the design with the prior art. *In re Leslie*, 547 F.2d 116, 192 USPQ 427 (CCPA 1977).

The following types of statements are not permissible in the specification:

(A) A disclaimer statement directed to any portion of the claimed design that is shown in solid lines in the drawings is not permitted in the specification of an issued design patent. However, the disclaimer statement may be included in the design application as originally filed to provide antecedent basis for a future amendment. See *Ex parte Remington*, 114 O.G. 761, 1905 C.D. 28 (Comm'r Pat. 1904); *In re Blum*, 374 F.2d 904, 153 USPQ 177 (CCPA 1967).

(B) Statements which describe or suggest other embodiments of the claimed design which are not illustrated in the drawing disclosure, except one that is a mirror image of that shown, are not permitted in the specification of an issued design patent. However, such statements may be included in the design application as originally filed to provide antecedent basis for a future amendment. In addition, statements which attempt to broaden the scope of the claimed design beyond that which is shown in the drawings are not permitted.

(C) Statements describing matters which are directed to function unrelated to the design.

¶ 15.46.01 Impermissible Special Description

The special description included in the specification is impermissible because [1]. See MPEP § 1503.01, subsection II. Therefore, the description should be canceled as any description of the design in the specification, other than a brief description of the drawing, is generally not necessary, since as a general rule, the illustration in the drawing views is its own best description.

Examiner Note:

In bracket 1, insert the reason why the special description is improper.

¶ 15.60 Amend All Figure Descriptions

For [1], the figure descriptions [2] amended to read: [3]

Examiner Note:

1. In bracket 1, insert reason.
2. In bracket 2, insert --should be-- or --have been--.
3. In bracket 3, insert amended text.

¶ 15.61 Amend Selected Figure Descriptions

For [1], the description(s) of Fig(s). [2] [3] amended to read: [4]

Examiner Note:

1. In bracket 1, insert reason.
2. In bracket 2, insert selected Figure descriptions.
3. In bracket 3, insert --should be-- or --have been--.
4. In bracket 4, insert amended text.

1503.02 Drawing

37 CFR 1.152. Design drawings.

The design must be represented by a drawing that complies with the requirements of § 1.84 and must contain a sufficient number of views to constitute a complete disclosure of the appearance of the design. Appropriate and adequate surface shading should be used to show the character or contour of the surfaces represented. Solid black surface shading is not permitted except when used to represent the color black as well as color contrast. Broken lines may be used to show visible environmental structure, but may not be used to show hidden planes and surfaces that cannot be seen through opaque materials. Alternate positions of a design component, illustrated by full and broken lines in the same view are not permitted in a design drawing. Photographs and ink drawings are not permitted to be combined as formal drawings in one application. Photographs submitted in lieu of ink drawings in design patent applications must not disclose environmental structure but must be limited to the design claimed for the article.

Every design patent application must include either a drawing or a photograph of the claimed design. As the drawing or photograph constitutes the entire visual disclosure of the claim, it is of utmost importance that the drawing or photograph be clear and

complete, and that nothing regarding the design sought to be patented is left to conjecture.

When inconsistencies are found among the views, the examiner should object to the drawings and request that the views be made consistent. *Ex parte Asano*, 201 USPQ 315, 317 (Bd. Pat. App. & Inter. 1978); *Hadco Products, Inc. v. Lighting Corp. of America Inc.*, 312 F. Supp. 1173, 1182, 165 USPQ 496, 503 (E.D. Pa. 1970), *vacated on other grounds*, 462 F.2d 1265, 174 USPQ 358 (3d Cir. 1972). When the inconsistencies are of such magnitude that the overall appearance of the design is unclear, the claim should be rejected under 35 U.S.C. 112, first paragraph, as nonenabling. See MPEP § 1504.04, subsection I.A.

Form paragraph 15.48 may be used to notify applicant of the necessity for good drawings.

¶ 15.48 Necessity for Good Drawings

The necessity for good drawings in a design patent application cannot be overemphasized. As the drawing constitutes the whole disclosure of the design, it is of utmost importance that it be so well executed both as to clarity of showing and completeness, that nothing regarding the design sought to be patented is left to conjecture. An insufficient drawing may be fatal to validity (35 U.S.C. 112, first paragraph). Moreover, an insufficient drawing may have a negative effect with respect to the effective filing date of a continuing application.

In addition to the criteria set forth in 37 CFR 1.81-1.88, design drawings must also comply with 37 CFR 1.152 as follows:

I. VIEWS

The drawings or photographs should contain a sufficient number of views to disclose the complete appearance of the design claimed, which may include the front, rear, top, bottom and sides. Perspective views are suggested and may be submitted to clearly show the appearance of three dimensional designs. If a perspective view is submitted, the surfaces shown would normally not be required to be illustrated in other views if these surfaces are clearly understood and fully disclosed in the perspective.

Views that are merely duplicative of other views of the design or that are flat and include no ornamentality may be omitted from the drawing if the specification makes this explicitly clear. See MPEP § 1503.01, subsection II. For example, if the left and right sides of a design are identical or a mirror image, a view should be provided of one side and a statement made

in the drawing description that the other side is identical or a mirror image. If the design has a flat bottom, a view of the bottom may be omitted if the specification includes a statement that the bottom is flat and unornamented. The term "unornamented" should not be used to describe visible surfaces which include structure that is clearly not flat. *Philco Corp. v. Admiral Corp.*, 199 F. Supp. 797, 131 USPQ 413 (D. Del. 1961).

Sectional views presented solely for the purpose of showing the internal construction or functional/mechanical features are unnecessary and may lead to confusion as to the scope of the claimed design. *Ex parte Tucker*, 1901 C.D. 140, 97 O.G. 187 (Comm'r Pat. 1901); *Ex parte Kohler*, 1905 C.D. 192, 116 O.G. 1185 (Comm'r Pat. 1905). Such views should be objected to under 35 U.S.C. 112, second paragraph, and their cancellation should be required. However, where the exact contour or configuration of the exterior surface of a claimed design is not apparent from the views of the drawing, and no attempt is made to illustrate features of internal construction, a sectional view may be included to clarify the shape of said design. *Ex parte Lohman*, 1912 C.D. 336, 184 O.G. 287 (Comm'r Pat. 1912). When a sectional view is added during prosecution, the examiner must determine whether there is antecedent basis in the original disclosure for the material shown in hatching in the sectional view (37 CFR 1.84(h)(3) and MPEP § 608.02).

II. SURFACE SHADING

While surface shading is not required under 37 CFR 1.152, it may be necessary in particular cases to shade the figures to show clearly the character and contour of all surfaces of any 3-dimensional aspects of the design. Surface shading is also necessary to distinguish between any open and solid areas of the article. However, surface shading should not be used on unclaimed subject matter, shown in broken lines, to avoid confusion as to the scope of the claim.

Lack of appropriate surface shading in the drawing as filed may render the design nonenabling under 35 U.S.C. 112, first paragraph. Additionally, if the surface shape is not evident from the disclosure as filed, the addition of surface shading after filing may comprise new matter. Solid black surface shading is not permitted except when used to represent the color

black as well as color contrast. Oblique line shading must be used to show transparent, translucent and highly polished or reflective surfaces, such as a mirror. A contrast in materials may be shown by using line shading and stippling to differentiate between the areas; such technique broadly claims this surface treatment without being limited to specific colors or materials.

Form paragraph 15.49 may be used to notify applicant that surface shading is necessary.

¶ 15.49 Surface Shading Necessary

The drawing figures should be appropriately and adequately shaded to show clearly the character and/or contour of all surfaces represented. See 37 CFR 1.152. This is of particular importance in the showing of three (3) dimensional articles where it is necessary to delineate plane, concave, convex, raised, and/or depressed surfaces of the subject matter, and to distinguish between open and closed areas. Solid black surface shading is not permitted except when used to represent the color black as well as color contrast.

III. BROKEN LINES

The two most common uses of broken lines are to disclose the environment related to the claimed design and to define the bounds of the claim. Structure that is not part of the claimed design, but is considered necessary to show the environment in which the design is associated, may be represented in the drawing by broken lines. This includes any portion of an article in which the design is embodied or applied to that is not considered part of the claimed design. *In re Zahn*, 617 F.2d 261, 204 USPQ 988 (CCPA 1980). A broken line showing is for illustrative purposes only and forms no part of the claimed design or a specified embodiment thereof. A boundary line may be shown in broken lines if it is not intended to form part of the claimed design. Applicant may choose to define the bounds of a claimed design with broken lines when the boundary does not exist in reality in the article embodying the design. It would be understood that the claimed design extends to the boundary but does not include the boundary. Where no boundary line is shown in a design application as originally filed, but it is clear from the design specification that the boundary of the claimed design is a straight broken line connecting the ends of existing full lines defining the claimed design, applicant may amend the drawing(s) to add a straight broken line connecting the ends of existing full lines

defining the claimed subject matter. Any broken line boundary other than a straight broken line may constitute new matter prohibited by 35 U.S.C. 132 and 37 CFR 1.121(f).

However, broken lines are not permitted for the purpose of indicating that a portion of an article is of less importance in the design. *In re Blum*, 374 F.2d 904, 153 USPQ 177 (CCPA 1967). Broken lines may not be used to show hidden planes and surfaces which cannot be seen through opaque materials. The use of broken lines indicates that the environmental structure or the portion of the article depicted in broken lines forms no part of the design, and is not to indicate the relative importance of parts of a design.

In general, when broken lines are used, they should not intrude upon or cross the showing of the claimed design and should not be of heavier weight than the lines used in depicting the claimed design. When broken lines cross over the full line showing of the claimed design and are defined as showing environment, it is understood that the surface which lies beneath the broken lines is part of the claimed design. When the broken lines crossing over the design are defined as boundaries, it is understood that the area within the broken lines is not part of the claimed design. Therefore, when broken lines are used which cross over the full line showing of the design, it is critical that the description of the broken lines in the specification explicitly identifies their purpose so that the scope of the claim is clear. As it is possible that broken lines with different purposes may be included in a single application, the description must make a visual distinction between the two purposes; such as --The broken lines immediately adjacent the shaded areas represent the bounds of the claimed design while all other broken lines are for illustrative purposes only; the broken lines form no part of the claimed design.-- Where a broken line showing of environmental structure must necessarily cross or intrude upon the representation of the claimed design and obscures a clear understanding of the design, such an illustration should be included as a separate figure in addition to the other figures which fully disclose the subject matter of the design. Further, surface shading should not be used on unclaimed subject matter shown in broken lines to avoid confusion as to the scope of the claim.

The following form paragraphs may be used, where appropriate, to notify applicant regarding the use of broken lines in the drawings.

¶ 15.50 *Design Claimed Shown in Full Lines*

The ornamental design which is being claimed must be shown in solid lines in the drawing. Dotted lines for the purpose of indicating unimportant or immaterial features of the design are not permitted. There are no portions of a claimed design which are immaterial or unimportant. See *In re Blum*, 374 F.2d 904, 153 USPQ 177 (CCPA 1967) and *In re Zahn*, 617 F.2d 261, 204 USPQ 988 (CCPA 1980).

¶ 15.50.01 *Use of Broken Lines in Drawing*

Environmental structure may be illustrated by broken lines in the drawing if clearly designated as environment in the specification. See 37 CFR 1.152 and MPEP § 1503.02, subsection III.

¶ 15.50.02 *Description of Broken Lines*

The following statement must be used to describe the broken lines on the drawing (MPEP § 1503.02, subsection III):

-- The broken line showing of [1] is for illustrative purposes only and forms no part of the claimed design. --

The above statement [2] inserted in the specification preceding the claim.

Examiner Note:

1. In bracket 1, insert name of structure.
2. In bracket 2, insert --must be-- or --has been--.

¶ 15.50.03 *Objectionable Use of Broken Lines In Drawings*

Dotted lines or broken lines used for environmental structure should not cross or intrude upon the representation of the claimed design for which design protection is sought. Such dotted lines may obscure the claimed design and render the disclosure indefinite (35 U.S.C. 112).

¶ 15.50.04 *Proper Drawing Disclosure With Use of Broken Lines*

Where broken lines showing environmental structure obscure the full line disclosure of the claimed design, a separate figure showing the broken lines must be included in the drawing in addition to the figures showing only claimed subject matter, 35 U.S.C. 112, first paragraph.

¶ 15.50.05 *Description of Broken Lines as Boundary of Design*

The following statement must be used to describe the broken line boundary of a design (MPEP § 1503.02, subsection III):

-- The broken line(s) which define the bounds of the claimed design form no part thereof.--

IV. SURFACE TREATMENT

The ornamental appearance of a design for an article includes its shape and configuration as well as any indicia, contrasting color or materials, graphic repre-

sentations, or other ornamentation applied to the article ("surface treatment"). Surface treatment must be applied to or embodied in an article of manufacture. Surface treatment, *per se* (i.e., not applied to or embodied in a specific article of manufacture), is not proper subject matter for a design patent under 35 U.S.C. 171. Surface treatment may either be disclosed with the article to which it is applied or in which it is embodied and must be shown in full lines or in broken lines (if unclaimed) to meet the statutory requirement. See MPEP § 1504.01. The guidelines that apply for disclosing computer-generated icons apply equally to all types of surface treatment. See MPEP § 1504.01(a).

A disclosure of surface treatment in a design drawing or photograph will normally be considered as *prima facie* evidence that the inventor considered the surface treatment shown is an integral part of the claimed design. An amendment canceling two-dimensional surface treatment or reducing it to broken lines will be permitted if it is clear from the application that applicant had possession of the basic design without the surface treatment at the time of filing of the application. See *In re Daniels*, 144 F.3d 1452, 1456-57, 46 USPQ2d 1788, 1790 (Fed. Cir. 1998). Applicant may remove surface treatment shown in a drawing or photograph of a design without such removal being treated as new matter, provided that the surface treatment does not obscure or override the underlying design. The removal of three-dimensional surface treatment that is an integral part of the configuration of the claimed design, for example, removal of beading, grooves, and ribs, will introduce prohibited new matter as the underlying configuration revealed by this amendment would not be apparent in the application as originally filed. See MPEP § 1504.04, subsection I.B.

V. PHOTOGRAPHS AND COLOR DRAWINGS

Drawings are normally required to be submitted in black ink on white paper. See 37 CFR 1.84(a)(1). Photographs are acceptable only in applications in which the invention is not capable of being illustrated in an ink drawing or where the invention is shown more clearly in a photograph (e.g., photographs of ornamental effects are acceptable). See also 37 CFR 1.81(c) and 1.83(c), and MPEP § 608.02.

Photographs submitted in lieu of ink drawings must comply with 37 CFR 1.84(b). Only one set of black and white photographs is required. Color photographs and color drawings may be submitted in design applications if filed with a petition under 37 CFR 1.84(a)(2). Petitions to accept color photographs or color drawings will be considered by the Supervisory Patent Examiner. A grantable petition under 37 CFR 1.84(a)(2) must explain why the color drawings or color photographs are necessary and must be accompanied by: (1) the fee set forth in 37 CFR 1.17(h); (2) three sets of the color photographs or color drawings; and (3) an amendment to the specification inserting the following statement --The file of this patent contains at least one drawing/photograph executed in color. Copies of this patent with color drawing(s)/photograph(s) will be provided by the Office upon request and payment of the necessary fee.-- See 37 CFR 1.84(a)(2)(iv) and MPEP § 608.02. The U.S. Patent and Trademark Office has waived 37 CFR 1.84(a)(2)(iii), and is no longer requiring a black and white photocopy of any color drawing or photograph. See 1246 O.G. 106 (May 22, 2001). If the photographs are not of sufficient quality so that all details in the photographs are reproducible, this will form the basis of subsequent objection to the quality of the photographic disclosure. No application will be issued until objections directed to the quality of the photographic disclosure have been resolved and acceptable photographs have been submitted and approved by the examiner. If the details, appearance and shape of all the features and portions of the design are not clearly disclosed in the photographs, this would form the basis of a rejection of the claim under 35 U.S.C. 112, first paragraph, as nonenabling.

Photographs and ink drawings must not be combined in a formal submission of the visual disclosure of the claimed design in one application. The introduction of both photographs and ink drawings in a design application would result in a high probability of inconsistencies between corresponding elements on the ink drawings as compared with the photographs.

When filing informal photographs or informal drawings with the original application, a disclaimer included in the specification or on the photographs themselves may be used to disclaim any surface ornamentation, logos, written matter, etc. which form no

part of the claimed design. See also MPEP § 1504.04, subsection I.B.

Color photographs and color drawings may be submitted in design applications if filed with a petition under 37 CFR 1.84(a)(2). Color may also be shown in pen and ink drawings by lining the surfaces of the design for color in accordance with the symbols in MPEP § 608.02. If the formal drawing in an application is lined for color, the following statement should be inserted in the specification for clarity and to avoid possible confusion that the lining may be surface treatment --The drawing is lined for color.-- However, lining a surface for color may interfere with a clear showing of the design as required by 35 U.S.C. 112, first paragraph, as surface shading cannot be used to define the contours of the design.

If color photographs or color drawings are filed with the original application, color will be considered an integral part of the disclosed and claimed design. The omission of color in later filed formal photographs or drawings will be permitted if it is clear from the application that applicant had possession of the basic design without the color at the time of filing of the application. See *In re Daniels*, 144 F.3d 1452, 1456-57, 46 USPQ2d 1788, 1790 (Fed. Cir. 1998) and MPEP 1504.04, subsection I.B. Note also 37 CFR 1.152, which requires that the disclosure in formal photographs be limited to the design for the article claimed.

¶ 15.05.03 Drawing/Photograph Disclosure Objected To

The drawing/photograph disclosure is objected to [1].

Examiner Note:

In bracket 1, insert statutory or regulatory basis for objection and an explanation.

¶ 15.05.04 Photoprints for Proposed Drawing Corrections

Photoprint(s) showing the proposed corrections highlighted, preferably in red ink, must be submitted for the examiner's approval. Care should be exercised to avoid introduction of new matter (35 U.S.C. 132; 37 CFR 1.121). In lieu of proposed corrections, formal drawings including any corrections may be submitted.

¶ 15.05.041 Informal Color Drawing(s)/Photograph(s) Submitted

Informal color photographs or drawings have been submitted for the purposes of obtaining a filing date. When formal drawings are submitted, any showing of color in a black and white drawing is limited to the symbols used to line a surface to show color (MPEP § 608.02). Lining entire surfaces of a design to show color(s) may interfere with a clear showing of the design as

required by 35 U.S.C. 112 because surface shading cannot be used simultaneously to define the contours of those surfaces. However, a surface may be partially lined for color with a description that the color extends across the entire surface; this technique would allow for the use of shading on the rest of the surface showing the contours of the design (37 CFR 1.152). In the alternative, a separate view, properly shaded to show the contours of the design but omitting the color(s), may be submitted if identified as shown only for clarity of illustration.

In any drawing lined for color, the following special description must be inserted in the specification (the specific colors may be identified for clarity):

--The drawing is lined for color.--

However, some designs disclosed in informal color photographs/drawings cannot be depicted in black and white drawings lined for color. For example, a design may include multiple shades of a single color which cannot be accurately represented by the single symbol for a specific color. Or, the color may be a shade other than a true primary or secondary color as represented by the drafting symbols and lining the drawing with one of the drafting symbols would not be an exact representation of the design as originally disclosed. In these situations, applicant may file a petition to accept formal color drawings or color photographs under 37 CFR 1.84(a)(2).

¶ 15.05.05 Drawing Correction Required Prior to Appeal

Any appeal of the design claim must include the proposed correction of the drawings approved by the examiner in accordance with *Ex parte Bevan*, 142 USPQ 284 (Bd. App. 1964), and must follow the procedure set forth in the PTO-1474 attached to Paper No. [1].

Examiner Note:

This form paragraph can be used in a FINAL rejection where an outstanding requirement for a drawing correction has not been satisfied.

¶ 15.07 Avoidance of New Matter

When preparing new drawings in compliance with the requirement therefor, care must be exercised to avoid introduction of anything which could be construed to be new matter prohibited by 35 U.S.C. 132 and 37 CFR 1.121.

¶ 15.45 Color Photographs/Drawings As Informal Drawings

For filing date purposes, in those design patent applications containing color photographs/drawings contrary to the requirement for ink drawings or black and white photographs, the Office of Initial Patent Examination has been authorized to construe the color photographs/drawings as informal drawings rather than to hold the applications incomplete as filed. By so doing, the Patent and Trademark Office can accept the applications without requiring applicants to file petitions to obtain the original deposit date as the filing date. However, color photographs or color drawings are not permitted in design applications in the absence of a grantable petition pursuant to 37 CFR 1.84(a)(2). Before the color photographs or color drawings in this application can be treated as formal drawings, applicant must submit [1].

Examiner Note:

In bracket 1, insert --a petition--, --the fee--, --statement in the specification--, --explanation of why color disclosure is necessary--, and/or -- three full sets of color photographs or color drawings--.

1503.03 Design Claim

The requirements for utility claims specified in 37 CFR 1.75 do not apply to design claims. Instead, the form and content of a design claim is set forth in 37 CFR 1.153:

37 CFR 1.153. ... claim...

(a) ... The claim shall be in formal terms to the ornamental design for the article (specifying name) as shown or as shown and described. More than one claim is neither required nor permitted.

A design patent application may only include a single claim. The single claim should normally be in formal terms to "The ornamental design for (*the article which embodies the design or to which it is applied*) as shown." The description of the article in the claim should be consistent in terminology with the title of the invention. See MPEP § 1503.01, subsection I.

When the specification includes a proper special description of the design (see MPEP § 1503.01, subsection II), or a proper showing of modified forms of the design or other descriptive matter has been included in the specification, the words "and described" must be added to the claim following the term "shown"; i.e., the claim must read "The ornamental design for (*the article which embodies the design or to which it is applied*) as shown and described."

The claimed design is shown by full lines in the drawing. It is not permissible to show any portion of the claimed design in broken lines. There are no portions of the claimed design which are immaterial or unimportant, and elements shown in broken lines in the drawing are not part of the claim. See MPEP § 1503.02, subsection III, and *In re Blum*, 374 F.2d 904, 153 USPQ 177 (CCPA 1967).

¶ 15.62 Amend Claim "As Shown"

For proper form (37 CFR 1.153), the claim [1] amended to read: "[2] claim: The ornamental design for [3] as shown."

¶ 15.63 Amend Claim "As Shown and Described"

For proper form (37 CFR 1.153), the claim [1] amended to read: "[2] claim: The ornamental design for [3] as shown and described."

¶ 15.64 *Addition of "And Described" to Claim*

Because of [1] -- and described -- [2] added to the claim after "shown."

1504 Examination

In design patent applications, ornamentality, novelty and nonobviousness are necessary prerequisites to the grant of a patent. The inventive novelty or unobviousness resides in the ornamental shape or configuration of the article in which the design is embodied or the surface ornamentation which is applied to or embodied in the design.

Novelty and nonobviousness of a design claim must generally be determined by a search in the pertinent design classes. It is also mandatory that the search be extended to the mechanical classes encompassing inventions of the same general type. Catalogs and trade journals are also to be consulted.

If the examiner determines that the claim of the design patent application does not satisfy the statutory requirements, the examiner will set forth in detail, and may additionally summarize, the basis for all rejections in an Official action. If an examiner determines that the claim in a design application is patentable under all statutory requirements, but formal matters still need to be addressed and corrected prior to allowance, an *Ex parte Quayle* action will be sent to applicant indicating allowability of the claim and identifying the necessary corrections.

¶ 15.19.01 *Summary Statement of Rejections*

The claim stands rejected under [1].

Examiner Note:

1. Use as summary statement of rejection(s) in Office action.
2. In bracket 1, insert appropriate basis for rejection, i.e., statutory provisions, etc.

¶ 15.58 *Claimed Design Is Patentable (Ex parte Quayle Actions)*

The claimed design is patentable over the references cited.

¶ 15.72 *Quayle Action*

This application is in condition for allowance except for the following formal matters: [1].

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire TWO MONTHS from the mailing date of this letter.

With respect to *pro se* design applications, the examiner should notify applicant in the first Office

action that it may be desirable for applicant to employ the services of a registered patent attorney or agent to prosecute the application. Applicant should also be notified that the U.S. Patent and Trademark Office cannot aid in the selection of an attorney or agent. If it appears that patentable subject matter is present and the disclosure of the claimed design complies with the requirements of 35 U.S.C.112, the examiner should include a copy of the "Guide To Filing A Design Patent Application" with the first Office action and notify applicant that it may be desirable to employ the services of a professional patent draftsman familiar with design practice to prepare the formal drawings. Applicant should also be notified that the U.S. Patent and Trademark Office cannot aid in the selection of a draftsman. The following form paragraph, where appropriate, may be used.

¶ 15.66 *Employ Services of Patent Attorney or Agent (Design Application Only)*

As the value of a design patent is largely dependent upon the skillful preparation of the drawings and specification, applicant might consider it desirable to employ the services of a registered patent attorney or agent. The U.S. Patent and Trademark Office cannot aid in the selection of an attorney or agent.

Applicant is advised of the availability of the publication "Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office." This publication is for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

¶ 15.66.01 *Employ Services of Professional Patent Draftsman (Design Application Only)*

As the value of a design patent is largely dependent upon the skillful preparation of the drawings, applicant might consider it desirable to employ the services of a professional patent draftsman familiar with design practice. The U.S. Patent and Trademark Office cannot aid in the selection of a draftsman.

Examiner Note:

This form paragraph should only be used in *pro se* applications where it appears that patentable subject matter is present and the disclosure of the claimed design complies with the requirements of 35 U.S.C. 112.

1504.01 Statutory Subject Matter for Designs

35 U.S.C. 171. *Patents for designs.*

Whoever invents any new, original, and ornamental design for an article of manufacture may obtain a patent therefor, subject to the conditions and requirements of this title.

The provisions of this title relating to patents for inventions shall apply to patents for designs, except as otherwise provided.

The language "new, original and ornamental design for an article of manufacture" set forth in 35 U.S.C. 171 has been interpreted by the case law to include at least three kinds of designs:

(A) a design for an ornament, impression, print, or picture applied to or embodied in an article of manufacture (surface indicia);

(B) a design for the shape or configuration of an article of manufacture; and

(C) a combination of the first two categories.

See *In re Schnell*, 46 F.2d 203, 8 USPQ 19 (CCPA 1931); *Ex parte Donaldson*, 26 USPQ2d 1250 (Bd. Pat. App. & Int. 1992).

A picture standing alone is not patentable under 35 U.S.C. 171. The factor which distinguishes statutory design subject matter from mere picture or ornamentation, *per se* (i.e., abstract design), is the embodiment of the design in an article of manufacture. Consistent with 35 U.S.C. 171, case law and USPTO practice, the design must be shown as applied to or embodied in an article of manufacture.

A claim to a picture, print, impression, etc. *per se*, that is not applied to or embodied in an article of manufacture should be rejected under 35 U.S.C. 171 as directed to nonstatutory subject matter. The following paragraphs may be used.

¶ 15.07.01 *Statutory Basis, 35 U.S.C. 171*

The following is a quotation of 35 U.S.C. 171:

Whoever invents any new, original, and ornamental design for an article of manufacture may obtain a patent therefor, subject to the conditions and requirements of this title.

The provisions of this title relating to patents for inventions shall apply to patents for designs, except as otherwise provided.

¶ 15.09 *35 U.S.C. 171 Rejection*

The claim is rejected under 35 U.S.C. 171 as directed to nonstatutory subject matter because the design is not shown embodied in or applied to an article.

Examiner Note:

This rejection should be used when the claim is directed to surface treatment which is not shown with an article in either full or broken lines.

¶ 15.44 *Design Inseparable From Article to Which Applied*

Design is inseparable from the article to which it is applied, and cannot exist alone merely as a scheme of ornamentation. It must be a definite preconceived thing, capable of reproduction,

and not merely the chance result of a method or of a combination of functional elements (35 U.S.C. 171; 35 U.S.C. 112, first and second paragraphs). See *Blisscraft of Hollywood v. United Plastics Co.*, 189 F. Supp. 333, 127 USPQ 452 (S.D.N.Y. 1960), 294 F.2d 694, 131 USPQ 55 (2d Cir. 1961).

Form paragraphs 15.38 and 15.40.01 may be used in a second or subsequent action, where appropriate (see MPEP § 1504.02).

1504.01(a) Computer-Generated Icons

To be directed to statutory subject matter, design applications for computer-generated icons must comply with the "article of manufacture" requirement of 35 U.S.C. 171.

I. GUIDELINES FOR EXAMINATION OF DESIGN PATENT APPLICATIONS FOR COMPUTER-GENERATED ICONS

The following guidelines have been developed to assist USPTO personnel in determining whether design patent applications for computer-generated icons comply with the "article of manufacture" requirement of 35 U.S.C. 171.

A. *General Principle Governing Compliance With the "Article of Manufacture" Requirement*

Computer-generated icons, such as full screen displays and individual icons, are 2-dimensional images which alone are surface ornamentation. See, e.g., *Ex parte Strijland*, 26 USPQ2d 1259 (Bd. Pat. App. & Int. 1992) (computer-generated icon alone is merely surface ornamentation). The USPTO considers designs for computer-generated icons embodied in articles of manufacture to be statutory subject matter eligible for design patent protection under 35 U.S.C. 171. Thus, if an application claims a computer-generated icon shown on a computer screen, monitor, other display panel, or a portion thereof, the claim complies with the "article of manufacture" requirement of 35 U.S.C. 171. Since a patentable design is inseparable from the object to which it is applied and cannot exist alone merely as a scheme of surface ornamentation, a computer-generated icon must be embodied in a computer screen, monitor, other display panel, or portion thereof, to satisfy 35 U.S.C. 171. See MPEP § 1502.

"We do not see that the dependence of the existence of a design on something outside itself is a reason for

holding it is not a design "for an article of manufacture." *In re Hruby*, 373 F.2d 997, 1001, 153 USPQ 61, 66 (CCPA 1967) (design of water fountain patentable design for an article of manufacture). The dependence of a computer-generated icon on a central processing unit and computer program for its existence itself is not a reason for holding that the design is not for an article of manufacture.

B. Procedures for Evaluating Whether Design Patent Applications Drawn to Computer-Generated Icons Comply With the "Article of Manufacture" Requirement

USPTO personnel shall adhere to the following procedures when reviewing design patent applications drawn to computer-generated icons for compliance with the "article of manufacture" requirement of 35 U.S.C. 171.

(A) Read the entire disclosure to determine what the applicant claims as the design and to determine whether the design is embodied in an article of manufacture. 37 CFR 1.71 and 1.152-1.154.

Since the claim must be in formal terms to the design "as shown, or as shown and described," the drawing provides the best description of the claim. 37 CFR 1.153.

(1) Review the drawing to determine whether a computer screen, monitor, other display panel, or portion thereof, is shown. 37 CFR 1.152.

Although a computer-generated icon may be embodied in only a portion of a computer screen, monitor, or other display panel, the drawing "must contain a sufficient number of views to constitute a complete disclosure of the appearance of the article." 37 CFR 1.152. In addition, the drawing must comply with 37 CFR 1.84.

(2) Review the title to determine whether it clearly describes the claimed subject matter. 37 CFR 1.153.

The following titles do not adequately describe a design for an article of manufacture under 35 U.S.C. 171: "computer icon"; or "icon." On the other hand, the following titles do adequately describe a design for an article of manufacture under 35 U.S.C. 171: "computer screen with an icon"; "display panel with a computer icon"; "portion of a computer screen with an icon image"; "portion of a display panel with a

computer icon image"; or "portion of a monitor displayed with a computer icon image."

(3) Review the specification to determine whether a characteristic feature statement is present. 37 CFR 1.71. If a characteristic feature statement is present, determine whether it describes the claimed subject matter as a computer-generated icon embodied in a computer screen, monitor, other display panel, or portion thereof. See *McGrady v. Aspenglas Corp.*, 487 F.2d 859, 208 USPQ 242 (S.D.N.Y. 1980) (descriptive statement in design patent application narrows claim scope).

(B) If the drawing does not depict a computer-generated icon embodied in a computer screen, monitor, other display panel, or a portion thereof, in either solid or broken lines, reject the claimed design under 35 U.S.C. 171 for failing to comply with the article of manufacture requirement.

(1) If the disclosure as a whole does not suggest or describe the claimed subject matter as a computer-generated icon embodied in a computer screen, monitor, other display panel, or portion thereof, indicate that:

(a) The claim is fatally defective under 35 U.S.C. 171; and

(b) Amendments to the written description, drawings and/or claim attempting to overcome the rejection will ordinarily be entered, however, any new matter will be required to be canceled from the written description, drawings and/or claims. If new matter is added, the claim should be rejected under 35 U.S.C. 112, first paragraph.

(2) If the disclosure as a whole suggests or describes the claimed subject matter as a computer-generated icon embodied in a computer screen, monitor, other display panel, or portion thereof, indicate that the drawing may be amended to overcome the rejection under 35 U.S.C. 171. Suggest amendments which would bring the claim into compliance with 35 U.S.C. 171.

(C) Indicate all objections to the disclosure for failure to comply with the formal requirements of the Rules of Practice in Patent Cases. 37 CFR 1.71, 1.81-1.85, and 1.152-1.154. Suggest amendments which would bring the disclosure into compliance with the formal requirements of the Rules of Practice in Patent Cases.

(D) Upon reply by applicant:

(1) Enter any amendments; and

(2) Review all arguments and the entire record, including any amendments, to determine whether the drawing, title, and specification clearly disclose a computer-generated icon embodied in a computer screen, monitor, other display panel, or portion thereof.

(E) If, by a preponderance of the evidence (see *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) (“After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.”)), the applicant has established that the computer-generated icon is embodied in a computer screen, monitor, other display panel, or portion thereof, withdraw the rejection under 35 U.S.C. 171.

II. EFFECT OF THE GUIDELINES ON PENDING DESIGN APPLICATIONS DRAWN TO COMPUTER-GENERATED ICONS

USPTO personnel shall follow the procedures set forth above when examining design patent applications for computer-generated icons pending in the USPTO as of April 19, 1996.

III. TREATMENT OF TYPE FONTS

Traditionally, type fonts have been generated by solid blocks from which each letter or symbol was produced. Consequently, the USPTO has historically granted design patents drawn to type fonts. USPTO personnel should not reject claims for type fonts under 35 U.S.C. 171 for failure to comply with the “article of manufacture” requirement on the basis that more modern methods of typesetting, including computer-generation, do not require solid printing blocks.

1504.01(b) Design Comprising Multiple Articles or Multiple Parts Embodied in a Single Article

While the claimed design must be embodied in an article of manufacture as required by 35 U.S.C. 171, it may encompass multiple articles or multiple parts within that article. *Ex parte Gibson*, 20 USPQ 249

(Bd. App. 1933). Multiple independent parts forming the claimed design may be disclosed in the drawing with or without the article being shown in broken lines. If the article is not disclosed in broken lines in the drawing, then the title must disclose the article in which the design is embodied and the association of the claimed parts must be shown by a bracket. In either case, the title must clearly define the articles or parts as a single entity, for example, set, pair, combination, unit, assembly, etc. See MPEP § 1503.01.

1504.01(c) Lack of Ornamentality

I. FUNCTIONALITY VS. ORNAMENTALITY

An ornamental feature or design has been defined as one which was “created for the purpose of ornamenting” and cannot be the result or “merely a by-product” of functional or mechanical considerations. *In re Carletti*, 328 F.2d 1020, 140 USPQ 653, 654 (CCPA 1964); *Blisscraft of Hollywood v. United Plastic Co.*, 189 F. Supp. 333, 337, 127 USPQ 452, 454 (S.D.N.Y. 1960), *aff’d*, 294 F.2d 694, 131 USPQ 55 (2d Cir. 1961). It is clear that the ornamentality of the article must be the result of a conscious act by the inventor, as 35 U.S.C. 171 requires that a patent for a design be given only to “whoever *invents* any new, original, and ornamental design for an article of manufacture.” Therefore, for a design to be ornamental within the requirements of 35 U.S.C. 171, it must be “created for the purpose of ornamenting.” *In re Carletti*, 328 F.2d 1020, 1022, 140 USPQ 653, 654 (CCPA 1964).

To be patentable, a design must be “primarily ornamental.” “In determining whether a design is *primarily functional or primarily ornamental* the claimed design is viewed in its entirety, for the ultimate question is not the functional or decorative aspect of each separate feature, but the overall appearance of the article, in determining whether the claimed design is dictated by the utilitarian purpose of the article.” *L. A. Gear Inc. v. Thom McAn Shoe Co.*, 988 F.2d 1117, 1123, 25 USPQ2d 1913, 1917 (Fed. Cir. 1993). The court in *Norco Products, Inc. v. Mecca Development, Inc.*, 617 F.Supp. 1079, 1080, 227 USPQ 724, 725 (D. Conn. 1985), held that a “primarily functional invention is not patentable” as a design.

A determination of ornamentality is not a quantitative analysis based on the size of the ornamental feature or features but rather a determination based on their ornamental contribution to the design as a whole.

While ornamentality must be based on the entire design, “[i]n determining whether a design is primarily functional, the purposes of the particular elements of the design necessarily must be considered.” *Power Controls Corp. v. Hybrinetics, Inc.*, 806 F.2d 234, 240, 231 USPQ 774, 778 (Fed. Cir. 1986). The court in *Smith v. M & B Sales & Manufacturing*, 13 USPQ2d 2002, 2004 (N. D. Cal. 1990), states that if “significant decisions about how to put it [the item] together and present it in the marketplace were informed by primarily ornamental considerations”, this information may establish the ornamentality of a design.

“However, a distinction exists between the *functionality of an article* or features thereof and the *functionality of the particular design of such article* or features thereof that perform a function.” *Avia Group International Inc. v. L. A. Gear California Inc.*, 853 F.2d 1557, 1563, 7 USPQ2d 1548, 1553 (Fed. Cir. 1988). The distinction must be maintained between the ornamental design and the article in which the design is embodied. The design for the article cannot be assumed to lack ornamentality merely because the article of manufacture would seem to be primarily functional.

II. HIDDEN IN USE

Knowledge that the article would be hidden during its end use based on the examiner’s experience in a given art or information that may have been submitted in the application itself would be considered *prima facie* evidence of the lack of ornamentality of the claim. “Visibility during an article’s ‘normal use’ is not a statutory requirement of § 171, but rather a guideline for courts to employ in determining whether the patented features are ‘ornamental.’” *Larson v. Classic Corp.*, 683 F. Supp. 1202, 1202, 7 USPQ2d 1747, 1747 (N.D. Ill. 1988). However, if the examiner based on his/her knowledge of an art is aware that a specific design “is clearly intended to be noticed during the process of sale and equally clearly intended to be completely hidden from view in the final use,” it is not necessary that a rejection be made under 35 U.S.C. 171. *In re Webb*, 916 F.2d 1553, 1558,

16 USPQ2d 1433, 1436 (Fed. Cir. 1990). However, a rejection for lack of ornamentality should be made if there is additional persuasive evidence of functionality, for example, a utility patent. Determination of whether a claimed design lacks ornamentality under 35 U.S.C. 171 must be made on a case-by-case basis as no category of articles can be considered in its entirety to be either all ornamental or all lacking in ornamentality.

In order to establish that a design is lacking in ornamentality based on the ultimate hidden end use of the article, the article must always be hidden in its end use to provide *prima facie* evidence of lack of ornamentality. In *Contico International, Inc. v. Rubbermaid Commercial Products, Inc.*, 506 F. Supp. 1072, 1076, 210 USPQ 649, 653 (8th Cir. 1981), the court held that the normal use of a dolly which supported refuse containers “entails frequent attachment to and detachment from the ‘Brute’ containers and, accordingly, that said dolly is not concealed in normal use.” Some types of articles which would be hidden intermittently are lingerie, garment hangers, tent pegs, inner soles for shoes.

III. ESTABLISHING A *PRIMA FACIE* BASIS FOR REJECTIONS UNDER 35 U.S.C. 171

To properly reject a claimed design under 35 U.S.C. 171 on the basis of a lack of ornamentality, an examiner must make a *prima facie* showing that the claimed design lacks ornamentality and provide a sufficient evidentiary basis for factual assumptions relied upon in such showing. The court in *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992), stated that “the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.”

Examples of proper evidentiary basis for a rejection under 35 U.S.C. 171 that a claim is lacking in ornamentality would be: (A) common knowledge in the art; (B) the appearance of the design itself; (C) the specification of a related utility patent; (D) information provided in the specification; or (E) the fact that an article would be hidden during its ultimate end use.

A rejection under 35 U.S.C. 171 for lack of ornamentality must be supported by evidence and rejections should not be made in the absence of such evidence.

IV. REJECTIONS MADE UNDER 35 U.S.C. 171

Rejections under 35 U.S.C. 171 for lack of ornamentality based on a proper *prima facie* showing fall into two categories:

(A) a design visible in its ultimate end use which is primarily functional based on the evidence of record; or

(B) a design not visible in its ultimate hidden end use, which is itself evidence that the design is primarily functional, *In re Stevens*, 173 F.2d 1015, 81 USPQ 362 (CCPA 1949), unless the design “is clearly intended to be noticed during the process of sale.” *In re Webb*, 916 F.2d 1553, 1558, 16 USPQ2d 1433, 1436 (Fed. Cir. 1990).

When the examiner has established a proper *prima facie* case of lack of ornamentality, “the burden of coming forward with evidence or argument shifts to the applicant.” *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). A rejection under 35 U.S.C. 171 for lack of ornamentality may be overcome by providing evidence from the inventor himself or a representative of the company that commissioned the design that there was an intent to create a design for the “purpose of ornamenting.” *In re Carletti*, 328 F.2d 1020, 1022, 140 USPQ 653, 654 (CCPA 1964). Form paragraph 15.08 or 15.08.01, where appropriate, may be used to reject a claim under 35 U.S.C. 171 for lack of ornamentality.

¶ 15.08 Lack of Ornamentality (Article Visible in End Use)

The claim is rejected under 35 U.S.C. 171 as being directed to nonstatutory subject matter in that it lacks ornamentality. To be patentable, a design must be “created for the purpose of ornamenting” the article in which it is embodied. See *Seiko-Epson Corp. v. Nu-Kate Int'l Inc.*, 190 F.3d 1360, 52 USPQ2d 1011 (Fed. Cir. 1999); *Best Lock Corp. v. Ilco Unican Corp.*, 94 F.3d 1563, 40 USPQ2d 1048 (Fed. Cir. 1996); *Avia Group International Inc. v. L. A. Gear California Inc.*, 853 F.2d 1557, 7 USPQ2d 1548 (Fed. Cir. 1988); *Power Controls Corp. v. Hybrinetics, Inc.*, 806 F.2d 234, 231 USPQ 774 (Fed. Cir. 1986); *In re Carletti*, 328 F.2d 1020, 140 USPQ 653 (CCPA 1964); *Hygienic Specialties Co. v. H.G. Salzman, Inc.*, 302 F.2d 614, 133 USPQ 96 (2d Cir. 1962); *A & H Manufacturing Co. v. Contempo Card Co.*, 576 F. Supp. 894, 221 USPQ 67 (D. R.I. 1983); *Blisscraft of Hollywood v. United Plastic Co.*, 189 F.Supp. 333, 127 USPQ 452 (S.D.N.Y. 1960), 294 F.2d 694, 131 USPQ 55 (2d Cir. 1961); *Jones v. Progress Ind. Inc.*, 163 F.Supp. 824, 119 USPQ 92 (D. R.I. 1958); and *Ex parte Webb*, 30 USPQ2d 1064 (Bd. Pat. App. & Inter. 1993).

The following evidence establishes a *prima facie* case of a lack of ornamentality: [1]

An affidavit/declaration under 37 CFR 1.132 may be submitted from applicant or a representative of the company, which commissioned the design, explaining specifically and in depth, which features or area of the claim were created with a concern for the appearance of the design not dictated by function.

Within the above affidavit/declaration, possible alternative ornamental designs which could have served the same function may also be submitted as evidence that the appearance of the claimed design was the result of ornamental considerations. *L. A. Gear v. Thom McAn Shoe Co.*, 988 F.2d 1117, 25 USPQ2d 1913 (Fed. Cir. 1993). Advertisements which emphasize the ornamentality of the article embodying the claimed design may also be submitted as evidence to rebut this rejection. *Berry Sterling Corp. v. Pescor Plastics Inc.*, 122 F.3d 1452, 43 USPQ2d 1953 (Fed. Cir. 1997). Evidence that the appearance of the design is ornamental may be shown by distinctness from the prior art as well as an attempt to develop or to maintain consumer recognition of the article embodying the design. *Seiko Epson Corp. v. Nu-Kote Int'l Inc.*, 190 F.3d 1360, 52 USPQ2d 1011 (Fed. Cir. 1999).

Examiner Note:

In bracket 1, insert source of evidence of lack of ornamentality, for example, a utility patent, a brochure, a response to a letter of inquiry, etc.

¶ 15.08.01 Lack of Ornamentality (Article Not Visible in End Use)

The claim is rejected under 35 U.S.C. 171 as being directed to nonstatutory subject matter in that the design lacks ornamentality. To be patentable, a design must be “created for the purpose of ornamenting” the article in which it is embodied. The ornamental design for an article which is hidden during its end use cannot be considered to be a “matter of concern” as its design would be “primarily functional.” See *Seiko Epson Corp. v. Nu-Kate Int'l Inc.*, 190 F.3d 1360, 52 USPQ2d 1011 (Fed. Cir. 1999); *In re Webb*, 916 F.2d 1553, 16 USPQ 2d 1433 (Fed. Cir. 1990); *In re Carletti*, 328 F.2d 1020, 140 USPQ 653 (CCPA 1964); *In re Cornwall*, 230 F.2d 457, 109 USPQ 57 (CCPA 1956); *In re Stevens*, 173 F.2d 1015, 81 USPQ 362 (CCPA 1949); *Larson v. Classic Corp.*, 683 F. Supp. 1202, 7 USPQ2d 1747 (N.D. Ill. 1988); *Norco Products, Inc. v. Mecca Development, Inc.*, 617 F. Supp. 1079, 227 USPQ 724 (D. Conn. 1985); *C & M Fiberglass Septic Tanks, Inc. v. T & N Fiberglass Mfg. Co.*, 214 USPQ 159 (D. S.C. 1981); *Blisscraft of Hollywood v. United Plastic Co.*, 189 F.Supp. 333, 127 USPQ 452 (S.D.N.Y. 1960), 294 F.2d 694, 131 USPQ 55 (2d Cir. 1961); and *Ex parte Webb*, 30 USPQ 2d 1064 (Bd. Pat. App. & Inter. 1993).

The following evidence establishes a *prima facie* case of lack of ornamentality: [1]

In an attempt to establish that the appearance of the design is a “matter of concern” during the period between its manufacture and its ultimate end use, applicant may submit a showing that the appearance of the article was of commercial concern to prospective customers or an affidavit/declaration from actual customers attesting to their concern with the design of the article. It would then be necessary to establish that during this period of visibility the design as a whole was created for the “purpose of ornament-

ing" or with "thought of ornament," and therefore, that the design is "primarily ornamental."

An affidavit/declaration under 37 CFR 1.132 may be submitted from applicant or a representative of the company, which commissioned the design, explaining specifically and in depth, which features or area of the claim were created with a concern for the appearance of the design not dictated by function.

Within the above affidavit/declaration, possible alternative ornamental designs which could have served the same function may also be submitted as evidence that the appearance of the claimed design was the result of ornamental considerations. *L. A. Gear v. Thom McAn Shoe Co.*, 988 F.2d 1117, 25 USPQ2d 1913 (Fed. Cir. 1993). Advertisements which emphasize the ornamentality of the article embodying the claimed design may also be submitted as evidence to rebut this rejection. *Berry Sterling Corp. v. Pescor Plastics Inc.*, 122 F.3d 1452, 43 USPQ2d 1953 (Fed. Cir. 1997). Evidence that the appearance of the design is ornamental may be shown by distinctness from the prior art as well as an attempt to develop or to maintain consumer recognition of the article embodying the design. *Seiko Epson Corp. v. Nu-Kote Int'l Inc.*, 190 F.3d 1360, 52 USPQ2d 1011 (Fed. Cir. 1999).

Attorney arguments are insufficient to establish the ornamentality of the claim as only the applicant or a representative of the company which commissioned the design can provide evidence of the motivating factors behind the creation of the design. *Power Controls Corp. v. Hybrinetics, Inc.*, 806 F.2d 234, 231 USPQ 774 (Fed. Cir. 1986); *Ex parte Webb*, 30 USPQ2d 1064 (Bd. Pat. App. & Inter. 1993).

This information will enable the examiner to determine if the design as a whole was created with "thought of ornament" meeting the requirement of 35 U.S.C. 171 that a design be ornamental. See *In re Carletti*, 328 F.2d 1020, 140 USPQ 653 (CCPA 1964).

Examiner Note:

In bracket 1, insert source of evidence of article being hidden in use, for example, knowledge of the art, a utility patent, a brochure, a response to a letter of inquiry.

V. EVALUATION OF EVIDENCE SUBMITTED TO OVERCOME A REJECTION UNDER 35 U.S.C. 171

In order to overcome a rejection of the claim under 35 U.S.C. 171 as lacking in ornamentality, applicant must provide evidence that he or she created the design claimed for the "purpose of ornamenting" as required by the court in *In re Carletti*, 328 F.2d 1020, 1022, 140 USPQ 653, 654 (CCPA 1964). This information must be submitted in the form of an affidavit or declaration under 37 CFR 1.132 over applicant's signature clearly explaining, specifically and in depth, which areas of the claimed design were created for primarily ornamental reasons. This may be demonstrated by showing that the creation of specific features was done with "thought of ornament." *In re*

Carletti, 328 F.2d 1020, 1022, 140 USPQ 653, 655 (CCPA 1964). Evidence to show ornamentality may also be submitted by way of an affidavit or declaration under 37 CFR 1.132 from a representative of the company which commissioned the design, as these sources could establish the intent behind the creation of the design. Applicant may also show that the functional features of the design can be equally accomplished in other ways by giving specific examples which establish that design choice was the basis for the selection of features. *Best Lock Corp. v. Ilco Unican Corp.*, 94 F.3d 1563, 40 USPQ2d 1048 (Fed. Cir. 1996); *Ex parte Webb*, 30 USPQ2d 1064 (Bd. Pat. App. & Inter. 1993). Attorney arguments are insufficient to establish such intent, as only the applicant can know the motivation behind the creation of a design. *Power Controls Corp. v. Hybrinetics, Inc.*, 806 F.2d 234, 231 USPQ 774 (Fed. Cir. 1986); *Ex parte Webb*, 30 USPQ2d 1064 (Bd. Pat. App. & Inter. 1993).

The mere display of the article embodying the design at trade shows or its inclusion in catalogs is insufficient to establish ornamentality. *Ex parte Webb*, 30 USPQ2d 1064 (Bd. Pat. App. & Inter. 1993). There must be some clear and specific indication of the ornamentality of the design in this evidence for it to be given probative weight in overcoming the *prima facie* lack of ornamentality. *Berry Sterling Corp. v. Pescor Plastics Inc.*, 122 F.3d 1452, 43 USPQ2d 1953 (Fed. Cir. 1997).

The examiner must then evaluate this evidence in light of the design as a whole to decide if the claim is primarily ornamental. It is important to be aware that this determination is not based on the size or amount of the features identified as ornamental but rather on their influence on the overall appearance of the design.

In a rejection of a claim under 35 U.S.C. 171 in which the evidentiary basis for the rejection is that the design would be hidden during its end use, the applicant must establish that the "article's design is a 'matter of concern' because of the nature of its visibility at some point between its manufacture or assembly and its ultimate use." *In re Webb*, 916 F.2d 1553, 1558, 16 USPQ2d 1433, 1436 (Fed. Cir. 1990).

Once applicant has proven that there is a period of visibility during which the ornamentality of the design is a "matter of concern," it is then necessary to determine whether the claimed design was primarily

ornamental during that period. *Larson v. Classic Corp.*, 683 F. Supp. 1202, 7 USPQ2d 1747 (N. D. Ill. 1988). The fact that a design would be visible during its commercial life is not sufficient evidence that the design was “created for the purpose of ornamenting” as required by the court in *In re Carletti*, 328 F.2d 1020, 1022, 140 USPQ 653, 654 (CCPA 1964). Examiners should follow the standard for determining ornamentality as outlined above.

“The possibility of encasing a heretofore concealed design element in a transparent cover for no reason other than to avoid this rule cannot avoid the visibility [guideline]... , lest it become meaningless.” *Norco Products Inc. v. Mecca Development Inc.*, 617 F. Supp. 1079, 1081, 227 USPQ 724, 726 (D. Conn. 1985). Applicant cannot rely on mere possibilities to provide factual evidence of ornamentality for the claimed design.

The requirements of visibility and ornamentality must be met to overcome a rejection under 35 U.S.C. 171 based on the article being hidden during its end use.

1504.01(d) Simulation

35 U.S.C. 171 requires that a design to be patentable be “original.” Clearly, a design which simulates an existing object or person is not original as required by the statute. The Supreme Court in *Gorham Manufacturing Co. v. White*, 81 U.S. (14 Wall) 511 (1871), described a design as “the thing invented or produced, for which a patent is given.” “The arbitrary chance selection of a form of a now well known and celebrated building, to be applied to toys, inkstands, paper - weights, etc. does not, in my opinion, evince the slightest exercise of invention....” *Bennage v. Phillippi*, 1876 C.D. 135, 9 O.G. 1159 (Comm’r Pat. 1876). This logic was reinforced by the CCPA in *In re Smith*, 25 USPQ 359, 360, 1935 C.D. 565, 566 (CCPA 1935), which stated that “to take a natural form, in a natural pose, ... does not constitute invention” when affirming the rejection of a claim to a baby doll. This premise was also applied in *In re Smith*, 25 USPQ 360, 362, 1935 C.D. 573, 575 (CCPA 1935), which held that a “baby doll simulating the natural features...of a baby without embodying some grotesqueness or departure from the natural form” is not patentable.

Therefore, a claim directed to a design for an article which simulates a well known or naturally occurring object or person should be rejected under 35 U.S.C. 171 as nonstatutory subject matter in that the claimed design lacks originality. Form paragraph 15.08.02 should be used. However, when a claim is rejected on this basis, examiners should provide evidence, if possible, of the appearance of the object, person or naturally occurring form in question so that a comparison may be made to the claimed design. Form paragraph 15.08.03 should be used. It would also be appropriate, if the examiner has prior art which anticipates or renders the claim obvious, to reject the claim under either 35 U.S.C. 102 or 103(a) concurrently. *In re Wise*, 340 F.2d 982, 144 USPQ 354 (CCPA 1965).

¶ 15.08.02 Simulation (Entire Article)

The claim is rejected under 35 U.S.C. 171 as being directed to nonstatutory subject matter in that the design lacks originality. The design is merely simulating [1] which applicant himself did not invent. See *In re Smith*, 25 USPQ 359, 1935 C.D. 565 (CCPA 1935); *In re Smith*, 25 USPQ 360, 1935 C.D. 573 (CCPA 1935); and *Bennage v. Phillippi*, 1876 C.D. 135, 9 O.G. 1159.

Examiner Note:

1. In bracket 1, insert the name of the article or person being simulated, e.g., the White House, Marilyn Monroe, an animal which is not stylized or caricatured in any way, a rock or shell to be used as paperweight, etc.
2. This form paragraph should be followed by form paragraph 15.08.03 when evidence has been cited to show the article or person being simulated.

¶ 15.08.03 Explanation of evidence cited in support of simulation rejection

Applicant’s design has in no way departed from the natural appearance of [1]. This reference is not relied on in this rejection but is supplied merely as representative of the usual or typical appearance of [2] in order that the claim may be compared to that which it is simulating.

Examiner Note:

1. In bracket 1, insert name of article or person being simulated and source (patent, publication, etc.).
2. In bracket 2, insert name of article or person being simulated.

1504.01(e) Offensive Subject Matter

Design applications which disclose subject matter which could be deemed offensive to any race, religion, sex, ethnic group, or nationality, such as those which include caricatures or depictions, should be rejected as nonstatutory subject matter under 35 U.S.C. 171. See also MPEP § 608. Form paragraph 15.10 should be used.

¶ 15.10 Offensive Subject Matter

The disclosure, and therefore the claim in this application, is rejected as being offensive and therefore improper subject matter for design patent protection under 35 U.S.C. 171. Such subject matter does not meet the statutory requirements of 35 U.S.C. 171. Moreover, since 37 CFR 1.3 proscribes the presentation of papers which are lacking in decorum and courtesy, and this includes depictions of caricatures in the disclosure, drawings, and/or a claim which might reasonably be considered offensive, such subject matter as presented herein is deemed to be clearly contrary to 37CFR 1.3. See MPEP § 608.

1504.02 Novelty

35 U.S.C. 102. Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in—

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a); or

(f) he did not himself invent the subject matter sought to be patented, or

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention

under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. 172. Right of priority.

The right of priority provided for by subsections (a) through (d) of section 119 of this title and the time specified in section 102(d) shall be six months in the case of designs. The right of priority provided for by section 119(e) of this title shall not apply to designs.

The standard for determining novelty under 35 U.S.C. 102 was set forth by the court in *In re Bartlett*, 300 F.2d 942, 133 USPQ 204 (CCPA 1962). "The degree of difference [from the prior art] required to establish novelty occurs when the average observer takes the new design for a different, and not a modified, already-existing design." 300 F.2d at 943, 133 USPQ at 205 (quoting *Shoemaker, Patents For Designs*, page 76). In design patent applications, the factual inquiry in determining anticipation over a prior art reference is the same as in utility patent applications. That is, the reference "must be identical in all material respects." *Hupp v. Siroflex of America Inc.*, 122 F.3d 1456, 43 USPQ2d 1887 (Fed. Cir. 1997).

The "average observer" test does not require that the claimed design and the prior art be from analogous arts when evaluating novelty. *In re Glavas*, 230 F.2d 447, 450, 109 USPQ 50, 52 (CCPA 1956). Insofar as the "average observer" under 35 U.S.C. 102 is not charged with knowledge of any art, the issue of analogoussness of prior art need not be raised. This distinguishes 35 U.S.C. 102 from 35 U.S.C. 103(a), which requires determination of whether the claimed design would have been obvious to "a person of ordinary skill in the art."

When a claim is rejected under 35 U.S.C. 102 as being unpatentable over prior art, those features of the design which are functional and/or hidden during end use may not be relied upon to support patentability. *In re Cornwall*, 230 F.2d 447, 109 USPQ 57 (CCPA 1956); *Jones v. Progress Ind. Inc.*, 119 USPQ 92 (D. R.I. 1958). Further, in a rejection of a claim under 35 U.S.C. 102, mere differences in functional considerations do not negate a finding of anticipation when determining design patentability. *Black & Decker, Inc. v. Pittway Corp.*, 636 F.2d 1193, 231 USPQ 252 (N.D. Ill. 1986).

It is not necessary for the examiner to cite or apply prior art to show that functional and/or hidden features are old in the art as long as the examiner has properly relied on evidence to support the *prima facie* lack of ornamentality of these individual features. If applicant wishes to rely on functional or hidden features as a basis for patentability, the same standard for establishing ornamentality under 35 U.S.C. 171 must be applied before these features can be given any patentable weight. See MPEP § 1504.01(c).

In evaluating a statutory bar based on 35 U.S.C. 102(b), the experimental use exception to a statutory bar for public use or sale (see MPEP § 2133.03(e)) does not usually apply for design patents. See *In re Mann*, 861 F.2d 1581, 8 USPQ2d 2030 (Fed. Cir. 1988). However, *Tone Brothers, Inc. v. Sysco Corp.*, 28 F.3d 1192, 1200, 31 USPQ2d 1321, 1326 (Fed. Cir. 1994) held that "experimentation directed to functional features of a product also containing an ornamental design may negate what otherwise would be considered a public use within the meaning of section 102(b)." See MPEP § 2133.03(e)(6).

Registration of a design abroad is considered to be equivalent to patenting under 35 U.S.C. 119(a)-(d) and 35 U.S.C. 102(d), whether or not the foreign grant

is published. (See *Ex parte Lancaster*, 151 USPQ 713 (Bd. App. 1965); *Ex parte Marinissen*, 155 USPQ 528 (Bd. App. 1966); *Appeal No. 239-48, Decided April 30, 1965*, 151 USPQ 711, (Bd. App. 1965); *Ex parte Appeal decided September 3, 1968*, 866 O.G. 16 (Bd. App. 1966). The basis of this practice is that if the foreign applicant has received the protection offered in the foreign country, no matter what the protection is called ("patent," "Design Registration," etc.), if the United States application is timely filed, a claim for priority will vest. If, on the other hand, the U.S. application is not timely filed, a statutory bar arises under 35 U.S.C. 102(d) as modified by 35 U.S.C. 172. In order for the filing to be timely for priority purposes and to avoid possible statutory bars, the U.S. design patent application must be made within 6 months of the foreign filing. See also MPEP § 1504.10.

The laws of each foreign country vary in one or more respects.

The following table sets forth the dates on which design rights can be enforced in a foreign country (INID Code (24)), and thus, are also useable in a 35 U.S.C. 102(d) rejection as modified by 35 U.S.C. 172. It should be noted that in many countries the date of registration or grant is the filing date.

Country or Organization	Date(s) Which Can Also Be Used for 35 U.S.C. 102(d) Purposes ¹ (INID Code (24))	Comment
AT-Austria	Protection starts on the date of publication of the design in the official gazette	
AU-Australia	Date of registration or grant which is the filing date	
BG-Bulgaria	Date of registration or grant which is the filing date	
BX-Benelux (Belgium, Luxembourg, and the Netherlands)	Date on which corresponding application became complete and regular according to the criteria set by the law	
CA-Canada	Date of registration or grant	
CH-Switzerland	Date of registration or grant which is the filing date	Minimum requirements: deposit application, object, and deposit fee
CL-Chile	Date of registration or grant	
CU-Cuba	Date of registration or grant which is the filing date	
CZ-Czech Republic	Date of registration or grant which is the filing date	
DE-Germany	Date of registration or grant	The industrial design right can be enforced by a court from the date of registration although it is in force earlier (as from the date of filing—as defined by law).
DK-Denmark	Date of registration or grant which is the filing date	
EG-Egypt	Date of registration or grant which is the filing date	
ES-Spain	Date of registration or grant	
FI-Finland	Date of registration or grant which is the filing date	
FR-France	Date of registration or grant which is the filing date	

Country or Organization	Date(s) Which Can Also Be Used for 35 U.S.C. 102(d) Purposes ¹ (INID Code (24))	Comment
GB-United Kingdom	Date of registration or grant which is the filing date	Protection arises automatically under the Design Right provision when the design is created. Proof of the date of the design creation needs to be kept in case the design right is challenged. The protection available to designs can be enforced in the courts following the date of grant of the Certificate of Registration as of the date of registration which stems from the date of first filing of the design in the UK or, if a priority is claimed under the Convention, as another country.
HU-Hungary	Date of registration or grant	With retroactive effect as from the filing date
JP-Japan	Date of registration or grant	
KR-Republic of Korea	Date of registration or grant	
MA-Morocco	Date of registration or grant which is the filing date	
MC-Monaco	Date of registration or grant which is the filing date	Date of prior disclosure declared on deposit
NO-Norway	Date of registration or grant which is the filing date	
OA-African Intellectual Property Organization (OAPI) (Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Cote d'Ivoire, Gabon, Guinea, Mali, Mauritania, Niger, Senegal, and Togo)	Date of registration or grant which is the filing date	
PT-Portugal	Date of registration or grant	
RO-Romania	Date of registration or grant which is the filing date	
RU-Russian Federation	Date of registration or grant which is the filing date	

Country or Organization	Date(s) Which Can Also Be Used for 35 U.S.C. 102(d) Purposes ¹ (INID Code (24))	Comment
SE-Sweden	Date of registration or grant	
TN-Tunisia	Date of registration or grant which is the filing date	
TT-Trinidad and Tobago	Date of registration or grant which is the filing date	
WO-World Intellectual Property Organization (WIPO)		Subject to Rule 14.2 of the Regulations (on defects), the International Bureau enters the international deposit in the International Register on the date on which it has in its possession the application together with the items required. Reproductions, samples, or models pursuant to Rule 12, and the prescribed fees.
<p>¹Based on information taken from the "Survey of Filing Procedures and Filing Requirements, as well as of Examination Methods and Publication Procedures, Relating to Industrial Designs" as adopted by the PCIPI Executive Coordination Committee of the World Intellectual Property Organization (WIPO) at its fifteenth session on November 25, 1994.</p>		

Rejections under 35 U.S.C. 102(d) as modified by 35 U.S.C. 172 should only be made when the examiner knows that the application for foreign registration/patent has actually issued before the U. S. filing date based on an application filed more than six (6) months prior to filing the application in the United States. If the grant of a registration/patent based on the foreign application is not evident from the record of the U. S. application or from information found within the preceding charts, then the statement below should be included in the first action on the merits of the application:

¶ 15.03.01 Foreign Filing More Than 6 Months Before U.S. Filing

Acknowledgment is made of the [1] application identified in the declaration which was filed more than six months prior to the filing date of the present application. Applicant is reminded that if the [2] application matured into a form of patent protection before the filing date of the present application it would constitute a statutory bar to the issuance of a design patent in the United States under 35 U.S.C. 102(d) in view of 35 U.S.C. 172.

Examiner Note:

In brackets 1 and 2, insert the name of country where application was filed.

Form paragraphs for use in rejections under 35 U.S.C. 102 are set forth below.

¶ 15.11 35 U.S.C. 102(a) Rejection

The claim is rejected under 35 U.S.C. 102(a) as being clearly anticipated by [1] because the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country before the invention thereof by the applicant for patent.

¶ 15.12 35 U.S.C. 102(b) Rejection

The claim is rejected under 35 U.S.C. 102(b) as being clearly anticipated by [1] because the invention was patented or described in a printed publication in this or a foreign country, or in public use or on sale in this country more than one (1) year prior to the application for patent in the United States.

¶ 15.13 35 U.S.C. 102(c) Rejection

The claim is rejected under 35 U.S.C. 102(c) because the invention has been abandoned.

¶ 15.14 35 U.S.C. 102(d)/172 Rejection

The claim is rejected under 35 U.S.C. 102(d), as modified by 35 U.S.C. 172, as being clearly anticipated by [1] because the invention was first patented or caused to be patented, or was the subject of an inventor's certificate by the applicant, or his/her legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than six (6) months before the filing of the application in the United States.

¶ 15.15 35 U.S.C. 102(e) Rejection

The claim is rejected under 35 U.S.C. 102(e) as being clearly anticipated by [1] because the invention was described in a patent or published application for patent by another filed in the United States before the invention thereof by the applicant for patent.

¶ 15.16 35 U.S.C. 102(f) Rejection

The claim is rejected under 35 U.S.C. 102(f) because applicant did not himself invent the subject matter sought to be patented.

¶ 15.17 35 U.S.C. 102(g) Rejection

The claim is rejected under 35 U.S.C. 102(g) because, before the applicant's invention thereof, the invention was made in this country by another who had not abandoned, suppressed or concealed it.

¶ 15.41 Functional, Structural Features Not Considered

Attention is directed to the fact that design patent applications are concerned solely with the ornamental appearance of an article of manufacture. The functional and/or structural features stressed by applicant in the papers are of no concern in design cases, and are neither permitted nor required. Function and structure fall under the realm of utility patent applications.

The following form paragraphs may be used in a second or subsequent action, where appropriate.

¶ 15.38 Rejection Maintained

The arguments presented have been carefully considered, but are not persuasive that the rejection of the claim under [1] should be withdrawn.

Examiner Note:

In bracket 1, insert basis of rejection.

¶ 15.40.01 Final Rejection Under Other Statutory Provisions

The claim is again and FINALLY REJECTED under [1] as [2].

Examiner Note:

1. In bracket 1, insert statutory basis.
2. In bracket 2, insert reasons for rejection.

1504.03 Nonobviousness

35 U.S.C. 103. Conditions for patentability; non-obvious subject matter.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

A claimed design that meets the test of novelty must additionally be evaluated for nonobviousness under 35 U.S.C 103(a).

I. GATHERING THE FACTS

The basic factual inquiries guiding the evaluation of obviousness, as outlined by the Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), are applicable to the evaluation of design patentability:

- (A) Determining the scope and content of the prior art;
- (B) Ascertaining the differences between the claimed invention and the prior art;
- (C) Resolving the level of ordinary skill in the art; and
- (D) Evaluating any objective evidence of nonobviousness (i.e., so-called "secondary considerations").

A. Scope of the Prior Art

The scope of the relevant prior art for purposes of evaluating obviousness under 35 U.S.C. 103(a) extends to all "analogous arts."

While the determination of whether arts are analogous is basically the same for both design and utility inventions (see MPEP § 904.01(c) and § 2141.01(a)), *In re Glavas*, 230 F.2d 447, 450 109 USPQ 50, 52 (CCPA 1956) provides specific guidance for evaluating analogous arts in the design context, which should

be used to supplement the general requirements for analogous art as follows:

The question in design cases is not whether the references sought to be combined are in analogous arts in the mechanical sense, but whether they are so related that the appearance of certain ornamental features in one would suggest the application of those features to the other.

Thus, if the problem is merely one of giving an attractive appearance to a surface, it is immaterial whether the surface in question is that of wall paper, an oven door, or a piece of crockery. . . .

On the other hand, when the proposed combination of references involves material modifications of the basic form of one article in view of another, the nature of the article involved is a definite factor in determining whether the proposed change involves [patentable] invention.

Therefore, where the differences between the claimed design and the prior art are limited to the application of ornamentation to the surface of an article, any prior art reference which discloses substantially the same surface ornamentation would be considered analogous art. Where the differences are in the shape or form of the article, the nature of the articles involved must also be considered.

B. Differences Between the Prior Art and the Claimed Design

In determining patentability under 35 U.S.C. 103(a), it is the overall appearance of the design that must be considered. *In re Leslie*, 547 F.2d 116, 192 USPQ 427 (CCPA 1977). The mere fact that there are differences between a design and the prior art is not alone sufficient to justify patentability. *In re Lamb*, 286 F.2d 610, 128 USPQ 539 (CCPA 1961).

All differences between the claimed design and the closest prior art reference should be identified in any rejection of the design claim under 35 U.S.C. 103(a). If any differences are considered *de minimis* or inconsequential from a design viewpoint, the rejection should so state.

C. Level of Ordinary Skill in the Art

In order to be unpatentable, 35 U.S.C. 103(a) requires that an invention must have been obvious to a designer having "ordinary skill in the art" to which the subject matter sought to be patented pertains. The "level of ordinary skill in the art" from which obviousness of a design claim must be evaluated under

35 U.S.C. 103(a) has been held by the courts to be the perspective of the "designer of . . . articles of the types presented." *In re Nalbandian*, 661 F.2d 1214, 1216, 211 USPQ 782, 784 (CCPA 1981); *In re Carter*, 673 F.2d 1378, 213 USPQ 625 (CCPA 1982).

D. Objective Evidence of Nonobviousness (Secondary Considerations)

Secondary considerations, such as commercial success and copying of the design by others, are relevant to the evaluation of obviousness of a design claim. Evidence of nonobviousness may be present at the time a *prima facie* case of obviousness is evaluated or it may be presented in rebuttal of a prior obviousness rejection.

II. PRIMA FACIE OBVIOUSNESS

Once the factual inquiries mandated under *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), have been made, the examiner must determine whether they support a conclusion of *prima facie* obviousness. To establish *prima facie* obviousness, all the claim limitations must be taught or suggested by the prior art.

In determining *prima facie* obviousness, the proper standard is whether the design would have been obvious to a designer of ordinary skill with the claimed type of article. *In re Nalbandian*, 661 F.2d 1214, 211 USPQ 782 (CCPA 1981).

As a whole, a design must be compared with something in existence, and not something brought into existence by selecting and combining features from prior art references. *In re Jennings*, 182 F.2d 207, 86 USPQ 68 (CCPA 1950). The "something in existence" referred to in *Jennings* has been defined as "...a reference... the design characteristics of which are basically the same as the claimed design..." *In re Rosen*, 673 F.2d 388, 391, 213 USPQ 347, 350 (CCPA 1982) (the primary reference did "...not give the same visual impression..." as the design claimed but had "...different overall appearance and aesthetic appeal...") Hence, it is clear that "design characteristics" means overall visual appearance. This definition of "design characteristics" is reinforced in the decision of *In re Harvey*, 12 F.3d 1061, 1063, 29 USPQ2d 1206, 1208 (Fed. Cir. 1993), and is supported by the earlier decisions of *In re Yardley*, 493 F.2d 1389, 181 USPQ 331, 334 (CCPA 1974) and *In re Leslie*, 547

F.2d 116, 192 USPQ 427, 431 (CCPA 1977). Specifically, in the *Yardley* decision, it was stated that “[t]he basic consideration in determining the patentability of designs over prior art is similarity of appearance.” 493 F.2d at 1392-93, 181 USPQ at 334. Therefore, in order to support a holding of obviousness, a basic reference must be more than a design concept; it must have an appearance substantially the same as the claimed design. *In re Harvey*, 12 F.3d 1061, 29 USPQ2d 1206 (Fed. Cir. 1993). Absent such a reference, no holding of obviousness under 35 U.S.C. 103(a) can be made, whether based on a single reference alone or in view of modifications suggested by secondary prior art.

A rejection under 35 U.S.C. 103(a) based on a single non-analogous reference would not be proper. The reason is that under 35 U.S.C. 103(a), a designer of ordinary skill would not be charged with knowledge of prior art that is not analogous to the claimed design.

Examiners are advised that differences between the claimed design and a basic reference may be held to be minor in nature and unrelated to the overall aesthetic appearance of the design with or without the support of secondary references. *In re Nalbandian*, 661 F.2d 1214, 211 USPQ 782 (CCPA 1981). If such differences are shown by secondary references, they should be applied so as to leave no doubt that those differences would have been obvious to a designer of ordinary skill in the art. *In re Sapp*, 324 F.2d 1021, 139 USPQ 522 (CCPA 1963).

When a claim is rejected under 35 U.S.C. 103(a) as being unpatentable over prior art, features of the design which are functional and/or hidden during end use may not be relied upon to support patentability. “[A] design claim to be patentable must also be ornamental; and functional features or forms cannot be relied upon to support its patentability.” *Jones v. Progress, Ind. Inc.*, 119 USPQ 92, 93 (D. R.I. 1958). “It is well settled that patentability of a design cannot be based on elements which are concealed in the normal use of the device to which the design is applied.” *In re Cornwall*, 230 F.2d 457, 459, 109 USPQ 57, 58 (CCPA 1956); *In re Garbo*, 287 F.2d 192, 129 USPQ 72 (CCPA 1961). It is not necessary that prior art be relied upon in a rejection under 35 U.S.C. 103(a) to show similar features to be functional and/or hidden in the art. However, examiners must provide evidence to support the *prima facie* functionality of such

features. Furthermore, hidden portions or functional features cannot be relied upon as a basis for patentability. If applicant wishes to rely on functional or hidden features as a basis for patentability, then the same standard for establishing ornamentality under 35 U.S.C. 171 must be applied before these features can be given any patentable weight. See MPEP § 1504.01(c).

A. Combining Prior Art References

A rejection under 35 U.S.C. 103(a) would be appropriate if a designer of ordinary skill would have been motivated to modify a basic reference by deleting features thereof or by interchanging with or adding features from pertinent secondary references. In order for secondary references to be considered, there must be some suggestion in the prior art to modify the basic design with features from the secondary references. *In re Borden*, 90 F.3d 1570, 1572, 39 USPQ2d 1524, 1526 (Fed. Cir. 1996). The long-standing test for properly combining references has been “...whether they are so related that the appearance of certain ornamental features in one would suggest the application of those features to the other.” *In re Glavas*, 230 F.2d 447, 450, 109 USPQ 50, 52 (CCPA 1956).

The prohibition against destroying the function of the design is inherent in the logic behind combining references to render a claimed invention obvious under 35 U.S.C. 103(a). If the proposed combination of the references so alters the primary reference that its broad function can no longer be carried out, the combination of the prior art would not have been obvious to a designer of ordinary skill in the art. It is permissible to modify the primary reference to the extent that the specific function of the article may be affected while the broad function is not affected. For example, a primary reference to a cabinet design claimed as airtight could be modified to no longer be airtight so long as its function as a cabinet would not be impaired.

1. Analogous Art

When a modification to a basic reference involves a change in configuration, both the basic and secondary references must be from analogous arts. *In re Glavas*, 230 F.2d 447, 109 USPQ 50 (CCPA 1956). The reason for this is two-fold. First, a designer of ordinary

skill is only charged with knowledge of art related to that of the claimed design. Second, the ornamental features of the references must be closely related in order for a designer of ordinary skill to have been motivated to have modified one in view of the other. Hence, when modifying a basic reference, a designer of ordinary skill would have looked at design features of other related references for precisely the purpose of observing the ornamental characteristics they disclosed.

Analogous art can be more broadly interpreted when applied to a claim that is directed to a design with a portion simulating a well known or naturally occurring object or person. The simulative nature of that portion of the design is *prima facie* evidence that art which simulates that portion would be within the level of ordinary skill under 35 U.S.C. 103(a).

2. Non-analogous Art

When modifying the surface of a basic reference so as to provide it with an attractive appearance, it is immaterial whether the secondary reference is analogous art, since the modification does not involve a change in configuration or structure and would not have destroyed the characteristics (appearance and function) of the basic reference. *In re Glavas*, 230 F.2d 447, 109 USPQ 50 (CCPA 1956).

III. REBUTTAL OF THE PRIMA FACIE CASE

Once a *prima facie* case of obviousness has been established, the burden shifts to the applicant to rebut it, if possible, with objective evidence of nonobviousness. Examples of secondary considerations are commercial success, expert testimony and copying of the design by others. Any objective evidence of nonobviousness or rebuttal evidence submitted by applicant, including affidavits or declarations under 37 CFR 1.132, must be considered by examiners in determining patentability under 35 U.S.C. 103(a).

When evidence of commercial success is submitted, examiners must evaluate it to determine whether there is objective evidence of success, and whether the success can be attributed to the ornamental design. *Litton System, Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 221 USPQ 97 (Fed. Cir. 1984); *In re Nalbandian*, 661 F.2d 1214, 211 USPQ 782 (CCPA 1981). An affidavit

or declaration under 37 CFR 1.132 has minimal evidentiary value on the issue of commercial success if there is no nexus or connection between the sales of the article in which the design is embodied and the ornamental features of the design. *Avia Group Int'l Inc. v. L.A. Gear*, 853 F.2d 1557, 7 USPQ2d 1548 (Fed. Cir. 1988).

Submission of expert testimony must establish the professional credentials of the person signing the affidavit or declaration, and should not express an opinion on the ultimate legal issue of obviousness since this conclusion is one of law. *Avia Group Int'l Inc. v. L.A. Gear*, 853 F.2d 1557, 7 USPQ2d 1548 (Fed. Cir. 1988); *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 227 USPQ 337 (Fed. Cir. 1985).

With regard to evidence submitted showing that competitors in the marketplace are copying the design, more than the mere fact of copying is necessary to make that action significant because copying may be attributable to other factors such as lack of concern for patent property or indifference with regard to the patentee's ability to enforce the patent. *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985).

"A *prima facie* case of obviousness can be rebutted if the applicant...can show that the art in any material respect 'taught away' from the claimed invention...A reference may be said to teach away when a person of ordinary skill, upon reading the reference...would be led in a direction divergent from the path that was taken by the applicant." *In re Haruna*, 249 F.3d 1327, 58 USPQ2d 1517 (Fed. Cir. 2001).

For additional information regarding the issue of objective evidence of nonobviousness, attention is directed to MPEP § 716 through § 716.06.

The following form paragraph may be used in an obviousness rejection under 35 U.S.C. 103(a), where appropriate.

¶ 15.18 35 U.S.C. 103(a) Rejection (Single Reference)

The claim is rejected under 35 U.S.C. 103(a) as being unpatentable over [1]. Although the invention is not identically disclosed or described as set forth in 35 U.S.C. 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a designer having ordinary skill in the art to which said subject matter pertains, the invention is not patentable.

¶ 15.70 *Preface, 35 U.S.C. 103(a) Rejection*

It would have been obvious to a designer of ordinary skill in the art at the time the invention was made to [1].

Examiner Note:

Insert explanation of the use of the reference applied in bracket 1.

¶ 15.67 *Rationale for 35 U.S.C. 103(a) Rejection (Single Reference)*

It is well settled that it is unobviousness in the overall appearance of the claimed design, when compared with the prior art, rather than minute details or small variations in design as appears to be the case here, that constitutes the test of design patentability. See *In re Frick*, 275 F.2d 741, 125 USPQ 191 (CCPA 1960) and *In re Lamb*, 286 F.2d 610, 128 USPQ 539 (CCPA 1961).

¶ 15.19 *35 U.S.C. 103(a) Rejection (Multiple References)*

The claim is rejected under 35 U.S.C. 103(a) as being unpatentable over [1] in view of [2].

Although the invention is not identically disclosed or described as set forth in 35 U.S.C. 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a designer of ordinary skill in the art to which said subject matter pertains, the invention is not patentable.

¶ 15.68 *Rationale for 35 U.S.C. 103(a) Rejection (Multiple References)*

This modification of the basic reference in light of the secondary prior art is proper because the applied references are so related that the appearance of features shown in one would suggest the application of those features to the other. See *In re Rosen*, 673 F.2d 388, 213 USPQ 347 (CCPA 1982); *In re Carter*, 673 F.2d 1378, 213 USPQ 625 (CCPA 1982), and *In re Glavas*, 230 F.2d 447, 109 USPQ 50 (CCPA 1956). Further, it is noted that case law has held that a designer skilled in the art is charged with knowledge of the related art; therefore, the combination of old elements, herein, would have been well within the level of ordinary skill. See *In re Antle*, 444 F.2d 1168, 170 USPQ 285 (CCPA 1971) and *In re Nalbandian*, 661 F.2d 1214, 211 USPQ 782 (CCPA 1981).

¶ 15.41 *Functional, Structural Features Not Considered*

Attention is directed to the fact that design patent applications are concerned solely with the ornamental appearance of an article of manufacture. The functional and/or structural features stressed by applicant in the papers are of no concern in design cases, and are neither permitted nor required. Function and structure fall under the realm of utility patent applications.

The following form paragraphs may be used in a second or subsequent action where appropriate.

¶ 15.38 *Rejection Maintained*

The arguments presented have been carefully considered, but are not persuasive that the rejection of the claim under [1] should be withdrawn.

Examiner Note:

In bracket 1, insert basis of rejection.

¶ 15.39 *Obviousness Under 35 U.S.C. 103(a) Repeated*

It remains the examiner's position that the [1] design claimed is obvious under 35 U.S.C. 103(a) over [2].

Examiner Note:

In bracket 1, insert name of design.

¶ 15.39.01 *35 U.S.C. 103(a) Rejection Repeated (Multiple References)*

It remains the examiner's position that the claim is obvious under 35 U.S.C. 103(a) over [1] in view of [2].

¶ 15.39.02 *Final Rejection Under 35 U.S.C. 103(a) (Single Reference)*

The claim is again and FINALLY REJECTED under 35 U.S.C. 103(a) over [1].

Examiner Note:

See paragraphs in MPEP Chapter 700, for "Action is Final" and "Advisory after Final" paragraphs.

¶ 15.40 *Final Rejection Under 35 U.S.C. 103(a) (Multiple References)*

The claim is again and FINALLY REJECTED under 35 U.S.C. 103(a) as being unpatentable over [1] in view of [2].

¶ 15.40.01 *Final Rejection Under Other Statutory Provisions*

The claim is again and FINALLY REJECTED under [1] as [2].

Examiner Note:

1. In bracket 1, insert statutory basis.
2. In bracket 2, insert reasons for rejection.

1504.04 Considerations Under 35 U.S.C. 112

35 U.S.C. 112. *Specification.*

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The drawing in a design application is incorporated into the claim by use of the claim language "as shown."

Additionally, the drawing disclosure can be supplemented by narrative description in the specification (see MPEP § 1503.01, subsection II). This description is incorporated into the claim by use of the language "as shown and described." See MPEP § 1503.03.

I. 35 U.S.C. 112, FIRST PARAGRAPH

A. Enablement and Sufficiency of Disclosure

A defect in the drawing or the narrative description in the specification that renders the design unclear, confusing, or incomplete supports a rejection of the claim under 35 U.S.C. 112, first paragraph, as being based on a nonenabling disclosure. An evaluation of the scope of the claim to determine if it meets the enablement requirement of 35 U.S.C. 112, first paragraph, cannot be based on the drawings alone. The scope of a claimed design is understood to be limited to those surfaces or portions of the article shown in the drawing in full lines in combination with any additional written description in the specification. The title does not define the scope of the claimed design but merely identifies the article in which it is embodied. See MPEP § 1503.01, subsection I. It is assumed that the claim has been crafted to protect that which the applicant "regards as his invention." *In re Zahn*, 617 F.2d 261, 204 USPQ 988 (CCPA 1980). Therefore, when visible portions of the article embodying the design are not shown, it is because they form no part of the claim to be protected. It is *prima facie* evidence that the scope of the claimed design is limited to those surfaces "as shown" in the application drawing(s) in the absence of any additional written disclosure. See MPEP § 1503.01, subsection II. "[T]he adequacy of the disclosure must be determined by reference to the scope asserted." *Philco Corp. v. Admiral Corp.*, 199 F. Supp. 797, 131 USPQ 413, 418 (D. Del. 1961).

Only those surfaces of the article that are visible at the point of sale or during use must be disclosed to meet the requirement of 35 U.S.C. 112, first paragraph, for an enabling disclosure. "The drawing should illustrate the design as it will appear to purchasers and users, since the appearance is the only thing that lends patentability to it under the design law." *Ex parte Kohler*, 1905 C.D. 192, 192, 116 O.G. 1185, 1185 (Comm'r Pat. 1905). The lack of disclo-

sure of those surfaces of the article which are hidden during sale or use does not violate the enablement requirements of the first paragraph of 35 U.S.C. 112 because the "patented ornamental design has no use other than its visual appearance...." *In re Harvey*, 12 F.3d 1061, 1064, 29 USPQ2d 1206, 1208 (Fed. Cir. 1993). Therefore, to make the "visual appearance" of the design merely involves the reproduction of what is shown in the drawings; it is not necessary that the functionality of the article be reproduced as this is not claimed. The function of a design is "that its appearance adds attractiveness, and hence commercial value, to the article embodying it." *Ex parte Cady*, 1916 C.D. 57, 61, 232 O.G. 619, 621 (Comm'r Pat. 1916).

The undisclosed surfaces not seen during sale or use are not required to be described in the specification even though the title of the design is directed to the complete article because the design is embodied only in those surfaces which are visible. *Ex parte Salsbury*, 38 USPQ 149, 1938 C.D. 6 (Comm'r Pat. 1938). While it is not necessary to show in the drawing those visible surfaces that are flat and unornamented, they should be described in the specification by way of a special description if they are considered part of the claimed design. *Ex parte Salsbury*, 38 USPQ 149, 1938 C.D. 6 (Comm'r Pat. 1938). Such special description may not be used to describe visible surfaces which include structure that is clearly not flat. *Philco Corp. v. Admiral Corp.*, 199 F. Supp. 797, 131 USPQ 413 (D. Del. 1961). See also MPEP § 1503.02.

Applications filed in which the title (in the claim) defines an entire article but the drawings and the specification fail to disclose portions or surfaces of the article that would be visible either during use or on sale, will not be considered to violate the enablement requirements of the first paragraph of 35 U.S.C. 112. Therefore, amendment to the title will not be required in such applications. However, examiners should include a statement in the first Office action on the merits (including a notice of allowability) indicating that the surface(s) or portion(s) of the article that would be normally visible but are not shown in the drawing or described in the specification are understood to form no part of the claimed design and therefore, the determination of patentability of the claimed design is based on the views of the article shown in

the drawing and the description in the specification. Form paragraph 15.85 may be used for this purpose.

When inconsistencies between the views of the drawings are so great that the overall appearance of the design is unclear, the claim should be rejected under 35 U.S.C. 112, first paragraph, as nonenabling. Otherwise, inconsistencies between drawing views will be objected to by the examiner and correction required by the applicant. See MPEP § 1503.02.

¶ 15.85 *Undisclosed visible surface(s)/portion(s) of article not forming part of the claimed design*

As the decision of *In re Zahn*, 617 F.2d 261, 204 USPQ 988 (CCPA 1980) holds that an ornamental design may be embodied in less than a complete article, it is understood that the surface(s) or portion(s) of the article that would normally be visible but are not shown in the drawing or described in the specification of the present application form(s) no part of the claimed design. Therefore, the determination of patentability of the claimed design is based on the views of the article shown in the drawing and the description in the specification.

Examiner Note:

In an examiner's amendment, the above statement should be included after form paragraph 13.02.

¶ 15.20.01 *Rejection, 35 U.S.C. 112, First Paragraph (Nonenabling)*

The claim is rejected under 35 U.S.C. 112, first paragraph, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same.

The claim is nonenabling because [1].

Examiner Note:

1. In bracket 1, insert a detailed explanation (with photoprint, if helpful) of the areas or portions of the design which are nonenabling.
2. This rejection should be followed by form paragraph 15.65 when the claim would seem to be fatally defective.

¶ 15.20.02 *Suggestion of Submission to Overcome Rejection Under 35 U.S.C. 112, First Paragraph (Nonenabling)*

It is suggested that applicant may submit large, clear sketches or photographs which show [1] in order that the examiner may be in a position to determine if the claim may be clarified without the addition of new matter (35 U.S.C. 132, 37 CFR 1.121).

Examiner Note:

In bracket 1, identify the areas or portions of the design which are unclear.

¶ 15.65 *Amendment May Not Be Possible*

The claim might be fatally defective; that is, it might not be possible to [1] without introducing new matter (35 U.S.C. 132, 37 CFR 1.121).

Examiner Note:

In bracket 1, identify portion of the claimed design which is insufficiently disclosed.

¶ 15.73 *Drawing Corrections Required*

Failure to submit proposed drawing corrections or additional drawing views overcoming all of the deficiencies in the drawing disclosure set forth above, or an explanation why proposed drawing corrections or additional drawing views are not necessary will result in the rejection of the claim under 35 U.S.C. 112, first paragraph, being made FINAL in the next Office action.

B. New Matter

New matter is subject matter which has no antecedent basis in the original specification, drawings or claim (MPEP § 608.04). An amendment to the claim must have antecedent basis in the original disclosure. 35 U.S.C. 132; 37 CFR 1.121(f). Prior to final action, all amendments will be entered in the applications and will be considered by the examiner. *Ex parte Hanback*, 231 USPQ 739 (Bd. Pat. App. & Inter. 1986). An amendment to the claim which has no antecedent basis in the specification and/or drawings as originally filed introduces new matter because that subject matter is not described in the application as originally filed. The claim must be rejected under 35 U.S.C. 112, first paragraph. An amendment to the disclosure not affecting the claim (such as environment in the title or in broken lines in the drawings), which has no antecedent basis in the application as originally filed, must be objected to under 35 U.S.C. 132 as lacking support in the application as originally filed and a requirement must be made to cancel the new matter.

The scope of a design claim is defined by what is shown in full lines in the application drawings. *In re Mann*, 861 F.2d 1581, 8 USPQ2d 2030 (Fed. Cir. 1988). The claim may be amended by broadening or narrowing its scope within the bounds of the disclosure as originally filed.

A change in the configuration of the claimed design is considered a departure from the original disclosure and introduces prohibited new matter (37 CFR 1.21(f)). See *In re Salmon*, 705 F.2d 1579, 217 USPQ 981 (Fed. Cir. 1983). This includes the removal of three-dimensional surface treatment that is an integral part of the configuration of the claimed design, for example, beading, grooves, and ribs. The underlying configuration revealed by such an amendment would not be apparent in the application as filed and, there-

fore, it could not be established that applicant was in possession of this amended configuration at the time the application was filed. An amendment which alters the appearance of the claimed design by removing two-dimensional, superimposed surface treatment may be permitted if it is clear from the application that applicant had possession of the underlying configuration of the design without the surface treatment at the time of filing of the application. See *In re Daniels*, 144 F.3d 1452, 1456-57, 46 USPQ2d 1788, 1790 (Fed. Cir. 1998).

Amendments to the title must have antecedent basis in the original application to be permissible. If an amendment to the title directed to the article in which the design is embodied has no antecedent basis in the original application, the claim will be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement thereof. *Ex parte Strijland*, 26 USPQ2d 1259 (Bd. Pat. App. & Inter. 1992). If an amendment to the title directed to the environment in which the design is used has no antecedent basis in the original application, it will be objected to under 35 U.S.C. 132 as introducing new matter into the disclosure. See MPEP § 1503.01, subsection I.

Examples of permissible amendments filed with the original application include: (A) a preliminary amendment filed simultaneously with the application papers, that is specifically identified in the original oath/declaration as required by 37 CFR 1.63 and MPEP § 608.04(b); and (B) the inclusion of a disclaimer in the original specification or on the drawings/photographs as filed. See 37 CFR 1.152 and MPEP § 1503.01 and § 1503.02.

An example of a permissible amendment submitted after the filing of the application would be an amendment that does not involve a departure from the configuration of the original disclosure (37 CFR 1.121(f)).

An example of an impermissible amendment which introduces new matter would be an amendment to the claim without antecedent basis in the original disclosure which would change the configuration or surface appearance of the original design by the addition of previously undisclosed subject matter. *In re Berkman*, 642 F.2d 427, 209 USPQ 45 (CCPA 1981).

When an amendment affecting the claim is submitted that introduces new matter into the drawing, specification or title and a rejection under 35 U.S.C. 112, first paragraph is made, the examiner should specifically identify in the Office action the subject matter which is not considered to be supported by the original disclosure. A statement by the examiner that merely generalizes that the amended drawing, specification or title contains new matter is not sufficient. Examiners should specifically identify the differences or changes made to the claimed design that are considered to introduce new matter into the original disclosure, and if possible, suggest how the amended drawing, specification or title can be corrected to overcome the rejection. Form paragraph 15.51 may be used.

If an amendment that introduces new matter into the claim is the result of a rejection under 35 U.S.C. 112, first paragraph for lack of enablement, and it is clear that the disclosure of the claimed design as originally filed cannot be corrected without the introduction of new matter, the record of the application should reflect that the claim is seen to be fatally defective. Form paragraph 15.65 may be used to set forth this position.

¶ 15.51 35 U.S.C. 112, First Paragraph Rejection (New Matter)

The claim is rejected under 35 U.S.C. 112, first paragraph as failing to comply with the description requirement thereof since the [1] introduces new matter not supported by the original disclosure. The original disclosure does not reasonably convey to a designer of ordinary skill in the art that applicant was in possession of the design now claimed at the time the application was filed. See *In re Daniels*, 144 F.3d 1452, 46 USPQ2d 1788 (Fed. Cir. 1998); *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

Specifically, there is no support in the original disclosure [2].

To overcome this rejection, applicant may attempt to demonstrate that the original disclosure establishes that he or she was in possession of the amended claim or [3].

Examiner Note:

1. In bracket 1, specify whether new drawing or amendment to the drawing, title or specification.
2. In bracket 2, specifically identify what is new matter so that the basis for the rejection is clear.
3. In bracket 3, insert specific suggestion how rejection may be overcome depending on the basis; such as, "the bracket in figures 3 and 4 of the new drawing may be corrected to correspond to the original drawing" or "the specification may be amended by deleting the special description."

¶ 15.65 *Amendment May Not Be Possible*

The claim might be fatally defective; that is, it might not be possible to [1] without introducing new matter (35 U.S.C. 132, 37 CFR 1.121).

Examiner Note:

In bracket 1, identify portion of the claimed design which is insufficiently disclosed.

¶ 15.51.01 *Amendment to Disclosure Not Affecting Claim - 35 U.S.C. 132 Objection (New Matter)*

The [1] is objected to under 35 U.S.C. 132 and 37 CFR 1.121 as introducing new matter not supported by the original disclosure. The original disclosure does not reasonably convey to a designer of ordinary skill in the art that applicant was in possession of the amended subject matter at the time the application was filed. See *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

Specifically, there is no support in the original disclosure [2].

To overcome this objection, applicant may attempt to demonstrate that the original disclosure establishes that he or she was in possession of the amended subject matter or [3].

Examiner Note:

1. In bracket 1, specify whether new drawing or amendment to the drawing, title or specification.
2. In bracket 2, specifically identify what is new matter so that the basis for the objection is clear.
3. In bracket 3, insert specific suggestion how the objection may be overcome depending on the basis; such as, "the broken line showing of environmental structure in Fig. 1 of the new drawing may be omitted to correspond to the original drawing" or "the title may be amended by deleting the reference to environmental structure".

II. 35 U.S.C. 112, SECOND PARAGRAPH

Defects in claim language give rise to a rejection of the claim under the second paragraph of 35 U.S.C. 112. The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. "[T]he definiteness of the language employed must be analyzed – not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *In re Moore*, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). A claim may appear indefinite when read in a vacuum, but may be definite upon reviewing the application disclosure or prior art teachings. Moreover, an otherwise definite claim in a vacuum may be uncertain when reviewing the application disclosure and prior art.

Moore, 439 F.2d at 1235 n.2, 169 USPQ at 238 n.2. See also MPEP § 2173.05(b).

Use of the phrases in the claim such as "or similar article," "or the like," or equivalent terminology has been held to be indefinite. See *Ex parte Pappas*, 23 USPQ2d 1636 (Bd. Pat. App. & Inter. 1992). However, the use of broadening language such as "or the like," or "or similar article" in the title when directed to the environment of the article embodying the design should not be the basis for a rejection under 35 U.S.C. 112, second paragraph. See MPEP § 1503.01, subsection I.

Examiners are reminded that there is no *per se* rule, and that the definiteness of claim language must be evaluated on the facts and circumstances of each application. The following form paragraphs may be used.

¶ 15.22.02 *Rejection, 35 U.S.C. 112, 2nd Paragraph ("Or the Like" In Claim)*

The claim is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is indefinite because of the use of the phrase "[1]" following the title. Cancellation of said phrase in the claim and each occurrence of the title throughout the papers, except the oath or declaration, will overcome the rejection. See *Ex parte Pappas*, 23 USPQ2d 1636 (Bd. App. & Inter. 1992) and 37 CFR 1.153.

Examiner Note:

1. This rejection should be used where there is another rejection in the Office action. For issue with an examiner's amendment, see form paragraph 15.69.01.
2. In bracket 1, insert --or the like-- or --or similar article--.
3. This form paragraph should not be used when "or the like" or "or similar article" in the title is directed to the environment of the article embodying the design.

¶ 15.69.01 *Remove Indefinite Language ("Or The Like") by Examiner's Amendment*

The phrase [1] in the claim following the title renders the claim indefinite. By authorization of [2] in a telephone interview on [3], the phrase has been cancelled from the claim and at each occurrence of the title throughout the papers, except the oath or declaration (35 U.S.C. 112, second paragraph, and 37 CFR 1.153). See *Ex parte Pappas*, 23 USPQ2d 1636 (Bd. Pat. App. & Inter. 1992).

Examiner Note:

In bracket 1, insert objectionable phrase, e.g., --or the like--, --or similar article--, etc.

The claim should be rejected as indefinite when it cannot be determined from the designation of the design as shown in the drawing, referenced in the title

and described in the specification what article of manufacture is being claimed, e.g., a design claimed as a "widget" which does not identify a known or recognizable article of manufacture. The following form paragraphs may be used.

¶ 15.22.03 Rejection, 35 U.S.C. 112, Second Paragraph (Title Fails to Specify a Known Article of Manufacture)

The claim as defined by the title is indefinite in that the title fails to identify an article of manufacture and the drawing disclosure does not inherently identify the article in which the design is embodied. Therefore, any attempt to clarify the title by specifying the article in which the design is embodied may introduce new matter. See 35 U.S.C. 132 and 37 CFR 1.121.

¶ 15.21.01 Rejection, 35 U.S.C. 112 (Second Paragraph) (Information Requested)

The claim is rejected for failing to particularly point out and distinctly claim the invention as required in 35 U.S.C. 112, second paragraph. The title of the article in which the design is embodied or applied is too ambiguous and therefore indefinite for the examiner to make a proper examination of the claim under 37 CFR 1.104.

Applicant is therefore required to provide a sufficient explanation of the nature and intended use of the article in which the claimed design is embodied or applied, so that a proper classification and reliable search can be made. See 37 CFR 1.154(b)(1); MPEP 1503.01. Additional information, if available, regarding analogous fields of search, pertinent prior art, advertising brochures and the filing of copending utility applications would also prove helpful. If a utility application has been filed, please furnish its application number.

This information should be submitted in the form of a separate paper, and should not be inserted in the specification (37 CFR 1.56). See also 37 CFR 1.97, 1.98 and 1.99.

III. RELATIONSHIP BETWEEN THE REQUIREMENTS OF THE FIRST AND SECOND PARAGRAPHS OF 35 U.S.C. 112

While the requirements of the first and second paragraphs of 35 U.S.C. 112 are separate and distinct, the relationship between these requirements is not always easily distinguishable in design patent practice, because the drawing disclosure (which is equivalent to the written description) is incorporated into the claim by the use of the claim language "as shown." This reference to the drawing in the claim is the basis for a rejection under 35 U.S.C. 112, first paragraph, when an amendment to the drawing disclosure of the design introduces new matter (35 U.S.C. 132). A rejection under 35 U.S.C. 112, first and second paragraphs, should be made when the drawing disclosure and the claim disagree, conflict or are inconsistent,

other than in scope, and confusion exists as to whether the claimed design is sufficiently disclosed in the enabling teachings of the drawings. For instance, if the subject matter defined in the claim is directed to a design embodied in a chair and the drawing only discloses a design embodied in a table, the claim should be rejected under 35 U.S.C. 112, first and second paragraphs, as being based on a nonenabling disclosure and as being indefinite since it is not clear what article of manufacture is being claimed. Form paragraph 15.21 may be used.

¶ 15.21 Rejection, 35 U.S.C. 112, First And Second Paragraphs

The claim is rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Examiner Note:

1. This form paragraph should not be used when it is appropriate to make one or more separate rejections under the first and/or the second paragraph of 35 U.S.C. 112. In other words, separate rejections under either the first or the second paragraph of 35 U.S.C. 112 are preferred. This form paragraph should only be used when either the first or the second paragraph of 35 U.S.C. 112 could be applicable, but due to some question of interpretation, uncertainty exists as to whether the claimed invention is sufficiently described in the enabling teachings of the specification or the claim language is indefinite.
2. A full explanation should be provided with this rejection.

Where the design claim would otherwise be patentable but for the presence of any rejection under 35 U.S.C. 112, first and/or second paragraphs, form paragraph 15.58.01 may be used.

¶ 15.58.01 Claimed Design Is Patentable (35 U.S.C. 112 Rejections)

The claimed design is patentable over the references cited. However, a final determination of patentability will be made upon resolution of the above rejection.

Form paragraphs 15.38 and 15.40.01 may be used in a second or subsequent action, where appropriate (see MPEP § 1504.02).

1504.05 Restriction

General principles of utility restriction are set forth in Chapter 800 of the MPEP. These principles are also applicable to design restriction practice with the exception of those differences set forth in this section.

Unlike a utility patent application, which can contain plural claims directed to plural inventions, a design patent application may only have a single claim and thus must be limited to patentably indistinct designs. Therefore, the examiner will require restriction in each design application which contains more than one patentably distinct design.

Restriction will be required under 35 U.S.C. 121 if a design patent application discloses multiple designs that are either independent or patentably distinct from each other and cannot be supported by a single claim. The issue of whether a search and examination of an entire application can be made without serious burden to an examiner (as noted in MPEP § 803) is not applicable to design applications when determining whether a restriction requirement should be made. If multiple designs are held to be patentably indistinct and can be covered by a single claim, any rejection of one over prior art will apply equally to all. *Ex parte Appeal No. 315-40*, 152 USPQ 71 (Bd. App. 1965).

I. INDEPENDENT INVENTIONS

Design inventions are independent if there is no apparent relationship between two or more disparate articles disclosed in the drawings; for example, a pair of eyeglasses and a door handle; a bicycle and a camera; an automobile and a bathtub. Also note examples in MPEP § 806.04. Restriction in such cases is clearly proper. This situation may be rarely presented since design patent applications are seldom filed containing disclosures of independent articles.

II. DISTINCT INVENTIONS

Design inventions are distinct if the overall appearance of two or more embodiments of an article as disclosed in the drawings are different in appearance or scope; for example, two embodiments of a brush, and their appearances are patentable (novel and unobvious) over each other. Restriction in such cases is also clearly proper. Distinct designs may constitute either multiple embodiments of the same article or they may be related as a combination and subcombination of the overall design. In addition, applications that include one or more embodiments disclosing all surfaces of an article as well as other embodiments disclosing only a portion of an article must be evaluated to determine whether the differences in scope patentably distinguish the overall appearance of the fully

disclosed embodiments over the partially disclosed embodiments. If the differences in scope between the embodiments render them patentably distinct, then restriction would be proper. In determining the question of patentable distinctness under 35 U.S.C. 121 in a design patent application, a search of the prior art may be necessary.

A. *Multiple Embodiments - Difference in Appearance*

It is permissible to illustrate more than one embodiment of a design invention in a single application. However, such embodiments may be presented only if they involve a single inventive concept and are not patentably distinct from one another. See *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959). Embodiments that are patentably distinct over one another do not constitute a single inventive concept and thus may not be included in the same design application. *In re Platner*, 155 USPQ 222 (Comm'r Pat. 1967). The disclosure of plural embodiments does not require or justify more than a single claim, which claim must be in the formal terms stated in MPEP § 1503.03. The specification should make clear that multiple embodiments are disclosed and should particularize the differences between the embodiments. If the disclosure of any embodiment relies on the disclosure of another embodiment for completeness to satisfy the requirements of 35 U.S.C. 112, first paragraph, the differences between the embodiments must be identified either in the figure descriptions or by way of a special description in the specification of the application as filed. For example, the second embodiment of a cabinet discloses a single view showing only the difference in the front door of the cabinet of the first embodiment; the figure description should state that this view "is a second embodiment of Figure 1, the only difference being the configuration of the door, it being understood that all other surfaces are the same as those of the first embodiment." This type of statement in the description is understood to incorporate the disclosure of the first embodiment to complete the disclosure of the second embodiment. However, in the absence of such a statement in the specification of an application as filed, the disclosure of one embodiment will normally not be permitted to provide antecedent basis for any

written or visual amendment to the disclosure of other embodiments.

The obviousness standard under 35 U.S.C. 103(a) must be applied in determining whether multiple embodiments may be retained in a single application. That is, the differences between the embodiments must either be *de minimis* and unrelated to their overall aesthetic appearance or must be obvious to a designer of ordinary skill in view of the analogous prior art in order to be retained in a single application. If the embodiments are not considered obvious under 35 U.S.C. 103(a), restriction must be required.

Form paragraph 15.27.02 or 15.27.03, if appropriate, may be used to notify applicant that restriction is not required because the embodiments are not patentably distinct.

¶ 15.27.02 Restriction Not Required - Change In Appearance (First Action - Non Issue)

This application discloses the following embodiments:

Embodiment 1 - Figs. [1]

Embodiment 2 - Figs. [2]

[3]

Multiple embodiments of a single inventive concept may be included in the same design application only if they are patentably indistinct. See *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959). Embodiments that are patentably distinct from one another do not constitute a single inventive concept and thus may not be included in the same design application. See *In re Platner*, 155 USPQ 222 (Comm'r Pat. 1967).

The above identified embodiments are considered by the examiner to present overall appearances that are not distinct from one another. Accordingly, they are deemed to comprise a single inventive concept and are being retained and examined in the same application. Any rejection of one embodiment over prior art will apply equally to all other embodiments. See *Ex parte Appeal No. 315-40*, 152 USPQ 71 (Bd. App. 1965). No argument asserting patentability based on the differences between the embodiments will be considered once the embodiments have been determined to comprise a single inventive concept. Failure of applicant to traverse this determination in reply to this action will be considered an admission of lack of patentable distinction between the above identified embodiments.

Examiner Note:

In bracket 3, add embodiments as necessary.

¶ 15.27.03 Restriction Not Required - Change In Appearance (First Action Issue)

This application discloses the following embodiments:

Embodiment 1 - Figs. [1]

Embodiment 2 - Figs. [2]

[3]

Multiple embodiments of a single inventive concept may be included in the same design application only if they are patentably

indistinct. See *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959). Embodiments that are patentably distinct from one another do not constitute a single inventive concept and thus may not be included in the same design application. See *In re Platner*, 155 USPQ 222 (Comm'r Pat. 1967).

The above identified embodiments are considered by the examiner to present overall appearances that are not distinct from one another. Accordingly, they are deemed to comprise a single inventive concept and are being retained and examined in the same application.

Examiner Note:

In bracket 3, add embodiments as necessary.

The following form paragraphs may be used in a restriction requirement.

¶ 15.27 Restriction Under 35 U.S.C. 121

This application discloses the following embodiments:

Embodiment 1 - Figs. [1]

Embodiment 2 - Figs. [2]

[3]

Multiple embodiments of a single inventive concept may be included in the same design application only if they are patentably indistinct. See *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959). Embodiments that are patentably distinct from one another do not constitute a single inventive concept and thus may not be included in the same design application. See *In re Platner*, 155 USPQ 222 (Comm'r Pat. 1967). The [4] create(s) patentably distinct designs.

The above embodiments divide into the following patentably distinct groups of designs:

Group I: Embodiment [5]

Group II: Embodiment [6]

[7]

Restriction is required under 35 U.S.C. 121 to one of the above identified patentably distinct groups of designs.

A reply to this requirement must include an election of a single group for prosecution on the merits, even if this requirement is traversed, 37 CFR 1.143. Any reply that does not include election of a single group will be held nonresponsive. Applicant is also requested to direct cancellation of all drawing figures and the corresponding descriptions which are directed to the nonelected groups.

Should applicant traverse this requirement on the grounds that the groups are not patentably distinct, applicant should present evidence or identify such evidence now of record showing the groups to be obvious variations of one another. If the groups are determined not to be patentably distinct and they remain in this application, any rejection of one group over prior art will apply equally to all other embodiments. See *Ex parte Appeal No. 315-40*, 152 USPQ 71 (Bd. App. 1965). No argument asserting patentability based on the differences between the groups will be considered once the groups have been determined to comprise a single inventive concept.

In view of the above requirement, action on the merits is deferred pending compliance with the requirement in accordance

with *Ex parte Heckman*, 135 USPQ 229 (P.O. Super. Exam. 1960).

Examiner Note:

1. In bracket 3, add embodiments as necessary.
2. In bracket 4, insert an explanation of the difference(s) between the designs.
3. In bracket 7, add groups as necessary.

¶ 15.27.01 *Restriction Under 35 U.S.C. 121 (Obvious Variations Within Group)*

This application discloses the following embodiments:

Embodiment 1 - Figs. [1]

Embodiment 2 - Figs. [2]

[3]

Multiple embodiments of a single inventive concept may be included in the same design application only if they are patentably indistinct. See *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959). Embodiments that are patentably distinct from one another do not constitute a single inventive concept and thus may not be included in the same design application. See *In re Platner*, 155 USPQ 222 (Comm'r Pat. 1967).

The above embodiments divide into the following patentably distinct groups of designs:

Group I: Embodiment [4]

Group II: Embodiment [5]

[6]

The embodiments disclosed within each group do not present overall appearances that are distinct from one another; i.e., they are considered by the examiner to be obvious variations of one another within the group. These embodiments thus comprise a single inventive concept and are grouped together. However, the [7] patentably distinguishes each group from the other(s).

Restriction is required under 35 U.S.C. 121 to one of the patentably distinct groups of the designs.

