described means, is constantly exposed to imminent danger, either from the explosive tendency of the substance to be used or from the liability of the vessel to burst which is required to be employed as a means of accomplishing the patented result. Where the patentee finds it necessary to employ any such dangerous means to accomplish the described end it cannot be held that his invention is useful, within the meaning of the patent law, even though it appears that the operator, when no such disaster happens, may be able to work out the described result by the described means, as it is quite clear that congress, in making provision to secure to inventors the exclusive right to their discoveries, never intended to promote any such as were in their nature constantly dangerous to the operator in employing the described means to accomplish the described result. Curt. Pat., 4th ed., secs. 106, 449.[121]

Inventions of this kind included a pre-windshield wiper expedient to permit driver vision in rain or fog which limited the driver's view to a three inch slot,[122] and an activation device for a traffic signal which did not work under certain conditions.[123]

On the other hand, patents have been issued on explosives, firearms, insecticides, and other dangerous articles of manufacture. "Utility" is called into question only when the hazards presented by "use as directed" greatly exceed those normal to the type of article claimed.

A series of drug cases have refined the Story test of "utility." Thus, in *Hartop,* the CCPA took judicial notice

> [T]hat many valued therapeutic substances or materials with desirable physiological properties, when administered to lower animals or humans, entail certain risks or may have undesirable side effects. True it is that such substance would be more useful if they were not dangerous or did not have undesirable side effects, but the fact remains that they are useful, useful to doctors, veterinarians and research workers, useful to patients,

[121] Mitchell v. Tilghman, 86 U.S. 287 (1873).

[122] Twentieth Century Motor Car & Supply Co. v. Holcomb Co., 220 Fed. 669 (2d Cir. 1915)("a highly dangerous expedient").

[123] Katz v. Horn Signal Mfg. Corp., 52 F.Supp. 453 (S.D.N.Y. 1943)("a menace to traffic instead of an aid").

both human and lower animal, and so are useful within the meaning of 35 U.S.C. §101. The use of drugs in medicine is frequently a matter of balancing risks to save a life. "Safety" is a relative matter.[124]

In *Anthony*, the CCPA declared that "Monase" was patentable even though the FDA had suspended the New Drug Application applicable to "Monase." "Monase" had been administered to over 400,000 patients and had proven effective in treating many types of mental depression. The FDA action was prompted by twelve reported cases of agranulocytosis. The CCPA declared that while the FDA's suspension order could not be "lightly regarded," the CCPA could only infer that "Monase" was unsafe *as originally labeled.*[125]

In *Burroughs Wellcome & Co. v. Eli Lilly & Co.*[126] the Second Circuit held that a globulin-insulin preparation was "useful" even though a clear solution might be mistaken by the lay purchaser for insulin alone, and thus be harmfully used.

With regard to pathogens, a distinction might be drawn between opportunistic pathogens and other pathogens. Opportunistic pathogens are those which are pathogenic only to vulnerable segments of the population or when the normal microbial flora of the body is eliminated. A number of industrially important species of microorganisms encompass opportunistically pathogenic strains: Pseudomonas aeruginosa; Escherichia coli, the Bacillus cereus group; and the propioni bacteria. Major pathogenic organisms are usually cultured only for use in vaccine production.

One of the few patents which actually notes the pathogenicity of the subject organism is U.S. Patent No. 2,513,-327 [1943], relating to the culturing of T. pallidium, the causative agent of syphilis.

Attorneys may wish to consider discussing safety measures in the application if the organism in question is highly pathogenic and the examiner raises the issue of utility. Safety ques-

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[124] In re Hartop, 311 F.2d 249, 255 (CCPA 1962) (thiobarbituric acid compound for use as anesthetic-hyphotic).

[125] In re Anthony, 414 F.2d 1383, 1394-1399 (CCPA 1969). In re Sichert, 566 F.2d 1154 (CCPA 1977). In re Watson, 517 F.2d 465 (CCPA 1975).