A reply to this requirement must include an election of a single group for prosecution on the merits, even if this requirement is traversed, 37 CFR 1.143. Any reply that does not include election of a single group will be held nonresponsive. Applicant is also requested to direct cancellation of all drawing figures and the corresponding descriptions which are directed to the nonelected groups.

Should applicant traverse this requirement on the grounds that the groups are not patentably distinct, applicant should present evidence or identify such evidence now of record showing the groups to be obvious variations of one another. If the groups are determined not to be patentably distinct and they remain in this application, any rejection of one group over prior art will apply equally to all other groups. See *Ex parte Appeal No. 315-40*, 152 USPQ 71 (Bd. App. 1965). No argument asserting patentability based on the differences between the groups will be considered once the groups have been determined to comprise a single inventive concept.

In view of the above requirement, action on the merits is deferred pending compliance with the requirement in accordance with *Ex parte Heckman*, 135 USPQ 229 (P.O. Super. Exam. 1960).

Examiner Note:

1. In bracket 3, add embodiments as necessary.
2. In bracket 6, add groups as necessary.
3. In bracket 7, insert an explanation of the difference(s) between the groups.

¶ 15.28 *Telephone Restriction Under 35 U.S.C. 121*

This application discloses the following embodiments:

Embodiment 1 - Figs. [1]

Embodiment 2 - Figs. [2]

[3]

Multiple embodiments of a single inventive concept may be included in the same design application only if they are patentably indistinct. See *In re Rubinfeld*, 123 USPQ 210 (CCPA 1959). Embodiments that are patentably distinct from one another do not constitute a single inventive concept and thus may not be included in the same design application. The [4] create(s) patentably distinct designs. See *In re Platner*, 155 USPQ 222 (Comm'r Pat. 1967).

The above disclosed embodiments divide into the following patentably distinct groups of designs:

Group I: Embodiment [5]

Group II: Embodiment [6]

[7]

Restriction is required under 35 U.S.C. 121 to one of the patentably distinct groups of designs.

During a telephone discussion with [8] on [9], a provisional election was made [10] traverse to prosecute the design(s) of group [11]. Affirmation of this election should be made by applicant in replying to this Office action.

Group [12] is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being for a nonelected design(s).

Examiner Note:

1. In bracket 3, add embodiments as necessary.
2. In bracket 4, insert an explanation of the difference(s) between the designs.
3. In bracket 7, add groups as necessary.
4. In bracket 10, insert --with-- or --without--.

¶ 15.28.01 *Telephone Restriction Under 35 U.S.C. 121 (Obvious Variations Within Group)*

This application discloses the following embodiments:

Embodiment 1 - Figs. [1]

Embodiment 2 - Figs. [2]

[3]

Multiple embodiments of a single inventive concept may be included in the same design application only if they are patentably indistinct. See *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959). Embodiments that are patentably distinct from one another do not constitute a single inventive concept and thus may not be included in the same design application. See *In re Platner*, 155 USPQ 222 (Comm'r Pat. 1967).

The above embodiments divide into the following patentably distinct groups of designs:

Group I: Embodiment [4]

Group II: Embodiment [5]

[6]

The embodiments disclosed within each group do not present overall appearances that are distinct from one another, i.e., they are considered by the examiner to be obvious variations of one another within the group. These embodiments thus comprise a single inventive concept and are grouped together. However, the [7] patentably distinguishes each group from the other(s).

Restriction is required under 35 U.S.C. 121 to one of the patentably distinct groups of designs.

During a telephone discussion with [8] on [9], a provisional election was made [10] traverse to prosecute the design(s) of group [11]. Affirmation of this election should be made by applicant in replying to this Office action.

Group [12] is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being for a nonelected design(s).

Examiner Note:

1. In bracket 3, add embodiments as necessary.
2. In bracket 6, add groups as necessary.
3. In bracket 7, insert an explanation of the differences between the groups.
4. In bracket 10, insert --with--or --without--.

¶ 15.31 Provisional Election Required (37 CFR 1.143)

Applicant is advised that the reply to be complete must include a provisional election of one of the enumerated designs, even though the requirement may be traversed (37 CFR 1.143).

B. Combination/Subcombination - Difference in Scope

A design claim covers the entire design as a whole. It is not limited to any part or portion of the design. However, a design claim may cover embodiments of different scope directed to the same inventive concept within a single application if the designs are not patentably distinct. *In re Rubinfield*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959). The court held that the inventive concept of a design is not limited to its embodiment in a single specific article, and as long as the various embodiments are not patentably distinct, they may be protected by a single claim. *Blumcraft of Pittsburgh v. Ladd*, 144 USPQ 562 (D.D.C. 1965). The determination that the design of the subcombination/element is patentably indistinct from the combination means that the designs are not patentable (novel and unobvious) over each other and may remain in the same application. If the embodiments are patentably distinct, the designs are considered to be separate inventions which require separate claims, and restriction to one or the other is necessary. See *In re Kelly*, 200 USPQ 560 (Comm'r Pat. 1978); *Ex parte Sanford*, 1914 C.D. 69, 204 O.G. 1346 (Comm'r

Pat. 1914); *Ex parte Heckman*, 135 USPQ 229 (P.O. Super. Exam. 1960). Form paragraph 15.27.04 or 15.17.05, if appropriate, may be used to notify applicant that restriction is not required because the embodiments required are not patentably distinct.

¶ 15.27.04 Restriction Not Required - Change In Scope (First Action - Non Issue)

This application discloses the following embodiments:

Embodiment 1 - Figs. [1]

Embodiment 2 - Figs. [2]

[3]

Designs which involve a change in scope may be included in the same design application only if they are patentably indistinct as design patent protection does not extend to patentably distinct segregable parts of a design. *Ex parte Sanford*, 1914 C.D. 69, 204 O.G. 1346 (Comm'r Pat. 1914); *Blumcraft of Pittsburgh v. Ladd*, 144 USPQ 562 (D.D.C. 1965).

The above identified embodiments are considered by the examiner to present overall appearances that are not distinct from one another. Accordingly, they are deemed to comprise a single inventive concept and have been examined together. Any rejection of one embodiment over prior art will apply equally to all other embodiments. *Ex parte Appeal No. 315-40*, 152 USPQ 71 (Bd. App. 1965). No argument asserting patentability based on the differences between the embodiments will be considered once the embodiments have been determined to comprise a single inventive concept. Failure of applicant to traverse this determination in reply to this Office action will be considered an admission of lack of patentable distinction between the embodiments.

Examiner Note:

In bracket 3, add embodiments as necessary.

Form paragraph 15.29 or 15.30, if applicable, may be used to make a restriction requirement.

¶ 15.27.05 Restriction Not Required - Change In Scope (First Action Issue)

This application discloses the following embodiments:

Embodiment 1 - Figs. [1]

Embodiment 2 - Figs. [2]

[3]

Designs which involve a change in scope may be included in the same design application only if they are patentably indistinct as design patent protection does not extend to patentably distinct segregable parts of a design. *Ex parte Sanford*, 1914 C.D. 69, 204 O.G. 1346 (Comm'r Pat. 1914); *Blumcraft of Pittsburgh v. Ladd*, 144 USPQ 562 (D.D.C. 1965).

The above identified embodiments are considered by the examiner to present overall appearances that are not distinct from one another. Accordingly, they are deemed to comprise a single inventive concept and have been examined together.

Examiner Note:

In bracket 3, add embodiments as necessary.

Form paragraph 15.29 or 15.30, if appropriate, may be used to make a restriction requirement.

¶ 15.29 *Restriction Under 35 U.S.C. 121 (Segregable Parts or Combination/Subcombination)*

This application discloses the following embodiments:

Embodiment 1 – Figs. [1] drawn to a [2].

Embodiment 2 – Figs. [3] drawn to a [4].

[5]

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I – Embodiment [6]

Group II – Embodiment [7]

[8]

The designs as grouped are distinct from each other since under the law a design patent covers only the invention disclosed as an entirety, and does not extend to patentably distinct segregable parts; the only way to protect such segregable parts is to apply for separate patents. See *Ex parte Sanford*, 1914 CD 69, 204 OG 1346 (Comm'r Pat. 1914); and *Blumcraft of Pittsburgh v. Ladd*, 144 USPQ 562 (D.D.C. 1965). It is further noted that patentably distinct combination/subcombination subject matter must be supported by separate claims, whereas only a single claim is permissible in a design patent application. See *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959).

[9]

Because the designs are distinct for the reason(s) given above, and have acquired separate status in the art, restriction for examination purposes as indicated is proper (35 U.S.C. 121).

A reply to this requirement must include an election of a single group for prosecution on the merits, even if this requirement is traversed. 37 CFR 1.143. Any reply that does not include an election of a single group will be held nonresponsive. Applicant is also requested to direct cancellation of all drawing figures and the corresponding descriptions which are directed to the nonelected groups.

Should applicant traverse this requirement on the grounds that the groups are not patentably distinct, applicant should present evidence or identify such evidence now of record showing the groups to be obvious variations of one another. If the groups are determined not to be patentably distinct and they remain in this application, any rejection of one group over the prior art will apply equally to all other groups. See *Ex parte Appeal No. 315-40*, 152 USPQ 71 (Bd. App. 1965). No argument asserting patentability based on the differences between the groups will be considered once the groups have been determined to comprise a single inventive concept.

In view of the above requirement, action on the merits is deferred pending compliance with the requirement in accordance with *Ex parte Heckman*, 135 USPQ 229 (P.O. Super. Exam. 1960).

Examiner Note:

1. In bracket 5, add embodiments as necessary.
2. In bracket 8, add groups as necessary.
3. In bracket 9, add comments, if necessary.

¶ 15.30 *Telephone Restriction Under 35 U.S.C. 121 (Segregable Parts or Combination/Subcombination)*

This application discloses the following embodiments:

Embodiment 1 – Figs. [1] drawn to a [2].

Embodiment 2 – Figs. [3] drawn to a [4].

[5]

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I – Embodiment [6]

Group II – Embodiment [7]

[8]

The designs as grouped are distinct from each other since under the law a design patent covers only the invention disclosed as an entirety, and does not extend to patentably distinct segregable parts; the only way to protect such segregable parts is to apply for separate patents. See *Ex parte Sanford*, 1914 CD 69, 204 OG 1346 (Comm'r Pat. 1914); and *Blumcraft of Pittsburgh v. Ladd*, 144 USPQ 562 (D.D.C. 1965). It is further noted that patentably distinct combination/subcombination subject matter must be supported by separate claims, whereas only a single claim is permissible in a design patent application. See *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959).

[9]

During a telephone discussion with [10] on [11], a provisional election was made [12] traverse to prosecute the invention of Group [13]. Affirmation of this election should be made by applicant in replying to this Office action.

Group [14] withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being for a nonelected invention.

Examiner Note:

1. In bracket 5, add embodiments as necessary.
2. In bracket 8, add groups as necessary.
3. In bracket 9, insert additional comments, if necessary.

Form paragraph 15.27.06 or 15.27.07, if appropriate, may be used to notify applicant that restriction is not required because the designs are not patentably distinct.

¶ 15.27.06 *Restriction Not Required (Change in Appearance and Scope – First Action Non Issue)*

This application discloses the following embodiments:

Embodiment 1 - Figs. [1] drawn to a [2].

Embodiment 2 - Figs. [3] drawn to a [4].

[5]

Embodiments [6] involve a difference in appearance. Multiple embodiments of a single inventive concept may be included in the same design application only if they are patentably indistinct. *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959). Embodiments that are patentably distinct from one another do not constitute a single inventive concept and thus may not be included in the same design application. *In re Plamer*, 155 USPQ 222 (Comm'r Pat. 1967).

Embodiment(s) [7] directed to the combination(s) in relation to Embodiment(s) [8] directed to the subcombination(s)/element(s). Designs which involve a change in scope may be included in the

same design application only if they are patentably indistinct as design protection does not extend to patentably distinct segregable parts of a design. *Ex parte Sanford*, 1914 C.D. 69, 204 O.G. 1346 (Comm'r Pat. 1914); *Blumcraft of Pittsburgh v. Ladd*, 144 USPQ 562 (D.D.C.1965).

The above identified embodiments are considered by the examiner to present overall appearances that are not distinct from one another. Accordingly, they are deemed to comprise a single inventive concept and have been examined together. Any rejection of one embodiment over prior art will apply equally to all other embodiments. *Ex parte Appeal No. 315-40*, 152 USPQ 71 (Bd. App. 1965). No argument asserting patentability based on the differences between the embodiments will be considered once the embodiments have been determined to comprise a single inventive concept. Failure of applicant to traverse this determination in reply to this action will be considered an admission of lack of patentable distinction between the embodiments.

Examiner Note:

1. In bracket 5, add embodiments as necessary.
2. Insert an explanation of the differences between the designs in the explanations of the embodiments; for example, Figs. 1 – 5 directed to a cup and saucer; Figs. 6 – 9 directed to a saucer.
3. It is possible and proper that embodiments may be listed in both explanatory paragraphs.

¶ 15.27.07 Restriction Not Required (Change in Appearance and Scope – First Action Issue)

This application discloses the following embodiments:

Embodiment 1 – Figs. [1] drawn to a [2].

Embodiment 2 – Figs. [3] drawn to a [4].

[5]

Embodiment(s) [6] involve a difference in appearance. Multiple embodiments of a single inventive concept may be included in the same design application only if they are patentably indistinct. *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959). Embodiments that are patentably distinct from one another do not constitute a single inventive concept and thus may not be included in the same design application. *In re Platner*, 155 USPQ 222 (Comm'r Pat. 1967).

Embodiment(s) [7] directed to the combination(s) in relation to Embodiment(s) [8] directed to the subcombination(s)/element(s). Designs which involve a change in scope may be included in the same design application only if they are patentably indistinct as design protection does not extend to patentably distinct segregable parts of a design. *Ex parte Sanford*, 1914 C.D. 69, 204 O.G. 1346 (Comm'r Pat. 1914); *Blumcraft of Pittsburgh v. Ladd*, 144 USPQ 562 (D.D.C.1965).

The above identified embodiments are considered by the examiner to present overall appearances that are not patentably distinct from one another. Accordingly, they were deemed to comprise a single inventive concept and have been examined together.

Examiner Note:

1. In bracket 5, add embodiments as necessary.
2. Insert an explanation of the differences between the designs in the explanations of the embodiments; for example, Figs. 1 – 5 directed to a cup and saucer; Figs. 6 – 9 directed to a saucer.

3. It is possible and proper that embodiments may be listed in both explanatory paragraphs.

The following form paragraphs may be used in a restriction requirement.

¶ 15.27.08 Restriction with Differences in Appearance and Scope

This application discloses the following embodiments:

Embodiment 1: Figs. [1] drawn to a [2].

Embodiment 2: Figs. [3] drawn to a [4].

[5]

The above embodiments divide into the following patentably distinct groups of designs:

Group I: Embodiment [6]

Group II: Embodiment [7]

[8]

Group(s) [9] involve a difference in appearance. Multiple embodiments of a single inventive concept may be included in the same design application only if they are patentably indistinct. *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959). Embodiments that are patentably distinct from one another do not constitute a single inventive concept and thus may not be included in the same design application. *In re Platner*, 155 USPQ 222 (Comm'r Pat. 1967). The [10] creates patentably distinct designs.

Group(s) [11] directed to the combination(s) in relation to Group(s) [12] directed to the subcombination(s)/element(s). The designs as grouped are distinct from each other since under the law a design patent covers only the design disclosed as an entirety, and does not extend to patentably distinct segregable parts; the only way to protect such segregable parts is to apply for separate patents. *Ex parte Sanford*, 1914 C.D. 69, 204 O.G. 1346 (Comm'r Pat. 1914); *Blumcraft of Pittsburgh v. Ladd*, 144 USPQ 562 (D.D.C.1965). It is further noted that combination/subcombination subject matter, if patentably distinct, must be supported by separate claims, whereas only a single claim is permissible in a design patent application. *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959).

In any groups that include multiple embodiments, the embodiments are considered by the examiner to be obvious variations of one another within the group and, therefore, patentably indistinct. These embodiments thus comprise a single inventive concept and are grouped together.

Restriction is required under 35 U.S.C. 121 to one of the patentably distinct groups of designs.

A reply to this requirement must include an election of a single group for prosecution on the merits even if this requirement is traversed. 37 CFR 1.143. Any reply that does not include an election of a single group will be held nonresponsive. Applicant is also requested to direct cancellation of all drawing figures and the corresponding descriptions which are directed to the nonelected groups.

Should applicant traverse this requirement on the grounds that the groups are not patentably distinct, applicant should present evidence or identify such evidence now of record showing the groups to be obvious variations of one another. If the groups are determined not to be patentably distinct and they remain in this

application, any rejection of one group over prior art will apply equally to all other groups. *Ex parte Appeal No. 315-40*, 152 USPQ 71 (Bd. App. 1965). No argument asserting patentability based on the differences between the groups will be considered once the groups have been determined to comprise a single inventive concept.

In view of the above requirement, action on the merits is deferred pending compliance with the requirement in accordance with *Ex parte Heckman*, 135 USPQ 229 (P.O. Super. Exam. 1960).

Examiner Note:

1. In bracket 5, add embodiments as necessary.
2. In bracket 8, add embodiments as necessary.
3. Insert an explanation of the differences between the designs in the explanations of the embodiments; for example, Figs. 1 – 5 directed to a cup and saucer; Figs. 6 – 9 directed to a saucer.
4. It is possible and proper that embodiments may be listed in both explanatory paragraphs.
5. In bracket 10, insert an explanation of the differences between the designs.
6. This form paragraph should be followed by form paragraph 8.23.01.

¶ 15.28.02 Telephone Restriction with Differences in Appearance and Scope

This application discloses the following embodiments:

Embodiment 1: Figs. [1] drawn to a [2].

Embodiment 2: Figs. [3] drawn to a [4].

[5]

The above embodiments divide into the following patentably distinct groups of designs:

Group I: Embodiment [6]

Group II: Embodiment [7]

[8]

Group(s) [9] involve a difference in appearance. Multiple embodiments of a single inventive concept may be included in the same design application only if they are patentably indistinct. *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959). Embodiments that are patentably distinct from one another do not constitute a single inventive concept and thus may not be included in the same design application. *In re Platner*, 155 USPQ 222 (Comm'r Pat. 1967). The [10] creates patentably distinct designs.

Group(s) [11] directed to the combination(s) in relation to Group(s) [12] directed to the subcombination(s)/element(s). The designs as grouped are distinct from each other since under the law a design patent covers only the design disclosed as an entirety, and does not extend to patentably distinct segregable parts; the only way to protect such segregable parts is to apply for separate patents. *Ex parte Sanford*, 1914 C.D. 69, 204 O.G. 1346 (Comm'r Pat. 1914); *Blumcraft of Pittsburg v. Ladd*, 144 USPQ 562 (D.D.C.1965). It is further noted that combination/subcombination subject matter, if patentably distinct, must be supported by separate claims, whereonly a single claim is permissible in a design patent application. *In re Rubinfeld*, 270 F.2d 391, 123 USPQ 210 (CCPA 1959).

In any groups that include multiple embodiments, the embodiments are considered by the examiner to be obvious variations of

one another within the group and, therefore, patentably indistinct. These embodiments thus comprise a single inventive concept and are grouped together.

Restriction is required under 35 U.S.C. 121 to one of the patentably distinct groups of designs.

During a telephone discussion with [13] on [14], a provisional election was made [15] traverse to prosecute the invention of Group [16]. Affirmation of this election should be made by applicant in replying to this Office action.

Group [17] is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being for a nonelected invention.

Examiner Note:

1. In bracket 5, add embodiments as necessary.
2. In bracket 8, add groups as necessary.
3. Insert an explanation of the differences between the designs in the explanations of the embodiments; for example, Figs. 1 – 5 directed to a cup and saucer; Figs. 6 – 9 directed to a saucer.
4. It is possible and proper that embodiments may be listed in both explanatory paragraphs.
5. In bracket 10, insert an explanation of the differences between the designs.
6. In bracket 15, insert --with-- or --without--.

¶ 15.33 Qualifying Statement To Be Used In Restriction When A Common Embodiment Is Included In More Than One Group

The common embodiment is included in more than a single group as it is patentably indistinct from the other embodiment(s) in those groups and to give applicant the broadest possible choices in his or her election. If the common embodiment is elected in this application, then applicant is advised that the common embodiment should not be included in any continuing application to avoid a rejection on the ground of double patenting under 35 U.S.C. 171 in the new application.

The following form paragraphs may be used to notify applicant that the nonelected invention(s) are withdrawn from consideration.

¶ 15.34 Groups Withdrawn From Consideration After Traverse

Group [1] withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being for a nonelected design, the requirement having been traversed in Paper No. [2].

¶ 15.35 Cancel Nonelected Design (Traverse)

The restriction requirement maintained in this application is or has been made final. Applicant must cancel Group [1] directed to the design(s) nonelected with traverse in Paper No. [2], or take other timely appropriate action (37 CFR 1.144).

¶ 15.36 Groups Withdrawn From Consideration Without Traverse

Group [1] withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being for the nonelected design. Election was made without traverse in Paper No. [2].

¶ 15.37 Cancellation of Nonelected Groups, No Traverse

In view of the fact that this application is in condition for allowance except for the presence of Group [1] directed to a design or designs nonelected without traverse in Paper No. [2], and without the right to petition, such Group(s) have been canceled.

1504.06 Double Patenting

There are generally two types of double patenting rejections. One is the "same invention" type double patenting rejection based on 35 U.S.C. 171 which states in the singular that an inventor "may obtain a patent." The second is the "nonstatutory-type" double patenting rejection based on a judicially created doctrine grounded in public policy and which is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. Nonstatutory double patenting includes rejections based on one-way determination of obviousness, and two-way determination of obviousness.

The charts in MPEP § 804 outline the procedure for handling all double patenting rejections.

Double patenting rejections are based on a comparison of the claims in a patent and an application or between two applications; the disclosure of the patent or application may be relied upon only to define the claim. 35 U.S.C. 171 specifically states that "a patent" may be obtained if certain conditions are met; this use of the singular makes it clear that only one patent may issue for a design.

Determining if a double patenting rejection is appropriate involves the answering the following inquiries: Is the same design being claimed twice? If the answer is yes, then a rejection under 35 U.S.C. 171 should be given on the grounds of "same invention" type double patenting. If not, are the designs directed to patentably indistinct variations of the same inventive concept? If the answer is yes, then a rejection based on the nonstatutory type double patenting should be given.

Double patenting rejections are based on a comparison of claims. While there is a direct correlation between the drawings in a design application and the claim, examiners must be aware that no such correlation is necessary in a utility application or patent. Several utility patents may issue with the identical drawing disclosure but with claims directed to different inventions. So any consideration of possible dou-

ble patenting rejections between a utility application or patent with a design application cannot be based on the utility drawing disclosure alone. *Anchor Hocking Corp. v. Eyelet Specialty Co.*, 377 F. Supp. 98, 183 USPQ 87 (D. Del. 1974). The examiner must be able to recreate the design claimed from the utility claims without any reliance whatsoever on the drawings.

If a provisional double patenting rejection (of any type) is the only rejection remaining in two conflicting applications, the examiner should withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the provisional double patenting rejection in the other application which rejection will be converted into a double patenting rejection when the first application issues as a patent. If more than two applications conflict with each other and one is allowed, the remaining applications should be cross rejected against the others as well as the allowed application. For this type of rejection to be appropriate, there must be either at least one inventor in common, or a common assignee. If the claims in copending design applications or a design patent and design applications have a common assignee but different inventive entities, rejections under 35 U.S.C. 102(e), (f) and (g)/103(a) must be considered in addition to the double patenting rejection. See MPEP § 804, § 2136, § 2137 and § 2138.

I. "SAME INVENTION" DOUBLE PATENTING REJECTIONS

A design - design statutory double patenting rejection based on 35 U.S.C. 171 prevents the issuance of a second patent for a design already patented. For this type of double patenting rejection to be proper, identical designs with identical scope must be twice claimed. *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). A design - utility "same invention" double patenting rejection is based on judicial doctrine as there is no statutory basis for this rejection because neither 35 U.S.C. 101 nor 35 U.S.C. 171 can be applied against both claims. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). The "same invention" type of double patenting rejection, whether statutory or nonstatutory, cannot be overcome by a

terminal disclaimer. *In re Swett*, 145 F.2d 631, 172 USPQ 72 (CCPA 1971).

¶ 15.23.02 Summary for "Same Invention" – Type Double Patenting Rejections

Applicant is advised that a terminal disclaimer may not be used to overcome a "same invention" type double patenting rejection. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); MPEP § 804.02.

Examiner Note:

This form paragraph should follow all "same invention" type double patenting rejections.

¶ 15.23 35 U.S.C. 171 Double Patenting Rejection (Design-Design)

The claim is rejected under 35 U.S.C. 171 on the ground of double patenting since it is claiming the same design as that claimed in United States Design Patent No. [1].

Examiner Note:

Form paragraph 15.23.02 should follow all "same invention" type double patenting rejections.

¶ 15.23.01 35 U.S.C. 171 Provisional Double Patenting Rejection (Design-Design)

The claim is provisionally rejected under 35 U.S.C. 171 on the ground of double patenting since it is claiming the same design as that claimed in copending Application No. [1]. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Examiner Note:

Form paragraph 15.23.02 should follow all "same invention" type double patenting rejections.

¶ 15.24.07 Double Patenting Rejection (Design-Utility)

The claim is rejected under the judicially created doctrine of double patenting as being directed to the same invention as that set forth in claim [1] of United States Patent No. [2]. See *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Examiner Note:

Form paragraph 15.23.02 should follow all "same invention" type double patenting rejections.

¶ 15.24.08 Provisional Double Patenting Rejection (Design-Utility)

The claim is provisionally rejected under the judicially created doctrine of double patenting as being directed to the same invention as that set forth in claim [1] of copending Application No. [2]. See *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

This is a provisional double patenting rejection because the claims have not in fact been patented.

Examiner Note:

Form paragraph 15.23.02 should follow all "same invention" type double patenting rejections.

¶ 15.24.01 35 U.S.C. 102(e) Provisional Rejection (Common Inventor or Assignee)

The claim is provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. [1] which has a common [2] with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the conflicting copending application. This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any unclaimed invention disclosed in the copending application was derived from the inventor of this application and thus not the invention "by another," or by a showing of a date of invention of any unclaimed subject matter prior to the effective U.S. filing date of the copending application under 37 CFR 1.131.

Examiner Note:

1. In bracket 2, insert --inventor-- or --assignee--.
2. This form paragraph is used when a copending application having an earlier filing date discloses the claimed invention and there is at least one common inventor or a common assignee.

¶ 15.24.11 35 U.S.C. 102(e) Rejection (Common Inventor or Assignee)

The claim is rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent No. [1] which has a common [2] with the instant application. Based upon the earlier effective U.S. filing date of the Patent, it would constitute prior art under 35 U.S.C. 102(e). This rejection might be overcome either by a showing under 37 CFR 1.132 that any unclaimed invention disclosed in the Patent was derived from the inventor of this application and thus not the invention "by another," or by a showing of a date of invention of any unclaimed subject matter prior to the effective U.S. filing date of the copending application under 37 CFR 1.131.

Examiner Note:

1. In bracket 2, insert --inventor-- or --assignee--.
2. This form paragraph is used when a United States Patent having an earlier filing date discloses the claimed invention and there is at least one common inventor or a common assignee.

¶ 15.24.05 Identical Claim: Common Assignee

The claim is directed to the same invention as that of the claim of commonly assigned copending Application No. [1]. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved. Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly. Failure to comply with this requirement will result in a holding of abandonment of this application.

II. NONSTATUTORY DOUBLE PATENTING REJECTIONS

A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

A nonstatutory double patenting rejection of the obviousness-type applies to claims directed to the *same inventive concept with different appearances or differing scope which are patentably indistinct from each other*. Nonstatutory categories of double patenting rejections which are not the "same invention" type may be overcome by the submission of a terminal disclaimer.

An obviousness-type double patenting rejection must be based on the obviousness standard of 35 U.S.C. 103(a). That is, differences between the claimed designs must either be *de minimis* and unrelated to their overall aesthetic appearance or must be obvious to a designer of ordinary skill in the art related to the claimed design in view of the prior art or case law. If the claims are considered obvious under 35 U.S.C. 103(a), an obviousness-type double patenting rejection must be made. While the earlier patent (if less than a year older than the application) or application is not technically "prior art," the principle involved is the same. *In re Zickendraht*, 319 F.2d 225, 138 USPQ 22 (CCPA 1963)(see concurring opinion of Judge Rich).

In determining whether to make an obviousness-type double patenting rejection between designs having differing scope, the examiner should compare the reference claim with the application claim. A rejection is appropriate if:

(A) The difference in scope is *de minimis* and unrelated to the overall aesthetic appearance of the claims being compared;

(B) Patent protection for the design, fully disclosed in and covered by the claim of the reference, would be extended by the allowance of the claim in the later filed application; and

(C) No terminal disclaimer has been filed.

This kind of obviousness-type double patenting rejection in designs will occur between designs which may be characterized as a combination (narrow claim) and a subcombination/element thereof (broad claim). If the designs are patentably indistinct and are directed to the same inventive concept the examiner must determine whether the subject matter of the narrower claim is fully disclosed in and covered by the broader claim of the reference. If the reference does *not* fully disclose the narrower claim, then a double patenting rejection should not be made. The additional disclosure necessary to establish that the applicant was in possession of the narrower claim at the time the broader claim was filed may be in a title or special description as well as in a broken line showing in the drawings. If the broader claim of the reference does not disclose the additional subject matter claimed in the narrower claim, then applicant could not have claimed the narrower claim at the time the application with the broader claim was filed and a rejection under nonstatutory double patenting would be inappropriate.

A nonstatutory double patenting rejection may be made between a patent and an application or provisionally between applications. Such rejection over a patent should only be given if the patent issued less than a year before the filing date of the application. If the patent is more than a year older than the application, the patent is considered to be "prior art" which may be applied in a rejection under 35 U.S.C. 102(b)/103(a). The purpose of a terminal disclaimer is to obviate a double patenting rejection by removing potential harm to the public by issuing a second patent. See MPEP § 804.

If the issue of double patenting is raised between a patent and a *continuing* application, examiners are reminded that this ground of rejection can only be made when the filing of the continuing application is voluntary and not the direct, unmodified result of restriction requirement under 35 U.S.C. 121. See MPEP § 804.01.

Examiners should particularly note that a design-design nonstatutory double patenting rejection does not *always* have to be made in both of the conflicting applications. For the most part, these rejections will be made in each of the conflicting applications; but, if the rejection is only appropriate in one direction, it is

proper to reject only one application. The criteria for determining whether a one-way obviousness determination is necessary or a two-way obviousness determination is necessary is set forth in MPEP § 804. However, in design-utility situations, a two-way obviousness determination is necessary for the rejection to be proper. *In re Dembiczak*, 175 F.3d 994, 50 USPQ2d 1614 (Fed. Cir. 1999).

The following form paragraphs may be used in making a double patenting rejection.

¶ 15.24.06 *Basis for Nonstatutory Double Patenting, "Heading Only"*

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Examiner Note:

This form paragraph must precede all nonstatutory double patenting rejections as a heading, except "same invention" type.

¶ 15.24 *Obviousness-type Double Patenting Rejection (Single Reference)*

The claim is rejected under the judicially created doctrine of the obviousness-type double patenting of the claim in United States Patent No. [1]. Although the conflicting claims are not identical, they are not patentably distinct from each other because [2].

Examiner Note:

1. In bracket 1, insert prior U.S. Patent Number.
2. In bracket 2, an explanation is necessary.
3. This form paragraph must be preceded by form paragraph 15.24.06 and followed by form paragraph 15.67.

¶ 15.24.03 *Provisional Obviousness-Type Double Patenting Rejection (Single Reference)*

The claim is provisionally rejected under the judicially created doctrine of the obviousness-type double patenting of the claim of copending Application No. [1]. Although the conflicting claims are not identical, they are not patentably distinct from each other because [2]. This is a provisional obviousness-type double pat-

enting rejection because the conflicting claims have not in fact been patented.

Examiner Note:

1. In bracket 1, insert conflicting application number.
2. In bracket 2, an explanation is necessary.
3. This form paragraph must be preceded by form paragraph 15.24.06 and followed by form paragraph 15.67.

¶ 15.67 *Rationale for 35 U.S.C. 103(a) Rejection (Single Reference)*

It is well settled that it is unobviousness in the overall appearance of the claimed design, when compared with the prior art, rather than minute details or small variations in design as appears to be the case here, that constitutes the test of design patentability. See *In re Frick*, 275 F.2d 741, 125 USPQ 191 (CCPA 1960) and *In re Lamb*, 286 F.2d 610, 128 USPQ 539 (CCPA 1961).

¶ 15.25 *Obviousness-Type Double Patenting Rejection (Multiple References)*

The claim is rejected under the judicially created doctrine of the obviousness-type double patenting of the claim(s) in United States Patent No. [1] in view of [2]. At the time applicant made the design, it would have been obvious to a designer of ordinary skill in the art to [3] as demonstrated by [4].

Examiner Note:

1. In bracket 1, insert conflicting patent number.
2. In bracket 2, insert secondary reference(s).
3. In brackets 3 and 4, insert explanation of basis for rejection.
4. This form paragraph must be preceded by form paragraph 15.24.06 and followed by form paragraph 15.68.

¶ 15.24.04 *Provisional Obviousness-Type Double Patenting Rejection (Multiple References)*

The claim is provisionally rejected under the judicially created doctrine of the obviousness-type double patenting of the claim of copending Application No. [1] in view of [2]. At the time applicant made the design, it would have been obvious to a designer of ordinary skill in the art to [3] as demonstrated by [4]. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Examiner Note:

1. In bracket 1, insert conflicting application number.
2. In bracket 2, insert secondary reference(s).
3. In bracket 3, insert an explanation.
4. This form paragraph must be preceded by form paragraph 15.24.06 and followed by form paragraph 15.68.

¶ 15.68 *Rationale for 35 U.S.C. 103(a) Rejection (Multiple References)*

This modification of the basic reference in light of the secondary prior art is proper because the applied references are so related that the appearance of those features shown in one would suggest the application of those features to the other. See *In re Rosen*, 673 F.2d 388, 213 USPQ 347 (CCPA 1982); *In re Carter*, 673 F.2d 1378, 213 USPQ 625 (CCPA 1982), and *In re Glavas*, 230 F.2d 447, 109 USPQ 50 (CCPA 1956). Further, it is noted that case law

has held that a designer skilled in the art is charged with knowledge of the related art; therefore, the combination of old elements, herein, would have been well within the level of ordinary skill. See *In re Antle*, 444 F.2d 1168, 170 USPQ 285 (CCPA 1971) and *In re Nalbandian*, 661 F.2d 1214, 211 USPQ 782 (CCPA 1981).

1504.10 Priority Under 35 U.S.C. 119 (a)-(d)

35 U.S.C. 172. Right of priority.

The right of priority provided for by subsections (a) through (d) of section 119 of this title and the time specified in section 102(d) shall be six months in the case of designs. The right of priority provided for by section 119(e) of this title shall not apply to designs.

The provisions of 35 U.S.C. 119(a)-(d) apply to design patent applications. However, in order to obtain the benefit of an earlier foreign filing date, the United States application must be filed within 6 months of the earliest date on which any foreign application for the same design was filed. Design applications may not make a claim for priority of a provisional application under 35 U.S.C. 119(e).

¶ 15.01 Conditions Under 35 U.S.C. 119(a)-(d)

Applicant is advised of conditions as specified in 35 U.S.C. 119(a)-(d). An application for a design patent for an invention filed in this country by any person who has, or whose legal representatives have previously filed an application for a design patent, or equivalent protection for the same design in a foreign country which offers similar privileges in the case of applications filed in the United States or in a WTO member country, or to citizens of the United States, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within six (6) months from the earliest date on which such foreign application was filed.

¶ 15.03 Untimely Priority Papers Returned

Receipt is acknowledged of the filing on [1] of a certified copy of the [2] application referred to in the oath or declaration. A claim for priority cannot be based on said application, since the United States application was filed more than six (6) months thereafter (35 U.S.C. 172).

The United States will recognize claims for the right of priority under 35 U.S.C. 119(a)-(d) based on applications filed under such bilateral or multilateral treaties as the "Hague Agreement Concerning the International Deposit of Industrial Designs" and the "Uniform Benelux Act on Designs and Models." In filing a claim for priority of a foreign application previously filed under such a treaty, certain information

must be supplied to the United States Patent and Trademark Office. In addition to the application number and the date of filing of the foreign application, the following information is required:

(A) the name of the treaty under which the application was filed,

(B) the name of at least one country other than the United States in which the application has the effect of, or is equivalent to, a regular national filing and

(C) the name and location of the national or inter-governmental authority which received the application.

¶ 15.02 Right of Priority Under 35 U.S.C. 119(b)

No application for design patent shall be entitled to the right of priority under 35 U.S.C. 119(b) unless a claim therefor and a certified copy of the original foreign application, specification and drawings upon which it is based are filed in the United States Patent and Trademark Office before the issue fee is paid, or at such time during the pendency of the application as required by the Commissioner not earlier than six (6) months after the filing of the application in this country. Such certification shall be made by the Patent Office, or other proper authority of the foreign country in which filed, and show the date of the application and of the filing of the specification and other papers. The Commissioner may require a translation of the papers filed if not in the English language, and such other information as deemed necessary.

The notation requirement on design patent application file wrappers when foreign priority is claimed is set forth in MPEP § 202.03.

¶ 15.04 Priority Under Bilateral or Multilateral Treaties

The United States will recognize claims for the right of priority under 35 U.S.C. 119(a)-(d) based on applications filed under such bilateral or multilateral treaties as the Hague Agreement Concerning the International Deposit of Industrial Designs, and the Benelux Designs Convention. In filing a claim for priority of a foreign application previously filed under such a treaty, certain information must be supplied to the United States Patent and Trademark Office. In addition to the application number and the date of filing of the application, the following information is requested: (1) the name of the treaty under which the application was filed; (2) the name of at least one country other than the United States in which the application has the effect of, or is equivalent to, a regular national filing; and (3) the name and location of the national or international governmental authority which received such application.

¶ 15.52 Examination of Priority Papers

While the U.S. Patent and Trademark Office does not normally examine the priority papers to determine whether the applicant is in fact entitled to the right of priority, in the case of a Design Patent application, the priority papers will normally be inspected to determine that the foreign application is in fact for the same

invention as the application in the United States (35 U.S.C. 119). Inspection of the papers herein indicates that the prior foreign application was not for the same invention as claimed in this application. Accordingly, the priority claim is improper, and the papers are being returned.

Attention is also directed to the paragraphs dealing with the requirements where an actual model was originally filed in Germany (MPEP § 201.14(b)).

See MPEP Chapter 200 and 37 CFR 1.55 for further discussion of the practice and procedure under 35 U.S.C. 119(a)-(d).

1504.20 Benefit Under 35 U.S.C. 120

35 U.S.C. 120. Benefit of earlier filing date in the United States.

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

If applicant is entitled under 35 U.S.C. 120 to the benefit of an earlier U.S. filing date, the statement that, "This is a division [continuation] of design Application No. — — —, filed — — —," should appear in the first sentence of the specification. As set forth in 37 CFR 1.78(a)(2), the specification must contain or be amended to contain such a reference in the first sentence following the title unless the reference is included in an application data sheet (37 CFR 1.76). The failure to timely submit such a reference is considered a waiver of any benefit under 35 U.S.C. 120.

Attention is directed to the requirements for "continuing" applications set forth in MPEP § 201.07, § 201.08, and § 201.11. Applicants are entitled to claim the benefit of the filing date of earlier applica-

tions for later claimed inventions under 35 U.S.C. 120 only when the earlier application discloses that invention in the manner required by 35 U.S.C. 112, first paragraph. In all continuation and divisional applications, a determination must be made by the examiner as to whether the conditions for priority under 35 U.S.C. 120 have been met. The disclosure of the claimed design in a continuation and divisional application must be the same as that of the original application. If this condition is not met, applicant is not entitled to the benefit of the earlier filing date and the examiner should notify applicant accordingly by specifying the reasons why applicant is not entitled to claim the benefit under 35 U.S.C. 120. Form paragraphs 2.09 and 2.10 may be used. The examiner should also require applicant to cancel the claim for priority in the first sentence of the specification.

In the absence of a statement in the application as originally filed incorporating by reference the disclosure of an earlier filed application, the disclosure in a continuing application may not be amended to conform to that of the earlier filed application for which priority is claimed. A mere statement that an application is a continuation or division of an earlier filed application is not an incorporation of anything into the application containing such reference for purposes of satisfying the disclosure requirements of 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See also MPEP 608.01(p).

When the first application is found to be fatally defective under 35 U.S.C. 112 because of insufficient disclosure to support an allowable claim and such position has been made of record by the examiner, a second design patent application filed as an alleged "continuation-in-part" of the first application to supply the deficiency is not entitled to the benefit of the earlier filing date. See *Hunt Co. v. Mallinckrodt Chemical Works*, 177 F.2d 583, 83 USPQ 277 (F.2d Cir. 1949) and cases cited therein. Also, a design application filed as a "continuation-in-part" that changes the shape or configuration of a design disclosed in an earlier application is not entitled to the benefit of the filing date of the earlier application. See *In re Salmon*, 705 F.2d 1579, 217 USPQ 981 (Fed. Cir. 1983).

Unless the filing date of an earlier application is actually needed, for example, in the case of an inter-

ference or to avoid an intervening reference, there is no need for the examiner to make a determination in a continuation-in-part application as to whether the requirement of 35 U.S.C. 120 is met. Note the holdings in *In re Corba*, 212 USPQ 825 (Comm'r Pat. 1981).

Form paragraph 15.74 may be used in a first Office action on the merits in any application which claims priority under 35 U.S.C. 120 to a prior application.

¶ 15.74 Continuation-In-Part Caution

Reference to this design application as a continuation-in-part under 35 U.S.C. 120 is acknowledged. Applicant is advised that design case law holds that any change to the shape or configuration of a design disclosed in an earlier application constitutes an entirely new design that cannot rely upon the earlier one for priority. See *In re Salmon*, 705 F.2d 1579, 217 USPQ 981 (Fed. Cir. 1983). Therefore, a later filed application that changes the shape or configuration of a design disclosed in a prior application does not satisfy the written description requirement of 35 U.S.C. 112, first paragraph, under 35 U.S.C. 120 and is not entitled to benefit of the earlier filing date. In addition, where an application is found to be fatally defective under 35 U.S.C. 112 because of an inadequate disclosure to support an allowable claim, a second design patent application filed as an alleged "continuation-in-part" of the first application to supply the deficiency is not entitled to the benefit of the earlier filing date. See *Hunt Co. v. Mallinckrodt Chemical Works*, 177 F.2d 583, 83 USPQ 277 (Fed. Cir. 1949). However, unless the filing date of the earlier application is actually needed, such as to avoid intervening prior art, the entitlement to priority in this CIP application will not be considered. See *In re Corba*, 212 USPQ 825 (Comm'r Pat. 1981).

Examiner Note:

This form paragraph should be used in the first action on the merits in any application which claims priority under 35 U.S.C. 120 as a continuation-in-part.

Where a continuation-in-part application claims benefit under 35 U.S.C. 120 of the filing date of an earlier application, a determination as to the propriety of this claim must be made if the earlier application claims the benefit of a foreign application under 35 U.S.C. 119(a) - (d). To determine the status of the foreign application, the charts in MPEP § 1504.02 should be used. If the conditions of 35 U.S.C. 120 are not met, then the claim for benefit of the earlier filing date under 35 U.S.C. 120 as a continuation-in-part should be denied and the claim for priority under 35 U.S.C. 119(a) - (d) should also be denied. If the foreign application for patent/registration has matured into a form of patent protection and would anticipate or render the claim in the alleged CIP application obvious, the design shown in the foreign application

papers would qualify as prior art under 35 U.S.C. 102(d)/172 and the claim should be rejected under 35 U.S.C. 102/103. Form paragraph 15.75 may be used.

¶ 15.75 Preface to Rejection in Alleged CIP Based on 35 U.S.C. 102(d)/172

Reference to this design application as a continuation-in-part under 35 U.S.C. 120 is acknowledged. Applicant is advised that design case law holds that any change to the shape or configuration of a design disclosed in an earlier application constitutes an entirely new design that cannot rely upon the earlier one for priority. See *In re Salmon*, 705 F.2d 1579, 217 USPQ 981 (Fed. Cir. 1983). Therefore, a later filed application that changes the shape or configuration of a design disclosed in a prior application, as in the present case, does not satisfy the written description requirement of 35 U.S.C. 112, first paragraph, under 35 U.S.C. 120 and is not entitled to benefit of the earlier filing date.

The parent application claimed foreign priority under 35 U.S.C. 119(a) - (d). Insofar as the foreign application has matured into a patent/registration more than six months before the filing date of the present application, it qualifies as prior art under 35 U.S.C. 102(d)/172.

Examiner Note:

This form paragraph should be followed with a rejection under 35 U.S.C. 102 or 103(a) depending on the difference(s) between this claim and the design shown in the priority papers.

Where the conditions of 35 U.S.C. 120 are met, a design application may be considered a continuing application of an earlier utility application. Conversely, this also applies to a utility application relying on the benefit of the filing date of an earlier filed design application. See *In re Chu*, 66 F.3d 292, 36 USPQ2d 1089 (Fed. Cir. 1995); *In re Salmon*, 705 F.2d 1579, 217 USPQ 981 (Fed. Cir. 1983). In addition, a design application may claim benefit from an earlier filed PCT application under 35 U.S.C. 120 if the U.S. was designated in the PCT application.

Note also *In re Berkman*, 642 F.2d 427, 209 USPQ 45 (CCPA 1981) where the benefit of a design patent application filing date requested under 35 U.S.C. 120 was denied in the later filed utility application of the same inventor. The Court of Customs and Patent Appeals took the position that the design application did not satisfy 35 U.S.C. 112, first paragraph, as required under 35 U.S.C. 120.

Form paragraph 15.26 may be used to remind applicant that a reference to the prior application must be included in the first sentence of the specification or in an application data sheet.

¶ 15.26 *Identification of Prior Application(s) in Nonprovisional Applications - Benefit of Priority Claimed*

Applicant is reminded of the following requirement:

In a continuation or divisional application (other than a continued prosecution application filed under 37 CFR 1.53(d)), the first sentence of the specification or the application data sheet (37 CFR 1.76) should include a reference to the prior application(s) from which benefit of priority is claimed. See 37 CFR 1.78. The following format is suggested: "This is a continuation (or division) of Application No. _____, filed _____, now (abandoned, pending or U.S. Patent No. _____)."

1504.30 Expedited Examination

37 CFR 1.155. *Expedited examination of design applications*

(a) The applicant may request that the Office expedite the examination of a design application. To qualify for expedited examination.

(1) The application must include drawings in compliance with § 1.84;

(2) The applicant must have conducted a preexamination search; and

(3) The applicant must file a request for expedited examination including:

(i) The fee set forth in § 1.17(k); and

(ii) A statement that a preexamination search was conducted. The statement must also indicate the field of search and include an information disclosure statement in compliance with § 1.98.

(b) The Office will not examine an application that is not in condition for examination (e.g., missing basic filing fee) even if the applicant files a request for expedited examination under this section.

37 CFR 1.155 establishes an expedited procedure for design applications. This expedited procedure became effective on September 8, 2000 and is available to all design applicants who first conduct a preliminary examination search and file a request for expedited treatment accompanied by the fee specified in 37 CFR 1.17(k). This expedited treatment is intended to fulfill a particular need by affording rapid design patent protection that may be especially important where marketplace conditions are such that new designs on articles are typically in vogue for limited periods of time.

A design application may qualify for expedited examination provided the following requirements are met:

(A) A request for expedited examination is filed (Form PTO/SB/27 may be used);

(B) The design application is complete and it includes drawings in compliance with 37 CFR 1.84 (see 37 CFR 1.154 and MPEP § 1503 concerning the requirements for a complete design application);

(C) A statement is filed indicating that a preexamination search was conducted (a search made by a foreign patent office satisfies this requirement). The statement must also include a list of the field of search such as by U.S. Class and Subclass (including domestic patent documents, foreign patent documents and nonpatent literature);

(D) An information disclosure statement in compliance with 37 CFR 1.98 is filed;

(E) The basic design application filing fee set forth in 37 CFR 1.16(f) is paid; and

(F) The fee for expedited examination set forth in 37 CFR 1.17(k) is paid.

EXPEDITED EXAMINATION PROCEDURE

Design applications requesting expedited examination and complying with the requirements of 37 CFR 1.155 are examined with priority and undergo expedited processing throughout the entire course of prosecution in the Office, including appeal, if any, to the Board of Patent Appeals and Interferences. All processing is expedited from the date the request is granted.

Design applicants seeking expedited examination may file a design application in the Office together with a corresponding request under 37 CFR 1.155 by hand-delivering the application papers and the request directly to the Design Technology Center (TC) Director's office. For applicants who choose to file a design application and the corresponding request under 37 CFR 1.155 by mail, the envelope should be addressed to:

Box Expedited Design
Commissioner for Patents
Washington, D.C. 20231

Box Expedited Design should only be used for the initial filing of design applications accompanied by a corresponding request for expedited examination under 37 CFR 1.155. Box Expedited Design should NOT be used for a request under 37 CFR 1.155 filed subsequent to the filing of the corresponding design

application. Instead, a subsequently filed request under 37 CFR 1.155 should be made by facsimile transmission to the Design TC Director's office indicating the corresponding application number.

Design application filings addressed to Box Expedited Design will be forwarded immediately to the Design TC Director's office. Whether an application requesting expedited examination is hand-delivered to the Design TC Director's office or mailed to Box Expedited Design, expedited processing is initiated at the Design TC Director's office provided the application (including the design application filing fee) is in condition for examination and a complete request under 37 CFR 1.155 (including the fee specified at 37 CFR 1.17(k)) qualifies the application for expedited examination.

Upon a decision by the Design TC Director to grant the request for expedited examination, fees are immediately processed, the application papers are promptly assigned an application number, and the application is dispatched to an examiner for expedited examination. In addition, the applicant is notified that examination is being expedited. The expedited treatment under 37 CFR 1.155 occurs through initial examination processing and throughout the entire prosecution in the Office. Whereas, an application granted special status pursuant to a successful "petition to make special" under MPEP § 708.02 is prioritized while it is on the examiner's docket so that the application will be examined out of turn responsive to each successive communication from the applicant requiring Office action. For a patentable design application, the expedited treatment under 37 CFR 1.155 would be a streamlined filing-to-issuance procedure. This procedure further expedites design application processing by decreasing clerical processing time as well as the time spent routing the application between processing steps.

Although a request under 37 CFR 1.155 may be filed subsequent to the filing of the design application, it is recommended that the request and the corresponding design application be filed together in order to optimize expeditious processing.

If an application requesting expedited examination is incomplete (not in condition for examination), an appropriate notice will be mailed to the applicant identifying the reasons why the application is incom-

plete and requiring correction thereof. The Office will not examine an application that is not in condition for examination even if the applicant files a request for expedited examination.

If an application requesting expedited examination fails to comply with one or more of the requirements for expedited examination under 37 CFR 1.155, but the application is otherwise complete, the applicant will be promptly notified and required to comply with all requirements under 37 CFR 1.155 within a shortened time period extendable under 37 CFR 1.136(a). Unless all requirements under 37 CFR 1.155 are timely met, the application will await action in its regular turn.

Once a request under 37 CFR 1.155 is granted, examiners will expedite examination by examining the application out-of-turn. Examiners are strongly encouraged to use telephone interviews to resolve minor problems. Clerical processing of the application will be expedited as well.

If the overall appearance of two or more patentably distinct embodiments of an article as disclosed in the drawings are different in appearance or scope, restriction will be required in accordance with MPEP § 1504.05. If applicant refuses to make an election without traverse, the application will not be further examined at that time, and the application will await action in its regular turn. Divisional applications directed to nonelected inventions will not qualify for expedited examination unless the divisional application meets on its own all requirements for expedited examination under 37 CFR 1.155. Similarly, expedited status will not carry over to a continuing application, including a CPA, unless the continuing application meets on its own all requirements for expedited examination under 37 CFR 1.155.

Once a request for expedited examination is granted, prosecution will proceed according to the procedure under 37 CFR 1.155. There is no provision for "withdrawal" from expedited examination procedure.

1505 Allowance and Term of Design Patent

35 U.S.C. 173. Term of design patent.

Patents for designs shall be granted for the term of fourteen years from the date of grant.

1509 Reissue of a Design Patent

See MPEP Chapter 1400 for practice and procedure in reissue applications.

For design reissue application fee, see 37 CFR 1.16(h). For fee for issuing a reissue design patent, see 37 CFR 1.18(b).

The term of a design patent may not be extended by reissue. *Ex parte Lawrence*, 70 USPQ 326 (Comm'r Pat. 1946).

1510 Reexamination

See MPEP Chapter 2200 for practice and procedure for reexamination applications.

1511 Protest

See MPEP Chapter 1900 for practice and procedure in protest.

1512 Relationship Between Design Patent, Copyright, and Trademark

I. DESIGN PATENT/COPYRIGHT OVERLAP

There is an area of overlap between copyright and design patent statutes where the author/inventor can secure both a copyright and a design patent. Thus an ornamental design may be copyrighted as a work of art and may also be subject matter of a design patent. The author/inventor may not be required to elect between securing a copyright or a design patent. See *In re Yardley*, 493 F.2d 1389, 181 USPQ 331. In *Mazer v. Stein*, 347 U.S. 201, 100 USPQ 325 (1954), the Supreme Court noted the election of protection doctrine but did not express any view on it since a design patent had been secured in the case and the issue was not before the Court.

See form paragraph 15.55 which repeats this information.

II. INCLUSION OF COPYRIGHT NOTICE

It is the policy of the U.S. Patent and Trademark Office to permit the inclusion of a copyright notice in a design patent application, and thereby any patent issuing therefrom, under the following conditions.

(A) A copyright notice must be placed adjacent to the copyright material and, therefore, may appear at

any appropriate portion of the patent application disclosure including the drawing. However, if appearing on the drawing, the notice must be limited in print size from 1/8 inch to 1/4 inch and must be placed within the "sight" of the drawing immediately below the figure representing the copyright material. If placed on a drawing in conformance with these provisions, the notice will not be objected to as extraneous matter under 37 CFR 1.84.

(B) The content of the copyright notice must be limited to only those elements required by law. For example, "© 1983 John Doe" would be legally sufficient under 17 U.S.C. 401 and properly limited.

(C) Inclusion of a copyright notice will be permitted only if the following waiver is included at the beginning (preferably as the first paragraph) of the specification to be printed for the patent:

A portion of the disclosure of this patent document contains material to which a claim for copyright is made. The copyright owner has no objection to the facsimile reproduction by anyone of the patent document or the patent disclosure, as it appears in the Patent and Trademark Office patent file or records, but reserves all other copyright rights whatsoever.

(D) Inclusion of a copyright notice after a Notice of Allowance has been mailed will be permitted only if the criteria of 37 CFR 1.312 have been satisfied.

Any departure from these conditions may result in a refusal to permit the desired inclusion. If the waiver required under condition (C) above does not include the specific language "(t)he copyright owner has no objection to the facsimile reproduction by anyone of the patent document or the patent disclosure, as it appears in the U.S. Patent and Trademark Office patent file or records....", the copyright notice will be objected to as improper.

See form paragraph 15.55 which repeats this information.

The files of design patents D-243,821, D-243,824, and D-243,920 show examples of an earlier similar procedure.

III. DESIGN PATENT/TRADEMARK OVERLAP

A design patent and a trademark may be obtained on the same subject matter. The CCPA, in *In re Mogen David Wine Corp.*, 328 F.2d 925, 140 USPQ 575 (CCPA 1964), later reaffirmed by the same court at

372 F.2d 593, 152 USPQ 593 (CCPA 1967), held that the underlying purpose and essence of patent rights are separate and distinct from those pertaining to trademarks, and that no right accruing from one is dependent or conditioned by the right concomitant to the other.

See form paragraph 15.55.01 which repeats this information.

IV. INCLUSION OF TRADEMARKS IN DESIGN PATENT APPLICATIONS

A. *Specification*

The use of trademarks in design patent application specifications is permitted under limited circumstances. See MPEP § 608.01(v). This section assumes that the proposed use of a trademark is a legal use under Federal trademark law.

B. *Title*

It is improper to use a trademark alone or coupled with the word "type" (e.g., Band-Aid type Bandage) in the title of a design. Examiners must object to the use of a trademark in the title of a design application and require its deletion therefrom.

C. *Drawings*

When a trademark is used in the drawing disclosure of a design application, the specification must include a statement preceding the claim identifying the trademark material forming part of the claimed design and

the name of the owner of the registered trademark. Form paragraph 15.76 may be used.

¶ 15.76 *Trademark in Drawing*

The [1] forming part of the claimed design is a registered trademark of [2]. The specification must be amended to include a statement preceding the claim identifying the trademark material forming part of the claimed design and the name of the owner of the trademark.

Examiner Note:

1. In bracket 1, identify the trademark material.
2. In bracket 2, identify the trademark owner.

Any derogatory use of a trademark in a design application is prohibited and will result in a rejection of the claim under 35 U.S.C. 171 as being offensive and, therefore, improper subject matter for design patent protection. Cf. *Dallas Cowboys Cheerleaders, Inc. v. Pussycat Cinema, Ltd.*, 604 F.2d 200, 203 USPQ 161 (2d Cir. 1979) and *Coca-Cola Co. v. Gemini Rising Inc.*, 346 F. Supp. 1183, 175 USPQ 56 (E.D.N.Y. 1972).

1513 **Miscellaneous**

With respect to copies of references being supplied to applicant in a design patent application, see MPEP § 707.05(a).

Effective May 8, 1985, the Statutory Invention Registration (SIR), 35 U.S.C. 157, and 37 CFR 1.293 - 1.297 replaced the former Defensive Publication Program. The Statutory Invention Registration (SIR) Program applies to utility, plant, and design applications. See MPEP Chapter 1100.



MANUAL OF PATENT EXAMINING PROCEDURE

The Manual of Patent Examining Procedure (MPEP) is a guide for patent examiners and applicants. It provides detailed instructions on the procedures for examining patent applications, including the requirements for patentability, the process of prior art searches, and the criteria for granting patents. The MPEP is published by the United States Patent and Trademark Office (USPTO) and is updated periodically to reflect changes in patent law and practice.

The MPEP is organized into several parts, each covering a different aspect of the patent examining process. Part 1, for example, discusses the requirements for patentability, including novelty, non-obviousness, and utility. Part 2 covers the process of prior art searches, and Part 3 discusses the criteria for granting patents. The MPEP is a valuable resource for patent examiners and applicants alike.

The MPEP is a comprehensive guide to the patent examining process. It provides detailed instructions on the procedures for examining patent applications, including the requirements for patentability, the process of prior art searches, and the criteria for granting patents. The MPEP is published by the United States Patent and Trademark Office (USPTO) and is updated periodically to reflect changes in patent law and practice.

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Chapter 1600 Plant Patents

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1601 Introduction: The Act, Scope, Type of Plants Covered

The right to a plant patent stems from:

35 U.S.C. 161. Patents for plants.

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.

The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

Asexually propagated plants are those that are reproduced by means other than from seeds, such as by the rooting of cuttings, by layering, budding, grafting, inarching, etc. Plants capable of sexual reproduction are not excluded from consideration if they have also been asexually reproduced.

With reference to tuber propagated plants, for which a plant patent cannot be obtained, the term "tuber" is used in its narrow horticultural sense as meaning a short, thickened portion of an underground branch. Such plants covered by the term "tuber propagated" are the Irish potato and the Jerusalem artichoke. This exception is made because this group alone, among asexually reproduced plants, is propagated by the same part of the plant that is sold as food.

The term "plant" has been interpreted to mean "plant" in the ordinary and accepted sense and not in the strict scientific sense and thus excludes bacteria. *In re Arzberger*, 112 F. 2d 834, 46 USPQ 32 (CCPA 1940). The term "plant" thus does not include asexual propagating material, *per se*. *Ex parte Hibberd*, 227 USPQ 443, 447 (Bd. Pat. App. & Int. 1985).

An asexually reproduced plant may alternatively be protected under 35 U.S.C. 101, as the Plant Patent Act (35 U.S.C. 161) is not an exclusive form of protection which conflicts with the granting of utility patents to plants. *Ex parte Hibberd*, 227 USPQ 443 (Bd. Pat. App. & Int. 1985). Inventions claimed under 35 U.S.C. 101 may include the same asexually reproduced plant which is claimed under 35 U.S.C. 161, as well as plant materials and processes involving plant materials. The filing of a terminal disclaimer may be used in appropriate situations to overcome an obviousness-type double patenting rejection based on claims to the asexually reproduced plant and/or fruit and propagating material thereof in an application under 35 U.S.C. 101 and the claim to the same asexually reproduced plant in an application under 35 U.S.C. 161.

35 U.S.C. 163. Grant.

In the case of a plant patent, the grant shall include the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States.

As provided in 35 U.S.C. 161, the rights associated with a plant patent include the rights associated with a utility patent, and the "right to exclude" has additional terms provided in 35 U.S.C. 163. A plant patent issuing from an application filed after June 7, 1995 has a term which expires 20 years after the filing date of the application, or any earlier filing date claimed under 35 U.S.C. 120, 121 or 365(c). See MPEP § 2701. Plant patent applications will be published pursuant to 35 U.S.C. 122(b).

1602 Rules Applicable

37 CFR 1.161. Rules applicable.

The rules relating to applications for patent for other inventions or discoveries are also applicable to applications for patents for plants except as otherwise provided.

1603 Elements of a Plant Application

37 CFR 1.163. *Specification and arrangement of application elements in a plant application.*

(b) The elements of the plant application, if applicable, should appear in the following order:

- (1) Plant application transmittal form.
- (2) Fee transmittal form.
- (3) Application data sheet (see § 1.76).
- (4) Specification.
- (5) Drawings (in duplicate).
- (6) Executed oath or declaration (§ 1.162).

An application for a plant patent consists of the same parts as other applications. For information pertaining to the oath or declaration, specification and claim, or drawings, see MPEP § 1604, § 1605, or § 1606, respectively.

1604 Applicant, Oath or Declaration

37 CFR 1.162. *Applicant, oath or declaration.*

The applicant for a plant patent must be the person who has invented or discovered and asexually reproduced the new and distinct variety of plant for which a patent is sought (or as provided in §§ 1.42, 1.43 and 1.47). The oath or declaration required of the applicant, in addition to the averments required by § 1.63, must state that he or she has asexually reproduced the plant. Where the plant is a newly found plant, the oath or declaration must also state that it was found in a cultivated area.

A Plant Patent Application (35 U.S.C. 161) Declaration, Form PTO/SB/03, may be used to submit a declaration. Form PTO/SB/81 may be used to appoint an attorney or agent. See MPEP § 402.

In an application for a plant patent, there can be joint inventors. See *Ex parte Kluis*, 70 USPQ 165 (Bd. App. 1945).

PLANT PATENTS

1604

Type a plus sign (+) inside this box →

Approved for use through 10/31/2002. OMB 0651-0032
 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<p align="center">PLANT PATENT APPLICATION (35 U.S.C. 161) DECLARATION (37 CFR 1.63)</p> <p><input type="checkbox"/> Declaration Submitted with Initial Filing OR <input type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)</p>	Attorney Docket Number	
	First Named Inventor	
	COMPLETE IF KNOWN	
	Application Number	/
	Filing Date	
	Group Art Unit	
Examiner Name		

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the new and distinct variety of:

plant named:

which is claimed and for which a plant patent is sought, the specification of which

is attached hereto OR was filed on (MM/DD/YYYY) as United States

Application Number and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claim, as amended by any amendment specifically referred to above.

I have asexually reproduced the plant to which this application applies.

Said plant was found in a cultivated area (check this box for newly found plant only)

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the National or PCT International filing date of the continuation-in-part.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Check Only if Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

Burden Hour Statement: This form is estimated to take 21 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Type a plus sign (+) inside this box → PTO/SB/03 (10-00)
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 Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

DECLARATION – Plant Patent Application

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.			
Application Number(s)	Filing Date (MM/DD/YYYY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.	
Direct all correspondence to: <input type="checkbox"/> Customer Number or Bar Code Label <input style="width: 100px;" type="text"/>		OR <input type="checkbox"/> Correspondence address below	
Name			
Address			
Address			
City		State	ZIP
Country		Telephone	Fax
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.			
NAME OF SOLE OR FIRST INVENTOR:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name		Family Name or Surname	
Inventor's Signature			Date
Residence: City	State	Country	Citizenship
Mailing Address			
Mailing Address			
City	State	Zip	Country
NAME OF SECOND INVENTOR:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name		Family Name or Surname	
Inventor's Signature			Date
Residence: City	State	Country	Citizenship
Mailing Address			
Mailing Address			
City	State	Zip	Country
<input type="checkbox"/> Additional inventors are being named on the _____ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.			

1605 Specification and Claim

35 U.S.C. 162. Description, claim.

No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible.

The claim in the specification shall be in formal terms to the plant shown and described.

37 CFR 1.163. Specification and arrangement of application elements in a plant application.

(a) The specification must contain as full and complete a disclosure as possible of the plant and the characteristics thereof that distinguish the same over related known varieties, and its antecedents, and must particularly point out where and in what manner the variety of plant has been asexually reproduced. For a newly found plant, the specification must particularly point out the location and character of the area where the plant was discovered.

(b) The elements of the plant application, if applicable, should appear in the following order:

- (1) Plant application transmittal form.
- (2) Fee transmittal form.
- (3) Application data sheet (see § 1.76).
- (4) Specification.
- (5) Drawings (in duplicate).
- (6) Executed oath or declaration (§ 1.162).

(c) The specification should include the following sections in order:

- (1) Title of the invention, which may include an introductory portion stating the name, citizenship, and residence of the applicant.
- (2) Cross-reference to related applications (unless included in the application data sheet).
- (3) Statement regarding federally sponsored research or development.
- (4) Latin name of the genus and species of the plant claimed.
- (5) Variety denomination.
- (6) Background of the invention.
- (7) Brief summary of the invention.
- (8) Brief description of the drawing.
- (9) Detailed botanical description.
- (10) A single claim.
- (11) Abstract of the disclosure.

(d) The text of the specification or sections defined in paragraph (c) of this section, if applicable, should be preceded by a section heading in upper case, without underlining or bold type.

37 CFR 1.164. Claim.

The claim shall be in formal terms to the new and distinct variety of the specified plant as described and illustrated, and may also recite the principal distinguishing characteristics. More than one claim is not permitted.

The specification should include a complete detailed description of the plant and the characteristics thereof that distinguish the same over related known varieties, and its antecedents, expressed in botanical terms in the general form followed in standard botanical textbooks or publications dealing with the varieties of the kind of plant involved (evergreen tree, dahlia plant, rose plant, apple tree, etc.), rather than a mere broad nonbotanical characterization such as commonly found in nursery or seed catalogs. The specification should also include the origin or parentage and the genus and species designation of the plant variety sought to be patented. The Latin name of the genus and species of the plant claimed should be stated and preceded by the heading set forth in 37 CFR 1.163(c)(4). The specification must particularly point out where, e.g., location or place of business, and in what manner the variety of plant has been asexually reproduced.

Form Paragraphs 16.01, 16.09, and 16.10 may be used to object to the disclosure under 37 CFR 1.163(a).

¶ 16.01 Specification, Manner of Asexually Reproducing

The application is objected to under 37 CFR 1.163(a) because the specification does not "particularly point out where and in what manner the variety of plant has been asexually reproduced". Correction is required.

¶ 16.09 Specification, Less Than Complete Description

The disclosure is objected to under 37 CFR 1.163(a) because the specification presents less than a full and complete botanical description and the characteristics which distinguish over related known varieties. More specifically: [1].

¶ 16.10 Specification, Location of Plant Not Disclosed

The disclosure is objected to under 37 CFR 1.163(a) because the specification does not particularly point out the location and character of the area where the plant was discovered.

Where color is a distinctive feature of the plant, the color should be positively identified in the specification by reference to a designated color as given by a recognized color dictionary or color chart.

Form Paragraphs 16.02 and 16.03 may be used to object to the disclosure or reject the claim, respectively, because of a lack of a clear and complete disclosure with regard to colors.

¶ 16.02 *Colors Specified Do Not Correspond With Those Shown*

The disclosure is objected to under 35 U.S.C. 112, first paragraph, because the [1] colors specified fail to correspond with those shown.

¶ 16.03 *Rejection, 35 U.S.C. 112, 1st Paragraph, Non-Support for Colors*

The claim is rejected under 35 U.S.C. 112, first paragraph, as being unsupported by a clear and complete disclosure with regard to [1] colors, for the following reasons: [2].

If the written description of a plant is deficient in certain respects (see, e.g., *In re Greer*, 484 F.2d 488, 179 USPQ 301 (CCPA 1973)), a clarification or additional description of the plant, or even a wholesale substitution of the original description so long as not totally inconsistent and unrelated to the original description and photograph of the plant may be submitted in reply to an Office action. Such submission will not constitute new matter under 35 U.S.C. 132. *Jessel v. Newland*, 195 USPQ 678, 684 (Dep. Comm'r Pat. 1977).

The rules on Deposit of Biological Materials, 37 CFR 1.801-1.809, do not apply to plant patent applications in view of the reduced disclosure requirements of 35 U.S.C. 162, even where a deposit of a plant has been made in conjunction with a utility application (35 U.S.C. 101).

A plant patent is granted only on the entire plant. It, therefore, follows that only one claim is necessary and only one is permitted. A method claim in a plant patent application is improper. An example of a proper claim would be "A new and distinct variety of hybrid tea rose plant, substantially as illustrated and described herein."

1606 Drawings

37 CFR 1.165. *Plant drawings.*

(a) Plant patent drawings should be artistically and competently executed and must comply with the requirements of § 1.84. View numbers and reference characters need not be employed unless required by the examiner. The drawing must disclose all the distinctive characteristics of the plant capable of visual representation.

(b) The drawings may be in color. The drawing must be in color if color is a distinguishing characteristic of the new variety.

Two copies of color drawings or photographs and a black and white photocopy that accurately depicts, to the extent possible, the subject matter shown in the color drawing or photograph must be submitted.

If the drawings or photographs are in color, two color copies of each drawing or photograph are required. If the required copies of the drawings are not included, the application will be accorded a filing date, but correction will be required before the application is forwarded for examination. The requirement under 37 CFR 1.165(b) for a black and white photocopy of any color drawing or photograph has been waived. See 1246 O.G. 106 (May 22, 2001).

37 CFR 1.84. *Standards for drawings.*

(c) *Identification of drawings.* Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin.

(e) *Type of paper.* Drawings submitted to the Office must be made on paper which is flexible, strong, white, smooth, non-shiny, and durable. All sheets must be reasonably free from cracks, creases, and folds. Only one side of the sheet may be used for the drawing. Each sheet must be reasonably free from erasures and must be free from alterations, overwritings, and interlineations. Photographs must be developed on paper meeting the sheet-size requirements of paragraph (f) of this section and the margin requirements of paragraph (g) of this section. See paragraph (b) of this section for other requirements for photographs.

(f) *Size of paper.* All drawing sheets in an application must be the same size. One of the shorter sides of the sheet is regarded as its top. The size of the sheets on which drawings are made must be:

- (1) 21.0 cm. by 29.7 cm. (DIN size A4), or
- (2) 21.6 cm. by 27.9 cm. (8 1/2 by 11 inches).

(g) *Margins.* The sheets must not contain frames around the sight (*i.e.*, the usable surface), but should have scan target points (*i.e.*, cross-hairs) printed on two cater-corner margin corners. Each sheet must include a top margin of at least 2.5 cm. (1 inch), a left side margin of at least 2.5 cm. (1 inch), a right side margin of at least 1.5 cm. (5/8 inch), and a bottom margin of at least 1.0 cm. (3/8 inch), thereby leaving a sight no greater than 17.0 cm. by 26.2 cm. on 21.0 cm. by 29.7 cm. (DIN size A4) drawing sheets, and a sight no greater than 17.6 cm. by 24.4 cm. (6 15/16 by 9 5/8 inches) on 21.6 cm. by 27.9 cm. (8 1/2 by 11 inch) drawing sheets.

(i) *Arrangement of views.* One view must not be placed upon another or within the outline of another. All views on the same sheet should stand in the same direction and, if possible, stand so that they can be read with the sheet held in an upright position. If views wider than the width of the sheet are necessary for the clearest illustration of the invention, the sheet may be turned on its side so that the top of the sheet, with the appropriate top margin to be used as the heading space, is on the right-hand side. Words must appear in a horizontal, left-to-right fashion when the page is either upright or turned so that the top becomes the right side, except for graphs utilizing standard scientific convention to denote the axis of abscissas (of X) and the axis of ordinates (of Y).

(t) *Numbering of sheets of drawings.* The sheets of drawings should be numbered in consecutive Arabic numerals, starting with 1, within the sight as defined in paragraph (g) of this section. These numbers, if present, must be placed in the middle of the top of the sheet, but not in the margin. The numbers can be placed on the right-hand side if the drawing extends too close to the middle of the top edge of the usable surface. The drawing sheet numbering must be clear and larger than the numbers used as reference characters to avoid confusion. The number of each sheet should be shown by two Arabic numerals placed on either side of an oblique line, with the first being the sheet number and the second being the total number of sheets of drawings, with no other marking.

(u) *Numbering of views.*

(1) The different views must be numbered in consecutive Arabic numerals, starting with 1, independent of the numbering of the sheets and, if possible, in the order in which they appear on the drawing sheet(s). Partial views intended to form one complete view, on one or several sheets, must be identified by the same number followed by a capital letter. View numbers must be preceded by the abbreviation "FIG." Where only a single view is used in an application to illustrate the claimed invention, it must not be numbered and the abbreviation "FIG." must not appear.

(2) Numbers and letters identifying the views must be simple and clear and must not be used in association with brackets, circles, or inverted commas. The view numbers must be larger than the numbers used for reference characters.

(x) *Holes.* No holes should be made by applicant in the drawing sheets.

Form Paragraphs 16.06, 16.06.01, 16.07, and 16.11 may be used to object to the drawing disclosure.

¶ 16.06 Drawings Must Be in Duplicate

The disclosure is objected to under 37 CFR 1.165(b) because applicant has not provided copies of the drawing in duplicate. Correction is required.

¶ 16.07 Drawing Figures Not Competently Executed

The disclosure is objected to under 37 CFR 1.165(a) because Fig. [1] not artistically and/or competently executed.

¶ 16.11 Drawings in Improper Scale

The disclosure is objected to under 37 CFR 1.165(a) because the drawings are of an inadequate scale to show the distinguishing features of the plant.

1607 Specimens

37 CFR 1.166. Specimens.

The applicant may be required to furnish specimens of the plant, or its flower or fruit, in a quantity and at a time in its stage of growth as may be designated, for study and inspection. Such specimens, properly packed, must be forwarded in conformity with instructions furnished to the applicant. When it is not possible to forward such specimens, plants must be made available for official inspection where grown.

Specimens of the plant variety, its flower or fruit, should not be submitted unless specifically called for by the examiner.

Form Paragraph 16.13 may be used to require specimens.

¶ 16.13 Specimens Are Required

Applicant [1] required to submit [2] in accordance with 37 CFR 1.166.

1608 Examination

37 CFR 1.167. Examination.

Applications may be submitted by the Patent and Trademark Office to the Department of Agriculture for study and report.

The authority for submitting plant applications to the Department of Agriculture for report is given in:

Executive Order No. 5464, October 17, 1930. Facilitating the consideration of applications for plant patents.

I, Herbert Hoover, President of the United States of America, under the authority conferred upon me by act of May 23, 1930 (Public No. 245) [now 35 U.S.C. 164], entitled "An act to provide for plant patents," and by virtue of all other powers vested in me relating thereto, do hereby direct the Secretary of Agriculture: (1) to furnish the Commissioner of Patents such available information of the Department of Agriculture, or (2) to conduct through the appropriate bureau or division of the department such research upon special problems, or (3) to detail to the Commissioner of Patents such officers and employees of the department, as the Commissioner may request for the purpose of carrying said act into effect.

35 U.S.C. 164. Assistance of Department of Agriculture.

The President may by Executive order direct the Secretary of Agriculture, in accordance with the requests of the Director, for the purpose of carrying into effect the provisions of this title with respect to plants (1) to furnish available information of the Department of Agriculture, (2) to conduct through the appropriate bureau or division of the Department research upon special problems, or (3) to detail to the Director officers and employees of the Department.

Plant applications are subject to the same examination process as any other national application. As such, the statutory provisions with regard to patentable subject matter, utility, novelty, obviousness, disclosure, and claim specificity requirements apply (35 U.S.C. 101, 102, 103, and 112). The sole exception in terms of applicability of these statutory provisions is set forth in 35 U.S.C. 162.

The prior art considered by the examiner is developed by a search of appropriate subclasses of the United States patent classification system as well as patent and nonpatent literature data bases. Where appropriate, a report may be obtained from the Agricultural Research Service, Horticultural Research Branch, Department of Agriculture.

1609 Report of Agricultural Research Service

Where the examiner considers it necessary to the examination of the plant patent application, a copy of the file and drawing of the application are forwarded to the National Program Leader for Horticultural Crops, Agricultural Research Service (ARS), U.S. Department of Agriculture, along with a request for a report as to whether the plant variety disclosed is new and distinct over known plant varieties. As the report is merely advisory to the Office, it is placed in the file but is not given a paper number. The copy of the report is customarily utilized by the examiner in the preparation of his or her action on the application.

The report may embody criticisms and objections to the disclosure, may offer suggestions for correction of such, or the report may merely state that:

"Examination of the specification submitted indicates that the variety described is not identical with others with which our specialists are familiar."

1610 The Action

The action on the application by the examiner will include all matters as provided for in other types of patent applications. See 37 CFR 1.161.

With reference to the examination of the claim, the language must be such that it is directed to the "new and distinct variety of plant." This is important as under no circumstance should the claim be directed to a new variety of flower or fruit in contradistinction to the plant bearing the flower or the tree bearing the fruit. This is in spite of the fact that it is accepted and general botanical parlance to say "A variety of apple or a variety of blackberry" to mean a variety of apple tree or a variety of blackberry plant.

Where the application is otherwise allowable, a claim which recites, for example "A new variety of apple characterized by," may be amended by the insertion of — tree — after "apple" by an examiner's amendment.

By the same token, the title of the invention must relate to the entire plant and not to its flower or fruit, thus: Apple Tree, Rose Plant.

Care should also be exercised that the specification does not contain unwarranted advertising, for example, "the disclosed plant being grown in the XYZ Nurseries of Topeka, Kansas." It follows, also, that in the drawings any showing in the background of a plant, as a sign carrying the name of an individual, nursery, etc., is objectionable and deletion thereof is required. Nor should the specification include laudatory expressions, such as, "The rose is prettier than any other rose." Such expressions are wholly irrelevant. Where the fruit is described, statements in the specification as to the character and quality of products made from the fruit are not necessary and should be deleted.

The Office action may include so much of any report of the ARS as the examiner deems necessary, or may embody no part of it. In the event of an interview, the examiner, in his or her discretion, may show the entire report to the inventor or attorney.

Form Paragraph 16.12 may be used to reference portions of the ARS report.

¶ 16.12 Report From U.S. Dept. of Agriculture

This application has been submitted to the U.S. Department of Agriculture for a report. Pertinent portions follow: [1]

The report of the ARS is not in the nature of a publication and matters raised therein within the personal knowledge of the specialists of the ARS are not sufficient basis for a rejection unless it is first ascertained by the examiner that the same can be supported by affidavits by said specialists (37 CFR 1.104(d)(2)). See *Ex parte Rosenberg*, 46 USPQ 393 (Bd. App. 1939).

Form Paragraphs 16.04 and 16.08, as appropriate, may be used to reject the claim.

¶ 16.04 Rejection, 35 U.S.C. 102

The claim is rejected under 35 U.S.C. 102 as failing to patentably distinguish over [1].

¶ 16.08 Rejection, 35 U.S.C. 112

The claim is rejected under 35 U.S.C. 112 [1] because [2].

1611 Issue

The preparation of a plant patent application for issue involves the same procedure as for other applications (37 CFR 1.161), with the exception that where there are color drawings, the better one of the two judged, for example, by its sharpness or cleanliness is selected to be printed in the patent.

The International Patent Classification symbols, most recent edition, should be placed in the issuing classification boxes on the file wrapper or on the Issue Classification slip of all plant patent applications being sent to issue.

All plant patent applications should contain an abstract when forwarded to the Office of Patent Publication.

1612 UPOV Convention

On November 8, 1981, the 1978 text of the "International Convention for the Protection of New Varieties of Plants" (generally known by its French acronym as the UPOV Convention) took effect in the United States and two other states that had not been party to the 1961 text, Ireland and New Zealand. As of September 24, 2000, 46 states were party to the UPOV Convention: Argentina, Australia, Austria, Belgium, Bolivia, Brazil, Bulgaria, Canada, Chile,

China, Colombia, Czech Republic, Denmark, Ecuador, Estonia, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan, Kenya, Kyrgyzstan, Mexico, Netherlands, New Zealand, Norway, Panama, Paraguay, Poland, Portugal, Republic of Moldova, Russian Federation, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Trinidad and Tobago, Ukraine, United Kingdom, United States of America, and Uruguay. Most states adhere to the 1978 text. The United States adheres to the 1991 text, and has a reservation under Article 35(2) of the text (which allows plant patents rather than breeder's rights certificates to be granted).

The 1961, 1978, and 1991 texts guarantee to plant breeders in each member state both national treatment and the right of priority in all other member states. In many states, new plant varieties are protected by breeders' rights laws rather than patent laws. Accordingly, the Paris (Industrial Property) Convention cannot always be relied on to provide these and other rights.

Insofar as the patenting of asexually reproduced plants in the United States is concerned, both national treatment and the right of priority have been accorded to foreign plant breeders since enactment of the plant patent law in 1930 (now 35 U.S.C. 161-164). See MPEP § 1613 for the right of priority based upon an application for plant breeder's rights.

Application of the UPOV Convention in the United States does not affect the examination of plant patent applications, except in one instance. It is now necessary as a condition for receiving a plant patent to register a variety denomination for that plant. Inclusion of the variety denomination in the patent comprises its registration.

The registration process in general terms consists of inclusion of a proposed variety denomination in the plant patent application. The examiner must evaluate the proposed denomination in light of UPOV Convention, Article 13. Basically, this Article requires that the proposed variety denomination not be identical with or confusingly similar to other names utilized in the United States or other UPOV member countries for the same or a closely related species. In addition, the proposed denomination must not mislead the average consumer as to the characteristics, value, or identity of the patented plant. Ordinarily, the denomination proposed for registration in the United States

must be the same as the denomination registered in another member state of UPOV.

Form Paragraph 16.05 may be used to object to the disclosure as lacking a common or market name or "denomination" of the plant.

¶ 16.05 Name or Denomination for Plant Missing

The disclosure is objected to under 37 CFR 1.121(e) because no "variety denomination" of the instant plant has been set forth in the disclosure. 37 CFR 1.163(c)(4). Correction by adding such a name is required.

¶ 16.05.01 Latin Name of Genus and Species of the Plant Claimed Missing

The disclosure is objected to under 37 CFR 1.121(e) because the Latin name of the genus and species of the instant plant has

not been set forth in the disclosure. 37 CFR 1.163(c)(4). Correction by adding such a name is required.

1613 Right of Priority Based upon Application for Plant Breeder's Rights

Pursuant to 35 U.S.C. 119(f), an application for a plant patent may rely upon an application for plant breeder's rights filed in a WTO member country (or in a foreign UPOV Contracting Party) for priority under 35 U.S.C. 119(a) through (c).



Chapter 1700 Miscellaneous

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1701 Office Personnel Not To Express Opinion on Validity or Patentability of Patent

Every patent is presumed to be valid. 35 U.S.C. 282, first sentence. Public policy demands that every employee of the United States Patent and Trademark Office (USPTO) refuse to express to any person any opinion as to the validity or invalidity of, or the patentability or unpatentability of any claim in any U.S. patent, except to the extent necessary to carry out

- (A) an examination of a reissue application of the patent,
- (B) a reexamination proceeding to reexamine the patent, or
- (C) an interference involving the patent.

The question of validity or invalidity is otherwise exclusively a matter to be determined by a court. Members of the patent examining corps are cautioned to be especially wary of any inquiry from any person outside the USPTO, including an employee of another U.S. Government agency, the answer to which might indicate that a particular patent should not have issued. No USPTO employee may pursue a bounty offered by a private sector source for identifying prior art. The acceptance of payments from outside sources

for prior art search activities may subject the employee to administrative disciplinary action.

When a field of search for an invention is requested, examiners should routinely inquire whether the invention has been patented in the United States. If the invention has been patented, no field of search should be suggested.

Employees of the USPTO, particularly patent examiners who examined an application which matured into a patent or a reissued patent or who conducted a reexamination proceeding, should not discuss or answer inquiries from any person outside the USPTO as to whether or not a certain reference or other particular evidence was considered during the examination or proceeding and whether or not a claim would have been allowed over that reference or other evidence had it been considered during the examination or proceeding. Likewise, *employees* are cautioned against answering any inquiry concerning any entry in the patent or reexamination file, including the extent of the field of search and any entry relating thereto. The record of the file of a patent or reexamination proceeding must speak for itself.

Practitioners can be of material assistance in this regard by refraining from making improper inquiries of members of the patent examining corps. Inquiries from members of the public relating to the matters discussed above must of necessity be refused and such refusal should not be considered discourteous or an expression of opinion as to validity or patentability.

1701.01 Office Personnel Not To Testify

It is the policy of the United States Patent and Trademark Office (USPTO) that its employees, including patent examiners, will not appear as witnesses or give testimony in legal proceedings, except under the conditions specified in 15 CFR Part 15, Subpart B. Any employee who testifies contrary to this policy will be *dismissed or removed*. The reasons for this policy are set out in 15 CFR 15.13.

Whenever an employee of the USPTO, including a patent examiner, is asked to testify or receives a subpoena, the employee shall immediately notify the Office of the USPTO General Counsel. Inquiries requesting testimony shall be also referred immediately to the Office of the USPTO General Counsel.

Patent examiners and other USPTO employees performing or assisting in the performance of quasi-judicial functions, are forbidden to testify as experts or to express opinions as to the validity of any patent.

Any individual desiring the testimony of an employee of the USPTO, including the testimony of a patent examiner or other quasi-judicial employee, must comply with the provisions of 15 CFR Part 15, Subpart B.

A request for testimony of an employee of the USPTO should be made to the Office of the USPTO General Counsel at least **10 working days** prior to the date of the expected testimony.

If an employee is authorized to testify, the employee will be limited to testifying about facts within the employee's personal knowledge. Employees are prohibited from giving expert or opinion testimony. *Fischer & Porter Co. v. Corning Glass Works*, 61 F.R.D. 321, 181 USPQ 329 (E.D. Pa. 1974). Likewise, employees are prohibited from answering hypothetical or speculative questions. *In re Mayewsky*, 162 USPQ 86, 89 (E.D. Va. 1969) (deposition of an examiner must be restricted to relevant matters of fact and must avoid any hypothetical or speculative questions or conclusions based thereon); *Shaffer Tool Works v. Joy Mfg. Co.*, 167 USPQ 170 (S.D. Tex. 1970) (deposition of examiner should be limited to matters of fact and must not go into hypothetical or speculative areas or the bases, reasons, mental processes, analyses, or conclusions of the examiner in acting upon a patent application). Employees will not be permitted to give testimony with respect to subject matter which is privileged. Several court decisions limit testimony with respect to quasi-judicial functions performed by employees. Those decisions include *United States v. Morgan*, 313 U.S. 409, 422 (1941) (improper to inquire into mental processes of quasi-judicial officer or to examine the manner and extent to which the officer considered an administrative record); *Western Electric Co. v. Piezo Technology, Inc.*, 860 F.2d 428, 8 USPQ2d 1853 (Fed. Cir. 1988) (patent examiner may not be compelled to answer questions which probe the examiner's technical knowledge of the subject matter of a patent); *McCulloch Gas Processing Co. v. Department of Energy*, 650 F.2d 1216, 1229 (Temp. Emer. Ct. App. 1981) (discovery of degree of expertise of individuals performing governmental functions not permitted); *In re*

Nilssen, 851 F.2d 1401, 7 USPQ2d 1500 (Fed. Cir. 1988) (technical or scientific qualifications of examiners-in-chief are not legally relevant in appeal under 35 U.S.C. 134 since board members need not be skilled in the art to render obviousness decision); *Lange v. Commissioner*, 352 F. Supp. 166, 176 USPQ 162 (D.D.C. 1972) (technical qualifications of examiners-in-chief not relevant in 35 U.S.C. 145 action).

In view of the discussion above, if an employee is authorized to testify in connection with the employee's involvement or assistance in a quasi-judicial proceeding which took place before the USPTO, the employee will not be permitted to give testimony in response to questions which seek:

(A) Information about that employee's:

- (1) Background;
 - (2) Expertise;
 - (3) Qualifications to examine or otherwise consider a particular patent or trademark application;
 - (4) Usual practice or whether the employee followed a procedure set out in any Office manual of practice (including the MPEP or TMEP) in a particular case;
 - (5) Consultation with another Office employee;
 - (6) Understanding of:
 - (a) A patented invention, an invention sought to be patented, or patent application, patent, reexamination or interference file;
 - (b) Prior art;
 - (c) Registered subject matter, subject matter sought to be registered, or a trademark application, registration, opposition, cancellation, interference, or concurrent use file;
 - (d) Any Office manual of practice;
 - (e) Office regulations;
 - (f) Patent, trademark, or other law; or
 - (g) The responsibilities of another Office employee;
 - (7) Reliance on particular facts or arguments;
- (B) To inquire into the manner in and extent to which the employee considered or studied material in performing a quasi-judicial function; or
- (C) To inquire into the bases, reasons, mental processes, analyses, or conclusions of that Office employee in performing the quasi-judicial function.

Any request for testimony addressed or delivered to the Office of the USPTO General Counsel shall comply with 15 CFR 15.14(c). All requests must be in *writing*. The need for a subpoena may be obviated where the request complies with 15 CFR 15.14(c) if the party requesting the testimony further meets the following conditions:

(A) The party requesting the testimony identifies the civil action or other legal proceeding for which the testimony is being taken. The identification shall include the:

- (1) Style of the case;
- (2) Civil action number;
- (3) District in which the civil action is pending;
- (4) Judge assigned to the case; and
- (5) Name, address, and telephone number of counsel for all parties in the civil action.

(B) The party agrees not to ask questions seeking information which is precluded by 15 CFR 15.16(b);

(C) The party shall comply with applicable provisions of the Federal Rules of Civil Procedure, including Rule 30, and give 10 working days notice to the Office of the USPTO General Counsel prior to the date a deposition is desired. Fifteen working days notice is required for any deposition which is desired to be taken between November 15 and January 15;

(D) The party agrees to notice the deposition at a place convenient to the USPTO. The Conference Room in the Office of the USPTO General Counsel is deemed to be a place convenient to the Office; and

(E) The party agrees to supply a copy of the transcript of the deposition to the USPTO for its records.

Absent a written agreement meeting the conditions specified in paragraphs (A) through (E), a party must comply with the precise terms of 15 CFR 15.14(c)(1) and the USPTO will not permit a deposition without issuance of a subpoena.

1702 Restrictions on Former Examiners

37 CFR 10.10. Restrictions on practice in patent cases.

(a) Only practitioners who are registered under § 10.6 or individuals given limited recognition under § 10.9 will be permitted to prosecute patent applications of others before the Office.

(b) No individual who has served in the patent examining corps of the Office may practice before the Office after termination of his or her service, unless he or she signs a written undertaking,

(1) Not to prosecute or aid in any manner in the prosecution of any patent application pending in any patent examining group during his or her period of service therein and

(2) Not to prepare or prosecute or to assist in any manner in the preparation or prosecution of any patent application of another (i) assigned to such group for examination and (ii) filed within two years after the date he or she left such group, without written authorization of the Director. Associated and related classes in other patent examining groups may be required to be included in the undertaking or designated classes may be excluded from the undertaking. When an application for registration is made after resignation from the Office, the applicant will not be registered if he or she has prepared or prosecuted or assisted in the preparation or prosecution of any patent application as indicated in the paragraph. Knowingly preparing or prosecuting or providing assistance in the preparation or prosecution of any patent application contrary to the provisions of this paragraph shall constitute misconduct under § 10.23(c)(13) of this part.

(c) A practitioner who is an employee of the Office cannot prosecute or aid in any manner in the prosecution of any patent application before the Office.

(d) Practice before the Office by Government employees is subject to any applicable conflict of interest laws, regulations or codes of professional responsibility.

See also MPEP § 309.

1703 The Official Gazette

The *Official Gazette of the United States Patent and Trademark Office (Official Gazette)* is published every Tuesday in two sections, the *Official Gazette – Patents* and the *Official Gazette – Trademarks*. The front portion of each *Official Gazette* is the same and is composed of the text of regular and special Patent and Trademark Office Notices (*Official Gazette Notices*) such as notices of patent and trademark suits, disclaimers filed, Certificates of Correction issued, lists of applications and patents available for license or sale, notices of 37 CFR 1.47 applications, and general information such as orders, notices, changes in rules, changes in classification, certain adverse decisions in interferences, the condition of work in the Office, registration of attorneys and agents, reprimands, suspensions, and exclusions of registered attorneys and agents, and notices to parties not reached by mail.

The *Official Gazette – Patents* reports the reexamination certificates, reissues, plant patents, utility patents, and design patents issued and statutory invention registrations (if any) published on that day. The *Official Gazette – Patents* also includes indexes to patents

by classification, state, and patentee. As to each patent, the following information is given:

- (A) Patent number;
- (B) Title of the invention;
- (C) Applicant's name;
- (D) Applicant's city and state of residence and, if unassigned, applicant's mailing address;
- (E) Assignee's name, city and state of residence, if assigned;
- (F) U.S. or PCT parent application data, if any;
- (G) Filing date;
- (H) Application number;
- (I) Foreign priority application data, if any;
- (J) International classification;
- (K) U.S. classification by class and subclass;
- (L) Number of claims;
- (M) Selected figure of the drawing, if any, except in the case of a plant patent;
- (N) A claim or claims; and
- (O) For reissue patents, the original patent number and issue date, and the original application number and filing date.

The *Official Gazette – Trademarks* contains, in addition to Patent and Trademark Office notices, an illustration of each trademark published for opposition, an alphabetical list of registered trademarks, a classified list of registered trademarks, an index of registrants, a list of canceled trademark registrations, and a list of renewed trademark registrations.

The *Official Gazette Notices* are available on the United States Patent and Trademark Office (USPTO) web site (www.uspto.gov). The information in the *Official Gazette* pertaining to each issued patent and each trademark registration can be obtained from the Patent Grants Database and the U.S. Trademark Electronic Search System (TESS) respectively, both also available on the USPTO web site. Paper copies of the *Official Gazette – Patents*, the *Official Gazette – Trademarks*, and Patent and Trademark Office Notices are available from the Government Printing Office. Orders should be addressed and subscriptions should be made payable to the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

1704 Application Records and Reports

The PALM (Patent Application Locating and Monitoring) System is the automated data management system used by the United States Patent and Trademark Office (USPTO) for the retrieval and/or online updating of the computer record of each patent application. The PALM System also maintains examiner time, activity, docket, and technical support staff backlog records.

Information retrieval from PALM is by means of video display terminals or the PALM intranet. Information update is by means of video display transactions and, predominantly, by means of transactions entered via bar code readers. Among other items, classification, examiner docket, attorney, inventor, and prosecution history data as well as the location of each application can be retrieved and updated online with PALM.

DOCKET REPORTS

The recording of changes to examiner dockets is accomplished by PALM simultaneously with the recording of incoming and outgoing communications, transfers of applications to and from dockets, and other types of updating of the application record. The status of each examiner's docket can be determined by means of online video display transactions or the PALM intranet and is supplemented by periodic printed reports. Docket reports that are generated by PALM include the individual examiner new, special, and amended docket which lists applications in priority order; the individual examiner rejected application docket; the individual examiner new application profile, which lists the totals of new applications in each docket, sorted by month of filing; and various summaries of the above reports at the art unit, Technology Center (TC), and corps levels.

BIWEEKLY TIME AND ACTIVITY REPORTS

All reporting of examiner time and activity is on a biweekly basis. Each examiner's examining and non-examining time, as listed on the examiner's Biweekly Time Worksheet, PTO-690E, is entered into PALM for use in the computation of productivity data. The biweekly reports produced include the individual Biweekly Examiner Time and Activity Report which lists, by application number, all applications for which

actions have been counted during the biweekly period. The type of action counted for each application is also indicated on the report. This report also includes examiner time data, an action summary, and cumulative summaries to date for the current quarter and fiscal year. Various summary reports at the Art Unit, TC, and Corps levels are also produced.

1705 Examiner Docket, Time, and Activity Recordation

Actions prepared by examiners are submitted to their respective legal instrument examiners for processing in accordance with the procedures set forth below.

PROCEDURES FOR REPORTING AN EXAMINER'S ACTION

(A) The examiner completes an Examiner's Case Action Worksheet, Form PTO-1472, which identifies the type of action prepared. The worksheet is attached to the application for processing by the legal instrument examiner;

(B) The legal instrument examiner checks the worksheet to verify that the examiner provided all necessary information relating to that action;

(C) The legal instrument examiner enters the type of action and the count date thereof on the Contents flap of the file wrapper; and

(D) The legal instrument examiner enters the examiner's action for the application directly into PALM using a bar code reader.

Each examiner's action that is counted and reported to the PALM system will be listed by application number on the Biweekly Examiner Time and Activity Report. The examiner should check his/her Biweekly Examiner Time and Activity Report to verify that all applications worked on for the biweekly report period are properly listed.

Examples of examiner's actions that are reported to PALM by the legal instrument examiner, but are not listed on the Biweekly Examiner Time and Activity Report, include examiner's amendments, actions in reexamination proceedings, interview summaries, transfers of applications, and supplemental Office actions and miscellaneous Office letters which do not set a period for reply.

FORM PTO-1472
(Rev. 3-95)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

EXAMINER'S CASE ACTION WORKSHEET

Application No. _____	Legal Instrument Examiner _____
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CHECK TYPE OF ACTION		DATE OF COUNT _____
<input type="checkbox"/> Non-Final Rejection	<input type="checkbox"/> Restriction/Election Only	<input type="checkbox"/> Final Rejection
<input type="checkbox"/> Ex Parte Quayle	<input type="checkbox"/> Allowance	<input type="checkbox"/> Advisory Action
<input type="checkbox"/> Examiner's Answer (Including Supplemental)	<input type="checkbox"/> Reply Brief Noted	<input type="checkbox"/> Non-Entry of Reply Brief
<input type="checkbox"/> Notice of Defective Appeal Brief	<input type="checkbox"/> Interference SPE _____ Approval for Disposal	<input type="checkbox"/> Suspension SPE _____ (Initial)
<input type="checkbox"/> Allowance After Examiner's Answer	<input type="checkbox"/> SIR Disposal (use only after FAOM)	<input type="checkbox"/> Post-Allowance Communication
<input type="checkbox"/> Miscellaneous Office Letter (With Shortened Statutory Period Set)	<input type="checkbox"/> Notice of Non-Responsive Amendment (With One Month Time Limit Set)	<input type="checkbox"/> Miscellaneous Office Letter (No Response Period Set)
<input type="checkbox"/> Letter Requiring Formal Drawings	<input type="checkbox"/> Supplemental Action	<input type="checkbox"/> Response to a Rule 312 Amendment
<input type="checkbox"/> Restart Time Period (e.g., Missing References)	<input type="checkbox"/> Interview Summary	<input type="checkbox"/> Authorization to Change Previous Office Action SPE _____ (Initial)
<input type="checkbox"/> Abandonment	<input type="checkbox"/> Express Abandonment Date: _____	<input type="checkbox"/> Abandonment After Examiner's Answer

Examiner's Name: _____ GAU: _____

COUNTING OF FIRST ACTION ON THE MERITS (FAOM)

Office actions on the merits consist of rejections (final and non-final), *Ex parte Quayle* actions, and allowances.

The first time an examiner performs one of the above merit actions, he/she receives credit for a First Action on the Merits (FAOM) on the production reports.

A second/subsequent but FAOM usually occurs when the first action is a restriction/election action and the second action is an action on the merits. The examiner indicates the type of second action on the Examiner's Case Action Worksheet, and the PALM system will automatically determine if it is a FAOM. If the second action is a FAOM, the action will be listed and credited on the Biweekly Examiner Time and Activity Report as a Second/Subsequent FAOM.

COUNTING OF DISPOSALS

An examiner receives a "disposal" count for the following actions:

- (A) Allowance;
- (B) Abandonment;
- (C) Examiner's Answer;
- (D) International Preliminary Examination Report;
- (E) Statutory Invention Registration (SIR) disposal (only after a FAOM; see MPEP § 1101); and
- (F) Interference wherein the application would be in condition for allowance but for the interference.

These same items constitute the "disposals" for performance evaluation of examining art units and TCs. However, disposals at the Office level consist only of allowances and abandonments.

For either an allowance or an abandonment after an Examiner's Answer or decision by a court or the Board of Patent Appeals and Interferences, no disposal credit is received, though these actions are indicated on the Biweekly Examiner Time and Activity Report.

CORRECTION INFORMATION

(A) If any information is either missing from or incorrect on the Biweekly Examiner Time and Activity Report, the examiner should promptly notify the

legal instrument examiner by providing all the pertinent information necessary to make the changes to the PALM system (e.g., examining hours, application number, type of action, etc.).

(B) The legal instrument examiner will report the necessary changes and corrections directly into PALM. These changes will be listed on the next Biweekly Examiner Time and Activity Report.

(C) If any information is missing from the last Biweekly Examiner Time and Activity Report of a quarter (except at the end of a fiscal year) or is incorrect, the examiner should promptly notify the legal instrument examiner and his/her supervisory patent examiner (SPE). The legal instrument examiner will make the appropriate changes directly into the PALM system. The changes will be listed on the next Biweekly Examiner Time and Activity Report. However, these changes will not be reflected in the last Quarter's Report; the examiner's SPE may manually make an adjustment to the records to show these changes.

(D) In order to ensure that all PALM reports are correct at the end of the fiscal year (rating period), a special correction cycle is provided on the PALM system. If any information is missing from or is incorrect on the last Biweekly Examiner Time and Activity Report, the examiner should immediately notify the legal instrument examiner and his/her SPE. These changes will be reflected in the examiner's final biweekly report for the entire fiscal year.

1706 Disclosure Documents

A service provided by the United States Patent and Trademark Office (USPTO) is the acceptance and preservation for two years of "Disclosure Documents" as evidence of the date of conception of an invention.

THE PROGRAM

A paper disclosing an invention (called a Disclosure Document) and signed by the inventor or inventors may be forwarded to the USPTO by the inventor (or by any one of the inventors when there are joint inventors), by the owner of the invention, or by the attorney or agent of the inventor(s) or owner. The Disclosure Document will be retained for two years, and then be destroyed unless it is referred to in a separate letter in a related patent application filed within those two years.

THE DISCLOSURE DOCUMENT IS NOT A PATENT APPLICATION, AND THE DATE OF ITS RECEIPT IN THE USPTO WILL NOT BECOME THE EFFECTIVE FILING DATE OF ANY PATENT APPLICATION SUBSEQUENTLY FILED. THESE DOCUMENTS WILL BE KEPT IN CONFIDENCE BY THE USPTO.

This program does not diminish the value of the conventional, witnessed, permanently bound, and page-numbered laboratory notebook or notarized records as evidence of conception of an invention.

CONTENT OF DISCLOSURE

The benefits afforded by the Disclosure Document will depend directly upon the adequacy of the disclosure. It is strongly recommended that the document contain a clear and complete explanation of the manner and process of making and using the invention in sufficient detail to enable a person having ordinary knowledge in the field of the invention to make and use the invention. When the nature of the invention permits, a drawing or sketch should be included. The use or utility of the invention should be described, especially in chemical inventions. Where the invention is directed to a design, the appearance presented by the object should be described.

PREPARATION OF THE DOCUMENT

A standard format for the Disclosure Document is required to facilitate the USPTO's electronic data capture and storage. The Disclosure Document (including drawings or sketches) must be on white letter-size (8 1/2 by 11-inch) or A4 (21.0 by 29.7 cm) paper, written on one side only, with each page numbered. Text and drawings must be sufficiently dark to permit reproduction with commonly used office copying machines. Oversized papers, even if foldable to the above dimensions, will not be accepted. Attachments such as videotapes and working models will not be accepted and will be returned.

OTHER ENCLOSURES

The Disclosure Document must be accompanied by a separate cover letter signed by the inventor stating that he or she is the inventor and requesting that the material be received under the Disclosure Document Program. The inventor's request may take the following form:

The undersigned, being the inventor of the disclosed invention, requests that the enclosed papers be accepted under the Disclosure Document Program, and that they be preserved for a period of two years.

A Disclosure Document Deposit Request form (PTO/SB/95) can also be used as a cover letter. This form is available at the USPTO's Internet site or by calling the USPTO General Information Services Division (see MPEP § 1730).

A notice with an identifying number and date of receipt in the USPTO will be mailed to the customer, indicating that the Disclosure Document may be relied upon only as evidence of conception and that a patent application should be diligently filed if patent protection is desired. The USPTO prefers that applicants send two copies of the cover letter or Disclosure Document Deposit Request form and one copy of the Disclosure Document, along with a self-addressed stamped envelope. The second copy of the cover letter or form will be returned with the notice. It is not necessary to submit more than one copy of the document in order for it to be accepted under the Disclosure Document Program.

A notice with an identifying number and date of receipt in the USPTO will be mailed to the customer, indicating that the Disclosure Document may be relied upon only as evidence of conception and that a patent application should be diligently filed if patent protection is desired. The USPTO prefers that applicants send two copies of the cover letter or Disclosure Document Deposit Request form and one copy of the Disclosure Document, along with a self-addressed stamped envelope. The second copy of the cover letter or form will be returned with the notice. It is not necessary to submit more than one copy of the document in order for it to be accepted under the Disclosure Document Program.

DISPOSITION

The Disclosure Document will be preserved by the USPTO for two years after its receipt. It will then be destroyed unless it is referred to in a separate letter in a related patent application filed within the two-year period. The separate letter filed in the related patent application must identify not only the patent application, but also the Disclosure Document by its title, number, and date of receipt in the USPTO. Acknowledgment of such letters will be made in the next official communication or in a separate letter from the USPTO.

ACKNOWLEDGMENT

When a paper referring to a Disclosure Document is filed in a patent application within 2 years after the filing of a Disclosure Document, the examining Technology Center (TC) technical support staff member will prepare either (1) a memorandum indicating that a reference to Disclosure Document No. -- has been made in Patent Application No. --, or (2) a copy of the

paper filed in the application referring to the Disclosure Document. The memorandum or copy is forwarded to the Customer Contact Team of the Office of Initial Patent Examination (OIPE).

Upon receipt, the Customer Service Branch of the OIPE prepares a retention label (PTO-150) and attaches it to the Disclosure Document, and indicates such on the forwarded memo or copy, and returns the memo or copy to the TC. The returned memo or copy is stapled to the inside left flap of the file wrapper so that the examiner's attention is directed to it when the next Office action is prepared. If prosecution before the examiner has been concluded, a separate letter indicating that the Disclosure Document will be retained should be sent to the applicant by the examining TC technical support staff member.

After the acknowledging letter is mailed, the paper number of the acknowledgment is noted in the application file. The returned memo or copy is stapled to and retained with the original paper referring to the Disclosure Document in the file wrapper.

FEE

A fee of \$10, as set forth in 37 CFR 1.21(c), in the form of a check or money order made payable to "Assistant Commissioner for Patents" must accompany the Disclosure Document when it is submitted to the USPTO. Documents not accompanied by the full fee will be returned. Mail the Disclosure Document along with the fee to:

Box DD
Assistant Commissioner for Patents
Washington, DC 20231

Applicants can request a copy of their Disclosure Document as filed in the USPTO if they are the original submitters of the document. The request must be made in writing and accompanied by a fee for \$25.

Fees are subject to change annually. To confirm current fees, contact the General Information Services Division or visit the USPTO's Internet site (see MPEP § 1730).

NOTICE TO INVENTORS

The two-year retention period is not a "grace period" during which the inventor can wait to file his or her patent application without possible loss of ben-

efits. It must be recognized that, in order to establish priority of invention, an affidavit or testimony referring to a Disclosure Document must usually also establish diligence in completing the invention or in filing the patent application after the filing of the Disclosure Document.

Inventors are also reminded that any public use or sale in the United States or publication of the invention anywhere in the world more than one year prior to the filing of a patent application on that invention will prohibit the granting of a U.S. patent on it. See 35 U.S.C. 102(b). Foreign patent laws in this regard may be much more restrictive than U.S. laws.

The USPTO advises inventors who are not familiar with the requirements of U.S. patent law and procedures to consult an attorney or agent registered to practice before the USPTO. A list of *Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office* can be found at the USPTO's Internet site. See MPEP § 1730 for additional sources of this list.

As a service to USPTO's customers, the three Partnership Patent and Trademark Depository Libraries (PTDLs) listed below have been authorized to act as USPTO's "agent" in accepting documents under the Disclosure Document Program. This service provides customers with a completed transaction on-site, eliminating the wait for USPTO notification of acceptance. The documents are stamped with an identifying number and date at the time of receipt by the PTDL. Original documents are sent to the USPTO for processing and retention.

Sunnyvale Center for Innovation, Invention and Ideas
(Sci³)
465 South Mathilda Avenue
Sunnyvale, CA 94086
408-730-7290
Fax: 408-735-8762

Great Lakes Patent and Trademark Center at the
Detroit Public Library (GLPTC)
5201 Woodward Avenue (second level)
Detroit, MI 48202
313-833-3379 or 800-547-0619
Fax: 313-833-6481

South Central Intellectual Property Partnership at
Rice University (SCIPPR)
Fondren Library - MS220
6100 South Main Street
Houston, TX 77521-1892
713-285-5196
Fax: 713-737-6341

To locate a Patent and Trademark Depository Library (PTDL) near you, consult the complete listing of PTDLs found in every issue of the *Official Gazette*, call the USPTO General Information Services Division, or access the USPTO's Internet site (see MPEP § 1730). The nationwide network of PTDLs has collections of patents and patent-related reference materials available to the public, including automated access to USPTO data bases. Contact the PTDL prior to your visit to learn about its collections, services, and hours.

1711 U.S.-Philippines Search Exchange

The United States-Philippines search exchange program involves patent applications filed in the United States which are subsequently followed by corresponding applications filed in the Republic of the Philippines and patent applications filed in the Philippines subsequently followed by corresponding applications filed in the United States.

The program operates as follows:

The applicant files his or her application in the United States Patent and Trademark Office (USPTO) which will process the application in the normal manner and examine the application in the usual time sequence.

If the applicant should later file a corresponding application in the Philippines Patent Office, he or she may elect to use the special filing procedure. Under this special filing procedure, applicant files his or her application in the Philippines accompanied by a notice of election to participate in the special procedure, which notice of election contains a certification that the description (excluding references to related applications), claims, and drawings are identical to those of the corresponding application originally filed in the United States. The earlier filed application must be fully identified, and, in applications without a claim of priority, a certified copy of the earlier filed U.S. application must be submitted to the Philippines

Patent Office. In addition, applicant must also agree that all amendments to his or her U.S. application will also be made with respect to his or her application filed in the Philippines.

In the USPTO, applicant will regularly file two copies of each amendment. One copy must be marked "Copy for Philippines Patent Office." Upon termination of prosecution, the USPTO shall remove all copies so marked from the U.S. file and promptly forward the same to the Philippines Patent Office.

Election forms for participation in this special program must be signed in duplicate and simultaneously accompany the application to be filed in the Philippines.

Upon receipt of properly filed notice of election, the Philippines Patent Office will notify the USPTO of the election by forwarding one copy of the election forms to the USPTO. The Philippines Patent Office will defer action on the Philippines application pending receipt of information as to the disposition of the application by the USPTO. If no such information is received by the Philippines Office within a reasonable amount of time from the date of filing in the Philippines, the Philippines Office may, either on its own initiative, or at applicant's request, inquire as to the status of the U.S. application and, if desired, proceed with its own independent examination.

Upon disposal of the application by the USPTO, appropriate information will be sent to the Philippines Patent Office which will include all necessary identifying data, whether allowed or abandoned, notice of allowance, copies of documents cited during examination, a copy of the last office action and, when necessary, any earlier actions which may be included by reference in the last action. The Philippines Office will then make its own complete office action based upon the claims as amended with USPTO, performing whatever checks desired and searching for copending interfering applications. Alternatively, the Philippines may request applicant to show cause why the results of the U.S. examination should not be accepted in the Philippines. All avenues of appeal will remain open to the applicant.

Where copending applications are cited and applied during examination in the USPTO full examination will not be forwarded to the Philippines Patent Office, and the fact that a U.S. copending application was

cited would be noted as a matter of information, since such references are inapplicable in the Philippines.

Where the application originates in the Philippines Patent Office and is subsequently filed in the USPTO, a similar procedure as outlined above, consonant with U.S. law, will be followed.

It is believed that this program will facilitate the handling of U.S. origin applications filed in the Republic of the Philippines resulting in a savings in time and expense of prosecution to U.S. applicants.

1720 Dissemination of Court and Board of Patent Appeals and Interferences Decisions

COURT DECISIONS

The Office of the Solicitor forwards to the Office of the Assistant Commissioner for Patents copies of all recent court decisions in patent cases where a precedential opinion is issued. The Office of the Assistant Commissioner for Patents will routinely provide copies of these opinions to TC Directors, the Patent Academy, and the Director of the Office of Patent Quality Review.

TC Directors, in turn, are to make copies available to supervisors and other individuals as the TC Director determines to be appropriate. TC Directors are encouraged to discuss the contents of the opinions in their staff meetings, particularly where such meetings are being held to reinforce examination quality.

BOARD OF PATENT APPEALS AND INTERFERENCES DECISIONS

A decision rendered by the Board of Patent Appeals and Interferences (Board) is returned to the examiner through the TC Director and the examiner's supervisor. The examiner takes action consistent with the decision rendered by the Board unless rehearing of the Board decision will be requested (MPEP § 1214.04). The TC Director may circulate and discuss the decision among some or all of the supervisors in the TC, and the supervisors, in turn, may circulate the decision among the examiners in their art units, depending on the subject matter or issues in the decisions.

1721 Treatment of Court and Board of Patent Appeals and Interferences Decisions Affecting Patent and Trademark Office Policy and Practice

In the event the Board of Patent Appeals and Interferences (Board) or court decision is one that significantly adds to the body of law by, for example, addressing a new legal or procedural issue, or providing a new interpretation of a prior decision, such a decision may result in an internal United States Patent and Trademark Office (USPTO) memorandum pointing out the significance of the decision to the examination process.

When any examiner or supervisor in the Patent Examining Corps concludes that a recent decision of the Board or a court affects existing USPTO policy or practice, he or she should bring the matter to the attention of his/her TC Director through normal chain-of-command procedures.

When the TC Director believes that guidance to the Corps is warranted as a result of a decision, the TC Director should consult with the Deputy Commissioner for Patent Examination Policy and provide a draft of the guidance that is recommended as appropriate under the circumstances. The Deputy Assistant Commissioner for Patent Examination Policy will then consult appropriate Office officials, as necessary, to formulate a recommendation to the Assistant Commissioner for Patents on the policy implications of the opinion.

It may be necessary for the Commissioner, General Counsel, Solicitor, Chief Administrative Patent Judge, A/C for Patents, Deputy A/C for Patent Examination Policy, Deputy A/C for Patents and TC Director making the recommendation to meet to review and discuss the policy ramifications of the case enabling the Commissioner to decide how the USPTO will proceed.

Communication of the decision on the policy implications of the court or Board decision will normally take place by either notice in the *Official Gazette* and/or via memorandum to USPTO personnel. Ultimately, the policy implications of the decision will be officially incorporated into the Manual of Patent Examining Procedure and Patent Academy curriculum materials during the next update cycle for these reference materials.

1730 Information Sources

IN GENERAL

General information about patents, trademarks, products and services offered by the United States Patent and Trademark Office (USPTO), and other related information is available by contacting the USPTO's General Information Services Division at:

800-PTO-9199 or 703-308-HELP
(FAX) 703-305-7786
(TDD) 703-305-7785

An automated message system is available 7 days a week, 24 hours a day providing informational responses to frequently asked questions and the ability to order certain documents. Customer service representatives are available to answer questions, send materials or connect customers with other offices of the USPTO from 8:30 a.m. - 8:00 p.m. EST/EDT, Monday-Friday excluding federal holidays.

For other technical patent information needs, the Patent Assistance Center can be reached through customer service representatives at the above numbers, Monday through Friday (except federal holidays) from 8:30 a.m. to 5:00 p.m. EST/EDT.

For questions or concerns relating to other technical trademark matters, the Trademark Assistance Center can be reached at 703-308-9000 or by facsimile at 703-308-7016.

General information brochures can also be obtained in person from the Patent Search Room located in Crystal Plaza 3, Room 1A03, 2021 South Clark Place, Arlington, VA 22202.

USPTO INTERNET SITE

General Information

The USPTO web site (<http://www.uspto.gov> or <ftp.uspto.gov>) provides a wealth of information to all users. The USPTO web site offers links to news and notices (such as announcements, press releases, *Official Gazette* Notices and *Federal Register* Notices), USPTO contacts and addresses, activities and education related pages (such as the PTDL and Independent Inventor programs and the Kids Pages), patent specific information (such as issued patents and published patent applications, general information pertaining to applying for a patent, electronic filing of

patent applications, and reference materials such as the MPEP and examination guidelines), and trademark specific information (such as the Trademark Manual of Examining Procedure and the U.S. Trademark Electronic Search System (TESS)). In addition, the web site allows downloading of a variety of USPTO forms (including PCT forms), ordering copies of patents and trademarks, accessing a list of all current fees, paying patent maintenance fees, replenishing deposit accounts, accessing various legal materials, linking to related web sites, etc.

Patent Related Databases

The USPTO web site offers two patent database collections which provide the public with flexible and powerful search capabilities. The Patent Grants Database provides access to the full-text of all U.S. patents issued since 1976, and to the full-page images of all U.S. patents issued since 1790. The Patent Applications Database provides both full-text and full-page images of all U.S. patent applications published since March 15, 2001.

Patent Electronic Business Center

The Patent Electronic Business Center (EBC) allows USPTO customers to retrieve data, check the status of pending actions, and submit information and applications. The tools currently available in the Patent EBC are Patent Application Information Retrieval (PAIR) and the Electronic Filing System (EFS).

PAIR (<http://pair.uspto.gov>) provides customers direct secure access to their own patent application status information, as well as to general patent information publicly available.

EFS allows customers to electronically file patent application documents securely via the Internet. EFS is a system for submitting new utility patent applications and pre-grant publication submissions in electronic publication-ready form. EFS includes software to help customers prepare submissions in eXtensible Markup Language (XML) format and to assemble the various parts of the application as an electronic submission package. EFS also allows the submission of Computer Readable Format (CRF) sequence listings for pending biotechnology patent applications which were filed in paper form.

PCT

For questions and information concerning the Patent Cooperation Treaty (PCT), the PCT Help Desk is available to provide assistance and may be reached by telephone at (703) 305-3257 between the hours of 9:00 am and 4:30 pm (EST/EDT), Monday through Friday, or by facsimile at (703) 305-2919, 24 hours a day. In addition, helpful information is available through the internet at the PCT Legal Office page of the USPTO web site and at the World Intellectual Property Office web site (<http://www.wipo.org/>).

USPTO SEARCH AND INFORMATION RESOURCE FACILITIES

The following USPTO search and information resource facilities are accessible to the public:

(A) Patent Search Room (Crystal Plaza 3, 1A03) at (703) 308-HELP

(Hours: Weekdays, 8:00 a.m. to 8:00 p.m., EST/EDT);

(B) Patent Image Retrieval (Crystal Mall 1, 1A02) at (703) 308-6001

(Hours: Weekdays, 8:00 a.m. to 8:00 p.m., EST/EDT);

(C) Patent Assignment Search Room (Crystal Plaza 3, 2C03) at (703) 308-2768

(Hours: Weekdays, 8:30 a.m. to 5:00 p.m., EST/EDT); and

(D) Scientific and Technical Information Center (Crystal Plaza 3/4, 2C08) at (703) 308-0810

(Hours: Weekdays, 8:30 a.m. to 5:00 p.m., EST/EDT).

REGISTERED PRACTITIONERS

The USPTO cannot recommend any particular attorney or agent, or aid in the selection of an attorney or agent. A list of *Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office* may be purchased in paper form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (202-512-1800), or on floppy diskette or CD-ROM from the USPTO's Office of Electronic Information Products and Services (703-306-2600). It is also available on the USPTO web site.

To obtain a list of registered patent attorneys and agents for a particular area, customers may either write to the Commissioner of Patents and Trademarks,

Box OED, Washington, DC, 20231, contact a customer service representative through the USPTO's General Information Services Division (see "In General" above), or acquire the information from the USPTO web site. The attorneys and agents list may be examined without charge at Patent and Trademark Depository Libraries (PTDLs) and at many other libraries throughout the U.S. Many large cities also have associations of patent attorneys and agents which may be consulted.

MISCELLANEOUS

Recently Filed Applications

For information and questions concerning recently filed patent applications and filing receipts, contact the Customer Service Center of the Office of Initial Patent Examination at (703) 308-1202 (hours: weekdays, 8:30 a.m. to 5:00 p.m., EST/EDT; the Customer Service Center hours for receipt of mail are weekdays, 8:30 a.m. to 12 midnight, EST/EDT).

Status Information

For information on the status of a patent application, contact the File Information Unit at (703) 308-2733.

Copies of Documents

Inquiries regarding certified copies of documents, including patent applications-as-filed, patent related file wrappers, patent copies, and reproduced copies of individual replacement pages or previous revisions of the MPEP, should be directed to the Certification Division at (703) 308-9726 or 1-800-972-6382. Orders for certified copies may be placed by facsimile when paying by VISA®, MasterCard®, American Express®, Discover®, or USPTO Deposit Account at (703) 308-7048. Orders for uncertified copies of patents may be placed by phone at (703) 305-8716 or by fax at (703) 305-8759. To order file histories for self-service copying, contact the File Information Unit at (703) 308-2733.

Maintenance Fees

Information regarding maintenance fees may be obtained by contacting the Status and Entity Division at (703) 308-5068, or by accessing the maintenance fee automated voice response system, 24 hours a day,

seven days a week, at (703) 308-5036 or (703) 308-5037. Status requests can also be faxed to the Status and Entity Division at (703) 308-5077.

Assignments

For questions pertaining to filing assignments or other documents affecting title, contact the Assignment Division at (703) 308-9723. Documents may be submitted to the Assignment Division by facsimile at (703) 306-5995. See MPEP § 302.09 for additional information.

Petitions

For matters decided by the Office of Petitions, the appropriate USPTO personnel may be reached at (703) 305-9282 or by facsimile at (703) 308-6916. Papers hand-carried to the Office of Petitions should be delivered to Crystal Plaza 4, Room 3C23, 2201 South Clark Place, Arlington, Virginia, 22202.

PatentIn

For information regarding orders for the PatentIn software program, call the Office of Electronic Information Products and Services at (703) 306-2600. For assistance using PatentIn, call (703) 306-4119.



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1896 The Differences Between a National Application Filed Under 35 U.S.C. 111(a) and a National Stage Application Filed Under 35 U.S.C. 371**INTRODUCTION**

This chapter is designed to be a guide for patent examiners in searching and examining applications filed under the Patent Cooperation Treaty (PCT). Applicants desiring additional information for filing international applications should obtain a copy of the PCT Applicant's Guide from the World Intellectual Property Organization (WIPO) in Geneva, Switzerland.

The Articles and Regulations under the PCT are reproduced in Appendix T of this Manual and the Administrative Instructions are reproduced in Appendix AI of this Manual. The text of the *PCT Applicant's Guide*, the monthly *PCT Newsletter*, the weekly *PCT Gazette*, downloadable PCT forms, and additional information about the processing of international applications are available from WIPO's website (www.wipo.int/pct).

PCT applications are processed by the International Application Processing Division within the U.S. Patent and Trademark Office.

1801 Basic Patent Cooperation Treaty (PCT) Principles**MAJOR CONCEPTS OF THE PCT**

The Patent Cooperation Treaty (PCT) enables the U.S. applicant to file one application, "an international application," in a standardized format in English in the U.S. Receiving Office (the U.S. Patent and Trademark Office), and have that application acknowledged as a regular national filing in as many member countries to the PCT as the applicant "designates" or "elects," that is, names, as countries in

which patent protection is desired. In the same manner, the PCT enables foreign applicants to file a PCT international application, designating the United States of America, in their home language in their home patent office and have the application acknowledged as a regular U.S. national filing. The PCT also provides for a search and publication after 18 months from the priority date. Upon payment of national fees and the furnishing of any required translation, usually 20 months after the filing of any priority application for the invention, or the international filing date if no priority is claimed, the application will be subjected to national procedures for granting of patents in each of the designated countries. If a demand for an international preliminary examination is filed within 19 months from the priority date, the period for entering the national stage is extended to 30 months from the priority date.

The PCT offers an alternative route to filing patent applications directly in the patent offices of those countries which are members of the PCT. It does not preclude taking advantage of the priority rights and other advantages provided under the Paris Convention and the WTO administered Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement). The PCT provides an additional and optional foreign filing route to patent applicants.

The filing, search and publication procedures are provided for in Chapter I of the PCT. Additional procedures for a preliminary examination of PCT international applications are provided for in optional PCT Chapter II.

In most instances a national U.S. application (NA) is filed first. An international application for the same subject matter will then be filed subsequently within the priority year provided by the Paris Convention and the priority benefit of the U.S. national application filing date will be claimed.

RECEIVING OFFICE (RO)

The international application (IA) must be filed in the prescribed receiving Office (RO) (PCT Article 10). The United States Patent and Trademark Office will act as a receiving Office for United States residents and nationals (35 U.S.C. 361(a)). Under PCT Rule 19.1(a)(iii), the International Bureau of the World Intellectual Property Organization will also act as a Receiving Office for U.S. residents and nationals. The

receiving Office functions as the filing and formalities review organization for international applications. International applications must contain upon filing the designation of at least one country in which patent protection is desired and must meet certain standards for completeness and formality (PCT Articles 11(1) and 14(1)).

Where a priority claim is made, the date of the earlier filed national application is used as the date for determining the timing of international processing, including the various transmittals, the payment of certain international and national fees, and publication of the application. Where no priority claim is made, the international filing date will be considered to be the "priority date" for timing purposes (PCT Article 2(xi)).

The international application is subject to the payment of certain fees upon filing, or within 1 month thereafter, and at the expiration of 12 months from the priority date or within 1 month thereafter. The receiving Office will grant an international filing date to the application, collect fees, handle informalities by direct communication with the applicant, and monitor all corrections (35 U.S.C. 361(d)). By 13 months from the priority date, the receiving Office should prepare and transmit a copy of the international application, called the search copy (SC), to the International Searching Authority (ISA); and forward the original, called the record copy (RC), to the International Bureau (IB) (PCT Rules 22.1 and 23). A second copy of the international application, the home copy (HC), remains in the receiving Office (PCT Article 12(1)). Once the receiving Office has transmitted copies of the application, the International Searching Authority becomes the focus of international processing.

INTERNATIONAL SEARCHING AUTHORITY (ISA)

The basic function of the International Searching Authority (ISA) is to conduct a prior art search of inventions claimed in international applications; it does this by searching in at least the minimum documentation defined by the Treaty (PCT Articles 15 and 16 and PCT Rule 34). At the option of the applicant, either the U.S. Patent and Trademark Office or the European Patent Office will act as an International Searching Authority for international applications filed in the United States Receiving

Office. The International Searching Authority is also responsible for checking the content of the title and abstract (PCT Rules 37.2 and 38.2). An international search report (SR) will normally be issued by the International Searching Authority within 3 months from the receipt of the search copy (usually about 16 months after the priority date) (PCT Rule 42). Copies of the International Search Report and prior art cited will be sent to the applicant by the ISA/US (PCT Rules 43 and 44.1). The search report will contain a listing of documents found to be relevant and will identify the claims in the application to which they are pertinent. However, no judgments or statements as to patentability will be made (PCT Rule 43.9). Once the international search report has been completed and transmitted, international processing continues before the International Bureau.

INTERNATIONAL BUREAU (IB)

The basic functions of the International Bureau (IB) are to maintain the master file of all international applications and to act as the publisher and central coordinating body under the Treaty. The World Intellectual Property Organization (WIPO) in Geneva, Switzerland performs the duties of the International Bureau.

If the applicant has not filed a certified copy of the priority document in the receiving Office with the international application, or requested upon filing that the receiving Office prepare and transmit to the International Bureau a copy of the prior U.S. national application, the priority of which is claimed, the applicant must submit such a document directly to the International Bureau or the receiving Office not later than 16 months after the priority date (PCT Rule 17). The Request form contains a box which can be checked requesting that the receiving Office prepare the certified copy. This is only possible, of course, if the receiving Office is a part of the same national Office where the priority application was filed.

The applicant has normally 2 months from the date of transmittal of the International Search Report to amend the claims by filing an amendment directly with the International Bureau (PCT Article 19 and PCT Rule 46). The International Bureau will then normally publish the international application along with the search report and any amended claims (Amdt) at the expiration of 18 months from the priority date

(PCT Article 21). The international publication is in pamphlet form with a front page containing bibliographical data, the abstract, and a figure of the drawing (PCT Rule 48). The pamphlet also contains the search report and any amendments to the claims submitted by the applicant. If the application is published in a language other than English, the search report and abstract are also published in English. The International Bureau publishes a *PCT Gazette* in the French and English languages which contains information similar to that on the front pages of published international applications, as well as various indexes and announcements (PCT Rule 86). The International Bureau also transmits copies of the international application to all the designated Offices (PCT Article 20 and PCT Rule 47).

DESIGNATED OFFICE (DO) and ELECTED OFFICE (EO)

The designated Office is the national Office (for example, the USPTO) acting for the state or region designated under Chapter I. Similarly, the elected Office is the national Office acting for the state or region elected under Chapter II.

If no "Demand" for international preliminary examination has been filed within 19 months of the priority date, the applicant must complete the requirements for entering the national stage within 20 months from the priority date of the international application, unless the individual designated Office grants additional time. The applicant also has the right to amend the application within 1 month from the fulfillment of the requirements under PCT Article 22. After this month has expired (PCT Article 28 and PCT Rule 52), each designated Office will make its own determination as to the patentability of the application based upon its own specific national or regional laws (PCT Article 27(5)).

If the applicant desires to obtain the benefit of delaying the entry into the national stage until 30 months from the priority date, a Demand for international preliminary examination must be filed with an appropriate International Preliminary Examining Authority within 19 months of the priority date. Those states in which the Chapter II procedure is desired must be "elected" in the Demand.

The original Demand is forwarded to the International Bureau by the International Preliminary Exam-

ining Authority. The International Bureau then notifies the various elected Offices that the applicant has entered Chapter II and that the application should not be considered withdrawn for failure to enter the national stage within 20 months from the priority date.

The examiner of the International Preliminary Examining Authority may comment on lack of unity of invention, note errors, and issue a written "opinion" as to whether each claim is "novel," involves "inventive step," and is "industrially applicable." If a written "opinion" is issued by the examiner, the applicant may reply to the opinion by arguments and amendments within the time period set for reply. The examiner will then issue the international preliminary examination report which presents the examiner's final position as to whether each claim is "novel," involves "inventive step," and is "industrially applicable" by 28 months from the priority date. A copy of the international preliminary examination report is sent to the applicant and to the International Bureau. The International Bureau then communicates a copy of the international preliminary examination report to each elected Office.

The applicant must complete the requirements for entering the national stage by the expiration of 30 months from the priority date to avoid any question of withdrawal of the application as to that elected Office.

1802 PCT Definitions

The PCT contains definitions in PCT Article 2 and in PCT Rule 2, which are found in MPEP Appendix T. Additional definitions are found in 35 U.S.C. 351, MPEP Appendix L, 37 CFR 1.401, MPEP Appendix R, Section 101 of the PCT Administrative Instructions and MPEP Appendix AI.

1803 Reservations Under the PCT Taken by the United States of America

The United States of America had originally declared that it was not bound by Chapter II (PCT Article 64 (1)), but withdrew that reservation on July 1, 1987.

It has also declared that, as far as the United States of America is concerned, international publication is not required (PCT Article 64 (3)). Accordingly, under

PCT Article 64(3)(b), if the United States is the only PCT Contracting State designated in an international application, the international application will not be published by the International Bureau (IB) at 18 months. Even though the United States Patent and Trademark Office has begun pre-grant publication under 35 U.S.C. 122(b), the United States has not removed its reservation under PCT Article 64(3) because not all United States patent applications are published. See 35 U.S.C. 122(b)(2). The application will, however, be published under 35 U.S.C. 122(b) if it enters the national stage in the United States. It will be published again if it is allowed to issue as a United States patent.

The United States of America also made a reservation under PCT Article 64(4) which relates to the prior art effective date of a U.S. patent issuing from an international application. See 35 U.S.C. 102(e) and 363.

The above reservations under PCT Article 64(3) and (4) are still in effect.

The U.S. Receiving Office continues to accept applications only in English. See 35 U.S.C. 361(c). PCT Rules 20.4(c), 26.3^{ter}(a) and 26.3^{ter}(c) permit an international filing date to be accorded even though portions of an international application are in a language not acceptable to the Receiving Office. PCT Rules 20.4(c), 26.3^{ter}(a) and 26.3^{ter}(c) are not compatible with the national law applied by the United States Patent and Trademark Office (USPTO) as Receiving Office. Thus, the USPTO has taken a reservation on adherence to these Rules pursuant to PCT Rules 20.4(d), 26.3^{ter}(b) and 26.3^{ter}(d). As a result, PCT Rules 20.4(c), 26.3^{ter}(a) and 26.3^{ter}(c) shall not apply to the USPTO as Receiving Office for as long as the aforementioned incompatibility exists.

Also, PCT Rules 49.5(c^{bis}) and 49.5(k) continue not to be compatible with the national law applied by the USPTO as a Designated Office. See 35 U.S.C. 371(c)(2). As a result, PCT Rules 49.5(c^{bis}) and 49.5(k) shall not apply to the USPTO as Designated Office for as long as the aforementioned incompatibility exists. See the International Bureau's notice published in *PCT Gazette* No. 07/1992.

1805 Where to File an International Application

35 U.S.C. 361. Receiving Office.

(a) The Patent and Trademark Office shall act as a Receiving Office for international applications filed by nationals or residents of the United States. In accordance with any agreement made between the United States and another country, the Patent and Trademark Office may also act as a Receiving Office for international applications filed by residents or nationals of such country who are entitled to file international applications.

See 37 CFR 1.421 - 1.425 as to who can file an international application.

Only if at least one of the applicants is a resident or national of the United States of America may an international application be filed in the United States Receiving Office (PCT Article 9(1) and (3), PCT Rules 19.1 and 19.2, 35 U.S.C. 361(a) and 37 CFR 1.412(a), 1.421). The concepts of residence and nationality are defined in PCT Rule 18.1. For the purpose of filing an international application, the applicant may be either the inventor or the successor in title of the inventor (assignee or owner). However, the laws of the various designated States regarding the requirements for applicants must also be considered when filing an international application. For example, the patent law of the United States of America requires that, for the purposes of designating the United States of America, the applicant(s) must be the inventor(s) (35 U.S.C. 373, PCT Article 27(3)).

The United States Receiving Office is located in Crystal Plaza, Building 2, 8th floor, 2011 South Clark Place, Arlington, Virginia. International applications and related papers may be deposited directly with the United States Receiving Office or be mailed to: Assistant Commissioner for Patents, Box PCT, Washington, DC 20231. It should be noted that the "Express Mail" provisions of 37 CFR 1.10 apply to the filing of all applications and papers filed in the U.S. Patent and Trademark Office, including PCT international applications and related papers and fees. It should be further noted, however, that PCT international applications and papers relating to international applications are specifically excluded from the Certificate of Mailing or Transmission procedures under 37 CFR 1.8. This means, for example, that a Demand for international preliminary examination cannot be filed using the Certificate of Mailing or Transmission prac-

tice under 37 CFR 1.8 if the date of mailing is the date needed for official purposes. If 37 CFR 1.8 is improperly used, the date to be accorded the paper will be the date of actual receipt in the Office unless the receipt date falls on a Saturday, Sunday, or Federal holiday in which case the date of receipt will be the next succeeding day which is not a Saturday, Sunday, or Federal holiday (37 CFR 1.6).

Irrespective of the Certification practice under 37 CFR 1.8(a), facsimile transmission (without the benefit of the certificate under 37 CFR 1.8(a)) may be used to submit certain papers in international applications. However, facsimile transmission may not be used for the filing of an international application, the filing of drawings under 37 CFR 1.437, or the filing of a copy of the international application, and the basic national fee to enter the U.S. national stage under 35 U.S.C. 371. See 37 CFR 1.6(d)(3) and (4), 1.8(a)(2)(i)(D), and 1.8(a)(2)(i)(F). The Demand for international preliminary examination may be filed by facsimile transmission. See MPEP § 1834.01.

The United States Receiving Office staff is available to offer guidance on PCT requirements and procedures. See MPEP § 1730 for information on contacting the staff and other available means for obtaining information.

WARNING - although the United States patent law at 35 U.S.C. 21(a) authorizes the Commissioner to prescribe by rule that any paper or fee required to be filed in the Patent and Trademark Office will be considered filed in the Office on the date on which it was deposited with the United States Postal Service, PCT Rule 20.1(a) provides for marking the "date of actual receipt on the request." Although the "Express Mail" provisions under 37 CFR 1.10 have not been contested to date regarding PCT applications, applicants should be aware of a possible different interpretation by foreign authorities.

PCT Rule 19.4 provides for transmittal of an international application to the International Bureau as Receiving Office in certain instances. For example, when the international application is filed with the United States Receiving Office and the language in which the international application is filed is not accepted by the United States Receiving Office, or if the applicant does not have the requisite residence or nationality, the application may be forwarded to the International Bureau for processing in its capacity as a

Receiving Office. See 37 CFR 1.412(c)(6). The Receiving Office of the International Bureau will consider the international application to be received as of the date accorded by the United States Receiving Office. This practice will avoid the loss of a filing date in those instances where the United States Receiving Office is not competent to act, but where the international application indicates an applicant to be a national or resident of a PCT Contracting state or is in a language accepted under PCT Rule 12.1(a) by the International Bureau as a Receiving Office. Of course, where questions arise regarding residence or nationality, i.e., the U.S. is not clearly competent, the application will be forwarded to the International Bureau as Receiving Office. Note, where no residence or nationality is indicated, the U.S. is not competent, and the application will be forwarded to the International Bureau as Receiving Office so long as the necessary fee is paid. The fee is an amount equal to the transmittal fee.

If all of the applicants are indicated to be residents or nationals of non-PCT Contracting States, PCT Rule 19.4 does not apply, and the application is denied an international filing date.

1807 Agent or Common Representative and General Power of Attorney

37 CFR 1.455. Representation in international applications.

(a) Applicants of international applications may be represented by attorneys or agents registered to practice before the Patent and Trademark Office or by an applicant appointed as a common representative (PCT Art. 49, Rules 4, 8 and 90 and § 10.10). If applicants have not appointed an attorney or agent or one of the applicants to represent them, and there is more than one applicant, the applicant first named in the request and who is entitled to file in the U.S. Receiving Office shall be considered to be the common representative of all the applicants. An attorney or agent having the right to practice before a national office with which an international application is filed and for which the United States is an International Searching Authority or International Preliminary Examining Authority may be appointed to represent the applicants in the international application before that authority. An attorney or agent may appoint an associate attorney or agent who shall also then be of record (PCT Rule 90.1(d)). The appointment of an attorney or agent, or of a common representative, revokes any earlier appointment unless otherwise indicated (PCT Rule 90.6(b) and (c)).

(b) Appointment of an agent, attorney or common representative (PCT Rule 4.8) must be effected either in the Request form, signed by all applicants, or in a separate power of attorney submit-

ted either to the United States Receiving Office or to the International Bureau.

(c) Powers of attorney and revocations thereof should be submitted to the United States Receiving Office until the issuance of the international search report.

(d) The addressee for correspondence will be as indicated in section 108 of the Administrative Instructions.

Where an appointment of an agent or common representative is effected by a separate power of attorney, that power of attorney must be submitted to either the receiving Office or the International Bureau. However, a power of attorney appointing an agent or sub-agent to represent the applicant specifically before the International Searching Authority or the International Preliminary Examining Authority must be submitted directly to that Authority.

“GENERAL” POWER OF ATTORNEY

“General” powers of attorney are recognized for the purpose of filing and prosecuting an international application before the international authorities. The original general power of attorney should be deposited with the International Application Processing Division which is the central focus for PCT matters throughout the Office. Any applications relying thereon must include a copy thereof. A general power of attorney form is provided in the annex to the PCT Applicant’s Guide.

Any general power of attorney must be filed with the receiving Office if the appointment was for the purposes of the international phase generally, or with the International Searching Authority or International Preliminary Examining Authority if the appointment was specifically to represent the applicant before that Authority. The appointment will then be effective in relation to any particular application filed by that applicant provided that the general power of attorney is referred to in the request, the Demand or a separate notice, and that a copy of the general power of attorney is attached to that request, Demand or separate notice. That copy of the signed original need not, itself, be separately signed. See Annex Z of the PCT Applicant’s Guide for a suitable model form for a general power of attorney. The PCT Applicant’s Guide is available from the International Bureau in Geneva, Switzerland. It can be viewed or ordered online from WIPO’s website (<http://www.wipo.int/pct/en/>).

1808 Change in or Revocation of the Appointment of an Agent or a Common Representative

PCT Rule 90.

Agents and Common Representatives

90.6. Revocation and Renunciation

(a) Any appointment of an agent or common representative may be revoked by the persons who made the appointment or by their successors in title, in which case any appointment of a sub-agent under Rule 90.1(d) by that agent shall also be considered as revoked. Any appointment of a subagent under Rule 90.1(d) may also be revoked by the applicant concerned.

(b) The appointment of an agent under Rule 90.1(a) shall, unless otherwise indicated, have the effect of revoking any earlier appointment of an agent made under that Rule.

(c) The appointment of a common representative shall, unless otherwise indicated, have the effect of revoking any earlier appointment of a common representative.

(d) An agent or a common representative may renounce his appointment by a notification signed by him.

(e) Rule 90.4(b) and (c) shall apply, *mutatis mutandis*, to a document containing a revocation or renunciation under this Rule.

37 CFR 1.455. Representation in international applications.

(a) Applicants of international applications may be represented by attorneys or agents registered to practice before the Patent and Trademark Office or by an applicant appointed as a common representative (PCT Art. 49, Rules 4, 8 and 90 and § 10.10). If applicants have not appointed an attorney or agent or one of the applicants to represent them, and there is more than one applicant, the applicant first named in the request and who is entitled to file in the U.S. Receiving Office shall be considered to be the common representative of all the applicants. An attorney or agent having the right to practice before a national office with which an international application is filed and for which the United States is an International Searching Authority or International Preliminary Examining Authority may be appointed to represent the applicants in the international application before that authority. An attorney or agent may appoint an associate attorney or agent who shall also then be of record (PCT Rule 90.1(d)). The appointment of an attorney or agent, or of a common representative, revokes any earlier appointment unless otherwise indicated (PCT Rule 90.6(b) and (c)).

(b) Appointment of an agent, attorney or common representative (PCT Rule 4.8) must be effected either in the Request form, signed by all applicants, or in a separate power of attorney submitted either to the United States Receiving Office or to the International Bureau.

(c) Powers of attorney and revocations thereof should be submitted to the United States Receiving Office until the issuance of the international search report.

(d) The addressee for correspondence will be as indicated in section 108 of the Administrative Instructions.

The appointment of an agent or a common representative can be revoked. The document containing the revocation must be signed by the persons who made the appointment or by their successors in title. The appointment of a sub-agent may also be revoked by the applicant concerned. If the appointment of an agent is revoked, any appointment of a sub-agent by that agent is also considered revoked.

The appointment of an agent for the international phase in general automatically has the effect, unless otherwise indicated, of revoking any earlier appointment of an agent. The appointment of a common representative similarly has the effect, unless otherwise indicated, of revoking any earlier appointment of a common representative.

The rules for signing and submission of a power of attorney also apply to a revocation of an appointment.

Renunciation of an appointment may be made by means of a notification signed by the agent or common representative. The rules for signing and submission of a power of attorney apply also to a renunciation. The applicant is informed of the renunciation by the International Bureau.

U.S. attorneys or agents wishing to withdraw from representation in international applications may request to do so. To expedite the handling of requests for permission to withdraw as attorney, the request should be submitted in triplicate (original and two copies) to Box PCT and should indicate the present mailing addresses of the attorney who is withdrawing and of the applicant. Because the United States Patent and Trademark Office (USPTO) does not recognize law firms, each attorney of record must sign the notice of withdrawal, or the notice of withdrawal must contain a clear indication of one attorney signing on behalf of another.

The USPTO usually requires that there be at least 30 days between approval of withdrawal and the expiration date of a time response period so that the applicant will have sufficient time to obtain other representation or take other action. If less than 30 days remains in a running response period, a request to withdraw is normally disapproved.

For withdrawal of attorney or agent in the national stage, see MPEP § 402.06.

1810 Filing Date Requirements

PCT Article 11.

Filing Date and Effects of the International Application

(1) The receiving Office shall accord as the international filing date the date of receipt of the international application, provided that that Office has found that, at the time of receipt:

(i) the applicant does not obviously lack, for reasons of residence or nationality, the right to file an international application with the receiving Office,

(ii) the international application is in the prescribed language,

(iii) the international application contains at least the following elements:

(a) an indication that it is intended as an international application,

(b) the designation of at least one Contracting State,

(c) the name of the applicant, as prescribed,

(d) a part which on the face of it appears to be a description,

(e) a part which on the face of it appears to be a claim or claims.

35 U.S.C. 363. International application designating the United States: Effect.

An international application designating the United States shall have the effect, from its international filing date under article 11 of the treaty, of a national application for patent regularly filed in the Patent and Trademark Office except as otherwise provided in section 102(e) of this title.

35 U.S.C. 373. Improper Applicant.

An international application designating the United States, shall not be accepted by the Patent and Trademark Office for the national stage if it was filed by anyone not qualified under chapter 11 of this title to be an applicant for the purpose of filing a national application in the United States. Such international applications shall not serve as the basis for the benefit of an earlier filing date under section 120 of this title in a subsequently filed application, but may serve as the basis for a claim of the right of priority under subsections (a) through (d) of section 119 of this title, if the United States was not the sole country designated in such international application.

37 CFR 1.431. International application requirements.

(a) An international application shall contain, as specified in the Treaty and the Regulations, a Request, a description, one or more claims, an abstract, and one or more drawings (where required). (PCT Art. 3(2) and Section 207 of the Administrative Instructions.)

(b) An international filing date will be accorded by the United States Receiving Office, at the time of receipt of the international application, provided that:

(1) At least one applicant is a United States resident or national and the papers filed at the time of receipt of the international application so indicate (35 U.S.C. 361(a), PCT Art. 11(1)(i)).

(2) The international application is in the English language (35 U.S.C. 361(c), PCT Art. 11(1)(ii)).

(3) The international application contains at least the following elements (PCT Art. 11(1)(iii)):

(i) An indication that it is intended as an international application (PCT Rule 4.2);

(ii) The designation of at least one Contracting State of the International Patent Cooperation Union (§ 1.432);

(iii) The name of the applicant, as prescribed (note §§ 1.421-1.424);

(iv) A part which on the face of it appears to be a description; and

(v) A part which on the face of it appears to be a claim.

(c) Payment of the basic portion of the international fee (PCT Rule 15.2) and the transmittal and search fees (§ 1.445) may be made in full at the time the international application papers required by paragraph (b) of this section are deposited or within one month thereafter. The basic, transmittal, and search fee payable is the basic, transmittal, and search fee in effect on the receipt date of the international application.

(1) If the basic, transmittal and search fees are not paid within one month from the date of receipt of the international application and prior to the sending of a notice of deficiency, applicant will be notified and given one month within which to pay the deficient fees plus a late payment fee equal to the greater of:

(i) Fifty percent of the amount of the deficient fees up to a maximum amount equal to the basic fee; or

(ii) An amount equal to the transmittal fee (PCT Rule 16^{bis}).

(2) The one-month time limit set pursuant to this paragraph to pay deficient fees may not be extended.

(d) If the payment needed to cover the transmittal fee, the basic fee, the search fee, one designation fee and the late payment fee pursuant to paragraph (c) of this section is not timely made in accordance with PCT Rule 16^{bis}.1(e), the Receiving Office will declare the international application withdrawn under PCT Article 14(3)(a).

THE "INTERNATIONAL FILING DATE"

An international filing date is accorded on the date on which the international application was received by the receiving Office or pursuant to the correction of defects on a later date (PCT Articles 11(1) and 11(2)(b) and PCT Rules 20.1, 20.3, 20.4(a), 20.5, and 20.6): in the former case, the international filing date will be the date on which the international application was received by the receiving Office; in the latter case, the international filing date will be the date on

which the correction was received by the receiving Office. Any correction must be submitted by the applicant within certain time limits. Where all the sheets pertaining to the same international application are not received on the same day by the receiving Office, in most instances, the date of receipt of the application will be amended to reflect the date on which the last missing sheets were received. As an amended date of receipt may cause the priority claim to be forfeited, applicants should assure that all sheets of the application are deposited with the receiving Office on the same day. For particulars see PCT Rule 20.2.

An all too common occurrence is that applicants will file an international application in the U.S. Receiving Office and no applicant has a U.S. residence or nationality. Applicants are cautioned to be sure that at least one applicant is a resident or national of the U.S. before filing in the U.S. Receiving Office. Where no applicant indicated on the request papers is a resident or national of the United States, the USPTO is not a competent receiving Office for the international application under PCT Rule 19.1(a). Nonetheless, the date the international application was filed in the USPTO will not be lost as a filing date for the international application if at least one applicant is a resident or national of any PCT Contracting State. Under PCT Rule 19.4, the USPTO will receive the application on behalf of the International Bureau as receiving Office (PCT Rule 19.4(a)) and the USPTO will promptly transmit the international application to the International Bureau under PCT Rule 19.4(b). (See also MPEP § 1805.)

1812 Elements of the International Application

PCT Article 3.

The International Application

(1) Applications for the protection of inventions in any of the Contracting States may be filed as international applications under this Treaty.

(2) An international application shall contain, as specified in this Treaty and the Regulations, a request, a description, one or

more claims, one or more drawings (where required), and an abstract.

(3) The abstract merely serves the purpose of technical information and cannot be taken into account for any other purpose, particularly not for the purpose of interpreting the scope of the protection sought.

(4) The international application shall:

(i) be in a prescribed language;

(ii) comply with the prescribed physical requirements;

(iii) comply with the prescribed requirement of unity of invention;

(iv) be subject to the payment of the prescribed fees.

Any international application must contain the following elements: request, description, claim or claims, abstract and one or more drawings (where drawings are necessary for the understanding of the invention (PCT Article 3(2) and PCT Article 7(2)). The elements of the international application are to be arranged in the following order: the request, the description (other than any sequence listing part thereof), the claims, the abstract, the drawings, and the sequence listing part of the description (where applicable) (Administrative Instructions Section 207(a)). All the sheets contained in the international application must be numbered in consecutive Arabic numerals by using the following separate series of numbers: a first series applying to the request; a second series to the description, claims and abstract; a third series to the drawings (where applicable); and a further series to the sequence listing part of the description (where applicable) (PCT Rule 11.7 and Administrative Instructions Section 207(b)). Only one copy of the international application need be filed in the United States Receiving Office (37 CFR 1.433(a)). The request is made on a standardized form (Form PCT/RO/101), copies of which can be obtained from the USPTO. Letters requesting forms should be addressed to "Box PCT." The "Request" form can now be presented as a computer printout prepared using the PCT-EASY software. The details of a computer generated Request form are provided in Administrative Instructions Section 102^{bis}.

1817 PCT Member States

The following is a list of PCT Member States:

State	Ratification, Accession or Declaration	Date of Ratification, Accession or Declaration	Date From Which State May Be Designated
(1)Central African Republic°	Accession	15 September 1971	01 June 1978
(2)Senegal°	Ratification	08 March 1972	01 June 1978
(3)Madagascar	Ratification	27 March 1972	01 June 1978
(4)Malawi	Accession	16 May 1972	01 June 1978
(5)Cameroon°	Accession	15 March 1973	01 June 1978
(6)Chad°	Accession	12 February 1974	01 June 1978
(7)Togo°	Ratification	28 January 1975	01 June 1978
(8)Gabon°	Accession	06 March 1975	01 June 1978
(9)United States of America	Ratification	26 November 1975	01 June 1978
(10)Germany°°	Ratification	19 July 1976	01 June 1978
(11)Congo°	Accession	08 August 1977	01 June 1978
(12)Switzerland°°	Ratification	14 September 1977	01 June 1978
(13)United Kingdom°°	Ratification	24 October 1977	01 June 1978
(14)France°°	Ratification	25 November 1977	01 June 1978
(15)Russian Federation	Ratification	29 December 1977	01 June 1978
(16)Brazil	Ratification	09 January 1978	01 June 1978
(17)Luxembourg°°	Ratification	31 January 1978	01 June 1978
(18)Sweden°°	Ratification	17 February 1978	01 June 1978
(19)Japan	Ratification	01 July 1978	01 October 1978
(20)Denmark°°	Ratification	01 September 1978	01 December 1978
(21)Austria°°	Ratification	23 January 1979	23 April 1979
(22)Monaco°°	Ratification	22 March 1979	22 June 1979
(23)Netherlands°°	Ratification	10 April 1979	10 July 1979
(24)Romania	Ratification	23 April 1979	23 July 1979
(25)Norway	Ratification	01 October 1979	01 January 1980
(26)Liechtenstein°°	Accession	19 December 1979	19 March 1980

State	Ratification, Accession or Declaration	Date of Ratification, Accession or Declaration	Date From Which State May Be Designated
(27)Australia	Accession	31 December 1979	31 March 1980
(28)Hungary	Ratification	27 March 1980	27 June 1980
(29)Democratic People's Republic of Korea (North Korea)	Accession	08 April 1980	08 July 1980
(30)Finland ^{oo}	Ratification	01 July 1980	01 October 1980
(31)Belgium ^{oo}	Ratification	14 September 1981	14 December 1981
(32)Sri Lanka	Accession	26 November 1981	26 February 1982
(33)Mauritania ^o	Accession	13 January 1983	13 April 1983
(34)Sudan	Accession	16 January 1984	16 April 1984
(35)Bulgaria	Accession	21 February 1984	21 May 1984
(36)Republic of Korea (South Korea)	Accession	10 May 1984	10 August 1984
(37)Mali ^o	Accession	19 July 1984	19 October 1984
(38)Barbados	Accession	12 December 1984	12 March 1985
(39)Italy ^{oo}	Ratification	28 December 1984	28 March 1985
(40)Benin ^o	Accession	26 November 1986	26 February 1987
(41)Burkina Faso ^o	Accession	21 December 1988	21 March 1989
(42)Spain ^{oo}	Accession	16 August 1989	16 November 1989
(43)Canada	Ratification	02 October 1989	02 January 1990
(44)Greece ^{oo}	Accession	09 July 1990	09 October 1990
(45)Poland	Accession	25 September 1990	25 December 1990
(46)Côte d'Ivoire ^o	Ratification	31 January 1991	30 April 1991
(47)Guinea ^o	Accession	27 February 1991	27 May 1991
(48)Mongolia	Accession	27 February 1991	27 May 1991
(49)Czech Republic	Declaration	18 December 1992	01 January 1993
(50)Ireland ^{oo}	Ratification	01 May 1992	01 August 1992
(51)Portugal ^{oo}	Accession	24 August 1992	24 November 1992
(52)New Zealand	Accession	01 September 1992	01 December 1992

State	Ratification, Accession or Declaration	Date of Ratification, Accession or Declaration	Date From Which State May Be Designated
(53)Ukraine	Declaration	21 September 1992	25 December 1991
(54)Viet Nam	Accession	10 December 1992	10 March 1993
(55)Slovakia	Declaration	30 December 1992	01 January 1993
(56)Niger ^o	Accession	21 December 1992	21 March 1993
(57)Kazakstan	Declaration	16 February 1993	25 December 1991
(58)Belarus	Declaration	14 April 1993	25 December 1991
(59)Latvia	Accession	07 June 1993	07 September 1993
(60)Uzbekistan	Declaration	18 August 1993	25 December 1991
(61)China	Accession	01 October 1993	01 January 1994
(62)Slovenia	Accession	01 December 1993	01 March 1994
(63)Trinidad and Tobago	Accession	10 December 1993	10 March 1994
(64)Georgia	Declaration	18 January 1994	25 December 1991
(65)Kyrgyzstan	Declaration	14 February 1994	25 December 1991
(66)Republic of Moldova	Declaration	14 February 1994	25 December 1991
(67)Tajikistan	Declaration	14 February 1994	25 December 1991
(68) Kenya	Accession	08 March 1994	08 June 1994
(69)Lithuania	Accession	05 April 1994	05 July 1994
(70)Armenia	Declaration	17 May 1994	25 December 1991
(71)Estonia	Accession	24 May 1994	24 August 1994
(72)Liberia	Accession	27 May 1994	27 August 1994
(73)Swaziland	Accession	20 June 1994	20 September 1994
(74)Mexico	Accession	01 October 1994	01 January 1995
(75)Uganda	Accession	09 November 1994	09 February 1995
(76)Singapore	Accession	23 November 1994	23 February 1995
(77)Iceland	Accession	23 December 1994	23 March 1995
(78)Turkmenistan	Declaration	01 March 1995	25 December 1991
(79)The former Yugoslov Republic of Macedonia	Accession	10 May 1995	10 August 1995

State	Ratification, Accession or Declaration	Date of Ratification, Accession or Declaration	Date From Which State May Be Designated
(80)Albania	Accession	04 July 1995	04 October 1995
(81)Lesotho	Accession	21 July 1995	21 October 1995
(82)Azerbaijan	Accession	25 September 1995	25 December 1995
(83)Turkey ^{oo}	Accession	01 October 1995	01 January 1996
(84)Israel	Ratification	01 March 1996	01 June 1996
(85)Cuba	Accession	16 April 1996	16 July 1996
(86)Saint Lucia	Accession	30 May 1996	30 August 1996
(87)Bosnia and Herzegovina	Accession	07 June 1996	07 September 1996
(88) Yugoslavia	Ratification	01 November 1996	01 February 1997
(89)Ghana	Accession	26 November 1996	16 February 1997
(90)Zimbabwe	Accession	11 March 1997	11 June 1997
(91)Sierra Leone	Accession	17 March 1997	17 June 1997
(92)Indonesia	Accession	05 June 1997	05 September 1997
(93)Gambia	Accession	09 September 1997	09 December 1997
(94)Guinea-Bissau ^o	Accession	12 September 1997	12 December 1997
(95) Cyprus ^{oo}	Accession	01 January 1998	01 April 1998
(96) Croatia	Accession	01 April 1998	01 July 1998
(97) Grenada	Accession	22 June 1998	22 September 1998
(98) India	Accession	07 September 1998	07 December 1998
(99) United Arab Emirates	Accession	10 December 1998	10 March 1999
(100) South Africa	Accession	16 December 1998	16 March 1999
(101) Costa Rica	Accession	03 May 1999	03 August 1999
(102) Dominica	Accession	07 May 1999	07 August 1999
(103) United Republic of Tanzania	Accession	14 June 1999	14 September 1999
(104) Morocco	Accession	08 July 1999	08 October 1999
(105) Algeria	Ratification	08 December 1999	08 March 2000
(106) Antigua and Barbuda	Accession	17 December 1999	17 March 2000

State	Ratification, Accession or Declaration	Date of Ratification, Accession or Declaration	Date From Which State May Be Designated
(107) Mozambique	Accession	18 February 2000	18 May 2000
(108) Belize	Accession	17 March 2000	17 June 2000
(109) Colombia	Accession	29 November 2000	28 February 2001
(110) Ecuador	Accession	07 February 2001	07 May 2001
(111) Equatorial Guinea ^o	Accession	17 April 2001	17 July 2001
(112) Phillipines	Ratification	17 May 2001	17 August 2001
(113) Oman	Accession	26 July 2001	26 October 2001
(114) Zambia	Accession	15 August 2001	15 November 2001
<p>^oMembers of Africa Intellectual Property Organization (OAPI) regional patent system. Only regional patent protection is available for OAPI member states. A designation of any state is an indication that all OAPI states have been designated. Note: only one designation fee is due regardless of the number of OAPI member states designated.</p>			
<p>^{oo}Members of European Patent Convention (EPC) regional patent system. Either national patents or European patents for member States are available through PCT, except for Belgium, France, Greece, Ireland, Italy, Monaco, and Netherlands, for which only European patents are available if the PCT is used. Note: only one PCT designation fee is due if European patent protection is sought for one, several, or all EPC member countries.</p>			
<p>The following states are members of African Regional Industrial Property Organization (ARIPO) regional patent system: (4) Malawi, (34) Sudan, (68) Kenya, (73) Swaziland, (75) Uganda, (81) Lesotho, (89) Ghana, (90) Zimbabwe, and (93) Gambia.</p>			
<p>The following states are members of the Eurasian Patent Organization (EAPO) regional patent system: (15) Russian Federation, (57) Kazakstan, (58) Belarus, (65) Kyrgyzstan, (66) Republic of Moldova, (67) Tajikistan, (70) Armenia, (78) Turkmenistan, and (82) Azerbaijan. Yugoslavia is comprised of the Republics of Serbia and Montenegro. The World Intellectual Property Organization has utilized the two-letter code "YU" to refer to the Yugoslavia becoming a party to the Patent Cooperation Treaty. The United States understands that the scope of the territory covered by the designation encompasses only the Republics of Serbia and Montenegro.</p>			

1817.01 Designation of States and Precautionary Designations

37 CFR 1.432. *Designation of States and payment of designation and confirmation fees.*

(a) The designation of States including an indication that applicant wishes to obtain a regional patent, where applicable, shall appear in the Request upon filing and must be indicated as set forth in PCT Rule 4.9 and section 115 of the Administrative

Instructions. Applicant must specify at least one national or regional designation on filing of the international application for a filing date to be granted.

(b) If the fees necessary to cover all the national and regional designations specified in the Request are not paid by the applicant within one year from the priority date or within one month from the date of receipt of the international application if that month expires after the expiration of one year from the priority date, applicant will be notified and given one month within which to pay the deficient designation fees plus a late payment fee. The late

payment fee shall be equal to the greater of fifty percent of the amount of the deficient fees up to a maximum amount equal to the basic fee, or an amount equal to the transmittal fee (PCT Rule 16^{bis}). The one-month time limit set in the notification of deficient designation fees may not be extended. Failure to timely pay at least one designation fee will result in the withdrawal of the international application.

(1) The one designation fee must be paid:

(i) Within one year from the priority date;

(ii) Within one month from the date of receipt of the international application if that month expires after the expiration of one year from the priority date; or

(iii) With the late payment fee defined in this paragraph within the time set in the notification of the deficient designation fees or in accordance with PCT Rule 16^{bis}.1(e).

(2) If after a notification of deficient designation fees the applicant makes timely payment, but the amount paid is not sufficient to cover the late payment fee and all designation fees, the Receiving Office will, after allocating payment for the basic, search, transmittal and late payment fees, allocate the amount paid in accordance with PCT Rule 16^{bis}.1(c) and withdraw the unpaid designations. The notification of deficient designation fees pursuant to this paragraph may be made simultaneously with any notification pursuant to § 1.431(c).

(c) The amount payable for the designation fee set forth in paragraph (b) is:

(1) The designation fee in effect on the filing date of the international application, if such fee is paid in full within one month from the date of receipt of the international application;

(2) The designation fee in effect on the date such fee is paid in full, if such fee is paid in full later than one month from the date of receipt of the international application but within one year from the priority date;

(3) The designation fee in effect on the date one year from the priority date, if the fee was due one year from the priority date, and such fee is paid in full later than one month from the date of receipt of the international application and later than one year from the priority date; or

(4) The designation fee in effect on the international filing date, if the fee was due one month from the international filing date and after one year from the priority date, and such fee is paid in full later than one month from the date of receipt of the international application and later than one year from the priority date.

(d) On filing the international application, in addition to specifying at least one national or regional designation under PCT Rule 4.9(a), applicant may also indicate under PCT Rule 4.9(b) that all other designations permitted under the Treaty are made.

(1) Indication of other designations permitted by the Treaty under PCT Rule 4.9(b) must be made in a statement on the Request that any designation made under this paragraph is subject to confirmation (PCT Rule 4.9(c)) not later than the expiration of 15 months from the priority date by:

(i) Filing a written notice with the United States Receiving Office specifying the national and/or regional designations being confirmed;

(ii) Paying the designation fee for each designation being confirmed; and

(iii) Paying the confirmation fee specified in § 1.445(a)(4).

(2) Unconfirmed designations will be considered withdrawn. If the amount submitted is not sufficient to cover the designation fee and the confirmation fee for each designation being confirmed, the Receiving Office will allocate the amount paid in accordance with any priority of designations specified by applicant. If applicant does not specify any priority of designations, the allocation of the amount paid will be made in accordance with PCT Rule 16^{bis}.1(c).

The designation of States is the indication, in Box No. V of the request (except in the last sub-box of that Box), of the specific regional patents, national patents, and/or other kinds of protection the applicant is seeking. Specific designations for the purpose of obtaining national and regional patents are effected by indicating each Contracting State or region concerned. On the printed form, this is accomplished by marking the appropriate check-boxes next to the names of the States or regions. For detailed instructions regarding "specific" designations, see the "Notes to the Request Form (PCT/RO/101)," available from WIPO's website at www.wipo.int/pct/en/index.html.

All designations must be made in the international application on filing; none may be added later. However, there is a safety net designed to protect applicants who make mistakes or omissions among the specific designations, by way of making a precautionary designation of all other States which have not been specifically designated in the Request whose designation would be permitted under the Treaty.

In addition to specific designations described above, the applicant may, under PCT Rule 4.9(b), indicate in the request that all designations which would be permitted under the PCT are also made, provided that at least one specific designation is made and that the request also contains a statement relating to the confirmation of any precautionary designations so made. That statement must declare that any such designation is subject to confirmation (as provided in Rule 4.9(c)), and that any such designation which is not so confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit.

Precautionary designations are effected in practice by including the necessary statement in the last sub-box of Box No. V of the request (the statement is set out in the printed request form). Since the precaution-

ary designations are designed particularly to enable applicants to correct omissions and mistakes in the original list of specific designations, it is strongly recommended that applicants make the precautionary designations indication (by leaving the pre-printed statement in the printed form, if that form is used) unless there is a particular reason for doing otherwise. The request form makes provision for the applicant to omit designations if that is desired. It should be noted that no fees are payable in respect of precautionary designations except where the applicant later decides to confirm them.

Precautionary designations will be regarded as withdrawn by the applicant unless they are confirmed, but the applicant is not obliged to confirm them. The precautionary designation procedure enables the applicant to make, in the request, all designations permitted by the PCT in addition to those made specifically. For this purpose, the request must also contain a statement that any precautionary designations so made are subject to confirmation as provided in Rule 4.9(c) and that any designation which is not so confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. Noting that the confirmation of designations is entirely at the applicant's discretion, no notification is sent to the applicant reminding him or her that the time limit for confirming precautionary designations is about to expire. Applicants are cautioned that in order for the confirmation of a designation of the U.S. to be valid, the inventor must have been named in the application papers as filed, 37 CFR 1.421(b).

APPLICANT FOR PURPOSES OF EACH DESIGNATION

Where there is but a single applicant, the right to file an international application and to designate contracting states or regions (EP or OAPI) exists if the applicant is a resident or national of a contracting state. The applicant can be an individual, corporate entity or other concern. If the United States is to be designated, it is particularly important to note that the applicant must also be the inventor.

In the case where there are several applicants who are different for different designated states, the right to file an international application and to designate contracting states or regions (EP or OAPI) exists if at

least one of them is a resident or national of a contracting state. If the United States is to be designated, it is important to note that the applicant must also be the inventor. If the inventor is not also the applicant, the designation of the United States is invalid.

1817.02 Continuation or Continuation-in-Part Indication in the Request

*PCT Rule 4.
The Request (Contents)*

4.14. Continuation or Continuation-in-Part

If the applicant wishes his international application to be treated, in any designated State, as an application for a continuation or a continuation-in-part of an earlier application, he shall so indicate in the request and shall identify the parent application involved.

Box No. V and the Supplemental Box of the Request form should be used where the applicant has an earlier application in a country designated in the international application and where special title or treatment of the international application is desired. For example, if the applicant has a pending United States application, the international application could contain additional subject matter and be treated as a continuation-in-part in the United States, if the United States is designated in the international application (PCT Rule 4.14). In this example, the entries to be placed in Box No. V would be as follows: "United States of America; continuation-in-part;" and in the Supplemental Box, an entry such as "Continuation of Box No. V, Parent application for U.S. designation: United States of America, 20 May 1981, 222,222" identifying the earlier pending application should be inserted.

1819 Earlier International or International-Type Search

*PCT Rule 4.
Request (Contents)*

4.11. Reference to Earlier Search

If an international or international-type search has been requested on an application under Article 15(5) or if the applicant wishes the International Searching Authority to base the interna-

tional search report wholly or in part on the results of a search, other than an international or international-type search, made by the national Office or intergovernmental organization which is the International Searching Authority competent for the international application; the request shall contain a reference to that fact. Such reference shall either identify the application (or its translation, as the case may be) in respect of which the earlier search was made by indicating country, date and number, or the said search by indicating, where applicable, date and number of the request for such search.

Certain International Searching Authorities refund part or all of the international search fee or reduce the amount of the international search fee where the international search can be based wholly or partly on an earlier search (whether an international, international-type, or other search) made by them. The United States provides for a reduced search fee where there is a corresponding prior U.S. national nonprovisional application.

Where the earlier search by the International Searching Authority was made in relation to a national, regional (for instance, European) or international application, that application must be identified in Box No. VII of the request by an indication of the country of filing (or the European Patent Office), and the number and filing date of that application. Note that, if the earlier search was made on the basis of a translation of that application into a language other than that in which the application was filed, that translation must also be identified in Box No. VII. Where the earlier search was made independently of a patent granting procedure (for instance, a standard search by the European Patent Office), a reference must be made to the date of the request for that search and the number given to the request by the International Searching Authority.

The United States Patent and Trademark Office performs an international-type search on all U.S. national applications filed on and after 01 June 1978. No specific request by the applicant is required and no number identifying the international-type search is assigned by the Office. All earlier U.S. applications referred to in Box No. VI and Box No. VII as well as all U.S. applications referred to in separate transmittal letters will be considered by the Office. See 37 CFR 1.104(a)(3) and (a)(4). The forms to be used for recording an international-type search can be obtained

from the International Application Processing Division.

Box No. VII should be used to identify related international applications whether or not priority of that application is claimed.

1820 Signature of Applicant

*PCT Rule 4.
Request (Contents)*

4.15. Signature

(a) Subject to paragraph (b), the request shall be signed by the applicant or, if there is more than one applicant, by all of them.

(b) Where two or more applicants file an international application which designates a State whose national law requires that national applications be filed by the inventor and where an applicant for that designated State who is an inventor refused to sign the request or could not be found or reached after diligent effort, the request need not be signed by that applicant if it is signed by at least one applicant and a statement is furnished explaining, to the satisfaction of the receiving Office, the lack of the signature concerned.

SIGNATURE OF APPLICANT OR AGENT

The international application must be signed in Box No. IX of the request by the applicant, or, where there are two or more applicants, by all of them. Subject to certain conditions, the request may be signed by the agent instead of the applicant(s). Pursuant to 37 CFR 1.4(d), the request filed may be either an original, or a copy thereof. Certain papers may be filed by facsimile transmission. See 37 CFR 1.6(d) and the discussion in MPEP § 1805.

The international application may be signed by an agent, but in that case the agent must be appointed as such by the applicant in a separate power of attorney signed by the applicant. If there are two or more applicants, the request may be signed by an agent on behalf of all or only some of them; in that case the agent must be appointed as such in one or more powers of attorney signed by the applicants on whose behalf the agent signs the application. Where a power of attorney appointing an agent who signs an international application is missing, the signature is treated as missing until the power of attorney is submitted.

The signature should be executed in black indelible ink. The name of each person signing the international

application should be indicated (preferably typewritten) next to the signature. Where a person signs on behalf of a legal entity (an organization such as a corporation, university, nonprofit organization, or governmental agency), his or her name and the capacity in which he or she signs should be indicated. Proof of the person's authority to sign on behalf of the legal entity will be required if that person does not possess apparent authority to sign on behalf of the legal entity. An officer (President, Vice-President, Secretary, Treasurer, Chief Executive Officer, Chief Operating Officer or Chief Financial Officer) of an organization is presumed to have authority to sign on behalf of that organization. The signature of the chairman of the board is also acceptable, but not the signature of an individual director. Variations of these titles (such as vice-president for sales, executive vice-president, assistant treasurer, vice-chairman of the board of directors) are acceptable. A person having a title (manager, director, administrator, general counsel) that does not clearly set forth that person as an officer of the organization is not presumed to be an officer or to have the authority to sign on behalf of the organization. An attorney does not generally have apparent authority to sign on behalf of an organization.

Proof that a person has the authority to sign on behalf of a legal entity may take the form of a copy of a resolution of the board of directors, a provision of the bylaws, or a copy of a paper properly delegating authority to that person to sign the international application on behalf of the legal entity.

It is also acceptable to have a person sign the international application on behalf of a legal entity if that person submits a statement that the person has the authority to sign the international application on behalf of the legal entity. This statement should be on a separate paper and must not appear on the Request (or Demand) form itself. The statement must include a clause such as "The undersigned (whose title is supplied below) is empowered to sign the Request on behalf of the applicant."

A power of attorney or authorization of agent from a person signing on behalf of a legal entity to a registered patent attorney or agent will be required if the attorney or agent signs the international application. Additional proof of authority may be required by the USPTO in any international application.

Where an applicant is temporarily unavailable, the international application can be filed without his or her signature. The lack of an applicant's signature or of a signed power of attorney is a correctable defect under PCT Article 14(1)(a)(i) and (b), and can be remedied by filing a copy of the request (or, where the request has been signed by an agent, of a power of attorney) duly signed by the applicant within the time limit fixed by the receiving Office for the correction of this defect.

APPLICANT INVENTOR UNAVAILABLE OR UNWILLING TO SIGN THE INTERNATIONAL APPLICATION OR OTHER DOCUMENTS

The PCT provides a special procedure, where two or more applicants file an international application designating the United States of America, which enables the international application to proceed if an applicant inventor for the United States of America refuses to sign or cannot be found or reached after diligent effort. This procedure makes an exception to the general rule that all applicants must sign the request (or a separate power of attorney appointing an agent who then signs the request). Its operation is limited to signature of the request by applicants for the purposes of the designation of a State whose national law requires that national applications be filed by the inventor (the United States of America is the only Contracting State to have such a requirement in its national law).

It is provided by PCT Rule 4.15(b) that, where an applicant inventor for the designation of the United States of America refused to sign the request or could not be found or reached after diligent effort, the request need not be signed by that applicant inventor if it is signed by at least one applicant and a statement is furnished explaining, to the satisfaction of the receiving Office, the lack of the signature concerned. If such a statement is furnished to the satisfaction of the receiving Office, the international application complies with the requirements of PCT Article 14(1)(a)(i) for the purposes of all designated States (including the United States of America) without adverse consequences in the international phase. However, additional proofs may be required by the United States Patent and Trademark Office after entry into the national phase if the required oath or declara-

tion by the inventor is not signed by all the applicant inventors.

The lack of a signature constitutes a defect under PCT Article 14(1)(a)(i), and the statement must thus be filed within the time limit set by the receiving Office for correction of such defects in accordance with PCT Article 14(1)(b) and PCT Rule 26.2. That time limit is fixed, in each case, in the invitation by the receiving Office to correct any defects under PCT Article 14(1)(a); the time limit must be reasonable under the circumstances, must be not less than 1 month from the date of the invitation, and may be extended by the receiving Office at any time before a decision is taken under PCT Rule 26.

If the request lacks the signature of an applicant inventor for the United States of America and a satisfactory statement cannot be furnished for the purposes of PCT Rule 4.15(b), the international application will be considered withdrawn. The Receiving Office will issue a declaration of withdrawal.

Provisions similar to PCT Rule 4.15(b) apply to excuse a lack of signature by an applicant inventor for the United States of America of certain other documents connected with the international application, provided that a similar statement is furnished explaining the lack of signature to the Office or Authority concerned. These documents are the Demand, any notice of a later election, and a notice of withdrawal of the international application, a designation, a priority claim, or an election. Note, however, that the signatures of all the applicants are not required for all of those documents for example, the Demand may be signed by the common representative (including an applicant who is considered to be the common representative).

PCT Rule 4.15(b) is implemented in the United States through 37 CFR 1.425, which provides:

37 CFR 1.425. Filing by other than inventor.

Where an international application which designates the United States of America is filed and where one or more inventors refuse to sign the Request for the international application or cannot be found or reached after diligent effort, the Request need not be signed by such inventor if it is signed by another applicant. Such international application must be accompanied by a statement explaining to the satisfaction of the Commissioner the lack of the signature concerned.

Where there are joint inventors other than the nonsigning applicant inventor, the available joint inven-

tors should sign the request form on behalf of themselves and the nonsigning inventor. Where a sole inventor or all of the joint inventors refuse to sign the request or can not be located, another applicant may make the application on behalf of the nonsigning inventor(s). In both instances, the application must be accompanied by a statement explaining the facts that the nonsigning inventor(s) either refuse to sign or cannot be located after diligent effort. Such proof should take the form of statements by persons with first hand knowledge of the pertinent facts.

APPLICANT INVENTOR DECEASED

37 CFR 1.422. When the inventor is dead.

In case of the death of the inventor, the legal representative (executor, administrator, etc.) of the deceased inventor may file an international application which designates the United States of America.

The Office no longer requires proof of authority of the legal representative of a deceased inventor. However, any person acting as a legal representative of a deceased inventor should ensure that he or she is properly acting in such a capacity. See MPEP § 409.01(b).

1821 The Request

A general overview of certain aspects of the request follows.

37 CFR 1.434. The request.

(a) The request shall be made on a standardized form (PCT Rules 3 and 4). Copies of printed Request forms are available from the Patent and Trademark Office. Letters requesting printed forms should be marked "Box PCT."

(b) The Check List portion of the Request form should indicate each document accompanying the international application on filing.

(c) All information, for example, addresses, names of States and dates, shall be indicated in the Request as required by PCT Rule 4 and Administrative Instructions 110 and 201.

(d) International applications which designate the United States of America:

(1) Shall include the name, address and signature of the inventor, except as provided by §§ 1.421(d), 1.422, 1.423 and 1.425;

(2) Shall include a reference to any copending national application or international application designating the United States of America, if the benefit of the filing date for the prior copending application is to be claimed; and

(3) May include in the Request a declaration of the inventors as provided for in PCT Rule 4.17(iv).

The request must either be made on a printed form to be filled in with the required indications or be presented as a computer printout complying with the Administrative Instructions. Any prospective applicant may obtain copies of the printed request form, free of charge, from the receiving Office with which he/she plans to file his/her international application, or from the International Bureau. Details of the requirements for the request if presented as a computer printout are set out in Administrative Instructions Section 102^{bis}.

As provided in Administrative Instructions Section 102^{bis}(c), reduced fees are payable in respect of an international application containing the request in PCT-EASY format filed, together with a PCT-EASY diskette, with a receiving Office which, under paragraph (a), accepts the filing of such international applications. The World Intellectual Property Organization (WIPO) maintains a PCT-EASY Help Desk for helping applicants with the PCT-EASY software.

The request contains a petition for the international application to be processed according to the PCT and must also contain certain indications. It must contain the title of the invention. It must identify the applicant (normally the inventor if the United States of America is designated), and the agent (if any), and must contain the designation of at least one Contracting State. The request must contain an indication of any wish of the applicants to obtain a European patent rather than, or in addition to, a national patent in respect of a designated State.

DATES

Each date appearing in the international application or in any correspondence must be indicated by the Arabic number of the day, the name of the month and the Arabic number of the year, in that order. In the request, after, below or above that indication, the date should be repeated in parentheses with a two-digit Arabic numeral each for the number of the day, the number of the month and the last two figures of the year, in that order and separated by periods, slashes or hyphens, for example, 10 June 1986 (10.06.86); (10/06/86) or (10-06-86).

Any prospective applicant may obtain English language Request forms free of charge from the United States Patent and Trademark Office, Box PCT, Washington, DC 20231. The request forms are also avail-

able from WIPO's web site. The Request may not contain any matter that is not specified in PCT Rules 4.1 to 4.17 or permitted under PCT Rule 4.18(a) by the Administrative Instructions. Any additional material will be deleted *ex officio* (Administrative Instructions Section 303).

SUPPLEMENTAL BOX

This box is used for any material which cannot be placed in one of the previous boxes because of space limitations. The supplemental information placed in this box should be clearly entitled with the Box number from which it is continued, e.g., "Continuation of Box No. IV."

FILE REFERENCE

The applicant or his/her agent may indicate a file reference in the box provided for the purpose on the first sheet of the request form, on each page of the other elements of the international application, on the first sheet of the demand form, and in any other correspondence relating to the international application. PCT Rule 11.6(f) indicates that the file reference may be included in the top margin of the sheets of the international application. As provided in Administrative Instructions Section 109, the file reference may be composed either of letters of the Latin alphabet or Arabic numerals, or both. It may not exceed 12 characters. The receiving Office, the International Bureau, the International Searching Authority and the International Preliminary Examining Authority (International Authorities) will use the file reference in correspondence with the applicant. According to the guidelines published by WIPO, and available from its web site, the applicant is to be notified if the file reference used by the applicant is corrected by one of the International Authorities. See *Helfgott & Karas P.C. v. Dickinson*, 209 F.3d 1328, 1336, 54 USPQ2d 1425, 1431 (Fed. Cir. 2000), where the Federal Circuit indicated that Section 10.1 of the PCT International Preliminary Examination Guidelines instructs the International Preliminary Examining Authority to send the applicant a copy of the corrected sheet of the Demand or a separate notification if the file reference specified by the applicant on the Demand is corrected by the International Preliminary Examining Authority.

TITLE OF INVENTION

The Request must contain the title of the invention; the title must be short (preferably 2 to 7 words) and precise (PCT Rule 4.3). The title in Box No. I of the Request is considered to be the title of the application. The title appearing on the first page of the description (PCT Rule 5.1(a)) and on the page containing the abstract should be consistent with the title indicated in Box No. I of the Request form.

A title should not be changed by the examiner merely because it contains words which are not considered descriptive of the invention. Words, for example, such as "improved" or "improvement of" are acceptable. If the title is otherwise not descriptive of the invention, a change to a more descriptive title should be made and the applicant informed thereof in the search report.

Where the title is missing or is inconsistent with the title in the description, the receiving Office invites the applicant to correct the missing or inconsistent title.

APPLICANT

Any resident or national of a Contracting State may file an international application. Where there are two or more applicants, at least one of them must be a national or a resident of a PCT Contracting State.

The question whether an applicant is a resident or national of a Contracting State depends on the national law of that State and is decided by the receiving Office. Also, possession of a real and effective industrial or commercial establishment in a Contracting State may be considered residence in that State, and a legal entity constituted according to the national law of a Contracting State is considered a national of that State.

The applicant must be identified by the indication of his/her name and address and by marking next to that indication, the check-box "This person is also inventor" in Box No. II, or "applicant and inventor" in Box No. III, where the applicant is also the inventor or one of the inventors, or the check-box "applicant only" where the applicant is not the inventor or one of the inventors. Where the applicant is a corporation or other legal entity (that is, not a natural person), the check-box "applicant only" must be marked. The applicant's nationality and residence must also be indicated.

NAMES

The names of a natural person must be indicated by the family name followed by the given name(s). Academic degrees or titles or other indications which are not part of the person's name must be omitted. The family name should preferably be written in capital letters.

The name of a legal entity must be indicated by its full official designation (preferably in capital letters).

ADDRESSES

Addresses must be indicated in such a way as to satisfy the requirements for prompt postal delivery at the address indicated and must consist of all the relevant administrative units up to and including the house number (if any). The address must also include the country.

1823 The Description

PCT Article 5.

The Description

The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

PCT Rule 5.

The Description

5.1. Manner of the Description

(a) The description shall first state the title of the invention as appearing in the request and shall:

(i) specify the technical field to which the invention relates;

(ii) indicate the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention, and, preferably, cite the documents reflecting such art;

(iii) disclose the invention, as claimed, in such terms that the technical problem (even if not expressly stated as such) and its solution can be understood, and state the advantageous effects, if any, of the invention with reference to the background art;

(iv) briefly describe the figures in the drawings, if any;

(v) set forth at least the best mode contemplated by the applicant for carrying out the invention claimed; this shall be done in terms of examples, where appropriate, and with reference to the drawings, if any; where the national law of the designated State does not require the description of the best mode but is satisfied with the description of any mode (whether it is the best contemplated or not), failure to describe the best mode contemplated shall have no effect in that State;

(vi) indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry and the way in which it can be made and used, or, if it can only be used, the way in which it can be used; the term *industry* is to be understood in its broadest sense as in the Paris Convention for the Protection of Industrial Property.

(b) The manner and order specified in paragraph (a) shall be followed except when, because of the nature of the invention, a different manner or a different order would result in a better understanding and a more economic presentation.

(c) Subject to the provisions of paragraph (b), each of the parts referred to in paragraph (a) shall preferably be preceded by an appropriate heading as suggested in the Administrative Instructions.

*PCT Administrative Instruction Section 204.
Headings of the Parts of the Description*

The headings of the parts of the description should be as follows:

- (i) for matter referred to in Rule 5.1(a)(i), "Technical Field";
- (ii) for matter referred to in Rule 5.1(a)(ii), "Background Art";
- (iii) for matter referred to in Rule 5.1(a)(iii), "Disclosure of Invention";
- (iv) for matter referred to in Rule 5.1(a)(iv), "Brief Description of Drawings";
- (v) for matter referred to in Rule 5.1(a)(v), "Best Mode for Carrying Out the Invention," or, where appropriate, "Mode(s) for Carrying Out the Invention";
- (vi) for matter referred to in Rule 5.1(a)(vi), "Industrial Applicability";
- (vii) for matter referred to in Rule 5.2(a), "Sequence Listing";
- (viii) for matter referred to in Rule 5.2(b), "Sequence Listing Free Text."

*PCT Administrative Instruction Section 209.
Indications as to Deposited Biological Material
on a Separate Sheet*

(a) To the extent that any indication with respect to deposited biological material is not contained in the description, it may be given on a separate sheet. Where any such indication is so given, it shall preferably be on Form PCT/RO/134 and, if furnished at the time of filing, the said Form shall, subject to paragraph (b), preferably be attached to the request and referred to in the check list referred to in Rule 3.3 (a)(ii).

(b) For the purposes of the Japanese Patent Office when Japan is designated, paragraph (a) applies only to the extent that the said Form or sheet is included as one of the sheets of the description of the international application at the time of filing.

37 CFR 1.435. The description.

(a) The application must meet the requirements as to the content and form of the description set forth in PCT Rules 5, 9, 10, and 11 and sections 204 and 208 of the Administrative Instructions.

(b) In international applications designating the United States the description must contain upon filing an indication of the best mode contemplated by the inventor for carrying out the claimed invention.

The description must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. It must start with the title of the invention as appearing in Box No. I of the request. PCT Rule 5 contains detailed requirements as to the manner and order of the description, which, generally, should be in six parts. Those parts should have the following headings: "Technical Field," "Background Art," "Disclosure of Invention," "Brief Description of Drawings," "Best Mode for Carrying Out the Invention" or, where appropriate, "Mode(s) for Carrying Out the Invention," "Industrial Applicability," "Sequence Listing," and "Sequence Listing Free Text," where applicable.

The details required for the disclosure of the invention so that it can be carried out by a person skilled in the art depend on the practice of the national Offices. It is therefore recommended that due account be taken of national practice in the United States of America when the description is drafted.

The need to amend the description during the national phase may thus be avoided.

This applies likewise to the need to indicate the "best mode for carrying out the invention." If at least one of the designated Offices requires the indication of the best mode (for instance, the United States Patent and Trademark Office), that best mode must be indicated in the description.

A description drafted with due regard to what is said in these provisions will be accepted by all the designated Offices. It might require more care than the drafting of a national patent application, but certainly much less effort than the drafting of multiple applications, which is necessary where the PCT route is not used for filing in several countries.

**1823.01 Reference to Deposited
Biological Material**

PCT Rule 13^{bis}.

Inventions Relating to Biological Material.

13^{bis}.1. Definition

For the purposes of this Rule, "reference to deposited biological material" means particulars given in an international applica-

tion with respect to the deposit of a biological material with a depositary institution or to the biological material so deposited.

13^{bis}.2. References (General)

Any reference to deposited biological material shall be made in accordance with this Rule and, if so made, shall be considered as satisfying the requirements of the national law of each designated State.

13^{bis}.3. References: Contents; Failure to Include Reference or Indication

(a) A reference to deposited biological material shall indicate:

- (i) the name and address of the depositary institution with which the deposit was made;
- (ii) the date of deposit of the biological material with that institution;
- (iii) the accession number given to the deposit by that institution; and
- (iv) any additional matter of which the International Bureau has been notified pursuant to Rule 13^{bis}.7(a)(i), provided that the requirement to indicate that matter was published in the Gazette in accordance with Rule 13^{bis}.7(c) at least two months before the filing of the international application.

(b) Failure to include a reference to deposited biological material or failure to include, in a reference to deposited biological material, an indication in accordance with paragraph (a), shall have no consequence in any designated State whose national law does not require such reference or such indication in a national application.

13^{bis}.4. References: Time Limit for Furnishing Indications

(a) Subject to paragraphs (b) and (c), if any of the indications referred to in Rule 13^{bis}.3(a) is not included in a reference to deposited biological material in the international application as filed but is furnished to the International Bureau:

- (i) within 16 months from the priority date, the indication shall be considered by any designated Office to have been furnished in time;
- (ii) after the expiration of 16 months from the priority date, the indication shall be considered by any designated Office to have been furnished on the last day of that time limit if it reaches the International Bureau before the technical preparations for international publication have been completed.

(b) If the national law applicable by a designated Office so requires in respect of national applications, that Office may require that any of the indications referred to in Rule 13^{bis}.3(a) be furnished earlier than 16 months from the priority date, provided that the International Bureau has been notified of such requirement pursuant to Rule 13^{bis}.7(a)(ii) and has published such requirement in the Gazette in accordance with Rule 13^{bis}.7(c) at least two months before the filing of the international application.

(c) Where the applicant makes a request for early publication under Article 21(2)(b), any designated Office may consider

any indication not furnished before the technical preparations for international publication have been completed as not having been furnished in time.

(d) The International Bureau shall notify the applicant of the date on which it received any indication furnished under paragraph (a), and

(i) if the indication was received before the technical preparations for international publication have been completed, indicate that date, and include the relevant data from the indication, in the pamphlet published under Rule 48;

(ii) if the indication was received after the technical preparations for international publication have been completed, notify that date and the relevant data from the indication to the designated Offices.

13^{bis}.5. References and Indications for the Purposes of One or More Designated States; Different Deposits for Different Designated States; Deposits with Depositary Institutions Other Than Those Notified

(a) A reference to deposited biological material shall be considered to be made for the purposes of all designated States, unless it is expressly made for the purposes of certain of the designated States only; the same applies to the indications included in the reference.

(b) References to different deposits of the biological material may be made for different designated States.

(c) Any designated Office may disregard a deposit made with a depositary institution other than one notified by it under Rule 13^{bis}.7(b).

13^{bis}.6. Furnishing of Samples

Pursuant to Articles 23 and 40, no furnishing of samples of the deposited biological material to which a reference is made in an international application shall, except with the authorization of the applicant, take place before the expiration of the applicable time limits after which national processing may start under the said Articles. However, where the applicant performs the acts referred to in Articles 22 or 39 after international publication but before the expiration of the said time limits, the furnishing of samples of the deposited biological material may take place, once the said acts have been performed. Notwithstanding the previous provision, the furnishing of samples of the deposited biological material may take place under the national law applicable by any designated Office as soon as, under that law, the international publication has the effects of the compulsory national publication of an unexamined national application.

13^{bis}.7. National Requirements: Notification and Publication

(a) Any national Office may notify the International Bureau of any requirement of the national law:

(i) that any matter specified in the notification, in addition to those referred to in Rule 13^{bis}.3(a)(i), (ii) and (iii), is required to be included in a reference to deposited biological material in a national application;

(ii) that one or more of the indications referred to in Rule 13^{bis}.3(a) are required to be included in a national application as filed or are required to be furnished at a time specified in the notification which is earlier than 16 months after the priority date.

(b) Each national Office shall notify the International Bureau of the depositary institutions with which the national law permits deposits of biological materials to be made for the purposes of patent procedure before that Office or, if the national law does not provide for or permit such deposits, of that fact.

(c) The International Bureau shall promptly publish in the Gazette requirements notified to it under paragraph (a) and information notified to it under paragraph (b).

*PCT Administrative Instruction Section 209.
Indications as to Deposited Biological Material
on a Separate Sheet*

(a) To the extent that any indication with respect to deposited biological material is not contained in the description, it may be given on a separate sheet. Where any such indication is so given, it shall preferably be on Form PCT/RO/134 and, if furnished at the time of filing, the said Form shall, subject to paragraph (b), preferably be attached to the request and referred to in the check list referred to in Rule 3.3 (a)(ii).

(b) For the purposes of the Japanese Patent Office when Japan is designated, paragraph (a) applies only to the extent that the said Form or sheet is included as one of the sheets of the description of the international application at the time of filing.

REFERENCES TO DEPOSITED BIOLOGICAL MATERIAL IN THE CASE OF MICROBIOLOGICAL INVENTIONS

The PCT does not require the inclusion of a reference to a biological material and/or to its deposit with a depositary institution in an international application; it merely prescribes the contents of any "reference to deposited biological material" (defined as "particulars given ... with respect to the deposit of biological material ... or to the biological material so deposited") which is included in an international application, and when such a reference must be furnished. It follows that the applicant may see a need to make such a reference only when it is required for the purpose of disclosing the invention claimed in the international application in a manner sufficient for the invention to be carried out by a person skilled in the art that is, when the law of at least one of the designated States provides for the making, for this purpose, of a reference to a deposited biological material if the invention involves the use of a biological material that is not available to the public. Any reference to a deposited biological material furnished separately from the

description will be included in the pamphlet containing the published international application.

A reference to a deposited biological material made in accordance with the requirements of the PCT must be regarded by each of the designated Offices as satisfying the requirements of the national law applicable in that Office with regard to the contents of such references and the time for furnishing them.

A reference may be made for the purposes of all designated States or for one or only some of the designated States. A reference is considered to be made for the purpose of all designated States unless it is expressly made for certain designated States only. References to different deposits may be made for the purposes of different designated States.

There are two kinds of indication which may have to be given with regard to the deposit of the biological material, namely:

(A) indications specified in the PCT Regulations themselves; and

(B) additional indications by the national (or regional) Office of (or acting for) a State designated in the international application and which have been published in the PCT Gazette; these additional indications may relate not only to the deposit of the biological material but also to the biological material itself.

The indications in the first category are:

- (1) the name and address of the depositary institution with which the deposit was made;
- (2) the date of the deposit with that institution; and
- (3) the accession number given to the deposit by that institution.

U.S. requirements include the name and address of the depositary institution at the time of filing, the date of the deposit or a statement that the deposit was made on or before the priority date of the international application and, to the extent possible, a taxonomic description of the biological material. See Annex L of the PCT Applicant's Guide.

The national laws of some of the national (or regional) Offices require that, besides indications concerning the deposit of a biological material, an indication be given concerning the biological material itself; such as, for example, a short description of its characteristics, at least to the extent that this information is available to the applicant. These requirements must be met in the case of international applications for which

any such Office is a designated Office, provided that the requirements have been published in the PCT Gazette. Annex L of the PCT Applicant's Guide indicates, for each of the national (or regional) Offices, the requirements (if any) of this kind which have been published.

If any indication is not included in a reference to a deposited biological material contained in the international application as filed, it may be furnished to the International Bureau within 16 months after the priority date unless the International Bureau has been notified (and, at least 2 months prior to the filing of the international application, it has published in the PCT Gazette) that the national law requires the indication to be furnished earlier. However, if the applicant makes a request for early publication, all indications should be furnished by the time the request is made, since any designated Office may regard any indication not furnished when the request is made as not having been furnished in time.

No check is made in the international phase to determine whether a reference has been furnished within the prescribed time limit. However, the International Bureau notifies the designated Offices of the date(s) on which indications, not included in the international application as filed, were furnished to it. Those dates are also mentioned in the pamphlet containing the published international application. Failure to include a reference to a deposited biological material (or any indication required in such a reference) in the international application as filed, or failure to furnish it (or the indication) within the prescribed time limit, has no consequence if the national law does not require the reference (or indication) to be furnished in a national application. Where there is a consequence, it is the same as that which applies under the national law.

To the extent that indications relating to the deposit of a biological material are not given in the description, because they are furnished later, they may be given in the "optional sheet" provided for that purpose. If the sheet is submitted when the international application is filed, a reference to it should be made in the check list contained on the last sheet of the request form. Should Japan be designated, such a sheet must, if used, be included as one of the sheets of the description at the time of filing; otherwise the indications given in it will not be taken into account by the Japa-

nese Patent Office in the national phase. If the sheet is furnished to the International Bureau later, it must be enclosed with a letter.

Each national (or regional) Office whose national law provides for deposits of biological material for the purposes of patent procedure notifies the International Bureau of the depositary institutions with which the national law permits such deposits to be made. Information on the institutions notified by each of those Offices is published by the International Bureau in the PCT Gazette.

A reference to a deposit cannot be disregarded by a designated Office for reasons pertaining to the institution with which the biological material was deposited if the deposit referred to is one made with a depositary institution notified by that Office. Thus, by consulting the PCT Gazette or Annex L of the PCT Applicant's Guide, the applicant can be sure that he has deposited the biological material with an institution which will be accepted by the designated Office.

International Searching Authorities and International Preliminary Examining Authorities are not expected to request access to deposited biological material. However, in order to retain the possibility of access to a deposited biological material referred to in an international application which is being searched or examined by such an Authority, the PCT provides that the Authorities may, if they fulfill certain conditions, ask for samples. Thus, an Authority may only ask for samples if it has notified the International Bureau (in a general notification) that it may require samples and the International Bureau has published the notification in the PCT Gazette. The only Authority which has made such a notification (and thus the only Authority which may request samples) is the Japanese Patent Office. If a sample is asked for, the request is directed to the applicant, who then becomes responsible for making the necessary arrangements for the sample to be provided.

The furnishing of samples of a deposit of a biological material to third persons is governed by the national laws applicable in the designated Offices. PCT Rule 13^{bis}.6(b), however, provides for the delaying of any furnishing of samples under the national law applicable in each of the designated (or elected) Offices until the start of the national phase, subject to the ending of this "delaying effect" brought about by the occurrence of either of the following two events:

(A) the applicant has, after international publication of the international application, taken the steps necessary to enter the national phase before the designated Office.

(B) international publication of the international application has been effected, and that publication has the same effects, under the national law applicable in the designated Office, as the compulsory national publication of an unexamined national application (in other words, the international application has qualified for the grant of "provisional protection").

1823.02 Nucleotide and/or Amino Acid Sequence Listings

PCT Rule 5. The Description

5.2. Nucleotide and/or Amino Acid Sequence Disclosure

(a) Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences, the description shall contain a sequence listing complying with the standard prescribed by the Administrative Instructions and presented as a separate part of the description in accordance with that standard.

(b) Where the sequence listing part of the description contains any free text as defined in the standard provided for in the Administrative Instructions, that free text shall also appear in the main part of the description in the language thereof.

PCT Rule 13^{ter}. Nucleotide and/or Amino Acid Sequence Listings

13^{ter}.1. Sequence Listing for International Authorities

(a) Where the International Searching Authority finds that the international application contains disclosure of one or more nucleotide and/or amino acid sequences but:

(i) the international application does not contain a sequence listing complying with the standard provided for in the Administrative Instructions, that Authority may invite the applicant to furnish to it, within a time limit fixed in the invitation, a sequence listing complying with that standard;

(ii) the applicant has not already furnished a sequence listing in computer readable form complying with the standard provided for in the Administrative Instructions, that Authority may invite the applicant to furnish to it, within a time limit fixed in the invitation, a sequence listing in such a form complying with that standard.

(b) *[Deleted]*

(c) If the applicant does not comply with an invitation under paragraph (a) within the time limit fixed in the invitation, the International Searching Authority shall not be required to search

the international application to the extent that such noncompliance has the result that a meaningful search cannot be carried out.

(d) Where the International Searching Authority finds that the description does not comply with Rule 5.2(b), it shall invite the applicant to file the required correction. Rule 26.4 shall apply *mutatis mutandis* to any correction offered by the applicant. The International Searching Authority shall transmit the correction to the receiving Office and to the International Bureau.

(e) Paragraphs (a) and (c) shall apply *mutatis mutandis* to the procedure before the International Preliminary Examining Authority.

(f) Any sequence listing not contained in the international application as filed shall not, subject to Article 34, form part of the international application.

13^{ter}.2. Sequence Listing for Designated Office

Once the processing of the international application has started before a designated Office, Rule 13^{ter}.1(a) shall apply *mutatis mutandis* to the procedure before that Office. No designated Office shall require the applicant to furnish to it a sequence listing other than a sequence listing complying with the standard provided for in the Administrative Instructions.

PCT Administrative Instruction Section 208. Sequence Listings

Any nucleotide and/or amino acid sequence listing ("sequence listing") filed as part of the international application, or furnished together with the international application or subsequently (whether in printed form or computer readable form), shall comply with Annex C.

I. REQUIREMENTS FOR SEQUENCE LISTINGS

Where an international application discloses one or more nucleotide and/or amino acid sequences, the description must contain a sequence listing complying with the standard specified in the Administrative Instructions. The standard is set forth in detail in Annex C - Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in International Patent Applications Under the PCT. The standard allows the applicant to draw up a single sequence listing which is acceptable to all receiving Offices, International Searching and Preliminary Examining Authorities for the purposes of the international phase, and to all designated and elected Offices for the purposes of the national phase. The International Searching Authority and the International Preliminary Examining Authority may, in some cases, invite the applicant to furnish a listing complying with that standard. The applicant may also be invited to furnish a listing in a computer readable form provided for in the

PCT Administrative Instructions. It is advisable for the applicant to submit a listing of the sequence in computer readable form, if such a listing is required by the competent International Searching Authority or International Preliminary Examining Authority, together with the international application rather than to wait for an invitation by the International Searching Authority or International Preliminary Examining Authority.

The computer readable form is not mandatory in international applications to be searched by the United States International Searching Authority or examined by the United States International Preliminary Examining Authority. However, if a computer readable form of a sequence listing is not provided, a search or examination will be performed only to the extent possible in the absence of the computer readable form. The U.S. sequence rules (37 CFR 1.821 - 1.825) and the PCT sequence requirements are substantively consistent. In this regard, full compliance with the requirements of the U.S. rules will ensure compliance with the applicable PCT requirements. The European Patent Office (EPO), since January 1, 1993, requires nucleotide and amino acid sequences to be in computer readable form. Applicants should be cognizant of this requirement and ensure compliance with EPO requirements if the EPO is to be the search or examination authority. See also MPEP § 1848. For a detailed discussion of the U.S. sequence rules, see MPEP § 2420 - § 2421.04.

II. QUALIFYING FOR REDUCED BASIC FEE BY FILING SEQUENCE LISTING ON COMPACT DISC RATHER THAN ON PAPER

PCT Administrative Instruction Section 801.

Filing of International Applications Containing Sequence Listings

(a) Pursuant to Rules 89^{bis} and 89^{ter}, where an international application contains disclosure of one or more nucleotide and/or amino acid sequence listings ("sequence listings"), the receiving Office may, if it is prepared to do so, accept that the sequence listing part of the description, as referred to in Rule 5.2(a), be filed, at the option of the applicant:

- (i) only on an electronic medium in the computer readable form referred to in Annex C; or
- (ii) both on an electronic medium in that computer readable form and on paper in the written form referred to in Annex C; provided that the other elements of the international application

are filed as otherwise provided for under the Regulations and these Instructions.

(b) Any receiving Office which is prepared to accept the filing in computer readable form of the sequence listing part of international applications under paragraph (a) shall notify the International Bureau accordingly. The notification shall specify the electronic media on which the receiving Office will accept such filings. The International Bureau shall promptly publish any such information in the Gazette.

(c) A receiving Office which has not made a notification under paragraph (b) may nevertheless decide in a particular case to accept an international application the sequence listing part of which is filed with it under paragraph (a).

(d) Where the sequence listing part is filed in computer readable form under paragraph (a) but not on an electronic medium specified by the receiving Office under paragraph (b), that Office shall, under Article 14(1)(a)(v), invite the applicant to furnish to it a replacement sequence listing part on an electronic medium specified under paragraph (b).

(e) Where an international application containing a sequence listing part in computer readable form is filed under paragraph (a) with a receiving Office which is not prepared, under paragraph (b) or (c), to accept such filings, Section 333(b) and (c) shall apply.

New Part 8 of the Administration Instructions became effective January 11, 2001. Under Administrative Instructions Section 801(a), applicants may file the nucleotide and/or amino acid sequence listing part of the description of an international application on an electronic medium in computer readable form with certain receiving Offices. At the present time, the United States Receiving Office (RO/US) has not notified the International Bureau (IB) under Administrative Instructions Section 801(b) that it will be generally accepting the filing of international applications under Administrative Instructions Section 801(a). The RO/US will, however, accept such applications in a particular case pursuant to Administrative Instructions Section 801(c), provided that applicant follows the Guidelines set forth below in subsection II. A.

PCT Administrative Instruction Section 803.

Calculation of Basic Fee for International Applications Containing Sequence Listings

Where the sequence listing part of an international application is filed in electronic form under Section 801(a), the basic fee payable in respect of that application shall comprise the following two components:

- (i) a basic component calculated as provided in the Schedule of Fees in respect of all pages filed on paper (that is, all pages of the request, description (excluding the sequence listing part if also filed on paper), claims, abstract and drawings), and

(ii) an additional component, in respect of the sequence listing part, equal to 400 times the fee per sheet as referred to in item 1(b) of the Schedule of Fees, regardless of the actual length of the sequence listing part filed in computer readable form and regardless of the fact that the sequence listing part may have been filed both in written form and in computer readable form.

Applicants will usually achieve a significant fee savings by filing international applications with sequence listings over four hundred (400) pages long under Administrative Instructions Section 801(a). The potentially reduced basic fee described in Administrative Instructions Section 803 is available to applications filed pursuant to the Guidelines below. Applicants who do not wish to file under Administrative Instructions Section 801(a) may submit the sequence listing part under conventional filing procedures but will not be eligible for the potentially reduced basic fee described in Administrative Instructions Section 803.

When filing an international application under Administrative Instructions Section 801(a), applicant should not submit a paper copy of the Sequence Listing part. To address potential concerns regarding electronic media reliability, the RO/US will test the readability of sequence listing parts submitted on compact disc media and notify applicant of the results. As detailed in the Guidelines below, applicant may elect to have the readability testing and notification performed on an expedited basis.

A. *Guidelines on Qualifying for Reduced Basic Fee Under PCT Administrative Instructions Section 803*

1. What to Submit

The applicant is required to submit a complete copy of the international application, wherein the sequence listing part of the application is submitted on electronic media rather than on paper. The application is to be accompanied by a transmittal letter entitled "Compact Disc Transmittal Form For Submission Of Sequence Listing To The United States Receiving Office Under PCT Administrative Instructions - Part 8."

(a) Complete International Application with Sequence Listing Part on Electronic Media

Applicant shall submit a paper copy of the complete international application, with the exception that

the sequence listing part is provided on electronic media rather than on paper. Four (4) copies of the sequence listing part are to be included with the application, each copy on an electronic medium or set of electronic media if additional capacity is needed. One copy, called the "computer readable form" (CRF) copy required by the Administrative Instructions (see Annex C of the Administrative Instructions, paragraphs 39-46), may be submitted on any acceptable medium under 37 CFR 1.824(c), although compact disc (CD) media is preferred. The remaining three copies must be submitted only on one of the following types of CD media:

(1) CD-R

Type: 120mm Compact Disc Recordable

Specification: ISO 9660, 650MB; or

(2) CD-ROM

Type: ISO/IEC 10149:1995, 120mm Compact Disc Read Only Memory

Specification: ISO 9660, 650MB

Each electronic medium shall be enclosed in a hard protective case within a padded envelope, and the four (4) copies shall be labeled as follows:

- (1) "COPY 1 - SEQUENCE LISTING PART;"
- (2) "COPY 2 - SEQUENCE LISTING PART;"
- (3) "COPY 3 - SEQUENCE LISTING PART;"

and

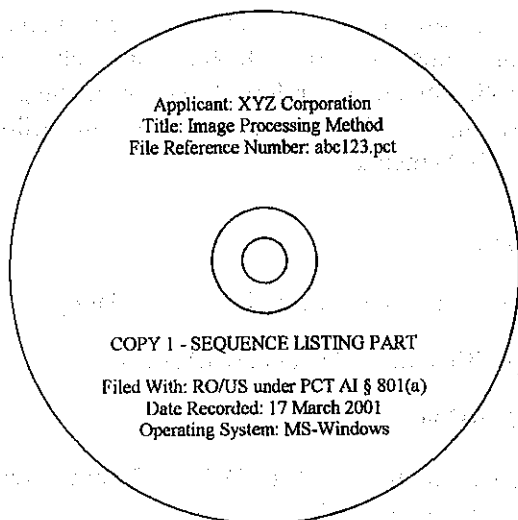
- (4) "CRF"

Additionally, the labeling shall contain the following information:

- (1) Name of Applicant
- (2) Title of Invention
- (3) Applicant's or Agent's File Reference Number
- (4) Date of Recording
- (5) Computer Operating System Used
- (6) Name of the Competent Authority (i.e. the RO/US)
- (7) Indication that the Sequence Listing part is being filed under Administrative Instructions Section 801(a)

(8) If the Sequence Listing file consumes more than one CD, an indication such as "DISK 1/3", "DISK 2/3", and "DISK 3/3"

An example of a properly labeled electronic medium appears below.



The electronic medium itself must be neatly labeled with the required information. Labeling of the protective case is recommended, but not required. Sequence listings submitted for correction, rectification, or amendment must satisfy the additional labeling requirements of Administrative Instructions Section 802(b).

The CDs shall contain only the sequence listing part. No tables, programs, or explanatory files shall appear on the same CD as the sequence listing. The sequence listing file must be in compliance with the American Standard Code for Information Interchange (ASCII) and formatted in accordance with Administrative Instructions Annex C, paragraph 41. No file compression, copy protection, or encryption techniques are permitted.

(b) Compact Disc Transmittal Form for Submission of Sequence Listing to the United States Receiving Office Under PCT Administrative Instructions - Part 8.

If applicant desires for an application to be accepted pursuant to Administrative Instructions Section 801(c), the application must be submitted with a document entitled "Compact Disc Transmittal Form For Submission Of Sequence Listing To The United States Receiving Office Under PCT Administrative Instructions - Part 8." This document must be separate and apart from any other transmittal letter or form, and include the following information:

- (1) Name of Applicant
- (2) Applicant's or Agent's File Reference Number
- (3) Title of Invention
- (4) Name of Sequence Listing File (as per CD directory)
- (5) Size of Sequence Listing File (in bytes or kilobytes as per CD directory)
- (6) Date of Sequence Listing File (as per CD directory)
- (7) Statement that the four (4) submitted copies of the Sequence Listing are identical
- (8) Contact information for CD readability testing
 - (a) Name of Contact
 - (b) Telephone Number
 - (c) Facsimile Number
- (9) Signature of Applicant, Agent, or Common Representative

The requirement for a separate transmittal form cannot be satisfied by incorporating the above information into any other document. A sample copy of a "Compact Disc Transmittal Form For Submission Of Sequence Listing To The United States Receiving Office Under PCT Administrative Instructions - Part 8" is reproduced on the following page.

COMPACT DISC TRANSMITTAL FORM FOR SUBMISSION OF SEQUENCE LISTING TO THE UNITED STATES RECEIVING OFFICE UNDER PCT ADMINISTRATIVE INSTRUCTIONS - PART 8	<i>For Receiving Office Use Only</i>	
<i>For Receiving Office Use Only</i>	International Application Number <i>For Receiving Office Use Only</i>	
Date of transmission back to applicant	Date of receipt in RO/US	CDs received

INTERNATIONAL APPLICATION DATA
Name of Applicant: _____
Applicant's or Agent's File Reference Number: _____
Title of Invention: _____

APPLICANT'S CONTACT INFORMATION	SEQUENCE LISTING FILE ON CD
Name of Contact: _____	Name of File (as per CD directory): _____
Telephone Number: _____	Size of File (in bytes or kilobytes): _____
Facsimile Number: _____	Date of File (as per CD directory): _____

STATEMENT
I hereby certify that the four copies of the Sequence Listing submitted herewith are identical.
Signature of Applicant, Agent, or Common Representative: _____
Name of Person Signing: _____

<i>For Receiving Office Use Only</i>	
ACKNOWLEDGEMENT OF RECEIPT OF FILES ON COMPACT DISC	
The Sequence Listing file identified on this Compact Disc Transmittal Form was received by the RO/US and tested on a USPTO computer with the following results.	
COPY 1:	<input type="checkbox"/> READABLE <input type="checkbox"/> UNREADABLE <input type="checkbox"/> MISSING
COPY 2:	<input type="checkbox"/> READABLE <input type="checkbox"/> UNREADABLE <input type="checkbox"/> MISSING
COPY 3:	<input type="checkbox"/> READABLE <input type="checkbox"/> UNREADABLE <input type="checkbox"/> MISSING
CRF:	<input type="checkbox"/> READABLE <input type="checkbox"/> UNREADABLE <input type="checkbox"/> MISSING
_____	_____
(name of tester)	(date)
If one or more copies of the Sequence Listing file is indicated as "UNREADABLE" or "MISSING" above:	
<input type="checkbox"/> Applicant must file _____ replacement copies along with a statement that the replacement copies contain no new matter within _____ days from the transmission date of this Acknowledgement.	
<input type="checkbox"/> The RO/US will produce the necessary replacement copies. Applicant must pay a service charge of \$ _____ within _____ month(s) from the transmission date of this Acknowledgement.	

2. Where to Submit

The manner of submission of the application depends on whether or not the applicant wishes to have readability testing of the CD expedited. The RO/US will test the readability of the sequence listing part submitted on CD media irrespective of whether or not expedited service (see subsection (b) below) is requested. The test will verify the "readability" of the data on the CD, but it will not verify compliance with other requirements of the international application, which will be evaluated by the RO/US in due course. After the readability test has been performed, the RO/US will transmit an "Acknowledgement of Receipt of Files on Compact Disc" to applicant via facsimile.

(a) Submission Without Request for Expedited Readability Testing and Notification

When expedited readability testing and notification is not being requested (see subsection (b) below), the entire international application, including the items set forth in subsection II.A.1.(a) and (b) above, should be mailed to:

Assistant Commissioner of Patents

Box PCT

Washington, DC 20231

(b) Requesting Expedited Readability Testing and Notification

To encourage use of CD media for submission, the RO/US will expedite the testing and notification procedure upon request by the applicant. Under the expedited procedure, the RO/US will perform a readability test and transmit the "Acknowledgement of Receipt of Files on Compact Disc" to applicant via facsimile within 3 working days. There is no charge for the expedited service.

To request the expedited service, applicant must schedule hand delivery of the entire international application, including the CDs and transmittal letter set forth in subsection II.A.1.(a) and (b) above, by contacting the PCT Operations Receptionist on (703) 305-3165. Once applicant has scheduled delivery with the PCT Operations Receptionist, the entire international application, including the items set forth in sub-

section II.A.1.(a) and (b) above, are to be hand delivered to:

PCT Operations Receptionist

Crystal Plaza 2 - 8th Floor

2011 South Clark Place

Arlington, VA 22202

1824 The Claims

PCT Article 6.

The Claims

The claim or claims shall define the matter for which protection is sought. Claims shall be clear and concise. They shall be fully supported by the description.

PCT Rule 6.

The Claims

6.1. Number and Numbering of Claims

(a) The number of the claims shall be reasonable in consideration of the nature of the invention claimed.

(b) If there are several claims, they shall be numbered consecutively in Arabic numerals.

(c) The method of numbering in the case of the amendment of claims shall be governed by the Administrative Instructions.

6.2. References to Other Parts of the International Application

(a) Claims shall not, except where absolutely necessary, rely, in respect of the technical features of the invention, on references to the description or drawings. In particular, they shall not rely on such references as: "as described in part ... of the description," or "as illustrated in figure ... of the drawings."

(b) Where the international application contains drawings, the technical features mentioned in the claims shall preferably be followed by the reference signs relating to such features. When used, the reference signs shall preferably be placed between parentheses. If inclusion of reference signs does not particularly facilitate quicker understanding of a claim, it should not be made. Reference signs may be removed by a designated Office for the purposes of publication by such Office.

6.3. Manner of Claiming

(a) The definition of the matter for which protection is sought shall be in terms of the technical features of the invention.

(b) Whenever appropriate, claims shall contain:

(i) a statement indicating those technical features of the invention which are necessary for the definition of the claimed subject matter but which, in combination, are part of the prior art,

(ii) a characterizing portion - preceded by the words "characterized in that," "characterized by," "wherein the improvement comprises," or any other words to the same effect - stating concisely the technical features which, in combination with the features stated under (i), it is desired to protect.

(c) Where the national law of the designated State does not require the manner of claiming provided for in paragraph (b), failure to use that manner of claiming shall have no effect in that State provided the manner of claiming actually used satisfies the national law of that State.

6.4. Dependent Claims

(a) Any claim which includes all the features of one or more other claims (claim in dependent form, hereinafter referred to as "dependent claim") shall do so by a reference, if possible at the beginning, to the other claim or claims and shall then state the additional features claimed. Any dependent claim which refers to more than one other claim ("multiple dependent claim") shall refer to such claims in the alternative only. Multiple dependent claims shall not serve as a basis for any other multiple dependent claim. Where the national law of the national Office acting as International Searching Authority does not allow multiple dependent claims to be drafted in a manner different from that provided for in the preceding two sentences, failure to use that manner of claiming may result in an indication under Article 17(2)(b) in the international search report. Failure to use the said manner of claiming shall have no effect in a designated State if the manner of claiming actually used satisfies the national law of that State.

(b) Any dependent claim shall be construed as including all the limitations contained in the claim to which it refers or, if the dependent claim is a multiple dependent claim, all the limitations contained in the particular claim in relation to which it is considered.

(c) All dependent claims referring back to a single previous claim, and all dependent claims referring back to several previous claims, shall be grouped together to the extent and in the most practical way possible.

6.5. Utility Models

Any designated State in which the grant of a utility model is sought on the basis of an international application may, instead of Rules 6.1 to 6.4, apply in respect of the matters regulated in those Rules the provisions of its national law concerning utility models once the processing of the international application has started in that State, provided that the applicant shall be allowed at least two months from the expiration of the time limit applicable under Article 22 to adapt his application to the requirements of the said provisions of the national law.

PCT Administrative Instruction Section 205.

Numbering and Identification of Claims Upon Amendment

(a) Amendments to the claims under Article 19 or Article 34(2)(b) may be made either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed. All the claims appearing on a replacement sheet shall be numbered in Arabic numerals. Where a

claim is cancelled, no renumbering of the other claims shall be required. In all cases where claims are renumbered, they shall be renumbered consecutively.

(b) The applicant shall, in the letter referred to in the second and third sentences of Rule 46.5(a) or in the second and fourth sentences of Rule 66.8(a), indicate the differences between the claims as filed and the claims as amended. He shall, in particular, indicate in the said letter, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether:

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

37 CFR 1.436. The claims.

The requirements as to the content and format of claims are set forth in PCT Art. 6 and PCT Rules 6, 9, 10 and 11 and shall be adhered to. The number of the claims shall be reasonable, considering the nature of the invention claimed.

The claim or claims must "define the matter for which protection is sought." Claims must be clear and concise. They must be fully supported by the description. PCT Rule 6 contains detailed requirements as to the number and numbering of claims, the extent to which any claim may refer to other parts of the international application, the manner of claiming, and dependent claims. As to the manner of claiming, the claims must, whenever appropriate, be in two distinct parts; namely, the statement of the prior art and the statement of the features for which protection is sought ("the characterizing portion").

The physical requirements for the claims are the same as those for the description. Note that the claims must commence on a new sheet.

The procedure for rectification of obvious errors is explained in MPEP § 1836. The omission of an entire sheet of the claims cannot be rectified without affecting the international filing date. It is recommended that a request for rectification of obvious errors in the claims be made only if the error is liable to affect the international search; otherwise, the rectification should be made by amending the claims.

The claims can be amended during the international phase under PCT Article 19 on receipt of the international search report, during international preliminary examination if the applicant has filed a Demand, and during the national phase.

Multiple dependent claims are permitted in international applications before the United States Patent and Trademark Office as an International Searching and International Preliminary Examining Authority or as a Designated or Elected Office, if they are in the alternative only and do not serve as a basis for any other multiple dependent claim (PCT Rule 6.4(a), 35 U.S.C. 112). The claims, being an element of the application, should start on a new page (PCT Rule 11.4). Page numbers and line numbers must not be placed in the margins (PCT Rule 11.6(e)).

The number of claims shall be reasonable, considering the nature of the invention claimed (37 CFR 1.436).

1825 The Drawings

PCT Article 7. The Drawings

(1) Subject to the provisions of paragraph (2)(ii), drawings shall be required when they are necessary for the understanding of the invention.

(2) Where, without being necessary for the understanding of the invention, the nature of the invention admits of illustration by drawings:

- (i) the applicant may include such drawings in the international application when filed.
- (ii) any designated Office may require that the applicant file such drawings with it within the prescribed time limit.

PCT Rule 7. The Drawings

7.1. Flow Sheets and Diagrams

Flow sheets and diagrams are considered drawings.

7.2. Time Limit

The time limit referred to in Article 7(2)(ii) shall be reasonable under the circumstances of the case and shall, in no case, be shorter than two months from the date of the written invitation requiring the filing of drawings or additional drawings under the said provision.

PCT Rule 11.