[126] 150 F.2d 946, 949 (2d Cir. 1945).

tions ought not be routinely addressed since patents are directed to skilled microbiologists, and since the patent might be put into evidence by a hostile product liability plaintiff.

[2] Vaccines

The application should describe the proper (1) vaccination techniques; (2) potency tests; (3) safety tests; (4) sterility tests; (5) purity tests; (6) identity tests; and (7) maintenance procedures. In describing the vaccination techniques, it should indicate the recommended dosage and route of administration. Known sensitizing substances should be indicated. Maintenance procedure information includes such points as the statement of a maintenance temperature, shelf life, or a need to protect the vaccine from exposure to sunlight.

[3] Biological Products and Methods Used Presently Only in Research

Brenner v. Manson[127] arose when two inventors claimed precisely the same invention: a process yielding a steroid then the subject of cancer research. Following established Patent Office procedure, the examiner declined to investigate possible interference or priority claims, but proceeded to determine whether the invention claimed was allowable. He concluded that the invention lacked utility. The CCPA reversed and the Supreme Court granted certiorari to resolve the conflict.

On the appeal, the Court raised two questions: "is a chemcial process 'useful' within the meaning of §101 either (1) because it works—*i.e.,* produces the intended product? or (2) because the compound yielded belongs to a class of compounds now the subject of serious scientific investigation? The Court rejected both propositions.

The philosophical underpinning for the holding was the Court's expressed belief that, "[T]he basic *quid pro quo* con-

[127] 383 U.S. 519, 532 (1965).

templated by the Constitution and Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."[128]

The Court added, *in dictum,* that "[T]hese arguments for and against the patentability of a process which either has no known use or is useful only in the sense that it may be an object of scientific research would apply equally to the patenting of the product produced by the process.[129]

This approach, set forth in *Brenner,* was elaborated upon by the CCPA in *Kirk,*[130] where patent protection was claimed for certain new steroid compounds of value "as intermediates in the preparation of biologically active compounds and in some cases on account of their biological properties.[131] In a 3-2 decision, the CCPA held, "if a process for producing a product of only conjectural use is not itself 'useful' within §101, it cannot be said that the starting materials for such a process, *i.e.,* the presently claimed intermediates—are useful.[132]

In a similar case, *Joly,*[133] the CCPA decided that a patent application relating to Esters of 2-enols of Steroids, and Preparation Thereof had been properly rejected for insufficient disclosure of utility. "A useless product does not become useful by conversion into another useless product."[134] Judges Rich and Smith vigorously dissented.

Two further cases illustrate the problems foreign patentees have encountered in trying to cope with the *Brenner* requirement. In *Hafner,* a German patentee was denied a U.S. patent

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[128] Id., 534. In re Abitibi-Price Inc., 1 Biotechnology L. Rpt. 48, 55 (Can. Comm'r Pats., March 18, 1982), echoes *Brenner v. Manson,* stating that a new organism, to be patentable, must be "useful," not a "mere laboratory curiosity."

[129] Id., 535.

[130] 376 F.2d 936 (CCPA 1967).

[131] Id., 941.

[132] Id., 945.

[133] 376 F.2d 906 (CCPA 1967).

[134] Id., 907.

where the application failed to contain a disclosure of utility—such disclosure was unnecessary in Germany.[135] *Yasuko Kawai v. Matlesics* raised the question whether compliance with §112 would render the invention unpatentable in Japan. In a clear statement of the CCPA's post-*Brenner* interpretation of the utility requirement, the Court stated in *Yasuko Kawai:*

> We think it now settled that an invention cannot be considered as having been reduced to practice in the sense that a patent can be granted for it unless a practical utility has been discovered where such utility would not be obvious.[136]

Until recently, methods of cutting DNA with restriction enzymes were used only in research, and were arguably unpatentable for lack of "utility" in the *Brenner* sense.