Physical Requirements of the International Application

11.5. Size of Sheets

The size of the sheets shall be A4 (29.7 cm x 21 cm). However, any receiving Office may accept international applications on sheets of other sizes provided that the record copy, as transmitted to the International Bureau, and, if the competent International Searching Authority so desires, the search copy, shall be of A4 size.

11.6. Margins

(c) On sheets containing drawings, the surface usable shall not exceed 26.2 cm x 17.0 cm. The sheets shall not contain frames around the usable or used surface. The minimum margins shall be as follows:

- top: 2.5 cm
- left side: 2.5 cm
- right side: 1.5 cm
- bottom: 1.0 cm

11.11. Words in Drawings

(a) The drawings shall not contain text matter, except a single word or words, when absolutely indispensable, such as "water," "steam," "open," "closed," "section on AB," and, in the case of electric circuits and block schematic or flow sheet diagrams, a few short catchwords indispensable for understanding.

(b) Any words used shall be so placed that, if translated, they may be pasted over without interfering with any lines of the drawings.

11.13. Special Requirements for Drawings

(a) Drawings shall be executed in durable, black, sufficiently dense and dark, uniformly thick and well-defined, lines and strokes without colorings.

(b) Cross-sections shall be indicated by oblique hatching which should not impede the clear reading of the reference signs and leading lines.

(c) The scale of the drawings and the distinctness of their graphical execution shall be such that a photographic reproduction with a linear reduction in size to two-thirds would enable all details to be distinguished without difficulty.

(d) When, in exceptional cases, the scale is given on a drawing, it shall be represented graphically.

(e) All numbers, letters and reference lines, appearing on the drawings, shall be simple and clear. Brackets, circles or inverted commas shall not be used in association with numbers and letters.

(f) All lines in the drawings shall, ordinarily, be drawn with the aid of drafting instruments.

(g) Each element of each figure shall be in proper proportion to each of the other elements in the figure, except where the use of a different proportion is indispensable for the clarity of the figure.

(h) The height of the numbers and letters shall not be less than 0.32 cm. For the lettering of drawings, the Latin and, where customary, the Greek alphabets shall be used.

(i) The same sheet of drawings may contain several figures. Where figures on two or more sheets form in effect a single complete figure, the figures on the several sheets shall be so arranged that the complete figure can be assembled without concealing any part of any of the figures appearing on the various sheets.

(j) The different figures shall be arranged on a sheet or sheets without wasting space, preferably in an upright position, clearly separated from one another. Where the figures are not

arranged in an upright position, they shall be presented sideways with the top of the figures at the left side of the sheet.

(k) The different figures shall be numbered in Arabic numerals consecutively and independently of the numbering of the sheets.

(l) Reference signs not mentioned in the description shall not appear in the drawings, and vice versa.

(m) The same features, when denoted by reference signs, shall, throughout the international application, be denoted by the same signs.

(n) If the drawings contain a large number of reference signs, it is strongly recommended to attach a separate sheet listing all reference signs and the features denoted by them.

37 CFR 1.437. *The drawings.*

(a) Subject to paragraph (b) of this section, when drawings are necessary for the understanding of the invention, or are mentioned in the description, they must be part of an international application as originally filed in the United States Receiving Office in order to maintain the international filing date during the national stage (PCT Art. 7).

(b) Drawings missing from the application upon filing will be accepted if such drawings are received within 30 days of the date of first receipt of the incomplete papers. If the missing drawings are received within the 30-day period, the international filing date shall be the date on which such drawings are received. If such drawings are not timely received, all references to drawings in the international application shall be considered non-existent (PCT Art. 14(2), Administrative Instruction 310).

(c) The physical requirements for drawings are set forth in PCT Rule 11 and shall be adhered to.

The international application must contain drawings when they are necessary for the understanding of the invention. Moreover where, without drawings being actually necessary for the understanding of the invention, its nature admits of illustration by drawings, the applicant may include such drawings and any designated Office may require the applicant to file such drawings during the national phase. Flow sheets and diagrams are considered drawings. "Guidelines for Drawings Under the Patent Cooperation Treaty," published in the *PCT Gazette* (No. 7/1978), may be obtained, in English and French, from the International Bureau.

Drawings must be presented on one or more separate sheets. They may not be included in the description, the claims or the abstract. They may not contain text matter, except a single word or words when absolutely indispensable. Note that if the drawings contain text matter not in English but in a language accepted under PCT Rule 12.1(a) by the International Bureau as a Receiving Office, the international application

will be transmitted to the International Bureau for processing in its capacity as a Receiving Office. See 37 CFR 1.412(c)(6)(ii). If the drawings contain text matter not in a language accepted under PCT Rule 12.1(a) by the International Bureau as a Receiving Office, the application will be denied an international filing date.

All lines in the drawings must, ordinarily, be drawn with the aid of a drafting instrument and must be executed in black, uniformly thick and well-defined lines. PCT Rules 11.10 to 11.13 contain detailed requirements as to further physical requirements of drawings. Drawings newly executed according to national standards may not be required during the national phase if the drawings filed with the international application comply with PCT Rule 11. The examiner may require new drawings where the drawings which were accepted during the international phase did not comply with PCT Rule 11. A file reference may be indicated in the upper left corner on each sheet of the drawings as for the description.

All of the figures constituting the drawings must be grouped together on a sheet or sheets without waste of space, preferably in an upright position and clearly separated from each other. Where the drawings or tables cannot be presented satisfactorily in an upright position, they may be placed sideways, with the tops of the drawings or tables on the left-hand side of the sheet.

The usable surface of sheets (which must be of A4 size) must not exceed 26.2 cm x 17.0 cm. The sheets must not contain frames around the usable surface. The minimum margins which must be observed are: top and left side: 2.5 cm; right side: 1.5 cm; bottom: 1.0 cm.

All sheets of drawings must be numbered in the center of either the top or the bottom of each sheet but not in the margin in numbers larger than those used as reference signs in order to avoid confusion with the latter. For drawings, a separate series of page numbers is to be used. The number of each sheet of the drawings must consist of two Arabic numerals separated by an oblique stroke, the first being the sheet number and the second being the total number of sheets of drawings. For example, "2/5" would be used for the second sheet of drawings where there are five in all.

Different figures on the sheets of drawings must be numbered in Arabic numerals consecutively and independently of the numbering of the sheets and, if possible, in the order in which they appear. This numbering should be preceded by the expression "Fig."

The PCT makes no provision for photographs. Nevertheless, they are allowed by the International Bureau where it is impossible to present in a drawing what is to be shown (for instance, crystalline structures). Where, exceptionally, photographs are submitted, they must be on sheets of A4 size, they must be black and white, and they must respect the minimum margins and admit of direct reproduction. Color photographs are not accepted.

The procedure for rectification of obvious errors in the drawings is explained in MPEP § 1836. The omission of an entire sheet of drawings cannot be rectified without affecting the international filing date. Changes other than the rectification of obvious errors are considered amendments.

The drawings can be amended during the international phase only if the applicant files a Demand for international preliminary examination. The drawings can also be amended during the national phase.

If drawings are referred to in an international application and are not found in the search copy file, the examiner should refer the application to a Special Program Examiner in his or her Technology Center. See Administrative Instructions Section 310.

1826 The Abstract

PCT Rule 8. The Abstract

8.1. Contents and Form of the Abstract

(a) The abstract shall consist of the following:

(i) a summary of the disclosure as contained in the description, the claims, and any drawings; the summary shall indicate the technical field to which the invention pertains and shall be drafted in a way which allows the clear understanding of the technical problem, the gist of the solution of that problem through the invention, and the principal use or uses of the invention;

(ii) where applicable, the chemical formula which, among all the formulae contained in the international application, best characterizes the invention.

(b) The abstract shall be as concise as the disclosure permits (preferably 50 to 150 words if it is in English or when translated into English).

(c) The abstract shall not contain statements on the alleged merits or value of the claimed invention or on its speculative application.

(d) Each main technical feature mentioned in the abstract and illustrated by a drawing in the international application shall be followed by a reference sign, placed between parentheses.

8.2. Figure

(a) If the applicant fails to make the indication referred to in Rule 3.3(a)(iii), or if the International Searching Authority finds that a figure or figures other than that figure or those figures suggested by the applicant would, among all the figures of all the drawings, better characterize the invention, it shall, subject to paragraph (b), indicate the figure or figures which should accompany the abstract when the latter is published by the International Bureau. In such case, the abstract shall be accompanied by the figure or figures so indicated by the International Searching Authority. Otherwise, the abstract shall, subject to paragraph (b), be accompanied by the figure or figures suggested by the applicant.

(b) If the International Searching Authority finds that none of the figures of the drawings is useful for the understanding of the abstract, it shall notify the International Bureau accordingly. In such case, the abstract, when published by the International Bureau, shall not be accompanied by any figure of the drawings even where the applicant has made a suggestion under Rule 3.3(a)(iii).

8.3. Guiding Principles in Drafting

The abstract shall be so drafted that it can efficiently serve as a scanning tool for purposes of searching in the particular art, especially by assisting the scientist, engineer or researcher in formulating an opinion on whether there is a need for consulting the international application itself.

37 CFR 1.438. The abstract.

(a) Requirements as to the content and form of the abstract are set forth in PCT Rule 8, and shall be adhered to.

(b) Lack of an abstract upon filing of an international application will not affect the granting of a filing date. However, failure to furnish an abstract within one month from the date of the notification by the Receiving Office will result in the international application being declared withdrawn.

The abstract must consist of a summary of the disclosure as contained in the description, the claims and any drawings. Where applicable, it must also contain the most characteristic chemical formula. The abstract must be as concise as the disclosure permits (preferably 50 to 150 words if it is in English or when translated into English). National practice (see MPEP § 608.01(b)) also provides a maximum of 150 words for the abstract. See 37 CFR 1.72(b). The PCT range of 50 - 150 words is not absolute but publication problems could result when the PCT limit is increased beyond the 150 word limit. Maintaining the PCT upper limit is encouraged. As a rule of thumb, it can be said that the volume of the text of the abstract, including one of the figures from the drawings (if

any), should not exceed what can be accommodated on an A4 sheet of typewritten matter, 1 1/2 spaced. The abstract of the international application as filed must begin on a new sheet following the claims (Administrative Instructions Section 207). The other physical requirements must correspond to those for the description. The abstract must be so drafted that it can efficiently serve as a scanning tool for the purposes of searching in the particular art. These and other requirements concerning the abstract are spelled out in detail in PCT Rule 8. Useful guidance can be obtained from the "Guidelines for the Preparation of Abstracts Under the Patent Cooperation Treaty," published in the PCT Gazette (No. 5/1978). Those Guidelines may be obtained, in English and French, from the International Bureau.

The abstract should be primarily related to what is new in the art to which the invention pertains. Phrases should not be used which are implicit, (for instance, "the invention relates to ..."), and statements on the alleged merits or value of the invention are not allowed.

Where the receiving Office finds that the abstract is missing, it invites the applicant to furnish it within a time limit fixed in the invitation. The international application is considered withdrawn if no abstract is furnished to the receiving Office within the time limit fixed. Where the receiving Office has not invited the applicant to furnish an abstract, the International Searching Authority establishes one. The same applies where the abstract does not comply with the requirements outlined in the preceding paragraphs. Where the abstract is established by the International Searching Authority, the applicant may submit comments on it within 1 month from the date of mailing of the international search report, (PCT Rule 38.2(b)).

SUMMARY OF ABSTRACT REQUIREMENTS

Preferably 50-150 words. Should contain:

- (A) Indication of field of invention.
- (B) Clear indication of the technical problem.
- (C) Gist of invention's solution of the problem.
- (D) Principal use or uses of the invention.
- (E) Reference numbers of the main technical features placed between parentheses.
- (F) Where applicable, chemical formula which best characterizes the invention.

Should not contain:

- (A) Superfluous language.
- (B) Legal phraseology such as "said" and "means."
- (C) Statements of alleged merit or speculative application.
- (D) Prohibited items as defined in PCT Rule 9.

1827 Fees

A complete list of Patent Cooperation Treaty fee amounts which are to be paid to the United States Patent and Trademark Office, for both the national and international stages, can be found at the beginning of each weekly issue of the *Official Gazette* of the United States Patent and Trademark Office and on the PCT Legal Office page of the USPTO web site (see MPEP § 1730). Applicants are urged to refer to this list before submitting any fees to the USPTO.

Pursuant to PCT Rules 14.1(c), 15.4(a), and 16.1(f), the basic, transmittal, and search fee payable is the basic, transmittal, and search fee in effect on the filing date of the international application. See 37 CFR 1.431(c).

1828 Priority Claim and Document

An applicant who claims the priority of one or more earlier national or international applications for the same invention must indicate on the Request, at the time of filing, the country in or for which it was filed, the date of filing, and the application number. See PCT Article 8 and PCT Rule 4.10 for priority claim particulars and PCT Rule 90^{bis}.3 for withdrawal of priority claims. Note that under PCT Rule 4.10, an applicant may claim the priority of an application filed in or for a State which is a Member of the World Trade Organization (WTO), even if that State is not party to the Paris Convention for the Protection of Industrial Property (Paris Convention). However, a PCT Contracting State that is not a Member of the WTO would not be obliged to recognize the effects of such a priority claim.

Effective July 1, 1998, applicant may correct or add a priority claim by a notice submitted to the Receiving Office or the International Bureau within 16 months from the priority date, or where the priority date is changed, within 16 months from the priority date so changed, whichever period expires first. All priority

claim additions or changes must, however, be submitted no later than 4 months from the international filing date. PCT Rule 26^{bis}.1 and 37 CFR 1.451 and 1.465.

Under the PCT procedure, the applicant may file the certified copy of the earlier filed national application together with the international application in the receiving Office for transmittal with the record copy, or alternatively the certified copy may be submitted by the applicant to the International Bureau or the receiving Office not later than 16 months from the priority date or, if the applicant has requested early processing in any designated Office, not later than the time such processing or examination is requested. The International Bureau will normally furnish copies of the certified copy to the various designated Offices so that the applicant will not normally be required to submit certified copies to each designated Office.

For use of the priority document in national stage applications filed under 35 U.S.C. 371, see MPEP §1893.03(c).

1830 International Application Transmittal Letter

A PCT international application transmittal letter, Form PTO-1382, is available free of charge for applicants to use when filing PCT international applications with the United States Receiving Office. The form is intended to simplify the filing of PCT international applications by providing a one-page letter which covers the most common requests and concerns of applicants. Specifically covered are:

(A) Requests under 37 CFR 1.451 for preparation and transmittal to the International Bureau of certified copies of the U.S. national applications, the priority of which is claimed in international application;

(B) Choice of Searching Authority to conduct the international search. Applicants may choose either the U.S. Patent and Trademark Office or the European Patent Office as the International Searching Authority.

(C) Authorizations for any required additional search fees requested by the United States International Searching Authority to be charged to a Deposit Account subject to oral confirmation of the authorization. It should be noted that if the European Patent Office is chosen as the Searching Authority, any supplemental search fees requested by that Office are payable directly to the European Patent Office.

(D) Indications of information concerning differences in disclosure, if any, between the international application and related applications to assist in determining any foreign transmittal licensing requirements as well as for other purposes; and

(E) Requests for foreign transmittal license.

1832 License Request for Foreign Filing Under the PCT

A license for foreign filing is not required to file an international application in the United States Receiving Office but may be required before the applicant or the U.S. Receiving Office can forward a copy of the international application to a foreign patent office, the International Bureau or other foreign authority (35 U.S.C. 368, 37 CFR 5.1 and 5.11). A foreign filing license to permit transmittal to a foreign office or international authority is not required if the international application does not disclose subject matter in addition to that disclosed in a prior U.S. national application filed more than 6 months prior to the filing of the international application (37 CFR 5.11(a)). In all other instances (direct foreign filings outside the PCT or filings in a foreign receiving Office), the applicant should petition for a license for foreign filing (37 CFR 5.12) and if appropriate, identify any additional subject matter in the international application which was not in the earlier U.S. national application (37 CFR 5.14 (c)). This request and disclosure information may be supplied on the PCT international application transmittal letter, Form PTO-1382.

If no petition or request for a foreign filing license is included in the international application, and it is clear that a license is required because of the designation of foreign countries and the time at which the Record Copy must be transmitted, it is current Office practice to construe the filing of such an international application to include a request for a foreign filing license. If the license can be granted, it will be issued without further correspondence. If no license can be issued, or further information is required, applicant will be contacted. The automatic request for a foreign filing license does not apply to the filing of a foreign application outside the PCT.

EFFECT OF SECRECY ORDER

If a secrecy order is applied to an international application, the application will not be forwarded

to the International Bureau as long as the secrecy order remains in effect (PCT Article 27(8) and 35 U.S.C. 368). If the secrecy order remains in effect, the international application will be declared withdrawn (abandoned) because the Record Copy of the international application was not received in time by the International Bureau (37 CFR 5.3(d), PCT Article 12(3), and PCT Rule 22.3). It is, however, possible to prevent abandonment as to the United States of America if it has been designated, by fulfilling the requirements of 35 U.S.C. 371(c).

1834 Correspondence

PCT Rule 92. Correspondence

92.1. Need for Letter and for Signature

(a) Any paper submitted by the applicant in the course of the international procedure provided for in the Treaty and these Regulations, other than the international application itself, shall, if not itself in the form of a letter, be accompanied by a letter identifying the international application to which it relates. The letter shall be signed by the applicant.

(b) If the requirements provided for in paragraph (a) are not complied with, the applicant shall be informed as to the non-compliance and invited to remedy the omission within a time limit fixed in the invitation. The time limit so fixed shall be reasonable in the circumstances; even where the time limit so fixed expires later than the time limit applying to the furnishing of the paper (or even if the latter time limit has already expired), it shall not be less than 10 days and not more than one month from the mailing of the invitation. If the omission is remedied within the time limit fixed in the invitation, the omission shall be disregarded; otherwise, the applicant shall be informed that the paper has been disregarded.

(c) Where non-compliance with the requirements provided for in paragraph (a) has been overlooked and the paper taken into account in the international procedure, the non-compliance shall be disregarded.

92.2. Languages

(a) Subject to Rules 55.1 and 66.9 and to paragraph (b) of this Rule, any letter or document submitted by the applicant to the International Searching Authority or the International Preliminary Examining Authority shall be in the same language as the international application to which it relates. However, where a translation of the international application has been transmitted under Rule 23.1(b) or furnished under Rule 55.2, the language of such translation shall be used.

(b) Any letter from the applicant to the International Searching Authority or the International Preliminary Examining Authority may be in a language other than that of the international application, provided the said Authority authorizes the use of such language.

(c) *[Deleted]*

(d) Any letter from the applicant to the International Bureau shall be in English or French.

(e) Any letter or notification from the International Bureau to the applicant or to any national Office shall be in English or French.

PCT Administrative Instruction Section 105. Identification of International Application With Two or More Applicants

Where any international application indicates two or more applicants, it shall be sufficient, for the purpose of identifying that application, to indicate, in any Form or correspondence relating to such application, the name of the applicant first named in the request. The provisions of the first sentence of this Section do not apply to the demand or to a notice effecting later elections.

NOTIFICATION UNDER PCT RULE 92.1(b) OF DEFECTS WITH REGARD TO CORRESPONDENCE

If the Office finds that papers, other than the international application itself, are not accompanied by a letter identifying the international application to which they relate, or are accompanied by an unsigned letter, or are furnished in the form of an unsigned letter, it notifies the applicant and invites him or her to remedy the omission. The Office disregards the said papers or letter if the omission is not remedied within the time limit fixed in the invitation (PCT Rule 92.1(b)). If the omission has been overlooked and the paper taken into account, the omission is disregarded.

CORRESPONDENCE ADDRESS

Where there is a sole applicant without an agent in an international application, correspondence will be sent to the applicant at his or her indicated address; or, if he or she has appointed one or more agents, to that agent or the first-mentioned of those agents; or, if he or she has not appointed an agent but has indicated a special address for notifications, at that special address.

Where there are two or more applicants who have appointed one or more common agents, correspondence will be addressed to that agent or the first-mentioned of those agents. Where no common agent has been appointed, correspondence will be addressed to the common representative (either the appointed common representative or the applicant who is considered to be the common representative (PCT Rule 90.2) at

the indicated address; or, if the common representative has appointed one or more agents, to that agent or the first-mentioned of those agents; or, if the common representative has not appointed an agent but has indicated a special address for notifications, at that address.

FILING OF CORRESPONDENCE BY MAIL

The "Express Mail" procedure set forth at 37 CFR 1.10 applies to "[a]ny correspondence received by the Patent and Trademark Office." Accordingly, papers filed with the USPTO in international applications will be accorded by the U.S. Patent and Trademark Office the date of deposit with the United States Postal Service as shown on the "date-in" on the "Express Mail" mailing label as the date of filing in the USPTO if the provisions of 37 CFR 1.10 are complied with. See MPEP § 513.

If there is a question regarding the date of deposit, the Express Mail provisions of 37 CFR 1.10(c)-(e) require, in addition to using the "Express Mail Post Office to Addressee" service, an indication of the "Express Mail" mailing label number on each paper or fee. In situations wherein the correspondence includes several papers directed to the same application (for example, Request, description, claims, abstract, drawings, and other papers) the correspondence may be submitted with a cover or transmittal letter, which should itemize the papers. The cover or transmittal letter must have the "Express Mail" mailing label number thereon.

The certificate of mailing by first class mail procedure set forth at 37 CFR 1.8 differs from the 37 CFR 1.10 Express Mail procedure. See 37 CFR 1.8(a)(2)(i)(D) and (E). It is important to understand that the 37 CFR 1.8 certificate of mailing procedure CANNOT be used for filing any papers during the international stage if the date of deposit is desired. If the 37 CFR 1.8 certificate of mailing procedure is used, the paper and/or fee will be accorded the date of receipt in the USPTO unless the receipt date falls on a Saturday, Sunday, or Federal holiday in which case the date of receipt will be the next succeeding day which is not a Saturday, Sunday, or Federal holiday (37 CFR 1.6(a)(3)). Accordingly, the certificate of mailing procedures of 37 CFR 1.8 are not available to have a submission during the international stage con-

sidered as timely filed if the submission is not physically received at the USPTO on or before the due date.

1834.01 Use of Telegraph, Teleprinter, Facsimile Machine

PCT Rule 92.4 provides that a national Office may receive documents by telegraph, teleprinter, or facsimile machine. However, the United States Patent and Trademark Office has not informed the International Bureau that it accepts such submissions other than facsimile transmissions. Accordingly, applicants may not currently file papers in international applications with the United States Patent and Trademark Office via telegraph or teleprinter.

Generally, any paper may be filed by facsimile transmission with certain exceptions which are identified in 37 CFR 1.6(d). It should be noted that a facsimile transmission of a document is not permitted and, if submitted, will not be accorded a date of receipt if the document is:

- (A) Required by statute to be certified;
- (B) A drawing submitted under 37 CFR 1.437;
- (C) An international application for patent; or
- (D) A copy of the international application and the basic national fee necessary to enter the national stage, as specified in 37 CFR 1.494(b) or 37 CFR 1.495(b).

Facsimile transmission may be used to submit substitute sheets (other than drawings), extensions of time, power of attorney, fee authorizations (other than the basic national fee), confirmation of precautionary designations, Demands, response to written opinions, oaths or declarations, petitions, and translations in international applications.

A Certificate of Transmission may be used as provided in 37 CFR 1.8(a)(1) except in the instances specifically excluded in 37 CFR 1.8(a)(2). Note particularly that the Certificate of Transmission cannot be used for the filing of an international application for patent or correspondence in an international application before the U.S. Receiving Office, the U.S. International Searching Authority, or the U.S. International Preliminary Examining Authority. Guidelines for facsimile transmission are clearly set forth in 37 CFR 1.6(d) and should be read before transmitting by facsimile machine.

A signature on a document received via facsimile in a permitted situation is acceptable as a proper signature. See PCT Rule 92.4(b) and 37 CFR 1.4(d)(1)(ii).

The receipt date of a document transmitted via facsimile is the date in the USPTO on which the transmission is completed, unless the receipt date is a Saturday, Sunday, or Federal holiday in which case the date of receipt will be the next succeeding day which is not a Saturday, Sunday, or Federal holiday (37 CFR 1.6(a)(3)). See 37 CFR 1.6(d). Where a document is illegible or part of the document is not received, the document will be treated as not received to the extent that it is illegible or the transmission failed. See PCT Rule 92.4(c).

1834.02 Irregularities in the Mail Service

PCT Rule 82.

Irregularities in the Mail Service

82.1. Delay or Loss in Mail

(a) Any interested party may offer evidence that he has mailed the document or letter five days prior to the expiration of the time limit. Except in cases where surface mail normally arrives at its destination within two days of mailing, or where no airmail service is available, such evidence may be offered only if the mailing was by airmail. In any case, evidence may be offered only if the mailing was by mail registered by the postal authorities.

(b) If the mailing, in accordance with paragraph (a), of a document or letter is proven to the satisfaction of the national Office or intergovernmental organization which is the addressee, delay in arrival shall be excused, or, if the document or letter is lost in the mail, substitution for it of a new copy shall be permitted, provided that the interested party proves to the satisfaction of the said Office or organization that the document or letter offered in substitution is identical with the document or letter lost.

(c) In the cases provided for in paragraph (b), evidence of mailing within the prescribed time limit, and, where the document or letter was lost, the substitute document or letter as well as the evidence concerning its identity with the document or letter lost shall be submitted within one month after the date on which the interested party noticed or with due diligence should have noticed the delay or the loss, and in no case later than six months after the expiration of the time limit applicable in the given case.

(d) Any national Office or intergovernmental organization which has notified the International Bureau that it will do so shall, where a delivery service other than the postal authorities is used to mail a document or letter, apply the provisions of paragraphs (a) to (c) as if the delivery service was a postal authority. In such a case, the last sentence of paragraph (a) shall not apply but evidence may be offered only if details of the mailing were recorded by the delivery service at the time of mailing. The notification may contain an indication that it applies only to mailings using

specified delivery services or delivery services which satisfy specified criteria. The International Bureau shall publish the information so notified in the Gazette.

(e) Any national Office or intergovernmental organization may proceed under paragraph (d):

(i) even if, where applicable, the delivery service used was not one of those specified, or did not satisfy the criteria specified, in the relevant notification under paragraph (d), or

(ii) even if that Office or organization has not sent to the International Bureau a notification under paragraph (d).

82.2. Interruption in the Mail Service

(a) Any interested party may offer evidence that on any of the 10 days preceding the day of expiration of the time limit the postal service was interrupted on account of war, revolution, civil disorder, strike, natural calamity, or other like reason, in the locality where the interested party resides or has his place of business or is staying.

(b) If such circumstances are proven to the satisfaction of the national Office or intergovernmental organization which is the addressee, delay in arrival shall be excused, provided that the interested party proves to the satisfaction of the said Office or organization that he effected the mailing within five days after the mail service was resumed. The provisions of Rule 82.1(c) shall apply *mutatis mutandis*.

DELAY OR LOSS IN MAIL

Delay or loss in the mail shall be excused when it is proven to the satisfaction of the receiving Office that the concerned letter or document was mailed at least five days before the expiration of the time limit. The mailing must have been by registered air mail or, where surface mail would normally arrive at the destination concerned within two days of mailing, by registered surface mail (PCT Rule 82.1(a) to (c)). PCT Rule 82 contains detailed provisions governing the situation where a letter arrives late or gets lost due to irregularities in the mail service, for example, because the mail service was interrupted due to a strike. The provisions operate to excuse failure to meet a time limit for filing a document for up to six months after the expiration of the time limit concerned, provided that the document was mailed at least five days before the expiration of the time limit. In order to take advantage of these provisions, the mailing must have been by registered airmail or, where surface mail would normally arrive at the destination concerned within two days of mailing, by registered surface mail. Evidence is required to satisfy the Office, and a substitute document must be filed promptly—see PCT Rule 82.1(b) and (c) for details.

INTERRUPTION IN MAIL SERVICE

The provisions of PCT Rule 82.1(c) apply *mutatis mutandis* for interruptions in the mail service caused by war, revolution, civil disorder, strike, natural calamity or other like reasons (PCT Rule 82.2).

Special provisions also apply to mail interruptions caused by war, revolution, civil disorder, strike, natural calamity or other like reasons—see PCT Rule 82.2 for details.

See PCT Rule 80.5 for guidance on periods which expire on a non-working day.

1836 Rectification of Obvious Errors

PCT Rule 91.

Obvious Errors in Documents

91.1. Rectification

(a) Subject to paragraphs (b) to (g^{quater}), obvious errors in the international application or other papers submitted by the applicant may be rectified.

(b) Errors which are due to the fact that something other than what was obviously intended was written in the international application or other paper shall be regarded as obvious errors. The rectification itself shall be obvious in the sense that anyone would immediately realize that nothing else could have been intended than what is offered as rectification.

(c) Omissions of entire elements or sheets of the international application, even if clearly resulting from inattention, at the stage, for example, of copying or assembling sheets, shall not be rectifiable.

(d) Rectification may be made on the request of the applicant. The authority having discovered what appears to be an obvious error may invite the applicant to present a request for rectification as provided in paragraphs (e) to (g^{quater}). Rule 26.4 shall apply *mutatis mutandis* to the manner in which rectifications shall be requested.

(e) No rectification shall be made except with the express authorization:

- (i) of the receiving Office if the error is in the request,
- (ii) of the International Searching Authority if the error is in any part of the international application other than the request or in any paper submitted to that Authority,
- (iii) of the International Preliminary Examining Authority if the error is in any part of the international application other than the request or in any paper submitted to that Authority, and
- (iv) of the International Bureau if the error is in any paper, other than the international application or amendments or corrections to that application, submitted to the International Bureau.

(f) Any authority which authorizes or refuses any rectification shall promptly notify the applicant of the authorization or refusal and, in the case of refusal, of the reasons therefor. The authority which authorizes a rectification shall promptly notify the International Bureau accordingly. Where the authorization of the

rectification was refused, the International Bureau shall, upon request made by the applicant prior to the time relevant under paragraph (g^{bis}), (g^{ter}), or (g^{quater}) and subject to the payment of a special fee whose amount shall be fixed in the Administrative Instructions, publish the request for rectification together with the international application. A copy of the request for rectification shall be included in the communication under Article 20 where a copy of the pamphlet is not used for that communication or where the international application is not published by virtue of Article 64(3).

(g) The authorization for rectification referred to in paragraph (e) shall, subject to paragraphs (g^{bis}), (g^{ter}), and (g^{quater}), be effective:

(i) where it is given by the receiving Office or by the International Searching Authority, if its notification to the International Bureau reaches that Bureau before the expiration of 17 months from the priority date;

(ii) where it is given by the International Preliminary Examining Authority, if it is given before the establishment of the international preliminary examination report;

(iii) where it is given by the International Bureau, if it is given before the expiration of 17 months from the priority date.

(g^{bis}) If the notification made under paragraph (g)(i) reaches the International Bureau, or if the rectification made under paragraph (g)(iii) is authorized by the International Bureau, after the expiration of 17 months from the priority date but before the technical preparations for international publication have been completed, the authorization shall be effective and the rectification shall be incorporated in the said publication.

(g^{ter}) Where the applicant has asked the International Bureau to publish his international application before the expiration of 18 months from the priority date, any notification made under paragraph (g)(i) must reach, and any rectification made under paragraph (g)(iii) must be authorized by, the International Bureau, in order for the authorization to be effective, not later than at the time of the completion of the technical preparations for international publication.

(g^{quater}) Where the international application is not published by virtue of Article 64(3), any notification made under paragraph (g)(i) must reach, and any rectification made under paragraph (g)(iii) must be authorized by, the International Bureau, in order for the authorization to be effective, not later than at the time of the communication of the international application under Article 20.

Obvious errors in the international application or other papers submitted by the applicant may generally be rectified under PCT Rule 91, if the rectification is authorized, as required, within the applicable time limit. Any such rectification is free of charge. The omission of entire sheets of the description cannot be rectified, even if resulting from inattention at the stage of copying or assembling sheets.

Applicants often attempt to rely upon the priority application to establish a basis for obvious error. The

priority document (application) cannot be used to support obvious error corrections. The rectification is obvious only in the sense that anyone would immediately realize that nothing else could have been intended than what is offered as rectification. For example, a misspelled word could be considered an obvious error subject to rectification. A missing chemical formula or missing line of text would not be considered obvious error subject to rectification. However, improper identification of the application number of the file in which a paper is to be entered has been held to be an obvious error subject to rectification when the applicant did include the proper agent's file reference and other information properly identifying the application file. See *Helfgott & Karas P.C. v. Dickinson*, 209 F.3d 1328, 54 USPQ2d 1425 (Fed. Cir. 2000).

Rectifications must be authorized:

(A) If the error is in the request by the Receiving Office;

(B) If the error is in the description, the claims, the drawings or the abstract by the International Searching Authority, or by the International Preliminary Examining Authority where the international application is pending before the latter Authority;

(C) If the error is in any paper other than the international application or amendments or corrections to it by the International Bureau.

The request for rectification must be addressed to the authority competent to authorize the rectification. It must be filed in time for the rectification to be authorized and for notification of the authorization to reach the International Bureau before the expiration of the applicable time limit, namely:

(A) Where the authorization is given by the Receiving Office or the International Searching Authority its notification must reach the International Bureau before the expiration of 17 months from the priority date (or later, before the technical preparations for international publication have been completed);

(B) Where the authorization is given by the International Preliminary Examining Authority it must be given before the establishment of the international preliminary examination report;

(C) Where the authorization is given by the International Bureau it must be given before the expiration

of 17 months from the priority date (or later, before the technical preparations for international publication have been completed)

The patent examiner, in his or her capacity as an officer of either the International Searching Authority or International Preliminary Examining Authority, informs the applicant of the authorization or refusal to authorize the rectification of obvious errors. The International Searching Authority informs the applicant of the decision by use of Form PCT/ISA/217, while the International Preliminary Examining Authority informs the applicant of the decision by use of Form PCT/IPEA/412.

Where the examiner discovers what might be considered an obvious error, an invitation to request rectification (Form PCT/ISA/216 or PCT/IPEA/411) should be mailed to applicant.

1840 The International Searching Authority

35 U.S.C. 362. International Searching Authority and International Preliminary Examining Authority.

(a) The Patent and Trademark Office may act as an International Searching Authority and International Preliminary Examining Authority with respect to international applications in accordance with the terms and conditions of an agreement which may be concluded with the International Bureau, and may discharge all duties required of such Authorities, including the collection of handling fees and their transmittal to the International Bureau.

(b) The handling fee, preliminary examination fee, and any additional fees due for international preliminary examination shall be paid within such time as may be fixed by the Director.

37 CFR 1.413. The United States International Searching Authority.

(a) Pursuant to appointment by the Assembly, the United States Patent and Trademark Office will act as an International Searching Authority for international applications filed in the United States Receiving Office and in other Receiving Offices as may be agreed upon by the Commissioner, in accordance with agreement between the Patent and Trademark Office and the International Bureau (PCT Art. 16(3)(b)).

(b) The Patent and Trademark Office, when acting as an International Searching Authority, will be identified by the full title "United States International Searching Authority" or by the abbreviation "ISA/US."

(c) The major functions of the International Searching Authority include:

- (1) Approving or establishing the title and abstract;
- (2) Considering the matter of unity of invention;

(3) Conducting international and international-type searches and preparing international and international-type search reports (PCT Art. 15, 17 and 18, and PCT Rules 25, 33 to 45 and 47); and

(4) Transmitting the international search report to the applicant and the International Bureau.

The United States Patent and Trademark Office agreed to and was appointed by the PCT Assembly, to act as an International Searching Authority. As such an authority, a primary function is to establish documentary search reports on prior art with respect to inventions which are the subject of applications. See PCT Article 16.

Pursuant to an agreement concluded with the International Bureau, the USPTO, as an International Searching Authority, agreed to conduct international searches and prepare international search reports, for, in addition to the United States of America, Barbados, Brazil, India, Israel, Mexico, New Zealand, South Africa, and Trinidad and Tobago. The agreement stipulated the English language and specified that the subject matter to be searched is that which is searched or examined in United States national applications.

TRANSMITTAL OF THE SEARCH COPY TO THE INTERNATIONAL SEARCHING AUTHORITY

The "search copy" is transmitted by the Receiving Office to the International Searching Authority (PCT Article 12(1)), the details of the transmittal are provided in PCT Rule 23.

THE MAIN PROCEDURAL STEPS IN THE INTERNATIONAL SEARCHING AUTHORITY

The main procedural steps that any international application goes through in the International Searching Authority are (1) the making of the international search (PCT Article 15), and (2) the preparing of the international search report (PCT Article 18 and PCT Rule 43).

COMPETENT INTERNATIONAL SEARCHING AUTHORITY

In respect of international applications filed with the U.S. Receiving Office, the United States International Searching Authority, which is the Examining Corps of the United States Patent and Trademark Office, and the European Patent Office are competent

to carry out the international search (PCT Article 16, PCT Rules 35 and 36, 35 U.S.C. 362 and 37 CFR 1.413).

The United States Patent and Trademark Office has informed the International Bureau that in addition to the United States Patent and Trademark Office, the European Patent Office is competent as an International Searching Authority for searching all kinds of international applications filed in the United States Receiving Office on and after October 1, 1982. (PCT Article 16(2) and PCT Rule 35.2(a)(i).

MATTERS TO BE CONSIDERED WHEN CHOOSING AN INTERNATIONAL SEARCHING AUTHORITY

Choosing The European Patent Office (EPO) as an International Searching Authority could be advantageous to United States applicants who designate countries for European Regional patent protection in PCT International applications for the following reasons:

(A) Claims may be amended according to EPO search results before entering the European Office as a designated Office.

(B) The EPO search fee need not be paid upon entering the European Office as a designated Office.

(C) The EPO search results may be available for use in a U.S. priority application.

(D) The EPO international search may be obtained without the need for a European professional representative.

(E) The European Patent Office search could provide the U.S. applicant with the benefit of a European art search (which may be different from applicant's own or the USPTO's search) before it is necessary to enter the European Patent Office or other designated Offices.

Some of the disadvantages that may occur due to the European Patent Office making the international search are the following:

(A) Additional mailing time to and from the EPO Searching Authority may shorten the time for applicants to respond to various invitations from the EPO such as for comments on abstracts and payments of additional search fees as well as for PCT Article 19 amendments to the claims after issuance of the International Search Report.

(B) There may be more difficulty in solving any procedural problems between the applicant and the EPO than with the USPTO due to physical distance and time differences.

The PCT Applicant's Guide provides helpful information for communications with the European Patent Office.

1840.01 The European Patent Office as an International Searching Authority

Since October 1, 1982, the European Patent Office (EPO) has been available as a Searching Authority for PCT applications filed in the United States Receiving Office. The choice of Searching Authority, either the EPO or the United States Patent and Trademark Office, must be made by the applicant on filing the international application. The choice of Searching Authority may also be indicated on Form PTO-1382, the Transmittal Letter to the United States Receiving Office.

It should be noted that the European Patent Office will not search, by virtue of PCT Article 17(2)(a)(i), any international application to the extent that it considers that the international application relates to subject matter set forth in PCT Rule 39.1. Furthermore,

the European Patent Office is not equipped to search computer programs.

The international search fee for the European Patent Office must be paid to the United States Patent and Trademark Office (USPTO) as a Receiving Office at the time of filing the international application. The search fee for the European Patent Office is announced weekly in the *Official Gazette* in United States dollars. The search fee will change as costs and exchange rates require. If exchange rates fluctuate significantly, the fee may change frequently. Notice of changes will be published in the *Official Gazette* shortly before the effective date of any change.

If the European Patent Office as the International Searching Authority considers that the international application does not comply with the requirement of unity of invention as set forth in PCT Rule 13, the European Patent Office will invite applicants to timely pay directly to it an additional search fee in Deutsche Marks for each additional invention.

A revised fee calculation sheet (Form PCT/RO/101, Annex) having appropriate spaces to indicate the choice of International Searching Authority has been developed so that applicants may indicate which International Searching Authority is to make the search.

*PCT Rule 33.**Relevant Prior Art for the International Search**33.1. Relevant Prior Art for the International Search*

(a) For the purposes of Article 15(2), relevant prior art shall consist of everything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) and which is capable of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step (i.e., that it is or is not obvious), provided that the making available to the public occurred prior to the international filing date.

(b) When any written disclosure refers to an oral disclosure, use, exhibition, or other means whereby the contents of the written disclosure were made available to the public, and such making available to the public occurred on a date prior to the international filing date, the international search report shall separately mention that fact and the date on which it occurred if the making available to the public of the written disclosure occurred on a date which is the same as, or later than, the international filing date.

(c) Any published application or any patent whose publication date is the same as, or later than, but whose filing date, or, where applicable, claimed priority date, is earlier than the international filing date of the international application searched, and which would constitute relevant prior art for the purposes of Article 15(2) had it been published prior to the international filing date, shall be specially mentioned in the international search report.

33.2. Fields to Be Covered by the International Search

(a) The international search shall cover all those technical fields, and shall be carried out on the basis of all those search files, which may contain material pertinent to the invention.

(b) Consequently, not only shall the art in which the invention is classifiable be searched but also analogous arts regardless of where classified.

(c) The question what arts are, in any given case, to be regarded as analogous shall be considered in the light of what appears to be the necessary essential function or use of the invention and not only the specific functions expressly indicated in the international application.

(d) The international search shall embrace all subject matter that is generally recognized as equivalent to the subject matter of the claimed invention for all or certain of its features, even though, in its specifics, the invention as described in the international application is different.

33.3. Orientation of the International Search

(a) International search shall be made on the basis of the claims, with due regard to the description and the drawings (if any) and with particular emphasis on the inventive concept towards which the claims are directed.

(b) In so far as possible and reasonable, the international search shall cover the entire subject matter to which the claims are

directed or to which they might reasonably be expected to be directed after they have been amended.

*PCT Rule 39.**Subject Matter under Article 17(2)(a)(i)**39.1. Definition*

No International Searching Authority shall be required to search an international application if, and to the extent to which, its subject matter is any of the following:

- (i) scientific and mathematical theories,
- (ii) plant or animal varieties or essentially biological processes for the production of plants and animals, other than micro-biological processes and the products of such processes,
- (iii) schemes, rules or methods of doing business, performing purely mental acts or playing games,
- (iv) methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods,
- (v) mere presentations of information,
- (vi) computer programs to the extent that the International Searching Authority is not equipped to search prior art concerning such programs.

PCT Article 15 describes the objective of the international search, i.e., to uncover relevant prior art, and also describes the international-type search. It should be noted generally that an international-type search is performed on all U.S. national applications filed after June 1, 1978.

There are several benefits to applicants who use the PCT. One of the three most commonly mentioned benefits is the international search (and consequently the international search report). The others are the time delay gained before having to enter the national phase and the monetary savings since filing and translation fees are also deferred or indeed, may not be necessary depending upon the search results. The international search gives applicants the benefit of knowing the status of the prior art with respect to their invention before time for entry into the national stage. This affords applicants the time to make economic decisions whether to perfect their national stage filings.

The objective of the international search is to discover relevant prior art (PCT Article 15(2)). "Prior art" consists of everything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations); it is relevant in respect of the international application if it is capable of being of assistance in determining that the claimed invention is or is not new and that the claimed invention does or

does not involve an inventive step (i.e., that it is or is not obvious), and if the making available to the public occurred prior to the international filing date. For further details, see PCT Rule 33. The international search is made on the basis of the claims, with due regard to the description and the drawings (if any) contained in the international application (PCT Article 15(3)). Categories of relevant prior art as described in PCT Rule 33.1 are indicated in the search report under the section "Documents Considered To Be Relevant." The various letter designations are defined on the search report form (see PCT/ISA/210).

It is pointed out, for example, that:

(A) A category X reference defeats novelty or defeats inventive step when the reference is considered alone;

(B) A category Y reference is said to defeat or refute inventive step when combined with one or more other such references - the combination being obvious to a person skilled in the art;

(C) A category A reference is one showing the general state of the art but would not be considered to be of particular relevance;

(D) A category E reference is an earlier document which is published on or after the international filing date;

(E) A category P reference is a document published prior to the international filing date but later than the claimed priority date (commonly called an intervening reference).

These are the most commonly used categories of references.

The examiner should not view these categories strictly in the sense that they have a direct comparison to U.S. application of prior art references, for example, a category X reference defeats novelty and in that sense, it is closely analogous to U.S. consideration of 35 U.S.C. 102 prior art. However, a category X reference can also defeat inventive step which is analogous to U.S. consideration of 35 U.S.C. 103 prior art.

DOCUMENTS SEARCHED BY THE INTERNATIONAL SEARCHING AUTHORITY

The International Searching Authority must endeavor to discover as much of the relevant prior art as its facilities permit (PCT Article 15(4)), and, in any

case, must consult the so-called "minimum documentation" (PCT Rule 34).

CERTAIN SUBJECT MATTER NEED NOT BE SEARCHED

The USPTO has declared that it will search and examine, in international applications, all subject matter searched and examined in U.S. national applications. However under PCT Rule 39, no International Searching Authority is required to perform an international search where the international application relates to any of the following subject matters:

(A) Scientific and mathematical theories;

(B) Plant or animal varieties or essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes;

(C) Schemes, rules or methods of doing business, performing purely mental acts or playing games;

(D) Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods;

(E) Mere presentation of information; and

(F) Computer programs to the extent that it, the said Authority is not equipped to search prior art (PCT Article 17(2)(a)(i) and PCT Rule 39).

The applicant considering the filing of an international application may be well advised not to file one if the subject matter of the application falls into one of the above mentioned areas. If he or she still does file, the International Searching Authority may declare that it will not establish an international search report. Accordingly, applicant should take into consideration which International Searching Authority (e.g., European Patent Office) he or she selects to conduct the international search. It is to be noted, nevertheless, that the lack of the international search report in such case will not have, in itself, any influence on the validity of the international application and the latter's processing will continue, including its communication to the designated Offices.

The USPTO has declared that it will search and examine, in international applications, all subject matter searched and examined in U.S. national applications.

NO SEARCH REQUIRED IF CLAIMS ARE UNCLEAR

If the International Searching Authority considers that the description, the claims, or the drawings fail to comply with the prescribed requirements to such an extent that a meaningful search could not be carried out, it may declare that it will not establish a search report (PCT Article 17(2)(a)(ii)). Such declaration may also be made in respect of some of the claims only. The lack of the international search report will not, in itself, have any influence on the validity of the international application and the latter's processing will continue, including its communication to the designated Offices. Where only some of the claims are found to be unsearchable, the International Searching Authority will not search them, but will search the rest of the international application. Any unsearched claims will be indicated in the international search report.

1844 The International Search Report

PCT Article 18.

The International Search Report

(1) The international search report shall be established within the prescribed time limit and in the prescribed form.

(2) The international search report shall, as soon as it has been established, be transmitted by the International Searching Authority to the applicant and the International Bureau.

(3) The international search report or the declaration referred to in Article 17(2)(a) shall be translated as provided in the Regulations. The translations shall be prepared by or under the responsibility of the International Bureau.

The results of the international search will be recorded in the international search report (Form PCT/ISA/210), which is transmitted with Form PCT/ISA/220 to the applicant and with Form PCT/ISA/219 to the International Bureau. The search report will be published by the International Bureau and will serve as a basis for examination of the international application by the designated Offices and the International Preliminary Examination Authority.

The time limit for establishing the international search report or the declaration under Article 17(2)(a) that no search report will be established is 3 months from receipt of the search copy by the searching authority or 9 months from the priority date, whichever time limit expires later. To ensure timeliness, Office policy is to set a shorter period for the search

by the examiner so that any corrections to the report can be made timely and also to allow for review and mailing to the International Bureau. The Office strives to get all search reports to the International Bureau by 16 months from the priority date or, where there is no priority date, 9 months from the international filing date. See PCT Rule 42.1.

The search report should not contain any expressions of opinion, reasoning, argument or explanation as to any cited prior art. Any such comments would be inappropriate and should be used only if preliminary examination is or becomes a part of the international proceeding. The search report is only for the purpose of identifying prior art and not for commenting thereupon.

The printed international search report form (Form PCT/ISA/210) to be transmitted to the applicant and to the International Bureau contains two main sheets ("first sheet" and "second sheet") to be used for all searches. These two main sheets are intended for recording the important features of the search such as the fields searched and for citing documents revealed by the search. The printed international search report form also contains four optional continuation sheets for use where necessary. There are two continuation sheets for each of the "first sheet" and the "second sheet": "continuation of first sheet (1)" and "continuation of first sheet (2)", and "continuation of second sheet" and "patent family annex", respectively. The patent family annex sheet is not currently used by the United States International Searching Authority since patent family information is not readily available to the examiner. The "continuation of first sheet (1)" is to be used only where an indication is made on the first sheet that claims were found unsearchable (item 1) and/or unity of invention is lacking (item 2). The relevant indications must then be made on that continuation sheet. The "continuation of first sheet (2)" is to contain the text of the abstract where an abstract or an amended abstract has been established by the International Searching Authority (item 5) and an indication to that effect is made on the first sheet. The "continuation of second sheet" is to be used where the space on the second sheet is insufficient for the citation of documents. Lastly, the "extra sheet" may be used whenever additional space is required to complete information from the other sheets.

It is to be noted that only the "second sheet", the "continuation of second sheet" (if any) and the "continuation of first sheet (1)" (if any), will be the subject of international publication, as the "first sheet" and the "continuation of first sheet (2)" (if any) contain only information which will already appear on the front page of the pamphlet.

The international search report must list the classification identification of the fields searched using the IPC.

Where the international search report is entirely or partly based on a previous search made for an application relating to a similar subject, the relevant search files consulted for this previous search must also be identified in the report as having been consulted for the international application in question.

RESTRICTION OF THE SUBJECT OF THE INTERNATIONAL SEARCH

The report must indicate whether the search was restricted or not for any of the reasons indicated below.

If any such restrictions were applied, the claims in respect of which a search has not been carried out must be identified and the reasons of this should be indicated.

The three categories where such restrictions may arise are:

- (A) Lack of unity of invention;
- (B) Claims drawn to subject matter excluded from the search;
- (C) Claims in respect of which a meaningful search cannot be carried out.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference APG-001	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US00/00123	International filing date (<i>day/month/year</i>) 05 January 2000 (05.01.2000)	(Earliest) Priority Date (<i>day/month/year</i>) 05 January 1999 (05.01.1999)
Applicant Applegate, Inc.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. Certain claims were found unsearchable (See Box I).

3. Unity of invention is lacking (See Box II).

4. With regard to the title,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

5. With regard to the abstract,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No. 1

as suggested by the applicant.

None of the figures

because the applicant failed to suggest a figure.

because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/00123

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claim Nos.: 6-9
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet(1)) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/00123

Box III TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

The technical features mentioned in the abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

The abstract is too long (PCT Rule 8.1(b)). The abstract must be less than 150 words; or 200 words when no figure is to be published.

NEW ABSTRACT

Olefin (1) and methyl methacrylate copolymers (2) are disclosed which are particularly useful in manufacturing molded automotive parts.

INTERNATIONAL SEARCH REPORT		International application No. PCT/US00/00123		
A. CLASSIFICATION OF SUBJECT MATTER				
IPC(7) : C08F 8/14 US CL : 525/384, 422, 260; 524/225 According to International Patent Classification (IPC) or to both national classification and IPC				
B. FIELDS SEARCHED				
Minimum documentation searched (classification system followed by classification symbols) U.S. : 525/384, 422, 260, 265, 288, 300; 524/225; 233, 245				
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Grant & Hachk's Chemical Dictionary (Fifth Edition)				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X ---	US 4,069,001 A (LOOK) 19 July 1980 (19.07.80), column 2, lines 43-58, column 4, lines 1-23.	1-3 -----		
Y		4, 5		
Y	US 4,950,123 A (JOHNS et al) 03 March 1990 (03.03.90), column 2, lines 1-20	4, 5		
X, P	MILLER et al, Polymeric Composites, J. poly. chem. June 1999, Vol. 61, No. 6, pages 1261-1273, especially page 1268, third paragraph.	1-5		
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.				
* Special categories of cited documents: <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;"> "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed </td> <td style="width: 50%;"> "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family </td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family			
Date of the actual completion of the international search 13 July 2001 (13.07.2001)		Date of mailing of the international search report		
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230		Authorized officer Pat Examiner Telephone No. 703-305-0000		

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/00123

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-3, drawn to an olefin polymer.

Group II, claim(s) 4 and 5, drawn to a copolymer of vinyl acetate and methyl methacrylate.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of the Group I invention is the specific olefin polymer claimed therein while the special technical feature of the Group II invention is the particular vinyl acetate and methyl methacrylate copolymers claimed therein. Since the special technical feature of the Group I invention is not present in the Group II claims and the special technical feature of the Group II invention is not present in the Group I claims, unity of invention is lacking.

Continuation of B. FIELDS SEARCHED Item 3:

CAS

search terms: olefin, methyl methacrylate

AUTHENTICATION AND DATES

The identification of the International Searching Authority which established the international search report and the date on which the report was drawn up should be indicated in the search report. This date should be that of the drafting of the report by the search examiner who carried out the search. In addition to the date of actual completion of the international search, the international search report shall also indicate the date on which it was mailed to the applicant, which is important for the computation of the time limit for filing amendments to the claims under PCT Article 19. See PCT Rules 43.1 and 43.2.

The international search report shall indicate the name of an authorized officer of the International Searching Authority which means the person who actually performed the search work and prepared the search report. See PCT Rule 43.8. Note that the name is required but not the signature.

CONTENTS OF THE INTERNATIONAL SEARCH REPORT

The international search report (PCT Rule 43) contains, among other things, the citations of the documents considered to be relevant (PCT Rule 43.5 and Administrative Instructions Section 503), the classification of the subject matter of the invention (PCT Rule 43.3 and Administrative Instructions Section 504) and an indication of the fields searched (PCT Rule 43.6). Citations of particular relevance must be specially indicated (Administrative Instructions Section 505); citations of certain specific categories of documents are also indicated (Administrative Instructions Section 507); citations which are not relevant to all the claims must be cited in relation to the claim or claims to which they are relevant (Administrative Instructions Section 508); if only certain passages of the cited document are particularly relevant, they must be identified, for example, by indicating the page, the column or the lines, where the passage appears.

1844.01 Time for the International Search Report

Publication of the international application occurs at 18 months from the earliest priority date or, where

there is no priority date, 18 months from the international application filing date. The Office goal is to have the search report mailed in sufficient time to reach the International Bureau by the end of 16 months from the priority date or 9 months from the filing date if no priority claim is made. This is necessary since the technical preparations for publication are completed by 17.5 months from the earliest priority date. In view of the treaty mandated publication and the time needed for technical preparation, the Office sets time periods for completion of the search report which will ensure sufficient time to complete internal processing and review and achieve receipt of search report at the International Bureau by the 16th month from the priority date. See PCT Rule 42.1 for time limit for the search.

Thus, as a matter of practice, each Technology Center tends to set its internal time period for completion of the search report to meet the time limits set by the International Application Processing Division. The International Application Processing Division sets its time for completion to ensure adequate time for review, corrections (where necessary) and mailing.

The date of transmittal of the search report becomes critical for applicants since it starts the 2 month period for submission of amendments to the claims under PCT Article 19. See PCT Rule 46.1.

The Patent Cooperation Treaty is extremely date sensitive and for that reason, examiners are encouraged to complete the international search and prepare the search report promptly after receipt. Monitoring and tracking procedures have been devised to minimize the risk of late search reports and/or date transmission thereof.

1846 Sections of the Articles, Regulations, and Administrative Instructions Under the PCT Relevant to the International Search

PCT Articles 15 - 20 (Appendix T);

PCT Rules 33 - 47 (Appendix T); and

Administrative Instructions Sections 501 - 516 (Appendix AI).

1847 Refund of International Search Fee

37 CFR 1.446. *Refund of international application filing and processing fees.*

(a) Money paid for international application fees, where paid by actual mistake or in excess, such as a payment not required by law or treaty and its regulations, may be refunded. A mere change of purpose after the payment of a fee will not entitle a party to a refund of such fee. The Office will not refund amounts of twenty-five dollars or less unless a refund is specifically requested and will not notify the payor of such amounts. If the payor or party requesting a refund does not provide the banking information necessary for making refunds by electronic funds transfer, the Office may use the banking information provided on the payment instrument to make any refund by electronic funds transfer.

(b) Any request for refund under paragraph (a) of this section must be filed within two years from the date the fee was paid. If the Office charges a deposit account by an amount other than an amount specifically indicated in an authorization under § 1.25(b), any request for refund based upon such charge must be filed within two years from the date of the deposit account statement indicating such charge and include a copy of that deposit account statement. The time periods set forth in this paragraph are not extendable.

(c) Refund of the supplemental search fees will be made if such refund is determined to be warranted by the Commissioner or the Commissioner's designee acting under PCT Rule 40,2(c).

(d) The international and search fees will be refunded if no international filing date is accorded or if the application is withdrawn before transmittal of the record copy to the International Bureau (PCT Rules 15.6 and 16.2). The search fee will be refunded if the application is withdrawn before transmittal of the search copy to the International Searching Authority. The transmittal fee will not be refunded.

(e) The handling fee (§ 1.482(b)) will be refunded (PCT Rule 57.6) only if:

(1) The Demand is withdrawn before the Demand has been sent by the International Preliminary Examining Authority to the International Bureau, or

(2) The Demand is considered not to have been submitted (PCT Rule 54.4(a)).

Although 37 CFR 1.446(a) indicates that a "mere change of purpose after the payment of a fee will not entitle a party to a refund of such fee," 37 CFR 1.446(d) and (e) contain exceptions to this general statement.

According to 37 CFR 1.446(d), the search fee will be refunded if no international filing date is accorded or if the application is withdrawn before the search copy is transmitted to the International Searching Authority. The transmittal fee will not be refunded.

According to 37 CFR 1.446(e), the handling fee will be refunded if the Demand is withdrawn before the Demand has been sent by the International Prelim-

inary Examining Authority to the International Bureau.

Refund of the supplemental search fee will be made if the applicant is successful in a protest (filed pursuant to 37 CFR 1.477) to a holding of lack of unity of invention. The supplemental search fee must be paid and be accompanied by (1) a protest and (2) a request for refund of the supplemental search fee.

Any request for refund of the search fee made after the search copy has been transmitted to the International Searching Authority must be directed to the International Searching Authority and not to the Receiving Office. This is clearly necessary where applicant has chosen the European Patent Office as the International Searching Authority.

1848 Sequence Listings

PCT Rule 13^{ter}.

Nucleotide and/or Amino Acid Sequence Listings

13^{ter}.1. Sequence Listing for International Authorities

(a) Where the International Searching Authority finds that the international application contains disclosure of one or more nucleotide and/or amino acid sequences but:

(i) the international application does not contain a sequence listing complying with the standard provided for in the Administrative Instructions, that Authority may invite the applicant to furnish to it, within a time limit fixed in the invitation, a sequence listing complying with that standard;

(ii) the applicant has not already furnished a sequence listing in computer readable form complying with the standard provided for in the Administrative Instructions, that Authority may invite the applicant to furnish to it, within a time limit fixed in the invitation, a sequence listing in such a form complying with that standard.

(b) *[Deleted]*

(c) If the applicant does not comply with an invitation under paragraph (a) within the time limit fixed in the invitation, the International Searching Authority shall not be required to search the international application to the extent that such noncompliance has the result that a meaningful search cannot be carried out.

(d) Where the International Searching Authority finds that the description does not comply with Rule 5.2(b), it shall invite the applicant to file the required correction. Rule 26.4 shall apply *mutatis mutandis* to any correction offered by the applicant. The International Searching Authority shall transmit the correction to the receiving Office and to the International Bureau.

(e) Paragraphs (a) and (c) shall apply *mutatis mutandis* to the procedure before the International Preliminary Examining Authority.

(f) Any sequence listing not contained in the international application as filed shall not, subject to Article 34, form part of the international application.

*PCT Administrative Instruction Section 513.
Sequence Listings*

(a) Where the International Searching Authority receives a correction of a defect under Rule 13^{ter}.1(d), it shall:

(i) indelibly mark, in the upper right-hand corner of each replacement sheet, the international application number and the date on which that sheet was received;

(ii) indelibly mark, in the middle of the bottom margin of each replacement sheet, the words "SUBSTITUTE SHEET (RULE 13^{ter}.1(d))" or their equivalent in the language of publication of the international application;

(iii) indelibly mark on the letter containing the correction, or accompanying any replacement sheet, the date on which that letter was received;

(iv) keep in its files a copy of the letter containing the correction or, when the correction is contained in a replacement sheet, the replaced sheet, a copy of the letter accompanying the replacement sheet, and a copy of the replacement sheet;

(v) promptly transmit any letter and any replacement sheet to the International Bureau, and a copy thereof to the receiving Office.

(b) Where the international search report is based on a sequence listing that was not contained in the international application as filed but was furnished subsequently to the International Searching Authority, the international search report shall so indicate.

(c) Where a meaningful international search cannot be carried out because a sequence listing is not available to the International Searching Authority in the required form, that Authority shall so state in the international search report.

(d) The International Searching Authority shall indelibly mark, in the upper right-hand corner of the first sheet of any sequence listing in printed form which was not contained in the international application as filed but was furnished subsequently to that Authority, the words "SUBSEQUENTLY FURNISHED SEQUENCE LISTING" or their equivalent in the language of publication of the international application.

(e) The International Searching Authority shall keep in its files:

(i) any sequence listing in printed form which was not contained in the international application as filed but was furnished subsequently to that Authority; and

(ii) any sequence listing in computer readable form.

Where an international application contains disclosure of a nucleotide and/or amino acid sequence, the description must contain a listing of the sequence complying with the standard specified in the Administrative Instructions. See MPEP § 1823.02. If the International Searching Authority finds that an international application contains such a disclosure but that the description does not include such a listing or that the listing included does not comply with that standard, the International Searching Authority may

invite the applicant to furnish a listing complying with that standard.

If the International Searching Authority finds that a sequence listing is not in a computer readable form provided for in the Administrative Instructions, it may invite the applicant to furnish a listing to it in such a form. Again, the International Searching Authority would invite the applicant to supply the computer readable diskette or other acceptable electronic medium.

An invitation from the International Searching Authority to furnish a sequence listing complying with the standard specified in the Administrative Instructions, will specify a time limit for complying with the invitation. Any sequence listing furnished by the applicant must be accompanied by a statement to the effect that the listing does not include matter which goes beyond the disclosure in the international application as filed. If the applicant does not comply within that time limit, the search undertaken by the International Searching Authority may be restricted.

If the applicant wishes to include such a listing in the text of the description itself, appropriate amendments may be made later under PCT Article 34, provided that the applicant files a Demand for international preliminary examination.

The United States Receiving Office has not notified the International Bureau under Administrative Instructions Section 801(b) that it is prepared to accept the filing in computer readable form (CRF) of the sequence listing part of international applications under Administrative Instructions Section 801(a). However, Administrative Instructions Section 801(c) permits a receiving Office that has not notified the IB under Administrative Instructions Section 801(b) to decide in a particular case to accept such sequence listing filings. The RO/US will accept applications where the sequence listing is filed using CD-R or CD-ROM as the electronic medium, and where no paper copy of the sequence listing part is submitted. The application must be filed in accordance with the Guidelines set forth in MPEP § 1823.02, subsection II. A in order to be accepted. Under Administrative Instructions Section 803, there is a significant cost savings if such a submission is accepted. In such a case, the electronic submission counts as 400 sheets in addition to the actual number of sheets of the Request, description excluding the sequence listing part

thereof, claims, abstract and drawings. In such a case, four copies of the electronic submission are required. One copy goes to the IB as part of the Record copy; the second copy becomes part of the Home copy; the third copy becomes part of the Search copy; and the fourth copy goes to the Scientific and Technical Information Center (STIC) as the CRF. See MPEP § 1823.02.

1849 Subject Matter Excluded from International Search

The examiner is not required to perform an international search on claims which relate to any of the following subject matter:

- (A) Scientific and mathematical theories;
- (B) Plant or animal varieties or essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes;
- (C) Schemes, rules or methods of doing business, performing purely mental acts or playing games;
- (D) Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods;
- (E) Mere presentation of information; and
- (F) Computer programs to the extent that the Authority is not equipped to search prior art concerning such programs.

See PCT Rule 39. In addition, the examiner is not required to search the international application, to the extent that a meaningful search cannot be carried out, in certain cases where a nucleotide and/or amino acid sequence listing is not furnished in accordance with the prescribed standard or in a computer readable form. See PCT Administrative Instructions Section 513(c). However, the U.S. Patent and Trademark Office has declared that it will search and examine all subject matter searched and examined in U.S. national applications. If none of the claims are required to be searched, the examiner will declare that no search report will be established using form PCT/ISA/203. It should, nevertheless, be noted that the lack of an international search report in such a case does not, in itself, have any influence on the validity of the international application, the processing of which, including its communication to the designated Offices, continues.

1850 Unity of Invention Before the International Searching Authority

PCT Rule 40.

Lack of Unity of Invention (International Search)

40.1. Invitation to Pay

The invitation to pay additional fees provided for in Article 17(3)(a) shall specify the reasons for which the international application is not considered as complying with the requirement of unity of invention and shall indicate the amount to be paid.

40.2. Additional Fees

(a) The amount of the additional fee due for searching under Article 17(3)(a) shall be determined by the competent International Searching Authority.

(b) The additional fee due for searching under Article 17(3)(a) shall be payable direct to the International Searching Authority.

(c) Any applicant may pay the additional fee under protest, that is, accompanied by a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive. Such protest shall be examined by a three-member board or other special instance of the International Searching Authority or any competent higher authority, which, to the extent that it finds the protest justified, shall order the total or partial reimbursement to the applicant of the additional fee. On the request of the applicant, the text of both the protest and the decision thereon shall be notified to the designated Offices together with the international search report. The applicant shall submit any translation thereof with the furnishing of the translation of the international application required under Article 22.

(d) The three-member board, special instance or competent higher authority, referred to in paragraph (c), shall not comprise any person who made the decision which is the subject of the protest.

(e) Where the applicant has, under paragraph (c), paid an additional fee under protest, the International Searching Authority may, after a prior review of the justification for the invitation to pay an additional fee, require that the applicant pay a fee for the examination of the protest ("protest fee"). The protest fee shall be paid within one month from the date of the notification to the applicant of the result of the review. If the protest fee is not so paid, the protest shall be considered withdrawn. The protest fee shall be refunded to the applicant where the three-member board, special instance or higher authority referred to in paragraph (c) finds that the protest was entirely justified.

40.3. Time Limit

The time limit provided for in Article 17(3)(a) shall be fixed, in each case, according to the circumstances of the case, by the International Searching Authority; it shall not be shorter than 15 or 30 days, respectively, depending on whether the applicant's address is in the same country as or in a different country from that in

which the International Searching Authority is located, and it shall not be longer than 45 days, from the date of the invitation.

*PCT Administrative Instruction Section 502.
Transmittal of Protest Against Payment of Additional Fee
and Decision Thereon Where International Application Is
Considered to Lack Unity of Invention*

The International Searching Authority shall transmit to the applicant, preferably at the latest together with the international search report, any decision which it has taken under Rule 40.2(c) on the protest of the applicant against payment of an additional fee where the international application is considered to lack unity of invention. At the same time, it shall transmit to the International Bureau a copy of both the protest and the decision thereon, as well as any request by the applicant to forward the texts of both the protest and the decision thereon to the designated Offices.

37 CFR 1.475. Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made

without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

37 CFR 1.477. Protest to lack of unity of invention before the International Searching Authority.

(a) If the applicant disagrees with the holding of lack of unity of invention by the International Searching Authority, additional fees may be paid under protest, accompanied by a request for refund and a statement setting forth reasons for disagreement or why the required additional fees are considered excessive, or both (PCT Rule 40.2(c)).

(b) Protest under paragraph (a) of this section will be examined by the Commissioner or the Commissioner's designee. In the event that the applicant's protest is determined to be justified, the additional fees or a portion thereof will be refunded.

(c) An applicant who desires that a copy of the protest and the decision thereon accompany the international search report when forwarded to the Designated Offices may notify the International Searching Authority to that effect any time prior to the issuance of the international search report. Thereafter, such notification should be directed to the International Bureau (PCT Rule 40.2(c)).

THE REQUIREMENT FOR "UNITY OF INVENTION"

Any international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (PCT Article 3(4)(iii) and 17(3)(a), PCT Rule 3.1, and 37 CFR 1.475). Observance of this requirement is checked by the International Searching Authority and may be relevant in the national (or regional) phase.

The decision in *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 231 USPQ 590 (E.D. Va. 1986) held that the Patent and Trademark Office interpretation of 37 CFR 1.141(b)(2) as applied to unity of invention determinations in international applications was not in accordance with the Patent Cooperation Treaty and its implementing regulations. In the Caterpillar international application, the USPTO acting as an International Searching Authority, had held lack of unity of invention between a set of claims directed to a process for forming a sprocket and a set of claims drawn to an apparatus (die) for forging a sprocket. The court stated that it was an unreasonable interpretation to say that the expression "specifically designed" as found in former PCT Rule 13.2(ii) means that the process and apparatus have unity of invention if they can only be used with each other, as was set forth in MPEP § 806.05(e).

Therefore, when the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. No change was made in restriction practice in United States national applications filed under 35 U.S.C. 111 outside the PCT.

In applying PCT Rule 13.2 to international applications as an International Searching Authority, an International Preliminary Examining Authority and to national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2.

PCT Rule 13.2, as it was modified effective July 1, 1992, no longer specifies the combinations of categories of invention which are considered to have unity of invention. Those categories, which now appear as a part of Annex B to the Administrative Instructions, has been substituted with a statement describing the method for determining whether the requirement of unity of invention is satisfied. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

A. *Independent and Dependent Claims*

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classi-

fication of claims according to the subject matter of the invention claimed, for example, product, process, use or apparatus or means, etc.).

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

This method for determining whether unity of invention exists is intended to be applied even before the commencement of the international search. Where a search of the prior art is made, an initial determination of unity of invention, based on the assumption that the claims avoid the prior art, may be reconsidered on the basis of the results of the search of the prior art.

B. *Illustrations of Particular Situations*

There are three particular situations for which the method for determining unity of invention contained in PCT Rule 13.2 is explained in greater detail:

- (A) Combinations of different categories of claims;
- (B) So-called "Markush practice"; and
- (C) Intermediate and final products.

Principles for the interpretation of the method contained in PCT Rule 13.2, in the context of each of those situations are set out below. It is understood that the principles set out below are, in all instances, interpretations of and not exceptions to the requirements of PCT Rule 13.2.

Examples to assist in understanding the interpretation on the three areas of special concern referred to in the preceding paragraph are set out below.

C. *Combinations of Different Categories of Claims*

The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(A) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product; or

(B) In addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process; or

(C) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process, it being understood that a process is specially adapted for the manufacture of a product if it inherently results in the product and that an apparatus or means is specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art.

Thus, a process shall be considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and claimed process. The words "specially adapted" are not intended to imply that the product could not also be manufactured by a different process.

Also an apparatus or means shall be considered to be specifically designed for carrying out a claimed process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. Consequently, it would not be sufficient that the apparatus or means is merely capable of being used in carrying out the

claimed process. However, the expression "specifically designed" does not imply that the apparatus or means could not be used for carrying out another process, nor that the process could not be carried out using an alternative apparatus or means.

D. *"Markush Practice"*

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(C)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.

In paragraph (C)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

E. Intermediate and Final Products

The situation involving intermediate and final products is also governed by PCT Rule 13.2.

The term *intermediate* is intended to mean intermediate or starting products. Such products have the ability to be used to produce final products through a physical or chemical change in which the intermediate loses its identity.

Unity of invention shall be considered to be present in the context of intermediate and final products where the following two conditions are fulfilled:

(A) The intermediate and final products have the same essential structural element, in that:

(1) The basic chemical structures of the intermediate and the final products are the same, or

(2) The chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product; and

(B) The intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same essential structural element.

Unity of invention may also be considered to be present between intermediate and final products of which the structures are not known, for example, as between an intermediate having a known structure and a final product the structure of which is not known, or as between an intermediate of unknown structure and a final product of unknown structure. In order to satisfy unity in such cases, there shall be sufficient evidence to lead one to conclude that the intermediate and final products are technically closely interrelated as, for example, when the intermediate contains the same essential element as the final prod-

uct or incorporates an essential element into the final product.

It is possible to accept in a single international application different intermediate products used in different processes for the preparation of the final product, provided that they have the same essential structural element.

The intermediate and final products shall not be separated, in the process leading from one to the other, by an intermediate which is not new.

If the same international application claims different intermediates for different structural parts of the final product, unity shall not be regarded as being present between the intermediates.

If the intermediate and final products are families of compounds, each intermediate compound shall correspond to a compound claimed in the family of the final products. However, some of the final products may have no corresponding compound in the family of the intermediate products so that the two families need not be absolutely congruent.

As long as unity of invention can be recognized applying the above interpretations, the fact that, besides the ability to be used to produce final products, the intermediates also exhibit other possible effects or activities shall not affect the decision on unity of invention.

PCT Rule 13.3 requires that the determination of the existence of unity of invention be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

PCT Rule 13.3 is not intended to constitute an encouragement to the use of alternatives within a single claim, but is intended to clarify that the criterion for the determination of unity of invention (namely, the method contained in PCT Rule 13.2) remains the same regardless of the form of claim used.

PCT Rule 13.3 does not prevent an International Searching or Preliminary Examining Authority or an Office from objecting to alternatives being contained within a single claim on the basis of considerations such as clarity, the conciseness of claims or the claims fee system applicable in that Authority or Office.

LACK OF UNITY OF INVENTION

See Annex B of the Administrative Instructions for examples of unity of invention.

The search fee which the applicant is required to pay is intended to compensate the International Searching Authority for carrying out an international search on the international application, but only where the international application meets the "requirement of unity of invention". That means that the international application must relate to only one invention or must relate to a group of inventions which are so linked as to form a single general inventive concept (PCT Articles 3(4)(iii) and 17(3)(a)).

If the International Searching Authority finds that the international application does not comply with the requirement of unity of invention, the applicant will be invited to pay additional search fees. The International Searching Authority will specify the reasons for its findings and indicate the number of additional fees to be paid (PCT Rules 40.1, 40.2(a) and (b)). Such additional fees are payable directly to the International Searching Authority which is conducting the search, either the United States Patent and Trademark Office or European Patent Office, within the time limit fixed, which must not be shorter than 15 days, if the applicant's address is in the same country as the International Searching Authority; or 30 days, if applicant's address is in a country different than the country of the International Searching Authority; and not longer than 45 days from the date of the invitation (PCT Rule 40.3). The search fee amounts for the U.S. and the European Patent Office are found in each weekly edition of the *Official Gazette*.

The International Searching Authority will establish the international search report on those parts of international application which relate to the "main invention," that is, the invention or the group of inventions so linked as to form a single general inventive concept first mentioned in the claims (PCT Article 17(3)(a)). Moreover, the international search report will be established also on those parts of the international application which relate to any invention (or any group of inventions so linked as to form a single general inventive concept) in respect of which the applicant has paid any additional fee within the prescribed time limits.

Any applicant may pay the additional fee under protest, that is, accompanied by a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive

(PCT Rule 40.2(c)). Any such protest filed with the U.S. International Searching Authority will be examined and decided by a Technology Center Director (37 CFR 1.477). To the extent that the applicant's protest is found to be justified, total or partial reimbursement of the additional fee will be made. On the request of the applicant, the text of both the protest and the decision thereon is sent to the designated Offices together with the international search report (37 CFR 1.477).

Where, within the prescribed time limit, the applicant does not pay any additional fees or only pays some of the additional fees indicated, certain parts of the international application will consequently not be searched. The lack of an international search report in respect of such parts of the international application will, in itself, have no influence on the validity of the international application and processing of the international application will continue, both in the international and in the national (regional) phases. The unsearched claims, upon entry into the national stage, will be considered by the examiner and may be the subject of a holding of lack of unity of invention.

See MPEP § 1875.01 for telephone unity practice. It applies in the same manner under Chapter I.

UNITY OF INVENTION - NUCLEOTIDE SEQUENCES

Under 37 CFR 1.475 and 1.499 *et seq.*, when claims do not comply with the requirement of unity of invention, i.e., when the claimed subject matter does not involve "one or more of the same or corresponding special technical features," 37 CFR 1.475(a), an additional fee is required to maintain the claims in the same application. 37 CFR 1.476 (b).

The Commissioner has decided *sua sponte* to partially waive 37 CFR 1.475 and 1.499 *et seq.* to permit applicants to claim up to ten (10) nucleotide sequences that do not have the same or corresponding special technical feature without the payment of an additional fee. The PCT permits inventions that lack unity of invention to be maintained in the same international application for payment of additional fees. Thus, in international applications, for each group for which applicant has paid additional international search and/or preliminary examination fees, the USPTO has determined that up to four (4) such additional sequences per group is a reasonable number for examination. Further, claims directed to the selected

sequences will be examined with claims drawn to any sequence combinations which have a common technical feature with the selected sequences. Nucleotide sequences encoding the same protein are considered to satisfy the unity of invention standard and will continue to be examined together.

See MPEP § 803.04 for examples of nucleotide sequence claims impacted by this partial waiver of 37 CFR 1.475 and 1.499 *et seq.*

1851 Identification of Patent Documents

The examiner, in completing the international search report as well as the Chapter II written opinion and final report, is required to cite the references in accordance with the provisions of Administrative Instructions 503 and 611. These sections of the Administrative Instructions require reference citations to include, in addition to other information which is apparent from the forms which the examiner fills out, an indication of the two-letter country code of the country or entity issuing or publishing the document and the standard code for identifying the kind of patent document. The discussion which follows is limited to the identification of patent documents (and nonpatent publications) and a listing of the two-letter country codes for countries or other entities which issue or publish industrial property information.

The standard codes for identifying different kinds of patent documents are found in the "WIPO Handbook on Industrial Property Information and Documentation" - WIPO Standard ST.16 which is published by the World Intellectual Property Organization. The listing is extensive. The Special Program Examiners in each Technology Center (TC) have a complete copy of Standard ST.16. It is also accessible on WIPO's web site (<http://www.wipo.int/scit/en/>) under the heading "WIPO Standards and Other Documentation." Provided herein is an abbreviated version representing the countries and codes commonly used by the examiner in preparing search reports.

U.S. patents published before January 2, 2001 are Code A documents generally. Beginning with patents published on January 2, 2001, U.S. patents are Code B documents. Patent Application Publications, first published on March 15, 2001, are Code A documents. Reexamination certificates published before January 2, 2001 are Code B documents. Reexamination certificates published on or after January 2, 2001 are Code

C documents. Tables providing a complete list of the kind codes of patents and other documents published by the USPTO are included in MPEP § 901.04(a). All nonpatent literature documents are Code N. Numerical designations are sometimes found on published documents along with the letter code designation. These should be used by the examiner only if such numerical designation is on the document. Numerical codes along with letter codes can be found, for example, on certain published patent documents such as the German Offenlegungsschrift and published international applications. If numerical designations are not provided, the examiner should use only the letter code designation.

The most commonly cited documents are patents and published patent applications. A guideline for the citation of such documents is listed below. The listing is indicated in the order in which the elements should be listed.

In the case of a patent or published patent application:

(A) The Office that issued the document, by the two letter code (WIPO Standard ST.3);

(B) The number of the document as given to it by the Office that issued it (for Japanese patent documents the indication of the year of the reign of the Emperor must precede the serial number of the patent document);

(C) The kind of document, by the appropriate symbols as indicated on the original document or as given in Appendix II to WIPO Standard ST.16;

(D) The name of the patentee or applicant (in capital letters, where appropriate, abbreviated);

(E) The date of publication of the cited patent document indicated thereon;

(F) Where applicable, the pages, columns or lines where the relevant passages appear, or the relevant figures of the drawings.

The following examples illustrate the citation of a patent document as indicated above:

JP 50-14535 B (NCR CORP.) 28 May 1975 (28.05.75), see column 4, lines 3 to 27.

DE 3744403 A1 (A. JOSEF) 29 August 1991 (29-08-91), page 1, abstract.

US 4,540,573 A (NEURATH et al.) 10 September 1985 (10/09/85), see entire document, especially column 1, lines 10-23.

STANDARD CODE FOR THE IDENTIFICATION OF DIFFERENT KINDS OF PATENT DOCUMENTS

The Code is subdivided into mutually exclusive groups of letters. The groups characterize patent doc-

uments, nonpatent literature documents (N), and restricted documents (X). Groups 1-7 comprise letters enabling identification of documents pertaining to different publication levels.

Group 1	Use for the primary or major series of patent documents (excluding the utility model documents of Group 2 and the special series of patent documents of Group 3, below)
A	First publication level
B	Second publication level
C	Third publication level
Group 2	Use for utility model documents having a numbering series other than the documents of Group 1
U	First publication level
Y	Second publication level
Z	Third publication level
Group 3	Use for major special types of patent documents
M	Medicament patent documents
P	Plant patent documents
S	Design patent documents
Group 4	Use for special types of patent documents or documents derived from/relating to patent applications and not covered by Groups 1 to 3 above:
L	Documents, not covered by letter code W, relating to patent documents and containing bibliographic information and only the text of an abstract and/or claim(s) and, where appropriate, a drawing.
R	Separately published search reports

T	Publication, for information or other purposes, of the translation of the whole or part of a patent document already published by another office or organization
W	Documents relating to utility model documents falling in Group 2 and containing bibliographic information and only the text of an abstract and/or claim(s) and, where appropriate, a drawing
Group 5	Use for series of patent documents not covered by Groups 1 to 4, above
E	First publications level
F	Second publication level
G	Third publication level
Group 6	Use for series of patent documents or documents derived from/relating to patent applications not covered by Groups 1 to 5 above, according to the special requirements of each industrial property office
H	
I	
Group 7	Other
N	Non-patent literature documents
X	Documents restricted to the internal use of industrial property offices

List of Examples of Patent Documents, Previously and Currently Published, or Intended To Be Published, Divided According to Code

CODE: A	Patent Documents Identified as Primary or Major Series — First Publication Level
EXAMPLES:	
Australia	Standard or petty patent application
Austria	Patent application (Aufgebot)
Belgium	Brevet d'invention/ Uitvindingsoctrooi
Belgium	Brevet de perfectionnement/ Verbeteringsoctrooi
Belgium	Demande de brevet d'invention/ Uitvindingsoctrooiaanvraag
Brazil	Pedido de privilégio (Unexamined patent application for invention)
Bulgaria	Patentna zjavka predostavena za publichna inspektzija (Patent application made available to the public)
Canada	Patent (prior to October 1, 1989, under previous Patent Act)
Canada	Patent application laid open to public inspection under amended Patent Act, as of October 1, 1989)

China	Patent application published before the examination
Cuba	Patent application
Czechoslovakia	Patent application
Czechoslovakia	Inventor's certificate application
Czech Republic	Přihláška Vynálezu (Application for the protection of an invention — patent)
Denmark	Almindeligt tilgaengelig patentansøgning
Egypt	Patent specification
European Patent Office	Patent application published with search report
European Patent Office	Patent application published without search report
European Patent Office	Separate publication of the search report
Finland	Julkiseksi tullut patenttihakemus-Allmänt tillgänglig patentansökan
France	Brevet d'invention (old law)
France	Brevet d'invention première et unique publication
France	Certificat d'addition à un brevet d'invention, première et unique publication
France	Certificat d'utilité, première et unique publication

France	Certificat d'addition à un certificat d'utilité, première et unique publication	India	Patent specification
France	Demande de brevet d'invention, première publication	Ireland	Patent specification
France	Demande de certificat d'addition à un brevet d'invention, première publication	Israel	Bakashal lepatent (Application of patent for invention)
France	Demande de certificat d'utilité, première publication	Italy	Domanda di brevetto pubblicata
France	Demande de certificat d'addition à un certificat d'utilité, première publication	Japan	Kôkai tokkyo kôhō
Germany	Offenlegungsschrift	Japan	Kôhyo tokkyo kôhō
Germany (document published by the Patent Office of the former GDR)	Patentschrift (Ausschlusspatent), patent granted in accordance with paragraph 17.1 of the Patent Law of the former German Democratic Republic of October 27, 1983	Luxembourg	Brevet d'invention
Germany (document published by the Patent Office of the former GDR)	Patentschrift (Wirtschaftspatent), patent granted in accordance with paragraph 17.1 of the Patent Law of the former German Democratic Republic of October 27, 1983	Luxembourg	Certificat d'addition à un brevet d'invention
Greece	Diploma evresitechnias	Malawi	Patent application
Greece	Etisi gia Diploma evresitechnias	Mexico	Patent (Granted patent — according to old law)
Greece	Etisi gia Diploma tropopiisis	Mexico	Patent application (according to new law)
Hungary	Patent application	Mongolia	Patent
		Morocco	Brevet d'invention
		Netherlands	Terinzagegeleging
		New Zealand	Patent application
		Norway	Alment tilgjengelige patentsøknader
		OAPI	Brevet d'invention
		Pakistan	Patent specification
		Peru	Patente de invención
		Philippines	Patent for invention
		Poland	Opis zgłoszeniowy wynalazku
		Portugal	Pedido de patente de invenção
		Republic of Korea	Konggae t'ukho kongbo

Romania	Descrierea inventiei	Switzerland	Auslegeschrift/Fascicule de la demande/Fascicolo della domanda (Patent Application published and pertaining to the technical fields for which search and examination as to novelty are made)
Romania	Cerere de brevet de invente	Switzerland	Patentschrift/Fascicule du brevet/Fascicolo del brevetto (Patent published and pertaining to the technical fields for which neither search nor examination as to novelty are made)
Russian Federation	Zayavka na izobreteniyе (Published application for invention)	Tunisia	Talab Baraat Ekhtiraâ
Slovakia	Prihláska vynálezu (Published application for invention)	Turkey	Patent tarifnamesi
Slovenia	Patent	United Kingdom	Patent specification (old Law; not printed on documents)
Slovenia	Patent s skraj ³ anim trajanjem (Short-term patent)	United Kingdom	Patent application (new Law)
Soviet Union	Opisanie izobreteniya k patentu	United States of America	Patent (published before January 2, 2001)
Soviet Union	Opisanie izobreteniya k avtorskomu svidetelstvu	United States of America	Patent application publication (published beginning March 15, 2001)
Spain	Patente de invención	World Intellectual Property Organization	International application published with or without the international search report
Spain	Solicitud de patente con informe sobre el estado de la técnica (Patent application published with search report)	Yugoslavia	Patenta prijava koja se moze razgledati
Spain	Solicitud de patente sin informe sobre el estado de la técnica (Patent application published without search report)		
Sweden	Allmant tillgänglig patentansökan		

CODE: B	Patent Documents Identified as Primary or Major Series -Second Publication Level
EXAMPLES:	
Australia	Accepted standard or petty patent
Austria	Patentschrift
Belgium	Brevet d'invention/ Uitvindingsoctrooi
Brazil	Patente (granted patent of invention)
Canada	Reissue patent (prior to October 1, 1989, under previous Patent Act)
Cuba	Patente de invención
Czechoslovakia	Popis vynalezu k patentu
Czechoslovakia	Popis vynalezu k autorskému osvědčení
Czech Republic	Patentový spis (patent specification)
Denmark	Fremlaeggelseskraft (old Law)
Denmark	Patentskrift
Denmark	Patentskrift (amended)
Finland	Kuulutusjulkaisu - Utläggningsskrift
France	Brevet d'invention, deuxième publication de l'invention
France	Certificat d'addition à un brevet d'invention, deuxième publication de l'invention

France	Certificat d'utilité, deuxième publication de l'invention
France	Certificat d'addition à un certificat d'utilité, deuxième publication de l'invention
Germany	Auslegeschrift
Germany (document published by the Patent Office of the former GDR)	Patentschrift (Ausschlusspatent), patent granted in accordance with paragraph 18.1 of the Patent Law of the former German Democratic Republic of October 27, 1983
Germany (document published by the Patent Office of the former GDR)	Patentschrift (Wirtschaftspatent), patent granted in accordance with paragraph 18.1 of the Patent Law of the former German Democratic Republic of October 27, 1983
Greece	Diploma evresitechnias (Patent of invention)
Greece	Diploma tropopiisis (Patent of addition)
Hungary	Szabadalmi leiras
Indonesia	Patent granted in accordance with article 61 of the Patent Law, Number 6 of 1989 Concerning Patents
Japan	Tokkyo kôhô
Netherlands	Openbaar gemaakte octrooiaanvraag
Norway	Utlegningskrift
Poland	Opis patentowy

Portugal	Patente de invenção (Granted patent of published application)
Republic of Korea	T'ukho kongbo
Spain	Patente de invención con informe sobre el estado de la técnica (Patent specification with search report)
Spain	Patente de invención con examen previo (Patent specification published after examination)
Sweden	Utläggningsskrift
Switzerland	Patentschrift/Fascicule du brevet/Fascicolo del brevetto (Patent published and pertaining to the technical fields for which search and examination as to novelty are made)
United Kingdom	Amended patent specification (old Law)
United Kingdom	Patent specification (new Law)
United States of America	Reexamination certificate (published prior to January 2, 2001)
United States of America	Patent (published on or after January 2, 2001)

CODE: C	Patent Documents Identified as Primary or Major Series - Third Publication Level
EXAMPLES:	
Argentina	Patente de invención (Patent)
Australia	Standard or petty patent, amended after acceptance
Canada	Patent (under amended Patent Act, as of October 1, 1989)
Denmark	Patentskrift (old Law)
Finland	Patentti (Patent)
Germany	Patentschrift
Germany (document published by the Patent Office of the former GDR)	Patentschrift (Ausschlusspatent), Patent granted in accordance with paragraph 19 of the Patent Law of the former German Democratic Republic of October 27, 1983
Netherlands	Octrooi
Norway	Patent
Poland	Opis patentowy
Republic of Moldova	Patent specification
Romania	Brevet de inventie
Russian Federation	Patent na izobreteniyi (Patent for invention)
Sweden	Patentskrift
United Kingdom	Amended patent specification (new Law)

United States of America	Reexamination certificate (published on or after January 2, 2001)
Yugoslavia	Patentni spis (Patent specification)
CODE: E	Patent Documents Identified as Series Other Than the Documents Coded A, B, C, U, Y, Z, M, P, S, T, W, L or R - First Publication Level
EXAMPLES:	
Canada	Reissue patent (under amended Patent Act, as of October 1, 1989)
France	Certificat d'addition à brevet d'invention (old Law)
Sweden	Patentskrift i ändrad lydelse (Amended patent specification)
United States of America	Reissue patent
CODE: H	Patent Documents Identified in Series According to Special Requirements of Individual Industrial Property Offices
EXAMPLE:	
United States of America	Statutory invention registration

CODE: M	Medicament Patent Documents
EXAMPLES:	
France	Brevet spécial de médicament
France	Addition à un brevet spécial de médicament
CODE: P	Plant Patent Documents
EXAMPLE:	
United States of America	Plant patent
United States of America	Plant patent application publication
CODE: S	Design Patent Documents
EXAMPLES:	
Brazil	Pedido de privilégio (unexamined patent application for industrial model)
Russian Federation	Patent na promishlenniy obrazets (Design patent)
United States of America	Design patent

CODE: U	Utility Model Documents Having a Numbering Series Other Than the Documents Coded A, B or C— First Publication Level	Japan	Kôkai jitsuyô shin-an kôhô (Published unexamined utility model application)
EXAMPLES:		Japan	Tôroku jitsuyô shin-an kôhô (Published registered utility model application) (without substantive examination)
Austria	Gebrauchsmusterschrift (published with or without a search report)	Mexico	Utility model
Brazil	Pedido de privilégio (unexamined patent application for industrial model)	Poland	Opis zgłoszeniowy wzoru użytkowego
Bulgaria	Zajavka za polezni modeli predostavena za publiczna inspektzija (Utility model application made available to the public)	Portugal	Pedido de modelo de utilidade (Published application for a utility model)
Czech Republic	Užitný vzor (Utility model)	Republic of Korea	Konggae shilyong shin-an kongbo
Denmark	Almindeligt tilgængelig brugsmødelansøgning	Russian Federation	Svidetel'stvo na poleznuyu model (Certificate for utility model)
Denmark	Brugsmødel'skrift	Slovakia	Úžitkovy vzor (Utility model)
Finland	Hyödyllisyysmalli-Nyttighetsmodell (Utility model)	Spain	Solicitud de modelo de utilidad
Germany	Gebrauchsmuster	CODE: Y	Utility Model Documents Having a Numbering Series Other Than the Documents Coded A, B or C— Second Publication Level
Greece	Etisi gia Pistopiitiko Ipodigmatos Chrisimotitas (Utility model application)	EXAMPLES:	
Hungary	Hasznalati minta leiras (Utility model specification)	Brazil	Patente (granted patent of utility model)

Bulgaria	Opisanie na patent za polezen model (Description of a patent for utility model)
Denmark	Brugsmodelskrift
Denmark	Brugsmodelskrift (amended)
Greece	Pistopiitiko Ipodigmatos Chrisimotitas (Utility model)
Japan	Jitsuyô shin-an kôhô (Published examined utility model application)
Poland	Opis ochronny wzoru uzytkowego
Portugal	Modelo de utilidade (Granted utility model)
Republic of Korea	Shilyong shin-an kongbo (Utility model specification)
Spain	Modelo de utilidad
Spain	Model o de utilidad

Country Codes

The two-letter country codes listed below are set forth in WIPO Standard ST.3, which is published in the "WIPO Handbook on Industrial Property Information and Documentation" and is accessible via the internet at the WIPO website (www.wipo.org). WIPO Standard ST.3 provides, in Annex A, Section 1, a listing of two-letter country codes and/or organizational codes in alphabetic sequence of their short names for the states, other entities and intergovernmental organizations issuing or publishing industrial property documents. Codes for states or organizations that existed on January 1, 1978 but that no longer exist are provided in Annex B, Section 2. Annex B, Section 1 (not reproduced below) lists States for which the Codes have changed.

Annex A, Section 1

List of States, Other Entities and Intergovernmental Organizations, in Alphabetic Sequence of Their Short Names, and Their Corresponding Codes	
Afghanistan	AF
African Intellectual Property Organization (OAPI)	OA
African Regional Industrial Property Organization (ARIPO)	AP
Albania	AL
Algeria	DZ
Andorra	AD
Angola	AO
Anguilla	AI
Antigua and Barbuda	AG
Argentina	AR
Armenia	AM
Aruba	AW
Australia	AU
Austria	AT
Azerbaijan	AZ
Bahamas	BS
Bahrain	BH
Bangladesh	BD
Barbados	BB
Belarus	BY
Belgium	BE
Belize	BZ

Benelux Trademark Office (BBM) and Benelux Designs Office (BBDM)	BX	Croatia	HR
Benin	BJ	Cuba	CU
Bermuda	BM	Cyprus	CY
Bhutan	BT	Czech Republic	CZ
Bolivia	BO	Democratic People's Republic of Korea	KP
Bosnia and Herzegovina	BA	Democratic Republic of the Congo	CD
Botswana	BW	Denmark	DK
Bouvet Island	BV	Djibouti	DJ
Brazil	BR	Dominica	DM
Brunei Darussalam	BN	Dominican Republic	DO
Bulgaria	BG	East Timor	TP
Burkina Faso	BF	Ecuador	EC
Burundi	BI	Egypt	EG
Cambodia	KH	El Salvador	SV
Cameroon	CM	Equatorial Guinea	GQ
Canada	CA	Eritrea	ER
Cape Verde	CV	Estonia	EE
Cayman Islands	KY	Ethiopia	ET
Central African Republic	CF	Eurasian Patent Organization (EAPO)	EA
Chad	TD	European Community Trademark Office (See Office for Harmonization in the Internal Market)	EP
Chile	CL	European Patent Office (EPO)	EP
China	CN	Falkland Islands (Malvinas)	FK
Colombia	CO	Faroe Islands	FO
Comoros	KM	Fiji	FJ
Congo	CG	Finland	FI
Cook Islands	CK		
Costa Rica	CR		
Côte d'Ivoire	CI		

France	FR	Iraq	IQ
Gabon	GA	Ireland	IE
Gambia	GM	Israel	IL
Georgia	GE	Italy	IT
Germany	DE	Jamaica	JM
Ghana	GH	Japan	JP
Gibraltar	GI	Jordan	JO
Greece	GR	Kazakstan	KZ
Greenland	GL	Kenya	KE
Grenada	GD	Kiribati	KI
Guatemala	GT	Korea (See Democratic People's Republic of Korea; Republic of Korea)	
Guinea	GN	Kuwait	KW
Guinea-Bissau	GW	Kyrgyzstan	KG
Gulf Cooperation Council (see Patent Office of the Cooperation Council for the Arab States of the Gulf)		Laos	LA
Guyana	GY	Latvia	LV
Haiti	HT	Lebanon	LB
Holy See	VA	Lesotho	LS
Honduras	HN	Liberia	LR
Hong Kong (See The Hong Kong Special Administrative Region of The People's Republic of China)		Libya	LY
Hungary	HU	Liechtenstein	LI
Iceland	IS	Lithuania	LT
India	IN	Luxembourg	LU
Indonesia	ID	Macau	MO
International Bureau of the World Intellectual Property Organization (WIPO)	IB, WO	Madagascar	MG
Iran (Islamic Republic of)	IR	Malawi	MW
		Malaysia	MY
		Maldives	MV
		Mali	ML

Malta	MT	Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC)	GC
Mauritania	MR		
Mauritius	MU		
Mexico	MX	Peru	PE
Monaco	MC	Philippines	PH
Mongolia	MN	Poland	PL
Montserrat	MS	Portugal	PT
Morocco	MA	Qatar	QA
Mozambique	MZ	Republic of Korea	KR
Myanmar	MM	Republic of Moldova	MD
Namibia	NA	Romania	RO
Nauru	NR	Russian Federation	RU
Nepal	NP	Rwanda	RW
Netherlands	NL	Saint Helena	SH
Netherlands Antilles	AN	Saint Kitts and Nevis	KN
New Zealand	NZ	Saint Lucia	LC
Nicaragua	NI	Saint Vincent and the Grenadines	VC
Niger	NE	Samoa	WS
Nigeria	NG	San Marino	SM
Northern Mariana Islands	MP	Sao Tome and Principe	ST
Norway	NO	Saudi Arabia	SA
Office for Harmonization in the Internal Market (Trade- marks and Designs) (OHIM)	EM	Senegal	SN
Oman	OM	Seychelles	SC
Pakistan	PK	Sierra Leone	SL
Palau	PW	Singapore	SG
Panama	PA	Slovakia	SK
Papua New Guinea	PG	Slovenia	SI
Paraguay	PY	Solomon Islands	SB
		Somalia	SO

South Africa	ZA
South Georgia and the South Sandwich Islands	GS
Spain	ES
Sri Lanka	LK
Sudan	SD
Suriname	SR
Swaziland	SZ
Sweden	SE
Switzerland	CH
Syria	SY
Taiwan, Province of China	TW
Tajikistan	TJ
Tanzania (see United Republic of Tanzania)	
Thailand	TH
The Former Yugoslav Republic of Macedonia	MK
The Hong Kong Special Administrative Region of The People's Republic of China	HK
Togo	TG
Tonga	TO
Trinidad and Tobago	TT
Tunisia	TN
Turkey	TR
Turkmenistan	TM
Turks and Caicos Islands	TC
Tuvalu	TV
Uganda	UG
Ukraine	UA
United Arab Emirates	AE

United Kingdom	GB
United Republic of Tanzania	TZ
United States of America	US
Uruguay	UY
Uzbekistan	UZ
Vanuatu	VU
Vatican City State (See Holy See)	
Venezuela	VE
Viet Nam	VN
Virgin Islands (British)	VG
Western Sahara	EH
World Intellectual Property Organization (WIPO) (International Bureau of)	WO, IB
Yemen	YE
Yugoslavia	YU
Zambia	ZM
Zimbabwe	ZW
Annex B, Section 2	
List of States or Organizations That Existed on January 1, 1978, But That No Longer Exist	
Czechoslovakia	CS
Democratic Yemen	SY/YD
German Democratic Republic	DL/DD
International Patent Institute	IB
Soviet Union	SU

1852 International-Type Search*PCT Rule 41.**Earlier Search Other Than International Search***41.1. Obligation to Use Results; Refund of Fee**

If reference has been made in the request, in the form provided for in Rule 4.11, to an international-type search carried out under the conditions set out in Article 15(5) or to a search other than an international or international-type search, the International Searching Authority shall, to the extent possible, use the results of the said search in establishing the international search report on the international application. The International Searching Authority shall refund the search fee, to the extent and under the conditions provided for in the agreement under Article 16(3)(b) or in a communication addressed to and published in the Gazette by the International Bureau, if the international search report could wholly or partly be based on the results of the said search.

37 CFR 1.104. Nature of examination.**(a) Examiner's action.**

(3) An international-type search will be made in all national applications filed on and after June 1, 1978.

(4) Any national application may also have an international-type search report prepared thereon at the time of the national examination on the merits, upon specific written request therefor and payment of the international-type search report fee set forth in § 1.21(e). The Patent and Trademark Office does not require that a formal report of an international-type search be prepared in order to obtain a search fee refund in a later filed international application.

PCT Rule 41 provides that the applicant may request in a later filed international application that the report of the results of the international-type search, i.e., a search similar to an international search, but carried out on a national application (37 CFR 1.104(a)(3) and (a)(4)), be used in establishing an international search report on such international application. An international-type search is conducted on all U.S. national nonprovisional applications filed after June 1, 1978. Upon specific request, at the time of the examination of a U.S. national nonprovisional application and provided that the payment of the appropriate international-type search report fee has been made (37 CFR 1.21(e)) an international-type search report Form PCT/ISA/201 will also be prepared.

1853 Amendment Under PCT Article 19*PCT Article 19.**Amendment of the Claims before the International Bureau*

(1) The applicant shall, after having received the international search report, be entitled to one opportunity to amend the claims of the international application by filing amendments with the International Bureau within the prescribed time limit. He may, at the same time, file a brief statement, as provided in the Regulations, explaining the amendments and indicating any impact that such amendments might have on the description and the drawings.

(2) The amendments shall not go beyond the disclosure in the international application as filed.

(3) If the national law of any designated State permits amendments to go beyond the said disclosure, failure to comply with paragraph (2) shall have no consequence in that State.

*PCT Rule 46.**Amendment of Claims Before the International Bureau***46.1. Time Limit**

The time limit referred to in Article 19 shall be two months from the date of transmittal of the international search report to the International Bureau and to the applicant by the International Searching Authority or 16 months from the priority date, whichever time limit expires later, provided that any amendment made under Article 19 which is received by the International Bureau after the expiration of the applicable time limit shall be considered to have been received by that Bureau on the last day of that time limit if it reaches it before the technical preparations for international publication have been completed.

46.2. Where to File

Amendments made under Article 19 shall be filed directly with the International Bureau.

46.3. Language of Amendments

If the international application has been filed in a language other than the language in which it is published, any amendment made under Article 19 shall be in the language of publication.

46.4. Statement

(a) The statement referred to in Article 19(1) shall be in the language in which the international application is published and shall not exceed 500 words if in the English language or if translated into that language. The statement shall be identified as such by a heading, preferably by using the words "Statement under Article 19(1)" or their equivalent in the language of the statement.

(b) The statement shall contain no disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

46.5. Form of Amendments

The applicant shall be required to submit a replacement sheet for every sheet of the claims which, on account of an amendment or amendments under Article 19, differs from the sheet originally filed. The letter accompanying the replacement sheets shall draw attention to the differences between the replaced sheets and the replacement sheets. To the extent that any amendment results in the cancellation of an entire sheet, that amendment shall be communicated in a letter.

37 CFR 1.415. The International Bureau.

(a) The International Bureau is the World Intellectual Property Organization located at Geneva, Switzerland. It is the international intergovernmental organization which acts as the coordinating body under the Treaty and the Regulations (PCT Art. 2 (xix) and 35 U.S.C. 351(h)).

(b) The major functions of the International Bureau include:

- (1) Publishing of international applications and the International Gazette;
- (2) Transmitting copies of international applications to Designated Offices;
- (3) Storing and maintaining record copies; and
- (4) Transmitting information to authorities pertinent to the processing of specific international applications.

PCT Administrative Instruction Section 205.

Numbering and Identification of Claims Upon Amendment

(a) Amendments to the claims under Article 19 or Article 34(2)(b) may be made either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed. All the claims appearing on a replacement sheet shall be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims shall be required. In all cases where claims are renumbered, they shall be renumbered consecutively.

(b) The applicant shall, in the letter referred to in the second and third sentences of Rule 46.5(a) or in the second and fourth sentences of Rule 66.8(a), indicate the differences between the claims as filed and the claims as amended. He shall, in particular, indicate in the said letter, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether:

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The applicant has one opportunity to amend the claims only of the international application after issuance of the Search Report. The amendments to the claims must be filed directly with the International Bureau, usually within 2 months of the date of mailing of the Search Report. If the amendments to the claims are timely received by the International

Bureau, such amendments will be published as part of the pamphlet directly following the claims as filed. Article 19 offers applicants the opportunity to generally amend the claims before entering the designated Offices. The national laws of some designated Offices may grant provisional protection on the invention from the date of publication of the claims. Therefore, some applicants take advantage of the opportunity under Article 19 to polish the claims anticipating provisional protection. See PCT Rule 46.5.

1857 International Publication

PCT Article 21.

International Publication

(1) The International Bureau shall publish international applications.

(2)(a) Subject to the exceptions provided for in subparagraph (b) and in Article 64(3), the international publication of the international application shall be effected promptly after the expiration of 18 months from the priority date of that application.

(b) The applicant may ask the International Bureau to publish his international application any time before the expiration of the time limit referred to in subparagraph (a). The International Bureau shall proceed accordingly, as provided in the Regulations.

(3) The international search report or the declaration referred to in Article 17(2)(a) shall be published as prescribed in the Regulations.

(4) The language and form of the international publication and other details are governed by the Regulations.

(5) There shall be no international publication if the international application is withdrawn or is considered withdrawn before the technical preparations for publication have been completed.

(6) If the international application contains expressions or drawings which, in the opinion of the International Bureau, are contrary to morality or public order, or if, in its opinion, the international application contains disparaging statements as defined in the Regulations, it may omit such expressions, drawings, and statements, from its publications, indicating the place and number of words or drawings omitted, and furnishing, upon request, individual copies of the passages omitted.

PCT Article 29.

Effects of the International Publication

(1) As far as the protection of any rights of the applicant in a designated State is concerned, the effects, in that State, of the international publication of an international application shall, subject to the provisions of paragraphs (2) to (4), be the same as those which the national law of the designated State provides for the compulsory national publication of unexamined national applications as such.

(2) If the language in which the international publication has been effected is different from the language in which publications

under the national law are effected in the designated State, the said national law may provide that the effects provided for in paragraph (1) shall be applicable only from such time as:

(i) a translation into the latter language has been published as provided by the national law, or

(ii) a translation into the latter language has been made available to the public, by laying open for public inspection as provided by the national law, or

(iii) a translation into the latter language has been transmitted by the applicant to the actual or prospective unauthorized user of the invention claimed in the international application, or

(iv) both both the acts described in (i) and (iii), or both the acts described in (ii) and (iii), have taken place.

(3) The national law of any designated State may provide that, where the international publication has been effected, on the request of the applicant, before the expiration of 18 months from the priority date, the effects provided for in paragraph (1) shall be applicable only from the expiration of 18 months from the priority date.

(4) The national law of any designated State may provide that the effects provided for in paragraph (1) shall be applicable only from the date on which a copy of the international application as published under Article 21 has been received in the national Office of or acting for such State. The said Office shall publish the date of receipt in its gazette as soon as possible.

PCT Administrative Instruction Section 404.

International Publication Number of International Application

The International Bureau shall assign to each published international application an international publication number which shall be different from the international application number. The international publication number shall be used on the pamphlet and in the Gazette entry. It shall consist of the two-letter code WO followed by a two-digit designation of the last two numbers of the year of publication, a slant, and a serial number consisting of five digits (e.g., WO78/12345).

35 U.S.C. 374. Publication of international application.

The publication under the treaty defined in section 351(a) of this title, of an international application designating the United States shall confer the same rights and shall have the same effect under this title as an application for patent published under section 122(b), except as provided in sections 102(e) and 154(d) of this title.

The publication of international applications currently occurs every other Thursday. Under PCT Article 20 the International Bureau sends copies of published applications to each of the designated Offices on the day of publication. Until October 1, 1995, as a PCT member country, the U.S. Patent and Trademark Office received copies of all published international applications in printed form for inclusion in the examiner search files. The U.S. Patent and

Trademark Office now receives the published international applications on CD-ROM disks and in other electronic formats. For information on obtaining copies of these applications, see MPEP § 901.05(c). The applications are also published in the *PCT Gazette*, which can be accessed electronically through The Intellectual Property Digital Library Web site (<http://ipdl.wipo.int/>) of the World Intellectual Property Organization.

1857.01 Prior Art Effect of the International Publication

35 U.S.C. 374. Publication of international application.

The publication under the treaty defined in section 351(a) of this title, of an international application designating the United States shall confer the same rights and shall have the same effect under this title as an application for patent published under section 122(b), except as provided in sections 102(e) and 154(d) of this title.

35 U.S.C. 102. Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless —

(e) the invention was described in—

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

In certain situations the publication of an international application under PCT Article 21(2)(a) may be used as prior art as of its international filing date under 35 U.S.C. 102(e). In order for such a publication to be eligible for use as prior art under 35 U.S.C. 102(e) as of its international filing date the following conditions must be met:

(A) The U.S. application being examined must have been filed on or after November 29, 2000 (or filed prior to November 29, 2000 and voluntarily published); and

(B) The international application must have:

(1) been filed on or after November 29, 2000

(2) designated the United States;

(3) been published under Article 21(2)(a) in English; and

(4) entered the national stage under 35 U.S.C. 371.

If any of the above conditions have not been satisfied, the publication of the international application may only be used as prior art as of its publication date under 35 U.S.C. 102(a) or (b).

1859 Withdrawal of International Application or Designations

PCT Administrative Instruction Section 326.

Withdrawal by Applicant Under Rule 90^{bis}.1, 90^{bis}.2 or 90^{bis}.3

(a) The receiving Office shall promptly transmit to the International Bureau any notice from the applicant effecting withdrawal of the international application under Rule 90^{bis}.1, of a designation under Rule 90^{bis}.2 or of a priority claim under Rule 90^{bis}.3 which has been filed with it together with an indication of the date of receipt of the notice. If the record copy has not yet been sent to the International Bureau, the receiving Office shall transmit the said notice together with the record copy.

(b) If the search copy has already been sent to the International Searching Authority and the international application is withdrawn under Rule 90^{bis}.1 or a priority claim is withdrawn under Rule 90^{bis}.3, the receiving Office shall promptly transmit a copy of the notice effecting withdrawal to the International Searching Authority.

(c) If the search copy has not yet been sent to the International Searching Authority and the international application is withdrawn under Rule 90^{bis}.1, the receiving Office shall not send the search copy to the International Searching Authority and shall, subject to Section 322, refund the search fee to the applicant unless it has already been transferred to the International Searching Authority. If the search fee has already been transferred to the International Searching Authority, the receiving Office shall send a copy of the request and of the notice effecting withdrawal to that Authority.

(d) If the search copy has not yet been sent to the International Searching Authority and a priority claim is withdrawn under Rule 90^{bis}.3, the receiving Office shall transmit a copy of the notice effecting withdrawal to the International Searching Authority together with the search copy.

PCT Administrative Instruction Section 414.

Notification to the International Preliminary Examining Authority Where the International Application or the Designations of All Elected States Are Considered Withdrawn

If a demand has been submitted and the international application or the designations of all designated States which have been

elected are considered withdrawn under Article 14(1), (3) or (4), the International Bureau shall promptly notify the International Preliminary Examining Authority, unless the international preliminary examination report has already issued.