[4] Fermentation Processes

The specification should discuss the preparation of the inoculum, the preparation and sterilization of the fermentation medium, the fermentation equipment, the inoculation technique, the inoculation period, the conditions of temperature, pressure, pH, light, agitation, and aeration maintained during the fermentation; any products removed during the course of the fermentation (*e.g.*, substances toxic to the organism); precautions taken to detect or prevent contamination; and the recovery of the desired product. The fermentation medium might be solid or liquid, and can contain a variety of carbon, nitrogen, and inorganic ion sources. Additives might be employed to give the medium desirable physical characteristics, such as viscosity. The organism might be suspended in the medium, or immobilized in a specified manner. Fermentation equipment ranges from shake flasks to gigantic tank fermenters. The various process parameters will have both ranges which the organism can tolerate and values which optimize its production of the desired product. (These conditions

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[135] Application of Hafner, 410 F.2d 1403, 1405 (CCPA 1969).
[136] 480 F.2d 880, 886 (CCPA 1973).

may well differ from those favoring the growth of the organism.) One parameter's setting may moderate or accentuate the effect of varying another parameter.

The specification should give examples of yield obtained with various methods, conditions, equipment, materials, and strains.

When the organism is used to metabolize human waste or pollutants, or to leach minerals from low-grade ores, it is also desirable to discuss the manner in which the organism is brought into contact with the waste materials, polluted soil or water, or ore body in question.

[5] Use of Fermentation Products

If the product has a therapeutic use, the animal and clinical data suggesting this use should be disclosed, with disclosure of number, species, age, sex, and health of the experimental subjects, the dosage, the carrier, the routes of administration, the length of the study, and the apparent safety and efficacy of the drug.

Non-therapeutic uses of the product, such as the use of enzymes in food manufacture, should also be discussed, with any factors limiting such use, and any advantages or disadvantages of the product for such use, pointed out.

[6] Use of Microorganisms as Biological Controls of Pest Species

A variety of insect parasites and predators have been used as an alternative or supplement to the use of chemical pesticides. These include the use of *Bacillus popillae* to control the Japanese beetle; a polyhedrosis virus, to control the sawfly; and *Bacillus thuringiensis*, as a "broad spectrum" microbial agent. Since many factors can influence the effectiveness of microbial controls, this author cannot enumerate exhaustively all of the factors which might appropriately be disclosed in a patent directed to this field. These include:

(1) Whether the organism is pathogenic to man, or to any beneficial plants or animals (including insects);
(2) The best means of cultivating, storing, handling, and disseminating the organism, and the appropriate levels and pattern of application, the results of any testing of the safety or effectiveness of the organism;
(3) The effect on the organism's virulence, stability, persistence, dispersal and transmission of such factors as sunlight, temperature, humidity, rain, wind, pH (of soil, plant surfaces or plant tissues), and foliage morphology, density and growth;
(4) The species affected, and for each species, the developmental stage most affected;
(5) Significant interactions between the pathogen and other biological controls and chemical pesticides;
(6) The crops which the pathogen may be used to protect, and the degree of protection provided; and
(7) The preferred formulation of the pathogenic material for dissemination; including preferred "stickers," "spreaders," wetting agents, and other adjuvants, the equipment used in formulation of the product, and the methods of the standardization employed.[137]

§ 5.08 The Deposit of Inferior Strains and the "Best Mode" Requirement

There is reason to believe that patent applications do not always deposit their best strains. A popular account of the drug industry declared

> No company put its high-yielding pedigree organisms in the public culture collections. They deposited organisms that met the specification claimed in the patent—namely, that they could make this particular substance—but they did not certify that they could do so profitably.
>
> Technically, a skilled microbiologist could in time breed up the organisms in the public collections so that ultimately he had

[137] L. A. Falcon, Microbial Control as a Tool in Integrated Control Programs, in C. B. Huffaker, ed., *Biological Control*, chap. 15 (1971).

possession of high-yielding strains, but this process could take years, and even then, it might fail.[138]

This evaluation has been echoed in the professional literature. According to Silvestri and Gottlieb, "too frequently, the deposited strains are not the operative ones. The problem is further complicated by the fact that present methods of maintaining cultures do not guarantee the preservation of the useful properties.[139]

Failure to deposit the most productive strain is perilous, as under U.S. law it may be considered abandonment of the invention (35 U.S.C. §102), failure to disclose the "best mode" (35 U.S.C. §112), and an "unfair act" in restraint of trade under the FTC Act, Section 5 (15 U.S.C. §45).

Between 1836 and 1870, the patent statute required the inventor to "fully explain . . . the *several* modes in which he has contemplated the application of" his invention. In 1870, Congress changed this requirement to a duty to disclose the "best mode contemplated by the inventor of carrying out his invention." In a 1960 dictum, Judge Rich declared that the "best mode" requirement "does not permit an inventor to disclose only what he knows to be his second-best embodiment, retaining the best for himself."[140] (As Gerald Bjorge points out, the "best mode" requirement has its roots in a former statutory "deception" defense.[141]) By 1965, a patent had been held invalid for failure to reveal what the inventor, at the time of filing, thought to be the best mode."[142]

On the other hand, in an earlier case, the patent was sustained since at the time of filing there was an active dispute as to which of two modes was preferred.[143] (One commentator,

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[138] Pearson, *The Million Dollar Bugs*, 87 (1969).

[139] Silvestri and Gottlieb, Taxonomy and Legal Aspects of Industrially Important Microorganisms, 1 Global Impacts Applied Microbiol. 109, 111 (1964).

[140] In re Nelson, 280 F.2d 172, 184 (CCPA 1960).

[141] G. H. Bjorge, 59 JPOS 336 (1977), citing In re Monin, 364 F.2d 454 n.7 (CCPA 1966).

[142] Flick-Reedy Corp. v. Hydro-Line Mfg. Co., 351 F.2d 546 (7th Cir. 1965), cert. denied 383 U.S. 958 (1966).

[143] Benger Labs, Ltd. v. R. K. Laros Co., 209 F. Supp. 639 (E.D. Pa. 1962), aff'd 317 F.2d 455 (3d Cir. 1963).

however, suggests that both "preferred modes" should be disclosed.[144])

When a better mode is discovered *subsequent* to the filing of the application, there is no obligation to amend the application to disclose it.[145] The filing of a continuation, continuation-in-part, or reissue application, however, will probably necessitate a "best mode" update.[146] If a foreign application does not disclose the "best mode," it might not be possible to claim the benefit of the filing date of the foreign application.[147]

The "best mode" need not have been developed by the applicant; it must be disclosed if it were appreciated by the applicant at the time of filing.[148]

In *Indiana General Corp. v. Krystinel Corp.*, a patent on ferrite materials, with a claim reciting the acceptable ranges of the elements, was rejected for failure to disclose the best "recipe."[149] Similarly, one might expect a process claim reciting a species of microorganism used therein to be invalidated if the best strain were not disclosed.

In the *American Cyanamid* proceeding, the Federal Trade Commission asked the parties to brief this question: "should the respondents be ordered to provide . . . cultures . . . to other competitors in order to restore effective competition to the market?"[150]

The FTC's Final Order directed American Cyanamid to furnish any compulsory licensee who requested it with "viable *S. aureofaciens* cultures that are identical to or equivalent to any cultures furnished Chas. Pfizer & Co." (regarded as part of the "technical information and know-how" previously fur-

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[144] D. L. Carlson, The Best Mode Disclosure Requirement in Patent Practice, 60 JPOS 171, 194 (1978).

[145] Carter-Wallace, Inc. v. Riverton Labs, Inc., 433 F.2d 1034, 1038, 107 U.S.P.Q. 656 (2d Cir. 1970).

[146] Id.

[147] Standard Oil Co. v. Montedison, S.P.A., 454 F. Supp. 370, 206 U.S.P.Q. 676, 696 (D. Del. 1980).