The applicant may withdraw the international application by a notice addressed to the International Bureau or to the receiving Office and received before the expiration of 20 months from the priority date. Where a Demand for international preliminary examination has been filed before the expiration of 19 months from the priority date, the international application may be withdrawn by a notice addressed to the International Bureau or to the International Preliminary Examining Authority and received before the expiration of 30 months from the priority date. Any such withdrawal is free of charge. A notice of withdrawal must be signed by all the applicants. An appointed agent or appointed common representative may sign such a notice on behalf of the applicant or applicants who appointed him, but an applicant who is considered to be the common representative may not sign such a notice on behalf of the other applicants. As to the case where an applicant inventor for the United States of America refuses to sign or cannot be found or reached see PCT Rule 90^{bis}.5(b).

The applicant may prevent international publication by withdrawing the international application, provided that the notice of withdrawal reaches the International Bureau before the completion of technical preparations for that publication. The notice of withdrawal may state that the withdrawal is to be effective only on the condition that international publication can still be prevented. In such a case the withdrawal is not effective if the condition on which it was made cannot be met that is, if the technical preparations for international publication have already been completed. International publication may be postponed by withdrawing the priority claim.

The applicant may withdraw the designation of any State by a notice addressed to the International Bureau or to the receiving Office and received before the expiration of 20 months from the priority date. Where a Demand for international preliminary examination has been filed before the expiration of 19 months from the priority date, the designation of any elected State may be withdrawn by a notice addressed to the International Preliminary Examining Authority and received before the expiration of 30 months from the

priority date. Any such withdrawal is free of charge. A notice of withdrawal must be signed by all the applicants. An appointed agent or appointed common representative may sign such a notice on behalf of the applicant or applicants who appointed him, but an applicant who is considered to be the common representative may not sign such a notice on behalf of the other applicants. If all designations are withdrawn, the international application will be treated as withdrawn.

The applicant may withdraw a priority claim made in the international application by a notice addressed to the International Bureau or to the receiving Office and received before the expiration of 20 months from the priority date. Where a Demand for international preliminary examination has been filed before the expiration of 19 months from the priority date, the notice must be received before the expiration of 30 months from the priority date. In the latter case, the notice may also be addressed to the International Preliminary Examining Authority. Any or all of the priority claims may be so withdrawn. Any such withdrawal is free of charge. A notice of withdrawal must be signed by all the applicants. An appointed agent or appointed common representative may sign such a notice on behalf of the applicant or applicants who appointed him, but an applicant who is considered to be the common representative may not sign such a notice on behalf of the other applicants.

Where the withdrawal of a priority claim causes a change in the priority date of the international application, any time limit which is computed from the original priority date and which has not yet expired—for example, the time limit before which processing in the national phase cannot start—is computed from the priority date resulting from the change. (It is not possible to extend the time limit concerned if it has already expired when the priority claim is withdrawn.) However, if the notice of withdrawal reaches the International Bureau after the completion of the technical preparations for international publication, the International Bureau may proceed with the international publication on the basis of the time limit for international publication as computed from the original priority date.

1860 International Preliminary Examination

EXAMINATION PROCEDURE

The International Preliminary Examination is to be carried out in accordance with PCT Article 34 and PCT Rule 66. After the Demand is checked for compliance with PCT Rules 53 - 55, 57 and 58, the first step of the examiner is to study the description, the drawings (if any), and the claims of the international application and the documents describing the prior art as cited in the international search report.

A written opinion must be prepared if the examiner:

(A) Considers that the international application has any of the defects described in PCT Article 34(4) concerning subject matter which is not required to be examined or which is unclear or inadequately supported;

(B) Considers that the report should be negative with respect to any of the claims because of a lack of novelty, inventive step (non-obviousness) or industrial applicability as described in PCT Article 33(2) - (4);

(C) Notices any defects in the form or contents of the international application;

(D) Considers that any amendment goes beyond the disclosure in the international application as originally filed;

(E) Wishes to make an observation on the clarity of the claims, the description, the drawings or to the question whether the claims are fully supported by the description (PCT Rule 66.2);

(F) Decides not to carry out the international preliminary examination on a claim for which no International Search Report was issued; or

(G) Considers that no acceptable amino acid sequence listing is available in a form that would allow a meaningful international preliminary examination to be carried out.

The written opinion is prepared on form PCT/IPEA/408 to notify applicant of the defects found in the international application. The examiner is further required to fully state the reasons for his/her opinion (PCT Rule 66.2(b)) and invite a written reply, with amendments where appropriate (PCT Rule 66.2(c)), normally setting a 2 month time limit for the reply.

The applicant may reply to the invitation by making amendments or, if applicant disagrees with the opinion of the examiner, by submitting arguments, as the case may be, or both.

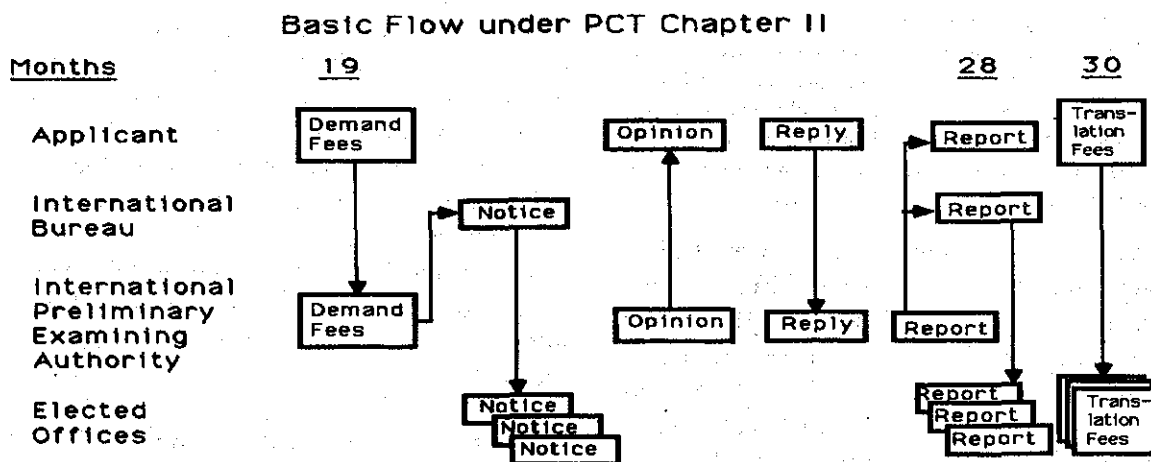
The U.S. Rules of Practice pertaining to international preliminary examination of international applications permit a second written opinion in those cases where sufficient time is available. Normally only one written opinion will be issued. Any reply received after the expiration of the set time limit will not normally be considered in preparing the international preliminary examination report. In situations, however, where the examiner has requested an amendment or where a later amendment places the application in

better condition for examination, the amendment may be considered by the examiner.

If the applicant does not reply to the written opinion within the set time period, the international preliminary examination report will be prepared after expiration of the time limit plus sufficient time to have any reply clear the Mail Center.

If, after initial examination of the international application, there is no negative statement or comment to be made, then only the international preliminary examination report will issue without a written opinion having been issued.

1861 Chapter II Basic Flow



1862 Agreement with the International Bureau To Serve as an International Preliminary Examination Authority

PCT Article 32.

The International Preliminary Examining Authority

- (1) International preliminary examination shall be carried out by the International Preliminary Examining Authority
- (2) In the case of demands referred to in Article 31(2)(a), the receiving Office, and, in the case of demands referred to in Article 31(2)(b), the Assembly, shall, in accordance with the applicable agreement between the interested International Preliminary Examining Authority or Authorities and the International Bureau,

specify the International Preliminary Examining Authority or Authorities competent for the preliminary examination.

(3) The provisions of Article 16(3) shall apply, *mutatis mutandis*, in respect of the International Preliminary Examining Authorities.

PCT Article 34.

Procedure before the International Preliminary Examining Authority

- (1) Procedure before the International Preliminary Examining Authority shall be governed by the provisions of this Treaty, the Regulations, and the agreement which the International Bureau shall conclude, subject to this Treaty and the Regulations, with the said Authority.

37 CFR 1.416. The United States International Preliminary Examining Authority.

(a) Pursuant to appointment by the Assembly, the United States Patent and Trademark Office will act as an International Preliminary Examining Authority for international applications filed in the United States Receiving Office and in other Receiving Offices as may be agreed upon by the Commissioner, in accordance with agreement between the Patent and Trademark Office and the International Bureau.

(b) The United States Patent and Trademark Office, when acting as an International Preliminary Examining Authority, will be identified by the full title "United States International Preliminary Examining Authority" or by the abbreviation "IPEA/US."

(c) The major functions of the International Preliminary Examining Authority include:

- (1) Receiving and checking for defects in the Demand;
- (2) Forwarding Demands in accordance with PCT Rule 59.3;
- (3) Collecting the handling fee for the International Bureau and the preliminary examination fee for the United States International Preliminary Examining Authority;
- (4) Informing applicant of receipt of the Demand;
- (5) Considering the matter of unity of invention;
- (6) Providing an international preliminary examination report which is a nonbinding opinion on the questions whether the claimed invention appears to be novel, to involve inventive step (to be nonobvious), and to be industrially applicable; and
- (7) Transmitting the international preliminary examination report to applicant and the International Bureau.

An agreement was concluded between the United States Patent and Trademark Office (USPTO) and the International Bureau under which the USPTO agreed to serve as an International Preliminary Examining Authority for those applications filed in the USPTO as a Receiving Office and for those international applications filed in other receiving Offices for which the USPTO has served as an International Searching Authority.

The agreement is provided for in PCT Articles 32(2) & (3) and 34(1), and in PCT Rules 59.1, 63.1, 72.1, and 77.1(a). Authority is given in 35 U.S.C. 361(c), 362(a) & (b) and in 364(a). 37 CFR 1.416(a) and PCT Administrative Instructions Section 103(c) are also relevant.

1864 The Demand and Preparation for Filing of Demand

37 CFR 1.480. Demand for international preliminary examination.

(a) On the filing of a proper Demand in an application for which the United States International Preliminary Examining Authority is competent and for which the fees have been paid, the

international application shall be the subject of an international preliminary examination. The preliminary examination fee (§ 1.482(a)(1)) and the handling fee (§ 1.482(b)) shall be due at the time of filing the Demand.

(b) The Demand shall be made on a standardized form. Copies of the printed Demand forms are available from the Patent and Trademark Office. Letters requesting printed Demand forms should be marked "Box PCT."

(c) If the Demand is made prior to the expiration of the 19th month from the priority date and the United States of America is elected, the provisions of § 1.495 shall apply rather than § 1.494.

(d) Withdrawal of a proper Demand prior to the start of the international preliminary examination will entitle applicant to a refund of the preliminary examination fee minus the amount of the transmittal fee set forth in § 1.445(a)(1).

Once applicant has requested the filing of an international application under Chapter I which affords applicants the benefit of an international search, applicant has the right to file a Demand for preliminary examination. The use of the term "Demand" distinguishes Chapter II from the "Request" under Chapter I. Applicants who timely and properly file a Demand for preliminary examination are able to defer or delay the time for entry into the national stage from 20 months (under Chapter I) to 30 months from the earliest priority date. It is not possible to file a Demand unless a proper Chapter I "Request" for an international application has been filed.

The Demand should be filed on PCT Form PCT/IPEA/401 along with the fee transmittal sheet. For information on obtaining these forms free of charge, see MPEP § 1730.

1864.01 Amendments Filed with Demand

PCT Rule 66.

Procedure before the International Preliminary Examining Authority

66.8. Form of Amendments

(a) Subject to paragraph (b), the applicant shall be required to submit a replacement sheet for every sheet of the international application which, on account of an amendment, differs from the sheet previously filed. The letter accompanying the replacement sheets shall draw attention to the differences between the replaced sheets and the replacement sheets and shall preferably also explain the reasons for the amendment.

(b) Where the amendment consists in the deletion of passages or in minor alterations or additions, the replacement sheet referred to in paragraph (a) may be a copy of the relevant sheet of the international application containing the alterations or

additions, provided that the clarity and direct reproducibility of that sheet are not adversely affected. To the extent that any amendment results in the cancellation of an entire sheet, that amendment shall be communicated in a letter which shall preferably also explain the reasons for the amendment.

37 CFR 1.485. Amendments by applicant during international preliminary examination.

(a) The applicant may make amendments at the time of filing the Demand. The applicant may also make amendments within the time limit set by the International Preliminary Examining Authority for reply to any notification under § 1.484(b) or to any written opinion. Any such amendments must:

(1) Be made by submitting a replacement sheet in compliance with PCT Rules 10 and 11.1 to 11.13 for every sheet of the application which differs from the sheet it replaces unless an entire sheet is cancelled; and

(2) Include a description of how the replacement sheet differs from the replaced sheet. Amendments that do not comply with PCT Rules 10 and 11.1 to 11.13 may not be entered.

(b) If an amendment cancels an entire sheet of the international application, that amendment shall be communicated in a letter

Amendments may be filed with the Demand (PCT Article 34) if desired to place the application claims in better condition for international preliminary examination. Such amendments, however, may not include new matter and must be accompanied by a description of how the replacement sheet differs from the replaced sheet.

Amendments filed after the Demand cannot be assured of consideration since the examiner will be taking up the application to draft the written opinion rather promptly because of the short examination period.

1864.02 Applicant's Right to File a Demand

PCT Article 31.

Demand for International Preliminary Examination

(2)(a) Any applicant who is a resident or national, as defined in the Regulations, of a Contracting State bound by Chapter II, and whose international application has been filed with the receiving Office of or acting for such State, may make a demand for international preliminary examination.

PCT Rule 54.

The Applicant Entitled to Make a Demand

54.1. Residence and Nationality

(a) Subject to the provisions of paragraph (b), the residence or nationality of the applicant shall, for the purposes of Article 31(2), be determined according to Rule 18.1(a) and (b).

(b) The International Preliminary Examining Authority shall, in the circumstances specified in the Administrative Instructions, request the receiving Office or, where the international application was filed with the International Bureau as receiving Office, the national Office of, or acting for, the Contracting State concerned to decide the question whether the applicant is a resident or national of the Contracting State of which he claims to be a resident or national. The International Preliminary Examining Authority shall inform the applicant of any such request. The applicant shall have an opportunity to submit arguments directly to the Office concerned. The Office concerned shall decide the said question promptly.

54.2. Right to Make a Demand

The right to make a demand under Article 31(2) shall exist if the applicant making the demand or, if there are two or more applicants, at least one of them is a resident or national of a Contracting State bound by Chapter II and the international application has been filed with a receiving Office of or acting for a Contracting State bound by Chapter II.

(i) *[Deleted]*

(ii) *[Deleted]*

54.3 International Applications Filed with the International Bureau as Receiving Office

Where the international application is filed with the International Bureau as receiving Office under Rule 19.1(a)(iii), the International Bureau shall, for the purposes of Article 31(2)(a), be considered to be acting for the Contracting State of which the applicant is a resident or national.

54.4. Applicant Not Entitled to Make a Demand

If the applicant does not have the right to make a demand or, in the case of two or more applicants, if none of them has the right to make a demand under Rule 54.2, the demand shall be considered not to have been submitted.

If there is a sole applicant, he or she must be a resident or national of a Contracting State bound by Chapter II of the PCT. If there are two or more applicants, it is sufficient that one of them be a resident or national of a Contracting State bound by Chapter II, regardless of the elected State(s) for which each applicant is indicated. Only applicants for the elected States are required to be indicated in the Demand. The detailed requirements for the various indications required in connection with each applicant (name and address, telephone number, facsimile machine

number or teleprinter address, nationality and residence) are the same as those required under PCT Rule 4 in connection with the Request. Note that any inventor who is not also an applicant is not indicated in the Demand.

If the recording of a change in the name or person has been requested under PCT Rule 92^{bis}.1 before the Demand was filed, it is the applicant(s) of record at the time when the Demand is filed who must be indicated in the Demand.

1864.03 States Which May Be Elected

PCT Article 31.

Demand for International Preliminary Examination

(4)(a) The demand shall indicate the Contracting State or States in which the applicant intends to use the results of the international preliminary examination ("elected States"). Additional Contracting States may be elected later. Election may relate only to Contracting States already designated under Article 4.

(b) Applicants referred to in paragraph (2)(a) may elect any Contracting State bound by Chapter II. Applicants referred to in paragraph (2)(b) may elect only such Contracting States bound by Chapter II as have declared that they are prepared to be elected by such applicants.

Only PCT member states which have ratified or acceded to Chapter II and which were designated in the Request may be elected under Chapter II. The Assembly has taken no action to allow persons who are residents or nationals of a State not party to the PCT or not bound by Chapter II to make a Demand under Article 31(2)(b).

1864.04 Agent's Right to Act

Any agent entitled to practice before the receiving Office where the international application was filed may represent the applicant before the international authorities (PCT Article 49).

If for any reason, the examiner needs to question the right of an attorney or agent to practice before the International Preliminary Examining Authority, the USPTO roster of registered attorneys and agents should be consulted. If the international application was filed with a receiving Office other than the United States, Form PCT/IPEA/410 may be used by the requesting IPEA to ask the receiving Office with

which the international application was filed, whether the agent named in the international application has the right to practice before that Office.

The PCT Article and Regulations governing the right to practice are PCT Article 49 and PCT Rule 83.

1865 Filing of Demand

PCT Article 31.

Demand for International Preliminary Examination

(1) On the demand of the applicant, his international application shall be the subject of an international preliminary examination as provided in the following provisions and the Regulations.

(3) The demand for international preliminary examination shall be made separately from the international application. The demand shall contain the prescribed particulars and shall be in the prescribed language and form.

(6)(a) The demand shall be submitted to the competent International Preliminary Examining Authority referred to in Article 32.

Applicants should mail the Demand and appropriate fees directly to the International Preliminary Examining Authority they desire to prepare the International Preliminary Examination Report. United States applicants who have had the international search prepared by the European Patent Office may also request the European Patent Office to act as the International Preliminary Examining Authority.

Demands filed in the European Patent Office should be addressed to:

European Patent Office
Erhardstrasse 27
D-80331 Munich
Federal Republic of Germany.

Demands directed to the United States Patent and Trademark Office should be addressed to:

Assistant Commissioner for Patents
Box PCT
Washington, DC 20231.

The "Express Mail" provisions of 37 CFR 1.10 may be used to file a Demand under Chapter II in the USPTO. Applicants are advised that failure to

comply with the provisions of 37 CFR 1.10 will result in the paper or fee being accorded the date of receipt and not the date of deposit. See MPEP § 513.

Demand for international preliminary examination may be submitted to the USPTO via facsimile. The Certificate of Mailing or Transmission practice under 37 CFR 1.8 CANNOT be used to file a Demand if the date of deposit is desired. If used, the date of the Demand will be the date of receipt in the USPTO. See MPEP § 513, § 1834, and § 1834.01.

All Demands filed in the USPTO must be in the English language.

PCT Rule 59.3 was amended July 1, 1998 to provide a safeguard in the case of a Demand filed with an International Preliminary Examining Authority which is not competent for the international preliminary examination of a particular international application. The USPTO may forward such a Demand to the International Bureau and the International Bureau will forward the Demand to a competent International Preliminary Examining Authority pursuant to PCT

Rule 59.3(c). The competent International Preliminary Examining Authority will process the Demand based on the date of receipt in the USPTO. See 37 CFR 1.416(c)(2).

CHOICE OF EXAMINING AUTHORITY

U.S. residents and nationals may choose to have the International Preliminary Examination done either by the IPEA/EP or the IPEA/US. The IPEA/EP has agreed that it would act as International Preliminary Examining Authority for any Chapter II case in which it served as the ISA. The IPEA/US will serve as International Preliminary Examining Authority for U.S. residents and nationals if the U.S. or EPO served as ISA.

The IPEA/US will also serve as International Preliminary Examining Authority for residents or nationals of Barbados, Brazil, India, Israel, Mexico, New Zealand, South Africa, and Trinidad and Tobago if the U.S. was the International Searching Authority.

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below:

IPEA/ US

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:
 The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA		Date of receipt of DEMAND	
Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION		Applicant's or agent's file reference CMC-123-PCT	
International application No. PCT/US00/999999	International filing date (day/month/year) 11 January 2000 (11.01.00)	(Earliest) Priority date (day/month/year) 11 January 1999 (11.01.99)	
Title of invention SELF-STEERING GEAR FOR SAILBOATS			
Box No. II APPLICANT(S)			
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) COLUMBIA MARINE CORPORATION 100 Front Street Annapolis, Maryland 20726 United States of America		Telephone No. 305-555-1122	Applicant's registration No. with the Office
		Facsimile No. 305-555-1123	
		Teleprinter No.	
State (that is, country) of nationality: US		State (that is, country) of residence: US	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) JONES, John Paul 200 Shady Grove Road Davidsonville, Maryland 20720 United States of America			
State (that is, country) of nationality: US		State (that is, country) of residence: US	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)			
State (that is, country) of nationality:		State (that is, country) of residence:	
<input type="checkbox"/> Further applicants are indicated on a continuation sheet.			

Form PCT/IPEA/401 (first sheet) (March 2001; reprint July 2001)

See Notes to the demand form

Sheet No. 2

International application No.
PCT/US00/99999

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is agent common representative
 and has been appointed earlier and represents the applicant(s) also for international preliminary examination.
 is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.
 is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

ADAMS, John
345 State Street
Boston, MA 02110
United States of America

Telephone No.
617-577-7777

Facsimile No.
617-577-7778

Teleprinter No.

Agent's registration No. with the Office
99,999

Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION

Statement concerning amendments:*

- The applicant wishes the international preliminary examination to start on the basis of:
 - the international application as originally filed
 - the description as originally filed as amended under Article 34
 - the claims as originally filed as amended under Article 19 (together with any accompanying statement) as amended under Article 34
 - the drawings as originally filed as amended under Article 34
 - The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.
 - The applicant wishes the start of the international preliminary examination to be postponed until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*
- * Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: English

- which is the language in which the international application was filed.
- which is the language of a translation furnished for the purposes of international search.
- which is the language of publication of the international application.
- which is the language of the translation (to be) furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The applicant hereby elects all eligible States *(that is, all States which have been designated and which are bound by Chapter II of the PCT)*

excluding the following States which the applicant wishes not to elect:

Sheet No. .3.

International application No.
PCT/US00/99999

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- | | | | |
|--|---|-------|--------|
| 1. translation of international application | : | _____ | sheets |
| 2. amendments under Article 34 | : | 2 | sheets |
| 3. copy (or, where required, translation) of amendments under Article 19 | : | _____ | sheets |
| 4. copy (or, where required, translation) of statement under Article 19 | : | _____ | sheets |
| 5. letter | : | 1 | sheets |
| 6. other (specify) | : | _____ | sheets |

For International Preliminary Examining Authority use only

	received	not received
1.	<input type="checkbox"/>	<input type="checkbox"/>
2.	<input type="checkbox"/>	<input type="checkbox"/>
3.	<input type="checkbox"/>	<input type="checkbox"/>
4.	<input type="checkbox"/>	<input type="checkbox"/>
5.	<input type="checkbox"/>	<input type="checkbox"/>
6.	<input type="checkbox"/>	<input type="checkbox"/>

The demand is also accompanied by the item(s) marked below:

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> fee calculation sheet | 5. <input type="checkbox"/> statement explaining lack of signature |
| 2. <input type="checkbox"/> original separate power of attorney | 6. <input type="checkbox"/> sequence listing in computer readable form |
| 3. <input type="checkbox"/> original general power of attorney | 7. <input type="checkbox"/> other (specify): |
| 4. <input type="checkbox"/> copy of general power of attorney; reference number, if any: | |

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

John Adams

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:
2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):
3. <input type="checkbox"/> The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply. <input type="checkbox"/> The applicant has been informed accordingly.
4. <input type="checkbox"/> The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.
5. <input type="checkbox"/> Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on:

CHAPTER II

PCT

FEE CALCULATION SHEET

Annex to the Demand

International application No. PCT/US00/99999	For International Preliminary Examining Authority use only Date stamp of the IPEA								
Applicant's or agent's file reference CMC-123-PCT									
Applicant COLUMBIA MARINE CORPORATION									
<p align="center">CALCULATION OF PRESCRIBED FEES</p> <p>1. Preliminary examination fee 490 P</p> <p>2. Handling fee (<i>Applicants from certain States are entitled to a reduction of 75% of the handling fee. Where the applicant is (or all applicants are) so entitled, the amount to be entered at H is 25% of the handling fee.</i>) 137 H</p> <p>3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box 627</p> <p align="center" style="border: 1px solid black; padding: 2px;">TOTAL</p>									
<p>MODE OF PAYMENT</p> <table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> authorization to charge deposit account with the IPEA (see below)</td> <td><input type="checkbox"/> cash</td> </tr> <tr> <td><input checked="" type="checkbox"/> cheque</td> <td><input type="checkbox"/> revenue stamps</td> </tr> <tr> <td><input type="checkbox"/> postal money order</td> <td><input type="checkbox"/> coupons</td> </tr> <tr> <td><input type="checkbox"/> bank draft</td> <td><input type="checkbox"/> other (specify):</td> </tr> </table>		<input type="checkbox"/> authorization to charge deposit account with the IPEA (see below)	<input type="checkbox"/> cash	<input checked="" type="checkbox"/> cheque	<input type="checkbox"/> revenue stamps	<input type="checkbox"/> postal money order	<input type="checkbox"/> coupons	<input type="checkbox"/> bank draft	<input type="checkbox"/> other (specify):
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<p>AUTHORIZATION TO CHARGE (OR CREDIT) DEPOSIT ACCOUNT <i>(This mode of payment may not be available at all IPEAs)</i></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Authorization to charge the total fees indicated above. <input checked="" type="checkbox"/> <i>(This check-box may be marked only if the conditions for deposit accounts of the IPEA so permit)</i> Authorization to charge any deficiency or credit any overpayment in the total fees indicated above. </td> <td style="width: 50%; vertical-align: top;"> IPEA/ <u>US</u> Deposit Account No. <u>99-1111</u> Date: <u>03 August 2001</u> Name: <u>John Adams</u> Signature: _____ </td> </tr> </table>		<input type="checkbox"/> Authorization to charge the total fees indicated above. <input checked="" type="checkbox"/> <i>(This check-box may be marked only if the conditions for deposit accounts of the IPEA so permit)</i> Authorization to charge any deficiency or credit any overpayment in the total fees indicated above.	IPEA/ <u>US</u> Deposit Account No. <u>99-1111</u> Date: <u>03 August 2001</u> Name: <u>John Adams</u> Signature: _____						
<input type="checkbox"/> Authorization to charge the total fees indicated above. <input checked="" type="checkbox"/> <i>(This check-box may be marked only if the conditions for deposit accounts of the IPEA so permit)</i> Authorization to charge any deficiency or credit any overpayment in the total fees indicated above.	IPEA/ <u>US</u> Deposit Account No. <u>99-1111</u> Date: <u>03 August 2001</u> Name: <u>John Adams</u> Signature: _____								

1866 Filling in of Headings on Chapter II Forms

The examiner will encounter several different forms for use in the Chapter II preliminary examination phase and most of the forms will have the same "header" information to be provided.

The notes below list the common identifying information requested on the top of the first page of most of the forms:

Applicant's mailing address - this is usually the attorney's address taken from the file wrapper.

Applicant's or Agent's File Reference - this is the applicant's or agent's application reference (or docket number) which is composed of either letters or numbers, or both, provided this reference does not exceed twelve characters. This reference may be found in the upper right hand box on the first sheet of the Demand, Form PCT/IPEA/401. See Administrative Instructions Section 109.

International Application Number - this is the 14 digit PCT application number as stamped and typed on the international application file wrapper and may also be found on the first page of the Demand, Form PCT/IPEA/401.

International Filing Date - this is the filing date printed on the international application file wrapper and may also be found on the first page of the Demand, Form PCT/IPEA/401.

Applicant (Name) - the first named applicant as set forth on the international application file wrapper and may also be found in box II of the Demand, Form PCT/IPEA/401.

1867 Preliminary Examination Fees

37 CFR 1.481. Payment of international preliminary examination fees.

(a) The handling and preliminary examination fees shall be paid within the time period set in PCT Rule 57.3. The handling fee or preliminary examination fee payable is the handling fee or preliminary examination fee in effect on the date of receipt of the Demand except under PCT Rule 59.3(a) where the fee payable is the fee in effect on the date of arrival of the Demand at the United States International Preliminary Examining Authority.

(1) If the handling and preliminary fees are not paid within the time period set in PCT Rule 57.3, applicant will be notified and given one month within which to pay the deficient fees plus a late payment fee equal to the greater of:

(i) Fifty percent of the amount of the deficient fees, but not exceeding an amount equal to double the handling fee; or

(ii) An amount equal to the handling fee (PCT Rule 58^{bis}.2).

(2) The one-month time limit set in this paragraph to pay deficient fees may not be extended.

(b) If the payment needed to cover the handling and preliminary examination fees, pursuant to paragraph (a) of this section, is not timely made in accordance with PCT Rule 58^{bis}.1(d), the United States International Preliminary Examination Authority will declare the Demand to be considered as if it had not been submitted.

The preliminary examination fee is for the benefit of the International Preliminary Examining Authority and the amount for the U.S. doing the preliminary examination is specified in 37 CFR 1.482. The fee is somewhat higher if the international search was performed by an authority other than the USPTO.

The handling fee is a fee for the benefit of the International Bureau and is collected by the International Preliminary Examining Authority. The amount of the handling fee is set out in the PCT schedule of fees which is annexed to the PCT Regulations.

The current amount of both the preliminary examination fee and the handling fee can be found in each weekly issue of the *Official Gazette*. Since supplements to the handling fee were deleted, no additional Chapter II fees are required other than any additional preliminary examination fee where additional inventions are determined to be present. The amount of this fee is also specified in 37 CFR 1.482 and in the weekly issues of the *Official Gazette*. See also PCT Rules 57 and 58.

The time limit for paying the preliminary examination fee and the handling fee is set forth in PCT Rules 57.3 and 58.1(b). 37 CFR 1.481(a) provides that the preliminary examination fee or handling fee payable is the preliminary examination fee or handling fee in effect on the date of receipt of the Demand in the United States International Preliminary Examining Authority. Effective July 1, 1998, PCT Rule 58bis.1(c) was added to consider the preliminary examination fee and handling fee to have been received before the expiration of the time limit set in PCT Rule 57.3 if the fees were submitted prior to the sending of an invitation to pay the fees.

Effective July 1, 1998, PCT Rule 58bis.1(a) was added to permit the International Preliminary Examining Authority to collect a late payment fee set forth in PCT Rule 58bis.2 if the fees for preliminary examination are not paid prior to the sending of the invitation

to pay the fees. If the preliminary examination fee and handling fee are not paid within the time set in PCT Rule 57.3, applicants will be notified and given 1 month within which to pay the deficient fees plus a late payment fee equal to the greater of: (1) 50% of the amount of the deficient fees, but not exceeding an amount equal to double the handling fee; or (2) an amount equal to the handling fee. See 37 CFR 1.481(a)(1)(i) and (ii). The 1 month time limit set forth in 37 CFR 1.481(a)(1) to pay deficient fees may not be extended. See 37 CFR 1.481(a)(2).

If the payment needed to cover the preliminary examination fee and handling fee is not timely made in accordance with PCT Rule 58bis.1(d), the United States International Preliminary Examining Authority will declare the Demand to be considered as if it had not been submitted. In this regard, where the Authority sends a notification that the Demand is considered not to have been made and applicant's payment is received, both on that same date, the fee is considered to be late and the notification remains effective. The fee must antedate the notice in order for the notice not to be effective. See 37 CFR 1.481(b).

1868 Correction of Defects in the Demand

PCT Rule 60.

Certain Defects in the Demand or Elections

60.1. Defects in the Demand

(a) If the demand does not comply with the requirements specified in Rules 53.1, 53.2(a)(i) to (iv), 53.2(b), 53.3 to 53.8, and 55.1, the International Preliminary Examining Authority shall invite the applicant to correct the defects within a time limit which shall be reasonable under the circumstances. That time limit shall not be less than one month from the date of the invitation. It may be extended by the International Preliminary Examining Authority at any time before a decision is taken.

(b) If the applicant complies with the invitation within the time limit under paragraph (a), the demand shall be considered as if it had been received on the actual filing date, provided that the demand as submitted contained at least one election and permitted the international application to be identified; otherwise, the demand shall be considered as if it had been received on the date on which the International Preliminary Examining Authority receives the correction.

(c) Subject to paragraph (d), if the applicant does not comply with the invitation within the time limit under paragraph (a), the

demand shall be considered as if it had not been submitted and the International Preliminary Examining Authority shall so declare.

(d) Where, to paragraph (d), if the applicant does not comply with the invitation within the time limit under paragraph (a), the demand shall be considered as if it had not been submitted and the International Preliminary Examining Authority shall so declare.

(e) If the defect is noticed by the International Bureau, it shall bring the defect to the attention of the International Preliminary Examining Authority, which shall then proceed as provided in paragraphs (a) to (d).

(f) If the demand does not contain a statement concerning amendments, the International Preliminary Examining Authority shall proceed as provided for in Rules 66.1 and 69.1(a) or (b).

(g) Where the statement concerning amendments contains an indication that amendments under Article 34 are submitted with the demand (Rule 53.9(c)) but no such amendments are, in fact, submitted, the International Preliminary Examining Authority shall invite the applicant to submit the amendments within a time limit fixed in the invitation and shall proceed as provided for in Rule 69.1(e).

60.2. Defects in Later Elections

(a) If the notice effecting a later election does not comply with the requirements of Rule 56, the International Bureau shall invite the applicant to correct the defects within a time limit which shall be reasonable under the circumstances. That time limit shall not be less than one month from the date of the invitation. It may be extended by the International Bureau at any time before a decision is taken.

(b) If the applicant complies with the invitation within the time limit under paragraph (a), the notice shall be considered as if it had been received on the actual filing date, provided that the notice as submitted contained at least one election and permitted the international application to be identified; otherwise, the notice shall be considered as if it had been received on the date on which the International Bureau receives the correction.

(c) Subject to paragraph (d), if the applicant does not comply with the invitation within the time limit under paragraph (a), the notice shall be considered as if it had not been submitted.

(d) Where, in respect of an applicant for a certain elected State, the signature required under Rule 56.1(b) and (c) or the name or address is lacking after the expiration of the time limit under paragraph (a), the later election of that State shall be considered as if it had not been made.

Defects in the Demand may be corrected. The type of correction determines whether the filing date of the Demand must be changed. The most common defects which result in the mailing of an invitation to correct are found in PCT Rules 53 and 55. If the applicant complies with the invitation, the Demand is considered as if it had been received on the actual filing date, i.e., the original date of receipt. See PCT Rule 60.1(b).

1869 Notification to International Bureau of Demand

PCT Article 31.

Demand for International Preliminary Examination

(7) Each elected Office shall be notified of its election.

The International Preliminary Examining Authority, pursuant to PCT Rule 61, promptly notifies the International Bureau and the applicant of the filing of any Demand. The International Bureau in turn notifies each elected Office of their election and also notifies the applicant that such notification has been made.

1870 Priority Document and Translation Thereof

PCT Rule 66.

Procedure before the International Preliminary Examining Authority

66.7. Priority Document

(a) If the International Preliminary Examining Authority needs a copy of the application whose priority is claimed in the international application, the International Bureau shall, on request, promptly furnish such copy. If that copy is not furnished to the International Preliminary Examining Authority because the applicant failed to comply with the requirements of Rule 17.1, the international preliminary examination report may be established as if the priority had not been claimed.

(b) If the application whose priority is claimed in the international application is in a language other than the language or one of the languages of the International Preliminary Examining Authority, that Authority may, where the validity of the priority claim is relevant for the formulation of the opinion referred to in Article 33(1), invite the applicant to furnish a translation in the said language or one of the said languages within two months from the date of the invitation. If the translation is not furnished within that time limit, the international preliminary examination report may be established as if the priority had not been claimed.

A copy of the priority document may be required by the examiner if necessary because of an intervening reference, and a translation thereof, if the priority document is not in English.

1871 Processing Amendments Filed Under Article 19 and Article 34 Prior to or at the Start of International Preliminary Examination

PCT Rule 62.

Copy of Amendments Under Article 19 for the International Preliminary Examining Authority

62.1. Amendments Made Before the Demand Is Filed

Upon receipt of a demand, or a copy thereof, from the International Preliminary Examining Authority, the International Bureau shall promptly transmit a copy of any amendments under Article 19, and any statement referred to in that Article, to that Authority, unless that Authority has indicated that it has already received such a copy.

62.2. Amendments Made After the Demand Is Filed

If, at the time of filing any amendments under Article 19, a demand has already been submitted, the applicant shall preferably, at the same time as he files the amendments with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments and any statement referred to in that Article. In any case, the International Bureau shall promptly transmit a copy of such amendments and statement to that Authority.

The documents making up the international application may include amendments of the claims filed by the applicant under PCT Article 19. PCT Article 19 amendments are exclusively amendments to the claims and these amendments can only be made after the search report has been established. PCT Article 19 amendments will be transmitted to the International Preliminary Examining Authority by the International Bureau. If a Demand for international preliminary examination has already been submitted, the applicant should preferably, at the time he files the PCT Article 19 amendments, also file a copy of the amendments with the International Preliminary Examining Authority. In the event that the time limit for filing amendments under PCT Article 19, as provided in PCT Rule 46.1, has not expired and the Demand includes a statement that the start of the international preliminary examination is to be postponed under PCT Rule 53.9(b), the international preliminary examination should not start before the examiner receives a copy of any amendments made under PCT Article 19 or a notice from the applicant that he does not wish to make amendments under PCT Article 19, or before the expiration of 20 months from the priority date, whichever occurs first.

The applicant has the right to amend the claims, the description, and the drawings, in the prescribed manner and before the start of international preliminary examination. The amendment must not go beyond the disclosure in the international application as filed. These amendments are referred to as PCT Article 34(2)(b) amendments. It should be noted that PCT Article 19 amendments are strictly amendments to the claims made during the Chapter I search phase while PCT Article 34(2)(b) amendments to the description, claims, and drawings are made during the Chapter II examination phase.

When amendments to the description, claims, or drawings are made under PCT Rule 66.8, they may be accompanied by an explanation. These amendments may have been submitted to avoid possible objections as to lack of novelty or lack of inventive step in view of the citations listed in the international search report; to meet any objections noted by the International Searching Authority under PCT Article 17(2)(a)(ii) (i.e., that all or at least some claims do not permit a meaningful search) or under PCT Rule 13 (i.e., that there is a lack of unity of invention); or to meet objections that may be raised for some other reason, e.g., to remedy some obscurity which the applicant himself/herself has noted in the original documents.

The amendments are made by the applicant of his/her own volition. This means that the applicant is not restricted to amendments necessary to remedy a defect in his/her international application. It does not, however, mean that the applicant should be regarded as free to amend in any way he/she chooses. Any amendment must not add subject matter which goes beyond the disclosure of the international application as originally filed. Furthermore, it should not itself cause the international application as amended to be objectionable under the PCT, e.g., the amendment should not introduce obscurity.

As a matter of policy and to ensure consistency in handling amendments filed under PCT Articles 19 and 34 of the PCT, the following guidelines for processing these amendments have been established:

(A) Any amendment which complies with 37 CFR 1.485(a) will be considered;

(B) Amendments filed after the Demand

(1) will be considered if filed before the application is docketed to the examiner,

(2) may be considered if filed after docketing. The examiner has discretion to consider such amendments if the examiner determines that the amendment places the application in better condition for examination or the examiner determines that the amendment should otherwise be entered;

(C) Amendments filed after expiration of the period for response to the written opinion

(1) will be considered if the amendment was requested by the examiner,

(2) may be considered if the examiner determines that the amendment places the application in better condition for examination or the examiner determines that the amendment should otherwise be entered.

It is expected, due to the relatively short time period for completion of preliminary examination, that the Chapter II application will be taken up for preparation of the written opinion promptly after docketing to the examiner and taken up for preparation of the final report promptly after the time expires for response to the written opinion (i.e., after allowing for mail processing). The examiner is not obliged to consider amendments or arguments which are filed after he/she has taken up the case for preparation of the written opinion or the final report.

Amendments timely filed but misdirected or are otherwise late reaching the examiner will be considered as in the case of regular domestic applications and may require a supplemental written opinion and/or final report.

Clearly, these guidelines offer the examiner flexibility. The examiner should be guided by the overriding principle that the final report (the PCT/IPEA/409) should be established with as few written opinions as possible and resolution of as many issues as possible consistent with the goal of a timely and quality report.

See also Administrative Instructions Section 602 regarding processing of amendments by the International Preliminary Examining Authority.

1872 Transmittal of Demand to the Examining Corps

PCT Administrative Instruction Section 605.

File to be used for International Preliminary Examination

Where the International Preliminary Examining Authority is part of the same national Office or intergovernmental organization

as the International Searching Authority, the same file shall serve the purposes of international search and international preliminary examination.

When the PCT International Application Processing Division has finished processing of the papers and fees filed with a complete Demand, a copy of the Demand and other papers are forwarded to the appropriate Technology Center for examination. The documents will be placed in the Search Copy file wrapper before forwarding to the examiner.

1873 Later Election of States

PCT Article 31.

Demand for International Preliminary Examination

(6)(b) Any later election shall be submitted to the International Bureau.

PCT Rule 56. Later Elections

56.1. Elections Submitted Later Than the Demand

(a) The election of States subsequent to the submission of the demand ("later election") shall be effected by a notice submitted to the International Bureau. The notice shall identify the international application and the demand, and shall include an indication as referred to in Rule 53.7(b)(ii).

(b) Subject to paragraph (c), the notice referred to in paragraph (a) shall be signed by the applicant for the elected States concerned or, if there is more than one applicant for those States, by all of them.

(c) Where two or more applicants file a notice effecting a later election of a State whose national law requires that national applications be filed by the inventor and where an applicant for that elected State who is an inventor refused to sign the notice or could not be found or reached after diligent effort, the notice need not be signed by that applicant ("the applicant concerned") if it is signed by at least one applicant and

(i) a statement is furnished explaining, to the satisfaction of the International Bureau, the lack of signature of the applicant concerned, or

(ii) the applicant concerned did not sign the request but the requirements of Rule 4.15(b) were complied with, or did not sign the demand but the requirements of Rule 53.8(b) were complied with.

(d) An applicant for a State elected by a later election need not have been indicated as an applicant in the demand.

(e) If a notice effecting a later election is submitted after the expiration of 19 months from the priority date, the International Bureau shall notify the applicant that the election does not have the effect provided for under Article 39(1)(a) and that the acts

referred to in Article 22 must be performed in respect of the elected Office concerned within the time limit applicable under Article 22.

(f) If, notwithstanding paragraph (a), a notice effecting a later election is submitted by the applicant to the International Preliminary Examining Authority rather than the International Bureau, that Authority shall mark the date of receipt on the notice and transmit it promptly to the International Bureau. The notice shall be considered to have been submitted to the International Bureau on the date marked.

56.2. Identification of the International Application

The international application shall be identified as provided in Rule 53.6.

56.3. Identification of the Demand

The demand shall be identified by the date on which it was submitted and by the name of the International Preliminary Examining Authority to which it was submitted.

56.4. Form of Later Elections

The notice effecting the later election shall preferably be worded as follows: "In relation to the international application filed with ... on ... under No. ... by ...(applicant) (and the demand for international preliminary examination submitted on ... to ...), the undersigned elects the following additional State(s) under Article 31 of the Patent Cooperation Treaty: ..."

56.5. Language of Later Elections

The later election shall be in the language of the demand.

Applicants may, after filing of the Demand, later, but still within 19 months of the priority date, elect additional States which have been previously designated and obtain the benefit of delaying the national stage until 30 months after the priority date in the additional elected States. All such later elections must be filed directly with the International Bureau and not the International Preliminary Examining Authority. Elections received after 19 months will not delay the time for entry into the national stage from 20 to 30 months.

1874 Determination if International Preliminary Examination Is Required and Possible

PCT Article 34.

Procedure Before the International Preliminary Examining Authority

(4)(a) If the International Preliminary Examining Authority considers

(i) that the international application relates to a subject matter on which the International Preliminary Examining Authority is not required, under the Regulations, to carry out an international preliminary examination, and an international preliminary examination, and in the particular case decides not to carry out such examination, or

(ii) that the description, the claims, or the drawings, are so unclear, or the claims are so inadequately supported by the description, that no meaningful opinion can be formed on the novelty, inventive step (non-obviousness), or industrial applicability, of the claimed invention, the said authority shall not go into the questions referred to in Article 33(1) and shall inform the applicant of this opinion and the reasons therefor.

(b) If any of the situations referred to in subparagraph (a) is found to exist in, or in connection with, certain claims only, the provisions of that subparagraph shall apply only to the said claims.

There are instances where international preliminary examination is not required because of the nature of the subject matter claimed and also because the claims are so indefinite that no examination is possible. Such instances should seldom occur, especially since most problems of this nature would have already been discovered and indicated at the time of the international search.

If it is found that certain claims of an international application relate to subject matter for which no international preliminary examination is required, on Form PCT/IPEA/408, check the appropriate box. It should be noted that subject matter which is normally examined under U.S. national procedure should also be examined as an International Preliminary Examining Authority.

The examiner should check the appropriate box if it is found that the description, claims or drawings are so unclear, or the claims are so inadequately supported by the description that no opinion could be formed as to the novelty, inventive step (nonobviousness) and industrial applicability of the claimed invention.

Subject matter not searched under Chapter I will not be the subject of a preliminary examination under Chapter II. This is so even if claims which were not searched under Chapter I are modified to be acceptable for examination.

1875 Unity of Invention Before the International Preliminary Examining Authority

PCT Article 34.

Procedure before the International Preliminary Examining Authority

(3)(a) If the International Preliminary Examining Authority considers that the international application does not comply with the requirement of unity of invention as set forth in the Regulations, it may invite the applicant, at his option, to restrict the claims so as to comply with the requirement or to pay additional fees.

(c) If the applicant does not comply with the invitation referred to in subparagraph (a) within the prescribed time limit, the International Preliminary Examining Authority shall establish an international preliminary examination report on those parts of the international application which relate to what appears to be the main invention and shall indicate the relevant facts in the said report. The national law of any elected State may provide that, where its national Office finds the invitation of the International Preliminary Examining Authority justified, those parts of the international application which do not relate to the main invention shall, as far as effects in that State are concerned, be considered withdrawn unless a special fee is paid by the applicant to that Office.

37 CFR 1.488. Determination of unity of invention before the International Preliminary Examining Authority.

(a) Before establishing any written opinion or the international preliminary examination report, the International Preliminary Examining Authority will determine whether the international application complies with the requirement of unity of invention as set forth in § 1.475.

(b) If the International Preliminary Examining Authority considers that the international application does not comply with the requirement of unity of invention, it may:

(1) Issue a written opinion and/or an international preliminary examination report, in respect of the entire international application and indicate that unity of invention is lacking and specify the reasons therefor without extending an invitation to restrict or pay additional fees. No international preliminary examination will be conducted on inventions not previously searched by an International Searching Authority.

(2) Invite the applicant to restrict the claims or pay additional fees, pointing out the categories of invention found, within a set time limit which will not be extended. No international preliminary examination will be conducted on inventions not previously searched by an International Searching Authority, or

(3) If applicant fails to restrict the claims or pay additional fees within the time limit set for reply, the International Preliminary Examining Authority will issue a written opinion and/or establish an international preliminary examination report on the main invention and shall indicate the relevant facts in the said report. In case of any doubt as to which invention is the main invention, the invention first mentioned in the claims and previously searched by an International Searching Authority shall be considered the main invention.

(c) Lack of unity of invention may be directly evident before considering the claims in relation to any prior art, or after taking the prior art into consideration, as where a document discovered during the search shows the invention claimed in a generic or linking claim lacks novelty or is clearly obvious, leaving two or more claims joined thereby without a common inventive concept. In such a case the International Preliminary Examining Authority may raise the objection of lack of unity of invention.

The examiner will usually begin the preliminary examination by checking the international application for unity of invention. The international preliminary examination will only be directed to inventions which have been searched by the International Searching Authority. All claims directed to inventions which have not been searched by the International Searching Authority will not be considered by the International Preliminary Examining Authority. If the examiner in the International Preliminary Examining Authority finds lack of unity of invention in the claims to be examined, an invitation is normally prepared and sent to the applicant requesting the payment of additional fees or the restriction of the claims on Form PCT/IPEA/405. Such an invitation will include the identification of what the examiner considers to be the "main invention" which will be examined if no additional fees are paid or restriction is made by the applicant.

The procedure before the International Preliminary Examining Authority regarding lack of unity of invention is governed by PCT Article 34(3)(a) through (c), PCT Rule 68 (see also PCT Rule 70.13), and 37 CFR 1.475 and 1.488. It should be noted that in most instances lack of unity of invention will have been noted and reported upon by the International Searching Authority which will have drawn up an International Search Report based on those parts of the international application relating to the invention, or unified linked group of inventions, first mentioned in the claims ("main invention"). If the applicant has paid additional search fees, additional inventions would also have been searched. No international preliminary examination will be conducted on inventions

not previously searched by an International Searching Authority (37 CFR 1.488(b)(2)).

Unity of invention must be addressed within 7 days from the date the PCT application is charged to the Technology Center from the PCT International Application Processing Division. This simply means that a determination must be made as to whether or not the international application relates to one invention or to a group of inventions so linked as to form a single general inventive concept.

If it is determined that the international application does meet the requirements for unity of invention and no additional fees will be requested, the international application must be returned to the Paralegal Specialist or Legal Instruments Examiner in the Technology Center so that an indication to that effect may be made on the PALM System which monitors deadlines such as the deadline for checking unity of invention.

If the examiner determines that unity of invention is lacking, there are two options:

(A) The examiner may conduct an international preliminary examination covering all the claimed and previously searched inventions and indicate that unity of invention is lacking and specify the reasons therefor without extending an invitation to restrict or pay additional fees (PCT Rule 68.1), or

(B) The examiner may invite the applicant to restrict the claims, so as to comply with the requirement, or pay additional fees, pointing out the categories of invention found. The invitation to restrict or pay additional fees shall state the reasons for which the international application is considered as not complying with the requirement of unity of invention. (PCT Rule 68.2). Inventions not previously searched will not be considered or included in the invitation.

The written opinion, if any, and the international preliminary examination report must be established on all inventions for which examination fees have been paid.

If the applicant fails to reply to the invitation to restrict the claims or pay additional examination fees due to lack of unity of invention, the written opinion and international preliminary examination report must be established on the claims directed to what appears to be the main invention (PCT Article 34(3)(c)). The main invention, in case of doubt, is the first claimed invention for which an international search report has

been issued by the International Searching Authority. The main invention, as viewed by the examiner, must be set forth on Form PCT/IPEA/405.

Whether or not the question of unity of invention has been raised by the International Searching Authority, it may be considered by the examiner when serving as an authorized officer of the International Preliminary Examining Authority. In the examiner's consideration, all documents cited by the International Searching Authority should be taken into account and any additional relevant documents considered. However, there are cases of lack of unity of invention, where, compared with the procedure of inviting the applicant to restrict the international application or pay additional fees (PCT Rule 68.2), little or no additional effort is involved in establishing the written opinion and the international preliminary examination report for the entire international application. Then reasons of economy may make it advisable for the examiner to use the option referred to in PCT Rule 68.1 by choosing not to invite the applicant to restrict the claims or to pay additional fees.

Unity of invention is defined by 37 CFR 1.475 which describes the circumstances in which the requirement of unity of invention is considered fulfilled.

1875.01 Preparation of Invitation Concerning Unity

The "Invitation to restrict or pay additional fees" Form PCT/IPEA/405 is used to invite the applicant, at his/her option, to restrict the claims to comply with the requirements of unity of invention or to pay additional examination fees. In addition, the examiner must explain the reasons why the international application is not considered to comply with the requirement of unity of invention. The examiner must also specify, on Form PCT/IPEA/405, at least one group or groups of claims which, if elected, would comply with the requirement for unity of invention.

INVITATION

In the space provided on form PCT/IPEA/405, the examiner should identify the disclosed inventions by claim numerals and indicate which disclosed inventions are so linked as to form a single general inven-

tive concept, thereby complying with the requirement of unity of invention. For example, claims to different categories of invention such as a product, claims to a process specifically adapted for the manufacture of the product and a claim for a use of the product would be considered related inventions which comply with the unity of invention requirement, whereas a claim to an apparatus for making the product in the same application would be considered a second invention for which additional fees would be required. The reasons for holding that unity of invention is lacking must be specified. See 37 CFR 1.475 and Annex B of the Administrative Instructions.

Also, the examiner should specify the main invention and claims directed thereto which will be examined if the applicant fails to restrict or pay additional fees. The main invention, in case of doubt, is the first claimed invention or related invention before the International Preliminary Examining Authority for which a search fee has been paid and an international search report has been prepared.

The examiner should indicate the total amount of additional fees required for examination of all claimed inventions.

In the box provided at the top of the form, the time limit for response is set according to PCT Rule 68.2, normally a 1 month time limit. Extensions of time are not permitted.

Since the space provided on Form PCT/IPEA/405 is limited, supplemental attachment sheets, supplied by the examiner, with reference back to the specific section, should be incorporated whenever necessary.

AUTHORIZED OFFICER

Form PCT/IPEA/405 must be signed by an examiner with at least partial signatory authority.

TELEPHONIC RESTRICTION PRACTICE

Telephone practice may be used in certain cases to allow applicants to elect an invention to be examined or to pay additional fees. Additional fees may be charged to a deposit account using the telephone practice only if:

(A) The Demand for International Preliminary Examination included an authorization to charge additional fees to a deposit account,

(B) Applicant or the legal representative or agent orally agrees to charge the additional fees to the account; and

(C) A complete record of the telephone conversation is included with the written opinion including:

- (1) Examiner's name;
- (2) Authorizing attorney's name;
- (3) Date of conversation;
- (4) Invention elected and/or inventions for which additional fees paid; and
- (5) Deposit account number and amount to be charged.

If applicant or the legal representative or agent refuses to either restrict the claims to one invention or authorize payment of additional fees, Form PCT/IPEA/499 should be prepared and mailed to applicant.

When the telephone practice is used in making lack of unity requirements, it is critical that the examiner orally inform applicant that there is no right to protest the holding of lack of unity of invention for any group of invention(s) for which no additional examination fee has been paid.

The examiner must further orally advise applicant that any protest to the holding of lack of unity or the amount of additional fee required must be filed in writing no later than one month from the mailing date of the written opinion or the international preliminary examination report if the lack of unity holding is first mailed with the IPER because there was no written opinion. The examiner should fill in the information on Form PCT/IPEA/499 "Chapter II PCT Telephone Memorandum for Lack of Unity" as a record of the telephonic holding of lack of unity.

37 CFR 1.475. Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered

to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

¶ 18.05 Heading for Lack of Unity Action (Not Involving Species)

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Examiner Note:

Begin all Lack of Unity actions with this heading.

¶ 18.06 Lack of Unity - Three Groups of Claims

- Group [1], claim(s) [2], drawn to [3].
Group [4], claim(s) [5], drawn to [6].
Group [7], claim(s) [8], drawn to [9].

Examiner Note:

1. In brackets 1,4 and 7, insert Roman numerals for each Group.
2. In brackets 2, 5 and 8, insert respective claim numbers.
3. In brackets 3, 6 and 9, insert respective names of grouped inventions.

¶ 18.06.01 Lack of Unity - Two (or Additional) Groups of Claims

- Group [1], claim(s) [2], drawn to [3].
Group [4], claim(s) [5], drawn to [6].

Examiner Note:

This form paragraph may be used alone or following form paragraph 18.06.

¶ 18.06.02 *Lack of Unity - One Additional Group of Claims*

Group [1], claim [2], drawn to [3].

Examiner Note:

This form paragraph may be used following either form paragraph 18.06 or 18.06.01.

¶ 18.07 *Lack of Unity - Reasons Why Inventions Lack Unity*

The inventions listed as Groups [1] do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: [2]

Examiner Note:

1. In bracket 1, insert appropriate Roman numerals for Groups involved.
2. In bracket 2, insert reasoning.

¶ 18.16 *Lack of Unity - Species - Heading*

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

[1]

Examiner Note:

In bracket 1, list each species by Fig. No. or embodiment.

¶ 18.17 *Lack of Unity - Species - Correspondence of the Claims to the Species*

The claims are deemed to correspond to the species listed above in the following manner:

[1]

The following claim(s) are generic: [2]

Examiner Note:

1. This form paragraph is to be used immediately following 18.16.
2. In bracket 1, for each species, list the claims, e.g., Fig.1 - claims 1, 3 and 6.
3. In bracket 2, identify each generic claim by number or insert the word --NONE--.

¶ 18.18 *Lack of Unity - Species - Reasons Why Unity Is Lacking*

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: [1]

Examiner Note:

1. This form paragraph is to be used immediately following form paragraph 18.17.
2. In bracket 1, insert reasoning.

¶ 18.19 *National Stage Restriction in 35 U.S.C. 371 Applications*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Examiner Note:

1. This form paragraph is to be used when making a restriction requirement in an application filed under the provisions of 35 U.S.C. 371.
2. This form paragraph is to be followed by form paragraphs 18.06 through 18.06.02, as appropriate, and by form paragraph 18.07.

¶ 18.20 *National Stage Election of Species in 35 U.S.C. 371 Applications*

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

[1]

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Examiner Note:

1. This form paragraph is to be used when making an election of species requirement in an application filed under the provisions of 35 U.S.C. 371.
2. In bracket 1, list each species by Fig. No. or embodiment.
3. This form paragraph is to be followed by form paragraphs 18.17 and 18.18.

¶ 18.21 *National Stage Election by Original Presentation in 35 U.S.C. 371 Applications*

Newly submitted claim [1] directed to an invention that lacks unity with the invention originally claimed for the following reasons: [2]

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim [3] withdrawn from consideration as being

directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

1875.02 Reply to Invitation Concerning Lack of Unity of Invention

PCT Administrative Instruction Section 603.

Transmittal of Protest Against Payment of Additional Fee and Decision Thereon Where International Application is Considered to Lack Unity of Invention

The International Preliminary Examining Authority shall transmit to the applicant, at the latest together with the international preliminary examination report, any decision which it has taken under Rule 68.3(c) on the protest of the applicant against payment of the additional fee where the international application is considered to lack unity of invention. At the same time, it shall transmit to the International Bureau a copy of both the protest and the decision thereon, as well as any request by the applicant to forward the texts of both the protest and the decision thereon to the elected Offices.

37 CFR 1.489. Protest to lack of unity of invention before the International Preliminary Examining Authority.

(a) If the applicant disagrees with the holding of lack of unity of invention by the International Preliminary Examining Authority, additional fees may be paid under protest, accompanied by a request for refund and a statement setting forth reasons for disagreement or why the required additional fees are considered excessive, or both.

(b) Protest under paragraph (a) of this section will be examined by the Commissioner or the Commissioner's designee. In the event that the applicant's protest is determined to be justified, the additional fees or a portion thereof will be refunded.

(c) An applicant who desires that a copy of the protest and the decision thereon, accompany the international preliminary examination report when forwarded to the Elected Offices, may notify the International Preliminary Examining Authority to that effect any time prior to the issuance of the international preliminary examination report. Thereafter, such notification should be directed to the International Bureau.

Applicant may reply by paying some or all additional fees or by restricting the claims to one invention. If applicant makes no reply within the set time limit, the international preliminary examination will proceed on the basis of the main invention only.

If applicant has paid an additional fee or fees, a protest to the holding of lack of unity of invention may be filed with the International Preliminary Examining Authority.

NOTIFICATION OF DECISION ON PROTEST

Form PCT/IPEA/420 is used by the Technology Center (TC) to inform the applicant of the decision

regarding applicant's protest on the payment of additional fees concerning unity of invention.

NOTIFICATION

The TC checks the appropriate box, i.e., 1 or 2. If box 2 is checked, a clear and concise explanation as to why the protest concerning the unity of invention was found to be unjustified must be given.

Since the space is limited, supplemental attachment sheet(s) should be incorporated whenever necessary.

AUTHORIZED OFFICER

Form PCT/IPEA/420 must be signed by a TC Director. See MPEP § 1002.02(e).

1876 Notation of Errors and Informalities by the Examiner

PCT Administrative Instruction Section 607.

Rectifications of Obvious Errors Under Rule 91.1

Where the International Preliminary Examining Authority authorizes a rectification of an obvious error under Rule 91.1, Rule 70.16 and Section 602(a) and (b) shall apply *mutatis mutandis*, provided that, where a sheet is marked as indicated in Section 602, the words "RECTIFIED SHEET (RULE 91)" shall be used.

Although the examiner is not responsible for discovering errors in the international application, if any errors come to the attention of the examiner, they should be noted and called to the applicant's attention. The examiner may invite applicant to rectify obvious errors using Form PCT/IPEA/411. Errors that are not obvious may be called to applicant's attention in item VII of PCT/IPEA/408.

AUTHORIZED OFFICER

Form PCT/IPEA/408 and 411 must be signed by an examiner having at least partial signatory authority.

1876.01 Request for Rectification and Notification of Action Thereon

NOTIFICATION OF DECISION CONCERNING REQUEST FOR RECTIFICATION

The rectification of obvious errors is governed by PCT Rules 91.1 and 66.5.

NOTIFICATION

If the applicant requests correction of any obvious errors in the international application or in any paper submitted to the International Preliminary Examining Authority, other than in the request, any acceptable correction should be authorized by using Form PCT/IPEA/412.

The procedure governing the rectification of obvious errors is set forth in PCT rules 91.1(d) and 26.4(a). Rectification may be made on the request of the applicant. Any rectification offered to the international preliminary examining authority may be stated in a letter addressed to the international preliminary examining authority if the rectification is of such a nature that it can be transferred from the letter to the international application without adversely affecting the clarity and direct reproducibility of the sheet on to which the rectification is to be transferred; otherwise, the applicant is required to submit a replacement sheet embodying the rectification and the letter accompanying the replacement sheet must draw attention to the differences between the replaced sheet and the replacement sheet.

The examiner after fully considering applicant's Request for Rectification of an obvious error, will notify applicant of the action taken on Form PCT/IPEA/412. Since the space provided is limited, supplemental sheet(s) should be incorporated whenever necessary.

AUTHORIZED OFFICER

Form PCT/IPEA/412 must be signed by an examiner having at least partial signatory authority.

1877 Nucleotide and/or Amino Acid Sequence Listings During the International Preliminary Examination

If the International Preliminary Examining Authority finds that the international application contains disclosure of one or more nucleotide and/or amino acid sequences but (A) the international application does not contain a sequence listing complying with the standard provided for in the Administrative Instructions, or (B) applicant has not furnished a sequence listing in computer readable form comply-

ing with the standard provided for in the Administrative Instructions, the International Preliminary Examining Authority may request the applicant to furnish such sequence listing or listing in computer readable form in accordance with the Administrative Instructions. PCT Rule 13^{ter}.1(e)

1878 Preparation of the Written Opinion*PCT Article 34.**Procedure Before the International Preliminary Examining Authority*

(2)(c) The applicant shall receive at least one written opinion from the International Preliminary Examining Authority unless such Authority considers that all of the following conditions are fulfilled:

- (i) the invention satisfies the criteria set forth in Article 33(1),
- (ii) the international application complies with the requirements of this Treaty and the Regulations in so far as checked by that Authority,
- (iii) no observations are intended to be made under Article 35(2), last sentence.

37 CFR 1.484. Conduct of international preliminary examination.

(a) An international preliminary examination will be conducted to formulate a non-binding opinion as to whether the claimed invention has novelty, involves an inventive step (is non-obvious) and is industrially applicable.

(b) International preliminary examination will begin promptly upon receipt of a proper Demand in an application for which the United States International Preliminary Examining Authority is competent, for which the fees for international preliminary examination (§ 1.482) have been paid, and which requests examination based on the application as filed or as amended by an amendment which has been received by the United States International Preliminary Examining Authority. Where a Demand requests examination based on a PCT Article 19 amendment which has not been received, examination may begin at 20 months without receipt of the PCT Article 19 amendment. Where a Demand requests examination based on a PCT Article 34 amendment which has not been received, applicant will be notified and given a time period within which to submit the amendment.

- (1) Examination will begin after the earliest of:
 - (i) Receipt of the amendment;
 - (ii) Receipt of applicant's statement that no amendment will be made; or
 - (iii) Expiration of the time period set in the notification.
- (2) No international preliminary examination report will be established prior to issuance of an international search report.

(c) No international preliminary examination will be conducted on inventions not previously searched by an International Searching Authority.

(d) The International Preliminary Examining Authority will establish a written opinion if any defect exists or if the claimed invention lacks novelty, inventive step or industrial applicability and will set a non-extendable time limit in the written opinion for the applicant to reply.

(e) If no written opinion under paragraph (d) of this section is necessary, or after any written opinion and the reply thereto or the expiration of the time limit for reply to such written opinion, an international preliminary examination report will be established by the International Preliminary Examining Authority. One copy will be submitted to the International Bureau and one copy will be submitted to the applicant.

(f) An applicant will be permitted a personal or telephone interview with the examiner, which must be conducted during the non-extendable time limit for reply by the applicant to a written opinion. Additional interviews may be conducted where the examiner determines that such additional interviews may be helpful to advancing the international preliminary examination procedure. A summary of any such personal or telephone interview must be filed by the applicant as a part of the reply to the written opinion or, if applicant files no reply, be made of record in the file by the examiner.

(g) If the application whose priority is claimed in the international application is in a language other than English, the United States International Preliminary Examining Authority may, where the validity of the priority claim is relevant for the formulation of the opinion referred to in Article 33(1), invite the applicant to furnish an English translation of the priority document within two months from the date of the invitation. If the translation is not furnished within that time limit, the international preliminary examination report may be established as if the priority had not been claimed.

A written opinion must be prepared if the examiner:

(A) Considers that the international application has any of the defects described in PCT Article 34(4);

(B) Considers that the report should be negative with respect to any of the claims because of a lack of novelty, inventive step (non-obviousness) or industrial applicability;

(C) Notices any defects in the form or contents of the international application under the PCT;

(D) Considers that any amendment goes beyond the disclosure in the international application as originally filed;

(E) Wishes to make an observation on the clarity of the claims, the description, the drawings or to question whether the claims are fully supported by the description;

(F) Decides not to carry out the international preliminary examination on a claim for which no International Search Report was issued; or

(G) Considers that no acceptable amino acid sequence listing is available in a form that would allow a meaningful international preliminary examination to be carried out.

The applicant must be notified on Form PCT/IPEA/408 of the defects found in the application. The examiner is further required to fully state the reasons for his/her opinion (PCT Rule 66.2(b)) and invite a written reply, with amendments where appropriate (PCT Rule 66.2(c)), setting a time limit for the reply of normally 2 months.

The examiner should insert the words "first" or "second", as the case may be, in the space provided on page 1 of the written opinion.

ITEM I. BASIS OF OPINION

Applicant has two opportunities to amend the international application prior to international preliminary examination. Under PCT Article 19, the applicant is entitled to one opportunity to amend the claims of the international application by filing amendments with the International Bureau within 2 months of the mailing of the international search report. See PCT Rule 46.1. Applicant is also permitted to make amendments before the International Preliminary Examining Authority under PCT Article 34(2)(b) and PCT Rule 66.1. Any amendment, however, that does not accompany the filing of the Demand but is filed later may not be considered unless it reaches the examiner before he/she takes up the application for examination.

For the purpose of completing Box I, Item 1, of Form PCT/IPEA/408, substitute and/or rectified sheets of the specification and drawings filed during Chapter I proceedings are considered to be originally filed pages/sheets and should be listed as originally filed pages/sheets. Only those amendments or rectifications to the specification and drawings filed on the date of Demand or after the filing of a Demand should be listed as later filed pages/sheets. Substitute and/or rectified sheets of claims filed during the Chapter I proceedings are also considered to be originally filed pages/sheets and should be listed as originally filed pages/sheets. However, amended sheets of claims filed under Article 19 in response to the international

search report are to be indicated as pages/sheets as amended under Article 19. Only those amendments, or rectifications to the claims filed on the date of Demand or after the filing of a Demand should be listed as later filed pages/sheets. All claims present on a sheet stamped AMENDED SHEET are listed as amended irrespective of which of the claims present on that sheet were actually amended. If a claim is made up of sheets filed on different dates, the latest date is the date that should be used for the claim.

ITEM II. PRIORITY

Item II of Form PCT/IPEA/408 is to inform applicant of non-establishment of a request for priority.

If applicant fails to furnish a copy or translation of the earlier application, whose priority has been claimed, within the time limit set by the examiner pursuant to PCT Rule 66.7, check box No. 1 and then check the first box of the subsection if applicant failed to furnish a copy of the earlier application whose priority has been claimed, and check the second box in the subsection if applicant failed to furnish a translation of the earlier application whose priority has been claimed.

When the claim for priority has been found invalid (e.g., the claimed priority date is more than one year prior to the international filing date and the notification under PCT Rule 4.10(d) has been provided or all claims are directed to inventions which were not described and enabled by the earlier application), check box No. 2 of Item II and indicate why the claim for priority has been found invalid following No. 3 "Additional observations". The examiner is reminded that when some claims in an international application are directed to an invention which was disclosed in the earlier application, the priority claim is valid provided that a copy and/or translation of the earlier application have/has been filed and the filing date of the earlier application is one year or less from the filing date of the international application.

ITEM III. NON-ESTABLISHMENT OF OPINION ON NOVELTY, INVENTIVE STEP AND INDUSTRIAL APPLICABILITY

Item III of Form PCT/IPEA/408 is intended to cover situations where some or all claims of an application are so unclear or inadequately supported by the description that the question of novelty, inventive step

(nonobviousness), and industrial applicability cannot be considered, or where the international application or claims thereof relate to subject matter which does not require international preliminary examination, or where no international search report has been established for the claims.

If some or all of the claims of an application relate to subject matter which does not require international preliminary examination, check the appropriate box, indicate which claims relate to that subject matter and specify the reasons.

If some or all of the claims of an application are so unclear that no meaningful opinion could be formed, check the appropriate box, indicate which claims are unclear and specify the reasons.

If some or all of the claims are so inadequately supported by the description that no meaningful opinion could be formed, check the appropriate box.

If no international search report has been established for certain claims, check the appropriate box and indicate the claim numbers.

ITEM IV. LACK OF UNITY OF INVENTION

Item IV of Form PCT/IPEA/408 should be used by the examiner to notify applicant that lack of unity of invention has been found.

If in reply to an invitation to restrict, applicant restricted the claims to a particular group, check the first box under subsection 1.

If applicant paid additional fees for examination of additional invention, check the second box under subsection 1.

If the additional fees were paid under protest, check the third box under subsection 1.

If applicant neither restricted nor paid additional fees in reply to the objection of lack of unity of invention, check the fourth box under subsection 1.

Subsection 2 of Item IV is to be completed if the examiner determines that unity of invention is lacking but chooses not to invite the applicant to restrict or pay additional fees.

Subsection 3 of Item IV is to be completed to indicate which claims were the subject of international preliminary examination.

If all claims are to be examined, check the first box under subsection 3.

If only some of the claims were the subject of international preliminary examination, check the second

box under subsection 3 and identify the claim numbers.

ITEM V. REASONED STATEMENT WITH REGARD TO NOVELTY, INVENTIVE STEP, AND INDUSTRIAL APPLICABILITY OF CLAIMS

In Item V, the examiner must list in summary form all claims with regard to the criteria of novelty (N), inventive step (IS), and industrial applicability (IA).

Item V is the main purpose of the Written Opinion. All claims without fatal defects are treated on the merits in Item V as to novelty, inventive step (nonobviousness) and industrial applicability.

The treatment of claims in Item V is similar in format to an Office action in a U.S. national patent application except that the words "rejection" and "patentability" are never used in a written opinion. On the international level, all written opinions are nonbinding and a patent does not issue; what does issue is an international preliminary examination report (IPER), which is nonbinding on the Elected States.

Examiner statements in Item V can be positive and/or negative. If, for example, claims define over the prior art and meet the test of novelty, inventive step (nonobviousness) and industrial applicability, a statement equivalent to detailed reasons for allowance in a corresponding U.S. application, indicating how the claims meet the tests of novelty, inventive step and industrial applicability is sufficient. If on the other hand it is the opinion of the examiner that some or all claims lack novelty, inventive step, and/or industrial applicability, specific reasons for the opinion employing PCT form paragraphs, if appropriate, must be given similar to those used in U.S. national applications including a statement of motivation to combine references cited regarding negative statements of inventive step.

Form paragraphs to be used by the examiners appear in the relevant sections of this Manual. All examiners are expected to use the PCT form paragraphs in formulating any negative statements listed in Item V.

Examiners are encouraged to indicate any amendments which applicant could present which would avoid a negative statement in the international preliminary examination report.

All international applications where an examination has been demanded should be searched by the exam-

iner at least to the point of bringing the previous search up to date. Prior art discovered in a search and applied in an Item V statement must be made of record in Item V. Prior art already cited on the international search report need not again be cited on the written opinion or international preliminary examination report. The subsequently discovered prior art is to be cited in compliance with PCT Rule 43.5 and Administrative Instructions Section 503 using the same citation format used on the international search report. Two copies of each newly cited reference should be included in the PCT Chapter II file when it is sent to PCT Operations for the mailing of the form PCT/IPEA/408. One of the copies of the newly cited reference will be sent to the applicant and one copy will be retained in the Chapter II file.

¶ 18.01 Lacks Novelty

Claim [1] novelty under PCT Article 33(2) as being anticipated by [2].

Examiner Note:

1. In bracket 1, pluralize 'claim' if needed, insert claim no.(s), and the verb --lack-- or --lacks--, as appropriate.
2. In bracket 2, insert name of prior art relied upon.

¶ 18.02 Lacks Inventive Step - One Reference

Claim [1] an inventive step under PCT Article 33(3) as being obvious over [2]. [3]

Examiner Note:

1. In bracket 1, pluralize 'claim' if needed, insert claim no.(s), and the verb --lack-- or --lacks--, as appropriate.
2. In bracket 2, insert name of prior art relied upon.
3. In bracket 3, add reasoning.

¶ 18.02.01 Lacks Inventive Step - Two References

Claim [1] an inventive step under PCT Article 33(3) as being obvious over [2] in view of [3]. [4]

Examiner Note:

1. In bracket 1, pluralize 'claim' if needed, insert claim no.(s), and the verb --lack-- or --lacks--, as appropriate.
2. In bracket 2, insert name of PRIMARY prior art relied upon.
3. In bracket 3, insert name of SECONDARY prior art relied upon.
4. In bracket 4, add reasoning.

¶ 18.02.02 Lacks Inventive Step - Additional Reference

Claim [1] an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of [2]. [3]

Examiner Note:

1. This form paragraph may follow either 18.02 or 18.02.01.
2. In bracket 1, pluralize 'claim' if needed, insert claim no.(s), and the verb --lack-- or --lacks--, as appropriate.

3. In bracket 2, insert name of additional prior art relied upon.
4. In bracket 3, add reasoning.

¶ 18.03 Lacks Industrial Applicability

Claim [1] industrial applicability as defined by PCT Article 33(4). [2]

Examiner Note:

1. In bracket 1, pluralize 'claim' if needed, insert claim no.(s), and the verb --lack-- or --lacks--, as appropriate.
2. In bracket 2, add reasoning.

¶ 18.04 Meets Novelty, Inventive Step and Industrial Applicability

Claim [1] the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest [2].

Examiner Note:

1. In bracket 1, pluralize 'claim' if needed, insert claim no.(s), and the verb --meet-- or --meets--, as appropriate.
2. In bracket 2, insert patentable subject matter.

ITEM VI. CERTAIN DOCUMENTS CITED

Item VI provides a convenient manner of listing two different types of documents:

(A) Published documents - by the application number or patent number as well as the publication date, filing date and priority date; and

(B) Nonwritten disclosure - by the kind of disclosure, date of the disclosure and the date of the written disclosure referring to the nonwritten disclosure.

ITEM VII. CERTAIN DEFECTS IN THE INTERNATIONAL APPLICATION

In Item VII, defects in the form and content of the international application are identified.

Examples of defects that would be listed in Item VII are:

(A) Informalities such as misplaced and/or omitted drawing numerals, misspelled words, grammatical errors, etc.

(B) An amendment to the drawings, description or claims which was not timely filed.

(C) Improper multiple-dependent claims (PCT Rule 6.4) if not indicated under Item III.

The following form paragraphs are used in Box VII of PCT/IPEA/408 or PCT/IPEA/409 "Certain defects in the international application" for noting technical defects.

¶ 18.08 Drawing Objections - Defects

The drawings are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or content thereof: [1]

Examiner Note:

In bracket 1, insert identification of defects in drawings.

¶ 18.08.01 Drawing Is Required

The subject matter of this application admits of illustration by drawing to facilitate understanding of the invention. Applicant is required under PCT Article 7(1) to furnish a drawing.

¶ 18.09 Description Defective

The description is objected to as containing the following defect(s) under PCT Rule 66.2(a)(iii) in the form or contents thereof: [1]

Examiner Note:

In bracket 1, insert the technical problem, e.g., misspelled word.

¶ 18.10 Claims Defective

Claim [1] objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: [2]

Examiner Note:

1. In bracket 1, pluralize 'claim' if needed, insert claim no.(s) and the appropriate verb --is-- or --are--.
2. In bracket 2, identify the technical deficiency.

ITEM VIII. CERTAIN OBSERVATIONS ON THE INTERNATIONAL APPLICATION

In Item VIII, the examiner notifies the applicant of observations made as to the clarity of the claims, the description, the drawings, or on the question whether the claims are fully supported by the description.

If the claims, the description, or the drawings are so unclear, or the claims are so inadequately supported by the description, that no meaningful opinion can be formed on the question of novelty, inventive step (nonobviousness) or industrial applicability, the applicant is so informed in Item III (PCT Article 34(4)(a)(ii)). Reasons for the examiner's opinion that the claims, description and drawings, etc., lack clarity must also be provided.

If the above situation is found to exist in certain claims only, the provisions of PCT Article 34(4)(ii) shall apply to those claims only.

If the lack of clarity of the claims, the description, or the drawings is of such a nature that it is possible to form a meaningful opinion on the claimed subject matter, then it is required that the examiner consider the claims and render a written opinion on novelty,

inventive step, and industrial applicability in Item V of Form PCT/IPEA/408.

Since the claims of an international application are not subject to a rejection on either art or indefiniteness consistent with U.S. practice, observations by the examiner with regard to clarity of the claims, the description and the drawings will be treated in the form of an objection in the written opinion in Item VIII.

The following form paragraphs are used in Box VIII "Certain observations on the international application" of PCT/IPEA/408 and PCT/IPEA/409 for noting objections which are substantive rather than merely technical in nature.

¶ 18.11 Drawing Objections - Lack Clarity

The drawings are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 7 because: [1]

Examiner Note:

In bracket 1, insert reasons why the drawings lack clarity, e.g., inaccurate showing.

¶ 18.12.01 Claims Objectionable - Inadequate Written Description

Claim [1] objected to as lacking clarity under PCT Rule 66.2(a)(v) because the claim [2] not fully supported by the description. The application, as originally filed, did not describe: [3]

Examiner Note:

1. In bracket 1, pluralize "claim" if needed, insert claim no.(s), and the verb --is-- or --are--, as appropriate.
2. In bracket 2, pluralize "claim" if needed, and insert the verb --is-- or --are--.
3. In bracket 3, identify subject matter not described in the application as filed.

¶ 18.13.01 Claims Objectionable - Non-Enabling Disclosure

Claim [1] objected to as lacking clarity under PCT Rule 66.2(a)(v) because the claim [2] not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because: [3]

Examiner Note:

1. In bracket 1, pluralize "claim" if needed, insert claim no.(s) and the appropriate verb --is-- or --are--.
2. In bracket 2, pluralize "claim" if needed, insert the verb --is-- or --are--.
3. In bracket 3, identify the claimed subject matter that is not enabled and explain why it is not enabled.

¶ 18.14.01 Claims Objectionable - Lack of Best Mode

Claim [1] objected to under PCT Rule 66.2(a)(v) because the claim [2] not fully supported by the description. The description fails to set forth the best mode contemplated by the applicant for carrying out the claimed invention as required by PCT Rule 5.1(a)(v) because: [3].

Examiner Note:

1. In bracket 1, pluralize "claim" if needed, insert claim no.(s) and the appropriate verb --is-- or --are--.
2. In bracket 2, pluralize "claim" if needed, and insert the appropriate verb --is-- or --are--.
3. In bracket 3, insert the objection and reasons.

¶ 18.15 Claims Objectionable - Indefiniteness

Claim [1] objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim [2] indefinite for the following reason(s): [3]

Examiner Note:

1. In brackets 1 and 2, pluralize "claim" if needed, insert claim no.(s) and the appropriate verb --is-- or --are--.
2. In bracket 3, insert reasons.

TIME TO REPLY

An invitation by the International Preliminary Examining Authority (IPEA) to applicant to reply to the examiner's written opinion will normally set a 2-month time limit for reply.

However, PCT Rule 69.2 sets forth time limits for the IPEA to establish the international preliminary examination report (IPER). Accordingly, a 1-month time limit should be set by the examiner in situations when a 2-month time limit would risk delaying the date of establishment of the IPER beyond:

- (A) 28 months from the priority date; or
- (B) 8 months from the date of payment of the handling fee referred to in PCT Rule 57.1 and the preliminary examination fee referred to in PCT Rule 58.1(a); or
- (C) 8 months from the date of receipt by the IPEA of the translation furnished under PCT Rule 55.2.

As a general rule, a 1-month time limit for reply to the written opinion should be set by the examiner if the written opinion (Form PCT/IPEA/408) has not been completed by the examiner within 24 months following the application's "priority date" as defined in PCT Article 2.

The United States rules pertaining to international preliminary examination of international applications do not provide for any extension of time to reply to a first written opinion. See 37 CFR 1.484(d) and MPEP §1878.02.

AUTHORIZED OFFICER

Every written opinion must be signed by an examiner having at least partial signatory authority.

The first document prepared by the examiner in most international applications during the international preliminary examination proceedings will be the written opinion. Normally only in those international applications where all the formal matters are proper and the claims are directed to inventions which have novelty, inventive step and industrial applicability will an international preliminary examination report be established without a written opinion having been issued first.

1878.01

1878.01(a) Prior Art Under Chapter II

PCT Article 33.

The International Preliminary Examination

(6) The international preliminary examination shall take into consideration all the documents cited in the international search report. It may take into consideration any additional documents considered to be relevant in the particular case.

PCT Rule 64.

Prior Art for International Preliminary Examination

64.1. Prior Art

(a) For the purposes of Article 33(2) and (3), everything made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) shall be considered prior art provided that such making available occurred prior to the relevant date.

(b) For the purposes of paragraph (a), the relevant date will be:

(i) subject to item (ii), the international filing date of the international application under international preliminary examination;

(ii) where the international application under international preliminary examination validly claims the priority of an earlier application, the filing date of such earlier application.

64.2. Non-Written Disclosures

In cases where the making available to the public occurred by means of an oral disclosure, use, exhibition or other non-written means ("non-written disclosure") before the relevant date as defined in Rule 64.1(b) and the date of such non-written disclosure is indicated in a written disclosure which has been made available to the public on a date which is the same as, or later than, the relevant date, the non-written disclosure shall not be considered part of the prior art for the purposes of Article 33(2) and (3). Nevertheless, the international preliminary examination report shall call attention to such non-written disclosure in the manner provided for in Rule 70.9.

64.3. Certain Published Documents

In cases where any application or any patent which would constitute prior art for the purposes of Article 33(2) and (3) had it been published prior to the relevant date referred to in Rule 64.1 was published on a date which is the same as, or later than, the relevant date but was filed earlier than the relevant date or claimed the priority of an earlier application which had been filed prior to the relevant date, such published application or patent shall not be considered part of the prior art for the purposes of Article 33(2) and (3). Nevertheless, the international preliminary examination report shall call attention to such application or patent in the manner provided for in Rule 70.10.

The relevant date for the purpose of considering prior art is defined in PCT Rule 64.1(b) as the international filing date or, where the international application contains a valid claim for priority, that date of priority.

In cases where any application or any patent which would constitute prior art for the purpose of international preliminary examination as to novelty and inventive step (nonobviousness) was published on or after the relevant date of the international application under consideration but was filed earlier than the relevant date or claimed the priority of an earlier application which was filed prior to the relevant date, the published application or patent is not to be considered part of the prior art for the purpose of international preliminary examination as to novelty and inventive step. Nevertheless, these documents are to be listed on Form PCT/IPEA/409 under the heading "CERTAIN PUBLISHED DOCUMENTS".

In determining whether there is inventive step, account should be taken of what the applicant acknowledges in his/her description as known. Such acknowledged prior art should be regarded as correct and used during preliminary examination where appropriate.

For oral or nonwritten disclosure, see PCT Rules 64.2 and 70.9.

1878.01(a)(1) Novelty Under Chapter II

Novelty is defined in PCT Article 33(2).

*PCT Article 33.**The International Preliminary Examination*

(2) For the purposes of the international preliminary examination, a claimed invention shall be considered novel if it is not anticipated by the prior art as defined in the Regulations.

1878.01(a)(2) Inventive Step Under Chapter II

Inventive step is defined in PCT Article 33(3).

*PCT Article 33.**The International Preliminary Examination*

(3) For purposes of the international preliminary examination, a claimed invention shall be considered to involve an inventive step if, having regard to the prior art as defined in the Regulations, it is not, at the prescribed relevant date, obvious to a person skilled in the art.

*PCT Rule 65.**Inventive Step or Non-Obviousness***65.1. Approach to Prior Art**

For the purposes of Article 33(3), the international preliminary examination shall take into consideration the relation of any particular claim to the prior art as a whole. It shall take into consideration the claim's relation not only to individual documents or parts thereof taken separately but also its relation to combinations of such documents or parts of documents, where such combinations are obvious to a person skilled in the art.

65.2. Relevant Date

For the purposes of Article 33(3), the relevant date for the consideration of inventive step (non-obviousness) is the date prescribed in Rule 64.1.

1878.01(a)(3) Industrial Applicability Under Chapter II

Industrial applicability is defined in PCT Article 33(4).

*PCT Article 33.**The International Preliminary Examination*

(4) For the purposes of the international preliminary examination, a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry. "Industry" shall be understood in its broadest sense, as in the Paris Convention for the Protection of Industrial Property.

1878.02 Reply to the Written Opinion*PCT Article 34.**Procedure before the International Preliminary Examining Authority*

(2)(a) The applicant shall have a right to communicate orally and in writing with the International Preliminary Examining Authority.

(b) The applicant shall have a right to amend the claims, the description, and the drawings, in the prescribed manner and within the prescribed time limit, before the international preliminary examination report is established. The amendment shall not go beyond the disclosure in the international application as filed.

(d) The applicant may respond to the written opinion.

*PCT Rule 66.**Procedure before the International Preliminary Examining Authority*

66.3. Formal Response to the International Preliminary Examining Authority

(a) The applicant may respond to the invitation referred to in Rule 66.2(c) of the International Preliminary Examining Authority by making amendments or - if he disagrees with the opinion of that Authority - by submitting arguments, as the case may be, or do both.

(b) Any response shall be submitted directly to the International Preliminary Examining Authority.

66.5. Amendment

Any change, other than the rectification of obvious errors, in the claims, the description, or the drawings, including cancellation of claims, omission of passages in the description, or omission of certain drawings, shall be considered an amendment.

66.6. Informal Communications with the Applicant.

The International Preliminary Examining Authority may, at any time, communicate informally, over the telephone, in writing, or through personal interviews, with the applicant. The said Authority shall, at its discretion, decide whether it wishes to grant more than one personal interview if so requested by the applicant, or whether it wishes to reply to any informal written communication from the applicant.

66.8. Form of Amendments

(a) Subject to paragraph (b), the applicant shall be required to submit a replacement sheet for every sheet of the international application which, on account of an amendment, differs from the sheet previously filed. The letter accompanying the replacement sheets shall draw attention to the differences between the replaced sheets and the replacement sheets and shall preferably also explain the reasons for the amendment.

(b) Where the amendment consists in the deletion of passages or in minor alterations or additions, the replacement sheet referred to in paragraph (a) may be a copy of the relevant sheet of the international application containing the alterations or additions, provided that the clarity and direct reproducibility of that sheet are not adversely affected. To the extent that any amendment results in the cancellation of an entire sheet, that amendment shall be communicated in a letter which shall preferably also explain the reasons for the amendment.

66.9. Language of Amendments

(a) Subject to paragraphs (b) and (c), if the international application has been filed in a language other than the language in which it is published, any amendment, as well as any letter referred to in Rule 66.8, shall be submitted in the language of publication.

(b) If the international preliminary examination is carried out, pursuant to rule 55.2, on the basis of a translation of the international application, any amendment, as well as any letter referred to in paragraph (a), shall be submitted in the language of that translation.

(c) Subject to Rule 55.3, if an amendment or letter is not submitted in a language as required under paragraph (a) or (b), the International Preliminary Examining Authority shall, if practicable, having regard to the time limit for establishing the international preliminary examination report, invite the applicant to furnish the amendment or letter in the required language within a time limit which shall be reasonable under the circumstances.

(d) If the applicant fails to comply, within the time limit under paragraph (c), with the invitation to furnish an amendment in the required language, the amendment shall not be taken into account for the purposes of the international preliminary examination. If the applicant fails to comply, within the time limit under paragraph (c), with the invitation to furnish a letter referred to in paragraph (a) in the required language, the amendment concerned need not be taken into account for the purposes of the international preliminary examination.

37 CFR 1.485. Amendments by applicant during international preliminary examination.

(a) The applicant may make amendments at the time of filing the Demand. The applicant may also make amendments within the time limit set by the International Preliminary Examining Authority for reply to any notification under § 1.484(b) or to any written opinion. Any such amendments must:

(1) Be made by submitting a replacement sheet in compliance with PCT Rules 10 and 11.1 to 11.13 for every sheet of the application which differs from the sheet it replaces unless an entire sheet is cancelled; and

(2) Include a description of how the replacement sheet differs from the replaced sheet. Amendments that do not comply with PCT Rules 10 and 11.1 to 11.13 may not be entered

(b) If an amendment cancels an entire sheet of the international application, that amendment shall be communicated in a letter.

All amendments in reply to a written opinion must be received within the time limit set for reply in order to be assured of consideration in the international preliminary examination report. Amendments filed at or before expiration of the period for reply will be considered. Since the examiner will begin to draw up the final report rather promptly after the time period expires, amendments filed after expiration of the reply period may not be considered. In view of the short time period for completion of preliminary examination, applicants are strongly encouraged to file any amendments promptly. 37 CFR 1.484(d) does not allow for extensions of time to reply to a written opinion. The policy of not allowing extensions of time is to ensure that the USPTO can meet its treaty deadline for transmission of the final report.

Any change, other than the rectification of obvious errors in the claims, the description, or the drawings, including the cancellation of claims, omission of passages in the description or omission of certain drawings will be considered an amendment (PCT Rule 66.5). The Patent and Trademark Office when acting as the International Preliminary Examining Authority will not accept any non-English applications or amendments.

Any amendments to the claims, the description, and the drawings in reply to a written opinion must (1) be made by submitting a replacement sheet for every sheet of the application which differs from the sheet it replaces unless an entire sheet is cancelled and (2) include a description of how the replacement sheet differs from the replaced sheet in accordance with PCT Rule 66.8.

In the particular case where the amendment cancels claims, passages in the description or certain drawings resulting in the cancellation of an entire sheet, the amendment must be submitted in the form of a letter cancelling the sheet (PCT Rule 66.8(a)).

Replacement sheets must be in typed form.

Any paper submitted by the applicant, if not in the form of a letter, must be accompanied by a letter signed by the applicant or agent (PCT Rule 92.1). The letter must draw attention to the differences between the replaced sheet and the replacement sheet.

The examiner should make sure that amendments filed in accordance with the PCT, which are necessary to correct any deficiencies notified to the applicant, do not go beyond the disclosure of the international application as filed, thus violating PCT Article 34(2)(b). In other words, no amendment should contain matter that cannot be substantiated by the application as originally filed. In a situation where new matter is introduced by amendment in reply to a written opinion, the international preliminary examination report will be established as if the amendment had not been made, and the report should so indicate. It shall also indicate the reasons why the amendment goes beyond the disclosure (PCT Rule 70.2(c)).

INTERVIEWS

The examiner or applicant may, during the time limit for reply to the written opinion, request a telephone or personal interview. Only one interview is a matter of right, whether by telephone or in person. Additional interviews may be authorized by the examiner in a particular international application where such additional interview may be helpful to advance the international preliminary examination procedure.

All interviews of substance must be made of record by using PCT/IPEA/428 Notice on Informal Communication with the Applicant.

When an interview is arranged, whether by telephone or in writing, and whether by the examiner or by the applicant, the matters for discussion should be stated.

The records of interviews or telephone conversations should indicate, where appropriate, whether a reply is due from the applicant or agent or whether the examiner wishes to issue an additional written opin-

ion or establish the international preliminary examination report.

If the applicant desires to reply to the written opinion, such reply must be filed within the time limit set for reply in order to assure consideration. No extensions to the time limit will be considered or granted. If no timely reply is received from the applicant, the international preliminary examination report will be established by the examiner, treating each claim substantially as it was treated in the written opinion. Replies to the written opinion which are not filed within the time limit set but which reach the examiner before the examiner takes up the application for preparation of the final report may be considered. Thus, only timely replies can be assured of consideration.

The applicant may reply to the invitation referred to in Rule 66.2(c) by making amendments or, if the applicant disagrees with the opinion of the authority, by submitting arguments, as the case may be, or both (PCT Rule 66.3).

If applicant does not reply to the written opinion, the international preliminary examination report will be prepared in time for forwarding to the International Division in finished form by 27 months from the priority date.

1879 Preparation of the International Preliminary Examination Report

PCT Article 35.

The International Preliminary Examination Report

(1) The international preliminary examination report shall be established within the prescribed time limit and in the prescribed form.

(2) The international preliminary examination report shall not contain any statement on the question whether the claimed invention is or seems to be patentable or unpatentable according to any national law. It shall state, subject to the provisions of paragraph (3), in relation to each claim, whether the claim appears to satisfy the criteria of novelty, inventive step (non-obviousness), and industrial applicability, as defined for the purposes of the international preliminary examination in Article 33(1) to (4). The statement shall be accompanied by the citation of the documents believed to support the stated conclusion with such explanations as the circumstances of the case may require. The statement shall also be accompanied by such other observation as the Regulations provide for.

(3)(a) If, at the time of establishing the international preliminary examination report, the International Preliminary Examining Authority considers that any of the situations referred to in Article 34(4)(a) exists, that report shall state this opinion and the reasons

therefor. It shall not contain any statement as provided in paragraph (2).

(b) If a situation under Article 34(4)(b) is found to exist, the international preliminary examination report shall, in relation to the claims in question, contain the statement as provided in subparagraph (a), whereas, in relation to the other claims, it shall contain the statement as provided in paragraph (2).

PCT Administrative Instruction Section 604.

Guidelines for Explanations Contained in the International Preliminary Examination Report

(a) Explanations under Rule 70.8 shall clearly point out to which of the three criteria of novelty, inventive step (non-obviousness) and industrial applicability referred to in Article 35(2), taken separately, any cited document is applicable and shall clearly describe, with reference to the cited documents, the reasons supporting the conclusion that any of the said criteria is or is not satisfied.

(b) Explanations under Article 35(2) shall be concise and preferably in the form of short sentences.

After examination of the international application, if there are no negative statements and/or negative comments for Form PCT/IPEA/408, then the only statement that will issue from the International Preliminary Examining Authority will be the international preliminary examination report (IPER).

The international preliminary examination report is established on Form PCT/IPEA/409.

The international preliminary examination report must be established within:

(A) 28 months from the priority date; or

(B) 8 months from the date of payment of the fees referred to in PCT Rules 57.1 and 58.1(a); or

(C) 8 months from the date of receipt by the International Preliminary Examining Authority of the translation furnished under PCT Rule 55.2, whichever expires last, as provided in PCT Rule 69.2.

To meet the 28-month date for establishing the report, Office practice is to complete internal processing by 27 months from the priority date in order to provide adequate time for reviewing, final processing and mailing. Thus, under normal circumstances, the applicant receives the report, at the latest, 2 months before national processing at the elected Offices may start. This ensures that he/she has time to consider whether, and in which elected Offices, he/she wants to enter the national stage and to take the necessary action.

The international preliminary examination report contains, among other things, a statement (in the form of simple "yes" or "no"), in relation to each claim which has been examined, on whether the claim appears to satisfy the criteria of novelty, inventive step (non-obviousness) and industrial applicability. The statement is, where appropriate, accompanied by the citation of relevant documents together with concise explanations pointing out the criteria to which the cited documents are applicable and giving reasons for the International Preliminary Examining Authority's conclusions. Where applicable, the report also includes remarks relating to the question of unity of invention.

The international preliminary examination report identifies the basis on which it is established, that is, whether, and if so, which amendments have been taken into account. Replacement sheets containing amendments under PCT Article 19 and/or Article 34 which have been taken into account are attached as "annexes" to the international preliminary examination report. Amendments under PCT Article 19 which have been considered as reversed by an amendment under PCT Article 34 or which have been superseded by later replacement sheets are not annexed to the report; neither are the letters which accompany replacement sheets.

The international preliminary examination report may not express a view on the patentability of the invention. PCT Article 35(2) expressly states that "the international preliminary examination report shall not contain any statement on the question whether the claimed invention is or seems to be patentable or unpatentable according to any national law."

CLASSIFICATION OF SUBJECT MATTER

The classification of the subject matter shall be either (1) that given by the International Searching Authority under PCT Rule 43.3, if the examiner agrees with such classification, or (2) shall be that which the examiner considers to be correct, if the examiner does not agree with that classification. Both the International Patent Classification (IPC) and the U.S. classification should be given. This classification is placed on the first sheet of the report.

ITEM I. BASIS OF REPORT

The international preliminary examination report will be established on the basis of any amendments, rectifications, priority and/or unity of invention holdings and shall answer the questions concerning novelty, inventive step, and industrial applicability for each of the claims under examination.

In completing Form PCT/IPEA/409, the examiner should first indicate any amendments and/or rectifications of obvious errors taken into account in establishing the international preliminary examination report. The amendments and/or rectifications should be indicated by references to the dates on which the amendments and/or rectifications were filed.

For the purpose of completing Box I, item 1, substitute and/or rectified sheets of the specification and drawings filed during Chapter I proceedings are considered to be originally filed pages/sheets and should be listed as originally filed pages/sheets. Only those amendments or rectifications to the specification and drawings filed on the date of Demand or after the filing of a Demand should be listed as later filed pages/sheets.

Substitute and/or rectified sheets of claims filed during the Chapter I proceedings are also considered to be originally filed claims and should be listed as originally filed claims. However, amended sheets of claims filed under Article 19 in response to the international search report are to be indicated as claims as amended under Article 19. Applicant's submission of a timely amendment to the claims alleged to be under Article 19 is accepted under Article 34 (not Article 19) unless the International Bureau has indicated the amendments were accepted under Article 19. Only those amendments, or rectifications to the claims filed on the date of Demand or after the filing of a Demand should be listed as later filed claims. All claims present on a sheet stamped AMENDED SHEET are listed as amended irrespective of which of the claims present on that sheet were actually amended. If a claim is made up of sheets filed on different dates, the latest date is the date that should be used for the claim.

Amendments and/or rectifications filed but not taken into account in the establishment of the report (e.g., an amendment not taken into account because the amendment went beyond the disclosure of the international application as filed or a rectification that is not considered to be merely a correction of an obvi-

ous error) are then indicated separately. The replacement sheets (but not replacement sheets superseded by later replacement sheets) or letters cancelling sheets under PCT Rule 66.8(a) are included as an annex to the report.

The final report package when sent to the International Application Processing Division for mailing must include copies of all amendments and rectifications entered and any cover letters to those amendments.

ITEM II. PRIORITY

Item II of Form PCT/IPEA/409 is to inform applicant of non-establishment of a request for priority. If the report is established as if the priority claim contained in the Request of the international application had not been made, it shall so indicate. This will occur in the event that the applicant has failed to comply with the invitation to furnish either

(A) a copy of the earlier application whose priority is claimed, or

(B) a translation of the earlier application, or

(C) where the priority claim is found invalid, e.g., the claimed priority date is more than one year prior to the international filing date (PCT Rule 17) or all claims are directed to inventions which were not described and enabled by the earlier application (PCT Rule 64.1), or

(D) where the priority claim has been withdrawn.

ITEM III. NON-ESTABLISHMENT OF OPINION WITH REGARD TO NOVELTY, INVENTIVE STEP OR INDUSTRIAL APPLICABILITY

Indications that a report has not been established on the questions of novelty, inventive step or industrial applicability, either as to some claims or as to all claims, are given in Item III on the Report. The examiner must specify that the report has not been established because:

(A) the application relates to subject matter which does not require international preliminary examination;

(B) the description, claims or drawings are so unclear that no meaningful opinion could be formed;

(C) the claims are so inadequately supported by the description that no meaningful opinion could be formed.

Where the report has not been established in relation to certain claims only, the claims affected must be specified.

ITEM IV. LACK OF UNITY OF INVENTION

If the applicant has paid additional fees or has restricted the claims in response to an invitation to do so or if the applicant has failed to respond to the invitation to pay additional fees or restrict the claims, the international preliminary examination report shall so indicate. The examiner should indicate whether:

- (A) the claims have been restricted;
- (B) additional fees have been paid without protest;
- (C) additional fees have been paid by the applicant under protest;
- (D) the applicant has neither restricted the claims nor paid additional fees;
- (E) the examiner was of the opinion that the international application did not comply with the requirement of unity of invention but decided not to issue an invitation to restrict the claims or pay additional fees.

In addition, if the examiner is examining less than all the claims, the examiner must indicate which parts of the international application were, and which parts were not, the subject of international preliminary examination.

In the case where additional fees were paid under protest, the text of the protest, together with the decision thereon, must be annexed to the report by International Application Processing Division IPEA personnel if the applicant has so requested.

Where an indication has been given under item (E) above, the examiner must also specify the reasons for which the international application was not considered as complying with the requirement of unity of invention.

ITEM V. REASONED STATEMENT UNDER ARTICLE 35(2) WITH REGARD TO NOVELTY, INVENTIVE STEP, AND INDUSTRIAL APPLICABILITY; AND CITATIONS AND EXPLANATIONS SUPPORTING SUCH STATEMENT

The examiner must indicate whether each claim appears to satisfy the criteria of novelty, inventive step (nonobviousness), and industrial applicability. The determination or statement should be made on

each of the three criteria taken separately. The determination as to any criteria should be negative if the criteria as to the particular claim is not satisfied. The examiner should always cite documents believed to support any negative determination as to novelty and inventive step. Any negative holding as to lack of industrial applicability must be fully explained. See the discussion under MPEP § 1878, Item V. The citation of documents should be in accordance with Administrative Instructions Sections 503 and 611. The procedure is the same as the procedure for search report citations. Explanations should clearly indicate, with reference to the cited documents, the reasons supporting the conclusions that any of the said criteria is or is not satisfied, unless the statement is positive and the reason for citing any document is easy to understand when consulting the document. If only certain passages of the cited documents are relevant, the examiner should identify them, for example, by indicating the page, column, or the lines where such passages appear. Preferably, a reasoned statement should be provided in all instances.

ITEM VI. CERTAIN DOCUMENTS CITED

If the examiner has discovered, or the international search report has cited, a relevant document which refers to a nonwritten disclosure, and the document was only published on or after the relevant date of the international application, the examiner must indicate on the international preliminary examination report:

- (A) the date on which the document was made available to the public;
- (B) the date on which the non-written public disclosure occurred.

The examiner should also identify any published application or patent and should provide for each such published application or patent the following indications:

- (A) its date of publication;
- (B) its filing date, and its claimed priority date (if any).

The Report may also indicate that, in the opinion of the International Preliminary Examining Authority, the priority date of the document cited has not been validly claimed (PCT Rule 70.10).

Guidelines explaining to the examiner the manner of indicating certain special categories of documents as well as the manner of indicating the claims to which the documents cited in such report are relevant are set forth in Administrative Instructions Sections 507(c), (d), and (e) and 508.

ITEM VII. CERTAIN DEFECTS IN THE INTERNATIONAL APPLICATION

If, in the opinion of the examiner, defects existing in the form or contents of the international application have not been suitably solved at the prescribed time limit for establishing the international preliminary examination report, the examiner may include this opinion in the report, and if included, must also indicate the reasons therefor. See the discussion under MPEP § 1878, Item VII.

ITEM VII. CERTAIN OBSERVATIONS ON THE INTERNATIONAL APPLICATION

If, in the opinion of the examiner, the clarity of claims, the description, and the drawings, or the ques-

tion as to whether the claims are fully supported by the description have not been suitably solved at the prescribed time limit for establishing the international preliminary examination report, the examiner may include this opinion in the report, and if included, must also indicate the reasons therefor. See the discussion under MPEP § 1878, Item VIII.

CERTIFICATION

When completing the certification of the report, the examiner must indicate the date on which the Demand for International Preliminary Examination was submitted and the date on which the examiner completed the report and the name and mailing address of the International Preliminary Examining Authority.

These last mentioned items may either be completed when including the other data or when completing the certification. Every international preliminary examination report must be signed by a primary examiner.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference IPI-001 PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/15678	International filing date (day/month/year) 05 June 1999 (05.06.1999)	Priority date (day/month/year) 05 June 1998 (05.06.1998)
International Patent Classification (IPC) or national classification and IPC IPC(7): A62C 27/00 and US Cl.: 280/004		
Applicant International Products, Inc.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of ___ sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ___ sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input checked="" type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 05 January 2000 (05.01.2000)	Date of completion of this report 14 July 2001 (14.07.2001)	
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Pat Examiner Telephone No. 703-305-3257	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/15678

I. Basis of the report

1. With regard to the elements of the international application:*

 the international application as originally filed. the description:

pages 1-6 _____ as originally filed

pages NONE _____, filed with the demand

pages NONE _____, filed with the letter of _____

 the claims:

pages 10 and 12-16 _____, as originally filed

pages NONE _____, as amended (together with any statement) under Article 19

pages 11 _____, filed with the demand

pages 11/1 _____, filed with the letter of 23 June 2000 (23.06.2000)

 the drawings:

pages 1-3 _____, as originally filed

pages NONE _____, filed with the demand

pages NONE _____, filed with the letter of _____

 the sequence listing part of the description:

pages NONE _____, as originally filed

pages NONE _____, filed with the demand

pages NONE _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. The amendments have resulted in the cancellation of: the description, pages NONE the claims, Nos. NONE the drawings, sheets/fig NONE5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

Form PCT/IPEA/409 (Box I) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/15678

II. Priority

- 1. This report has been established as if no priority has been claimed due to the failure to furnish within the prescribed time limit the requested:
 - copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
 - translation of the earlier application whose priority has been claimed (Rule 66.7(b)).

- 2. This report has been established as if no priority has been claimed due to the fact that the priority claim has been found invalid (Rule 64.1).

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT	International application No. PCT/US99/15678
III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	
1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:	
<input type="checkbox"/> the entire international application,	
<input checked="" type="checkbox"/> claims Nos. <u>11</u>	
because:	
<input type="checkbox"/> the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (<i>specify</i>):	
<input checked="" type="checkbox"/> the description, claims or drawings (<i>indicate particular elements below</i>) or said claims Nos. <u>11</u> are so unclear that no meaningful opinion could be formed (<i>specify</i>):	
Claim 11 has not been examined because it is an improper multiple dependent claim under PCT Rule 6.4(a) because it depends from another multiple dependent claim.	
<input type="checkbox"/> the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.	
<input type="checkbox"/> no international search report has been established for said claims Nos.	
2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:	
<input type="checkbox"/> the written form has not been furnished or does not comply with the standard.	
<input type="checkbox"/> the computer readable form has not been furnished or does not comply with the standard.	

Form PCT/IPEA/409 (Box III) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/15678

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- restricted the claims.
- paid additional fees.
- paid additional fees under protest.
- neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is

- complied with.
- not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-5, drawn to a fire-fighting vehicle with a particular high-visibility finish.

Group II, claim(s) 6-10, drawn to a fire hose made of PVC reinforced canvas.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of the Group I vehicle is the claimed high-visibility paint applied to the vehicle. The special technical feature of the Group II invention is the particular composition of the claimed fire hose. Since the special technical feature of the Group I invention is not present in the Group II claims and the special technical feature of the Group II invention is not present in the Group I claims, unity of invention is lacking.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- all parts.
- the parts relating to claims Nos. _____

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/15678

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 6-11	YES
	Claims 1-5	NO
Inventive Step (IS)	Claims 9-11	YES
	Claims 1-8	NO
Industrial Applicability (IA)	Claims 1-11	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS (Rule 70.7)

Claims 1-5 lack novelty under PCT Article 33(2) as being anticipated by Jones. Jones teaches the claimed fire-fighting vehicle including the claimed high-visibility polyester finish.

Claims 6-8 lack an inventive step under PCT Article 33(3) as being obvious over Johnson in view of Fairfield. Johnson does not teach the particular PVC compositions claimed for use in a fire hose but otherwise teaches all of the claimed elements for the claimed fire hose. Fairfield teaches that it is known to use the claimed PVC compositions as additives in canvas material intended for use as an inlet hose in a pumping system. Since each type of environment, the fire hose environment and the pumping equipment environment, demand resistance to fungus growths and dry rot it would have been obvious to one of ordinary skill in this art at the time this invention was made to provide the claimed PVC compositions as additives in the Johnson fire hose as taught by the Fairfield reference.

Claims 9-11 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the specific PVC compositions claimed as additives for the fire hose.

Claims 1-11 meet the criteria set out in PCT Article 33(4) and thus have industrial applicability, because the fire fighting vehicle and the claimed fire hose can be made and/or used in the fire fighting industry.

----- NEW CITATIONS -----

INTERNATIONAL PRELIMINARY EXAMINATION REPORT	International application No. PCT/US99/15678				
VI. Certain documents cited					
1. Certain published documents (Rule 70.10)					
<table style="width: 100%; border: none;"> <tr> <td style="width: 25%; text-align: center;">Application No <u>Patent No.</u></td> <td style="width: 25%; text-align: center;">Publication Date <u>(day/month/year)</u></td> <td style="width: 25%; text-align: center;">Filing Date <u>(day/month/year)</u></td> <td style="width: 25%; text-align: center;">Priority date (valid claim) <u>(day/month/year)</u></td> </tr> </table>	Application No <u>Patent No.</u>	Publication Date <u>(day/month/year)</u>	Filing Date <u>(day/month/year)</u>	Priority date (valid claim) <u>(day/month/year)</u>	
Application No <u>Patent No.</u>	Publication Date <u>(day/month/year)</u>	Filing Date <u>(day/month/year)</u>	Priority date (valid claim) <u>(day/month/year)</u>		
2. Non-written disclosures (Rule 70.9)					
<table style="width: 100%; border: none;"> <tr> <td style="width: 40%; text-align: center;"><u>Kind of non-written disclosure</u></td> <td style="width: 30%; text-align: center;">Date of non-written disclosure <u>(day/month/year)</u></td> <td style="width: 30%; text-align: center;">Date of written disclosure referring to non-written disclosure <u>(day/month/year)</u></td> </tr> </table>	<u>Kind of non-written disclosure</u>	Date of non-written disclosure <u>(day/month/year)</u>	Date of written disclosure referring to non-written disclosure <u>(day/month/year)</u>		
<u>Kind of non-written disclosure</u>	Date of non-written disclosure <u>(day/month/year)</u>	Date of written disclosure referring to non-written disclosure <u>(day/month/year)</u>			

Form PCT/IPEA/409 (Box VI) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/15678

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT	International application No. PCT/US99/15678
Supplemental Box (To be used when the space in any of the preceding boxes is not sufficient)	
Continuation of Certain Documents Cited 1. Certain published documents (Rule 70.10)	
Application No <u>Patent No.</u> None	Publication Date <u>(day/month/year)</u> None
Filing Date <u>(day/month/year)</u> None	Priority date (valid claim) <u>(day/month/year)</u> None
2. Non-written disclosures (Rule 70.9)	
<u>Kind of non-written disclosure</u> None	Date of non-written disclosure <u>(day/month/year)</u> None
Date of written disclosure referring to non-written disclosure <u>(day/month/year)</u> None	

Form PCT/IPEA/409 (Continuation Sheet) (July 1998)

1879.01 Time Limit for Preparing Report

PCT Rule 69.