[148] Benger Labs, Ltd. v. R. K. Laroes Co., 209 F. Supp. 639, 644, 135 U.S.P.Q. 11 (E.D. Pa. 1962), aff'd 317 F.2d 455, 137 U.S.P.Q. 693 (3d Cir. 1963).

[149] 297 F. Supp. 427, aff'd 421 F.2d 1023 (2d Cir. 1970).

[150] In re American Cyanamid Co., 63 FTC 1747, 1897 (Dec. 17, 1963).

nished to Pfizer).[151]

The FTC noted, in support of this directive, that

> The record shows a necessity for ordering Cyanamid to sell to applicants cultures of the production strains that were handed over to Pfizer. These production strains were not placed on public deposit when Cyanamid obtained its Duggar and Niedercorn patents. Although there is a requirement in Patent Office procedure that an applicant for a fermentation process must make available to the public a culture of the microorganism used in his process, Cyanamid deposited a very weak microorganism. In fact, the record shows that Niedercorn used a different and superior strain of microorganism in the fermentations described in his patent (Tr. 6432-38). As a consequence, Cyanamid has been able to obtain patents and at the same time keep secret the vital ingredient of the processes covered by the patents. Cf. 35 U.S.C. §112; Schriber-Schroth Co. v. Cleveland Trust Co., 305 U.S. 47, 57 (1938).[152]

The Sixth Circuit eventually ordered

> [T]hat respondent American Cyanamid Company furnish to any person licensed under this order, and making written request therefor, whatever technical information and know-how that American Cyanamid Company has in the past furnished Chas. Pfizer & Co., Inc., relating to the manufacture and use of chlortetracycline, and technical information and know-how to include a furnishing of viable S. aureofaciens cultures that are identical to or equivalent to any cultures furnished Chas. Pfizer & Co., Inc. The information to be made available hereunder shall be made available without charge other than the expense to respondent of furnishing such information; provided, however, that respondent American Cyanamid Company may require any such licensee to agree to keep said technical information and know-how confidential.[153]

Daus explains that the Duggar patent to the fermentation

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[151] Id., 1911.
[152] Id., 1905 n.14.
[153] 401 F.2d 574, 587 (6th Cir. 1968).

coproduct chlortetracycline "disclosed a weak, noncommercial strain."[154]

In *Hybritech v. Monoclonal Antibodies, Inc.*,[154.1] the trial court ruled that the '110 patent was invalid under 35 U.S.C. §112 because it failed to disclose the best mode known to Hybritech of constructing and screening hybridomas secreting antibodies suitable for use in a sandwich assays, but the Federal Circuit reversed since there was no evidence of concealment of a best mode for screening or producing high affinity monoclonal antibodies.

§ 5.09 Applications for Patent on Microbiological Inventions—Petitions to Make Special

New applications are normally reviewed in the order of their effective filing dates. A petition to "make special" an application, *i.e.*, to consider it out of order, will be granted:

(1) To assure manufacture of an invention, if the invention would not be manufactured should a patent not be granted;
(2) If actual infringement can be shown;
(3) If the applicant's state of health is poor, or if he is sixty-five years of age, or more;
(4) If the invention contributes to the restoration or maintenance of the basic life-sustaining natural elements—air, water and soil;
(5) If the invention contributes to the discovery or development, or more efficient utilization and conservation, of energy resources, or
(6) If the invention relates to the safety of research in the field of recombinant DNA.

The first category is of interest because many firms in the

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[154] Daus, Conditionally Available Cultures, 54 J.P.O.S. 187. 202 n.87 (1972).

[154.1] 227 USPQ 215 (N.D. Cal. 1985), rev'd, — USPQ — (App. No. 86-531, decided Sept. 19, 1986).

genetic engineering industry are still attempting to attract venture capital, and the prospect of a patent is a major bargaining chip in financing negotiations. The "environmental quality" category is of interest to those who have developed new strains of microbes for pollution control purposes. The "energy" category is of interest in that new strains may be devised for the exploitation of low grade fossil or nuclear fuels.