Start of and Time Limit for International Preliminary Examination

69.1. Start of International Preliminary Examination

(a) Subject to paragraphs (b) to (e), the International Preliminary Examining Authority shall start the international preliminary examination when it is in possession both of the demand and of either the international search report or a notice of the declaration by the International Searching Authority under Article 17(2)(a) that no international search report will be established.

(b) If the competent International Preliminary Examining Authority is part of the same national Office or intergovernmental organization as the competent International Searching Authority, the international preliminary examination may, if the International Preliminary Examining Authority so wishes and subject to paragraph (d), start at the same time as the international search.

(c) Where the statement concerning amendments contains an indication that amendments under Article 19 are to be taken into account (Rule 53.9(a)(i)), the International Preliminary Examining Authority shall not start the international preliminary examination before it has received a copy of the amendments concerned

(d) Where the statement concerning amendments contains an indication that the start of the international preliminary examination is to be postponed (Rule 53.9(b)), the International Preliminary Examining Authority shall not start the international preliminary examination before

(i) it has received a copy of any amendments made under Article 19,

(ii) it has received a notice from the applicant that he does not wish to make amendments under Article 19, or

(iii) the expiration of 20 months from the priority date, whichever occurs first.

(e) Where the statement concerning amendments contains an indication that amendments under Article 34 are submitted with the demand (Rule 53.9(c)) but no such amendments are, in fact, submitted, the International Preliminary Examining Authority shall not start the international preliminary examination before it has received the amendments or before the time limit fixed in the invitation referred to in Rule 60.1(g) has expired, whichever occurs first.

69.2. Time Limit for International Preliminary Examination

The time limit for establishing the international preliminary examination report shall be:

(i) 28 months from the priority date, or

(ii) eight months from the date of payment of the fees referred to in Rules 57.1 and 58.1(a), or

(iii) eight months from the date of receipt by the International Preliminary Examining Authority of the translation furnished under Rule 55.2, whichever expires last.

PCT Rule 69.2 was amended July 1, 1998. The time limit for preparing the international preliminary examination report is 28 months from the priority date, or 8 months from the date of payment of the fees referred to in PCT Rules 57.1 and 58.1(a), or 8 months from the date of receipt by the International Preliminary Examining Authority of the translation furnished under PCT Rule 55.2, whichever expires first. This time limit is 27 months internally to ensure sufficient time to process, review and mail the report in sufficient time to reach the International Bureau by 28 months from the earliest priority date.

1879.02 Transmittal of the International Preliminary Examination Report

PCT Article 36.

Transmittal, Translation, and Communication of the International Preliminary Examination Report

(1) The international preliminary examination report, together with the prescribed annexes, shall be transmitted to the applicant and to the International Bureau.

PCT Rule 71.

Transmittal of the International Preliminary Examination Report

71.1. Recipients

The International Preliminary Examining Authority shall, on the same day, transmit one copy of the international preliminary examination report and its annexes, if any, to the International Bureau, and one copy to the applicant.

71.2. Copies of Cited Documents

(a) The request under Article 36(4) may be presented any time during seven years from the international filing date of the international application to which the report relates.

(b) The International Preliminary Examining Authority may require that the party (applicant or elected Office) presenting the request pay to it the cost of preparing and mailing the copies. The level of the cost of preparing copies shall be provided for in the agreements referred to in Article 32(2) between the International Preliminary Examining Authorities and the International Bureau.

(c) *[Deleted]*

(d) Any International Preliminary Examining Authority may perform the obligations referred to in paragraphs (a) and (b) through another agency responsible to it.

The international preliminary examination report is transmitted to the International Bureau using a trans-

mittal Form PCT/IPEA/416. Every effort is made to ensure that the transmittal is effected in sufficient time to reach the International Bureau before the expiration of the time limit set in PCT Rule 69.2.

AUTHORIZED OFFICER

Form PCT/IPEA/416 must be signed by a primary examiner.

1879.03 Translations

PCT Article 36.

Transmittal, Translation, and Communication of the International Preliminary Examination Report

(2)(a) The international preliminary examination report and its annexes shall be translated into the prescribed languages.

(b) Any translation of the said report shall be prepared by or under the responsibility of the International Bureau, whereas any translation of the said annexes shall be prepared by the applicant.

PCT Rule 72.

Translation of the International Preliminary Examination Report

72.1. Languages

(a) Any elected State may require that the international preliminary examination report, established in any language other than the official language, or one of the official languages, of its national Office, be translated into English.

(b) Any such requirement shall be notified to the International Bureau, which shall promptly publish it in the Gazette.

72.2. Copy of Translation for the Applicant

The International Bureau shall transmit a copy of the translation referred to in Rule 72.1(a) of the international preliminary examination report to the applicant at the same time as it communicates such translation to the interested elected Office or Offices.

72.3. Observations on the Translation

The applicant may make written observations on what, in his opinion, are errors of translation in the translation of the international preliminary examination report and shall send a copy of any such observations to each of the interested elected Offices and a copy to the International Bureau.

The international preliminary examination report and any annexes are established in Chinese, English, French, German, Japanese, Russian or Spanish, if the international application was filed in one of those lan-

guages, or in English if the international application was filed in another language. Each elected State may require that the report, if it is not in (one of) the official language(s) of its national Office, be translated into English. In that case, the translation of the body of the report is prepared by International Bureau, which transmits copies to the applicant and to each interested elected Office. If any elected Office requires a translation of annexes to the report, the preparation and furnishing of that translation is the responsibility of the applicant.

The U.S. requires the final report and the annexes thereto to be in English. Translation of the annexes for national stage purposes is required pursuant to 35 U.S.C. 371(c)(5) and 37 CFR 1.495(e). Failure to timely provide such translation results in cancellation of the annexes.

1879.04 Confidential Nature of the Report

PCT Article 38.

Confidential Nature of the International Preliminary Examination

(1) Neither the International Bureau nor the International Preliminary Examining Authority shall, unless requested or authorized by the applicant, allow access within the meaning, and with the proviso, of Article 30(4) to the file of the international preliminary examination by any person or authority at any time, except by the elected Offices once the international preliminary examination report has been established.

(2) Subject to the provisions of paragraph (1) and Articles 36(1) and (3) and 37(3)(b), neither the International Bureau nor the International Preliminary Examining Authority shall, unless requested or authorized by the applicant, give information on the issuance or non-issuance of an international preliminary examination report and on the withdrawal or non-withdrawal of the demand or of any election.

1880 Withdrawal of Demand or Election

PCT Article 37.

Withdrawal of Demand or Election

- (1) The applicant may withdraw any or all elections.
- (2) If the election of all elected States is withdrawn, the demand shall be considered withdrawn.
- (3)(a) Any withdrawal shall be notified to the International Bureau.
- (b) The elected Office concerned and the International Preliminary Examining Authority concerned shall be notified accordingly by the International Bureau.

(4)(a) Subject to the provisions of subparagraph (b), withdrawal of the demand or of the election of a Contracting State shall, unless the national law of that State provides otherwise, be considered to be withdrawal of the international application as far as that State is concerned.

(b) Withdrawal of the demand or of the election shall not be considered to be withdrawal of the international application if such withdrawal is effected prior to the expiration of the applicable time limit under Article 22; however, any Contracting State may provide in its national law that the aforesaid shall apply only if its national Office has received, within the said time limit, a copy of the international application, together with a translation (as prescribed), and the national fee.

PCT Rule 90^{bis}

Withdrawals

90^{bis}.4. Withdrawal of the Demand, or of Elections

(a) The applicant may withdraw the demand or any or all elections at any time prior to the expiration of 30 months from the priority date.

(b) Withdrawal shall be effective upon receipt of a notice addressed by the applicant to the International Bureau.

(c) If the notice of withdrawal is submitted by the applicant to the International Preliminary Examining Authority, that Authority shall mark the date of receipt on the notice and transmit it promptly to the International Bureau. The notice shall be considered to have been submitted to the International Bureau on the date marked.

PCT Administrative Instruction Section 606.

Cancellation of Elections

The International Preliminary Examining Authority shall, if the election is in the demand, cancel *ex officio* the election of any State which is not a designated State or which is not bound by Chapter II of the Treaty, shall enclose that election within square brackets, shall draw a line between the square brackets while still leaving the election legible and shall enter, in the margin, the words "CANCELLED EX OFFICIO BY IPEA" or their equivalent in the language of the demand, and shall notify the applicant accordingly.

Any withdrawal of the Demand or any election must be sent to the International Bureau. Withdrawal, if timely, is effective upon receipt by the International Bureau.

1881 Receipt of Notice of Election by the Patent and Trademark Office

PCT Rule 61.

Notification of the Demand and Elections

61.2. Notification to the Elected Offices

(a) The notification provided for in Article 31(7) shall be effected by the International Bureau.

(b) The notification shall indicate the number and filing date of the international application, the name of the applicant, the filing date of the application whose priority is claimed (where priority is claimed), the date of receipt by the International Preliminary Examining Authority of the demand, and - in the case of a later election - the date of receipt of the notice effecting the later election. The latter date shall be the actual date of receipt by the International Bureau or, where applicable, the date referred to in Rule 56.1(f) or 60.2(b).

(c) The notification shall be sent to the elected Office together with the communication provided for in Article 20. Elections effected after such communication shall be notified promptly after they have been made.

(d) Where the applicant makes an express request to an elected Office under Article 40(2) before the communication provided for in Article 20 has taken place, the International Bureau shall, upon request of the applicant or the elected Office, promptly effect that communication to that Office.

61.3. Information for the Applicant

The International Bureau shall inform the applicant in writing of the notification referred to in Rule 61.2 and of the elected Offices notified under Article 31(7).

All notices of election are received by the PCT International Division from the International Bureau. The PCT International Division prepares the appropriate records of the election and places the paper in storage with the communicated copy of the international application until the national stage is entered.

1890 Receipt of Notice of Designation

After publication of the international application, between about 18 and 19 months from the priority date, the International Bureau notifies each national Office that it has been designated and at the same time forwards to each designated Office a copy of the international application, a copy of the search report (an English translation is sent to the U.S. if the search report was not in English), a copy of any amendment under PCT Article 19, and a copy of any

priority document (PCT Rule 47). Thus, the U.S. as a designated Office first becomes aware of the fact of its designation at about 18 to 19 months from the priority date and may begin a national stage application file from the papers forwarded by the International Bureau. See PCT Rule 24.2(b). Contracting States have the option of being notified of their designation earlier. The U.S. did not choose to be notified earlier.

The national stage papers sent by the International Bureau are received in the Designated/Elected Office (DO/EO) Section of the International Division of the USPTO. The papers are matched with applicant's submission for entry into the national stage in the U.S. and together make up the U.S. national stage application file. The DO/EO checks the national stage papers to be sure all necessary parts have been received from applicant and from the International Bureau. When the application is complete, a notice of acceptance and a filing receipt are mailed to applicant and the application is forwarded to the Office of Initial Patent Examination to be scanned electronically before the application is forwarded to the appropriate Technology Center.

1891 Receipt of Notice of Election and Preliminary Examination Report

If the U.S. is elected in a Demand for preliminary examination prior to 19 months from the priority date, applicant may postpone the steps needed for entry into the national stage from 20 to 30 months from the priority date. The USPTO will hold the national stage papers sent by the International Bureau awaiting applicant's submissions for entry into the national stage. The international application is examined and the results (the international preliminary examination report) are received by the USPTO for inclusion into the national stage file. The examination report is communicated to the elected Offices by the International Bureau.

The notice of election is communicated to the elected Office along with the PCT Article 20 communication or as soon thereafter as the International Bureau receives notice of the election. Election of a Contracting State, of course, is not possible unless that state was designated.

1893 National Stage (U.S. National Application Filed Under 35 U.S.C. 371)

37 CFR 1.9. Definitions.

(a)(1) A national application as used in this chapter means a U.S. application for patent which was either filed in the Office under 35 U.S.C. 111, or which entered the national stage from an international application after compliance with 35 U.S.C. 371.

(2) A provisional application as used in this chapter means a U.S. national application for patent filed in the Office under 35 U.S.C. 111(b).

(3) A nonprovisional application as used in this chapter means a U.S. national application for patent which was either filed in the Office under 35 U.S.C. 111(a), or which entered the national stage from an international application after compliance with 35 U.S.C. 371.

Thus, there are three types of U.S. national applications: a national stage application under the PCT (filed under 35 U.S.C. 371), a regular domestic national application filed under 35 U.S.C. 111(a), and a provisional application filed under 35 U.S.C. 111(b).

An applicant who uses the Patent Cooperation Treaty gains the benefit of

- (A) a delay in the time when papers must be submitted to the national offices;
- (B) an international search (to judge the level of the relevant prior art) before having to expend resources for filing fees, translations and other costs;
- (C) a delay in the expenditure of fees;
- (D) additional time for research;
- (E) additional time to evaluate financial, marketing, commercial and other considerations.

The time delay is, however, the benefit most often recognized as primary. Ultimately, applicant might choose to submit the national stage application. The national stage is unique compared to a domestic national application in that

(A) it is submitted later (i.e., normally 20 or 30 months or more from a claimed priority date as compared to 12 months for a domestic application claiming priority).

(B) the status of the prior art is generally known before the national stage begins and this is not necessarily so in a domestic national application.

(C) if the filing of an international application is to be taken into account in determining the patentability or validity of any application for patent or granted patent, then special provisions apply. See MPEP § 1895.01, subsection (E) and MPEP § 1896.

A "patent" under 35 U.S.C. 102(e)(2) refers to a patent granted on an application filed in the U.S. However, a patent issuing from an international application filed on or after November 29, 2000, which entered the national stage under 35 U.S.C. 371 is not considered to be filed in the U.S. for purposes of 35 U.S.C. 102(e)(2). Patents issuing in other countries throughout the world are not prior art under 35 U.S.C. 102(e).

IDENTIFICATION OF THE NATIONAL STAGE APPLICATION

Once the national stage application has been accorded an application number (the two digit series code followed by a six digit serial number), that number as well as the international application number should be used whenever papers or other communications are directed to the USPTO regarding the national stage application. The national stage application is tracked through the Patent Application Locating and Monitoring (PALM) system by the eight digit U.S. application number. Therefore, processing is expedited if the U.S. application number is indicated. The international application number is helpful for identification purposes and can be used to cross-check a possibly erroneous U.S. application number. Of course, the international filing date and the national stage entry date under 35 U.S.C. 371 should also be provided. See 37 CFR 1.5(a).

1893.01 Commencement and Entry

35 U.S.C. 371. National stage: Commencement.

(a) Receipt from the International Bureau of copies of international applications with any amendments to the claims, international search reports, and international preliminary examination reports including any annexes thereto may be required in the case of international applications designating or electing the United States.

(b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty.

(c) The applicant shall file in the Patent and Trademark Office —

(1) the national fee provided in section 41(a) of this title;

(2) a copy of the international application, unless not required under subsection (a) of this section or already communicated by the International Bureau, and a translation into the English language of the international application, if it was filed in another language;

(3) amendments, if any, to the claims in the international application, made under article 19 of the treaty, unless such amendments have been communicated to the Patent and Trademark Office by the International Bureau, and a translation into the English language if such amendments were made in another language;

(4) an oath or declaration of the inventor (or other person authorized under chapter 11 of this title) complying with the requirements of section 115 of this title and with regulations prescribed for oaths or declarations of applicants;

(5) a translation into the English language of any annexes to the international preliminary examination report, if such annexes were made in another language.

(d) The requirement with respect to the national fee referred to in subsection (c)(1), the translation referred to in subsection (c)(2), and the oath or declaration referred to in subsection (c)(4) of this section shall be complied with by the date of the commencement of the national stage or by such later time as may be fixed by the Director. The copy of the international application referred to in subsection (c)(2) shall be submitted by the date of the commencement of the national stage. Failure to comply with these requirements shall be regarded as abandonment of the application by the parties thereof, unless it be shown to the satisfaction of the Director that such failure to comply was unavoidable. The payment of a surcharge may be required as a condition of accepting the national fee referred to in subsection (c)(1) or the oath or declaration referred to in subsection (c)(4) of this section if these requirements are not met by the date of the commencement of the national stage. The requirements of subsection (c)(3) of this section shall be complied with by the date of the commencement of the national stage, and failure to do so shall be regarded as a cancellation of the amendments to the claims in the international application made under article 19 of the treaty. The requirement of subsection (c)(5) shall be complied with at such time as may be fixed by the Director and failure to do so shall be regarded as cancellation of the amendments made under article 34 (2)(b) of the treaty.

(e) After an international application has entered the national stage, no patent may be granted or refused thereon before the expiration of the applicable time limit under article 28 or article 41 of the treaty, except with the express consent of the applicant. The applicant may present amendments to the specification, claims, and drawings of the application after the national stage has commenced.

(f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with.

37 CFR 1.491. National stage commencement and entry.

(a) Subject to 35 U.S.C. 371(f), the national stage shall commence with the expiration of the applicable time limit under PCT Article 22(1) or (2), or under PCT Article 39(1)(a).

(b) An international application enters the national stage when the applicant has filed the documents and fees required by 35 U.S.C. 371(c) within the period set in § 1.494 or § 1.495.

Subject to 35 U.S.C. 371(f), commencement of the national stage occurs upon expiration of the applicable time limit, as stated in 35 U.S.C. 371(b) and 37 CFR 1.491(a).

Entry into the national stage occurs upon completion of certain acts, as stated in 37 CFR 1.491(b).

1893.01(a) Entry via the U.S. Designated Office

37 CFR 1.494. Entering the national stage in the United States of America as a Designated Office.

(a) Where the United States of America has not been elected by the expiration of 19 months from the priority date (see § 1.495), the applicant must fulfill the requirements of PCT Article 22 and 35 U.S.C. 371 within the time periods set forth in paragraphs (b) and (c) of this section in order to prevent the abandonment of the international application as to the United States of America. International applications for which those requirements are timely fulfilled will enter the national stage and obtain an examination as to the patentability of the invention in the United States of America.

(b) To avoid abandonment of the application, the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 20 months from the priority date:

(1) A copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the United States Patent and Trademark Office; and

(2) The basic national fee (see § 1.492(a)). The 20-month time limit may not be extended.

(c) If applicant complies with paragraph (b) of this section before expiration of 20 months from the priority date but omits:

(1) A translation of the international application, as filed, into the English language, if it was originally filed in another language (35 U.S.C. 371(c)(2)) and/or

(2) The oath or declaration of the inventor (35 U.S.C. 371(c)(4); see § 1.497), and a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17(iv) within the time limits provided for in the PCT Rule 26^{ter}.1, applicant will be so notified and given a period of time within which to file the translation and/or oath or declaration in order to prevent abandonment of the application. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than the expiration of 20 months after the priority date. The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the

expiration of 20 months after the priority date. A "Sequence Listing" need not be translated if the "Sequence Listing" complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b).

(d) A copy of any amendments to the claims made under PCT Article 19, and a translation of those amendments into English, if they were made in another language, must be furnished not later than the expiration of 20 months from the priority date. Amendments under PCT Article 19 which are not received by the expiration of 20 months from the priority date will be considered to be cancelled. The 20-month time limit may not be extended.

(e) Verification of the translation of the international application or any other document pertaining to an international application may be required where it is considered necessary, if the international application or other document was filed in a language other than English.

(f) The documents and fees submitted under paragraphs (b) and (c) of this section must, except for a copy of the international publication or translation of the international application that is identified as provided in § 1.417, be clearly identified as a submission to enter the national stage under 35 U.S.C. 371. Otherwise, the submission will be considered as being made under 35 U.S.C. 111(a).

(g) An international application becomes abandoned as to the United States 20 months from the priority date if the requirements of paragraph (b) of this section have not been complied with within 20 months from the priority date where the United States has been designated but not elected by the expiration of 19 months from the priority date. If the requirements of paragraph (b) of this section are complied with within 20 months from the priority date but any required translation of the international application as filed and/or the oath or declaration are not timely filed, an international application will become abandoned as to the United States upon expiration of the time period set pursuant to paragraph (c) of this section.

An international application designating the U.S. will enter the national stage via the U.S. Designated Office unless a Demand electing the U.S. is filed prior to the expiration of 19 months from the priority date whereupon entry will be via the U.S. Elected Office. The procedure for entry via the U.S. Designated Office is as prescribed in 37 CFR 1.494.

1893.01(a)(1) Submissions Required by 20 Months from the Priority Date

To begin entry into the national stage, applicant is required to comply with 37 CFR 1.494(b) within 20 months from the priority date unless election of the U.S. under Chapter II of the PCT has been made prior to 19 months from the priority date (see MPEP § 1893.01(b)). Thus, applicant must pay the

basic national fee on or before 20 months from the priority date and be sure that a copy of the international application has been received by the U.S. Designated Office prior to expiration of 20 months from the priority date. The notice referred to in PCT Rule 47.1(c) constitutes conclusive evidence of transmission of the international application. Payment of the basic national fee will indicate applicant's intention to enter the national stage and will provide a U.S. correspondence address in most instances.

Facsimile transmission is not acceptable for submission of the basic national fee and/or the copy of the international application. See 37 CFR 1.6(d). Likewise, the certificate of mailing procedures of 37 CFR 1.8 do not apply to the filing of the copy of the international application and payment of the basic national fee. See 37 CFR 1.8(a)(2)(i)(F).

Applicants cannot pay the basic national fee with a surcharge after the 20 month deadline. Failure to pay the basic national fee within 20 months from the priority date will result in abandonment of the application. The time for payment of the basic fee is not extendable.

Similarly, the copy of the international application is required to be provided within 20 months from the priority date. A copy of the international application is provided to the U.S. Designated Office by the International Bureau (the copy is ordinarily received shortly after publication at about 18 months from the priority date). The International Bureau also mails a confirmation (Form IB/308) to applicant upon which applicant can rely that the copy has been provided, see PCT Rule 47.1(c). The copy is placed in a file to await applicant's submission of the basic national fee and other national stage requirements.

If the basic national fee has been paid by expiration of 20 months from the priority date, but the required oath, declaration or translation has not been filed within 20 months from the priority date, as appropriate, the Office will send applicant a notice and provide a period of time to supply the deficiency as set forth in 37 CFR 1.494(c). The time period usually set is 1 month from the date of notification by the Office or 21 months from the priority date, whichever is later. This period may be extended pursuant to the provisions of 37 CFR 1.136(a). Thus, payment of the basic national fee on or before 20 months from the priority date will (1) cause the Office, after a check of

the national stage papers at 20 months, to mail a notice identifying any deficiencies and affording applicant a period for correction of those deficiencies, and (2) as in national practice under 37 CFR 1.53, enable applicants to extend the period of time under 37 CFR 1.136(a) for submission of a proper oath, declaration or translation. The international application enters the national stage under 35 U.S.C. 371 and 37 CFR 1.491 when the last of the items indicated in 35 U.S.C. 371(c) is timely received by the office.

An international application becomes abandoned if the copy of the international application or the filing fee have not been received by the U.S. Designated Office prior to expiration of 20 months from the priority date. A notification of any missing requirements pursuant to 37 CFR 1.494(c) will only be mailed in those instances where the applicant has paid the basic national fee within 20 months from the priority date.

The notice of missing requirements lists several items which 37 CFR 1.497(a) and (b) require and all of those items will have to be satisfied before the oath or declaration is considered accepted. Similarly, the translation must be a translation of the international application. A translation of less than all of the international application (e.g., untranslated words in the drawings or translations of those untranslated words in a different part of the document) or a translation that includes modification, e.g., the insertion of headings, is unacceptable. "Sequence Listing" need not be translated if the "Sequence Listing" complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b). See 37 CFR 1.494(c).

1893.01(a)(2) Article 19 Amendment (Filed With the International Bureau)

The international application may be amended under Article 19 after issuance of the search report. The amendment is forwarded to the U.S. Designated Office by the International Bureau for inclusion in the U.S. national stage application. Article 19 amendments which were made in English will be entered by substituting each page of amendment for the corresponding English language page of claims of the international application. If the Article 19 amendments were made in a language other than English, applicant must provide an English translation for the U.S. national stage application. The English transla-

tion of the amendment(s) must be submitted by 20 months from the priority date, unless the U.S. was elected by 19 months from the priority date in which case the English translation must be filed by 30 months, or the amendment(s) will be considered to be canceled, 35 U.S.C. 371(d). Where applicant elects to request early processing of the national stage application under 35 U.S.C. 371(f), subsequently received amendments made in the international stage (and English translations thereof) will not become part of the U.S. national stage application file. If such amendments are desired, they should be offered under 37 CFR 1.121 as a preliminary amendment or a responsive amendment under 37 CFR 1.111.

Applicants entering the national stage in the U.S. are encouraged to submit an amendment in accordance with 37 CFR 1.121 rather than an English translation of an Article 19 amendment. Sometimes when an Article 19 amendment is translated into English, it cannot be entered. That is, each page of an Article 19 amendment must be entered by substituting a page of amendment for the corresponding page of claims of the international application. After translation of a page, the translated page may no longer correspond to a page of the claims of the international application such that the amendment is capable of entry by substituting the page of English translation (of the amendment) for the corresponding page of claims of the international application without leaving an inconsistency. Where applicant chooses to submit an English translation of the Article 19 amendment, applicant should check to be sure that the English translation can be entered by substituting the pages of translation for corresponding pages of the claims of the international application without leaving an inconsistency. If entry of the page of translation causes inconsistencies in the claims of the international application the translation will not be entered. For example, if the translation of the originally filed application has a page which begins with claim 1 and ends with a first part of claim 2 with the remainder of claim 2 on the next page then translation of the Article 19 amendment to only claim 1 must include a substitute page or pages beginning with the changes to claim 1 and ending with the last of the exact same first part of claim 2. This enables the original translated first page of claims to be replaced by the translation of the amendment without changing the subsequent unamended

page(s). Alternatively, applicant may submit a preliminary amendment in accordance with 37 CFR 1.121.

1893.01(b) Entry via the U.S. Elected Office

37 CFR 1.495. Entering the national stage in the United States of America as an Elected Office.

(a) Where the United States of America has been elected by the expiration of 19 months from the priority date, the applicant must fulfill the requirements of 35 U.S.C. 371 within the time periods set forth in paragraphs (b) and (c) of this section in order to prevent the abandonment of the international application as to the United States of America. International applications for which those requirements are timely fulfilled will enter the national stage and obtain an examination as to the patentability of the invention in the United States of America.

(b) To avoid abandonment of the application, the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date:

(1) A copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the United States Patent and Trademark Office; and

(2) The basic national fee (see § 1.492(a)). The 30-month time limit may not be extended.

(c) If applicant complies with paragraph (b) of this section before expiration of 30 months from the priority date but omits:

(1) A translation of the international application, as filed, into the English language, if it was originally filed in another language (35 U.S.C. 371(c)(2)) and/or

(2) The oath or declaration of the inventor (35 U.S.C. 371(c)(4); see § 1.497), and a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17(iv) within the time limits provided for in PCT Rule 26^{ter}.1, applicant will be so notified and given a period of time within which to file the translation and/or oath or declaration in order to prevent abandonment of the application. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than the expiration of 30 months after the priority date. The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of 30 months after the priority date. A "Sequence Listing" need not be translated if the "Sequence Listing" complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b).

A "Sequence Listing" need not be translated if the "Sequence Listing" complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b).

(d) A copy of any amendments to the claims made under PCT Article 19, and a translation of those amendments into English, if they were made in another language, must be furnished not later than the expiration of 30 months from the priority date. Amendments under PCT Article 19 which are not received by the

expiration of 30 months from the priority date will be considered to be cancelled. The 30-month time limit may not be extended.

(e) A translation into English of any annexes to the international preliminary examination report, if the annexes were made in another language, must be furnished not later than the expiration of 30 months from the priority date. Translations of the annexes which are not received by the expiration of 30 months from the priority date may be submitted within any period set pursuant to paragraph (c) of this section accompanied by the processing fee set forth in § 1.492(f). Annexes for which translations are not timely received will be considered cancelled. The 30-month time limit may not be extended.

(f) Verification of the translation of the international application or any other document pertaining to an international application may be required where it is considered necessary, if the international application or other document was filed in a language other than English.

(g) The documents submitted under paragraphs (b) and (c) of this section must be clearly identified as a submission to enter the national stage under 35 U.S.C. 371, otherwise the submission will be considered as being made under 35 U.S.C. 111.

(h) An international application becomes abandoned as to the United States 30 months from the priority date if the requirements of paragraph (b) of this section have not been complied with within 30 months from the priority date and the United States has been elected by the expiration of 19 months from the priority date. If the requirements of paragraph (b) of this section are complied with within 30 months from the priority date but any required translation of the international application as filed and/or the oath or declaration are not timely filed, an international application will become abandoned as to the United States upon expiration of the time period set pursuant to paragraph (c) of this section.

An international application designating the U.S. will enter the national stage via the U.S. Elected Office if a Demand electing the U.S. is filed prior to the expiration of 19 months from the priority date. The procedure for entry via the U.S. Elected Office is as prescribed in 37 CFR 1.495.

1893.01(b)(1) Submissions Required by 30 Months from the Priority Date

To begin entry into the national stage, where election of the U.S. under Chapter II of the PCT has been made prior to 19 months from the priority date, applicant is required to comply with 37 CFR 1.495(b) within 30 months from the priority date. Thus, applicant must pay the basic national fee on or before 30 months from the priority date and be sure that a copy of the international application has been received by the U.S. Designated Office prior to expi-

ration of 30 months from the priority date. The notice referred to in PCT Rule 47.1(c) constitutes conclusive evidence of transmission of the international application. Payment of the basic national fee will indicate applicant's intention to enter the national stage and will provide a U.S. correspondence address in most instances.

Facsimile transmission is not acceptable for submission of the basic national fee and/or the copy of the international application. See 37 CFR 1.6(d). Likewise, the certificate of mailing procedures of 37 CFR 1.8 do not apply to the filing of the copy of the international application and payment of the basic national fee. See 37 CFR 1.8(a)(2)(i)(F).

Applicants cannot pay the basic national fee with a surcharge after the 30 months deadline. Failure to pay the basic national fee within 30 months from the priority date will result in abandonment of the application. The time for payment of the basic fee is not extendable.

Similarly, the copy of the international application is required to be provided within 30 months from the priority date. A copy of the international application is provided to the U.S. Designated Office by the International Bureau (the copy is ordinarily received shortly after publication at about 18 months from the priority date). The International Bureau also mails a confirmation (Form IB/308) to applicant upon which applicant can rely that the copy has been provided. See PCT Rule 47.1(c). The copy is placed in a file to await applicant's submission of the basic national fee and other national stage requirements.

If the basic national fee has been paid by expiration of 30 months from the priority date but the required oath, declaration, or translation has not been filed within 30 months from the priority date, as appropriate, the Office will send applicant a notice and provide a period of time to supply the deficiency as set forth in 37 CFR 1.495(c). The time period usually set is 1 month from the date of the notification by the Office or 31 months from the priority date, whichever is later. This period may be extended pursuant to the provisions of 37 CFR 1.136(a). Thus, payment of the basic national fee on or before 30 months from the priority date will (1) cause the Office, after a check of the national stage papers at 30 months, to mail a notice identifying any deficiencies and affording applicant a period for correction of those deficiencies,

and (2) as in national practice under 37 CFR 1.53, enable applicants to extend the period of time under 37 CFR 1.136(a) for submission of a proper oath, declaration, or translation. The international application enters the national stage under 35 U.S.C. 371 when the last of the items indicated in 35 U.S.C. 371(c) and 37 CFR 1.491 is timely received by the office.

An international application becomes abandoned if the copy of the international application or the basic national fee has not been received by the U.S. Designated Office prior to expiration of 30 months from the priority date. A notification of any missing requirements pursuant to 37 CFR 1.495 will only be mailed in those instances where the applicant has paid the basic national fee within 30 months from the priority date.

The notice of missing requirements lists several items which 37 CFR 1.497(a) and (b) require and all of those items will have to be satisfied before the oath or declaration is considered accepted. Similarly, the translation must be a translation of the international application. A translation of less than all of the international application (e.g., untranslated words in the drawings or translations of those untranslated words in a different part of the document) or a translation that includes modifications, e.g., the insertion of headings, is unacceptable. "Sequence Listing" need not be translated if the "Sequence Listing" complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b). See 37 CFR 1.495(c).

1893.01(b)(2) Article 19 and Article 34 Amendments (Filed with the International Preliminary Examining Authority)

Paragraph (d) of 37 CFR 1.495 states that if an Article 19 amendment is not received before expiration of 30 months from the priority date, it is considered to be canceled. Nevertheless, applicant may submit a preliminary amendment in accordance with 37 CFR 1.121 adding the substance of the Article 19 amendment to the national stage application. In some instances, entry of the subject matter via an amendment under 37 CFR 1.121 may be preferable to entry via Article 19. For example, where the Article 19 amendment was not filed in English the amendment

would have to be translated into English in order that it be submitted for entry into the national stage. The translation must be submitted before expiration of 30 months from the priority date and the substitute pages must be capable of insertion into the text of the international application. Thus, where an Article 19 amendment was made in the international stage the same amendment may be entered for the national stage either in accordance with 35 U.S.C. 371(c)(3) or the amendments may be added via a preliminary amendment in accordance with 37 CFR 1.121.

TRANSLATION OF AN ANNEX TO THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

The translation of an Annex to the international preliminary examination report must be submitted so that the translation of the originally filed application can be changed by replacing the originally filed application page(s) (of translation) with substitute page(s) of translation of the annex. Where applicant chooses to submit an English translation of the annex, applicant should check to be sure that the English translation can be entered by substituting the pages of translation for corresponding pages of the claims of the international application without leaving an inconsistency. If entry of the page of translation causes inconsistencies in the specification or claims of the international application the translation will not be entered. For example, if the translation of the originally filed application has a page which begins with claim 1 and ends with a first part of claim 2 with the remainder of claim 2 on the next page then translation of the annex to only claim 1 must include a substitute page or pages beginning with the changes to claim 1 and ending with the last of the exact same first part of claim 2. This enables the original translated first page of claims to be replaced by the translation of the annex without changing the subsequent unamended page(s). Alternatively applicant may submit a preliminary amendment in accordance with 37 CFR 1.121.

1893.01(c) Fees

Because the national stage fees are subject to change, applicants and examiners should always consult the *Official Gazette* for the current fee listing.

Applicants are cautioned that national stage fees are specifically provided for in 37 CFR 1.492 and autho-

rizations to charge fees under 37 CFR 1.16 do not constitute a specific authorization to charge national stage fees.

1893.01(d) Translation

Applicants entering the national stage in the U.S. are required to file a translation of the international application (if the international application was filed in another language). 35 U.S.C. 371(c)(2). A "Sequence Listing" need not be translated if the "Sequence Listing" complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b). See 37 CFR 1.495(c). The translation must be a translation of the international application as filed with any changes which have been properly accepted under PCT Rule 26 or any rectifications which have been properly accepted under PCT Rule 91. Amendments, even those considered to be minor or to not include new matter, may not be incorporated into the translation. If an amendment to the international application as filed is desired for the national stage, it may be submitted in accordance with 37 CFR 1.121. An amendment filed under 37 CFR 1.121 should be submitted within 1 month after completion of the 35 U.S.C. 371(c) requirements and entry into the national stage. See 37 CFR 1.496(a). If applicant has timely paid the basic national fee but the translation is missing or is defective, a notice of Missing Requirements will be sent to applicant setting a period to correct any missing or defective requirements. The time period is 21 months or 31 months from the priority date, as appropriate, or 1 month from the date of the notice, whichever expires later. The time period is subject to the provisions of 37 CFR 1.136(a).

1893.01(e) Oath/Declaration

37 CFR 1.497. *Oath or declaration under 35 U.S.C. 371(c)(4).*

(a) When an applicant of an international application desires to enter the national stage under 35 U.S.C. 371 pursuant to §§ 1.494 or 1.495, and a declaration in compliance with this section has not been previously submitted in the international application under PCT Rule 4.17(iv) within the time limits provided for in PCT Rule 26^{ter}.1, he or she must file an oath or declaration that:

- (1) Is executed in accordance with either §§ 1.66 or 1.68;
- (2) Identifies the specification to which it is directed;
- (3) Identifies each inventor and the country of citizenship of each inventor; and

(4) States that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.

(b)(1) The oath or declaration must be made by all of the actual inventors except as provided for in §§ 1.42, 1.43 or 1.47.

(2) If the person making the oath or declaration or any supplemental oath or declaration is not the inventor (§§ 1.42, 1.43, or §1.47), the oath or declaration shall state the relationship of the person to the inventor, and, upon information and belief, the facts which the inventor would have been required to state. If the person signing the oath or declaration is the legal representative of a deceased inventor, the oath or declaration shall also state that the person is a legal representative and the citizenship, residence and mailing address of the legal representative.

(c) Subject to paragraph (f) of this section, if the oath or declaration meets the requirements of paragraphs (a) and (b) of this section, the oath or declaration will be accepted as complying with 35 U.S.C. 371(c)(4) and §§ 1.494(c) or 1.495(c). However, if the oath or declaration does not also meet the requirements of § 1.63, a supplemental oath or declaration in compliance with § 1.63 or an application data sheet will be required in accordance with § 1.67.

(d) If the oath or declaration filed pursuant to 35 U.S.C. 371(c)(4) and this section names an inventive entity different from the inventive entity set forth in the international application, or a change to the inventive entity has been effected under PCT Rule 92^{bis} subsequent to the execution of any declaration which was filed under PCT Rule 4.17(iv), the oath or declaration must be accompanied by:

(1) A statement from each person being added as an inventor and from each person being deleted as an inventor that any error in inventorship in the international application occurred without deceptive intention on his or her part;

(2) The processing fee set forth in § 1.17(i); and

(3) If an assignment has been executed by any of the original named inventors, the written consent of the assignee (see § 3.73(b) of this chapter).

(e) The Office may require such other information as may be deemed appropriate under the particular circumstances surrounding the correction of inventorship.

(f) A new oath or declaration in accordance with this section must be filed to satisfy 35 U.S.C. 371(c)(4) if the declaration was filed under PCT Rule 4.17(iv), and:

(1) There was a change in the international filing date pursuant to PCT Rule 20.2 after the declaration was executed; or

(2) A change in the inventive entity was effected under PCT Rule 92^{bis} after the declaration was executed.

(g) If a priority claim has been corrected or added pursuant to PCT Rule 26^{bis} during the international stage after the declaration of inventorship was executed in the international application under PCT Rule 4.17(iv), applicant will be required to submit either a new oath or declaration or an application data sheet as set forth in § 1.76 correctly identifying the application upon which priority is claimed.

Applicants entering the national stage in the U.S. are required to file an oath or declaration of the inventor in accordance with 37 CFR 1.497(a) and (b). If the basic national fee has been paid by the expiration of 20 or 30 months from the priority date as appropriate, but the required oath or declaration has not been filed, the Office will send applicant a notice of Missing Requirements setting a time period to correct any missing or defective requirements. The time period is 21 months or 31 months from the priority date, as appropriate, or 1 month from the date of the notice, whichever expires later. The time period is subject to the provisions of 37 CFR 1.136(a). The oath or declaration must comply with the requirements of 35 U.S.C. 115 and with the regulations prescribed for oaths and declarations. See especially 37 CFR 1.497(a) and (b). Further, pursuant to 37 CFR 1.497(c), to avoid the need to submit a supplemental oath or declaration, the oath or declaration must comply with 37 CFR 1.63.

If an inventor refuses to execute the oath or declaration or is unavailable, applicant must file an oath or declaration and a petition in accordance with 37 CFR 1.47. Similarly, where an inventor is deceased or legally incapacitated, an oath or declaration in accordance with the provisions of 37 CFR 1.42 or 1.43 must be provided. To avoid abandonment the oath or declaration and petition (under 37 CFR 1.42, 1.43 and/or 1.47, as appropriate) must be filed either before expiration of 20 or 30 months from the priority date, as appropriate, or, where a notification of deficiency of the oath/declaration has been mailed, within the time for reply to that notification.

The Office no longer requires proof of authority of the legal representative of a deceased or legally incapacitated inventor. See MPEP § 409.01(b).

1893.02 Abandonment

If the requirements of 35 U.S.C. 371(c) are not complied with by the time period set in 37 CFR 1.494(b) and (c) or 37 CFR 1.495(b) and (c), as appropriate, the application is considered to be abandoned, see 37 CFR 1.494(g) and 37 CFR 1.495(h).

Examiners and applicants should be aware that sometimes papers filed for the national stage are deficient and abandonment results. For example, if the fee submitted does not include at least the amount of the

basic national fee that is due, the application becomes abandoned.

Applicant may file a petition to revive an abandoned application in accordance with the provisions of 37 CFR 1.137. See MPEP § 711.03(c).

1893.03 Prosecution of U.S. National Stage Applications Before the Examiner

37 CFR 1.496. Examination of international applications in the national stage.

(a) International applications which have complied with the requirements of 35 U.S.C. 371(c) will be taken up for action based on the date on which such requirements were met. However, unless an express request for early processing has been filed under 35 U.S.C. 371(f), no action may be taken prior to one month after entry into the national stage.

(b) A national stage application filed under 35 U.S.C. 371 may have paid therein the basic national fee as set forth in § 1.492(a)(4) if it contains, or is amended to contain, at the time of entry into the national stage, only claims which have been indicated in an international preliminary examination report prepared by the United States Patent and Trademark Office as satisfying the criteria of PCT Article 33(1)-(4) as to novelty, inventive step and industrial applicability. Such national stage applications in which the basic national fee as set forth in § 1.492(a)(4) has been paid may be amended subsequent to the date of entry into the national stage only to the extent necessary to eliminate objections as to form or to cancel rejected claims. Such national stage applications in which the basic national fee as set forth in § 1.492(a)(4) has been paid will be taken up out of order.

An international application which enters the national stage will be forwarded to the appropriate Technology Center (TC) for examination in turn based on the 35 U.S.C. 371(c) date of the application. As set forth in 37 CFR 1.496(b), if an application includes only claims which have been indicated in an IPER prepared by the USPTO to satisfy the criteria of PCT Article 33(1)-(4), the application qualifies for the reduced basic national fee set forth in 37 CFR 1.492(a)(4). Applications in which the reduced basic national fee has been paid will be taken up out of order by the examiner. See MPEP § 708 for a discussion of the order of examination of applications by examiners.

Once the national stage application has been taken up by the examiner, prosecution proceeds in the same manner as for a domestic application with the exceptions that:

(A) the international filing date is the date to keep in mind when searching the prior art; and

(B) unity of invention proceeds as under 37 CFR 1.475.

1893.03(a) How To Identify That an Application Is a U.S. National Stage Application

Applicant's initially deposited application must indicate that treatment as a national stage application (filed under 35 U.S.C. 371) is requested (see 37 CFR 1.494(f) and 37 CFR 1.495(g)). Otherwise, the application will be treated as an application filed under 35 U.S.C. 111(a).

That is, if applicant wishes the application to be filed under 35 U.S.C. 111(a), applicant's originally filed application papers need indicate simply that the papers are for a new U.S. patent application. If, however, applicant is filing papers for entry into the national stage of a PCT application, or to establish an effective date for provisional rights resulting from the filing of a PCT application under 35 U.S.C. 154(d), applicant must so state. See 37 CFR 1.417, 1.494(f) and 1.495(g). If the applicant's papers are not clearly identified as "a submission pursuant to 35 U.S.C. 154(d)(4)" or "a submission to enter the national stage under 35 U.S.C. 371," the submission will be considered as being made under 35 U.S.C. 111(a). As provided in 37 CFR 1.494(f) and 1.495(g), a copy of the international publication and/or a translation of the international application identified as provided in 37 CFR 1.417 can be used to fulfill the 35 U.S.C. 371(c)(2) requirements. Examination of the originally filed application papers occurs in either the Office of Initial Patent Examination or in the National Stage Processing Division of the Office of PCT Operations where it is determined whether applicant has asked that the papers be treated as a national stage filing under 35 U.S.C. 371. If the application is accepted for entry into the national stage, the National Stage Processing Division will fill out and mail Form PCT/DO/EO/903 indicating acceptance of the application as a national stage filing under 35 U.S.C. 371 and will stamp the face of the file with an indication that the application is filed under 35 U.S.C. 371. Accordingly, the three key indicators which reflect that an application is filed under 35 U.S.C. 371 are:

(A) The file face indication of a filing under 35 U.S.C. 371;

(B) The Form PCT/DO/EO/903 indicating acceptance of the application as a national stage filing under 35 U.S.C. 371; and

(C) Applicant's statement (or the equivalent) in the originally filed application papers that the application is a national stage filing under 35 U.S.C. 371. Applicants who use transmittal Form PCT/DO/EO/1390 will satisfy the requirement for such a statement since the form includes an indication that the application is a national stage filing under 35 U.S.C. 371.

Initially, the examiner should inspect the face of the file wrapper and/or the PALM bib-data sheet for an indication that it is filed under 35 U.S.C. 371 and should also check the application papers for the presence of Form PCT/DO/EO/903. If neither of these indications are present the application may, in the absence of evidence to the contrary (there is an indication in the originally filed application papers that processing as a national stage is desired), be treated as a filing under 35 U.S.C. 111(a). Thus, if both indications are present, the application should be treated as a filing under 35 U.S.C. 371. If the face of the file wrapper does not indicate a filing under 35 U.S.C. 371, but a properly completed Form PCT/DO/EO/903 is in the file, the examiner should complete the face of the file by adding "filed under 35 U.S.C. 371" in the upper left margin thereof. The examiner should initial and date this change. If the file wrapper does not include a properly completed Form PCT/DO/EO/903 but the face of the file indicates a filing under 35 U.S.C. 371, the application should be returned to the National Stage Processing Division of the Office of PCT Operations for certification that the application has been accepted for the national stage.

In accordance with the notice at 1077 O.G. 13 (14 April 1987), if the applicant files a U.S. national application and clearly identifies in the accompanying oath or declaration the specification to which it is directed by referring to a particular international application by PCT Application Number and International Filing Date and that he or she is executing the declaration as, and seeking a U.S. Patent as, the inventor of the invention described in the identified international application, then the application will be accepted as filed under 35 U.S.C. 371. Merely claiming priority of an international (PCT) application in an

oath or declaration will not serve to indicate a filing under 35 U.S.C. 371. Also, if there are any conflicting instructions as to whether the filing is under 35 U.S.C.

111(a) or 35 U.S.C. 371, the application will be accepted as filed under 35 U.S.C. 111(a).

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APPLICATION NUMBER 09/XXX,XXX	FILING DATE 04/02/2001	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO 1234-PCT	
APPLICANT Ted R. Wilson et al. **CONTINUING DOMESTIC DATA***** VERIFIED **371 (NAT'L STAGE) DATA***** VERIFIED THIS APPLN IS A 371 OF PCT/EP99/XXXXX 04/09/1999 **FOREIGN APPLICATIONS***** VERIFIED FED REP GERMANY XXX XX XXX.X 04/10/1998					
Foreign priority claimed 35 USC 119 (a-d) conditions met	<input type="radio"/> yes <input type="radio"/> no <input type="radio"/> yes <input type="radio"/> no <input type="radio"/> Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
Verified and acknowledged		Examiner's Name	Initials		
ADDRESS					
TITLE					
FILING FEE RECEIVED	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT NO. _____ for the following:		<input type="radio"/> All Fees <input type="radio"/> 1.16 Fees (Filing) <input type="radio"/> 1.17 Fees (Processing Ext. of Time) <input type="radio"/> 1.18 Fees (Issue) <input type="radio"/> Other _____ <input type="radio"/> Credit		



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT
United States Patent and Trademark Office
Washington, D.C. 20231
www.uspto.gov

U.S. APPLICATION NO. 09/ XXXXXX	FIRST NAMED APPLICANT Ted Wilson et al.	ATTY. DOCKET NO. 1234-PCT
INTERNATIONAL APPLICATION NO. PCT/EP99/XXXXX		
I.A. FILING DATE 09 APR 99	PRIORITY DATE 10 APR 98	
DATE MAILED: 04 APR 01		

JOHN SMITH
212 MAIN STREET
ANYTOWN, PA 12345

NOTIFICATION OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C. 371 AND 37 CFR 1.494 OR 1.495

1. The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated Office (37 CFR 1.494), an Elected Office (37 CFR 1.495), has determined that the above-identified international application has met the requirements of 35 U.S.C. 371, and is **ACCEPTED** for national patentability examination in the United States Patent and Trademark Office.

2. The United States Application Number assigned to the application is shown above and the relevant dates are:

02 APR 2001	02 APR 2001
DATE OF RECEIPT OF	DATE OF RECEIPT OF ALL
35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE "FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** The filing date of the above-identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

3. A request for immediate examination under 35 U.S.C. 371(f) was received on _____ and the application will be examined in turn.

4. The following items have been received:

- U.S. Basic National Fee.
- Copy of the international application.
- Translation of the international application into English.
- Oath or Declaration of inventor(s).
- Copy of Article 19 amendments. Translation of Article 19 amendments into English.
The Article 19 amendments have not been entered.
- The International Preliminary Examination Report in English and its Annexes, if any.
- Copy of the Annexes to the International Preliminary Examination Report (IPER).
 Translation of Annexes to the IPER into English.
The Annexes have not been entered.
- Preliminary amendment(s) filed 06 OCT 2000 and _____
- Information Disclosure Statement(s) filed 28 DEC 2000 and _____
- Assignment document.
- Power of Attorney and/or Change of Address.
- Substitute specification filed _____
- Indication of Small Entity Status.
- Priority Document.
- Copy of the International Search Report and copies of the references cited therein.
- Other:

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5).

Charles Pearson

Telephone: 703-305-3859

FORM PCT/DO/EO/903 (March 2001)

1893.03(b) The Filing Date of a U.S. National Stage Application

An international application designating the U.S. has two stages (international and national) with the filing date being the same in both stages. Often the date of entry into the national stage is confused with the filing date. It should be borne in mind that the filing date of the international stage application is also the filing date for the national stage application. Specifically, 35 U.S.C. 363 provides that

An international application designating the United States shall have the effect, from its international filing date under Article 11 of the treaty, of a national application for patent regularly filed in the Patent and Trademark Office except as otherwise provided in section 102(e) of this title.

Similarly, PCT Article 11(3) provides that

...an international filing date shall have the effect of a regular national application in each designated State as of the international filing date, which date shall be considered to be the actual filing date in each designated State.

37 CFR 1.496(a), first sentence, reads "International applications which have complied with the requirements of 35 U.S.C. 371(c) will be taken up for action based on the date on which such requirements were met." Thus, when the file wrapper label or PALM bib-data sheet is printed, the information is read from the PALM data base and the information printed in the filing date box is the date of entry into the national stage rather than the actual international filing date. See in the preceding section the sample National Stage Filing Under 35 U.S.C. 371 wherein the face of the file of national stage application number 07/XXX,XXX is shown with the date of entry into the national stage (11/08/91) shown in the FILING DATE box and the true U.S. filing date (01/10/90) is indicated just to the right of the international application number (PCT/EP90/XXXXX) in the CONTINUING DATA block.

Applicants are quite often confused as to the true filing date and will ask for corrected filing receipts thinking that the information thereon is wrong. This explanation should offer some clarity. For all legal purposes, the filing date is the PCT international filing date. The date of actual entry into the national stage is

otherwise the date provided in the PALM system. Any issued patent will have all of the relevant dates listed.

1893.03(c) The Priority Date, Priority Claim, and Priority Papers for a U.S. National Stage Application

A U.S. national stage application (filed under 35 U.S.C. 371) may include a claim under 35 U.S.C. 119(a) and 365(b), 35 U.S.C. 119(e), or 35 U.S.C. 120 and 365(c) for benefit of the filing date of a prior application or applications.

PRIORITY CLAIM UNDER 35 U.S.C. 119(a)

A national stage application which includes a priority claim under 35 U.S.C. 119(a) and 365(b) must refer to a priority application, the priority of which was also claimed in the international application. If the 35 U.S.C. 119(a) and 35 U.S.C. 365(b) priority claim is to an application, the priority of which was properly claimed in the international application, the claim for priority is acknowledged and the national stage application file is checked to see if the file contains a copy of the certified copy of the priority document submitted to the International Bureau.

If the 35 U.S.C. 119(a) and 365(b) priority claim in the national stage application is to an application, the priority of which was not claimed in the international application, the claim for priority must be denied for failing to meet the requirements of the Patent Cooperation Treaty, specifically PCT Rule 4.10.

For a comparison with 35 U.S.C. 119(a)-(d) priority claims in a national application filed under 35 U.S.C. 111(a) see MPEP § 1895.01.

THE CERTIFIED COPY

The requirement in PCT Rule 17 for a certified copy of the foreign priority application is normally fulfilled by applicant providing a certified copy to the Receiving Office or to the International Bureau within 16 months from the priority date. Subsequently, the International Bureau forwards a photocopy of the certified priority document when it forwards a copy of the international application (shortly after publication at 18 months from the priority date) to each Designated Office. The copy from the International Bureau is placed in the U.S. national stage file. The

International Bureau stamps the face of the photocopy of the certified priority document with an indication that the certified priority document was received at the International Bureau. The stamped copy of the priority document sent to the U.S. Office of PCT Operations from the International Bureau is acceptable to establish that applicant has filed a certified copy of the priority document. The examiner should acknowl-

edge in the next Office action that the certified copy of the foreign priority document has been filed. Note the example of an acceptable priority document with the stamp (box) in the upper right hand section indicating receipt by the International Bureau (WIPO) on 30 November 1992 and the stamped term "PRIORITY DOCUMENT."

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REPUBLIQUE FRANÇAISE

INSTITUT NATIONAL DE LA PROPRIÉTÉ INDUSTRIELLE

PRIORITY DOCUMENT

REC'D 3 0 NOV 1992

WIPO PCT

BREVETS D'INVENTION

CERTIFICATS D'UTILITÉ CERTIFICATS D'ADDITION

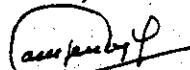
Copie officielle

Le Directeur général de l'Institut national de la propriété industrielle certifie que le document ci-annexé est la copie certifiée conforme, d'une demande de titre de propriété industrielle déposée à l'Institut.

Fait à Paris le - 7 SEP. 1992

Pour le Directeur général de l'Institut
national de la propriété industrielle

Le Chef de Division



Yves CAMPENON



29bis, rue de Lénine 75800 PARIS Cédex 08
Tél. (1) 42 94 52 52 Télex 290 368 INPI PARI Télécopie (1) 42 93 59 30
Établissement public national créé par la loi n° 31-444 du 19 avril 1951

BA 267/141190

If applicant has not forwarded a certified copy of the priority application in time for the International Bureau to forward it to the U.S. Designated Office with the copy of the international application, then applicant will have to provide a certified copy of the priority document during the national stage to fulfill the requirement of 37 CFR 1.55(a)(2).

PRIORITY CLAIM UNDER 35 U.S.C. 119(e), OR 120 AND 365(c)

A national stage application may include a priority claim under 35 U.S.C. 119(e), or 120 and 365(c) to a prior U.S. national application or under 35 U.S.C. 120 and 365(c) to a prior international application designating the U.S. The conditions for according benefit under 35 U.S.C. 120 are as described in MPEP § 201.07, § 201.08, and § 201.11 and are similar regardless of whether the U.S. national application is a national stage application filed under 35 U.S.C. 371 or a national application filed under 35 U.S.C. 111(a).

In order for a national stage application (of international application "X") to obtain benefit under 35 U.S.C. 119(e) of a prior U.S. provisional application, the national stage application must comply with the requirements set forth in 37 CFR 1.78(a)(4) through 37 CFR 1.78(a)(6). Public Law 106-113 amended 35 U.S.C. 119(e) to eliminate the copendency requirement for a nonprovisional application claiming benefit of a provisional application. 35 U.S.C. 119(e)(2) as amended became effective on November 29, 1999 and applies to provisional applications filed on or after June 8, 1995. 37 CFR 1.78(a)(4) requires that the prior provisional application must be entitled to a filing date as set forth in 37 CFR 1.53(c), and the basic filing fee set forth in 37 CFR 1.16(k) must be paid on the provisional application within the time period set forth in 37 CFR 1.53(g). Additionally, the provisional application must name as an inventor at least one inventor named in the later filed international application "X" and disclose the named inventor's invention claimed in at least one claim of the national stage application in the manner provided by the first paragraph of 35 U.S.C. 112. The national stage application must contain a reference to the provisional application (either in an application data sheet (37 CFR 1.76) or in the first sentence of the specification), identifying it as a provisional application, and including the provisional application number (series code and serial

number). If the provisional application was filed in a language other than English, the national stage application must also contain an English language translation of the non-English language provisional application and a statement that the translation is accurate. The required reference to the earlier provisional application and the English language translation must be submitted within the time period provided by 37 CFR 1.78(a)(5). This time period is not extendable.

In order for a national stage application (of international application "X") to obtain benefit under 35 U.S.C. 120 and 365(c) of a prior filed copending nonprovisional application or prior filed copending international application designating the United States of America, the national stage application must comply with the requirements set forth in 37 CFR 1.78(a)(1) through 37 CFR 1.78(a)(3). The prior nonprovisional application or international application must name as an inventor at least one inventor named in the later filed international application "X" and disclose the named inventor's invention claimed in at least one claim of the national stage application in the manner provided by the first paragraph of 35 U.S.C. 112. The national stage application must contain a reference to the prior nonprovisional or international application (either in an application data sheet (37 CFR 1.76) or in the first sentence of the specification), identifying it by application number (series code and serial number) or international application number and international filing date and indicating the relationship of the applications. There is a non-extendable time period for submitting the required reference to the earlier application. If the national stage application claims the benefit of a prior international application designating the United States of America, the first sentence of the specification of the national stage application must include an indication of whether the prior international application was published under PCT Article 21(2) in English (regardless of whether benefit for such an application is claimed in the application data sheet). See 37 CFR 1.78(a)(2). The required reference to the earlier filed application must be submitted within the time period set forth in 37 CFR 1.78(a)(2). This time period is not extendable.

A prior filed nonprovisional application is copending with the national stage application if the prior U.S.

national application was pending on the international filing date of the national stage application.

A prior international application designating the United States of America is copending with the national stage application if the prior international application was not abandoned or withdrawn on the international filing date of international application "X."

Note: a national stage application filed under 35 U.S.C. 371 may not claim benefit of the filing date of the international application of which it is the national stage since its filing date is the date of filing of that international application. See also MPEP § 1893.03(b). Stated differently, since the international application is not an earlier application (it has the same filing date as the national stage), a priority claim in the national stage to the international application is inappropriate. Accordingly, it is not necessary for the applicant to amend the first sentence of the specification to reference the international application number that was used to identify the application during international processing of the application by the international authorities prior to commencement of the national stage under 35 U.S.C. 371.

For a comparison with 35 U.S.C. 120 priority claims in a national application filed under 35 U.S.C. 111(a), see MPEP § 1895.

1893.03(d) Unity of Invention

37 CFR 1.499. Unity of invention during the national stage

If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the examiner. Review of any such requirement is provided under §§ 1.143 and 1.144.

PCT Rule 13 was amended effective July 1, 1992. 37 CFR 1.475 was amended effective May 1, 1993 to correspond to PCT Rule 13.

Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage (filed under 35 U.S.C. 371) applications. Restriction practice continues to apply to U.S. national applications filed under 35 U.S.C. 111(a).

When making a lack of unity of invention requirement, the examiner must (1) list the different groups

of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group.

The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

A process is "specially adapted" for the manufacture of a product if the claimed process inherently produces the claimed product with the technical relationship being present between the claimed process and the claimed product. The expression "specially adapted" does not imply that the product could not also be manufactured by a different process.

An apparatus or means is specifically designed for carrying out the process when the apparatus or means is suitable for carrying out the process with the technical relationship being present between the claimed apparatus or means and the claimed process. The expression specifically designed does not imply that the apparatus or means could not be used for carrying out another process, nor does it imply that the process could not be carried out using an alternative apparatus or means.

Note: the determination regarding unity of invention is made without regard to whether a group of inventions is claimed in separate claims or as alternatives within a single claim. The basic criteria for unity of invention are the same, regardless of the manner in which applicant chooses to draft a claim or claims.

1893.03(e) Papers Received from the International Bureau and Placed in a U.S. National Stage Application File

The national stage application includes papers forwarded by the International Bureau and papers from applicant. Some of the papers from the International Bureau are identified in this section with a brief note as to their importance to the national stage application. The examiner should review each such paper and the important aspect indicated.

THE PAMPHLET

The Pamphlet includes

(A) a cover page with the applicant/inventor data, the application data (serial number, filing date, etc.) and the Abstract (and, if appropriate, a figure of drawing),

(B) the description, claims and drawing parts of the international application, and

(C) the search report (Form PCT/ISA/210).

The cover page is important as a source of the correct application data, most importantly the filing date and priority date accorded to the international application. If the pamphlet is published in English, applicant need not submit a copy of the international application to the Patent and Trademark Office. The Office will use the description, claims, abstract and drawings as published in the pamphlet for the U.S. national stage examination under 35 U.S.C. 371. The description, claims and drawing parts of the international application reflect the application subject matter on the international filing date and are important for comparison with any amendments to check for new

matter. The search report reflects the International Searching Authority's opinion regarding the prior art.

The abstract that appears on the cover page of the pamphlet will be published by the printing contractor if the national stage application (1) issues as a United States Patent or (2) is published as a patent application publication unless applicant amends the abstract and, for purposes of the patent application publication, complies with the requirements for publication. The burden on the applicant is to comply with PCT Rule 11.4 when the international application is filed. Since applicant has already complied with PCT Rule 11.4 by filing the abstract on a separate sheet when the international application was filed, it is improper for the examiner of the U.S. national stage application to require an abstract on a separate sheet during national stage processing of the international application.

THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

If the international application underwent preliminary examination, the International Preliminary Examination Report (Form PCT/IPEA/409) reflects the International Preliminary Authority's non-binding opinion regarding novelty, inventive step and industrial applicability. The examiner may adopt any portion or all of this opinion upon consideration in the national stage so long as it is consistent with U.S. practice. The examiner should comment upon the Report in the first Office action on the merits to reflect that the Report has been considered. The comment may be a mere acknowledgement.

THE PRIORITY DOCUMENT

See the discussion in MPEP § 1893.03(c).

NOTIFICATION OF WITHDRAWAL

If the national stage application papers include a Notification of Withdrawal (PCT/IB/307), the examiner must check the date of receipt of the 35 U.S.C. 371 requirements (the 371 date) on Form PCT/DO/EO/903 to be sure that the 371 date is not later than the date of withdrawal. If it is later, the national stage application must be returned to the PCT Legal Office for a decision regarding the propriety of entry into the national stage.

1893.03(f) Drawings and PCT Rule 11

The drawings for the national stage application must comply with PCT Rule 11. The copy of the drawings provided by the International Bureau has already been checked and should be in compliance with PCT Rule 11. Accordingly, the drawing provided by the International Bureau should be acceptable. Sometimes, applicant submits a drawing for use in the national stage application and a check will be made by the Official Draftsman. The Official Draftsman may not impose requirements beyond those imposed by the Patent Cooperation Treaty (e.g., PCT Rule 11). The examiner does indeed have the authority to require new or more acceptable drawings if the drawings were published without meeting all requirements under the PCT for drawings. Unless the applicant requests the use of drawings which he or she has submitted, the drawings to be employed in the national stage are those which are a part of the Article 20 communication.

1893.03(g) Information Disclosure Statement in a National Stage Application

An extensive discussion of Information Disclosure Statement practice is to be found in MPEP § 609. Although not specifically stated therein, the duty to disclose information material to patentability as defined in 37 CFR 1.56 is placed on individuals associated with the filing and prosecution of a national stage application in the same manner as for a domestic national application. The declaration requires the same averments with respect to the duty under 37 CFR 1.56.

When an international application is filed under the Patent Cooperation Treaty (PCT), prior art documents may be cited by the examiner in the international search report and/or the international preliminary examination report. When a national stage application is filed under 35 U.S.C. 371, or a national application is filed under 35 U.S.C. 111 claiming benefit of the filing date of the international application, it is often desirable to have the examiner consider the documents cited in the international application when examining the national application.

As a result of an agreement among the European Patent Office (EPO), Japanese Patent Office (JPO),

and the United States Patent and Trademark Office (USPTO), copies of documents cited in the international search report issued by any one of these International Searching Authority Offices generally are being sent to the other Offices when designated in the international application. Accordingly, in many national stage applications where the international search was conducted by the EPO, JPO, or USPTO, copies of the documents cited in the international search report are made available to the examiner in the national stage application.

When all the requirements for a national stage application have been completed, applicant is notified (Form PCT/DO/EO/903) of the acceptance of the application under 35 U.S.C. 371, including an itemized list of the items received. The itemized list includes an indication of whether a copy of the international search report and copies of the references cited therein are present in the national stage file. The examiner will consider the documents cited in the international search report, without any further action by applicant under 37 CFR 1.97 and 1.98, when both the international search report and copies of the documents are indicated to be present in the national stage file. The examiner will note the consideration in the first Office action. There is no requirement that the examiners list the documents on a PTO-892 form. See form paragraphs 6.53, 6.54, and 6.55 (reproduced in MPEP § 609). Otherwise, applicant must follow the procedure set forth in 37 CFR 1.97 and 1.98 in order to ensure that the examiner considers the documents cited in the international search report.

This practice applies only to documents cited in the international search report relative to a national stage application filed under 35 U.S.C. 371. It does not apply to documents cited in an international preliminary examination report that are not cited in the search report. It does not apply to applications filed under 35 U.S.C. 111(a) claiming the benefit of an international application filing date.

1895 A Continuation or Continuation- In-Part Application of a PCT Application Designating the United States

It is possible to file a U.S. national application under 35 U.S.C. 111(a) during the pendency (prior to

the abandonment) of an international application which designates the United States without completing the requirements for entering the national stage under 35 U.S.C. 371(c). The ability to take such action is based on provisions of the United States patent law. 35 U.S.C. 363 provides that "[a]n international application designating the United States shall have the effect, from its international filing date under article 11 of the treaty, of a national application for patent regularly filed in the Patent and Trademark Office...." 35 U.S.C. 371(d) indicates that failure to timely comply with the requirements of 35 U.S.C. 371(c) "shall be regarded as abandonment ... by the parties thereof...." It is therefore clear that an international application which designates the United States has the effect of a pending U.S. application from the international application filing date until its abandonment as to the United States. The first sentence of 35 U.S.C. 365(c) specifically provides that "[i]n accordance with the conditions and requirements of section 120 of this title, ... a national application shall be entitled to the benefit of the filing date of a prior international application designating the United States." The condition of 35 U.S.C. 120 relating to the time of filing requires the later application to be filed before the patenting or abandonment of or termination of proceedings on the first application. The filing of continuations and continuations-in-part of a PCT application designating the U.S. was used primarily in instances where there was difficulty in obtaining a signed oath or declaration by the expiration of the time for entry into the national stage. Since applicants are now notified of missing or defective oaths or declarations and/or translations, and are given a time period to respond which is extendable under 37 CFR 1.136(a), the use of this practice may well diminish.

A continuing application under 35 U.S.C. 365(c) and 120 must be filed before the abandonment or patenting of the prior application.

To obtain benefit under 35 U.S.C. 120 of a prior PCT application designating the U.S., the continuing U.S. national application must

(A) include an appropriate reference to the prior PCT application (either in the application data sheet (37 CFR 1.76) or in the first sentence of the specification),

(B) include an indication of whether the prior PCT international application was published under

PCT Article 21(2) in English in the first sentence of the specification regardless of whether benefit for such application is claimed in the application data sheet (if the continuing U.S. national application was filed on or after November 29, 2000),

(C) be copending with the prior PCT application, and

(D) have at least one inventor in common with the prior PCT application.

See MPEP § 201.11. A U.S. national application is copending with an international application if the prior international application was pending on the filing date of the subsequent U.S. national application.

If the prior application is an international application, the examiner must ascertain (C) and (D) above by either examining the national stage application file of the international application, or by examining the international application file, or requiring applicant to submit sufficient proof that the international application was copending with the U.S. national (35 U.S.C. 111(a)) application claiming benefit under 35 U.S.C. 120. If the parent international application was not copending (i.e., abandoned or withdrawn), benefit under 35 U.S.C. 120 is not possible.

If priority is claimed under 35 U.S.C. 120 in a third U.S. national application to a first national or international application via a second international application, the examiner must examine the second international application to see if it contains a proper reference and indication of publication language for benefit under 35 U.S.C. 120 of the first filed application. The second international application must include an appropriate reference in the Request to the prior U.S. national application. The appropriate reference in the Request should identify the parent application and include an indication that it is a continuation or continuation-in-part of the first filed U.S. application, PCT Rule 4.14. In order for the examiner to determine if the international application meets the above noted requirements, the examiner should review the copy of the Request form in the international application file or the cover page of the published international application. If the copy is not in the file, the International Application Processing Division may obtain a copy from the International Bureau.

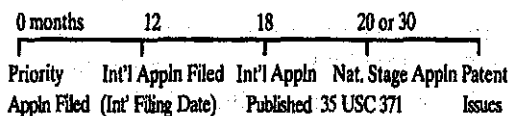
1895.01 Handling of and Considerations In the Handling of National Applications Under 35 U.S.C. 371 and 35 U.S.C. 111(a) Continuations and Continuations-In-Part of a PCT Application

A national application can be either a national stage application submitted under 35 U.S.C. 371 or a national application filed under 35 U.S.C. 111(a).

NATIONAL APPLICATIONS SUBMITTED UNDER 35 U.S.C. 371

These applications are the result of an international application filed under the PCT entering the national stage in the United States. They are called national stage applications. The national stage application papers are placed in a domestic application file wrapper and the phrase "FILED UNDER 35 U.S.C. 371" is stamped on the front of the file wrapper. In addition, a "Notification of Acceptance of Application under 35 U.S.C. 371 and 37 CFR 1.494 or 1.495" (Form PCT/DO/EO/903) is placed in the file.

A typical time line involving an international and a national stage application is illustrated as follows:



Although the illustrated time line is typical, there is no requirement that there be a priority application, nor is there any requirement that the national stage application be submitted after the international application is published.

National stage applications submitted under 35 U.S.C. 371 are treated differently in certain respects than national applications filed under 35 U.S.C. 111(a). Treatment of 35 U.S.C. 371 applications differs from treatment of 35 U.S.C. 111(a) applications as follows:

A. Filing Date As Applicant's Date Of Invention

By virtue of 35 U.S.C. 363, the U.S. filing date of a national stage application is the international filing

date (the filing date of the international application) for the purpose of determining whether information is prior art (i.e., has an effective date) relative to the invention claimed in the national stage application. The date which appears in the "filing date" box on the front of the file wrapper of a national stage application, however, is the date on which the requirements of 35 U.S.C. 371(c) were complied with, and typically is not the same as the international filing date of the application. The international filing date is the critical date for determining whether or not a particular reference is available as prior art against the application. The international filing date will appear next to the international application number in the CONTINUING DATA section on the file wrapper label and in the "Notification of Acceptance of Application under 35 U.S.C. 371 and 37 CFR 1.494 or 1.495" (Form PCT/DO/EO/903).

B. 35 U.S.C. 119(a) And 365(b) Priority In National Stage Application

The filing date of a national stage application is the international filing date. Pursuant to 35 U.S.C. 365(b), a priority claim under 35 U.S.C. 119(a) is proper if (a) a claim for priority was made in the international application, and (b) the application was filed within 12 months prior to the international filing date. See MPEP § 1893.03(c). The examiner should acknowledge the priority claim and priority document in the next Office action and on the file wrapper as in any 35 U.S.C. 119(a) situation, if appropriate.

C. Priority Document

In national stage applications, a photocopy of the foreign priority document is received from the International Bureau and placed in the national stage application file. This copy of the foreign priority document is sufficient to establish that applicant has filed a certified copy of the priority document. The copy received from the International Bureau bears a "WIPO" stamp. If a copy of the foreign priority document is not in the national stage application file, the examiner should consult with a Special Program Examiner in his or her Technology Center. A certified copy of a priority document filed as a U.S. provisional application in the U.S. national stage application because 37 CFR 1.55(a)(2) does not apply to priority claims under 35 U.S.C. 111(b) is not required in the

U.S. national stage application because 37 CFR 1.55(a)(2) does not apply to priority claims under 35 U.S.C. 119(e).

D. Unity Of Invention

Restriction practice in both international and national stage applications is determined under unity of invention principles as set forth in 37 CFR 1.475 and 1.499. Restriction practice under 35 U.S.C. 121, as it applies to national applications submitted under 35 U.S.C. 111(a), is not applicable to either international or national stage applications. However, a continuing application claiming benefit under 35 U.S.C. 365(c) to an international application or to a national stage application is not a national stage application and, therefore, the restriction practice under 35 U.S.C. 121 is applicable.

E. Filing Date For Prior Art Purposes Under 35 U.S.C. 102(e)

1. When Examining Applications Filed Prior to November 29, 2000 Which Were Not Voluntarily Published Under 35 U.S.C. 122(b)

Once a patent issues from a national stage application, the filing date for prior art purposes under 35 U.S.C. 102(e), when being cited against an application filed prior to November 29, 2000, which has not been voluntarily published under 35 U.S.C. 122(b), is not the international filing date, but is the date on which the requirements of 35 U.S.C.

371(c)(1), (2) and (4) were met (copy of the international application with any necessary translation, national fee and oath or declaration were filed). However, as the international application is usually published approximately 18 months from the priority date, this publication generally will have an earlier date for prior art purposes than the 35 U.S.C. 102(e) date of the U.S. patent. A copy of the published international application can be obtained through the Foreign Patents Branch of the Scientific and Technical Information Center (STIC). The publication number and publication date appear on the first page of the U.S. patent.

Note that a publication under 35 U.S.C. 122(b) of a U.S. national stage application will have no prior art effect under 35 U.S.C. 102(e) against an application

filed before November 29, 2000, which has not been voluntarily published under 35 U.S.C. 122(b).

2. When Examining Applications Filed on or After November 29, 2000, or Applications Filed Before November 29, 2000 Which Were Voluntarily Published Under 35 U.S.C. 122 (b)

The publication of a U.S. national stage application will have a 35 U.S.C. 102(e) date for prior art purposes as of its international filing date, provided that the application was published under PCT Article 21(2)(a) in the English language, against an application filed on or after November 29, 2000, or filed before November 29, 2000 and voluntarily published under 35 U.S.C. 122(b).

Note that any publication under 35 U.S.C. 122(b) of a U.S. national stage application which was published in the international stage under PCT Article 21(2)(a) in a language other than English or any United States Patent issuing from any national stage application will have no prior art effect under 35 U.S.C. 102(e)(1) or (2) against an application filed on or after November 29, 2000, or filed before November 29, 2000 and voluntarily published under 35 U.S.C. 122(b).

F. International Publication Number And The Publication Date

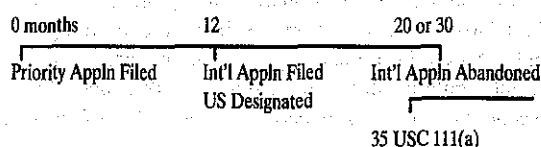
The International Publication Number and the Publication Date **MUST** be in the national stage application if the application is allowed. The International Publication Number and the Publication date can be found in the DO/US Worksheet WIPO Publication block. If the Publication Number and the Publication date are not found on the worksheet or if the worksheet is missing, the information may be taken either from the International Publication or the PCT Gazette page. The examiner should ensure that the International Publication Number and the Publication date are in one of these three locations before the application is sent to Office of Patent Publication.

CONTINUATION, CIP, OR DIVISION OF INTERNATIONAL APPLICATION FILED UNDER 35 U.S.C. 111(a)

Rather than filing a national stage application, a continuing application (i.e., continuation, C-I-P, or

division) under 35 U.S.C. 111(a) of the international application may be filed. Pursuant to 35 U.S.C. 365(c), a regular national application filed under 35 U.S.C. 111(a) and 37 CFR 1.53(b) (not under 37 CFR 1.53(d) or former 37 CFR 1.60 or 1.62) may claim benefit of the filing date of an international application which designates the United States.

A typical time line involving a continuing application filed during the pendency of an international application is illustrated as follows:



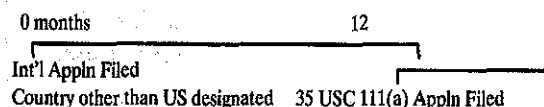
The continuing application must be filed before the international application becomes abandoned as to the U.S. as set forth in 37 CFR 1.494 and 1.495. An appropriate sentence (such as "This is a continuation of International Application PCT/EP90/00000, with an international filing date of January 4, 1990, published in English under PCT Article 21(2) and now abandoned.") must appear in the first sentence of the specification. In addition, all other conditions of 35 U.S.C. 120 (such as having at least one common inventor) must be satisfied. A copy of the international application (and an English translation) may be required by the examiner to perfect the claim for benefit under 35 U.S.C. 120 and 365(c) if necessary, for example, where an intervening reference is found and applied in a rejection of one or more claims.

A claim for foreign priority under 35 U.S.C. 119(a)-(d) must be made in the continuing application in the same manner as a claim for foreign priority under 35 U.S.C. 365(b) in a national stage application. In the same manner as with a national stage application, a foreign priority claim is proper if (1) a claim for foreign priority was made in the international application, and (2) the foreign application was filed within 12 months prior to the international filing date. A certified copy of any foreign priority document must be provided by the applicant if the parent international application has not entered the national stage under 35 U.S.C. 371 (the photocopy received

from the International Bureau cannot be used). If the parent international application has entered the national stage under 35 U.S.C. 371, the applicant, in the continuing application, may state that the priority document is contained in the national stage application.

35 U.S.C. 119(a)-(d) AND 365(a) PRIORITY CLAIM TO INTERNATIONAL APPLICATION IN 35 U.S.C. 111(a) NATIONAL APPLICATION

An application filed under 35 U.S.C. 111(a) may make a claim for foreign priority under 35 U.S.C. 119(a)-(d) and 365(a) to an international application which designates at least one country other than the United States (the U.S. may also be designated). In this situation, applicant must file a certified copy of the international application in the application filed under 35 U.S.C. 111(a) and the applicant must satisfy all other requirements of 35 U.S.C. 119(a)-(d). A typical time line for this situation is illustrated as follows:



The examiner should acknowledge the priority claim and priority document in the next Office action and on the file wrapper as in any 35 U.S.C. 119(a)-(d) situation, if appropriate.

1896 The Differences Between a National Application Filed Under 35 U.S.C. 111(a) and a National Stage Application Filed Under 35 U.S.C. 371

The following section describes the differences between a U.S. national application filed under 35 U.S.C. 111(a), including those claiming benefit of a PCT application under 35 U.S.C. 120 (a **continuation** or a **continuation-in-part** of a PCT application), and a U.S. **national stage application** (filed under 35 U.S.C. 371).

<i>Chart of Some Common Differences</i>		
	National Applications (filed under 35 U.S.C. 111(a))	National Stage Applications (filed under 35 U.S.C. 371)
Filing Date	Deposit date in USPTO of specification, claim and any necessary drawing	International filing date of PCT application
35 U.S.C. 119(a)-(d) Priority Requirement	Claim & certified copy provided by applicant	Copy of certified copy provided by WIPO, claim by applicant
Unity of Invention	U.S. restriction practice	Unity of invention practice under 37 CFR 1.499
Filing Fees	37 CFR 1.16	37 CFR 1.492
Reference to Application in Declaration	Attached application, U.S. Application No., etc.	Same as in a 35 U.S.C. 111(a) filing or may refer to the international application
Copendency with International Application	Applicant provides proof	Not an issue

The differences between a national application filed under 35 U.S.C. 111(a) and a national stage application filed under 35 U.S.C. 371 are often subtle, but the differences are important.

FILING DATE

The filing date of a 35 U.S.C. 111(a) application is the date when the USPTO receives a specification, claim, and any drawings. See 37 CFR 1.53(b).

The filing date of a PCT international application is the date applicant satisfies Article 11 requirements, i.e., includes a specification, claim, U.S. residency or nationality, prescribed language, designation of a contracting state, and names of the applicant.

In this regard, note that 35 U.S.C. 363 provides that,

An international application designating the United States shall have the effect, from its international filing date under Article 11 of the treaty, of a national application for patent regularly filed in the Patent and Trademark Office except as otherwise provided in section 102(e) of this title.

Similarly, PCT Article 11(3) provides:

(3) Subject to Article 64(4), any international application fulfilling the requirement listed in items (i) to (iii) of paragraph (1) and accorded an international filing date shall have the effect of a regular national application in each designated State as of the international filing date, which date shall be considered to be the actual filing date in each designated State.

PCT Article 64(4), in turn, provides:

(4)(a) Any State whose national law provides for prior art effect of its patents as from a date before publication, but does not equate for prior art purposes the priority date claimed under the Paris Convention for the Protection of Industrial Property to the actual filing date in that State, may declare that the filing outside that State of an international application designating that State is not equated to an actual filing in that State for prior art purposes.

(b) Any State making a declaration under subparagraph (a) shall to that extent not be bound by the provisions of Article 11(3).

(c) Any State making a declaration under subparagraph (a) shall, at the same time, state in writing the date from which, and the conditions under which, the prior art effect of any international application designating that State becomes effective in that State. This statement may be modified at any time by notification addressed to the Director General.

Accordingly, under PCT Article 64(4), the United States is free to have laws that, for prior art purposes, do not treat the filing of an international application designating the United States as equal to an actual filing in the United States. Additionally, under PCT Article 64(4)(c), the United States may modify the

date from which, and the conditions under which, the prior art effect of any international application designating the United States becomes effective in the United States.

EFFECTIVE DATE AS A REFERENCE

Publications Under 35 U.S.C. 122(b) as References

When examining an application filed before November 29, 2000, which has not been voluntarily published under 35 U.S.C. 122(b), publications under 35 U.S.C. 122(b) of 35 U.S.C. 111(a) applications and national stage applications are never effective as references as they are only available as references as of their publication date which can only be after November 29, 2000.

When examining an application filed on or after November 29, 2000, or filed before November 29, 2000 and voluntarily published under 35 U.S.C. 122(b), a publication under 35 U.S.C. 122(b) of a 35 U.S.C. 111(a) application will have an effective date as a reference under 35 U.S.C. 102(e) as of its earliest effective filing date, excluding any international filing dates except when the international application to which benefit is being claimed was published under PCT Article 21(2)(a) in English. In such a situation the effective date as a reference of the publication of the 35 U.S.C. 111(a) application will be its earliest effective filing date, including the international filing date. A publication under 35 U.S.C. 122(b) of a national stage application, when being cited against an application filed on or after November 29, 2000, or filed before November 29, 2000 and voluntarily published under 35 U.S.C. 122(b), will be effective as a reference under 35 U.S.C. 102(e)(1) as of its international filing date only if it was published in the international stage under PCT Article 21(2)(a) in English. Otherwise, such a publication of a national stage application is effective as a reference only as of its publication date under 35 U.S.C. 102(a) or (b), where appropriate.

U.S. Patents as References

Regardless of when the application being examined was filed, the effective date as a reference of a patent which has issued from a 35 U.S.C. 111(a) application is always its earliest effective filing date, excluding any international filing dates. In contrast the effective

date as a reference of a U.S. patent which has issued from a national stage application will differ based on the application being examined. When examining an application filed before November 29, 2000, which has not been voluntarily published under 35 U.S.C. 122(b), a U.S. patent issuing from a national stage application will be effective as a reference as of the date the national stage application satisfied the requirements of 35 U.S.C. 371(c)(1), (2), and (4) (copy of the international application with any necessary translation, national fee and oath or declaration were filed). However, when examining an application filed on or after November 29, 2000 or filed before November 29, 2000 and voluntarily published under 35 U.S.C. 122(b), a U.S. patent issuing from a national stage application will only be effective as a reference under 35 U.S.C. 102(a) or (b), where appropriate, as of the date on which it issued as a U.S. patent.

35 U.S.C. 119(a)-(d) PRIORITY REQUIREMENTS

The certified copy of the foreign priority application must be provided to the Office by applicant in a U.S. national application filed under 35 U.S.C. 111(a). Where applicant filed an international application claiming priority to an earlier filed national application, the certified copy of the priority application is required to be provided to the International Bureau by applicant during the international stage. The International Bureau (WIPO) then sends a copy of the certified copy of the priority application to each designated office for inclusion in the national stage application. A U.S. national stage application filed under 35 U.S.C. 371 will have a photocopy of the priority document with the first page stamped by the International Bureau to indicate that it is a priority document received by WIPO and the date of such receipt. Such a photocopy is acceptable in a U.S. national stage application to establish that applicant has filed a certified copy of the priority document. If the photocopy is missing from the national stage application file, either the document has been misplaced or it was not provided due to a defect in priority during the international stage. If the priority claim was not in accordance with PCT Rule 4.10 or the priority document was not provided in accordance with PCT Rule 17, the photocopy of the priority document

will not have been provided by the International Bureau.

UNITY OF INVENTION

U.S. national applications filed under 35 U.S.C. 111(a) are subject to restriction practice in accordance with 37 CFR 1.141-1.146. See MPEP § 803. U.S. national stage applications filed under 35 U.S.C. 371 are subject to unity of invention practice in accordance with 37 CFR 1.475 and 1.499 (effective May 1, 1993).

FILING FEES

U.S. national applications filed under 35 U.S.C. 111(a) are subject to the national application filing fees set forth at 37 CFR 1.16. U.S. national stage applications filed under 35 U.S.C. 371 are subject to the national stage fees prescribed at 37 CFR 1.492.

REFERENCE TO APPLICATION IN DECLARATION

Applicant's oath or declaration is required to identify the specification to which it is directed (37 CFR 1.63(b)(1)). The specification may be identified in a U.S. national application filed under 35 U.S.C. 111(a) by reference to an attached specification or by reference to the application number and filing date of a specification previously filed in the Office. MPEP § 601.01(a) gives the minimum requirements for identification of the specification. U.S. national stage applications filed under 35 U.S.C. 371 may identify the specification (in the oath or declaration) in the same manner as applications filed under 35 U.S.C. 111(a) or may identify the specification by reference to the application number and filing date of the international application.



Chapter 1900 Protest

1901 Protest Under 37 CFR 1.291

- 1901.01 Who Can Protest
- 1901.02 Information Which Can Be Relied on in Protest
- 1901.03 How Protest Is Submitted
- 1901.04 When Should the Protest Be Submitted
- 1901.05 Initial Office Handling and Acknowledgment of Protest
- 1901.06 Examiner Treatment of Protest
- 1901.07 Protestor Participation
- 1901.07(a) Filing of Multiple Papers Relating to Same Issues

1906 Supervisory Review of an Examiner's Decision Adverse to Protestor

1907 Unauthorized Participation by Protestor

1920 Citation of Prior Art Under 37 CFR 1.501(a)

1901 Protest Under 37 CFR 1.291

37 CFR 1.291. Protests by the public against pending applications.

(a) Protests by a member of the public against pending applications will be referred to the examiner having charge of the subject matter involved. A protest specifically identifying the application to which the protest is directed will be entered in the application file if:

(1) The protest is submitted prior to the date the application was published or the mailing of a notice of allowance under § 1.311, whichever occurs first; and

(2) The protest is either served upon the applicant in accordance with § 1.248, or filed with the Office in duplicate in the event service is not possible.

(b) Protests raising fraud or other inequitable conduct issues will be entered in the application file, generally without comment on those issues. Protests which do not adequately identify a pending patent application will be returned to the protestor and will not be further considered by the Office. A protest submitted in accordance with the second sentence of paragraph (a) of this section will be considered by the Office if the application is still pending when the protest and application file are brought before the examiner and it includes:

(1) A listing of the patents, publications, or other information relied upon;

(2) A concise explanation of the relevance of each listed item;

(3) A copy of each listed patent or publication or other item of information in written form or at least the pertinent portions thereof; and

(4) An English language translation of all the necessary and pertinent parts of any non-English language patent, publication, or other item of information in written form relied upon.

(c) A member of the public filing a protest in an application under paragraph (a) of this section will not receive any communications from the Office relating to the protest, other than the return

of a self-addressed postcard which the member of the public may include with the protest in order to receive an acknowledgment by the Office that the protest has been received. In the absence of a request by the Office, an applicant has no duty to, and need not, reply to a protest. The limited involvement of the member of the public filing a protest pursuant to paragraph (a) of this section ends with the filing of the protest, and no further submission on behalf of the protestor will be considered, except for additional prior art, or unless such submission raises new issues which could not have been earlier presented.

37 CFR 1.248. Service of papers; manner of service; proof of service; proof of service in cases other than interferences.

(a) Service of papers must be on the attorney or agent of the party if there be such or on the party if there is no attorney or agent, and may be made in any of the following ways:

(1) By delivering a copy of the paper to the person served;

(2) By leaving a copy at the usual place of business of the person served with someone in his employment;

(3) When the person served has no usual place of business, by leaving a copy at the person's residence, with some person of suitable age and discretion who resides there;

(4) Transmission by first class mail. When service is by mail the date of mailing will be regarded as the date of service;

(5) Whenever it shall be satisfactorily shown to the Commissioner that none of the above modes of obtaining or serving the paper is practicable, service may be by notice published in the *Official Gazette*.

(b) Papers filed in the Patent and Trademark Office which are required to be served shall contain proof of service. Proof of service may appear on or be affixed to papers filed. Proof of service shall include the date and manner of service. In the case of personal service, proof of service shall also include the name of any person served, certified by the person who made service. Proof of service may be made by:

(1) An acknowledgement of service by or on behalf of the person served or

(2) A statement signed by the attorney or agent containing the information required by this section.

(c) See § 1.646 for service of papers in interferences.

The degree of participation allowed a protestor is solely within the discretion of the Commissioner of Patents and Trademarks.

37 CFR 1.291(a) gives recognition to the value of written protests in bringing information to the attention of the Office and in avoiding the issuance of invalid patents. All protests must be submitted prior to the publication of the application or the mailing of a notice of allowance, whichever occurs first, because no protest or other form of preissuance opposition to the grant of a patent may be initiated after publication of the application without the applicant's express

written consent as specified by 35 U.S.C. 122(c). 37 CFR 1.291(a) provides that public protests against pending applications will be referred to the examiner having charge of the subject matter involved and will be entered in the application file if the protest is submitted prior to the date the application was published or the mailing of a notice of allowance under 37 CFR 1.311, whichever occurs first, and the protest is either served upon the applicant or filed in duplicate in the event service is not possible. Paragraph (b) of 37 CFR 1.291 assures members of the public that a protest will be fully considered by the Office if the protest is submitted in accordance with 37 CFR 1.291(a), the application is still pending when the protest and application file are brought before the examiner, and the protest includes:

(A) a listing of the patents, publications, or other information relied on;

(B) a concise explanation of the relevance of each listed item;

(C) a copy of each listed patent, publication, or other item of information in written form, or at least the pertinent portions thereof; and

(D) an English language translation of all necessary and pertinent parts of any non-English language document relied on.

A party obtaining knowledge of an application pending in the Office may file a protest against the application and may therein call attention to any facts within protestor's knowledge which, in protestor's opinion, would make the grant of a patent thereon improper.

A protestor does not, however, by the mere filing of a protest, obtain the "right" to argue the protest before the Office. Active participation by a protestor "ends with the filing of the protest, and no further submission on behalf of the protestor will be considered, except for additional prior art, or unless such submission raises new issues which could not have been earlier presented." 37 CFR 1.291(c). The USPTO will acknowledge the receipt of a protest in an original or a reissue application file only if a self-addressed postcard is included with the protest (see MPEP § 1901.05). The question of whether or not a patent will issue is a matter between the applicant and the Office acting on behalf of the public.

1901.01 Who Can Protest

Any member of the public, including private persons, corporate entities, and government agencies, may file a protest under 37 CFR 1.291. A protest may be filed by an attorney or other representative on behalf of an unnamed principal since 37 CFR 1.291 does not require that the principal be identified.

1901.02 Information Which Can Be Relied on in Protest

Any information which, in the protestor's opinion, would make the grant of a patent improper can be relied on in a protest under 37 CFR 1.291(a). While prior art documents, such as patents and publications, are most often the types of information relied on in protests, 37 CFR 1.291(a) is not limited to prior art documents. Protests may be based on any facts or information adverse to patentability. The content and substance of the protest are more important than whether prior art documents, or some other form of evidence adverse to patentability, are being relied on. The Office recognizes that when evidence other than prior art documents is relied on, problems may arise as to authentication and the probative value to assign to such evidence. However, the fact that such problems may arise, and have to be resolved, does not preclude the Office from considering such evidence, nor does it mean that such evidence cannot be relied on in a protest under 37 CFR 1.291. Information in a protest should be set forth in the manner required by 37 CFR 1.291(b).

The following are examples of the kinds of information, in addition to prior art documents, which can be relied on in a protest under 37 CFR 1.291(a):

(A) Information demonstrating that the invention was publicly "known or used by others in this country... before the invention thereof by the applicant for patent" and is therefore barred under 35 U.S.C. 102(a) and/or 103.

(B) Information that the invention was "in public use or on sale in this country, more than 1 year prior to the date of the application for patent in the United States" (35 U.S.C. 102(b)).

(C) Information that the applicant "has abandoned the invention" (35 U.S.C. 102(c)) or "did not himself invent the subject matter sought to be patented" (35 U.S.C. 102(f)).

(D) Information relating to inventorship under 35 U.S.C. 102(g).

(E) Information relating to sufficiency of disclosure or failure to disclose best mode, under 35 U.S.C. 112.

(F) Any other information demonstrating that the application lacks compliance with the statutory requirements for patentability.

(G) Information indicating "fraud" or "violation of the duty of disclosure" under 37 CFR 1.56 may be the subject of a protest under 37 CFR 1.291(a). Protests raising fraud or other inequitable conduct issues will be entered in the application file, generally without comment on those issues. 37 CFR 1.291(b).

Different forms of evidence may accompany, or be submitted as a part of, a protest under 37 CFR 1.291(a). Conventional prior art documents such as patents and publications are the most common form of evidence. However, other forms of evidence can likewise be submitted. Some representative examples of other forms of evidence are litigation-related materials such as complaints, answers, depositions, answers to interrogatories, exhibits, transcripts of hearings or trials, court orders and opinions, stipulations of the parties, etc. Where only a portion of the litigation-related materials is relevant to the protest, protestors are encouraged to submit only the relevant portion(s).

In a protest based on an alleged public use or sale by, or on behalf of, the applicant or applicant's assignee, evidence of such public use or sale may be submitted along with affidavits or declarations identifying the source(s) of the evidence and explaining its relevance and meaning. Such evidence might include documents containing offers for sale by applicant or applicant's assignee, orders, invoices, receipts, delivery schedules, etc. The Office will make a decision as to whether or not public use or sale has been established based on the evidence the Office has available. If applicant denies the authenticity of the documents and/or evidence, or if the alleged public use and/or sale is by a party other than applicant or applicant's assignee, protestor may find it desirable or necessary to proceed via 37 CFR 1.292 (public use proceedings) rather than by a protest under 37 CFR 1.291.

While the forms in which evidence and/or information may be submitted with, or as a part of, a protest under 37 CFR 1.291(a) are not limited, protestors

must recognize that such submissions may encounter problems such as establishing authenticity and/or the probative value to apply to the evidence. Obviously, the Office will have to evaluate each item of evidence and/or information submitted with a view as to both its authenticity and what weight to give thereto.

Information which is subject to a court-imposed protective or secrecy order may be submitted with, or as a part of, a protest under 37 CFR 1.291(a). Trade secret information which was obtained by a protestor through agreements with others can likewise be submitted. Such information, if submitted, will be treated in accordance with the guidelines set forth in MPEP § 724 and will be made public if a reasonable examiner would consider the information important in deciding whether to allow the application to issue as a patent.

1901.03 How Protest Is Submitted

A protest under 37 CFR 1.291(a) must be submitted in writing, must specifically identify the application to which the protest is directed by application number or serial number and filing date, and must include a listing of all patents, publications, or other information relied on; a concise explanation of the relevance of each listed item; an English language translation of all relevant parts of any non-English language document; and be accompanied by a copy of each patent, publication, or other document relied on. Protestors are encouraged to use form PTO-1449 "Information Disclosure Statement" (or an equivalent form) when preparing a protest under 37 CFR 1.291, especially the listing enumerated under 37 CFR 1.291(b)(1). See MPEP § 609. In addition, the protest and any accompanying papers must either (1) reflect that a copy of the same has been served upon the applicant or upon the applicant's attorney or agent of record; or (2) be filed with the Office in duplicate in the event service is not possible.

It is important that any protest against a pending application specifically identify the application to which the protest is directed with the identification being as complete as possible. If possible, the following information should be placed on the protest:

(A) Name of Applicant(s).

(B) Application number (mandatory).

(C) Filing date of application.

(D) Title of invention.

- (E) Group art unit number (if known).
- (F) Name of examiner to whom the application is assigned (if known).
- (G) Current status and location of application (if known).
- (H) The word "ATTENTION:" followed by the area of the Office to which the protest is directed as set forth below.

In addition to the above information, the protest itself should be clearly identified as a "PROTEST UNDER 37 CFR 1.291(a)." If the protest includes exhibits or other attachments, these should also contain identifying information thereon in order to prevent them from becoming inadvertently separated and lost.

Any protest can be submitted by mail to the Assistant Commissioner for Patents, Washington, D.C. 20231, and should be directed to the attention of the Director of the particular Technology Center in which the application is pending. If the protestor is unable to specifically identify the application to which the protest is directed, but, nevertheless, believes such an application to be pending, the protest should be directed to the attention of the Office of Petitions, along with as much identifying data for the application as possible. Protests which do not adequately identify a pending patent application will be returned to the protestor and will not be further considered by the Office.

Where a protest is directed to a reissue application for a patent which is involved in litigation, the outside envelope and the top right-hand portion of the protest should be marked with the words "REISSUE LITIGATION." The notations preferably should be written in a bright color with a felt point marker. Any "REISSUE LITIGATION" protest mailed to the Office should be so marked and mailed to BOX DAC. However, in view of the urgent nature of most "REISSUE LITIGATION" protests, protestor may wish to hand-carry the protest to the appropriate area in order to ensure prompt receipt and to avoid any unnecessary delays.

INITIAL PROTEST SUBMISSION MUST BE COMPLETE

A protest must be complete and contain a copy of every document relied on by protestor, whether the document is a prior art document, court litigation

material, affidavit, or declaration, etc.; because a protestor will *not* be given an opportunity to supplement or complete any protest which is incomplete. Active participation by protestor ends with the filing of the initial protest, as provided in 37 CFR 1.291(c), and no further submission on behalf of protestor will be acknowledged or considered, except for additional prior art, or unless such submission clearly raises new issues which could not have been earlier presented. Protests which will not be entered in the application file include those further submissions in violation of 37 CFR 1.291(c) by which protestor merely seeks to participate in the examination process. For example, mere arguments relating to an Office action or an applicant's reply would not qualify as a new protest. Likewise, additional comments seeking to bring in further or even new data or information with respect to an issue previously raised by protestor would not qualify as a new protest. The Office will not add these arguments or comments to the original protest and will not enter them in the application file.

Even new protests which also argue Office actions or replies or any matter beyond the new issue should not be accepted. Improper protests will be returned by the Technology Center (TC) Director. While improper protests will be returned, a new protest by an earlier protestor will be proper and can be entered if it is clearly limited to new issues which could not have been earlier presented, and thereby constitutes a new protest.

As indicated in 37 CFR 1.291(b)(3), a protest must be accompanied by a copy of each prior art document relied on in order to ensure consideration by the examiner, although a protest without copies of prior art documents will not necessarily be ignored. While a protest without copies of documents will not necessarily be ignored, the submission of such documents with the protest will obviously expedite and ensure consideration of the documents, which consideration might not otherwise occur. Further, some documents which are available to protestor may not be otherwise available to the Office.

Every effort should be made by a protestor to serve a copy of the protest upon the attorney or agent of record or upon the applicant if no attorney or agent is of record. Of course, the copy served upon applicant or upon applicant's attorney or agent should be a complete copy including a copy of each prior art or other

document relied on in the same manner as required by 37 CFR 1.291(a) for the Office copy. The protest filed in the Office should reflect, by an appropriate "Certificate of Service," that service has been made as provided in 37 CFR 1.291(a). Only in those instances where service is not possible should the protest be filed in duplicate in order that the Office can attempt service.

1901.04 When Should the Protest Be Submitted

A protest under 37 CFR 1.291(a) must be submitted prior to the date the application was published or the mailing of a notice of allowance under 37 CFR 1.311, whichever occurs first, and the application must be pending when the protest and application file are brought before the examiner in order to be ensured of consideration. As a practical matter, any protest should be submitted as soon as possible after the protestor becomes aware of the existence of the application to which the protest is to be directed. By submitting a protest early in the examination process, i.e., before the Office acts on the application if possible, the protestor ensures that the protest will receive maximum consideration and will be of the most benefit to the Office in its examination of the application. A protest submitted after the mailing of the notice of allowance will not knowingly be ignored if the protest includes prior art documents which clearly anticipate or clearly render obvious one or more claims. However, the likelihood of consideration of a protest decreases as the patent date approaches.

A protest filed after final rejection and complying with 37 CFR 1.291(a) will be considered if the application is still pending when the protest and application are provided to the examiner. However, prosecution will not ordinarily be reopened after final rejection if the prior art cited in the protest is merely cumulative of the prior art cited in the final rejection. If a protest is not submitted within the time period set forth in 37 CFR 1.291(a)(1) it will be acknowledged as set forth in MPEP § 1901.05 only if a self-addressed postcard is included with the protest, and referred to the examiner having charge of the subject matter involved for handling as set forth in MPEP § 1901.06.

A protest with regard to a reissue application should be filed within the 2-month period following

announcement of the filing of the reissue application in the *Official Gazette*. If, for some reason, the protest of the reissue application cannot be filed within the 2-month period provided by MPEP § 1441, the protest can be submitted at a later time, but the protestor must be aware that reissue applications are "special" and a later filed protest may be received after action by the examiner. Any request by a protestor in a reissue application for an extension of the 2-month period following the announcement in the *Official Gazette* will be considered only if filed in the form of a petition under 37 CFR 1.182 and accompanied by the petition fee set forth in 37 CFR 1.17(h). The petition under 37 CFR 1.182 and the petition fee must be filed prior to the expiration of the 2-month period provided by MPEP § 1441. The petition must explain why the additional time is necessary and the nature of the protest intended. A copy of such petition must be served upon applicant in accordance with 37 CFR 1.248. The petition should be directed to the appropriate Technology Center (TC) which will forward the petition to the Office of Petitions for decision. Any such petition will be critically reviewed as to demonstrated need before being granted since the delay of examination of a reissue application of another party is being requested. Accordingly, the requests should be made only where necessary, for the minimum period required, and with a justification establishing the necessity for the extension.

If the protest is a "REISSUE LITIGATION" protest, it is particularly important that it be filed early if protestor wishes it considered at the time the Office first acts on the application. Protestors should be aware that the Office will entertain petitions under 37 CFR 1.182, when accompanied by the petition fee set forth in 37 CFR 1.17(h), to waive the 2-month delay period of MPEP § 1441 in appropriate circumstances. Accordingly, protestors to reissue applications cannot automatically assume that the full 2-month delay period of MPEP § 1441 will always be available.

If a protest is filed in a reissue application related to a patent involved in a pending interference proceeding, the reissue application should be referred to the Office of the Deputy Commissioner for Patent Examination Policy before the protest is considered and the application is acted on by the TC. See also MPEP § 1441 as to the filing of a protest in a reissue application.

1901.05 Initial Office Handling and Acknowledgment of Protest

PROTESTS REFERRED TO EXAMINER

Protests filed against pending applications will be referred to the examiner having charge of the application involved. 37 CFR 1.291(a). A protest specifically identifying the application to which it is directed will be entered in the application file, if (1) the protest is submitted prior to the publication of the application or the mailing of a notice of allowance under 37 CFR 1.311, whichever occurs first, (see MPEP § 1901.04) and (2) a copy has been served on applicant in accordance with 37 CFR 1.248, or a duplicate copy is filed with the Office in the event service is not possible. 37 CFR 1.291(a).

A protest where the application is specifically identified, which is submitted in conformance with 37 CFR 1.291(a) and (b), will be considered by the Office.

PROTEST DOES NOT INDICATE SERVICE

If the protest filed in the Office does not, however, indicate service on applicant or applicant's attorney or agent, and is not filed in duplicate, then the Office will undertake to determine whether or not service has been made by contacting applicant or applicant's attorney or agent by telephone or in writing to ascertain if service has been made. If service has not been made and no duplicate has been filed, then the Office may request protestor to file such a duplicate before the protest is referred to the examiner. Alternatively, if the protest involves only a few pages, the Office may, in its sole discretion, elect to reproduce the protest rather than delay referring it to the examiner. If duplicate protest papers are mailed to applicant or applicant's attorney or agent by the Office, the application file should reflect that fact, either by a letter transmitting the protest or, if no transmittal letter is used, simply by an appropriate notation in the "Contents" section of the application file wrapper.

ACKNOWLEDGMENT OF PROTEST

A protestor in an original or reissue application will not receive any communications from the Office relat-

ing to the protest, or to the application, other than the return of a self-addressed postcard which protestor may include with the protest in order to receive an acknowledgment that the protest has been received by the Office. 37 CFR 1.291(c). The Office will acknowledge a protest by return of the self-addressed postcard prior to the protest's entry into the application file or return to the protestor, as appropriate.

APPLICATIONS AND STATUS THEREOF MAINTAINED IN CONFIDENCE

The postcard acknowledging receipt of a protest in other than a reissue application will not and must not indicate whether such application in fact exists or the status of any such application. Office employees must exercise care to ensure that matters relating to applications are *not* discussed with protestor or communicated in writing to protestor. Original applications are, of course, required by 35 U.S.C. 122 to be kept in confidence unless published pursuant to 35 U.S.C. 122(b). Thus, unless a protestor has been granted access to an original application, the protestor is not entitled to obtain from the Office any information concerning the same, including the mere fact that such an application exists. Petitions for access to patent applications with the exception of applications involved in or related to a proceeding before the Board of Patent Appeals or Interferences are decided by the Office of Petitions pursuant to delegation contained in MPEP § 1002.02(b). Reissue applications filed on, or after, March 1, 1977 are pursuant to 37 CFR 1.11(b) "open to inspection by the general public." After an application is published pursuant to 35 U.S.C. 122(b), a copy of the file wrapper of the published application may be requested by filing a written request under 37 CFR 1.14(c)(2) including the fee as set forth in 37 CFR 1.19(b)(2).

The Office will communicate with the applicant regarding any protest entered in an application file and may require the applicant to supply information pursuant to 37 CFR 1.291(c), including replies to specific questions raised by the protest, in order for the Office to decide any issues raised thereby. Under 37 CFR 1.291(c), the examiner can require the applicant to reply to the protest and answer specific questions raised by the protest.

1901.06 Examiner Treatment of Protest

Office practice as defined in 37 CFR 1.291(a) gives recognition to the value of the written protests in avoiding the issuance of invalid patents. However, the fact that one or more protests has been filed in an application, whether the application is an original application or a reissue application, does not relieve the examiner from conducting a *normal* examination on the merits, including the required search. Evidence submitted in a protest will be considered on the same basis as other *ex parte* evidence. *In re Reuter*, 651 F.2d 751, 758, 210 USPQ 249, 255 (CCPA 1981).

INITIAL REVIEW

An examiner initially receiving a protest will immediately review the same for the following:

(A) To ensure that either the protest or the application file wrapper indicates that a copy of the protest has been served on applicant or applicant's attorney or agent. If a copy is not indicated as having been served on applicant or applicant's attorney and is not filed in duplicate, then the examiner should undertake to determine whether or not service has been made by contacting applicant or applicant's attorney or agent, but *not* protestor. If it has, this should be noted on the protest or on the application file. If service has not been made, the protest and application file should be brought to the attention of the TC Director for appropriate action. See MPEP § 1901.05.

(B) A protest raising issues of "fraud," "inequitable conduct," or "violation of duty of disclosure" will be entered in the application file, generally without comments on those issues.

If a protest is filed in a reissue application and the reissue application is related to a patent involved in a pending interference proceeding, such application should be referred to the Office of Patent Legal Administration before considering the protest and acting on the applications.

PERIOD FOR COMMENTS BY APPLICANT

If the primary examiner's initial review reveals that the protest is ready for consideration during the examination, the examiner may nevertheless consider it desirable, or necessary, to obtain applicant's comments on the protest before further action. In such sit-

uations, the examiner will offer applicant an opportunity to file comments within a set period, usually 1 month, unless circumstances warrant a longer period.

Form Paragraph 19.01 can be used to offer applicant an opportunity to file comments on the protest.

¶ 19.01 Period for Comments on Protest by Applicant

A protest against issuance of a patent based upon this application has been filed under 37 CFR 1.291(a) on [1], and a copy [2]. Any comments or reply applicant desires to file before consideration of the protest must be filed by [3].

Examiner Note:

1. Applicant is normally given one month to submit any comments, unless circumstances in the case would warrant a longer period.
2. A copy of this Office action is NOT sent to the protestor. See 37 CFR 1.291(c).
3. In bracket 2, insert either-- has been served on applicant-- or-- is attached hereto--.

Where necessary or desirable to decide questions raised by the protest, under 37 CFR 1.291(c) the primary examiner can require the applicant to reply to the protest and answer specific questions raised by the protest. The primary examiner cannot require a reply to questions relating to "fraud," "inequitable conduct," or "violation of the duty of disclosure" since those issues are generally not commented on by the Office. Any questions directed to applicant by the primary examiner must be limited to seeking answers reasonably necessary in order for the primary examiner to decide questions raised by the protest and which are before the primary examiner for decision. The primary examiner is not permitted, under 37 CFR 1.291(c), to seek answers to questions which are not before the primary examiner for decision. The primary examiner must use care in requiring information from applicant pursuant to 37 CFR 1.291(c) to ensure that the required information is necessary to the decision to be made.

Form Paragraph 19.02 can be used to require additional information from applicant regarding issues raised by the protest.

¶ 19.02 Requirement for Information

The protest under 37 CFR 1.291 filed on [1] has been considered. In order to reach a full and proper consideration of the issues raised therein, it is necessary to obtain additional information from applicant regarding these issues. In particular [2]. The failure to reply to this requirement for information within ONE MONTH or THIRTY DAYS, whichever is longer, of the mailing date of

this requirement will result in abandonment of the application. This time period may be extended under the provisions of 37 CFR 1.136.

Examiner Note:

While the examiner normally should not need further information from applicant, this form paragraph may be used to request specific additional information from the applicant.

PROTESTOR NOT PERMITTED TO COMPLETE INCOMPLETE PROTEST

A protestor may not complete an incomplete protest, nor further participate in, or inquire as to the status of, any Office proceedings relating to the initial protest. 37 CFR 1.291. The examiner must not, therefore, communicate with protestor in any way and will not consider a later submission by protestor, except for additional prior art, or unless such submission raises new issues which could not have been earlier raised and constitutes in effect a new protest (see MPEP § 1901.07). Improper protests will be returned by the TC Director.

TREATMENT OF TIMELY SUBMITTED PROTEST

If the protest has been timely submitted, i.e., before the publication of the application or the mailing of a notice of allowance under 37 CFR 1.311, whichever occurs first, and the application is still pending when the protest and application file are brought before the examiner, the examiner must consider each of the prior art or other documents submitted in conformance with 37 CFR 1.291(b). At least those prior art documents which the examiner relies on in rejecting claims will be made of record by means of form PTO-892, unless the protestor has listed such prior art or other documents on form PTO-1449 (or an acceptable substitute as provided by MPEP § 609), in which case the examiner will place the examiner's initials adjacent to the citations in the boxes provided on the form PTO-1449 (see MPEP § 609). Where the prior art or other documents have not been cited on a PTO-892, or listed and initialed on a PTO-1449, the examiner will place a notation in the protest paper adjacent to the reference to the documents. The notation should include the examiner's initials and the term "checked." The examiner will also indicate in the next

Office action that all documents submitted have been considered.

It is not intended that the examiner be overly technical in construing 37 CFR 1.291(b) and refuse consideration of a protest because it does not include all of the contents enumerated by 37 CFR 1.291(b). The examiner should consider the protest to the extent it is helpful even though one or more of the listed items is omitted.

Where prior art or other documents are considered by the examiner, even though not submitted in full conformance with 37 CFR 1.291(b), the examiner *must*, for all those documents considered but not listed on the form PTO-892, (1) mark "checked" and place the examiner's initials beside each citation, or (2) where all the documents cited on a given page have been considered, mark "All checked" and place the examiner's initials in the left-hand margin beside the citations. See MPEP § 609. Where prior art or other documents are listed by the protestor on form PTO-1449, even though not submitted in full conformance with 37 CFR 1.291(b), the examiner *must*, for all those documents considered, place the examiner's initials adjacent to the citations in the boxes provided on the form PTO-1449. Where the prior art or other documents are listed by the protestor on form PTO-1449, but are not submitted in full compliance with 37 CFR 1.291(b), the examiner *must*, for all those documents not considered, draw a line through the citation on the form PTO-1449. See MPEP § 609. If a protest entered in an application file complies with 37 CFR 1.291(b), the examiner is required to fully consider *all* the issues, except for any issues of "fraud," "inequitable conduct," or "duty of disclosure" raised by the protestor, and clearly state the examiner's position thereon in detail.

PROTEST FILED AFTER ALLOWANCE OR THE PUBLICATION OF THE APPLICATION

If the protest is submitted after the publication of the application or the mailing of a notice of allowance under 37 CFR 1.311, whichever occurs first, it should not be entered in the application file. The applicant should be notified that the protest is untimely and that it is not being entered in the application file. The handling of the protest will vary depending on the particular situation as follows.

A. *Service of Copy Included*

Where the protest includes an indication of service of copy on the applicant, the original protest should be discarded.

B. *Service of Copy Not Included*

Where the protest does not include an indication of service, the duplicate copy of the protest (if present) should be discarded and the original protest papers should be sent to the applicant along with the notification of nonentry.

COPIES OF DOCUMENTS NOT SUBMITTED

If the protest is not accompanied by a copy of each prior art or other document relied on as required by 37 CFR 1.291(b), the examiner will consider the documents submitted. The protestor cannot be assured that the examiner will consider the missing document(s). However, if the examiner does so, the examiner will either cite the document on form PTO-892 or place a notation in the protest paper adjacent to the reference to the document which will include the examiner's initials and the term "checked." If the examiner considered a document not submitted, the next Office action will so indicate.

CONSIDERATION OF PROTESTOR'S ARGUMENTS

In view of the value of written protests, the examiner must give careful consideration to the points and arguments made on behalf of the protestor. Any Office action by the examiner treating the merits of a timely submitted protest complying with 37 CFR 1.291(b) must specifically consider and make evident by detailed reasoning the examiner's position as to the major arguments and points raised by the protestor. While it is not necessary for the examiner to respond to each and every minute argument or point, the major arguments and points must be specifically covered. The examiner will not, under any circumstances, treat or discuss those arguments or points directed to "fraud," "inequitable conduct," or "violation of duty of disclosure."

RESULTS OF CONSIDERATION REPORTED TO TECHNOLOGY CENTER (TC) DIRECTOR

After the examiner has considered the protest, the examiner will report the results of such consideration to the TC Director.

1901.07 Protestor Participation

In accordance with the limited protestor participation in protests, 37 CFR 1.291(c) was amended effective July 1, 1982; and further amended on December 1, 1997, to provide that:

"limited involvement of the member of the public filing a protest . . . ends with the filing of the protest, and no further submission on behalf of the protestor will be considered, except for additional prior art, or unless such submission raises new issues which could not have been earlier presented."

37 CFR 1.291(c) was amended effective December 1, 1997, by removing the blanket limitation of one protest per protestor, and now provides for a second or subsequent submission in the form of additional prior art. However, mere argument that is later submitted by an initial protestor would not be entered and would be returned unless it is shown that the argument relates to a new issue that could not have been earlier raised. Prior art submitted by a previous protestor prior to the publication of the application or the mailing of the notice of allowance under 37 CFR 1.311, whichever occurs first, will be made of record without a showing that it relates to a new issue. However, it should be noted that entry of later submitted prior art in the file record does not assure its consideration by the examiner if submitted late in the examination process. See MPEP § 1901 and § 1901.04. Accordingly, initial protests should be as complete as possible when first filed. The mere filing of a protest does not grant access to protestor or relieve the Office of its obligations under 35 U.S.C. 122 to maintain applications "in confidence." Nor does the mere filing of a protest automatically mean that protestor will have any "right" to participate to any particular degree. 37 CFR 1.291(c) does not permit protestor, or any other member of the public, to contact or receive information from the Office as to the disposition or status of the protest, or the application to which it is directed, or to participate in any Office proceedings relating to the protest. The Office does not serve cop-

ies of Office actions or other documents mailed by the Office on protestors, and does not require applicants to serve copies of papers filed with the Office on protestors. Furthermore, a protestor is not permitted to participate in interviews, appeal a decision by the examiner adverse to the protestor to the Board of Patent Appeals and Interferences, or participate in an appeal by applicant. The disposition of the protest will, once it has been filed under paragraph (c), be an *ex parte* matter between the Office and the applicant. Where protestor has access to an application, for example, a reissue application which is open to the public and may be inspected under 37 CFR 1.11, the proceedings may thereby be monitored.

Under 37 CFR 1.291(c), applicant may be required by the Office to reply to a protest. Any reply thereto would be *ex parte* and would not be served on the protestor. The *ex parte* nature of the requirements for information under paragraph (c) differs from past practice under which information could be required, or requested, from applicant and one or more protestors.

1901.07(a) Filing of Multiple Papers Relating to Same Issues

Under 37 CFR 1.291(c), protestor participation ends with the filing of the initial protest, and protestor will not be allowed to complete any protest that is incomplete. No further submission on behalf of protestor will be considered, except for additional prior art, or unless such submission clearly raises new issues which could not have been earlier presented. Protests which will not be entered in the application file include those further submissions in violation of 37 CFR 1.291(c) by which protestor seeks to participate in the examination process. For example, mere arguments relating to an Office action or an applicant's reply would not qualify as a new issue. Likewise, additional comments seeking to bring in further or even new data or information with respect to an issue previously raised by protestor would not qualify as a new issue. Even new protests which also argue

Office actions or replies or any matter beyond the new issue should not be accepted. Improper protests will be refused consideration and returned by the Technology Center (TC) Director. While improper protests will be returned, a new protest by an earlier protestor will be proper and can be entered if it is clearly limited to new issues which could not have been earlier presented.

1906 Supervisory Review of an Examiner's Decision Adverse to Protestor

As pointed out in MPEP § 1901.07, a protestor cannot appeal to the Board of Patent Appeals and Interferences from an adverse decision of the examiner. Further, a decision by examiner adverse to a protestor is final, and under the restricted protestor participation permitted under 37 CFR 1.291(c) is not petitionable to the Commissioner.

1907 Unauthorized Participation by Protestor

Office personnel must exercise care to ensure that substantive matters relating to the application are not discussed *ex parte* with protestor or communicated in writing *ex parte* to protestor. The examiner must not communicate in any manner with protestor. See 37 CFR 1.291(c).

1920 Citation of Prior Art Under 37 CFR 1.501(a)

37 CFR 1.501(a) permits any person at any time during the period of enforceability of a patent to cite to the Office, in writing, prior art consisting of patent and printed publications which that person states to be pertinent and applicable to the patent and believes to have a bearing on the patentability of any claim(s) of the patent. See MPEP § 2202 - § 2208.



Chapter 2000 Duty of Disclosure

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2000.01 Introduction

This Chapter deals with the duties owed toward the U.S. Patent and Trademark Office by the inventor and every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor or the inventor's assignee. These duties, of candor and good faith and disclosure, have been codified in 37 CFR 1.56, as promulgated pursuant to carrying out the duties of the Commissioner under Sections 2, 3, 131, and 132 of Title 35 of the United States Code.

2001 Duty of Disclosure, Candor, and Good Faith

37 CFR 1.56. Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

37 CFR 1.56 defines the duty to disclose information to the Office.

2001.01 Who Has Duty To Disclose

37 CFR 1.56. Duty to disclose information material to patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

Individuals having a duty of disclosure are limited to those who are "substantively involved in the preparation or prosecution of the application." This is intended to make clear that the duty does not extend to typists, clerks, and similar personnel who assist with an application.

The word "with" appears before "the assignee" and "anyone to whom there is an obligation to assign" to make clear that the duty applies only to individuals, not to organizations. For instance, the duty of disclosure would not apply to a corporation or institution as such. However, it would apply to individuals within the corporation or institution who were substantively involved in the preparation or prosecution of the application, and actions by such individuals may affect the rights of the corporation or institution.

2001.03 To Whom Duty of Disclosure Is Owed

37 CFR 1.56(a) states that the "duty of candor and good faith" is owed "in dealing with the Office" and that all associated with the filing and prosecution of a patent application have a "duty to disclose to the Office" material information. This duty "in dealing with" and "to" the Office extends, of course, to all dealings which such individuals have with the Office, and is not limited to representations to or dealings with the examiner. For example, the duty would extend to proceedings before the Board of Patent Appeals and Interferences and the Office of the Assistant Commissioner for Patents.

2001.04 Information Under 37 CFR 1.56(a)

37 CFR 1.56. Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) Prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

The language of 37 CFR 1.56 (and 37 CFR 1.555) has been modified effective March 16, 1992 to emphasize that there is a duty of candor and good faith which is broader than the duty to disclose material information. 37 CFR 1.56 further states that "no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."

The Office strives to issue valid patents. The Office has both an obligation not to unjustly issue patents and an obligation not to unjustly deny patents. Innovation and technological advancement are best served when an inventor is issued a patent with the scope of protection that is deserved. The rules as adopted serve to remind individuals associated with the preparation and prosecution of patent applications of their duty of candor and good faith in their dealings with the Office, and will aid the Office in receiving, in a timely manner, the information it needs to carry out effective and efficient examination of patent applications.

The amendment to 37 CFR 1.56 was proposed to address criticism concerning a perceived lack of certainty in the materiality standard. The rule as promulgated will provide greater clarity and hopefully minimize the burden of litigation on the question of inequitable conduct before the Office, while providing the Office with the information necessary for effective and efficient examination of patent applications. 37 CFR 1.56 has been amended to present a clearer and more objective definition of what information the Office considers material to patentability. The rules do not define fraud or inequitable conduct which have elements both of materiality and of intent.

The definition of materiality in 37 CFR 1.56 does not impose substantial new burdens on applicants, but is intended to provide the Office with the information it needs to make a proper and independent determination on patentability. It is the patent examiner who should make the determination after considering all the facts involved in the particular case.

37 CFR 1.56 states that each individual associated with the filing and prosecution of a patent application has a duty to disclose all information known to that individual to be material to patentability as defined in the section. Thus, the duty applies to contemporaneously or presently known information. The fact that information was known years ago does not mean that

it was recognized that the information is material to the present application.

The term "information" as used in 37 CFR 1.56 means all of the kinds of information required to be disclosed and includes any information which is "material to patentability." Materiality is defined in 37 CFR 1.56(b) and discussed herein at MPEP § 2001.05. In addition to prior art such as patents and publications, 37 CFR 1.56 includes, for example, information on possible prior public uses, sales, offers to sell, derived knowledge, prior invention by another, inventorship conflicts, and the like.

The term "information" is intended to be all encompassing, similar to the scope of the term as discussed with respect to 37 CFR 1.291(a) (see MPEP § 1901.02). 37 CFR 1.56(a) also states: "The Office encourages applicants to carefully examine: (1) prior art cited in search reports of a foreign patent office in a counterpart application, and (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office." The sentence does not create any new duty for applicants, but is placed in the text of the rule as helpful guidance to individuals who file and prosecute patent applications.

It should be noted that the rules are *not* intended to require information *favorable* to patentability such as, for example, evidence of commercial success of the invention. Similarly, the rules are not intended to require, for example, disclosure of information concerning the level of skill in the art for purposes of determining obviousness.

37 CFR 1.56(a) states that the duty to disclose information exists until the application becomes abandoned. The duty to disclose information, however, does not end when an application becomes allowed but extends until a patent is granted on that application. The rules provide for information being considered after a notice of allowance is mailed and before the issue fee is paid (37 CFR 1.97(d)) (see MPEP § 609, paragraph B(3)). The rules also provide for an application to be withdrawn from issue

(A) because one or more claims are unpatentable (37 CFR 1.313(c)(1));

(B) for express abandonment so that information may be considered in a continuing application before a patent issues (37 CFR 1.313(c)(3)); or

(C) for consideration of a request for continued examination (RCE) under 37 CFR 1.114 (37 CFR 1.313(a) and (c)(2)). Note that RCE practice does not apply to utility or plant applications filed before June 8, 1995 or to design applications. See MPEP § 706.07(h).

See MPEP § 1308 for additional information pertaining to withdrawal of an application from issue.

In a continuation-in-part application, individuals covered by 37 CFR 1.56 have a duty to disclose to the Office all information known to be material to patentability which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application. See 37 CFR 1.56(e).

37 CFR 1.56 provides that the duty of disclosure can be met by submitting information to the Office in the manner prescribed by 37 CFR 1.97 and 1.98. See MPEP § 609. Applicants are provided certainty as to when information will be considered, and applicants will be informed when information is not considered. Note, however, that the Office may order or conduct reexamination proceedings based on prior art that was cited but whose relevance to patentability of the claims was not discussed in any prior related Office proceeding. See MPEP § 2242.

The Office does not believe that courts should, or will, find violations of the duty of disclosure because of unintentional noncompliance with 37 CFR 1.97 and 1.98. If the noncompliance is intentional, however, the applicant will have assumed the risk that the failure to submit the information in a manner that will result in its being considered by the examiner may be held to be a violation.

The Office does not anticipate any significant change in the quantity of information cited to the Office. Presumably, applicants will continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality. An incentive remains to submit the information to the Office because it will result in a strengthened patent and will avoid later questions of materiality and intent to deceive. In addition, the new rules will actually facilitate the filing of

information since the burden of submitting information to the Office has been reduced by eliminating, in most cases, the requirement for a concise statement of the relevance of each item of information listed in an information disclosure statement. It should also be noted that 37 CFR 1.97(h) states that the filing of an information disclosure statement shall not be considered to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR 1.56.

2001.05 Materiality Under 37 CFR 1.56(b)

37 CFR 1.56. *Duty to disclose information material to patent ability.*

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

Under the rule, information is not material unless it comes within the definition of 37 CFR 1.56(b)(1) or (2). If information is not material, there is no duty to disclose the information to the Office. Thus, it is theoretically possible for applicants to draft claims and a specification to avoid a *prima facie* case of obviousness over a reference and then to be able to withhold the reference from the examiner. The Office believes that most applicants will wish to submit the information, however, even though they may not be required to do so, to strengthen the patent and avoid the risks of an incorrect judgment on their part on materiality or that it may be held that there was an intent to deceive the Office.

2001.06 Sources of Information

All individuals covered by 37 CFR 1.56 (reproduced in MPEP § 2001.01) have a duty to disclose to the U.S. Patent and Trademark Office all material information they are *aware* of regardless of the source of or how they become aware of the information. Materiality controls whether information must be disclosed to the Office, not the circumstances under which or the source from which the information is obtained. If material, the information must be disclosed to the Office. The duty to disclose material information extends to information such individuals are aware of prior to or at the time of filing the application or become aware of during the prosecution thereof.

Such individuals may be or become aware of material information from various sources such as, for example, co-workers, trade shows, communications from or with competitors, potential infringers, or other third parties, related foreign applications (see MPEP § 2001.06(a)), prior or copending United States patent applications (see MPEP § 2001.06(b)), related litigation (see MPEP § 2001.06(c)) and preliminary examination searches.

2001.06(a) Prior Art Cited in Related Foreign Applications

Applicants and other individuals, as set forth in 37 CFR 1.56, have a duty to bring to the attention of the Office any material prior art or other information cited or brought to their attention in any related foreign application. The inference that such prior art or other information is material is especially strong where it is the only prior art cited or where it has been used in rejecting the same or similar claims in the foreign application. See *Gemveto Jewelry Co. v. Lambert Bros., Inc.*, 542 F. Supp. 933, 216 USPQ 976 (S.D. N.Y. 1982) wherein a patent was held invalid or unenforceable because patentee's foreign counsel did not disclose to patentee's United States counsel or to the Office prior art cited by the Dutch Patent Office in connection with the patentee's corresponding Dutch application. The court stated, 542 F. Supp. at 943, 216 USPQ at 985:

Foreign patent attorneys representing applicants for U.S. patents through local correspondent firms surely must be held to the same standards of conduct which

apply to their American counterparts; a double standard of accountability would allow foreign attorneys and their clients to escape responsibility for fraud or inequitable conduct merely by withholding from the local correspondent information unfavorable to patentability and claiming ignorance of United States disclosure requirements.

2001.06(b) Information Relating to or From Copending United States Patent Applications

The individuals covered by 37 CFR 1.56 have a duty to bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications which are "material to patentability" of the application in question. As set forth by the court in *Armour & Co. v. Swift & Co.*, 466 F.2d 767, 779, 175 USPQ 70, 79 (7th Cir. 1972):

[W]e think that it is unfair to the busy examiner, no matter how diligent and well informed he may be, to assume that he retains details of every pending file in his mind when he is reviewing a particular application . . . [T]he applicant has the burden of presenting the examiner with a complete and accurate record to support the allowance of letters patent.

See also MPEP § 2004, paragraph 9.

Accordingly, the individuals covered by 37 CFR 1.56 cannot assume that the examiner of a particular application is necessarily aware of other applications which are "material to patentability" of the application in question, but must instead bring such other applications to the attention of the examiner. For example, if a particular inventor has different applications pending in which similar subject matter but patentably indistinct claims are present that fact must be disclosed to the examiner of each of the involved applications. Similarly, the prior art references from one application must be made of record in another subsequent application if such prior art references are "material to patentability" of the subsequent application.

Normally, if the application under examination is identified as a continuation or continuation-in-part of an earlier application, the examiner will consider the prior art cited in the earlier application. The examiner must indicate in the first Office action whether the prior art in a related earlier application has been

reviewed. Accordingly, no separate citation of the same prior art need be made in the later application.

2001.06(c) Information From Related Litigation

Where the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office. Examples of such material information include evidence of possible prior public use or sales, questions of inventorship, prior art, allegations of "fraud," "inequitable conduct," and "violation of duty of disclosure." Another example of such material information is any assertion that is made during litigation which is contradictory to assertions made to the examiner. *Environ Prods., Inc. v. Total Containment, Inc.*, 43 USPQ2d 1288, 1291 (E.D. Pa. 1997). Such information might arise during litigation in, for example, pleadings, admissions, discovery including interrogatories, depositions, and other documents and testimony.

Where a patent for which reissue is being sought is, or has been, involved in litigation which raised a question material to examination of the reissue application, such as the validity of the patent, or any allegation of "fraud," "inequitable conduct," or "violation of duty of disclosure," the existence of such litigation must be brought to the attention of the Office by the applicant at the time of, or shortly after, filing the application, either in the reissue oath or declaration, or in a separate paper, preferably accompanying the application, as filed. Litigation begun after filing of the reissue application should be promptly brought to the attention of the Office. The details and documents from the litigation, insofar as they are "material to patentability" of the reissue application as defined in 37 CFR 1.56, should accompany the application as filed, or be submitted as promptly thereafter as possible. See *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1258, 1259, 43 USPQ2d 1666, 1670-71 (Fed. Cir. 1997) (patent held unenforceable due to inequitable conduct based on patentee's failure to disclose a relevant reference and for failing to disclose ongoing litigation).

For example, the defenses raised against validity of the patent, or charges of "fraud" or "inequitable con-

duct" in the litigation, would normally be "material to the examination" of the reissue application. It would, in most situations, be appropriate to bring such defenses to the attention of the Office by filing in the reissue application a copy of the court papers raising such defenses. At a minimum, the applicant should call the attention of the Office to the litigation, the existence and the nature of any allegations relating to validity and/or "fraud," or "inequitable conduct" relating to the original patent, and the nature of litigation materials relating to these issues. Enough information should be submitted to clearly inform the Office of the nature of these issues so that the Office can intelligently evaluate the need for asking for further materials in the litigation. See MPEP § 1442.04.

2001.06(d) Information Relating to Claims Copied From a Patent

Where claims are copied or substantially copied from a patent, 37 CFR 1.607(c) requires applicant shall, at the time he or she presents the claim(s), identify the patent and the numbers of the patent claims. Failure to comply with 37 CFR 1.607(c) may result in the issuance of a requirement for information as to why an identification of the source of the copied claims was not made.⁷

Clearly, the information required by 37 CFR 1.607(c) as to the source of copied claims is material information under 37 CFR 1.56 and failure to inform the USPTO of such information may violate the duty of disclosure.

2002 Disclosure — By Whom and How Made

37 CFR 1.56. Duty to disclose information material to patentability.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

2002.01 By Whom Made

37 CFR 1.56(d) makes clear that information may be disclosed to the Office through an attorney or agent of record or through a *pro se* inventor, and that other

individuals may satisfy their duty of disclosure to the Office by disclosing information to such an attorney, agent, or inventor who then is responsible for disclosing the same to the Office. Information that is not material need not be passed along to the Office.

2002.02 Must be in Writing

37 CFR 1.2. *Business to be transacted in writing.*

All business with the Patent and Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

37 CFR 1.4. *Nature of correspondence and signature requirements.*

(b) Since each file must be complete in itself, a separate copy of every paper to be filed in a patent or trademark application, patent file, trademark registration file, or other proceeding must be furnished for each file to which the paper pertains, even though the contents of the papers filed in two or more files may be identical. The filing of duplicate copies of correspondence in the file of an application, patent, trademark registration file, or other proceeding should be avoided, except in situations in which the Office requires the filing of duplicate copies. The Office may dispose of duplicate copies of correspondence in the file of an application, patent, trademark registration file, or other proceeding.

A disclosure under 37 CFR 1.56 must be in writing as prescribed by 37 CFR 1.2, and a copy of any such disclosure must be filed in each application or other proceeding to which the disclosure pertains (37 CFR 1.4(b)).

2003 Disclosure — When Made

In reissue applications, applicants are encouraged to file information disclosure statements at the time of filing or within 2 months of filing, since reissue applications are taken up "special" (see MPEP § 1442 and § 1442.03). However, in a reissue where waiver of the normal 2 month delay period of 37 CFR 1.176 is being requested (see MPEP § 1441), the statement should be filed at the time of filing the application, or as soon thereafter as possible.

The presumption of validity is generally strong when prior art was before and considered by the

Office and weak when it was not. See *Bolkcom v. Carborundum Co.*, 523 F.2d 492, 498, 186 USPQ 466, 471 (6th Cir. 1975).

2003.01 Disclosure After Patent Is Granted

BY CITATIONS OF PRIOR ART UNDER 37 CFR 1.501

Where a patentee or any member of the public (including private persons, corporate entities, and government agencies) has prior patents or printed publications which the patentee or member of the public desires to have made of record in the patent file, patentee or such member of the public may file a citation of such prior art with the U.S. Patent and Trademark Office pursuant to 37 CFR 1.501. Such citations and papers will be entered without comment by the Office. The Office does not of course consider the citation and papers but merely places them of record in the patent file. Information which may be filed under 37 CFR 1.501 is limited to prior art patents and printed publications. Any citations which include items other than patents and printed publications will not be entered in the patent file. See MPEP § 2202 through § 2208.

BY REEXAMINATION

Where any person, including patentee, has prior art patents and/or printed publications which said person desires to have the U.S. Patent and Trademark Office consider after a patent has issued, such person may file a request for reexamination of the patent (see 37 CFR 1.510 and MPEP § 2209 through § 2220).

2004 Aids to Compliance With Duty of Disclosure

While it is not appropriate to attempt to set forth procedures by which attorneys, agents, and other individuals may ensure compliance with the duty of disclosure, the items listed below are offered as examples of possible procedures which could help avoid problems with the duty of disclosure. Though compliance with these procedures may not be required, they are presented as helpful suggestions for avoiding duty of disclosure problems.

1. Many attorneys, both corporate and private, are using letters and questionnaires for applicants and others involved with the filing and prosecution of the application and checklists for themselves and applicants to ensure compliance with the duty of disclosure. The letter generally explains the duty of disclosure and what it means to the inventor and assignee. The questionnaire asks the inventor and assignee questions about

- the origin of the invention and its point of departure from what was previously known and in the prior art,

- possible public uses and sales,

- prior publication, knowledge, patents, foreign patents, etc.

The checklist is used by the attorney to ensure that the applicant has been informed of the duty of disclosure and that the attorney has inquired of and cited material prior art.

The use of these types of aids would appear to be most helpful, though not required, in identifying prior art and may well help the attorney and the client avoid or more easily explain a potentially embarrassing and harmful “fraud” allegation.

2. It is desirable to ask questions about inventorship. Who is the proper inventor? Are there disputes or possible disputes about inventorship? If there are questions, call them to the attention of the U.S. Patent and Trademark Office.

3. It is desirable to ask questions of the inventor about the disclosure of the best mode. Make sure that the best mode is described. See MPEP § 2165 - § 2165.04.

4. It is desirable for an attorney or agent to make certain that the inventor, especially a foreign inventor, recognizes his or her responsibilities in signing the oath or declaration. See 37 CFR 1.69(a).

37 CFR 1.69. Foreign language oaths and declarations.

(a) Whenever an individual making an oath or declaration cannot understand English, the oath or declaration must be in a language that such individual can understand and shall state that such individual understands the content of any documents to which the oath or declaration relates.

Note MPEP § 602.06 for a more detailed discussion.

5. It is desirable for an attorney or agent to carefully evaluate and explain to the applicant and others involved the scope of the claims, particularly the broadest claims. Ask specific questions about possible prior art which might be material in reference to the broadest claim or claims. There is some tendency to mistakenly evaluate prior art in the light of the gist of what is regarded as the invention or narrower interpretations of the claims, rather than measuring the art against the broadest claim with all of its reasonable interpretations. It is desirable to pick out the broadest claim or claims and measure the materiality of prior art against a reasonably broad interpretation of these claims.

6. It may be useful to evaluate the materiality of prior art or other information from the viewpoint of whether it is the closest prior art or other information. This will tend to put the prior art or other information in better perspective. See *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 1374, 54 USPQ2d 1001, 1005 (Fed. Cir. 2000) (“A withheld reference may be highly material when it discloses a more complete combination of relevant features, even if those features are before the patent examiner in other references.” (citations omitted)). However, 37 CFR 1.56 may still require the submission of prior art or other information which is not as close as that of record.

7. Care should be taken to see that prior art or other information cited in a specification or in an information disclosure statement is properly described and that the information is not incorrectly or incompletely characterized. It is particularly important for an attorney or agent to review, before filing, an application which was prepared by someone else, e.g., a foreign application. It is also important that an attorney or agent make sure that foreign clients, including foreign applicants, attorneys, and agents understand the requirements of the duty of disclosure, and that the U.S. attorney or agent review any information disclosure statements or citations to ensure that compliance with 37 CFR 1.56 is present. See *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 54 USPQ2d 1001 (Fed. Cir. 2000). During prosecution patentee submitted an untranslated 29-page Japanese reference as well as a concise explanation of its relevance and an existing one-page partial English translation, both of which were

directed to less material portions of the reference. The untranslated portions of the Japanese reference "contained a more complete combination of the elements claimed [in the patent] than anything else before the PTO." 204 F.3d at 1374, 54 USPQ2d at 1005. The patentee, whose native language was Japanese, was held to have understood the materiality of the reference. "The duty of candor does not require that the applicant translate every foreign reference, but only that the applicant refrain from submitting partial translations and concise explanations that it knows will misdirect the examiner's attention from the reference's relevant teaching." 204 F.3d at 1378, 54 USPQ2d at 1008. See also *Gemveto Jewelry Co. v. Lambert Bros., Inc.*, 542 F. Supp. 933, 216 USPQ 976 (S.D.N.Y. 1982) wherein a patent was held invalid or unenforceable because patentee's foreign counsel did not disclose to patentee's United States counsel or to the Office prior art cited by the Dutch Patent Office in connection with the patentee's corresponding Dutch application. The court stated, 542 F. Supp. at 943, 216 USPQ at 985:

Foreign patent attorneys representing applicants for U.S. patents through local correspondent firms surely must be held to the same standards of conduct which apply to their American counterparts; a double standard of accountability would allow foreign attorneys and their clients to escape responsibility for fraud or inequitable conduct merely by withholding from the local correspondent information unfavorable to patentability and claiming ignorance of United States disclosure requirements.

8. Care should be taken to see that inaccurate statements or inaccurate experiments are not introduced into the specification, either inadvertently or intentionally. For example, stating that an experiment "was run" or "was conducted" when in fact the experiment was not run or conducted is a misrepresentation of the facts. No results should be represented as actual results unless they have actually been achieved. Paper examples should not be described using the past tense. See MPEP § 608.01(p) and § 707.07(l). Also, misrepresentations can occur when experiments which were run or conducted are inaccurately reported in the specification, e.g., an experiment is changed by leaving out one or more ingredients. See *Steierman v. Connelly*, 192 USPQ 433 (Bd. Pat. Int. 1975); 192 USPQ 446 (Bd. Pat. Int. 1976).

9. Do not rely on the examiner of a particular application to be aware of other applications belonging to

the same applicant or assignee. It is desirable to call such applications to the attention of the examiner even if there is only a question that they might be "material to patentability" of the application the examiner is considering. It is desirable to be particularly careful that prior art or other information in one application is cited to the examiner in other applications to which it would be material. Do not assume that an examiner will necessarily remember, when examining a particular application, other applications which the examiner is examining, or has examined. See *Armour & Co. v. Swift & Co.*, 466 F.2d 767, 779, 175 USPQ 70, 79 (7th Cir. 1972); *KangaROOS U.S.A., Inc. v. Caldor, Inc.*, 585 F. Supp. 1516, 1522, 1528-29, 222 USPQ 703, 708, 713-14 (S.D. N.Y. 1984), *vacated and remanded*, 778 F.2d 1571, 228 USPQ 32 (Fed. Cir. 1985).

While vacating the summary judgment and remanding for trial in *KangaROOS*, the Court of Appeals for the Federal Circuit stated that a "lapse on the part of the examiner does not excuse the applicant." 778 F.2d at 1576, 228 USPQ at 35.

10. When in doubt, it is desirable and safest to submit information. Even though the attorney, agent, or applicant doesn't consider it necessarily material, someone else may see it differently and embarrassing questions can be avoided. The court in *U.S. Industries v. Norton Co.*, 210 USPQ 94, 107 (N.D. N.Y. 1980) stated "In short, the question of relevancy in close cases, should be left to the examiner and not the applicant." See also *LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 22 USPQ2d 1025 (Fed. Cir. 1992).

11. It may be desirable to submit information about prior uses and sales even if it appears that they may have been experimental, not involve the specifically claimed invention, or not encompass a completed invention. See *Hycor Corp. v. The Schlueter Co.*, 740 F.2d 1529, 1534-37, 222 USPQ 553, 557-559 (Fed. Cir. 1984). See also *LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 22 USPQ2d 1025 (Fed. Cir. 1992).

12. Submit information promptly. An applicant, attorney, or agent who is aware of prior art or other information and its significance should submit same early in prosecution, e.g., before the first action by the examiner, and not wait until after allowance. Potentially material information discovered late in the pros-

ecution should be immediately submitted. That the issue fee has been paid is no reason or excuse for failing to submit information. See *Elmwood Liquid Products, Inc. v. Singleton Packing Corp.*, 328 F. Supp. 974, 170 USPQ 398 (M.D. Fla. 1971).

13. It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to applicant's attention and/or are known to be of most significance. See *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F. Supp. 948, 175 USPQ 260 (S.D. Fla. 1972), *aff'd*, 479 F.2d 1338, 178 USPQ 577 (5th Cir. 1973), *cert. denied*, 414 U.S. 874 (1974). But cf. *Molins PLC v. Textron Inc.*, 48 F.3d 1172, 33 USPQ2d 1823 (Fed. Cir. 1995).

14. Watch out for continuation-in-part applications where intervening material information or documents may exist; particularly watch out for foreign patents and publications related to the parent application and dated more than 1 year before the filing date of the CIP. These and other intervening documents may be material information. See *In re Ruscetta*, 255 F.2d 687, 690-91, 118 USPQ 101, 104 (CCPA 1958); *In re van Lagenhoven*, 458 F.2d 132, 173 USPQ 426 (CCPA 1972); *Chromalloy American Corp. v. Alloy Surfaces Co.*, 339 F. Supp. 859, 173 USPQ 295 (D. Del. 1972).

15. Watch out for information that might be deemed to be prior art under 35 U.S.C. 102(f) and (g).

Prior art under 35 U.S.C. 102(f) may be available under 35 U.S.C. 103. See *OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401, 43 USPQ2d 1641, 1644 (Fed. Cir. 1997) (35 U.S.C. "102(f) is a prior art provision for purposes of § 103"); *Dale Electronics v. R.C.L. Electronics*, 488 F.2d 382, 386, 180 USPQ 225, 227 (1st Cir. 1973); and *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. App. 1981).

Note also that evidence of prior invention under 35 U.S.C. 102(g) may be available under 35 U.S.C. 103, such as in *In re Bass*, 474 F.2d 1276, 177 USPQ 178 (CCPA 1973).

Note 35 U.S.C. 103(c) disqualifies 35 U.S.C. 102(f)/103 or 102(g)/103 prior art which was, at the time the second invention was made, owned by or subject to an obligation of assignment to, the person who owned the first invention. Further note that

35 U.S.C. 103(c) disqualifies 35 U.S.C. 102(e)/103 prior art for applications filed on or after November 29, 1999. See MPEP § 706.02(1) - § 706.02(1)(2).

16. Watch out for information picked up by the inventors and others at conventions, plant visits, in-house reviews, etc. See, for example, *Dale Electronics v. R.C.L. Electronics*, 488 F.2d 382, 386-87, 180 USPQ 225, 228 (1st Cir. 1973).

17. Make sure that all of the individuals who are subject to the duty of disclosure, such as spelled out in 37 CFR 1.56, are informed of and fulfill their duty.

18. Finally, if information was specifically considered and discarded as not material, this fact might be recorded in an attorney's file or applicant's file, including the reason for discarding it. If judgment might have been bad or something might have been overlooked inadvertently, a note made at the time of evaluation might be an invaluable aid in explaining that the mistake was honest and excusable. Though such records are not required, they could be helpful in recalling and explaining actions in the event of a question of "fraud" or "inequitable conduct" raised at a later time.

2005 Comparison to Requirement for Information

Under 37 CFR 1.56, each individual associated with the filing and prosecution of a patent application has a duty to disclose on his or her own initiative information material to patentability under 37 CFR 1.56. By contrast, under 37 CFR 1.105, an examiner or other Office employee is authorized to require, from parties identified in 37 CFR 1.56, information reasonably necessary to examine or treat a matter in an application. The provisions of 37 CFR 1.105 are detailed in MPEP § 704 *et seq.* The criteria for requiring information under 37 CFR 1.56, i.e., materiality to the patentability of claimed subject matter, is substantially higher than the criteria for requiring information under 37 CFR 1.105, i.e., reasonable necessity to the examination of the application. Thus, information required by the examiner pursuant to 37 CFR 1.105 would not necessarily be considered material to patentability in itself, but would be necessary to obtain a complete record from which a determination of patentability will be made.

2010 Office Handling of Duty of Disclosure/Inequitable Conduct Issues

Determination of inequitable conduct issues requires an evaluation of the intent of the party involved. While some court decisions have held that intent may be inferred in some circumstances, consideration of the good faith of the party, or lack thereof, is often required. In several court decisions, a high level of proof of intent to mislead the Office was required in order to prove inequitable conduct under 37 CFR 1.56. See *In re Harito*, 847 F.2d 801, 6 USPQ2d 1930 (Fed. Cir. 1988) and *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 5 USPQ2d 1112 (Fed. Cir. 1987). The Office is not the best forum in which to determine whether there was an "intent to mislead"; such intent is best determined when the trier of facts can observe demeanor of witnesses subjected to cross-examination. A court, with subpoena power, is presently the best forum to consider duty of disclosure issues under the present evidentiary standard for finding an "intent to mislead." The court proceeding involves two participating adverse parties. This is not the case in the Office, since even "protesting" parties are not permitted to participate under the rules. Also, it is the courts and not the Office that are in the best position to fashion an equitable remedy to fit the precise facts in those cases where inequitable conduct is established. Furthermore, inequitable conduct is not set by statute as a criteria for patentability but rather is a judicial application of the doctrine of unclean hands which is appropriate to be handled by the courts rather than by an administrative body. Because of the lack of tools in the Office to deal with this issue and because of its sensitive nature and potential impact on a patent, Office determinations generally will not deter subsequent litigation of the same issue in the courts on appeal or in separate litigation. Office determinations would significantly add to the expense and time involved in obtaining a patent with little or no benefit to the patent owner or any other parties with an interest.

Accordingly, the Office does not investigate and reject original or reissue applications under 37 CFR 1.56. Likewise, the Office will not comment upon duty of disclosure issues which are brought to the attention of the Office in original or reissue applica-

tions except to note in the application, in appropriate circumstances, that such issues are no longer considered by the Office during its examination of patent applications. Examination of lack of deceptive intent in reissue applications will continue but without any investigation of inequitable conduct issues. Applicant's statement of lack of deceptive intent normally will be accepted as dispositive except in special circumstances such as an admission or judicial determination of fraud or inequitable conduct. See MPEP § 2022.05.

2012 Reissue Applications Involving Issues of Fraud, Inequitable Conduct, and/or Violation of Duty of Disclosure

Questions of "fraud," "inequitable conduct," or violation of "duty of disclosure" or "candor and good faith" can arise in reissue applications.

REQUIREMENT FOR "ERROR WITHOUT ANY DECEPTIVE INTENTION"

Both 35 U.S.C. 251 and 37 CFR 1.175 promulgated pursuant thereto require that the error must have arisen "without any deceptive intention." *In re Heany*, 1911 C.D. 138, 180 (1911), unequivocally states:

Where such a condition [fraudulent or deceptive intention] is shown to exist the right to reissue the patent is forfeited.

Similarly, the court in *In re Clark*, 522 F.2d 623, 627, 187 USPQ 209, 213 (CCPA 1975) indicated:

Reissue is not available to rescue a patentee who had presented claims limited to avoid particular prior art and then had failed to disclose that prior art . . . after that failure to disclose has resulted in invalidating of the claims.

It is clear that "fraud" cannot be purged through the reissue process. See conclusions of Law 89 and 91 in *Intermountain Research and Eng'g Co. v. Hercules Inc.*, 171 USPQ 577, 631-32 (C.D. Cal. 1971).

Clearly, where several patents or applications stem from an original application which contained fraudulent claims ultimately allowed, the doctrine of unclean hands bars allowance or enforcement of any of the claims of any of the applications or patents. See *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245, 19 USPQ 228, 230 (1933); *East Chicago*

Machine Tool Corp. v. Stone Container Corp., 181 USPQ 744, 748 (N.D. Ill.), *modified*, 185 USPQ 210 (N.D. Ill. 1974). See also *Chromalloy American Corp. v. Alloy Surfaces Co.*, 339 F. Supp. 859, 173 USPQ 295 (D. Del. 1972) and *Strong v. General Electric Co.*, 305 F. Supp. 1084, 162 USPQ 141 (N.D. Ga. 1969), *aff'd*, 434 F.2d 1042, 168 USPQ 8 (5th Cir. 1970), *cert. denied*, 403 U.S. 906 (1971) where fraud or inequitable conduct affecting only certain claims or only one of related patents was held to affect the other claims or patent. Clearly, "fraud" practiced or attempted in an application which issues as a patent is "fraud" practiced or attempted in connection with any subsequent application to reissue that patent. The reissue application and the patent are inseparable as far as questions of "fraud," "inequitable conduct," or "violation of the duty of disclosure" are concerned. See *In re Heany, supra*; and *Norton v. Curtiss*, 433 F.2d 779, 792, 167 USPQ 532, 543 (CCPA 1970), wherein the court stated:

We take this to indicate that any conduct which will prevent the enforcement of a patent after the patent issues should, if discovered earlier, prevent the issuance of the patent.

Clearly, if a reissue patent would not be enforceable after its issue because of "fraud," "inequitable conduct" or "violation of the duty of disclosure" during the prosecution of the patent sought to be reissued, the reissue patent application should not issue. Under such circumstances, an appropriate remedy would be to reject the claims in the application in accordance with 35 U.S.C. 251. See MPEP § 1448.

The examiner is **not to make any investigation** as to the lack of deceptive intent requirement in reissue applications. Applicant's statement (in the oath or declaration) of lack of deceptive intent will be accepted as dispositive except in special circumstances such as **an admission or judicial determination** of fraud, inequitable conduct or violation of the duty of disclosure, where no investigation need be made and the fact of the admission or judicial determination exists *per se*. Also, any admission of fraud, inequitable conduct or violation of the duty of disclosure must be explicit, unequivocal, and not subject to other interpretation. Where a rejection is made based upon such an admission (see MPEP § 1448) and applicant responds with any reasonable interpretation of the facts that would not lead to a conclusion of fraud,

inequitable conduct or violation of the duty of disclosure, the rejection should be withdrawn. Alternatively, if applicant shows that the admission noted by the examiner was not in fact an admission, the rejection should also be withdrawn.

2012.01 Collateral Estoppel

The Supreme Court in *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 169 USPQ 513 (1971) set forth the rule that once a patent has been declared invalid via judicial inquiry, a collateral estoppel barrier is created against further litigation involving the patent, unless the patentee-plaintiff can demonstrate "that he did not have" a full and fair chance to litigate the validity of his patent in "the earlier case." See also *Ex parte Varga*, 189 USPQ 209 (Bd. App. 1973). As stated in *Kaiser Industries Corp. v. Jones & Laughlin Steel Corp.*, 515 F.2d 964, 987, 185 USPQ 343, 362 (3rd Cir. 1975):

In fashioning the rule of *Blonder-Tongue*, Justice White for a unanimous Court made it clear that a determination of patent invalidity, after a thorough and equitable judicial inquiry, creates a collateral estoppel barrier to further litigation to enforce that patent.

Under 35 U.S.C. 251, the Commissioner can reissue a patent only if there is "error without any deceptive intention." The Commissioner is without authority to reissue a patent when "deceptive intention" was present during prosecution of the parent application. See *In re Clark*, 522 F.2d 62, 187 USPQ 209 (CCPA 1975) and *In re Heany*, 1911 C.D. 138, 180 (1911). Thus, the collateral estoppel barrier applies where reissue is sought of a patent which has been held invalid or unenforceable for "fraud" or "violation of duty of disclosure" in procuring of said patent. It was held in *In re Kahn*, 202 USPQ 772, 773 (Comm'r Pat. 1979):

Therefore, since the Kahn patent was held invalid, *inter alia*, for "failure to disclose material facts of which * * * [Kahn] was aware" this application may be stricken under 37 CFR 1.56 via the doctrine of collateral estoppel as set forth in *Blonder-Tongue, supra*.

The Patent and Trademark Office . . . has found no clear justification for not adhering to the doctrine of collateral estoppel under *Blonder-Tongue* in this case.

Applicant has had his day in court. He appears to have had a full and fair chance to litigate the validity of his patent.

See MPEP § 2259 for collateral estoppel in reexamination proceedings.

2013 Protests Involving Issues of Fraud, Inequitable Conduct, and/or Violation of Duty of Disclosure

37 CFR 1.291 permits protests by the public against pending applications.

Submissions under 37 CFR 1.291 are not limited to prior art documents such as patents and publications, but are intended to include any information, which in the protestor's opinion, would make or have made the grant of the patent improper (see MPEP § 1901.02). This includes, of course, information indicating the presence of "fraud" or "inequitable conduct" or "violation of the duty of disclosure," which will be entered in the application file, generally without comment. See MPEP § 1901.06.

Protests should be in conformance with 37 CFR 1.291(a) and (b), and include a statement of the alleged facts involved, the point or points to be reviewed, and the action requested. Any briefs or memoranda in support of the petition, and any affidavits, declarations, depositions, exhibits, or other material in support of the alleged facts, should accompany the protest.

2014 Duty of Disclosure in Reexamination Proceedings

As provided in 37 CFR 1.555, the duty of disclosure in reexamination proceedings applies to the patent owner. That duty is a continuing obligation on the part of the patent owner throughout the proceedings. However, issues of "fraud," "inequitable conduct," or "violation of duty of disclosure" are not considered in reexamination. See MPEP § 2280. If questions of "fraud" or "inequitable conduct" or "violation of the duty of disclosure" are discovered during reexamination proceedings, the existence of such questions will be noted by the examiner in an Office action without further comment. See MPEP § 2258.

For the patent owner's duty to disclose prior or concurrent proceedings in which the patent is or was involved, see MPEP § 2282 and § 2001.06(c).

2016 Fraud, Inequitable Conduct, or Violation of Duty of Disclosure Affects All Claims

A finding of "fraud," "inequitable conduct," or violation of duty of disclosure with respect to any claim in an application or patent, renders all the claims thereof unpatentable or invalid. See *Chromalloy American Corp. v. Alloy Surfaces Co.*, 339 F. Supp. 859, 173 USPQ 295 (D.Del. 1972) and *Strong v. General Electric Co.*, 305 F. Supp. 1084, 162 USPQ 141 (N.D. Ga. 1969), *aff'd*, 434 F.2d 1042, 168 USPQ 8 (5th Cir. 1970), *cert. denied*, 403 U.S. 906 (1971). In *J. P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1561, 223 USPQ 1089, 1093-94 (Fed. Cir. 1984), the court stated:

Once a court concludes that inequitable conduct occurred, all the claims — not just the particular claims in which the inequitable conduct is directly connected — are unenforceable. See *generally*, cases collected in 4 Chisum, PATENTS, paragraph 19.03[6] at 19-85 n. 10 (1984). Inequitable conduct "goes to the patent right as a whole, independently of particular claims." *In re Clark* 522 F.2d 623, 626, 187 USPQ 209, 212 (CCPA).

The court noted in footnote 8 of *Stevens*:

In *In re Multiple Litigation Involving Frost Patent*, 540 F.2d 601, 611, 191 USPQ 241, 249 (3rd. Cir. 1976), some claims were upheld despite nondisclosure with respect to others. The case is not precedent in this court.

As stated in *Genveto Jewelry Co. v. Lambert Bros., Inc.*, 542 F. Supp. 933, 943, 216 USPQ 976, 984 (S. D. N. Y. 1984) (quoting Patent Law Perspectives, 1977 Developments, § G.1 [1]-189):

The gravamen of the fraud defense is that the patentee has failed to discharge his duty of dealing with the examiner in a manner free from the taint of "fraud or other inequitable conduct." If such conduct is established in connection with the prosecution of a patent, the fact that the lack of candor did not directly affect *all* the claims in the patent has never been the governing principle. It is the inequitable conduct that generates the unenforceability of the patent and we cannot think of cases where a patentee partially escaped the consequences of his wrongful acts by arguing that he only committed acts of omission or commission with respect to a limited number of claims. It is an all or nothing proposition. [Emphasis in original.]

2022.05 Determination of "Error Without Any Deceptive Intention"

If the application is a reissue application, the action by the examiner may extend to a determination as to whether at least one "error" required by 35 U.S.C. 251 has been alleged, i.e., identified. Further, the examiner should determine whether applicant has *averred* in the

reissue oath or declaration, as required by 37 CFR 1.175(a)(2), (b)(1), and (b)(2), that all "errors" arose "without any deceptive intention." However, the examiner should not normally comment or question as to whether in fact the averred statement as to lack of deceptive intention appears correct or true. See MPEP § 1414.



Chapter 2100 Patentability

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2105 Patentable Subject Matter — Living Subject Matter

The decision of the Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980), held that microorganisms produced by genetic engineering are not excluded from patent protection by 35 U.S.C. 101. It is clear from the Supreme Court decision and opinion that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. The test set down by the Court for patentable subject matter in this area is whether the living matter is the result of human intervention.

In view of this decision, the Office has issued these guidelines as to how 35 U.S.C. 101 will be interpreted.

The Supreme Court made the following points in the *Chakrabarty* opinion:

1. "Guided by these canons of construction, this Court has read the term 'manufacture' in § 101 in accordance with its dictionary definition to mean 'the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery.'"

2. "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."

3. "The Act embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.' 5 Writings of Thomas Jefferson, at 75-76. See *Graham v. John Deere Co.*, 383 U.S. 1, 7-10 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word 'art' with 'process,' but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 act inform us that Congress intended statutory subject matter to 'include any thing under the sun that is made by man.' S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952)."

4. "This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable."

5. "Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law

that $E=mc^2$; nor could Newton have patented the law of gravity.”

6. “His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter — a product of human ingenuity ‘having a distinctive name, character [and] use.’”

7. “Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent’s microorganism is the result of human ingenuity and research.”

8. After reference to *Funk Seed Co. & Kalo Co.*, 333 U.S.127 (1948), “Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.”

A review of the Court statements above as well as the whole *Chakrabarty* opinion reveals:

(A) That the Court did not limit its decision to genetically engineered living organisms;

(B) The Court enunciated a very broad interpretation of “manufacture” and “composition of matter” in 35 U.S.C. 101 (Note esp. quotes 1, 2, and 3 above);

(C) The Court set forth several tests for weighing whether patentable subject matter under 35 U.S.C. 101 is present, stating (in quote 7 above) that:

The relevant distinction was not between living and inanimate things but between products of nature, whether living or not, and human-made inventions.

The tests set forth by the Court are (note especially the italicized portions):

(A) “The laws of nature, physical phenomena and abstract ideas” are not patentable subject matter.

(B) A “nonnaturally occurring manufacture or composition of matter — a product of human ingenuity — having a distinctive name, character, [and] use” is patentable subject matter.

(C) “[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are ‘manifestations of... nature, free to all men and reserved exclusively to none.’”

(D) “[T]he production of articles for use from raw materials prepared by giving to these materials *new forms, qualities, properties, or combinations whether by hand labor or by machinery*” [emphasis added] is a “manufacture” under 35 U.S.C. 101.

In analyzing the history of the Plant Patent Act of 1930, the Court stated: “In enacting the Plant Patent Act, Congress addressed both of these concerns [the concern that plants, even those artificially bred, were products of nature for purposes of the patent law and the concern that plants were thought not amenable to the written description]. It explained at length its belief that the work of the plant breeder ‘in aid of nature’ was patentable invention. S. Rep. No. 315, 71st Cong., 2d Sess., 6-8 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess., 7-9 (1930).”

The Office will decide the questions as to patentable subject matter under 35 U.S.C. 101 on a case-by-case basis following the tests set forth in *Chakrabarty*, e.g., that “a nonnaturally occurring manufacture or composition of matter” is patentable, etc. It is inappropriate to try to attempt to set forth here in advance the exact parameters to be followed.

The standard of patentability has not and will not be lowered. The requirements of 35 U.S.C. 102 and 103 still apply. The tests outlined above simply mean that a rational basis will be present for any 35 U.S.C. 101 determination. In addition, the requirements of 35 U.S.C. 112 must also be met. In this regard, see MPEP § 608.01(p).

Following this analysis by the Supreme Court of the scope of 35 U.S.C. 101, the Federal Circuit held that patentable subject matter under 35 U.S.C. 101 includes seeds and seed-grown plants, even though plant protection is also available under the Plant Patent Act (35 U.S.C. 161 - 164) and the Plant Variety Protection Act (7 U.S.C. 2321 *et. seq.*). *Pioneer Hi-Bred International Inc. v. J.E.M. AG Supply Inc.*, 200 F.3d 1374, 53 USPQ2d 1440, 1442-43 (Fed. Cir. 2000) (Title 35 and the Plant Variety Protection Act are not in conflict; there is simply a difference in the rights and obligations of each statute.). See also *Ex parte Hibberd*, 227 USPQ 443 (Bd. Pat. App. & Inter. 1985), wherein the Board held that plant subject matter may be the proper subject of a patent under 35 U.S.C. 101 even though such subject matter may be protected under the Plant Patent Act or the Plant Variety Protection Act. Following the reasoning in

Chakrabarty, the Board of Patent Appeals and Interferences has also determined that animals are patentable subject matter under 35 U.S.C. 101. In *Ex parte Allen*, 2 USPQ2d 1425 (Bd. Pat. App. & Inter. 1987), the Board decided that a polyploid Pacific coast oyster could have been the proper subject of a patent under 35 U.S.C. 101 if all the criteria for patentability were satisfied. Shortly after the *Allen* decision, the Commissioner of Patents and Trademarks issued a notice (Animals - Patentability, 1077 O.G. 24, April 21, 1987) that the Patent and Trademark Office would now consider nonnaturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.

If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter. Furthermore, the claimed invention must be examined with regard to all issues pertinent to patentability, and any applicable rejections under 35 U.S.C. 102, 103, or 112 must also be made.

2106 Patentable Subject Matter - Computer-Related Inventions

I. INTRODUCTION

These Examination Guidelines for Computer-Related Inventions ("Guidelines") are to assist Office personnel in the examination of applications drawn to computer-related inventions. "Computer-related inventions" include inventions implemented in a computer and inventions employing computer-readable media. The Guidelines are based on the Office's current understanding of the law and are believed to be fully consistent with binding precedent of the Supreme Court, the Federal Circuit and the Federal Circuit's predecessor courts.

These Guidelines do not constitute substantive rule-making and hence do not have the force and effect of law. These Guidelines have been designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Rejections will be based upon the substantive law and it is these rejections which are appealable. Consequently, any

failure by Office personnel to follow the Guidelines is neither appealable nor petitionable.

The Guidelines alter the procedures Office personnel will follow when examining applications drawn to computer-related inventions and are equally applicable to claimed inventions implemented in either hardware or software. The Guidelines also clarify the Office's position on certain patentability standards related to this field of technology. Office personnel are to rely on these Guidelines in the event of any inconsistent treatment of issues between these Guidelines and any earlier provided guidance from the Office.

Office personnel should no longer rely on the Freeman-Walter-Abele test to determine whether a claimed invention is directed to statutory subject matter. *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368, 1374, 47 USPQ2d 1596, 1601-02 (Fed. Cir. 1998) ("After *Diehr* and *Chakrabarty*, the Freeman-Walter-Abele test has little, if any, applicability to determining the presence of statutory subject matter.").

Office personnel have had difficulty in properly treating claims directed to methods of doing business. Claims should not be categorized as methods of doing business. Instead, such claims should be treated like any other process claims, pursuant to these Guidelines when relevant. See, e.g., *State Street*, 149 F.3d at 1374-75, 47 USPQ2d at 1602 (Fed. Cir. 1998); *In re Toma*, 575 F.2d 872, 877-78, 197 USPQ 852, 857 (CCPA 1978); *In re Musgrave*, 431 F.2d 882, 893, 167 USPQ 280, 289-90 (CCPA 1970). See also *In re Schrader*, 22 F.3d 290, 297-98, 30 USPQ2d 1455, 1461-62 (Fed. Cir. 1994) (Newman, J., dissenting); *Paine, Webber, Jackson & Curtis, Inc. v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 564 F. Supp. 1358, 1368-69, 218 USPQ 212, 220 (D. Del. 1983).

The appendix which appears at the end of this section includes a flow chart of the process Office personnel will follow in conducting examinations for computer-related inventions.

II. DETERMINE WHAT APPLICANT HAS INVENTED AND IS SEEKING TO PATENT

It is essential that patent applicants obtain a prompt yet complete examination of their applications. Under the principles of compact prosecution, each claim

should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to some statutory requirement. Thus, Office personnel should state all reasons and bases for rejecting claims in the first Office action. Deficiencies should be explained clearly, particularly when they serve as a basis for a rejection. Whenever practicable, Office personnel should indicate how rejections may be overcome and how problems may be resolved. A failure to follow this approach can lead to unnecessary delays in the prosecution of the application.

Prior to focusing on specific statutory requirements, Office personnel must begin examination by determining what, precisely, the applicant has invented and is seeking to patent, and how the claims relate to and define that invention. (As the courts have repeatedly reminded the Office: "The goal is to answer the question 'What did applicants invent?'" *In re Abele*, 684 F.2d 902, 907, 214 USPQ 682, 687. Accord, e.g., *Arrhythmia Research Tech. v. Corazonix Corp.*, 958 F.2d 1053, 1059, 22 USPQ2d 1033, 1038 (Fed. Cir. 1992).) Consequently, Office personnel will no longer begin examination by determining if a claim recites a "mathematical algorithm." Rather they will review the complete specification, including the detailed description of the invention, any specific embodiments that have been disclosed, the claims and any specific, substantial, and credible utilities that have been asserted for the invention.

A. **Identify and Understand Any Practical Application Asserted for the Invention**

The claimed invention as a whole must accomplish a practical application. That is, it must produce a "useful, concrete and tangible result." *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601-02. The purpose of this requirement is to limit patent protection to inventions that possess a certain level of "real world" value, as opposed to subject matter that represents nothing more than an idea or concept, or is simply a starting point for future investigation or research (*Brenner v. Manson*, 383 U.S. 519, 528-36, 148 USPQ 689, 693-96); *In re Ziegler*, 992, F.2d 1197, 1200-03, 26 USPQ2d 1600, 1603-06 (Fed. Cir. 1993)). Accordingly, a complete disclosure should contain some indication of the practical application

for the claimed invention, i.e., why the applicant believes the claimed invention is useful.

Apart from the utility requirement of 35 U.S.C. 101, usefulness under the patent eligibility standard requires significant functionality to be present to satisfy the useful result aspect of the practical application requirement. See *Arrhythmia*, 958 F.2d at 1057, 22 USPQ2d at 1036. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make the invention eligible for patenting. For example, a claim directed to a word processing file stored on a disk may satisfy the utility requirement of 35 U.S.C. 101 since the information stored may have some "real world" value. However, the mere fact that the claim may satisfy the utility requirement of 35 U.S.C. 101 does not mean that a useful result is achieved under the practical application requirement. The claimed invention as a whole must produce a "useful, concrete and tangible" result to have a practical application.

Although the courts have yet to define the terms useful, concrete, and tangible in the context of the practical application requirement for purposes of these guidelines, the following examples illustrate claimed inventions that have a practical application because they produce useful, concrete, and tangible result:

- Claims drawn to a long-distance telephone billing process containing mathematical algorithms were held to be directed to patentable subject matter because "the claimed process applies the Boolean principle to produce a useful, concrete, tangible result without pre-empting other uses of the mathematical principle." *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 1358, 50 USPQ2d 1447, 1452 (Fed. Cir. 1999);

- "[T]ransformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces 'a useful, concrete and tangible result' -- a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades." *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601; and

- Claims drawn to a rasterizer for converting discrete waveform data samples into anti-aliased pixel illumination intensity data to be displayed on a display means were held to be directed to patentable subject matter since the claims defined "a specific machine to produce a useful, concrete, and tangible result." *In re Alappat*, 33 F.3d 1526, 1544, 31 USPQ2d 1545, 1557 (Fed. Cir. 1994).

A process that consists solely of the manipulation of an abstract idea is not concrete or tangible. See *In re Warmerdam*, 33 F.3d 1354, 1360, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). See also *Schrader*, 22 F.3d at 295, 30 USPQ2d at 1459. Office personnel have the burden to establish a *prima facie* case that the claimed invention as a whole is directed to solely an abstract idea or to manipulation of abstract ideas or does not produce a useful result. Only when the claim is devoid of any limitation to a practical application in the technological arts should it be rejected under 35 U.S.C. 101. Compare *Musgrave*, 431 F.2d at 893, 167 USPQ at 289; *In re Foster*, 438 F.2d 1011, 1013, 169 USPQ 99, 101 (CCPA 1971). Further, when such a rejection is made, Office personnel must expressly state how the language of the claims has been interpreted to support the rejection.

The applicant is in the best position to explain why an invention is believed useful. Office personnel should therefore focus their efforts on pointing out statements made in the specification that identify all practical applications for the invention. Office personnel should rely on such statements throughout the examination when assessing the invention for compliance with all statutory criteria. An applicant may assert more than one practical application, but only one is necessary to satisfy the utility requirement. Office personnel should review the entire disclosure to determine the features necessary to accomplish at least one asserted practical application.

B. Review the Detailed Disclosure and Specific Embodiments of the Invention To Determine What the Applicant Has Invented

The written description will provide the clearest explanation of the applicant's invention, by exemplifying the invention, explaining how it relates to the prior art and explaining the relative significance of various features of the invention. Accordingly, Office

personnel should begin their evaluation of a computer-related invention as follows:

— determine what the programmed computer does when it performs the processes dictated by the software (i.e., the functionality of the programmed computer) (*Arrhythmia*, 958 F.2d at 1057, 22 USPQ at 1036, "It is of course true that a modern digital computer manipulates data, usually in binary form, by performing mathematical operations, such as addition, subtraction, multiplication, division, or bit shifting, on the data. But this is only how the computer does what it does. Of importance is the significance of the data and their manipulation in the real world, i.e., what the computer is doing.");

— determine how the computer is to be configured to provide that functionality (i.e., what elements constitute the programmed computer and how those elements are configured and interrelated to provide the specified functionality); and

— if applicable, determine the relationship of the programmed computer to other subject matter outside the computer that constitutes the invention (e.g., machines, devices, materials, or process steps other than those that are part of or performed by the programmed computer). (Many computer-related inventions do not consist solely of a computer. Thus, Office personnel should identify those claimed elements of the computer-related invention that are not part of the programmed computer, and determine how those elements relate to the programmed computer. Office personnel should look for specific information that explains the role of the programmed computer in the overall process or machine and how the programmed computer is to be integrated with the other elements of the apparatus or used in the process.)

Patent applicants can assist the Office by preparing applications that clearly set forth these aspects of a computer-related invention.

C. Review the Claims

The claims define the property rights provided by a patent, and thus require careful scrutiny. The goal of claim analysis is to identify the boundaries of the protection sought by the applicant and to understand how the claims relate to and define what the applicant has indicated is the invention. Office personnel must first determine the scope of a claim by thoroughly analyzing the language of the claim before determin-

ing if the claim complies with each statutory requirement for patentability. See *In re Hiniker Co.*, 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998) (“[T]he name of the game is the claim.”).

Office personnel should begin claim analysis by identifying and evaluating each claim limitation. For processes, the claim limitations will define steps or acts to be performed. For products, the claim limitations will define discrete physical structures or materials. Product claims are claims that are directed to either machines, manufactures or compositions of matter. The discrete physical structures or materials may be comprised of hardware or a combination of hardware and software.

Office personnel are to correlate each claim limitation to all portions of the disclosure that describe the claim limitation. This is to be done in all cases, i.e., whether or not the claimed invention is defined using means or step plus function language. The correlation step will ensure that Office personnel correctly interpret each claim limitation.

The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. The following are examples of language that may raise a question as to the limiting effect of the language in a claim:

- (A) statements of intended use or field of use,
- (B) “adapted to” or “adapted for” clauses,
- (C) “wherein” clauses, or
- (D) “whereby” clauses.

This list of examples is not intended to be exhaustive.

Office personnel must rely on the applicant’s disclosure to properly determine the meaning of terms used in the claims. *Markman v. Westview Instruments*, 52 F.3d 967, 980, 34 USPQ2d 1321, 1330 (Fed. Cir.) (*en banc*), *aff’d*, U.S., 116 S. Ct. 1384 (1996). An applicant is entitled to be his or her own lexicographer, and in many instances will provide an explicit definition for certain terms used in the claims. Where an explicit definition is provided by the applicant for a

term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a “lexicographic vacuum, but in the context of the specification and drawings.”). Office personnel should determine if the original disclosure provides a definition consistent with any assertions made by applicant. See, e.g., *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (inventor may define specific terms used to describe invention, but must do so “with reasonable clarity, deliberateness, and precision” and, if done, must “set out his uncommon definition in some manner within the patent disclosure” so as to give one of ordinary skill in the art notice of the change” in meaning) (quoting *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387-88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992)). Any special meaning assigned to a term “must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention.” *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998). If an applicant does not define a term in the specification, that term will be given its “common meaning.” *Paulsen*, at 30 F. 3d 1480, 31 USPQ2d at 1674.

If the applicant asserts that a term has a meaning that conflicts with the term’s art-accepted meaning, Office personnel should encourage the applicant to amend the claim to better reflect what applicant intends to claim as the invention. If the application becomes a patent, it becomes prior art against subsequent applications. Therefore, it is important for later search purposes to have the patentee employ commonly accepted terminology, particularly for searching text-searchable databases.

Office personnel must always remember to use the perspective of one of ordinary skill in the art. Claims and disclosures are not to be evaluated in a vacuum. If elements of an invention are well known in the art, the applicant does not have to provide a disclosure that describes those elements. In such a case the elements will be construed as encompassing any and every art-recognized hardware or combination of hardware and software technique for implementing the defined requisite functionalities.

Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.").

Where means plus function language is used to define the characteristics of a machine or manufacture invention, claim limitations must be interpreted to read on only the structures or materials disclosed in the specification and "equivalents thereof." (Two *en banc* decisions of the Federal Circuit have made clear that the Office is to interpret means plus function language according to 35 U.S.C. 112, sixth paragraph. In the first, *In re Donaldson*, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994), the court held:

The plain and unambiguous meaning of paragraph six is that one construing means-plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure. Paragraph six does not state or even suggest that the PTO is exempt from this mandate, and there is no legislative history indicating that Congress intended that the PTO should be. Thus, this court must accept the plain and precise language of paragraph six.

Consistent with *Donaldson*, in the second decision, *In re Alappat*, 33 F.3d 1526, 1540, 31 USPQ2d 1545, 1554 (Fed. Cir. 1994) (*in banc*), the Federal Circuit held:

Given *Alappat's* disclosure, it was error for the Board majority to interpret each of the means clauses in claim 15 so broadly as to "read on any and every means for per-

forming the function" recited, as it said it was doing, and then to conclude that claim 15 is nothing more than a process claim wherein each means clause represents a step in that process. Contrary to suggestions by the Commissioner, this court's precedents do not support the Board's view that the particular apparatus claims at issue in this case may be viewed as nothing more than process claims.

Disclosure may be express, implicit or inherent. Thus, at the outset, Office personnel must attempt to correlate claimed means to elements set forth in the written description. The written description includes the original specification and the drawings. Office personnel are to give the claimed means plus function limitations their broadest reasonable interpretation consistent with all corresponding structures or materials described in the specification and their equivalents including the manner in which the claimed functions are performed. See *Kemco Sales, Inc. v. Control Papers Company, Inc.*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000). Further guidance in interpreting the scope of equivalents is provided in MPEP § 2181 through § 2186.

While it is appropriate to use the specification to determine what applicant intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not impose that limitation. A broad interpretation of a claim by Office personnel will reduce the possibility that the claim, when issued, will be interpreted more broadly than is justified or intended. An applicant can always amend a claim during prosecution to better reflect the intended scope of the claim.

Finally, when evaluating the scope of a claim, every limitation in the claim must be considered. Office personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered. See, e.g., *Diamond v. Diehr*, 450 U.S. at 188-89, 209 USPQ at 9 ("In determining the eligibility of respondents' claimed process for patent protection under 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.").

III. CONDUCT A THOROUGH SEARCH OF THE PRIOR ART

Prior to classifying the claimed invention under 35 U.S.C. 101, Office personnel are expected to conduct a thorough search of the prior art. Generally, a thorough search involves reviewing both U.S. and foreign patents and nonpatent literature. In many cases, the result of such a search will contribute to Office personnel's understanding of the invention. Both claimed and unclaimed aspects of the invention described in the specification should be searched if there is a reasonable expectation that the unclaimed aspects may be later claimed. A search must take into account any structure or material described in the specification and its equivalents which correspond to the claimed means plus function limitation, in accordance with 35 U.S.C. 112, sixth paragraph and MPEP § 2181 through § 2186.

IV. DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. 101

A. Consider the Breadth of 35 U.S.C. 101 Under Controlling Law

As the Supreme Court has held, Congress chose the expansive language of 35 U.S.C. 101 so as to include "anything under the sun that is made by man." *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09, 206 USPQ 193, 197 (1980). Accordingly, section 101 of title 35, United States Code, provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

In *Chakrabarty*, 447 U.S. at 308-309, 206 USPQ at 197, the court stated:

In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope. The relevant legislative history also supports a broad construction. The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]." Act of Feb. 21, 1793, ch. 11, § 1, 1 Stat. 318. The Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement."

V Writings of Thomas Jefferson, at 75-76. See *Graham v. John Deere Co.*, 383 U.S. 1, 7-10 (148 USPQ 459, 462-464) (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man." S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952). [Footnote omitted]

This perspective has been embraced by the Federal Circuit:

The plain and unambiguous meaning of section 101 is that any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may be patented if it meets the requirements for patentability set forth in Title 35, such as those found in sections 102, 103, and 112. The use of the expansive term "any" in section 101 represents Congress's intent not to place any restrictions on the subject matter for which a patent may be obtained beyond those specifically recited in section 101 and the other parts of Title 35. . . . Thus, it is improper to read into section 101 limitations as to the subject matter that may be patented where the legislative history does not indicate that Congress clearly intended such limitations.

Alappat, 33 F.3d at 1542, 31 USPQ2d at 1556.

As cast, 35 U.S.C. 101 defines four categories of inventions that Congress deemed to be the appropriate subject matter of a patent; namely, processes, machines, manufactures and compositions of matter. The latter three categories define "things" while the first category defines "actions" (i.e., inventions that consist of a series of steps or acts to be performed). See 35 U.S.C. 100(b) ("The term 'process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.").

Federal courts have held that 35 U.S.C. 101 does have certain limits. First, the phrase "anything under the sun that is made by man" is limited by the text of 35 U.S.C. 101, meaning that one may only patent something that is a machine, manufacture, composition of matter or a process. See, e.g., *Alappat*, 33 F.3d at 1542, 31 USPQ2d at 1556; *Warmerdam*, 33 F.3d at 1358, 31 USPQ2d at 1757 (Fed. Cir. 1994). Second, 35 U.S.C. 101 requires that the subject matter sought to be patented be a "useful" invention. Accordingly, a complete definition of the scope of 35 U.S.C. 101,

reflecting Congressional intent, is that any new and useful process, machine, manufacture or composition of matter under the sun that is made by man is the proper subject matter of a patent.

The subject matter courts have found to be outside the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena. While this is easily stated, determining whether an applicant is seeking to patent an abstract idea, a law of nature or a natural phenomenon has proven to be challenging. These three exclusions recognize that subject matter that is not a practical application or use of an idea, a law of nature or a natural phenomenon is not patentable. See, e.g., *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 507 (1874) (“idea of itself is not patentable, but a new device by which it may be made practically useful is”); *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86, 94, 40 USPQ 199, 202 (1939) (“While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”); *Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759 (“steps of ‘locating’ a medial axis, and ‘creating’ a bubble hierarchy . . . describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic ‘abstract idea’”).

Courts have expressed a concern over “preemption” of ideas, laws of nature or natural phenomena. The concern over preemption was expressed as early as 1852. See *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) (“A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.”); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132, 76 USPQ 280, 282 (1948) (combination of six species of bacteria held to be nonstatutory subject matter). The concern over preemption serves to bolster and justify the prohibition against the patenting of such subject matter. In fact, such concerns are only relevant to claiming a scientific truth or principle. Thus, a claim to an “abstract idea” is nonstatutory because it does not represent a practical application of the idea, not because it would preempt the idea.

B. *Classify the Claimed Invention as to Its Proper Statutory Category*

To properly determine whether a claimed invention complies with the statutory invention requirements of 35 U.S.C. 101, Office personnel should classify each claim into one or more statutory or nonstatutory categories. If the claim falls into a nonstatutory category, that should not preclude complete examination of the application for satisfaction of all other conditions of patentability. This classification is only an initial finding at this point in the examination process that will be again assessed after the examination for compliance with 35 U.S.C. 102, 103, and 112 is completed and before issuance of any Office action on the merits.

If the invention as set forth in the written description is statutory, but the claims define subject matter that is not, the deficiency can be corrected by an appropriate amendment of the claims. In such a case, Office personnel should reject the claims drawn to nonstatutory subject matter under 35 U.S.C. 101, but identify the features of the invention that would render the claimed subject matter statutory if recited in the claim.

1. *Nonstatutory Subject Matter*

Claims to computer-related inventions that are clearly nonstatutory fall into the same general categories as nonstatutory claims in other arts, namely natural phenomena such as magnetism, and abstract ideas or laws of nature which constitute “descriptive material.” Abstract ideas, *Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759, or the mere manipulation of abstract ideas, *Schrader*, 22 F.3d at 292-93, 30 USPQ2d at 1457-58, are not patentable. Descriptive material can be characterized as either “functional descriptive material” or “nonfunctional descriptive material.” In this context, “functional descriptive material” consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of “data structure” is “a physical or logical relationship among data elements, designed to support specific data manipulation functions.” The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) “Nonfunctional descriptive material” includes but is not limited to music, literary works and a compilation or mere arrangement of data.

Both types of “descriptive material” are nonstatutory when claimed as descriptive material *per se*. *Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759. When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and *Warmerdam*, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure *per se* held nonstatutory). When nonfunctional descriptive material is recorded on some computer-readable medium, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance. *In re Sarkar*, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978) (“[E]ach invention must be evaluated as claimed; yet semantogenic considerations preclude a determination based solely on words appearing in the claims. In the final analysis under 101, the claimed invention, as a whole, must be evaluated for what it is.”) (quoted with approval in *Abele*, 684 F.2d at 907, 214 USPQ at 687). See also *In re Johnson*, 589 F.2d 1070, 1077, 200 USPQ 199, 206 (CCPA 1978) (“form of the claim is often an exercise in drafting”). Thus, nonstatutory music is not a computer component and it does not become statutory by merely recording it on a compact disk. Protection for this type of work is provided under the copyright law.

Claims to processes that do nothing more than solve mathematical problems or manipulate abstract ideas or concepts are more complex to analyze and are addressed below.

If the “acts” of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. *Schrader*, 22 F.3d at 294-95, 30 USPQ2d at 1458-59. Thus, a process consisting solely of mathematical operations,

i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application (i.e., executing a “mathematical algorithm”); or
- simply manipulate abstract ideas, e.g., a bid (*Schrader*, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (*Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.

Cf. *Alappat*, 33 F.3d at 1543 n.19, 31 USPQ2d at 1556 n.19 in which the Federal Circuit recognized the confusion:

The Supreme Court has not been clear . . . as to whether such subject matter is excluded from the scope of 101 because it represents laws of nature, natural phenomena, or abstract ideas. See *Diehr*, 450 U.S. at 186 (viewed mathematical algorithm as a law of nature); *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972) (treated mathematical algorithm as an “idea”). The Supreme Court also has not been clear as to exactly what kind of mathematical subject matter may not be patented. The Supreme Court has used, among others, the terms “mathematical algorithm,” “mathematical formula,” and “mathematical equation” to describe types of mathematical subject matter not entitled to patent protection standing alone. The Supreme Court has not set forth, however, any consistent or clear explanation of what it intended by such terms or how these terms are related, if at all.

Certain mathematical algorithms have been held to be nonstatutory because they represent a mathematical definition of a law of nature or a natural phenomenon. For example, a mathematical algorithm representing the formula $E = mc^2$ is a “law of nature” — it defines a “fundamental scientific truth” (i.e., the relationship between energy and mass). To comprehend how the law of nature relates to any object, one invariably has to perform certain steps (e.g., multiplying a number representing the mass of an object by the square of a number representing the speed of light). In such a case, a claimed process which consists solely of the steps that one must follow to solve the mathematical representation of $E = mc^2$ is indistinguishable from the law of nature and would “pre-

empt" the law of nature. A patent cannot be granted on such a process.

(a) Functional Descriptive Material: "Data Structures" Representing Descriptive Material *Per Se* or Computer Programs Representing Computer Listings *Per Se*

Data structures not claimed as embodied in computer-readable media are descriptive material *per se* and are not statutory because they are not capable of causing functional change in the computer. See, e.g., *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure *per se* held nonstatutory). Such claimed data structures do not define any structural and functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a data structure defines structural and functional interrelationships between the data structure and the computer software and hardware components which permit the data structure's functionality to be realized, and is thus statutory.

Similarly, computer programs claimed as computer listings *per se*, i.e., the descriptions or expressions of the programs, are not physical "things." They are neither computer components nor statutory processes, as they are not "acts" being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. Accordingly, it is important to distinguish claims that define descriptive material *per se* from claims that define statutory inventions.

Computer programs are often recited as part of a claim. Office personnel should determine whether the computer program is being claimed as part of an otherwise statutory manufacture or machine. In such a case, the claim remains statutory irrespective of the fact that a computer program is included in the claim. The same result occurs when a computer program is

used in a computerized process where the computer executes the instructions set forth in the computer program. Only when the claimed invention taken as a whole is directed to a mere program listing, i.e., to only its description or expression, is it descriptive material *per se* and hence nonstatutory.

Since a computer program is merely a set of instructions capable of being executed by a computer, the computer program itself is not a process and Office personnel should treat a claim for a computer program, without the computer-readable medium needed to realize the computer program's functionality, as nonstatutory functional descriptive material. When a computer program is claimed in a process where the computer is executing the computer program's instructions, Office personnel should treat the claim as a process claim. See paragraph IV.B.2(b), below. When a computer program is recited in conjunction with a physical structure, such as a computer memory, Office personnel should treat the claim as a product claim. See paragraph IV.B.2(a), below.

(b) Nonfunctional Descriptive Material

Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided.

Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such "descriptive material" is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).)

The policy that precludes the patenting of nonfunctional descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an article of manufacture. For example, music is commonly sold to consumers in the format of a compact disc. In such cases, the known compact disc acts as nothing more than a carrier for nonfunctional descriptive material. The purely nonfunctional descriptive material cannot alone provide the practical application for the manufacture.

Office personnel should be prudent in applying the foregoing guidance. Nonfunctional descriptive material may be claimed in combination with other functional descriptive multi-media material on a computer-readable medium to provide the necessary functional and structural interrelationship to satisfy the requirements of 35 U.S.C. 101. The presence of the claimed nonfunctional descriptive material is not necessarily determinative of nonstatutory subject matter. For example, a computer that recognizes a particular grouping of musical notes read from memory and upon recognizing that particular sequence, causes another defined series of notes to be played, defines a functional interrelationship among that data and the computing processes performed when utilizing that data, and as such is statutory because it implements a statutory process.

(c) Natural Phenomena Such as Electricity and Magnetism

Claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, *per se*, and as such are nonstatutory natural phenomena. *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-14 (1853). However, a signal claim directed to a practical application of electromagnetic energy is statutory regardless of its transitory nature. See *O'Reilly*, 56 U.S. at 114-19; *In re Breslow*, 616 F.2d 516, 519-21, 205 USPQ 221, 225-26 (CCPA 1980).

2. Statutory Subject Matter

For the purposes of a 35 U.S.C. 101 analysis, it is of little relevance whether the claim is directed to a machine or a process. The legal principles are the same. *AT&T Corp. v. Excel Communications, Inc.*,

172 F.3d 1352, 1357, 50 USPQ2d 1447, 1451 (Fed. Cir. 1999).

(a) Statutory Product Claims

Products may be either machines, manufactures, or compositions of matter.

A *machine* is "a concrete thing, consisting of parts or of certain devices and combinations of devices." *Burr v. Duryee*, 68 U.S. (1 Wall.) 531, 570 (1863).

A *manufacture* is "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties or combinations, whether by hand labor or by machinery." *Chakrabarty*, 447 U.S. at 308, 206 USPQ at 196-97 (quoting *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931)).

A *composition of matter* is "a composition of two or more substances [or] . . . a[] composite article, whether [it] be the result[] of chemical union, or of mechanical mixture, or whether . . . [it] be [a] gas[], fluid[], powder[], or solid[]." *Id.* at 308, 206 USPQ at 197 (quoting *Shell Development Co. v. Watson*, 149 F. Supp. 279, 280, 113 USPQ 265, 266 (D.D.C. 1957), *aff'd per curiam*, 252 F.2d 861, 116 USPQ 428 (D.C. Cir. 1958)).

If a claim defines a useful machine or manufacture by identifying the physical structure of the machine or manufacture in terms of its hardware or hardware and software combination, it defines a statutory product. See, e.g., *Lowry*, 32 F.3d at 1583, 32 USPQ2d at 1034-35; *Warmerdam*, 33 F.3d at 1361-62, 31 USPQ2d at 1760.

Office personnel must treat each claim as a whole. The mere fact that a hardware element is recited in a claim does not necessarily limit the claim to a specific machine or manufacture. Cf. *In re Iwahashi*, 888 F.2d 1370, 1374-75, 12 USPQ2d 1908, 1911-12 (Fed. Cir. 1989), cited with approval in *Alappat*, 33 F.3d at 1544 n.24, 31 USPQ2d at 1558 n.24.

A claim limited to a machine or manufacture, which has a practical application in the technological arts, is statutory. In most cases, a claim to a specific machine or manufacture will have a practical application in the technological arts. See *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557 ("the claimed invention as a whole is directed to a combination of interrelated elements which combine to form a machine for converting discrete waveform data samples into anti-

aliased pixel illumination intensity data to be displayed on a display means. This is not a disembodied mathematical concept which may be characterized as an 'abstract idea,' but rather a specific machine to produce a useful, concrete, and tangible result."); and *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601 ("the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces 'a useful, concrete and tangible result' – a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades."). Also see *AT&T*, 172 F.3d at 1358, 50 USPQ2d at 1452 (Claims drawn to a long-distance telephone billing process containing mathematical algorithms were held patentable subject matter because the process used the algorithm to produce a useful, concrete, tangible result without preempting other uses of the mathematical principle.).

(b) Statutory Process Claims

A claim that requires one or more acts to be performed defines a process. However, not all processes are statutory under 35 U.S.C. 101. *Schrader*, 22 F.3d at 296, 30 USPQ2d at 1460. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in i) below), or (B) be limited to a practical application within the technological arts (discussed in ii) below). See *Diamond v. Diehr*, 450 U.S. at 183-84, 209 USPQ at 6 (quoting *Cochran v. Deener*, 94 U.S. 780, 787-88 (1877)) ("A [statutory] process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.... The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence."). See also *Alapat*, 33 F.3d at 1543, 31 USPQ2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 USPQ at 10). See also *id.* at 1569, 31 USPQ2d at 1578-79 (New-

man, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). If a physical transformation occurs outside the computer, a disclosure that permits a skilled artisan to practice the claimed invention, i.e., to put it to a practical use, is sufficient. On the other hand, it is necessary for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a process merely manipulates concepts or converts one set of numbers into another.

A claimed process is clearly statutory if it results in a physical transformation outside the computer, i.e., falls into one or both of the following specific categories ("safe harbors").

i) Safe Harbors

- Independent Physical Acts (Post-Computer Process Activity)

A process is statutory if it requires physical acts to be performed outside the computer independent of and following the steps to be performed by a programmed computer, where those acts involve the manipulation of tangible physical objects and result in the object having a different physical attribute or structure. *Diamond v. Diehr*, 450 U.S. at 187, 209 USPQ at 8. Thus, if a process claim includes one or more post-computer process steps that result in a physical transformation outside the computer (beyond merely conveying the direct result of the computer operation), the claim is clearly statutory.

Examples of this type of statutory process include the following:

- A method of curing rubber in a mold which relies upon updating process parameters, using a computer processor to determine a time period for curing the rubber, using the computer processor to determine when the time period has been reached in the curing process and then opening the mold at that stage.
- A method of controlling a mechanical robot which relies upon storing data in a computer that represents various types of mechanical movements of the robot, using a computer processor to calculate positioning of the robot in relation to given tasks to be performed by the robot, and controlling

the robot's movement and position based on the calculated position.

Examples of claimed processes that do not achieve a practical application include:

- step of "updating alarm limits" found to constitute changing the number value of a variable to represent the result of the calculation (*Parker v. Flook*, 437 U.S. 584, 585, 198 USPQ 193, 195 (1978));
- final step of "equating" the process outputs to the values of the last set of process inputs found to constitute storing the result of calculations (*In re Gelnovatch*, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979); and
- step of "transmitting electrical signals representing" the result of calculations (*In re De Castelet*, 562 F.2d 1236, 1244, 195 USPQ 439, 446 (CCPA 1977) ("That the computer is instructed to transmit electrical signals, representing the results of its calculations, does not constitute the type of 'post solution activity' found in *Flook*, [437 U.S. 584, 198 USPQ 193 (1978)], and does not transform the claim into one for a process merely using an algorithm. The final transmitting step constitutes nothing more than reading out the result of the calculations.")); and
- step of displaying a calculation as a gray code scale (*In re Abele*, 684 F.2d 902, 908, 214 USPQ 682, 687 (CCPA 1982)).

- Manipulation of Data Representing Physical Objects or Activities (Pre-Computer Process Activity)

Another statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data (*In re Gelnovatch*, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979) (data-gathering step did not measure physical phenomenon); *Arrhythmia*, 958 F.2d at 1056, 22 USPQ2d at 1036), where the data comprises signals corresponding to physical objects or activities external to the computer system, and where the process causes a physical transformation of the signals which are intangible representations of the physical objects or activities. *Schrader*, 22 F.3d at 294, 30 USPQ2d at 1459 citing with approval *Arrhythmia*, 958 F.2d at

1058-59, 22 USPQ2d at 1037-38; *Abele*, 684 F.2d at 909, 214 USPQ at 688; *In re Taner*, 681 F.2d 787, 790, 214 USPQ 678, 681 (CCPA 1982).

Examples of this type of claimed statutory process include the following:

- A method of using a computer processor to analyze electrical signals and data representative of human cardiac activity by converting the signals to time segments, applying the time segments in reverse order to a high pass filter means, using the computer processor to determine the amplitude of the high pass filter's output, and using the computer processor to compare the value to a predetermined value. In this example the data is an intangible representation of physical activity, i.e., human cardiac activity. The transformation occurs when heart activity is measured and an electrical signal is produced. This process has real world value in predicting vulnerability to ventricular tachycardia immediately after a heart attack.
- A method of using a computer processor to receive data representing Computerized Axial Tomography ("CAT") scan images of a patient, performing a calculation to determine the difference between a local value at a data point and an average value of the data in a region surrounding the point, and displaying the difference as a gray scale for each point in the image, and displaying the resulting image. In this example the data is an intangible representation of a physical object, i.e., portions of the anatomy of a patient. The transformation occurs when the condition of the human body is measured with X-rays and the X-rays are converted into electrical digital signals that represent the condition of the human body. The real world value of the invention lies in creating a new CAT scan image of body tissue without the presence of bones.
- A method of using a computer processor to conduct seismic exploration, by imparting spherical seismic energy waves into the earth from a seismic source, generating a plurality of reflected signals in response to the seismic energy waves at a set of receiver positions in an array, and summing the reflection signals to produce a signal simulating the reflection response of the earth to the seismic energy. In this example, the electrical signals processed by the computer represent reflected seismic

energy. The transformation occurs by converting the spherical seismic energy waves into electrical signals which provide a geophysical representation of formations below the earth's surface. Geophysical exploration of formations below the surface of the earth has real world value.

Examples of claimed processes that independently limit the claimed invention to safe harbor include:

- a method of conducting seismic exploration which requires generating and manipulating signals from seismic energy waves before "summing" the values represented by the signals (*Taner*, 681 F.2d at 788, 214 USPQ at 679); and
- a method of displaying X-ray attenuation data as a signed gray scale signal in a "field" using a particular algorithm, where the antecedent steps require generating the data using a particular machine (e.g., a computer tomography scanner). *Abele*, 684 F.2d at 908, 214 USPQ at 687 ("The specification indicates that such attenuation data is available only when an X-ray beam is produced by a CAT scanner, passed through an object, and detected upon its exit. Only after these steps have been completed is the algorithm performed, and the resultant modified data displayed in the required format.").

Examples of claimed processes that do not limit the claimed invention to pre-computing safe harbor include:

- "perturbing" the values of a set of process inputs, where the subject matter "perturbed" was a number and the act of "perturbing" consists of substituting the numerical values of variables (*Gelnovatch*, 595 F.2d at 41 n.7, 201 USPQ at 145 n.7 ("Appellants' claimed step of perturbing the values of a set of process inputs (step 3), in addition to being a mathematical operation, appears to be a data-gathering step of the type we have held insufficient to change a nonstatutory method of calculation into a statutory process.... In this instance, the perturbed process inputs are not even measured values of physical phenomena, but are instead derived by numerically changing the values in the previous set of process inputs.")); and

- selecting a set of arbitrary measurement point values (*Sarkar*, 588 F.2d at 1331, 200 USPQ at 135).

If a claim does not clearly fall into one or both of the safe harbors, the claim may still be statutory if it is limited to a practical application in the technological arts.

ii) Computer-Related Processes Limited to a Practical Application in the Technological Arts

There is always some form of physical transformation within a computer because a computer acts on signals and transforms them during its operation and changes the state of its components during the execution of a process. Even though such a physical transformation occurs within a computer, such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process. What is determinative is not how the computer performs the process, but what the computer does to achieve a practical application. See *Arrhythmia*, 958 F.2d at 1057, 22 USPQ2d at 1036.

A process that merely manipulates an abstract idea or performs a purely mathematical algorithm is nonstatutory despite the fact that it might inherently have some usefulness. In *Sarkar*, 588 F.2d at 1335, 200 USPQ at 139, the court explained why this approach must be followed:

No mathematical equation can be used, as a practical matter, without establishing and substituting values for the variables expressed therein. Substitution of values dictated by the formula has thus been viewed as a form of mathematical step. If the steps of gathering and substituting values were alone sufficient, every mathematical equation, formula, or algorithm having any practical use would be per se subject to patenting as a "process" under 101. Consideration of whether the substitution of specific values is enough to convert the disembodied ideas present in the formula into an embodiment of those ideas, or into an application of the formula, is foreclosed by the current state of the law.

For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See *Alappat*, 33 F.3d at 1543, 31 USPQ2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 USPQ at 10). See also *Alappat*

33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See *AT&T*, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc)). For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory.

Examples of this type of claimed statutory process include the following:

- A computerized method of optimally controlling transfer, storage and retrieval of data between cache and hard disk storage devices such that the most frequently used data is readily available.
- A method of controlling parallel processors to accomplish multi-tasking of several computing tasks to maximize computing efficiency. See, e.g., *In re Bernhart*, 417 F.2d 1395, 1400, 163 USPQ 611,616 (CCPA 1969).
- A method of making a word processor by storing an executable word processing application program in a general purpose digital computer's memory, and executing the stored program to impart word processing functionality to the general purpose digital computer by changing the state of the computer's arithmetic logic unit when program instructions of the word processing program are executed.
- A digital filtering process for removing noise from a digital signal comprising the steps of calculating a mathematical algorithm to produce a correction signal and subtracting the correction signal from the digital signal to remove the noise.

V. EVALUATE APPLICATION FOR COMPLIANCE WITH 35 U.S.C. 112

Office personnel should begin their evaluation of an application's compliance with 35 U.S.C. 112 by considering the requirements of 35 U.S.C. 112, second paragraph. The second paragraph contains two separate and distinct requirements: (A) that the claim(s) set forth the subject matter applicants regard as the invention, and (B) that the claim(s) particularly point out and distinctly claim the invention. An application will be deficient under 35 U.S.C. 112, second paragraph when (A) evidence including admissions, other than in the application as filed, shows applicant has stated that he or she regards the invention to be different from what is claimed, or when (B) the scope of the claims is unclear.

After evaluation of the application for compliance with 35 U.S.C. 112, second paragraph, Office personnel should then evaluate the application for compliance with the requirements of 35 U.S.C. 112, first paragraph. The first paragraph contains three separate and distinct requirements:

- (A) adequate written description,
- (B) enablement, and
- (C) best mode.

An application will be deficient under 35 U.S.C. 112, first paragraph when the written description is not adequate to identify what the applicant has invented, or when the disclosure does not enable one skilled in the art to make and use the invention as claimed without undue experimentation. Deficiencies related to disclosure of the best mode for carrying out the claimed invention are not usually encountered during examination of an application because evidence to support such a deficiency is seldom in the record. *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 1548-49, 41 USPQ2d 1801, 1804 (Fed. Cir. 1997).

If deficiencies are discovered with respect to 35 U.S.C. 112, Office personnel must be careful to apply the appropriate paragraph of 35 U.S.C. 112.

A. Determine Whether the Claimed Invention Complies with 35 U.S.C. 112, Second Paragraph Requirements

1. Claims Setting Forth the Subject Matter Applicant Regards as Invention

Applicant's specification must conclude with claim(s) that set forth the subject matter which the applicant regards as the invention. The invention set forth in the claims is presumed to be that which applicant regards as the invention, unless applicant considers the invention to be something different from what has been claimed as shown by evidence, including admissions, outside the application as filed. An applicant may change what he or she regards as the invention during the prosecution of the application.

2. Claims Particularly Pointing Out and Distinctly Claiming the Invention

Office personnel shall determine whether the claims set out and circumscribe the invention with a reasonable degree of precision and particularity. In this regard, the definiteness of the language must be analyzed, not in a vacuum, but always in light of the teachings of the disclosure as it would be interpreted by one of ordinary skill in the art. Applicant's claims, interpreted in light of the disclosure, must reasonably apprise a person of ordinary skill in the art of the invention. However, the applicant need not explicitly recite in the claims every feature of the invention. For example, if an applicant indicates that the invention is a particular computer, the claims do not have to recite every element or feature of the computer. In fact, it is preferable for claims to be drafted in a form that emphasizes what the applicant has invented (i.e., what is new rather than old). *In re Dossel*, 115 F.3d 942, 946, 42 USPQ2d 1881, 1884 (Fed. Cir. 1997).

A means plus function limitation is distinctly claimed if the description makes it clear that the means corresponds to well-defined structure of a computer or computer component implemented in either hardware or software and its associated hardware platform. *Atmel Corp. v. Information Storage Devices Inc.*, 198 F.3d 1374, 1380, 53 USPQ2d 1225, 1229 (Fed. Cir. 1999); *B. Braun Medical, Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1899 (Fed. Cir. 1997). Such means may be defined as:

- a programmed computer with a particular functionality implemented in hardware or hardware and software;
- a logic circuit or other component of a programmed computer that performs a series of specifically identified operations dictated by a computer program; or
- a computer memory encoded with executable instructions representing a computer program that can cause a computer to function in a particular fashion.

The scope of a "means" limitation is defined as the corresponding structure or material (e.g., a specific logic circuit) set forth in the written description and equivalents. See MPEP § 2181 through § 2186. Thus, a claim using means plus function limitations without corresponding disclosure of specific structures or materials that are not well-known fails to particularly point out and distinctly claim the invention. *Dossel*, 115 F.3d at 946-47, 42 USPQ2d at 1884-85. For example, if the applicant discloses only the functions to be performed and provides no express, implied or inherent disclosure of hardware or a combination of hardware and software that performs the functions, the application has not disclosed any "structure" which corresponds to the claimed means. Office personnel should reject such claims under 35 U.S.C. 112, second paragraph. *B. Braun Medical*, 124 F.3d at 1424, 43 USPQ2d at 1899. The rejection shifts the burden to the applicant to describe at least one specific structure or material that corresponds to the claimed means in question, and to identify the precise location or locations in the specification where a description of at least one embodiment of that claimed means can be found. In contrast, if the corresponding structure is disclosed to be a memory or logic circuit that has been configured in some manner to perform that function (e.g., using a defined computer program), the application has disclosed "structure" which corresponds to the claimed means.

When a claim or part of a claim is defined in computer program code, whether in source or object code format, a person of skill in the art must be able to ascertain the metes and bounds of the claimed invention. In certain circumstances, as where self-documenting programming code is employed, use of programming language in a claim would be permissible because such program source code presents "suffi-

ciently high-level language and descriptive identifiers” to make it universally understood to others in the art without the programmer having to insert any comments. See *Computer Dictionary* 353 (Microsoft Press, 2ed. 1994) for a definition of “self-documenting code.” Applicants should be encouraged to functionally define the steps the computer will perform rather than simply reciting source or object code instructions.

B. Determine Whether the Claimed Invention Complies with 35 U.S.C. 112, First Paragraph Requirements

1. Adequate Written Description

The satisfaction of the enablement requirement does not satisfy the written description requirement. See *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977) (a specification may be sufficient to enable one skilled in the art to make and use the invention, but still fail to comply with the written description requirement). See also *In re DiLeone*, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971). For the written description requirement, an applicant’s specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998). The claimed invention subject matter need not be described literally, i.e., using the same terms, in order for the disclosure to satisfy the description requirement. Software aspects of inventions may be described functionally. See *Robotic Vision Sys. v. View Eng’g, Inc.*, 112 F.3d 1163, 1166, 42 USPQ2d 1619, 1622-23 (Fed. Cir. 1997); *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 1549, 41 USPQ2d 1801, 1805 (Fed. Cir. 1997); *In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1537-38, 25 USPQ2d 1241, 1248-49 (Fed. Cir. 1992).

2. Enabling Disclosure

An applicant’s specification must enable a person skilled in the art to make and use the claimed invention without undue experimentation. The fact that experimentation is complex, however, will not make

it undue if a person of skill in the art typically engages in such complex experimentation. For a computer-related invention, the disclosure must enable a skilled artisan to configure the computer to possess the requisite functionality, and, where applicable, interrelate the computer with other elements to yield the claimed invention, without the exercise of undue experimentation. The specification should disclose how to configure a computer to possess the requisite functionality or how to integrate the programmed computer with other elements of the invention, unless a skilled artisan would know how to do so without such disclosure. See, e.g., *Dossel*, 115 F.3d at 946-47, 42 USPQ2d at 1884-85; *Northern Telecom v. Datapoint Corp.*, 908 F.2d 931, 941-43, 15 USPQ2d 1321, 1328-30 (Fed. Cir.1990) (judgment of invalidity reversed for clear error where expert testimony on both sides showed that a programmer of reasonable skill could write a satisfactory program with ordinary effort based on the disclosure); *DeGeorge v. Bernier*, 768 F.2d 1318, 1324, 226 USPQ 758, 762-63 (Fed. Cir. 1985) (superseded by statute with respect to issues not relevant here) (invention was adequately disclosed for purposes of enablement even though all of the circuitry of a word processor was not disclosed, since the undisclosed circuitry was deemed inconsequential because it did not pertain to the claimed circuit); *In re Phillips*, 608 F.2d 879, 882-83, 203 USPQ 971, 975 (CCPA 1979) (computerized method of generating printed architectural specifications dependent on use of glossary of predefined standard phrases and error-checking feature enabled by overall disclosure generally defining errors); *In re Donohue*, 550 F.2d 1269, 1271, 193 USPQ 136, 137 (CCPA 1977) (“Employment of block diagrams and descriptions of their functions is not fatal under 35 U.S.C. 112, first paragraph, providing the represented structure is conventional and can be determined without undue experimentation.”); *In re Knowlton*, 481 F.2d 1357, 1366-68, 178 USPQ 486, 493-94 (CCPA 1973) (examiner’s contention that a software invention needed a detailed description of all the circuitry in the complete hardware system reversed).

For many computer-related inventions, it is not unusual for the claimed invention to involve more than one field of technology. For such inventions, the disclosure must satisfy the enablement standard for each aspect of the invention. See *In re Naquin*, 398

F.2d 863, 866, 158 USPQ 317, 319 CCPA 1968) (“When an invention, in its different aspects, involves distinct arts, that specification is adequate which enables the adepts of each art, those who have the best chance of being enabled, to carry out the aspect proper to their specialty.”); *Ex parte Zechnall*, 194 USPQ 461, 461 (Bd. App. 1973) (“appellants’ disclosure must be held sufficient if it would enable a person skilled in the electronic computer art, in cooperation with a person skilled in the fuel injection art, to make and use appellants’ invention”). As such, the disclosure must teach a person skilled in each art how to make and use the relevant aspect of the invention without undue experimentation. For example, to enable a claim to a programmed computer that determines and displays the three-dimensional structure of a chemical compound, the disclosure must

- enable a person skilled in the art of molecular modeling to understand and practice the underlying molecular modeling processes; and
- enable a person skilled in the art of computer programming to create a program that directs a computer to create and display the image representing the three-dimensional structure of the compound.

In other words, the disclosure corresponding to each aspect of the invention must be enabling to a person skilled in each respective art.

In many instances, an applicant will describe a programmed computer by outlining the significant elements of the programmed computer using a functional block diagram. Office personnel should review the specification to ensure that along with the functional block diagram the disclosure provides information that adequately describes each “element” in hardware or hardware and its associated software and how such elements are interrelated. See *In re Scarbrough*, 500 F.2d 560, 565, 182 USPQ 298, 301-02 (CCPA 1974) (“It is not enough that a person skilled in the art, by carrying on investigations along the line indicated in the instant application, and by a great amount of work eventually might find out how to make and use the instant invention. The statute requires the application itself to inform, not to direct others to find out for themselves (citation omitted).”); *Knowlton*, 481 F.2d at 1367, 178 USPQ at 493 (disclosure must constitute more than a “sketchy explanation of flow diagrams or a bare group of program listings together with a refer-

ence to a proprietary computer on which they might be run”). See also *In re Gunn*, 537 F.2d 1123, 1127-28, 190 USPQ 402, 405 (CCPA 1976); *In re Brandstatter*, 484 F.2d 1395, 1406-07, 179 USPQ 286, 294 (CCPA 1973); and *In re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727-28 (CCPA 1971).

VI. DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. 102 AND 103

As is the case for inventions in any field of technology, assessment of a claimed computer-related invention for compliance with 35 U.S.C. 102 and 103 begins with a comparison of the claimed subject matter to what is known in the prior art. If no differences are found between the claimed invention and the prior art, the claimed invention lacks novelty and is to be rejected by Office personnel under 35 U.S.C. 102. Once distinctions are identified between the claimed invention and the prior art, those distinctions must be assessed and resolved in light of the knowledge possessed by a person of ordinary skill in the art. Against this backdrop, one must determine whether the invention would have been obvious at the time the invention was made. If not, the claimed invention satisfies 35 U.S.C. 103. Factors and considerations dictated by law governing 35 U.S.C. 103 apply without modification to computer-related inventions. Moreover, merely using a computer to automate a known process does not by itself impart nonobviousness to the invention. See *Dann v. Johnston*, 425 U.S. 219, 227-30, 189 USPQ 257, 261 (1976); *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described *supra* in paragraphs IV.B.1(a) and IV. B.1(b). Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. *In re Dembiczak*, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999). Nonfunctional descriptive material cannot render nonobvious

an invention that would have otherwise been obvious. Cf. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or
- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of non-functional descriptive material.

VII. CLEARLY COMMUNICATE FINDINGS, CONCLUSIONS AND THEIR BASES

Once Office personnel have concluded the above analyses of the claimed invention under all the statutory provisions, including 35 U.S.C. 101, 112, 102 and 103, they should review all the proposed rejections and their bases to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions and reasons which support them.

Appendix to Examination Guidelines for Computer-Related Inventions**Computer-Related Inventions****II. Determine What Applicant Has Invented and Is Seeking to Patent**

- A. Identify and Understand Any Practical Application Asserted for the Invention
- B. Review the Detailed Disclosure and Specific Embodiments of the Invention to Determine What Applicant Has Invented
- C. Review the Claims

**III. Conduct a Thorough Search of the Prior Art****IV. Determine Whether the Claimed Invention Complies with 35 U.S.C. 101****V. Evaluate Application for Compliance with 35 U.S.C. 112**

- A. Determine Whether the Claimed Invention Complies with 35 U.S.C. 112, Second Paragraph
 - 1. Claims Setting Forth the Subject Matter Applicant Regards as Invention
 - 2. Claims Particularly Pointing Out and Distinctly Claiming the Invention
- B. Determine Whether the Claimed Invention Complies with 35 U.S.C. 112, First Paragraph
 - 1. Adequate Written Description
 - 2. Enabling Disclosure

**VI. Determine Whether the Claimed Invention Complies with 35 U.S.C. 102 and 103****VII. Clearly Communicate Findings, Conclusions and Their Bases**

A-1

2106.01 Computer Programming and 35 U.S.C. 112, First Paragraph

The requirements for sufficient disclosure of inventions involving computer programming is the same as for all inventions sought to be patented. Namely, there must be an adequate written description, the original disclosure should be sufficiently enabling to allow one to make and use the invention as claimed, and there must be presentation of a best mode for carrying out the invention.

The following guidelines, while applicable to a wide range of arts, are intended to provide a guide for analyzing 35 U.S.C. 112, first paragraph, issues in applications involving computer programs, software, firmware, or block diagram cases wherein one or more of the "block diagram" elements are at least partially comprised of a computer software component. It should be recognized that sufficiency of disclosure issues in computer cases necessarily will require an inquiry into both the sufficiency of the disclosed hardware as well as the disclosed software due to the interrelationship and interdependence of computer hardware and software.

WRITTEN DESCRIPTION

The function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied on, the specific subject matter later claimed by him or her; how the specification accomplishes this is not material. *In re Herschler*, 591 F.2d 693, 700-01, 200 USPQ 711, 717 (CCPA 1979) and further reiterated in *In re Kaslow*, 707 F.2d 1366, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983). See also MPEP § 2163 - § 2163.04.

BEST MODE

The purpose of the best mode requirement is to "restrain inventors from applying for patents while at the same time concealing from the public the preferred embodiments of their inventions which they have in fact conceived," *In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA 1962); "only evidence of concealment + (accidental or intentional) is to be considered [in judging the adequacy of a best mode disclosure]. That evidence, in order to result in affirmance of a best mode rejection, must tend to show that the quality of an applicant's best mode dis-

closure is so poor as to effectively result in concealment." *In re Sherwood*, 613 F.2d 809, 816-817, 204 USPQ 537, 544 (CCPA 1980). Also, see *White Console Indus. v. Vega Servo-Control Inc.*, 214 USPQ 796, 824 (S.D. Mich. 1982), *aff'd on related grounds*, 713 F.2d 788, 218 USPQ 961 (Fed. Cir. 1983). See also MPEP § 2165 - § 2165.04.

There are two factual inquiries to be made in determining whether a specification satisfies the best mode requirement. First, there must be a subjective determination as to whether at the time the application was filed, the inventor knew of a best mode of practicing the invention. Second, if the inventor had a best mode of practicing the invention, there must be an objective determination as to whether the best mode was disclosed in sufficient detail to allow one skilled in the art to practice it. *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 41 USPQ2d 1801, 1804 (Fed. Cir. 1997); *Chemcast Corp. v. Arco Industries*, 913 F.2d 923, 927-28, 16 USPQ2d 1033, 1036 (Fed. Cir. 1990). "As a general rule, where software constitutes part of a best mode of carrying out an invention, description of such a best mode is satisfied by a disclosure of the functions of the software. This is because, normally, writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed. . . . [F]low charts or source code listings are not a requirement for adequately disclosing the functions of software." *Fonar Corp.*, 107 F.3d at 1549, 41 USPQ2d at 1805 (citations omitted).

ENABLEMENT

When basing a rejection on the failure of the applicant's disclosure to meet the enablement provisions of the first paragraph of 35 U.S.C. 112, the examiner must establish on the record that he or she has a reasonable basis for questioning the adequacy of the disclosure to enable a person of ordinary skill in the art to make and use the claimed invention without resorting to *undue experimentation*. See *In re Brown*, 477 F.2d 946, 177 USPQ 691 (CCPA 1973); *In re Ghiron*, 442 F.2d 985, 169 USPQ 723 (CCPA 1971). Once the examiner has advanced a reasonable basis for questioning the adequacy of the disclosure, it becomes incumbent on the applicant to rebut that challenge and factually demonstrate that his or her application disclosure is in fact sufficient. See *In re Doyle*, 482 F.2d

1385, 1392, 179 USPQ 227, 232 (CCPA 1973); *In re Scarbrough*, 500 F.2d 560, 566, 182 USPQ 298, 302 (CCPA 1974); *In re Ghiron*, *supra*. See also MPEP § 2106, paragraph V.B.2 and § 2164 - § 2164.08(c).

2106.02 Disclosure in Computer Programming Cases

To establish a reasonable basis for questioning the adequacy of a disclosure, the examiner must present a factual analysis of a disclosure to show that a person skilled in the art would not be able to make and use the claimed invention without resorting to undue experimentation.

In computer applications, it is not unusual for the claimed invention to involve two areas of prior art or more than one technology, e.g., an appropriately programmed computer and an area of application of said computer. *White Consol. Indus.*, 214 USPQ at 821. In regard to the "skilled in the art" standard, in cases involving both the art of computer programming, and another technology, the examiner must recognize that the knowledge of persons skilled in both technologies is the appropriate criteria for determining sufficiency. See *In re Naquin*, 398 F.2d 863, 158 USPQ 317 (CCPA 1968); *In re Brown*, 477 F.2d 946, 177 USPQ 691 (CCPA 1973); and *White Consol. Indus. v. Vega Servo-Control, Inc.*, 214 USPQ 796, 822 (S.D.Mich. 1982), *aff'd on related grounds*, 713 F.2d 788, 218 USPQ 961 (Fed. Cir. 1983).

In a typical computer application, system components are often represented in a "block diagram" format, i.e., a group of hollow rectangles representing the elements of the system, functionally labelled, and interconnected by lines. Such block diagram computer cases may be categorized into (A) systems which include but are more comprehensive than a computer and (B) systems wherein the block elements are totally within the confines of a computer.

BLOCK ELEMENTS MORE COMPREHENSIVE THAN A COMPUTER

The first category of such block diagram cases involves systems which include a computer as well as other system hardware and/or software components. In order to meet his or her burden of establishing a reasonable basis for questioning the adequacy of such disclosure, the examiner should initiate a factual analysis of the system by focusing on each of the individ-

ual block element components. More specifically, such an inquiry should focus on the diverse functions attributed to each block element as well as the teachings in the specification as to how such a component could be implemented. If based on such an analysis, the examiner can reasonably contend that more than routine experimentation would be required by one of ordinary skill in the art to implement such a component or components, that component or components should specifically be challenged by the examiner as part of a 35 U.S.C. 112, first paragraph rejection. Additionally, the examiner should determine whether certain of the hardware or software components depicted as block elements are themselves complex assemblages which have widely differing characteristics and which must be precisely coordinated with other complex assemblages. Under such circumstances, a reasonable basis may exist for challenging such a functional block diagram form of disclosure. See *In re Ghiron*, 442 F.2d 985, 169 USPQ 723 (CCPA 1971) and *In re Brown*, *supra*. Moreover, even if the applicant has cited prior art patents or publications to demonstrate that particular block diagram hardware or software components are old, it should not always be considered as self-evident how such components are to be interconnected to function in a disclosed complex manner. See *In re Scarbrough*, 500 F.2d 560, 566, 182 USPQ 298, 301 (CCPA 1974) and *In re Forman*, 463 F.2d 1125, 1129, 175 USPQ 12, 16 (CCPA 1972). Furthermore, in complex systems including a digital computer, a microprocessor, or a complex control unit as one of many block diagram elements, timing between various system elements may be of the essence and without a timing chart relating the timed sequences for each element, an unreasonable amount of work may be required to come up with the detailed relationships an applicant alleges that he or she has solved. See *In re Scarbrough*, 500 F.2d at 566, 182 USPQ at 302.

For example, in a block diagram disclosure of a complex claimed system which includes a microprocessor and other system components controlled by the microprocessor, a mere reference to a prior art, commercially available microprocessor, without any description of the precise operations to be performed by the microprocessor, fails to disclose how such a microprocessor would be properly programmed to either perform any required calculations

or to coordinate the other system components in the proper timed sequence to perform the functions disclosed and claimed. If, in such a system, a particular program is disclosed, such a program should be carefully reviewed to ensure that its scope is commensurate with the scope of the functions attributed to such a program in the claims. See *In re Brown*, 477 F.2d at 951, 177 USPQ at 695. If the disclosure fails to disclose any program and if more than routine experimentation would be required of one skilled in the art to generate such a program, the examiner clearly would have a reasonable basis for challenging the sufficiency of such a disclosure. The amount of experimentation that is considered routine will vary depending on the facts and circumstances of individual cases. No exact numerical standard has been fixed by the courts, but the "amount of required experimentation must, however, be reasonable." *White Consol. Indus.*, 713 F.2d at 791, 218 USPQ at 963. One court apparently found that the amount of experimentation involved was reasonable where a skilled programmer was able to write a general computer program, implementing an embodiment form, within 4 hours. *Hirschfield v. Banner*, 462 F. Supp. 135, 142, 200 USPQ 276, 279 (D.D.C. 1978), *aff'd*, 615 F.2d 1368 (D.C. Cir. 1986), *cert. denied*, 450 U.S. 994 (1981). On the other hand, another court found that, where the required period of experimentation for skilled programmers to develop a particular program would run to 1 to 2 man years, this would be "a clearly unreasonable requirement" (*White Consol. Indus.*, 713 F.2d at 791, 218 USPQ at 963).

BLOCK ELEMENTS WITHIN A COMPUTER

The second category of block diagram cases occurs most frequently in pure data processing applications where the combination of block elements is totally within the confines of a computer, there being no interfacing with external apparatus other than normal input/output devices. In some instances, it has been found that particular kinds of block diagram disclosures were sufficient to meet the enabling requirement of 35 U.S.C. 112, first paragraph. See *In re Knowlton*, 481 F.2d 1357, 178 USPQ 486 (CCPA 1973), *In re Comstock*, 481 F.2d 905, 178 USPQ 616 (CCPA 1973). Most significantly, however, in both the *Comstock* and *Knowlton* cases, the decisions turned on the appellants' disclosure of (A) a reference to and reli-

ance on an identified prior art computer system and (B) an operative computer program for the referenced prior art computer system. Moreover, in *Knowlton* the disclosure was presented in such a detailed fashion that the individual program's steps were specifically interrelated with the operative structural elements in the referenced prior art computer system. The court in *Knowlton* indicated that the disclosure did not merely consist of a sketchy explanation of flow diagrams or a bare group of program listings together with a reference to a proprietary computer in which they might be run. The disclosure was characterized as going into considerable detail in explaining the interrelationships between the disclosed hardware and software elements. Under such circumstances, the Court considered the disclosure to be concise as well as full, clear, and exact to a sufficient degree to satisfy the literal language of 35 U.S.C. 112, first paragraph. It must be emphasized that because of the significance of the program listing and the reference to and reliance on an identified prior art computer system, absent either of these items, a block element disclosure within the confines of a computer should be scrutinized in precisely the same manner as the first category of block diagram cases discussed above.

Regardless of whether a disclosure involves block elements more comprehensive than a computer or block elements totally within the confines of a computer, the examiner, when analyzing method claims, must recognize that the specification must be adequate to teach how to practice the claimed method. If such practice requires a particular apparatus, it is axiomatic that the application must therefore provide a sufficient disclosure of that apparatus if such is not already available. See *In re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971) and *In re Gunn*, 537 F.2d 1123, 1128, 190 USPQ 402, 406 (CCPA 1976). When the examiner questions the adequacy of computer system or computer programming disclosures, the examiner's reasons for finding the specification to be nonenabling should be supported by the record as a whole. In this regard, it is also essential for the examiner to reasonably challenge evidence submitted by the applicant. For example, in *In re Naquin*, *supra*, affiant's statement unchallenged by the examiner, that the average computer programmer was familiar with the subroutine necessary for performing the claimed process, was held to be a

statement of fact which rendered the examiner's rejection baseless. In other words, unless the examiner presents a reasonable basis for challenging the disclosure in view of the record as a whole, a 35 U.S.C. 112, first paragraph rejection in a computer system or computer programming application will not be sustained on appeal. See *In re Naquin, supra*, and *In re Morehouse*, 545 F.2d 162, 165-66, 192 USPQ 29, 32 (CCPA 1976).

While no specific universally applicable rule exists for recognizing an insufficiently disclosed application involving computer programs, an examining guideline to generally follow is to challenge the sufficiency of such disclosures which fail to include either the computer program itself or a reasonably detailed flowchart which delineates the sequence of operations the program must perform. In programming applications software disclosure only includes a flowchart, as the complexity of functions and the generality of the individual components of the flowchart increase, the basis for challenging the sufficiency of such a flowchart becomes more reasonable because the likelihood of more than routine experimentation being required to generate a working program from such a flowchart also increases.

As stated earlier, once an examiner has advanced a reasonable basis or presented evidence to question the adequacy of a computer system or computer programming disclosure, the applicant must show that his or her specification would enable one of ordinary skill in the art to make and use the claimed invention without resorting to undue experimentation. In most cases, efforts to meet this burden involve submitting affidavits, referencing prior art patents or technical publications, arguments of counsel, or combinations of these approaches.

AFFIDAVIT PRACTICE (37 CFR 1.132)

In computer cases, affidavits must be critically analyzed. Affidavit practice usually initially involves analyzing the skill level and/or qualifications of the affiant, which should be of the routineer in the art. When an affiant's skill level is higher than that required by the routineer for a particular application, an examiner may challenge the affidavit since it would not be made by a routineer in the art, and therefore would not be probative as to the amount of experimentation required by a routineer in the art to

implement the invention. An affiant having a skill level or qualifications above that of the routineer in the art would require less experimentation to implement the claimed invention than that for the routineer. Similarly, an affiant having a skill level or qualifications below that of the routineer in the art would require more experimentation to implement the claimed invention than that for the routineer in the art. In either situation, the standard of the routineer in the art would not have been met.

In computer systems or programming cases, the problems with a given affidavit, which relate to the sufficiency of disclosure issue, generally involve affiants submitting few facts to support their conclusions or opinions. Some affidavits may go so far as to present conclusions on the ultimate legal question of sufficiency. *In re Brandstadter*, 484 F.2d 1395, 179 USPQ 286 (CCPA 1973), illustrates the extent of the inquiry into the factual basis underlying an affiant's conclusions or opinions. In *Brandstadter*, the invention concerned a stored program controller (computer) programmed to control the storing, retrieving, and forwarding of messages in a communications system. The disclosure consisted of broadly defined block diagrams of the structure of the invention and no flowcharts or program listings of the programs of the controller. The Court quoted extensively from the Examiner's Office Actions and Examiner's Answer in its opinion where it was apparent that the Examiner consistently argued that the disclosure was merely a broad system diagram in the form of labelled block diagrams along with statements of a myriad of desired results. Various affidavits were presented in which the affiants stated that all or some of the system circuit elements in the block diagrams were either well-known in the art or "could be constructed" by the skilled design engineer, that the controller was "capable of being programmed" to perform the stated functions or results desired, and that the routineer in the art "could design or construct or was able to program" the system. The Court did consider the affiants' statements as being some evidence on the ultimate legal question of enablement but concluded that the statements failed in their purpose since they recited conclusions or opinions with few facts to support or buttress these conclusions. With reference to the lack of a disclosed computer program or even a flowchart of the program to control the message switching

system, the record contained no evidence as to the number of programmers needed, the number of man-hours and the level of skill of the programmers to produce the program required to practice the invention.

It should be noted also that it is not opinion evidence directed to the ultimate legal question of enablement, but rather factual evidence directed to the amount of time and effort and level of knowledge required for the practice of the invention from the disclosure alone which can be expected to rebut a *prima facie* case of nonenablement. See *Hirschfield*, 462 F. Supp. at 143, 200 USPQ at 281. It has also been held that where an inventor described the problem to be solved to an affiant, thus enabling the affiant to generate a computer program to solve the problem, such an affidavit failed to demonstrate that the application alone would have taught a person of ordinary skill in the art how to make and use the claimed invention. See *In re Brown*, 477 F.2d at 951, 177 USPQ at 695. The Court indicated that it was not factually established that the applicant did not convey to the affiant vital and additional information in their several meetings in addition to that set out in the application. Also of significance for an affidavit to be relevant to the determination of enablement is that it must be probative of the level of skill of the routinier in the art as of the time the applicant filed his application. See *In re Gunn*, 537 F.2d at 1128, 190 USPQ at 406. In this case, each of the affiants stated what was known at the time he executed the affidavit, and not what was known at the time the applicant filed his application.

REFERENCING PRIOR ART DOCUMENTS

Earlier, it had been discussed that citing in the specification the commercial availability of an identified prior art computer system is very pertinent to the issue of enablement. But in some cases, this approach may not be sufficient to meet the applicant's burden. Merely citing in an affidavit extracts from technical publications in order to satisfy the enablement requirement is not sufficient if it is not made clear that a person skilled in the art would know which, or what parts, of the cited circuits could be used to construct the claimed device or how they could be interconnected to act in combination to produce the required results. See *In re Forman*, 463 F.2d at 1129, 175 USPQ at 16. This analysis would appear to be less critical where the circuits comprising applicant's

system are essentially standard components comprising an identified prior art computer system and a standard device attached thereto.

Prior art patents are often relied on by applicants to show the state of the art for purposes of enablement. However, these patents must have an issue date earlier than the effective filing date of the application under consideration. See *In re Budnick*, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976). An analogous point was made in *In re Gunn*, *supra*, where the court indicated that patents issued after the filing date of the applicant's application are not evidence of subject matter known to any person skilled in the art since their subject matter may have been known only to the patentees and the Patent and Trademark Office.

Merely citing prior art patents to demonstrate that the challenged components are old may not be sufficient proof since, even if each of the enumerated devices or labelled blocks in a block diagram disclosure were old, *per se*, this would not make it self-evident how each would be interconnected to function in a disclosed complex combination manner. Therefore, the specification in effect must set forth the integration of the prior art; otherwise, it is likely that undue experimentation, or more than routine experimentation would be required to implement the claimed invention. See *In re Scarbrough*, 560 F.2d at 565, 182 USPQ at 301. The court also noted that any cited patents which are used by the applicant to demonstrate that particular box diagram hardware or software components are old must be analyzed as to whether such patents are germane to the instant invention and as to whether such patents provide better detail of disclosure as to such components than an applicant's own disclosure. Also any patent or publication cited to provide evidence that a particular programming technique is well-known in the programming art does not demonstrate that one of ordinary skill in the art could make and use correspondingly disclosed programming techniques unless both programming techniques are of approximately the same degree of complexity. See *In re Knowlton*, 500 F.2d 566, 572, 183 USPQ 33, 37 (CCPA 1974).

ARGUMENTS OF COUNSEL

Arguments of counsel may be effective in establishing that an examiner has not properly met his

or her burden or has otherwise erred in his or her position. In these situations, an examiner may have failed to set forth any basis for questioning the adequacy of the disclosure or may not have considered the whole specification, including the drawings and the written description. However, it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).

2107 Guidelines for Examination of Applications for Compliance with the Utility Requirement

I. INTRODUCTION

The following Guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the utility requirements of 35 U.S.C. 101 and 112. These Guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The Guidelines do not alter the substantive requirements of 35 U.S.C. 101 and 112, nor are they designed to obviate the examiner's review of applications for compliance with all other statutory requirements for patentability. The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

II. EXAMINATION GUIDELINES FOR THE UTILITY REQUIREMENT

Office personnel are to adhere to the following procedures when reviewing patent applications for

compliance with the "useful invention" ("utility") requirement of 35 U.S.C. 101 and 112, first paragraph.

(A) Read the claims and the supporting written description.

(1) Determine what the applicant has claimed, noting any specific embodiments of the invention.

(2) Ensure that the claims define statutory subject matter (i.e., a process, machine, manufacture, composition of matter, or improvement thereof).

(3) If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.

(B) Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible:

(1) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility"), and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.

(i) A claimed invention must have a specific and substantial utility. This requirement excludes "throw-away," "insubstantial," or "nonspecific" utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. 101.

(ii) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

(2) If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a

readily apparent well-established utility, reject the claim(s) under 35 U.S.C. 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under 35 U.S.C. 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The 35 U.S.C. 112, first paragraph, rejection imposed in conjunction with a 35 U.S.C. 101 rejection should incorporate by reference the grounds of the corresponding 35 U.S.C. 101 rejection.

(3) If the applicant has not asserted any specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility, impose a rejection under 35 U.S.C. 101, emphasizing that the applicant has not disclosed a specific and substantial utility for the invention. Also impose a separate rejection under 35 U.S.C. 112, first paragraph, on the basis that the applicant has not disclosed how to use the invention due to the lack of a specific and substantial utility. The 35 U.S.C. 101 and 112 rejections shift the burden of coming forward with evidence to the applicant to:

(i) Explicitly identify a specific and substantial utility for the claimed invention; and

(ii) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established at the time of filing. The examiner should review any subsequently submitted evidence of utility using the criteria outlined above. The examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.

(C) Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner

should specifically explain the scientific basis for his or her factual conclusions.

(1) Where the asserted utility is not specific or substantial, a *prima facie* showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The *prima facie* showing must contain the following elements:

(i) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;

(ii) Support for factual findings relied upon in reaching this conclusion; and

(iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(2) Where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. The *prima facie* showing must contain the following elements:

(i) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;

(ii) Support for factual findings relied upon in reaching this conclusion; and

(iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(3) Where no specific and substantial utility is disclosed or is well-established, a *prima facie* showing of no specific and substantial utility need only establish that applicant has not asserted a utility and that, on the record before the examiner, there is no known well-established utility.

(D) A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.

Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing

evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

Once a *prima facie* showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a patent or a printed publication that rebuts the basis or logic of the *prima facie* showing. If the applicant responds to the *prima facie* rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained.

If the applicant satisfactorily rebuts a *prima facie* rejection based on lack of utility under 35 U.S.C. 101, withdraw the 35 U.S.C. 101 rejection and the corresponding rejection imposed under 35 U.S.C. 112, first paragraph.

2107.01 General Principles Governing Utility Rejections

35 U.S.C. 101. Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof may obtain a patent therefor, subject to the conditions and requirements of this title.

See MPEP § 2107 for guidelines for the examination of applications for compliance with the utility requirement of 35 U.S.C. 101.

The Office must examine each application to ensure compliance with the “useful invention” or utility requirement of 35 U.S.C. 101. In discharging this

obligation, however, Office personnel must keep in mind several general principles that control application of the utility requirement. As interpreted by the Federal courts, 35 U.S.C. 101 has two purposes. First, 35 U.S.C. 101 defines which categories of inventions are eligible for patent protection. An invention that is not a machine, an article of manufacture, a composition or a process cannot be patented. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980); *Diamond v. Diehr*, 450 U.S. 175, 209 USPQ 1 (1981). Second, 35 U.S.C. 101 serves to ensure that patents are granted on only those inventions that are “useful.” This second purpose has a Constitutional footing — Article I, Section 8 of the Constitution authorizes Congress to provide exclusive rights to inventors to promote the “useful arts.” See *Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991). Thus, to satisfy the requirements of 35 U.S.C. 101, an applicant must claim an invention that is statutory subject matter and must show that the claimed invention is “useful” for some purpose either explicitly or implicitly. Application of this latter element of 35 U.S.C. 101 is the focus of these guidelines.

Deficiencies under the “useful invention” requirement of 35 U.S.C. 101 will arise in one of two forms. The first is where it is not apparent why the invention is “useful.” This can occur when an applicant fails to identify any specific and substantial utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966); *In re Ziegler*, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993). The second type of deficiency arises in the rare instance where an assertion of specific and substantial utility for the invention made by an applicant is not credible.

I. SPECIFIC AND SUBSTANTIAL REQUIREMENTS

To satisfy 35 U.S.C. 101, an invention must be “useful.” Courts have recognized that the term “useful” used with reference to the utility requirement can be a difficult term to define. *Brenner v. Manson*, 383 U.S. 519, 529, 148 USPQ 689, 693 (1966) (simple everyday word like “useful” can be “pregnant with ambiguity when applied to the facts of life.”). Where an applicant has set forth a specific and substantial

utility, courts have been reluctant to uphold a rejection under 35 U.S.C. 101 solely on the basis that the applicant's opinion as to the nature of the specific and substantial utility was inaccurate. For example, in *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980), the court reversed a finding by the Office that the applicant had not set forth a "practical" utility under 35 U.S.C. 101. In this case the applicant asserted that the composition was "useful" in a particular pharmaceutical application and provided evidence to support that assertion. Courts have used the labels "practical utility," "substantial utility," or "specific utility" to refer to this aspect of the "useful invention" requirement of 35 U.S.C. 101. The Court of Customs and Patent Appeals has stated:

Practical utility is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.

Nelson v. Bowler, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

Practical considerations require the Office to rely on the inventor's understanding of his or her invention in determining whether and in what regard an invention is believed to be "useful." Because of this, Office personnel should focus on and be receptive to assertions made by the applicant that an invention is "useful" for a particular reason.

Specific Utility

A "specific utility" is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. A general

statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a "useful" invention may arise from what has been disclosed by the applicant. *Knapp v. Anderson*, 477 F.2d 588, 177 USPQ 688 (CCPA 1973).

Substantial Utility

A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

- (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
- (B) A method of treating an *unspecified* disease or condition;
- (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
- (D) A method of making a material that itself has no specific, substantial, and credible utility; and
- (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

Office personnel must be careful not to interpret the phrase “immediate benefit to the public” or similar formulations in other cases to mean that products or services based on the claimed invention must be “currently available” to the public in order to satisfy the utility requirement. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 USPQ 689, 695 (1966). Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a “substantial” utility.

Research Tools

Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact “useful” in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as “research tool,” “intermediate” or “for research purposes” are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

II. WHOLLY INOPERATIVE INVENTIONS; “INCREDIBLE” UTILITY

An invention that is “inoperative” (i.e., it does not operate to produce the results claimed by the patent applicant) is not a “useful” invention in the meaning of the patent law. See, e.g., *Newman v. Quigg*, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989); *In re Harwood*, 390 F.2d 985, 989, 156 USPQ 673, 676 (CCPA 1968) (“An inoperative invention, of course, does not satisfy the requirement of 35 U.S.C. 101 that an invention be useful.”). However, as the Federal Circuit has stated, “[t]o violate [35 U.S.C.] 101 the claimed device must be totally

incapable of achieving a useful result.” *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992) (emphasis added). See also *E.I. du Pont De Nemours and Co. v. Berkley and Co.*, 620 F.2d 1247, 1260 n.17, 205 USPQ 1, 10 n.17 (8th Cir. 1980) (“A small degree of utility is sufficient . . . The claimed invention must only be capable of performing some beneficial function . . . An invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely . . . A commercially successful product is not required . . . Nor is it essential that the invention accomplish all its intended functions . . . or operate under all conditions . . . partial success being sufficient to demonstrate patentable utility . . . In short, the defense of non-utility cannot be sustained without proof of total incapacity.”) If an invention is only partially successful in achieving a useful result, a rejection of the claimed invention as a whole based on a lack of utility is not appropriate. See *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA), *reh’g denied*, 480 F.2d 879 (CCPA 1973); *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971).

Situations where an invention is found to be “inoperative” and therefore lacking in utility are rare, and rejections maintained solely on this ground by a Federal court even rarer. In many of these cases, the utility asserted by the applicant was thought to be “incredible in the light of the knowledge of the art, or factually misleading” when initially considered by the Office. *In re Citron*, 325 F.2d 248, 253, 139 USPQ 516, 520 (CCPA 1963). Other cases suggest that on initial evaluation, the Office considered the asserted utility to be inconsistent with known scientific principles or “speculative at best” as to whether attributes of the invention necessary to impart the asserted utility were actually present in the invention. *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977). However cast, the underlying finding by the court in these cases was that, based on the factual record of the case, it was clear that the invention could not and did not work as the inventor claimed it did. Indeed, the use of many labels to describe a single problem (e.g., a false assertion regarding utility) has led to some of the confusion that exists today with regard to a rejection based on the “utility” requirement. Examples of such

cases include: an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 USPQ 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 USPQ2d 1340 (Fed. Cir. 1989)), a flying machine operating on “flapping or flutter function” (*In re Houghton*, 433 F.2d 820, 167 USPQ 687 (CCPA 1970)), a “cold fusion” process for producing energy (*In re Swartz*, 232 F.3d 862, 56 USPQ2d 1703, (Fed. Cir. 2000)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 USPQ 221 (CCPA 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 USPQ 516 (CCPA 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 USPQ 221 (CCPA 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 USPQ 609 (CCPA 1969)). Thus, in view of the rare nature of such cases, Office personnel should not label an asserted utility “incredible,” “speculative” or otherwise unless it is clear that a rejection based on “lack of utility” is proper.

III. THERAPEUTIC OR PHARMACOLOGICAL UTILITY

Inventions asserted to have utility in the treatment of human or animal disorders are subject to the same legal requirements for utility as inventions in any other field of technology. *In re Chilowsky*, 229 F.2d 457, 461-2, 108 USPQ 321, 325 (CCPA 1956) (“There appears to be no basis in the statutes or decisions for requiring any more conclusive evidence of operativeness in one type of case than another. The character and amount of evidence needed may vary, depending on whether the alleged operation described in the application appears to accord with or to contravene established scientific principles or to depend upon principles alleged but not generally recognized, but the degree of certainty as to the ultimate fact of operativeness or inoperativeness should be the same in all cases”); *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967) (“Thus, in the usual case where the mode of operation alleged can be readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned, and no further evidence is required.”). As such, phar-

macological or therapeutic inventions that provide any “immediate benefit to the public” satisfy 35 U.S.C. 101. The utility being asserted in *Nelson* related to a compound with pharmacological utility. *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980). Office personnel should rely on *Nelson* and other cases as providing general guidance when evaluating the utility of an invention that is based on any therapeutic, prophylactic, or pharmacological activities of that invention.

Courts have repeatedly found that the mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides an “immediate benefit to the public” and thus satisfies the utility requirement. As the Court of Customs and Patent Appeals held in *Nelson v. Bowler*:

Knowledge of the pharmacological activity of any compound is obviously beneficial to the public. It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility.

Nelson v. Bowler, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

In *Nelson v. Bowler*, the court addressed the practical utility requirement in the context of an interference proceeding. *Bowler* challenged the patentability of the invention claimed by *Nelson* on the basis that *Nelson* had failed to sufficiently and persuasively disclose in his application a practical utility for the invention. *Nelson* had developed and claimed a class of synthetic prostaglandins modeled on naturally occurring prostaglandins. Naturally occurring prostaglandins are bioactive compounds that, at the time of *Nelson*’s application, had a recognized value in pharmacology (e.g., the stimulation of uterine smooth muscle which resulted in labor induction or abortion, the ability to raise or lower blood pressure, etc.). To support the utility he identified in his disclosure, *Nelson* included in his application the results of tests demonstrating the bioactivity of his new substituted prostaglandins relative to the bioactivity of naturally occurring prostaglandins. The court concluded that *Nelson* had satisfied the practical utility requirement in identifying the synthetic prostaglandins as pharma-

cologically active compounds. In reaching this conclusion, the court considered and rejected arguments advanced by Bowler that attacked the evidentiary basis for Nelson's assertions that the compounds were pharmacologically active.

In *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980), an inventor claimed protection for pharmaceutical compositions for treating leukemia. The active ingredient in the compositions was a structural analog to a known anticancer agent. The applicant provided evidence showing that the claimed analogs had the same general pharmaceutical activity as the known anticancer agents. The court reversed the Board's finding that the asserted pharmaceutical utility was "incredible," pointing to the evidence that showed the relevant pharmacological activity.

In *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), the Federal Circuit affirmed a finding by the Board of Patent Appeals and Interferences that a pharmacological utility had been disclosed in the application of one party to an interference proceeding. The invention that was the subject of the interference count was a chemical compound used for treating blood disorders. Cross had challenged the evidence in Iizuka's specification that supported the claimed utility. However, the Federal Circuit relied extensively on *Nelson v. Bowler* in finding that Iizuka's application had sufficiently disclosed a pharmacological utility for the compounds. It distinguished the case from cases where only a generalized "nebulous" expression, such as "biological properties," had been disclosed in a specification. Such statements, the court held, "convey little explicit indication regarding the utility of a compound." *Cross*, 753 F.2d at 1048, 224 USPQ at 745 (citing *In re Kirk*, 376 F.2d 936, 941, 153 USPQ 48, 52 (CCPA 1967)).

Similarly, courts have found utility for therapeutic inventions despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition. The Federal Circuit, in *Cross v. Iizuka*, 753 F.2d 1040, 1051, 224 USPQ 739, 747-48 (Fed. Cir. 1985), commented on the significance of data from *in vitro* testing that showed pharmacological activity:

We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the

screening chain, *in vitro* testing, may establish a practical utility for the compound in question. Successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an *in vivo* utility.

The Federal Circuit has reiterated that therapeutic utility sufficient under the patent laws is not to be confused with the requirements of the FDA with regard to safety and efficacy of drugs to marketed in the United States.

FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. *Scott [v. Finney]*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 [(Fed.Cir. 1994)]. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). Accordingly, Office personnel should not construe 35 U.S.C. 101, under the logic of "practical" utility or otherwise, to require that an applicant demonstrate that a therapeutic agent based on a claimed invention is a safe or fully effective drug for humans. See, e.g., *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Anthony*, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969); *In re Watson*, 517 F.2d 465, 186 USPQ 11 (CCPA 1975).

These general principles are equally applicable to situations where an applicant has claimed a process for treating a human or animal disorder. In such cases, the asserted utility is usually clear — the invention is asserted to be useful in treating the particular disorder. If the asserted utility is credible, there is no basis to challenge such a claim on the basis that it lacks utility under 35 U.S.C. 101.

See MPEP § 2107.03 for special considerations for asserted therapeutic or pharmacological utilities.

IV. RELATIONSHIP BETWEEN 35 U.S.C. 112, FIRST PARAGRAPH, AND 35 U.S.C. 101

A deficiency under 35 U.S.C. 101 also creates a deficiency under 35 U.S.C. 112, first paragraph. See *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); *In re Jolles*, 628 F.2d 1322, 1326 n.10, 206 USPQ 885, 889 n.11 (CCPA 1980); *In re Fouche*, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971) (“If such compositions are in fact useless, appellant’s specification cannot have taught how to use them.”). Courts have also cast the 35 U.S.C. 101/35 U.S.C. 112 relationship such that 35 U.S.C. 112 presupposes compliance with 35 U.S.C. 101. See *In re Ziegler*, 992 F.2d 1197, 1200-1201, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993) (“The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. 101 that the specification disclose as a matter of fact a practical utility for the invention. ... If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112.”); *In re Kirk*, 376 F.2d 936, 942, 153 USPQ 48, 53 (CCPA 1967) (“Necessarily, compliance with § 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention.”). For example, the Federal Circuit noted, “[o]bviously, if a claimed invention does not have utility, the specification cannot enable one to use it.” *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). As such, a rejection properly imposed under 35 U.S.C. 101 should be accompanied with a rejection under 35 U.S.C. 112, first paragraph. It is equally clear that a rejection based on “lack of utility,” whether grounded upon 35 U.S.C. 101 or 35 U.S.C. 112, first paragraph, rests on the same basis (i.e., the asserted utility is not credible). To avoid confusion, any rejection that is imposed on the basis of 35 U.S.C. 101 should be accompanied by a rejection based on 35 U.S.C. 112, first paragraph. The 35 U.S.C. 112, first paragraph, rejection should be set out as a separate rejection that incorporates by reference the factual basis and conclusions set forth in the 35 U.S.C. 101 rejection. The 35 U.S.C. 112, first paragraph, rejection should indicate that because the invention as claimed does not have utility, a person skilled in the art would not be able to use the invention as claimed, and as such, the claim is

defective under 35 U.S.C. 112, first paragraph. A 35 U.S.C. 112, first paragraph, rejection should not be imposed or maintained unless an appropriate basis exists for imposing a rejection under 35 U.S.C. 101. In other words, Office personnel should not impose a 35 U.S.C. 112, first paragraph, rejection grounded on a “lack of utility” basis unless a 35 U.S.C. 101 rejection is proper. In particular, the factual showing needed to impose a rejection under 35 U.S.C. 101 must be provided if a rejection under 35 U.S.C. 112, first paragraph, is to be imposed on “lack of utility” grounds.

It is important to recognize that 35 U.S.C. 112, first paragraph, addresses matters other than those related to the question of whether or not an invention lacks utility. These matters include whether the claims are fully supported by the disclosure (*In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991)), whether the applicant has provided an enabling disclosure of the claimed subject matter (*In re Wright*, 999 F.2d 1557, 1561-1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)), whether the applicant has provided an adequate written description of the invention and whether the applicant has disclosed the best mode of practicing the claimed invention (*Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927-928, 16 USPQ2d 1033, 1036-1037 (Fed. Cir. 1990)). See also *Transco Products Inc. v. Performance Contracting Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994); *Glaxo Inc. v. Novopharm Ltd.* 52 F.3d 1043, 34 USPQ2d 1565 (Fed. Cir. 1995). The fact that an applicant has disclosed a specific utility for an invention and provided a credible basis supporting that specific utility does not provide a basis for concluding that the claims comply with all the requirements of 35 U.S.C. 112, first paragraph. For example, if an applicant has claimed a process of treating a certain disease condition with a certain compound and provided a credible basis for asserting that the compound is useful in that regard, but to actually practice the invention as claimed a person skilled in the relevant art would have to engage in an undue amount of experimentation, the claim may be defective under 35 U.S.C. 112, but not 35 U.S.C. 101. To avoid confusion during examination, any rejection under 35 U.S.C. 112, first paragraph, based on grounds other than “lack of utility” should be imposed separately from any rejection imposed due to “lack of util-

ity” under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph.

2107.02 Procedural Considerations Related to Rejections for Lack of Utility

I. THE CLAIMED INVENTION IS THE FOCUS OF THE UTILITY REQUIREMENT

The claimed invention is the focus of the assessment of whether an applicant has satisfied the utility requirement. Each claim (i.e., each “invention”), therefore, must be evaluated on its own merits for compliance with all statutory requirements. Generally speaking, however, a dependent claim will define an invention that has utility if the claim from which it depends has defined an invention having utility. An exception to this general rule is where the utility specified for the invention defined in a dependent claim differs from that indicated for the invention defined in the independent claim from which the dependent claim depends. Where an applicant has established utility for a species that falls within an identified genus of compounds, and presents a generic claim covering the genus, as a general matter, that claim should be treated as being sufficient under 35 U.S.C. 101. Only where it can be established that other species clearly encompassed by the claim do not have utility should a rejection be imposed on the generic claim. In such cases, the applicant should be encouraged to amend the generic claim so as to exclude the species that lack utility.

It is common and sensible for an applicant to identify several specific utilities for an invention, particularly where the invention is a product (e.g., a machine, an article of manufacture or a composition of matter). However, regardless of the category of invention that is claimed (e.g., product or process), an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112; additional statements of utility, even if not “credible,” do not render the claimed invention lacking in utility. See, e.g., *Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984) (“When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown.”); *In re Gottlieb*, 328 F.2d 1016, 1019,

140 USPQ 665, 668 (CCPA 1964) (“Having found that the antibiotic is useful for some purpose, it becomes unnecessary to decide whether it is in fact useful for the other purposes ‘indicated’ in the specification as possibly useful.”); *In re Malachowski*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988). Thus, if applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established.

Statements made by the applicant in the specification or incident to prosecution of the application before the Office cannot, standing alone, be the basis for a lack of utility rejection under 35 U.S.C. 101 or 35 U.S.C. 112. *Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft m.b.h.*, 945 F.2d 1546, 1553, 20 USPQ2d 1332, 1338 (Fed. Cir. 1991) (It is not required that a particular characteristic set forth in the prosecution history be achieved in order to satisfy 35 U.S.C. 101.). An applicant may include statements in the specification whose technical accuracy cannot be easily confirmed if those statements are not necessary to support the patentability of an invention with regard to any statutory basis. Thus, the Office should not require an applicant to strike nonessential statements relating to utility from a patent disclosure, regardless of the technical accuracy of the statement or assertion it presents. Office personnel should also be especially careful not to read into a claim unclaimed results, limitations or embodiments of an invention. See *Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961). Doing so can inappropriately change the relationship of an asserted utility to the claimed invention and raise issues not relevant to examination of that claim.

II. IS THERE AN ASSERTED OR WELL-ESTABLISHED UTILITY FOR THE CLAIMED INVENTION?

Upon initial examination, the examiner should review the specification to determine if there are any statements asserting that the claimed invention is useful for any particular purpose. A complete disclosure should include a statement which identifies a specific and substantial utility for the invention.

A. An Asserted Utility Must Be Specific and Substantial

A statement of specific and substantial utility should fully and clearly explain why the applicant believes the invention is useful. Such statements will usually explain the purpose of or how the invention may be used (e.g., a compound is believed to be useful in the treatment of a particular disorder). Regardless of the form of statement of utility, it must enable one ordinarily skilled in the art to understand why the applicant believes the claimed invention is useful.

Except where an invention has a well-established utility, the failure of an applicant to specifically identify why an invention is believed to be useful renders the claimed invention deficient under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph. In such cases, the applicant has failed to identify a "specific and substantial utility" for the claimed invention. For example, a statement that a composition has an unspecified "biological activity" or that does not explain why a composition with that activity is believed to be useful fails to set forth a "specific and substantial utility." *Brenner v. Manson*, 383 US 519, 148 USPQ 689 (1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful insufficient under 35 U.S.C. 101); *In re Ziegler*, 992 F.2d 1197, 1201, 26 USPQ2d 1600, 1604 (Fed. Cir. 1993) (disclosure that composition is "plastic-like" and can form "films" not sufficient to identify specific and substantial utility for invention); *In re Kirk*, 376 F.2d 936, 153 USPQ 48 (CCPA 1967) (indication that compound is "biologically active" or has "biological properties" insufficient standing alone). See also *In re Joly*, 376 F.2d 906, 153 USPQ 45 (CCPA 1967); *Kawai v. Metlesics*, 480 F.2d 880, 890, 178 USPQ 158, 165 (CCPA 1973) (contrasting description of invention as sedative which did suggest specific utility to general suggestion of "pharmacological effects on the central nervous system" which did not). In contrast, a disclosure that identifies a particular biological activity of a compound and explains how that activity can be utilized in a particular therapeutic application of the compound does contain an assertion of specific and substantial utility for the invention.

Situations where an applicant either fails to indicate why an invention is considered useful, or where the

applicant inaccurately describes the utility should rarely arise. One reason for this is that applicants are required to disclose the best mode known to them of practicing the invention at the time they file their application. An applicant who omits a description of the specific and substantial utility of the invention, or who incompletely describes that utility, may encounter problems with respect to the best mode requirement of 35 U.S.C. 112, first paragraph.

B. No Statement of Utility for the Claimed Invention in the Specification Does Not Per Se Negate Utility

Occasionally, an applicant will not explicitly state in the specification or otherwise assert a specific and substantial utility for the claimed invention. If no statements can be found asserting a specific and substantial utility for the claimed invention in the specification, Office personnel should determine if the claimed invention has a well-established utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible. If an invention has a well-established utility, rejections under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph, based on lack of utility should not be imposed. *In re Folkers*, 344 F.2d 970, 145 USPQ 390 (CCPA 1965). For example, if an application teaches the cloning and characterization of the nucleotide sequence of a well-known protein such as insulin, and those skilled in the art at the time of filing knew that insulin had a well-established use, it would be improper to reject the claimed invention as lacking utility solely because of the omitted statement of specific and substantial utility.

If a person of ordinary skill would not immediately recognize a specific and substantial utility for the claimed invention (i.e., why it would be useful) based on the characteristics of the invention or statements made by the applicant, the examiner should reject the application under 35 U.S.C. 101 and under 35 U.S.C. 112, first paragraph, as failing to identify a specific and substantial utility for the claimed invention. The rejection should clearly indicate that the basis of the rejection is that the application fails to identify a specific and substantial utility for the invention. The

rejection should also specify that the applicant must reply by indicating why the invention is believed useful and where support for any subsequently asserted utility can be found in the specification as filed. See MPEP § 2701.

If the applicant subsequently indicates why the invention is useful, Office personnel should review that assertion according to the standards articulated below for review of the credibility of an asserted utility.

III. EVALUATING THE CREDIBILITY OF AN ASSERTED UTILITY

A. *An Asserted Utility Creates a Presumption of Utility*

In most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101. See, e.g., *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (CCPA 1965); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977). As the Court of Customs and Patent Appeals stated in *In re Langer*:

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 503 F.2d at 1391, 183 USPQ at 297 (emphasis in original). The "Langer" test for utility has been used by both the Federal Circuit and the Court of Customs and Patent Appeals in evaluation of rejections under 35 U.S.C. 112, first paragraph, where the rejection is based on a deficiency under 35 U.S.C. 101. In *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), the Federal Circuit explicitly adopted the Court of Customs and Patent Appeals's formulation of the "Langer" standard for 35 U.S.C. 112, first paragraph rejections, as it was expressed in a slightly reworded format in *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971), namely:

[A] specification disclosure which contains a teaching of the manner and process of making and using the invention

in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. (emphasis added).

Thus, *Langer* and subsequent cases direct the Office to presume that a statement of utility made by an applicant is true. See *In re Langer*, 503 F.2d at 1391, 183 USPQ at 297; *In re Malachowski*, 530 F.2d 1402, 1404, 189 USPQ 432, 435 (CCPA 1976); *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). For obvious reasons of efficiency and in deference to an applicant's understanding of his or her invention, when a statement of utility is evaluated, Office personnel should not begin by questioning the truth of the statement of utility. Instead, any inquiry must start by asking if there is any reason to question the truth of the statement of utility. This can be done by simply evaluating the logic of the statements made, taking into consideration any evidence cited by the applicant. If the asserted utility is credible (i.e., believable based on the record or the nature of the invention), a rejection based on "lack of utility" is not appropriate. Clearly, Office personnel should not begin an evaluation of utility by assuming that an asserted utility is likely to be false, based on the technical field of the invention or for other general reasons.

Compliance with 35 U.S.C. 101 is a question of fact. *Raytheon v. Roper*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983) *cert. denied*, 469 U.S. 835 (1984). Thus, to overcome the presumption of truth that an assertion of utility by the applicant enjoys, Office personnel must establish that it is more likely than not that one of ordinary skill in the art would doubt (i.e., "question") the truth of the statement of utility. The evidentiary standard to be used throughout *ex parte* examination in setting forth a rejection is a preponderance of the totality of the evidence under consideration. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992): ("After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument."); *In re Corkill*, 771 F.2d 1496, 1500, 226 USPQ 1005, 1008 (Fed. Cir. 1985). A preponder-

ance of the evidence exists when it suggests that it is more likely than not that the assertion in question is true. *Herman v. Huddleston*, 459 U.S. 375, 390 (1983). To do this, Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered “false” by a person of ordinary skill in the art. Of course, a person of ordinary skill must have the benefit of both facts and reasoning in order to assess the truth of a statement. This means that if the applicant has presented facts that support the reasoning used in asserting a utility, Office personnel must present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the applicant’s assertion of utility. *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). The initial evidentiary standard used during evaluation of this question is a preponderance of the evidence (i.e., the totality of facts and reasoning suggest that it is more likely than not that the statement of the applicant is false).

B. When Is an Asserted Utility Not Credible?

Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being “wrong,” even when there may be reason to believe that the assertion is not entirely accurate. Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility.

One situation where an assertion of utility would not be considered credible is where a person of ordinary skill would consider the assertion to be “incredible in view of contemporary knowledge” and where nothing offered by the applicant would counter what contemporary knowledge might otherwise suggest. Office personnel should be careful, however, not to label certain types of inventions as “incredible” or “speculative” as such labels do not provide the correct focus for the evaluation of an assertion of utility.

“Incredible utility” is a conclusion, not a starting point for analysis under 35 U.S.C. 101. A conclusion that an asserted utility is incredible can be reached only after the Office has evaluated both the assertion of the applicant regarding utility and any evidentiary basis of that assertion. The Office should be particularly careful not to start with a presumption that an asserted utility is, *per se*, “incredible” and then proceed to base a rejection under 35 U.S.C. 101 on that presumption.

Rejections under 35 U.S.C. 101 have been rarely sustained by federal courts. Generally speaking, in these rare cases, the 35 U.S.C. 101 rejection was sustained either because the applicant failed to disclose any utility for the invention or asserted a utility that could only be true if it violated a scientific principle, such as the second law of thermodynamics, or a law of nature, or was wholly inconsistent with contemporary knowledge in the art. *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967). Special care therefore should be taken when assessing the credibility of an asserted therapeutic utility for a claimed invention. In such cases, a previous lack of success in treating a disease or condition, or the absence of a proven animal model for testing the effectiveness of drugs for treating a disorder in humans, should not, standing alone, serve as a basis for challenging the asserted utility under 35 U.S.C. 101.

IV. INITIAL BURDEN IS ON THE OFFICE TO ESTABLISH A *PRIMA FACIE* CASE AND PROVIDE EVIDENTIARY SUPPORT THEREOF

To properly reject a claimed invention under 35 U.S.C. 101, the Office must (A) make a *prima facie* showing that the claimed invention lacks utility, and (B) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. *In re Gaubert*, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975) (“Accordingly, the PTO must do more than merely question operability - it must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability.”). If the Office cannot develop a proper *prima facie* case and provide evidentiary support for a rejection under 35 U.S.C. 101, a rejection on this ground should not be imposed. See, e.g., *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) (“[T]he

examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.... If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.”). See also *Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 USPQ 848 (Fed. Cir. 1985) (applying *prima facie* case law to 35 U.S.C. 101); *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984).

The *prima facie* showing must be set forth in a well-reasoned statement. Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

Where the asserted utility is not specific or substantial, a *prima facie* showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The *prima facie* showing must contain the following elements:

(A) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is neither both specific and substantial nor well-established;

(B) Support for factual findings relied upon in reaching this conclusion; and

(C) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

Where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed

invention. The *prima facie* showing must contain the following elements:

(A) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;

(B) Support for factual findings relied upon in reaching this conclusion; and

(C) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

Where no specific and substantial utility is disclosed or is well-established, a *prima facie* showing of no specific and substantial utility need only establish that applicant has not asserted a utility and that, on the record before the examiner, there is no known well-established utility.

It is imperative that Office personnel use specificity in setting forth and initial rejection under 35 U.S.C. 101 and support any factual conclusions made in the *prima facie* showing.

By using specificity, the applicant will be able to identify the assumptions made by the Office in setting forth the rejection and will be able to address those assumptions properly.

V. EVIDENTIARY REQUESTS BY AN EXAMINER TO SUPPORT AN ASSERTED UTILITY

In appropriate situations the Office may require an applicant to substantiate an asserted utility for a claimed invention. See *In re Pottier*, 376 F.2d 328, 330, 153 USPQ 407, 408 (CCPA 1967) (“When the operativeness of any process would be deemed unlikely by one of ordinary skill in the art, it is not improper for the examiner to call for evidence of operativeness.”). See also *In re Jolles*, 628 F.2d 1322, 1327, 206 USPQ 885, 890 (CCPA 1980); *In re Citron*, 325 F.2d 248, 139 USPQ 516 (CCPA 1963); *In re Novak*, 306 F.2d 924, 928, 134 USPQ 335, 337 (CCPA 1962). In *In re Citron*, the court held that when an “alleged utility appears to be incredible in the light of the knowledge of the art, or factually misleading, applicant must establish the asserted utility by acceptable proof.” 325 F.2d at 253, 139 USPQ at 520. The court approved of the board’s decision which affirmed the rejection under 35 U.S.C. 101 “in view of the art knowledge of the lack of a cure for cancer and the

absence of any clinical data to substantiate the allegation.” 325 F.2d at 252, 139 USPQ at 519 (emphasis in original). The court thus established a higher burden on the applicant where the statement of use is incredible or misleading. In such a case, the examiner should challenge the use and require sufficient evidence of operativeness. The purpose of this authority is to enable an applicant to cure an otherwise defective factual basis for the operability of an invention. Because this is a curative authority (e.g., evidence is requested to enable an applicant to support an assertion that is inconsistent with the facts of record in the application), Office personnel should indicate not only why the factual record is defective in relation to the assertions of the applicant, but also, where appropriate, what type of evidentiary showing can be provided by the applicant to remedy the problem.

Requests for additional evidence should be imposed rarely, and only if necessary to support the scientific credibility of the asserted utility (e.g., if the asserted utility is not consistent with the evidence of record and current scientific knowledge). As the Federal Circuit recently noted, “[o]nly after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention’s asserted utility.” *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981)). In *Brana*, the court pointed out that the purpose of treating cancer with chemical compounds does not suggest, *per se*, an incredible utility. Where the prior art disclosed “structurally similar compounds to those claimed by applicants which have been proven *in vivo* to be effective as chemotherapeutic agents against various tumor models . . . , one skilled in the art would be without basis to reasonably doubt applicants’ asserted utility on its face.” 51 F.3d at 1566, 34 USPQ2d at 1441. As courts have stated, “it is clearly improper for the examiner to make a demand for further test data, which as evidence would be essentially redundant and would seem to serve for nothing except perhaps to unduly burden the applicant.” *In re Isaacs*, 347 F.2d 887, 890, 146 USPQ 193, 196 (CCPA 1965).

VI. CONSIDERATION OF A REPLY TO A *PRIMA FACIE* REJECTION FOR LACK OF UTILITY

If a rejection under 35 U.S.C. 101 has been properly imposed, along with a corresponding rejection under 35 U.S.C. 112, first paragraph, the burden shifts to the applicant to rebut the *prima facie* showing. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) (“The examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant. . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.”). An applicant can do this using any combination of the following: amendments to the claims, arguments or reasoning, or new evidence submitted in an affidavit or declaration under 37 CFR 1.132, or in a printed publication. New evidence provided by an applicant must be relevant to the issues raised in the rejection. For example, declarations in which conclusions are set forth without establishing a nexus between those conclusions and the supporting evidence, or which merely express opinions, may be of limited probative value with regard to rebutting a *prima facie* case. *In re Grunwell*, 609 F.2d 486, 203 USPQ 1055 (CCPA 1979); *In re Buchner*, 929 F.2d 660, 18 USPQ2d 1331 (Fed. Cir. 1991). See MPEP § 716.01(a) through § 716.01(c).

If the applicant responds to the *prima facie* rejection, Office personnel should review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained. If the record as a whole would make it more likely than not that the asserted utility for the claimed invention would be considered credible by a person of ordinary skill in the art, the

Office cannot maintain the rejection. *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

VII. EVALUATION OF EVIDENCE RELATED TO UTILITY

There is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted utility, therapeutic or otherwise. Rather, the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed (*Ex parte Ferguson*, 117 USPQ 229 (Bd. App. 1957)), and whether the asserted utility appears to contravene established scientific principles and beliefs. *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967); *In re Chilowsky*, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956). Furthermore, the applicant does not have to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt." *In re Irons*, 340 F.2d 974, 978, 144 USPQ 351, 354 (CCPA 1965). Nor must an applicant provide evidence such that it establishes an asserted utility as a matter of statistical certainty. *Nelson v. Bowler*, 626 F.2d 853, 856-57, 206 USPQ 881, 883-84 (CCPA 1980) (reversing the Board and rejecting Bowler's arguments that the evidence of utility was statistically insignificant. The court pointed out that a rigorous correlation is not necessary when the test is reasonably predictive of the response). See also *Rey-Bellet v. Englehardt*, 493 F.2d 1380, 181 USPQ 453 (CCPA 1974) (data from animal testing is relevant to asserted human therapeutic utility if there is a "satisfactory correlation between the effect on the animal and that ultimately observed in human beings"). Instead, evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true.

2107.03 Special Considerations for Asserted Therapeutic or Pharmacological Utilities

The Federal courts have consistently reversed rejections by the Office asserting a lack of utility for inventions claiming a pharmacological or therapeutic utility where an applicant has provided evidence that reasonably supports such a utility. In view of this,

Office personnel should be particularly careful in their review of evidence provided in support of an asserted therapeutic or pharmacological utility.

I. A REASONABLE CORRELATION BETWEEN THE EVIDENCE AND THE ASSERTED UTILITY IS SUFFICIENT

As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980). An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof. The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted. Instead, as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use. *Nelson v. Bowler*, 626 F.2d 853, 857, 206 USPQ 881, 884 (CCPA 1980).

II. STRUCTURAL SIMILARITY TO COMPOUNDS WITH ESTABLISHED UTILITY

Courts have routinely found evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility as being supportive of an assertion of therapeutic utility for a new compound. In *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980), the claimed compounds were found to have utility based on a finding of a close structural relationship to daunorubicin and doxorubicin and shared pharmacological activity with those compounds, both of which were known to be useful in cancer chemotherapy. The evidence of close structural similarity with the known compounds was presented in conjunction with evidence demonstrating substantial activity of the claimed compounds in animals customarily employed for screening anticancer agents.

Such evidence should be given appropriate weight in determining whether one skilled in the art would find the asserted utility credible. Office personnel should evaluate not only the existence of the structural relationship, but also the reasoning used by the applicant or a declarant to explain why that structural similarity is believed to be relevant to the applicant's assertion of utility.

III. DATA FROM *IN VITRO* OR ANIMAL TESTING IS GENERALLY SUFFICIENT TO SUPPORT THERAPEUTIC UTILITY

If reasonably correlated to the particular therapeutic or pharmacological utility, data generated using *in vitro* assays, or from testing in an animal model or a combination thereof almost invariably will be sufficient to establish therapeutic or pharmacological utility for a compound, composition or process. A cursory review of cases involving therapeutic inventions where 35 U.S.C. 101 was the dispositive issue illustrates the fact that the Federal courts are not particularly receptive to rejections under 35 U.S.C. 101 based on inoperability. Most striking is the fact that in those cases where an applicant supplied a reasonable evidentiary showing supporting an asserted therapeutic utility, almost uniformly the 35 U.S.C. 101-based rejection was reversed. See, e.g., *In re Brana*, 51 F.3d 1560, 34 USPQ 1436 (Fed. Cir. 1995); *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980); *In re Malachowski*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1976); *In re Gaubert*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1975); *In re Gazave*, 379 F.2d 973, 154 USPQ 92 (CCPA 1967); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961). Only in those cases where the applicant was unable to come forward with any relevant evidence to rebut a finding by the Office that the claimed invention was inoperative was a 35 U.S.C. 101 rejection affirmed by the court. *In re Citron*, 325 F.2d 248, 253, 139 USPQ 516, 520 (CCPA 1963) (therapeutic utility for an uncharacterized biological extract not supported or scientifically credible); *In re Buting*, 418 F.2d 540, 543, 163 USPQ 689, 690 (CCPA 1969) (record did not establish a credible basis for the assertion that the single class of compounds in question would be use-

ful in treating disparate types of cancers); *In re Novak*, 306 F.2d 924, 134 USPQ 335 (CCPA 1962) (claimed compounds did not have capacity to effect physiological activity upon which utility claim based). Contrast, however, *In re Buting* to *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973), *reh'g denied*, 480 F.2d 879 (CCPA 1973), in which the court held that utility for a genus was found to be supported through a showing of utility for one species. In no case has a Federal court required an applicant to support an asserted utility with data from human clinical trials.

If an applicant provides data, whether from *in vitro* assays or animal tests or both, to support an asserted utility, and an explanation of why that data supports the asserted utility, the Office will determine if the data and the explanation would be viewed by one skilled in the art as being reasonably predictive of the asserted utility. See, e.g., *Ex parte Maas*, 9 USPQ2d 1746 (Bd. Pat. App. & Inter. 1987); *Ex parte Balzarini*, 21 USPQ2d 1892 (Bd. Pat. App. & Inter. 1991). Office personnel must be careful to evaluate all factors that might influence the conclusions of a person of ordinary skill in the art as to this question, including the test parameters, choice of animal, relationship of the activity to the particular disorder to be treated, characteristics of the compound or composition, relative significance of the data provided and, most importantly, the explanation offered by the applicant as to why the information provided is believed to support the asserted utility. If the data supplied is consistent with the asserted utility, the Office cannot maintain a rejection under 35 U.S.C. 101.

Evidence does not have to be in the form of data from an art-recognized animal model for the particular disease or disease condition to which the asserted utility relates. Data from any test that the applicant reasonably correlates to the asserted utility should be evaluated substantively. Thus, an applicant may provide data generated using a particular animal model with an appropriate explanation as to why that data supports the asserted utility. The absence of a certification that the test in question is an industry-accepted model is not dispositive of whether data from an animal model is in fact relevant to the asserted utility. Thus, if one skilled in the art would accept the animal tests as being reasonably predictive of utility in humans, evidence from those tests should

be considered sufficient to support the credibility of the asserted utility. *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Krimmel*, 292 F.2d 948, 953, 130 USPQ 215, 219 (CCPA 1961); *Ex parte Krepelka*, 231 USPQ 746 (Bd. Pat. App. & Inter. 1986). Office personnel should be careful not to find evidence unpersuasive simply because no animal model for the human disease condition had been established prior to the filing of the application. See *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956) ("The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it."); *In re Wooddy*, 331 F.2d 636, 639, 141 USPQ 518, 520 (CCPA 1964) ("It appears that no one on earth is certain as of the present whether the process claimed will operate in the manner claimed. Yet absolute certainty is not required by the law. The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it.").

IV. HUMAN CLINICAL DATA

Office personnel should not impose on applicants the unnecessary burden of providing evidence from human clinical trials. There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders (see *In re Isaacs*, 347 F.2d 889, 146 USPQ 193 (CCPA 1963); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974)), even with respect to situations where no art-recognized animal models existed for the human disease encompassed by the claims. *Ex parte Balzarini*, 21 USPQ2d 1892 (Bd. Pat. App. & Inter. 1991) (human clinical data is not required to demonstrate the utility of the claimed invention, even though those skilled in the art might not accept other evidence to establish the efficacy of the claimed therapeutic compositions and the operativeness of the claimed methods of treating humans). Before a drug can enter human clinical trials, the sponsor, often the applicant, must provide a convincing rationale to those especially skilled in the art (e.g., the Food and Drug Administration) that the investigation may be successful. Such a rationale would provide a basis for the sponsor's expectation that the investigation may be

successful. In order to determine a protocol for phase I testing, the first phase of clinical investigation, some credible rationale of how the drug might be effective or could be effective would be necessary. Thus, as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility.

V. SAFETY AND EFFICACY CONSIDERATIONS

The Office must confine its review of patent applications to the statutory requirements of the patent law. Other agencies of the government have been assigned the responsibility of ensuring conformance to standards established by statute for the advertisement, use, sale or distribution of drugs. The FDA pursues a two-prong test to provide approval for testing. Under that test, a sponsor must show that the investigation does not pose an unreasonable and significant risk of illness or injury and that there is an acceptable rationale for the study. As a review matter, there must be a rationale for believing that the compound could be effective. If the use reviewed by the FDA is not set forth in the specification, FDA review may not satisfy 35 U.S.C. 101. However, if the reviewed use is one set forth in the specification, Office personnel must be extremely hesitant to challenge utility. In such a situation, experts at the FDA have assessed the rationale for the drug or research study upon which an asserted utility is based and found it satisfactory. Thus, in challenging utility, Office personnel must be able to carry their burden that there is no sound rationale for the asserted utility even though experts designated by Congress to decide the issue have come to an opposite conclusion. "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws." *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994)).

Thus, while an applicant may on occasion need to provide evidence to show that an invention will work as claimed, it is improper for Office personnel to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness. See *In re*

Sichert, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Anthony*, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969); *In re Watson*, 517 F.2d 465, 186 USPQ 11 (CCPA 1975); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961); *Ex parte Jovanovics*, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981).

VI. TREATMENT OF SPECIFIC DISEASE CONDITIONS

Claims directed to a method of treating or curing a disease for which there have been no previously successful treatments or cures warrant careful review for compliance with 35 U.S.C. 101. The credibility of an asserted utility for treating a human disorder may be more difficult to establish where current scientific understanding suggests that such a task would be impossible. Such a determination has always required a good understanding of the state of the art as of the time that the invention was made. For example, prior to the 1980's, there were a number of cases where an asserted use in treating cancer in humans was viewed as "incredible." *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Buting*, 418 F.2d 540, 163 USPQ 689 (CCPA 1969); *Ex parte Stevens*, 16 USPQ2d 1379 (Bd. Pat. App. & Inter. 1990); *Ex parte Busse*, 1 USPQ2d 1908 (Bd. Pat. App. & Inter. 1986); *Ex parte Krepelka*, 231 USPQ 746 (Bd. Pat. App. & Inter. 1986); *Ex parte Jovanovics*, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981). The fact that there is no known cure for a disease, however, cannot serve as the basis for a conclusion that such an invention lacks utility. Rather, Office personnel must determine if the asserted utility for the invention is credible based on the information disclosed in the application. Only those claims for which an asserted utility is not credible should be rejected. In such cases, the Office should carefully review what is being claimed by the applicant. An assertion that the claimed invention is useful in treating a symptom of an incurable disease may be considered credible by a person of ordinary skill in the art on the basis of a fairly modest amount of evidence or support. In contrast, an assertion that the claimed invention will be useful in "curing" the disease may require a significantly greater amount of evidentiary support to be considered credible by a person of ordinary skill in the art. *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Jolles*,

628 F.2d 1322, 206 USPQ 885 (CCPA 1980). See also *Ex parte Ferguson*, 117 USPQ 229 (Bd. Pat. App. & Inter. 1957).

In these cases, it is important to note that the Food and Drug Administration has promulgated regulations that enable a party to conduct clinical trials for drugs used to treat life threatening and severely-debilitating illnesses, even where no alternative therapy exists. See 21 CFR 312.80-88 (1994). Implicit in these regulations is the recognition that experts qualified to evaluate the effectiveness of therapeutics can and often do find a sufficient basis to conduct clinical trials of drugs for incurable or previously untreatable illnesses. Thus, affidavit evidence from experts in the art indicating that there is a reasonable expectation of success, supported by sound reasoning, usually should be sufficient to establish that such a utility is credible.

2111 Claim Interpretation; Broadest Reasonable Interpretation

CLAIMS MUST BE GIVEN THEIR BROADEST REASONABLE INTERPRETATION

During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification." Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969) (Claim 9 was directed to a process of analyzing data generated by mass spectrographic analysis of a gas. The process comprised selecting the data to be analyzed by subjecting the data to a mathematical manipulation. The examiner made rejections under 35 U.S.C. 101 and 102. In the 35 U.S.C. 102 rejection, the examiner explained that the claim was anticipated by a mental process augmented by pencil and paper markings. The court agreed that the claim was not limited to using a machine to carry out the process since the claim did not explicitly set forth the machine. The court explained that "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from 'reading limitations of the specification into a claim,' to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have

no express basis in the claim.” The court found that applicant was advocating the latter, i.e., the impermissible importation of subject matter from the specification into the claim.). See also *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) (The court held that the PTO is not required, in the course of prosecution, to interpret claims in applications in the same manner as a court would interpret claims in an infringement suit. Rather, the “PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant’s specification.”).

The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999) (The Board’s construction of the claim limitation “restore hair growth” as requiring the hair to be returned to its original state was held to be an unreasonably broad interpretation of the limitation. The court held that, consistent with applicant’s disclosure and the disclosure of three patents from analogous arts using the same phrase to require only some increase in hair growth, one of ordinary skill would construe “restore hair growth” to mean that the claimed method increases the amount of hair grown on the scalp, but does not necessarily produce a full head of hair.).

2111.01 Plain Meaning

THE WORDS OF A CLAIM MUST BE GIVEN THEIR “PLAIN MEANING” UNLESS THEY ARE DEFINED IN THE SPECIFICATION

While the meaning of claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)

(discussed below). One must bear in mind that, especially in nonchemical cases, the words in a claim are generally not limited in their meaning by what is shown or disclosed in the specification. It is only when the specification provides definitions for terms appearing in the claims that the specification can be used in interpreting claim language. *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970). There is one exception, and that is when an element is claimed using language falling under the scope of 35 U.S.C. 112, 6th paragraph (often broadly referred to as means or step plus function language). In that case, the specification must be consulted to determine the structure, material, or acts corresponding to the function recited in the claim. *In re Donaldson*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994) (see MPEP § 2181- § 2186).

In *In re Zletz*, *supra*, the examiner and the Board had interpreted claims reading “normally solid polypropylene” and “normally solid polypropylene having a crystalline polypropylene content” as being limited to “normally solid linear high homopolymers of propylene which have a crystalline polypropylene content.” The court ruled that limitations, not present in the claims, were improperly imported from the specification. See also *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) (“Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their ‘broadest reasonable interpretation.’” 710 F.2d at 802, 218 USPQ at 292 (quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)) (emphasis in original). The court looked to the specification to construe “essentially free of alkali metal” as including unavoidable levels of impurities but no more.). Compare *In re Weiss*, 989 F.2d 1202, 26 USPQ2d 1885 (Fed. Cir. 1993) (unpublished decision - cannot be cited as precedent) (The claim related to an athletic shoe with cleats that “break away at a preselected level of force” and thus prevent injury to the wearer. The examiner rejected the claims over prior art teaching athletic shoes with cleats not intended to break off and rationalized that the cleats would break away given a high enough force. The court reversed the rejection stating that when interpreting a claim term which is ambiguous, such as ‘a preselected level of force,’ we must look to the specification for the meaning ascribed to that term by the

inventor.” The specification had defined “preselected level of force...” as that level of force at which the breaking away will prevent injury to the wearer during athletic exertion. It should be noted that the limitation was part of a means plus function element.)

“PLAIN MEANING” REFERS TO THE MEANING GIVEN TO THE TERM BY THOSE OF ORDINARY SKILL IN THE ART

When not defined by applicant in the specification, the words of a claim must be given their plain meaning. In other words, they must be read as they would be interpreted by those of ordinary skill in the art. *In re Sneed*, 710 F.2d 1544, 218 USPQ 385 (Fed. Cir. 1983) (The applicants had argued in an amendment after final rejection that the term “flexible plastic pipe,” as used in the claims, pertained only to pipes of 2-inch diameter and 3-inch diameter and not to a pipe of 1.5 inch diameter. This definition of “flexible” was also advanced in an affidavit. The prior art, however, described 1.5 inch pipe as flexible. The court held that the specification and the evidence (the prior art) failed to support the gloss appellants sought to put on the term “flexible.” Note that applicant had not defined “flexible plastic pipe” in the specification.); *In re Barr*, 444 F.2d 588, 597, 170 USPQ 330, 339 (CCPA 1971) (“The specification in this case attempts no definition of the claim language ‘a phenyl radical.’ Accordingly we must presume that the phrase was used in its commonly accepted technical sense.... [Applicants] have not referred us to any standard work on chemistry which indicates that the commonly accepted technical meaning of the words ‘a phenyl radical’, without more, would encompass the hydroxyphenyl radical. On the contrary, Hackh’s [Chemical Dictionary] quite plainly defines ‘phenyl’ as ‘the monovalent radical... derived from benzene... or phenol.’”).

APPLICANT MAY BE OWN LEXICOGRAPHER

Applicant may be his or her own lexicographer as long as the meaning assigned to the term is not repugnant to the term’s well known usage. *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). Any special meaning assigned to a term “must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of

experience in the field of the invention.” *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998).

2111.02 Weight of Preamble

“[A] claim preamble has the import that the claim as a whole suggests for it.” *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). “If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is ‘necessary to give life, meaning, and vitality’ to the claim, then the claim preamble should be construed as if in the balance of the claim.” *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (A preamble reciting “An abrasive article” was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated “it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an ‘abrasive article.’” Therefore, the preamble served to further define the structure of the article produced.)

PREAMBLE STATEMENTS LIMITING STRUCTURE

Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application “to gain an understanding of what the inventors actually invented and intended to encompass by the claim.”); *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention). See also *In re Stencel*, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987). (The claim at issue was directed to a driver for

setting a joint of a threaded collar, however the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. “[T]he framework - the teachings of the prior art - against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited.” *Id.* at 1073, 828 F.2d at 754.)

PREAMBLE STATEMENTS RECITING PURPOSE OR INTENDED USE

The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use “can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim.” *Corning Glass Works*, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention’s limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) (“where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation”); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim); *STX LLC v. Brine*, 211 F.3d 588, 591, 54 USPQ2d 1347, 1350 (Fed. Cir. 2000) (holding that the preamble phrase “which provides improved playing and handling characteristics” in a claim drawn to a head for a lacrosse stick was not a claim limitation).

During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim did not distinguish over the prior art apparatus). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board’s factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant’s claim 1 (a dispensing top for dispensing popcorn in a specified manner)) and cases cited therein. See also MPEP § 2112 - § 2112.02.

2111.03 Transitional Phrases

The transitional phrases “comprising”, “consisting essentially of” and “consisting of” define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.

The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981);

Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”).

The transitional phrase “consisting of” excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“consisting of” defined as “closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.”). A claim which depends from a claim which “consists of” the recited elements or steps cannot add an element or step. When the phrase “consists of” appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986).

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid “consisting essentially of” certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants’ specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). “A ‘consisting essentially of’ claim occupies a middle ground between closed claims that are written in a ‘consisting of’ format and fully open claims that are drafted in a ‘comprising’ format.” *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137

USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 (“PPG could have defined the scope of the phrase ‘consisting essentially of’ for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.”). See also *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) (“Although ‘consisting essentially of’ is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant’s burden to establish that a step practiced in a prior art method is excluded from his claims by ‘consisting essentially of’ language.”).

OTHER TRANSITIONAL PHRASES

Transitional phrases such as “having” must be interpreted in light of the specification to determine whether open or closed claim language is intended. See, e.g., *Lampi Corp. v. American Power Products Inc.*, 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000) (The term “having” was interpreted as open terminology, allowing the inclusion of other components in addition to those recited); *Crystal Semiconductor Corp. v. TriTech Microelectronics Int’l Inc.*, 246 F.3d 1336, 1348, 57 USPQ2d 1953, 1959

(Fed. Cir. 2001) (term “having” in transitional phrase “does not create a presumption that the body of the claim is open”); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997) (In the context of a cDNA having a sequence coding for human PI, the term “having” still permitted inclusion of other moieties.). The transitional phrase “composed of” has been interpreted in the same manner as either “consisting of” or “consisting essentially of,” depending on the facts of the particular case. See *AFG Industries, Inc. v. Cardinal IG Company*, 239 F.3d 1239, 1245, 57 USPQ2d 1776, 1780-81 (Fed. Cir. 2001) (based on specification and other evidence, “composed of” interpreted in same manner as “consisting essentially of”); *In re Bertsch*, 132 F.2d 1014, 1019-20, 56 USPQ 379, 384 (CCPA 1942) (“Composed of” interpreted in same manner as “consisting of”; however, court further remarked that “the words ‘composed of’ may under certain circumstances be given, in patent law, a broader meaning than ‘consisting of.’”).

2112 Requirements of Rejection Based on Inherency; Burden of Proof

The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. “The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness.” *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103.

A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. “There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.” *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

EXAMINER MUST PROVIDE RATIONALE OR EVIDENCE TENDING TO SHOW INHERENCY

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the refer-

ence did not disclose a separate third fastening element, either expressly or inherently.).

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

In *In re Schreiber*, 128 F.3d 1473, 44 USPQ2d 1429 (Fed. Cir. 1997), the court affirmed a finding that a prior patent to a conical spout used primarily to dispense oil from an oil can inherently performed the functions recited in applicant's claim to a conical container top for dispensing popped popcorn. The examiner had asserted inherency based on the structural similarity between the patented spout and applicant's disclosed top, i.e., both structures had the same general shape. The court stated:

[N]othing in Schreiber's [applicant's] claim suggests that Schreiber's container is of a 'different shape' than Harz's [patent]. In fact, [] an embodiment according to Harz (Fig. 5) and the embodiment depicted in Fig. 1 of Schreiber's application have the same general shape. For that reason, the examiner was justified in concluding that the opening of a conically shaped top as disclosed by Harz is inherently of a size sufficient to 'allow [] several kernels of popped popcorn to pass through at the same time' and that the taper of Harz's conically shaped top is inherently of such a shape 'as to by itself jam up the popped popcorn before the end of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted to the container.' The examiner

therefore correctly found that Harz established a prima facie case of anticipation.

In re Schreiber, 128 F.3d at 1478, 44 USPQ2d at 1432.

ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBTAINABLE DIFFERENCE

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

In *In re Fitzgerald*, the claims were directed to a self-locking screw-threaded fastener comprising a metallic threaded fastener having patches of crystallizable thermoplastic bonded thereto. The claim further specified that the thermoplastic had a reduced degree of crystallization shrinkage. The specification disclosed that the locking fastener was made by heating the metal fastener to melt a thermoplastic blank which is pressed against the metal. After the thermoplastic adheres to the metal fastener, the end product is cooled by quenching in water. The examiner made a rejection based on a U.S. patent to Barnes. Barnes taught a self-locking fastener in which the patch of thermoplastic was made by depositing thermoplastic powder on a metallic fastener which was then heated. The end product was cooled in ambient air, by cooling air or by contacting the fastener with a water trough. The court first noted that the two fasteners were identical or only slightly different from each other. "Both fasteners possess the same utility, employ the same crystallizable polymer (nylon 11), and have an adherent plastic patch formed by melting and then cooling the polymer." *Id.* at 596 n.1, 619 F.2d at 70 n.1. The

court then noted that the Board had found that Barnes' cooling rate could reasonably be expected to result in a polymer possessing the claimed crystallization shrinkage rate. Applicants had not rebutted this finding with evidence that the shrinkage rate was indeed different. They had only argued that the crystallization shrinkage rate was dependent on the cool down rate and that the cool down rate of Barnes was much slower than theirs. Because a difference in the cool down rate does not necessarily result in a difference in shrinkage, objective evidence was required to rebut the 35 U.S.C. 102/103 *prima facie* case.

In *In re Schreiber*, 128 F.3d 1473, 1478, 44 USPQ2d 1429, 1432 (Fed.Cir.1997), the court held that applicant's declaration failed to overcome a *prima facie* case of anticipation because the declaration did not specify the dimensions of either the dispensing top that was tested or the popcorn that was used. Applicant's declaration merely asserted that a conical dispensing top built according to a figure in the prior art patent was too small to jam and dispense popcorn and thus could not inherently perform the functions recited in applicant's claims. The court pointed out the disclosure of the prior art patent was not limited to use as an oil can dispenser, but rather was broader than the precise configuration shown in the patent's figure. The court also noted that the Board of Patent Appeals and Interferences found as a factual matter that a scaled-up version of the top disclosed in the patent would be capable of performing the functions recited in applicant's claim.

See MPEP § 2113 for more information on the analogous burden of proof applied to product-by-process claims.

2112.01 Composition, Product, and Apparatus Claims

PRODUCT AND APPARATUS CLAIMS — WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT

Where the claimed and prior art products are identical or substantially identical in structure or composi-

tion, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.).

See also *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971) (Claim 1 was directed to a parachute canopy having concentric circumferential panels radially separated from each other by radially extending tie lines. The panels were separated "such that the critical velocity of each successively larger panel will be less than the critical velocity of the previous panel, whereby said parachute will sequentially open and thus gradually decelerate." The court found that the claim was anticipated by Menget. Menget taught a parachute having three circumferential panels separated by tie lines. The court upheld the rejection finding that applicant had failed to show that Menget did not possess the functional characteristics of the claims.); *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) (A patent to a pencil for cleaning fingernails was held invalid because a pencil of the same structure for writing was found in the prior art.).

COMPOSITION CLAIMS - IF THE COMPOSITION IS PHYSICALLY THE SAME, IT MUST HAVE THE SAME PROPERTIES

"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a *prima facie* case of unpatentability of Spada's polymer latexes for lack of novelty.").

2112.02 Process Claims

PROCESS CLAIMS - PRIOR ART DEVICE ANTICIPATES A CLAIMED PROCESS IF THE DEVICE CARRIES OUT THE PROCESS DURING NORMAL OPERATION

Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986) (The claims were directed to a method of enhancing color effects produced by ambient light through a process of absorption and reflection of the light off a coated substrate. A prior art reference to *Donley* disclosed a glass substrate coated with silver and metal oxide 200-800 angstroms thick. While *Donley* disclosed using the coated substrate to produce architectural colors, the absorption and reflection mechanisms of the claimed process were not disclosed. However, *King's* specification disclosed using a coated substrate of *Donley's* structure for use in his process. The Federal Circuit upheld the Board's finding that "*Donley* inherently performs the function disclosed in the method claims on appeal when that device is used in 'normal and usual operation' " and found that a *prima*

facie case of anticipation was made out. *Id.* at 138, 801 F.2d at 1326. It was up to applicant to prove that *Donley's* structure would not perform the claimed method when placed in ambient light.). See also *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) (Applicant claimed a process for preparing a hydrolytically-stable zeolitic aluminosilicate which included a step of "cooling the steam zeolite ... at a rate sufficiently rapid that the cooled zeolite exhibits a X-ray diffraction pattern" All the process limitations were expressly disclosed by a U.S. patent to *Hansford* except the cooling step. The court stated that any sample of *Hansford's* zeolite would necessarily be cooled to facilitate subsequent handling. Therefore, a *prima facie* case under 35 U.S.C. 102/103 was made. Applicant had failed to introduce any evidence comparing X-ray diffraction patterns showing a difference in cooling rate between the claimed process and that of *Hansford* or any data showing that the process of *Hansford* would result in a product with a different X-ray diffraction. Either type of evidence would have rebutted the *prima facie* case under 35 U.S.C. 102. A further analysis would be necessary to determine if the process was unobvious under 35 U.S.C. 103.); *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to *Dart* disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. *Dart* was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.).

PROCESS OF USE CLAIMS - NEW AND UN-OBVIOUS USES OF OLD STRUCTURES AND COMPOSITIONS MAY BE PATENTABLE

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or

structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (Claims 1 and 6, directed to a method of effecting nonaddictive analgesia (pain reduction) in animals, were found to be anticipated by the applied prior art which disclosed the same compounds for effecting analgesia but which was silent as to addiction. The court upheld the rejection and stated that the applicants had merely found a new property of the compound and such a discovery did not constitute a new use. The court went on to reverse the rejection of claims 2-5 and 7-10 which recited a process of using a new compound. The court relied on evidence showing that the nonaddictive property of the new compound was unexpected.). See also *In re Tomlinson*, 363 F.2d 928, 150 USPQ 623 (CCPA 1966) (The claim was directed to a process of inhibiting light degradation of polypropylene by mixing it with one of a genus of compounds, including nickel dithiocarbamate. A reference taught mixing polypropylene with nickel dithiocarbamate to lower heat degradation. The court held that the claims read on the obvious process of mixing polypropylene with the nickel dithiocarbamate and that the preamble of the claim was merely directed to the result of mixing the two materials. "While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." 363 F.2d at 934, 150 USPQ at 628 (emphasis in original).).

2113 Product-by-Process Claims

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the

developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

ONCE A PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS FOUND AND A 35 U.S.C. 102/103 REJECTION MADE, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBTAINABLE DIFFERENCE

"The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by mixing together various inorganic materials in solution and heating the resultant gel to form a crystalline metal silicate essentially free of alkali metal. The prior art described a process of making a zeolite which, after ion exchange to remove alkali metal, appeared to be "essentially free of alkali metal." The court upheld the rejection because the applicant had not come forward with any evidence that the prior art was not "essentially free of alkali metal" and therefore a different and unobvious product.).

Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (The prior art disclosed human nerve growth factor (b-NGF) isolated from human placental tissue. The claim was directed to b-NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced through genetic engi-

neering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an unobvious difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish unexpected properties since the materials appeared to be identical or only slightly different.).

THE USE OF 35 U.S.C. 102/103 REJECTIONS FOR PRODUCT-BY-PROCESS CLAIMS HAS BEEN APPROVED BY THE COURTS

“[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

2114 Apparatus and Article Claims - Functional Language

For a discussion of case law which provides guidance in interpreting the functional portion of means-plus-function limitations see MPEP § 2181 - § 2186.

APPARATUS CLAIMS MUST BE STRUCTURALLY DISTINGUISHABLE FROM THE PRIOR ART

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device *is*, not what a device *does*.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464,

1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original)

MANNER OF OPERATING THE DEVICE DOES NOT DIFFERENTIATE APPARATUS CLAIM FROM THE PRIOR ART

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) (The preamble of claim 1 recited that the apparatus was “for mixing flowing developer material” and the body of the claim recited “means for mixing ..., said mixing means being stationary and completely submerged in the developer material”. The claim was rejected over a reference which taught all the structural limitations of the claim for the intended use of mixing flowing developer. However, the mixer was only partially submerged in the developer material. The Board held that the amount of submersion is immaterial to the structure of the mixer and thus the claim was properly rejected.).

A PRIOR ART DEVICE CAN PERFORM ALL THE FUNCTIONS OF THE APPARATUS CLAIM AND STILL NOT ANTICIPATE THE CLAIM

Even if the prior art device performs all the functions recited in the claim, the prior art cannot anticipate the claim if there is any structural difference. It should be noted, however, that means plus function limitations are met by structures which are equivalent to the corresponding structures recited in the specification. *In re Ruskin*, 347 F.2d 843, 146 USPQ 211 (CCPA 1965) as implicitly modified by *In re Donaldson*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994). See also *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.).

2115 Material or Article Worked Upon by Apparatus

MATERIAL OR ARTICLE WORKED UPON DOES NOT LIMIT APPARATUS CLAIMS

"Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." *In re Young*, 75 F.2d 966, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

In *In re Young*, a claim to a machine for making concrete beams included a limitation to the concrete reinforced members made by the machine as well as the structural elements of the machine itself. The court held that the inclusion of the article formed within the body of the claim did not, without more, make the claim patentable.

In *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967), an apparatus claim recited "[a] taping machine comprising a supporting structure, a brush attached to said supporting structure, said brush being formed with projecting bristles which terminate in free ends to collectively define a surface to which adhesive tape will detachably adhere, and means for providing relative motion between said brush and said supporting structure while said adhesive tape is adhered to said surface." An obviousness rejection was made over a reference to Kienzle which taught a machine for perforating sheets. The court upheld the rejection stating that "the references in claim 1 to adhesive tape handling do not expressly or impliedly require any particular structure in addition to that of Kienzle." The perforating device had the structure of the taping device as claimed, the difference was in the use of the device, and "the manner or method in which such machine is to be utilized is not germane to the issue of patentability of the machine itself."

Note that this line of cases is limited to claims directed to machinery which works upon an article or material in its intended use. It does not apply to product claims or kit claims (i.e., claims directed to a plurality of articles grouped together as a kit).

2116 Material Manipulated in Process

The materials on which a process is carried out must be accorded weight in determining the patentability of a process. *Ex parte Leonard*, 187 USPQ 122 (Bd. App. 1974).

2116.01 Novel, Unobvious Starting Material or End Product

All the limitations of a claim must be considered when weighing the differences between the claimed invention and the prior art in determining the obviousness of a process or method claim. See MPEP § 2143.03.

In re Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996) addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product. In both cases, the Federal Circuit held that the use of *per se* rules is improper in applying the test for obviousness under 35 U.S.C. 103. Rather, 35 U.S.C. 103 requires a highly fact-dependent analysis involving taking the claimed subject matter as a whole and comparing it to the prior art. To support a rejection under 35 U.S.C. 103, the collective teachings of the prior art must have suggested to one of ordinary skill in the art that, at the time the invention was made, applicant's claimed invention would have been obvious. In applying this test to the claims on appeal in *Ochiai* and *Brouwer*, the court held that there simply was no suggestion or motivation in the prior art to make or use novel, nonobvious products in the claimed processes. Consequently, the court overturned the rejections based upon 35 U.S.C. 103.

Interpreting the claimed invention as a whole requires consideration of all claim limitations. Thus, proper claim construction requires treating language in a process claim which recites the making or using of a nonobvious product as a material limitation. Motivation to make or use the nonobvious product must be present in the prior art for a 35 U.S.C. 103 rejection to be sustained. The decision in *Ochiai* specifically dispelled any distinction between processes of making a product and methods of using a product with regard to the effect of any product limitations in either type of claim.

As noted in *Brouwer*, 77 F.3d at 425, 37 USPQ2d at 1666, the inquiry as to whether a claimed invention would have been obvious is “highly fact-specific by design”. Accordingly, obviousness must be assessed on a case-by-case basis. The following decisions are illustrative of the lack of *per se* rules in applying the test for obviousness under 35 U.S.C. 103 and of the fact-intensive comparison of claimed processes with the prior art: *In re Durden*, 763 F.2d 1406, 226 USPQ 359 (Fed. Cir. 1985) (The examiner rejected a claim directed to a process in which patentable starting materials were reacted to form patentable end products. The prior art showed the same chemical reaction mechanism applied to other chemicals. The court held that the process claim was obvious over the prior art.); *In re Albertson*, 332 F.2d 379, 141 USPQ 730 (CCPA 1964) (Process of chemically reducing one novel, nonobvious material to obtain another novel, nonobvious material was claimed. The process was held obvious because the reduction reaction was old.); *In re Kanter*, 399 F.2d 249, 158 USPQ 331 (CCPA 1968) (Process of siliconizing a patentable base material to obtain a patentable product was claimed. Rejection based on prior art teaching the siliconizing process as applied to a different base material was upheld.); Cf. *In re Pleuddemann*, 910 F.2d 823, 15 USPQ2d 1738 (Fed. Cir. 1990) (Methods of bonding polymer and filler using a novel silane coupling agent held patentable even though methods of bonding using other silane coupling agents were well known because the process could not be conducted without the new agent); *In re Kuehl*, 475 F.2d 658, 177 USPQ 250 (CCPA 1973) (Process of cracking hydrocarbons using novel zeolite catalyst found to be patentable even though catalytic cracking process was old. “The test under 103 is whether in view of the prior art the invention as a whole would have been obvious at the time it was made, and the prior art here does not include the zeolite, ZK-22. The obviousness of the process of cracking hydrocarbons with ZK-22 as a catalyst must be determined without reference to knowledge of ZK-22 and its properties.” 475 F.2d at 664-665, 177 USPQ at 255.); and *In re Mancy*, 499 F.2d 1289, 182 USPQ 303 (CCPA 1974) (Claim to a process for the production of a known antibiotic by cultivating a novel, unobvious microorganism was found to be patentable.).

2121 Prior Art; General Level of Operability Required to Make a *Prima Facie* Case

PRIOR ART IS PRESUMED TO BE OPERABLE/ ENABLING

When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07.

WHAT CONSTITUTES AN “ENABLING DISCLOSURE” DOES NOT DEPEND ON THE TYPE OF PRIOR ART THE DISCLOSURE IS CONTAINED IN

The level of disclosure required within a reference to make it an “enabling disclosure” is the same no matter what type of prior art is at issue. It does not matter whether the prior art reference is a U.S. patent, foreign patent, a printed publication or other. There is no basis in the statute (35 U.S.C. 102 or 103) for discriminating either in favor of or against prior art references on the basis of nationality. *In re Moreton*, 288 F.2d 708, 129 USPQ 227 (CCPA 1961).

2121.01 Use of Prior Art in Rejections Where Operability Is in Question

“In determining that quantum of prior art disclosure which is necessary to declare an applicant’s invention ‘not novel’ or ‘anticipated’ within section 102, the stated test is whether a reference contains an ‘enabling disclosure’... ” *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). A reference contains an “enabling disclosure” if the public was in possession of the claimed invention before the date of invention. “Such possession is effected if one of ordinary skill in the art could have combined the publication’s description of the invention with his [or her] own knowledge to make the claimed invention.” *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

I. 35 U.S.C. 102 REJECTIONS AND ADDITION OF EVIDENCE SHOWING REFERENCE IS OPERABLE

It is possible to make a 35 U.S.C. 102 rejection even if the reference does not itself teach one of ordinary skill how to practice the invention, i.e., how to make or use the article disclosed. If the reference teaches every claimed element of the article, secondary evidence, such as other patents or publications, can be cited to show public possession of the method of making and/or using. *In re Donohue*, 766 F.2d at 533, 226 USPQ at 621. See MPEP § 2131.01 for more information on 35 U.S.C. 102 rejections using secondary references to show that the primary reference contains an "enabling disclosure."

II. 35 U.S.C. 103 REJECTIONS AND USE OF INOPERATIVE PRIOR ART

"Even if a reference discloses an inoperative device, it is prior art for all that it teaches." *Beckman Instruments v. LKB Produkter AB*, 892 F.2d 1547, 1551, 13 USPQ2d 1301, 1304 (Fed. Cir. 1989). Therefore, "a non-enabling reference may qualify as prior art for the purpose of determining obviousness under 35 U.S.C. 103." *Symbol Technologies Inc. v. Opticon Inc.*, 935 F.2d 1569, 1578, 19 USPQ2d 1241, 1247 (Fed. Cir. 1991).

2121.02 Compounds and Compositions - What Constitutes Enabling Prior Art

ONE OF ORDINARY SKILL IN THE ART MUST BE ABLE TO MAKE OR SYNTHESIZE

Where a process for making the compound is not developed until after the date of invention, the mere naming of a compound in a reference, without more, cannot constitute a description of the compound. *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). Note, however, that a reference is presumed operable until applicant provides facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). Therefore, applicant must provide evidence showing that a process for making was not known at the time of the invention. See the following paragraph for the evidentiary standard to be applied.

A REFERENCE DOES NOT CONTAIN AN "ENABLING DISCLOSURE" IF ATTEMPTS AT MAKING THE COMPOUND OR COMPOSITION WERE UNSUCCESSFUL BEFORE THE DATE OF INVENTION

When a prior art reference merely discloses the structure of the claimed compound, evidence showing that attempts to prepare that compound were unsuccessful before the date of invention will be adequate to show inoperability. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1971). However, the fact that an author of a publication did not attempt to make the compound disclosed, without more, will not overcome a rejection based on that publication. *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) (In this case, the examiner had made a rejection under 35 U.S.C. 102(b) over a publication, which disclosed the claimed compound, in combination with two patents teaching a general process of making the particular class of compounds. The applicant submitted an affidavit stating that the authors of the publication had not actually synthesized the compound. The court held that the fact that the publication's author did not synthesize the disclosed compound was immaterial to the question of reference operability. The patents were evidence that synthesis methods were well known. The court distinguished *Wiggins*, in which a very similar rejection was reversed. In *Wiggins*, attempts to make the compounds using the prior art methods were all unsuccessful.). Compare *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968) (A claim to a compound was rejected over a patent to *De Boer* which disclosed compounds similar in structure to those claimed (obvious homologs) and a process of making these compounds. Applicant responded with an affidavit by an expert named Wiley which stated that there was no indication in the *De Boer* patent that the process disclosed in *De Boer* could be used to produce the claimed compound and that he did not believe that the process disclosed in *De Boer* could be adapted to the production of the claimed compound. The court held that the facts stated in this affidavit were legally sufficient to overcome the rejection and that applicant need not show that all known processes are incapable of producing the claimed compound for this showing would be practically impossible.).

2121.03 Plant Genetics - What Constitutes Enabling Prior Art

THOSE OF ORDINARY SKILL MUST BE ABLE TO GROW AND CULTIVATE THE PLANT

When the claims are drawn to plants, the reference, combined with knowledge in the prior art, must enable one of ordinary skill in the art to reproduce the plant. *In re LeGrice*, 301 F.2d 929, 133 USPQ 365 (CCPA 1962) (National Rose Society Annual of England and various other catalogues showed color pictures of the claimed roses and disclosed that applicant had raised the roses. The publications were published more than 1 year before applicant's filing date. The court held that the publications did not place the rose in the public domain. Information on the grafting process required to reproduce the rose was not included in the publications and such information was necessary for those of ordinary skill in the art (plant breeders) to reproduce the rose.). Compare *Ex parte Thomson*, 24 USPQ2d 1618 (Bd. Pat. App. & Inter. 1992) (Seeds were commercially available more than 1 year prior to applicant's filing date. One of ordinary skill in the art could grow the claimed cotton cultivar from the commercially available seeds. Thus, the publications describing the cotton cultivar had "enabled disclosures." The Board distinguished *In re LeGrice* by finding that the catalogue picture of the rose of *In re LeGrice* was the only evidence in that case. There was no evidence of commercial availability in enabling form since the asexually reproduced rose could not be reproduced from seed. Therefore, the public would not have possession of the rose by its picture alone, but the public would have possession of the cotton cultivar based on the publications and the availability of the seeds.).

2121.04 Apparatus and Articles - What Constitutes Enabling Prior Art

PICTURES MAY CONSTITUTE AN "ENABLING DISCLOSURE"

Pictures and drawings may be sufficiently enabling to put the public in the possession of the article pictured. Therefore, such an enabling picture may be used to reject claims to the article. However, the pic-

ture must show all the claimed structural features and how they are put together. *Jockmus v. Leviton*, 28 F.2d 812 (2d Cir. 1928). See also MPEP § 2125 for a discussion of drawings as prior art.

2122 Discussion of Utility in the Prior Art

UTILITY NEED NOT BE DISCLOSED IN REFERENCE

In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. *In re Schoenwald*, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992) (The application claimed compounds used in ophthalmic compositions to treat dry eye syndrome. The examiner found a printed publication which disclosed the claimed compound but did not disclose a use for the compound. The court found that the claim was anticipated since the compound and a process of making it was taught by the reference. The court explained that "no utility need be disclosed for a reference to be anticipatory of a claim to an old compound." 964 F.2d at 1124, 22 USPQ2d at 1673. It is enough that the claimed compound is taught by the reference.).

2123 Rejection Over Prior Art's Broad Disclosure Instead of Preferred Embodiments

PATENTS ARE RELEVANT AS PRIOR ART FOR ALL THEY CONTAIN

"The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)).

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361,

47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").

NONPREFERRED EMBODIMENTS CONSTITUTE PRIOR ART

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.).

2124 Exception to the Rule That the Critical Reference Date Must Precede the Filing Date

IN SOME CIRCUMSTANCES A FACTUAL REFERENCE NEED NOT ANTEDATE THE FILING DATE

In certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. *In re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism. Some specific examples in which later publications showing factual evidence can be cited

include situations where the facts shown in the reference are evidence "that, as of an application's filing date, undue experimentation would have been required, *In re Corneil*, 347 F.2d 563, 568, 145 USPQ 702, 705 (CCPA 1965), or that a parameter absent from the claims was or was not critical, *In re Rainer*, 305 F.2d 505, 507 n.3, 134 USPQ 343, 345 n.3 (CCPA 1962), or that a statement in the specification was inaccurate, *In re Marzocchi*, 439 F.2d 220, 223 n.4, 169 USPQ 367, 370 n.4 (CCPA 1971), or that the invention was inoperative or lacked utility, *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974), or that a claim was indefinite, *In re Glass*, 492 F.2d 1228, 1232 n.6, 181 USPQ 31, 34 n.6 (CCPA 1974), or that characteristics of prior art products were known, *In re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962)." *In re Koller*, 613 F.2d 819, 823 n.5, 204 USPQ 702, 706 n.5 (CCPA 1980) (quoting *In re Hogan*, 559 F.2d 595, 605 n.17, 194 USPQ 527, 537 n.17 (CCPA 1977) (emphasis in original)). However, it is impermissible to use a later factual reference to determine whether the application is enabled or described as required under 35 U.S.C. 112, first paragraph. *In re Koller*, 613 F.2d 819, 823 n. 5, 204 USPQ 702, 706 n.5 (CCPA 1980). References which do not qualify as prior art because they post-date the claimed invention may be relied upon to show the level of ordinary skill in the art at or around the time the invention was made. *Ex parte Erlich*, 22 USPQ 1463 (Bd. Pat. App. & Inter. 1992).

2125 Drawings as Prior Art

DRAWINGS CAN BE USED AS PRIOR ART

Drawings and pictures can anticipate claims if they clearly show the structure which is claimed. *In re Mraz*, 455 F.2d 1069, 173 USPQ 25 (CCPA 1972). However, the picture must show all the claimed structural features and how they are put together. *Jockmus v. Leviton*, 28 F.2d 812 (2d Cir. 1928). The origin of the drawing is immaterial. For instance, drawings in a design patent can anticipate or make obvious the claimed invention as can drawings in utility patents. When the reference is a utility patent, it does not matter that the feature shown is unintended or unexplained in the specification. The drawings must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art. *In re Aslanian*,

590 F.2d 911, 200 USPQ 500 (CCPA 1979). See MPEP § 2121.04 for more information on prior art drawings as “enabled disclosures.”

PROPORTIONS OF FEATURES IN A DRAWING ARE NOT EVIDENCE OF ACTUAL PROPORTIONS WHEN DRAWINGS ARE NOT TO SCALE

When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. See *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000) (The disclosure gave no indication that the drawings were drawn to scale. “[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.”). However, the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art. *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977) (“We disagree with the Solicitor’s conclusion, reached by a comparison of the relative dimensions of appellant’s and *Bauer*’s drawing figures, that *Bauer* ‘clearly points to the use of a chime length of roughly 1/2 to 1 inch for a whiskey barrel.’ This ignores the fact that *Bauer* does not disclose that his drawings are to scale. ... However, we agree with the Solicitor that *Bauer*’s teaching that whiskey losses are influenced by the distance the liquor needs to ‘traverse the pores of the wood’ (albeit in reference to the thickness of the barrelhead)” would have suggested the desirability of an increased chime length to one of ordinary skill in the art bent on further reducing whiskey losses.” 569 F.2d at 1127, 193 USPQ at 335-36.)

2126 Availability of a Document as a “Patent” for Purposes of Rejection Under 35 U.S.C. 102(a), (b), and (d)

THE NAME “PATENT” ALONE DOES NOT MAKE A DOCUMENT AVAILABLE AS A PRIOR ART PATENT UNDER 35 U.S.C. 102(a) or (b)

What a foreign country designates to be a patent may not be a patent for purposes of rejection under 35 U.S.C. 102(a) and (b); it is the substance of the rights conferred and the way information within the “patent” is controlled that is determinative. *In re Ekenstam*, 256 F.2d 321, 118 USPQ 349 (CCPA 1958). See the next paragraph for further explanation with respect to when a document can be applied in a rejection as a “patent.” See MPEP § 2135.01 for a further discussion of the use of “patents” in 35 U.S.C. 102(d) rejections.

A SECRET PATENT IS NOT AVAILABLE AS A REFERENCE UNDER 35 U.S.C. 102(a) or (b) UNTIL IT IS AVAILABLE TO THE PUBLIC BUT IT MAY BE AVAILABLE UNDER 35 U.S.C. 102(d) AS OF GRANT DATE

Secret patents are defined as patents which are insufficiently accessible to the public to constitute “printed publications.” Decisions on the issue of what is sufficiently accessible to be a “printed publication” are located in MPEP § 2128 - § 2128.01.

Even if a patent grants an exclusionary right (is enforceable), it is not available as prior art under 35 U.S.C. 102(a) or (b) if it is secret or private. *In re Carlson*, 983 F.2d 1032, 1037, 25 USPQ2d 1207, 1211 (Fed. Cir. 1992). The document must be at least minimally available to the public to constitute prior art. The patent is sufficiently available to the public for the purposes of 35 U.S.C. 102(a) or (b) if it is laid open for public inspection or disseminated in printed form. See, e.g., *In re Carlson*, 938 F.2d at 1037, 25 USPQ2d at 1211 (“We recognize that *Geschmacksmuster* on display for public view in remote cities in a far-away land may create a burden of discovery for one without the time, desire, or resources to journey there in person or by agent to observe that which was registered under German law. Such a burden, however, is by law imposed upon the hypothetical person of ordinary skill in the art who is charged with knowledge of all contents of the relevant prior art.”). The date that the patent is made available to the public is the date it is available as a 35 U.S.C. 102(a) or (b) reference. *In re Ekenstam*, 256 F.2d 321, 118 USPQ 349 (CCPA 1958). But a period of secrecy after granting the patent has been held to have no effect in connection with 35 U.S.C. 102(d). These patents are usable in rejections under 35 U.S.C. 102(d)

as of the date patent rights are granted. *In re Kathawala*, 9 F.3d 942, 28 USPQ2d 1789 (Fed. Cir. 1993). See MPEP § 2135 - § 2135.01 for more information on 35 U.S.C. 102(d).

2126.01 Date of Availability of a Patent as a Reference

DATE FOREIGN PATENT IS EFFECTIVE AS A REFERENCE IS USUALLY THE DATE PATENT RIGHTS ARE FORMALLY AWARDED TO ITS APPLICANT

The date the patent is available as a reference is generally the date that the patent becomes enforceable. This date is the date the sovereign formally bestows patent rights to the applicant. *In re Monks*, 588 F.2d 308, 200 USPQ 129 (CCPA 1978). There is an exception to this rule when the patent is secret as of the date the rights are awarded. *In re Ekenstam*, 256 F.2d 321, 118 USPQ 349 (CCPA 1958).

Note that MPEP § 901.05 summarizes in tabular form dates of patenting for many foreign patents. *Chisum*, Patents § 3.06[4] n.2 gives a good summary of decisions which specify reference availability dates for specific classes of foreign patents. A copy of *Chisum* is kept in the law library of the Solicitor's Office and in the Lutrelle F. Parker, Sr., Memorial Law Library located in CPK1-520.

2126.02 Scope of Reference's Disclosure Which Can Be Used to Reject Claims When the Reference Is a "Patent" but Not a "Publication"

OFTEN UNCLAIMED DETAILS FOUND IN THE PATENT SPECIFICATION CAN BE RELIED ON EVEN IF PATENT IS SECRET

When the patented document is used as a patent and not as a publication, the examiner is not restricted to the information conveyed by the patent claims but may use any information provided in the specification which relates to the subject matter of the patented claims when making a rejection under 35 U.S.C. 102(a), (b) or (d). *Ex parte Ovist*, 152 USPQ 709, 710 (Bd. App. 1963) (The claim of an Italian patent was generic and thus embraced the species disclosed in the examples, the Board added that the entire specifica-

tion was germane to the claimed invention and upheld the examiner's 35 U.S.C. 102(b) rejection.); *In re Kathawala*, 9 F.3d 942, 28 USPQ2d 1785 (Fed. Cir. 1993) (The claims at issue were rejected under 35 U.S.C. 102(d) by applicant's own parent applications in Greece and Spain. The applicant argued that the "invention ... patented in Spain was not the same 'invention' claimed in the U.S. application because the Spanish patent claimed processes for making [compounds for inhibition of cholesterol biosynthesis] and claims 1 and 2 were directed to the compounds themselves." 9 F.3d at 944, 28 USPQ2d at 1786. The Federal Circuit held that "when an applicant files a foreign application fully disclosing his invention and having the potential to claim his invention in a number of ways, the reference in section 102(d) to 'invention ... patented' necessarily includes all disclosed aspects of the invention." 9 F.3d at 945-46, 28 USPQ2d at 1789.)

In re Fuge, 272 F.2d 954, 957, 124 USPQ 105, 107 (CCPA 1959), does not conflict with the above decisions. This decision simply states "that, at the least, the scope of the patent embraces everything included in the [claim]." (emphasis added).

Note that the courts have interpreted the phrase "invention ... patented" in 102(a), (b), and (d) the same way and have cited decisions without regard to which of these subsections of 35 U.S.C. 102 was at issue in the particular case at hand. Therefore, it does not seem to matter to which subsection of 102 the cases are directed; the court decisions are interchangeable as to this issue.

2127 Domestic and Foreign Patent Applications as Prior Art

I. ABANDONED APPLICATIONS, INCLUDING PROVISIONAL APPLICATIONS

Abandoned Applications Disclosed to the Public Can Be Used as Prior Art

"An abandoned patent application may become evidence of prior art only when it has been appropriately disclosed, as, for example, when the abandoned patent [application] is reference[d] in the disclosure of another patent, in a publication, or by voluntary disclosure under [former Defensive Publication rule] 37 CFR 1.139." *Lee Pharmaceutical v. Kreps*,

577 F.2d 610, 613, 198 USPQ 601, 605 (9th Cir. 1978). An abandoned patent application becomes available as prior art only as of the date the public gains access to it. See 37 CFR 1.14(e) (2). However, the subject matter of an abandoned application, including both provisional and nonprovisional applications, referred to in a prior art U.S. patent may be relied on in a 35 U.S.C. 102(e) rejection based on that patent if the disclosure of the abandoned application is actually included or incorporated by reference in the patent. Compare *In re Lund*, 376 F.2d 982, 991, 153 USPQ 625, 633 (CCPA 1967) (The court reversed a rejection over a patent which was a continuation-in-part of an abandoned application. Applicant's filing date preceded the issue date of the patent reference. The abandoned application contained subject matter which was essential to the rejection but which was not carried over into the continuation-in-part. The court held that the subject matter of the abandoned application was not available to the public as of either the parent's or the child's filing dates and thus could not be relied on in the 102(e) rejection.). See also MPEP § 901.02. See MPEP § 2136.02 and § 2136.03 for the 35 U.S.C. 102(e) date of a U.S. patent claiming priority under 35 U.S.C. 119 or 120.

II. APPLICATIONS WHICH HAVE ISSUED INTO U.S. PATENTS

A 35 U.S.C. 102(e) Rejection Cannot Rely on Matter Which Was Canceled from the Application and Thus Did Not Get Published in the Issued Patent

Canceled matter in the application file of a U.S. patent cannot be relied upon in a rejection under 35 U.S.C. 102(e). *Ex Parte Stalego*, 154 USPQ 52, 53 (Bd. App. 1966). The canceled matter only becomes available as prior art as of the date the application issues into a patent since this is the date the application file wrapper becomes available to the public. *In re Lund*, 376 F.2d 982, 153 USPQ 625 (CCPA 1967). For more information on available prior art for use in 35 U.S.C. 102(e) rejections see MPEP § 2136.02.

III. FOREIGN APPLICATIONS OPEN FOR PUBLIC INSPECTION (LAID OPEN APPLICATIONS)

Laid Open Applications May Constitute "Published" Documents

When the specification is not issued in printed form but is announced in an official journal and anyone can inspect or obtain copies, it is sufficiently accessible to the public to constitute a "publication" within the meaning of 35 U.S.C. 102(a) and (b). See *In re Wyer*, 655 F.2d 221, 210 USPQ 790 (CCPA 1981).

Older cases have held that laid open patent applications are not "published" and cannot constitute prior art. *Ex parte Haller*, 103 USPQ 332 (Bd. App. 1953). However, whether or not a document is "published" for the purposes of 35 U.S.C. 102 and 103 depends on how accessible the document is to the public. As technology has made reproduction of documents easier, the accessibility of the laid open applications has increased. Items provided in easily reproducible form have thus become "printed publications" as the phrase is used in 35 U.S.C. 102. *In re Wyer*, 655 F.2d 221, 226, 210 USPQ 790, 794 (CCPA 1981) (Laid open Australian patent application held to be a "printed publication" even though only the abstract was published because it was laid open for public inspection, microfilmed, "diaz copies" were distributed to five suboffices having suitable reproduction equipment and the diazo copies were available for sale.). The contents of a foreign patent application should not be relied upon as prior art until the date of publication (i.e., the insertion into the laid open application) can be confirmed by an examiner's review of a copy of the document. See MPEP § 901.05.

IV. PENDING U.S. APPLICATIONS

As specified in 37 CFR 1.14(a), all pending U.S. applications are preserved in confidence except for published applications, reissue applications, and applications in which a request to open the complete application to inspection by the public has been granted by the Office (37 CFR 1.11(b)). However, if an application that has not been published has an assignee or inventor in common with the application being examined, a rejection will be proper in some circumstances. For instance, when the claims between the two applications are not independent or distinct, a

provisional double patenting rejection is made. See MPEP § 804. If the copending applications differ by at least one inventor and at least one of the applications would have been obvious in view of the other, a provisional rejection over 35 U.S.C. 102(e) or 103 is made when appropriate. See MPEP § 706.02(f), § 706.02(k), § 706.02(l)(1), and § 706.02(l)(3).

See MPEP § 706.02(a), § 804 and § 2136 *et seq.* for information pertaining to rejections relying on U.S. application publications.

2128 "Printed Publications" as Prior Art

A REFERENCE IS A "PRINTED PUBLICATION" IF IT IS ACCESSIBLE TO THE PUBLIC

A reference is proven to be a "printed publication" "upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." *In re Wyer*, 655 F.2d 221, 210 USPQ 790 (CCPA 1981) (quoting *I.C.E. Corp. v. Armco Steel Corp.*, 250 F. Supp. 738, 743, 148 USPQ 537, 540 (SDNY 1966)) ("We agree that 'printed publication' should be approached as a unitary concept. The traditional dichotomy between 'printed' and 'publication' is no longer valid. Given the state of technology in document duplication, data storage, and data retrieval systems, the 'probability of dissemination' of an item very often has little to do with whether or not it is 'printed' in the sense of that word when it was introduced into the patent statutes in 1836. In any event, interpretation of the words 'printed' and 'publication' to mean 'probability of dissemination' and 'public accessibility' respectively, now seems to render their use in the phrase 'printed publication' somewhat redundant.") *In re Wyer*, 655 F.2d at 226, 210 USPQ at 794.

See also *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986) (Starlight Archery argued that Carella's patent claims to an archery sight were anticipated under 35 U.S.C. 102(a) by an advertisement in a Wisconsin Bow Hunter Association (WBHA) magazine and a WBHA mailer prepared prior to Carella's filing date. However, there was no evidence as to when the mailer was received by any of the addressees. Plus, the magazine had not been mailed until 10 days after Carella's filing date. The

court held that since there was no proof that either the advertisement or mailer was accessible to any member of the public before the filing date there could be no rejection under 35 U.S.C. 102(a).)

ELECTRONIC PUBLICATIONS AS PRIOR ART

Status as a "Printed Publication"

An electronic publication, including an on-line database or Internet publication, is considered to be a "printed publication" within the meaning of 35 U.S.C. 102(a) and (b) provided the publication was accessible to persons concerned with the art to which the document relates. See *In re Wyer*, 655 F.2d 221, 227, 210 USPQ 790, 795 (CCPA 1981) ("Accordingly, whether information is printed, handwritten, or on microfilm or a magnetic disc or tape, etc., the one who wishes to characterize the information, in whatever form it may be, as a 'printed publication' * * * should produce sufficient proof of its dissemination or that it has otherwise been available and accessible to persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents." (citations omitted)). See also *Amazon.com v. Barnesandnoble.com*, 73 F. Supp. 2d 1228, 53 USPQ2d 1115, 1119 (W.D. Wash. 1999) (Pages from a website were relied on by defendants as an anticipatory reference (to no avail), however status of the reference as prior art was not challenged.); *In re Epstein*, 32 F.3d 1559, 31 USPQ2d 1817 (Fed. Cir. 1994) (Database printouts of abstracts which were not themselves prior art publications were properly relied as providing evidence that the software products referenced therein were "first installed" or "released" more than one year prior to applicant's filing date.).

The Office policy requiring recordation of the field of search and search results (see MPEP § 719.05) weighs in favor of finding that Internet and on-line database references cited by the examiner are "accessible to persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents." *Wyer*, 655 F.2d at 221, 210 USPQ at 790. Office copies of an electronic document must be retained if the same document may not be available for retrieval in the future. This is especially important for sources such as the Internet and online databases.

Date of Availability

Prior art disclosures on the Internet or on an on-line database are considered to be publicly available as of the date the item was publicly posted. If the publication does not include a publication date (or retrieval date), it cannot be relied upon as prior art under 35 U.S.C. 102(a) or (b), although it may be relied upon to provide evidence regarding the state of the art. Examiners may ask the Scientific and Technical Information Center to find the earliest date of publication. See MPEP § 901.06(a), paragraph IV. G.

Extent of Teachings Relied Upon

An electronic publication, like any publication, may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art. See MPEP § 2121.01 and § 2123. Note, however, that if an electronic document which is the abstract of a patent or printed publication is relied upon in a rejection under 35 U.S.C. 102 or 103, only the text of the abstract (and not the underlying document) may be relied upon to support the rejection. In situations where the electronic version and the published paper version of the same or a corresponding patent or printed publication differ appreciably, each may need to be cited and relied upon as independent references based on what they disclose.

Internet Usage Policy

See MPEP § 904.02(c) for the portions of the Internet Usage Policy pertaining to Internet searching and documenting search strategies. See MPEP § 707.05 for the proper citation of electronic documents.

EXAMINER NEED NOT PROVE ANYONE ACTUALLY LOOKED AT THE DOCUMENT

One need not prove someone actually looked at a publication when that publication is accessible to the public through a library or patent office. See *In re Wyer*, 655 F.2d 221, 210 USPQ 790 (CCPA 1981); *In re Hall*, 781 F.2d 897, 228 USPQ 453 (Fed. Cir. 1986).

2128.01 Level of Public Accessibility Required**A THESIS PLACED IN A UNIVERSITY LIBRARY MAY BE PRIOR ART IF SUFFICIENTLY ACCESSIBLE TO THE PUBLIC**

A doctoral thesis indexed and shelved in a library is sufficiently accessible to the public to constitute prior art as a "printed publication." *In re Hall*, 781 F.2d 897, 228 USPQ 453 (Fed. Cir. 1986). Even if access to the library is restricted, a reference will constitute a "printed publication" as long as a presumption is raised that the portion of the public concerned with the art would know of the invention. *In re Bayer*, 568 F.2d 1357, 196 USPQ 670 (CCPA 1978).

In *In re Hall*, general library cataloging and shelving practices showed that a doctoral thesis deposited in university library would have been indexed, cataloged and shelved and thus available to the public before the critical date. Compare *In re Cronyn*, 890 F.2d 1158, 13 USPQ2d 1070 (Fed. Cir. 1989) wherein doctoral theses were shelved and indexed by index cards filed alphabetically by student name and kept in a shoe box in the chemistry library. The index cards only listed the student name and title of the thesis. Two of three judges held that the students' theses were not accessible to the public. The court reasoned that the theses had not been either cataloged or indexed in a meaningful way since thesis could only be found if the researcher's name was known, but the name bears no relationship to the subject of the thesis. One judge, however, held that the fact that the theses were shelved in the library was enough to make them sufficiently accessible to the public. The nature of the index was not determinative. This judge relied on prior Board decisions (*Gulliksen v. Halberg*, 75 USPQ 252, 257 (Bd. App. 1937) and *Ex parte Hershberger*, 96 USPQ 54, 56 (Bd. App. 1952)), which held that shelving a single copy in a public library makes the work a "printed publication." It should be noted that these Board decisions have not been expressly overruled but have been criticized in other decisions. See *In re Tenney*, 254 F.2d 619, 117 USPQ 348 (CCPA 1958) (concurring opinion by *J. Rich*) (A document, of which there is but one copy, whether it be handwritten, typewritten or on microfilm, may be technically accessible to anyone who can find it. Such a document is not "printed" in the sense that a printing