The last category, whose relevance is evident, has had a tortured history. In January, 1977, in response to a suggestion by a member of the Interagency Committee on Recombinant DNA, the PTO decided to permit the accelerated processing of patent applications for inventions relating to recombinant DNA:

> Upon appropriate request, the Office will make special patent applications for inventions relating to recombinant DNA, including those that contribute to safety of research in the field. . . . Requests . . . must include a statement that the NIH guidelines . . . are being followed in any experimentation in this field, except that the statement may include an explanation of any deviations considered essential to avoid disclosure of proprietary information or loss of patent rights. The requests will be handled in the same manner as requests to make applications special that relate to energy or environmental quality.[155]

But several influential members of Congress thought that this decision was premature, and on February 24, 1977, the Secretaries of HEW and Commerce jointly announced the "temporary" suspension of accelerated processing for recombinant DNA research inventions. The announcement noted that the PTO would continue "accelerated processing of patent applications for laboratory equipment that contribute to safety in this field.[156]

The pros and cons of accelerated processing of recombinant DNA research invention patent applications are discussed in the February press release and in the minutes of the Intera-

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[155] 42 Fed. Reg. 2712-13 (January 13, 1977).

[156] U.S. Dept. of Commerce News C. 77-21 (released February 24, 1977) "Commerce Suspends Accelerated Processing of Patents on DNA Inventions."

gency Committee's March 29, 1977, meeting. Suffice it to say that the Interagency Committee recommended the reinstatement of the Order.[157] No action has been taken by the PTO in response to this recommendation.

In February 1984, the Association of Biotechnology Companies petitioned the Patent and Trademark Office to reinstate the "fast track" processing for recombinant DNA patent applications and to extend such processing generally to "directed genetic manipulations at the molecular and cellular levels." In March, the Petition was denied by Acting Commissioner Quigg. Quigg explained that there was a procedure (37 C.F.R. §1.102; MPEP §708.02 VIII) by which any patent applicant could request accelerated processing.

The PTO's past actions are entirely inconsistent with its present opinion that MPEP §708.02 VIII offers an adequate vehicle for the expedited protection of innovation in fields of special public interest, such as the protection of the environment, the development and conservation of energy resources, and the application of recombinant DNA technology in medicine, industry and agriculture. Even though the general procedure was promulgated in January 1966, the Office made special provisions for environmentally related inventions in April 1970, for energy-related inventions in January 1974, and for RDNA inventions in January 1977.

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[157] Summary, Minutes of Meeting (March 29, 1977) at 2-4.

CHAPTER 6

Utility Patent Protection of Plant and Animal Varieties

§ 6.01 Utility Patent Protection of Plant Varieties

In 1980, the APLA's Plant Variety Protection Committee reported:[1]

> As a result of the Chakrabarty decision, some of the Committee members feel that plants, whether asexually or sexually reproduced, are patentable[. The main area] of concern in attempting to obtain plant protection under 35 USC 101 is meeting the requirement of 35 USC 112. Various suggestions were made. For example, with non-hybrid plants, seeds could be deposited at the Department of Agriculture in the same manner that microorganisms are deposited. In the instance of hybrid plants, both the seed parent and pollen parent seed would have to be deposited. The question was also raised as to whether or not seeds could be characterized in a manner other than by describing the plant. Commissioner Bernard Leese of the Plant Variety Protection Office indicated there are any number of ways to characterize seeds. He also indicated that technology was avail-

[1] APLA Bulletin, 793-94 (December 1980).

able that would ensure storage of the seed to minimize mutation of and to preserve the seed for long periods of time.

Some concern was expressed about the possibility of multiple forms of protection for plants. However, it was pointed out that this was not a new problem in intellectual property law since it was possible, certainly at one time, to obtain both copyright protection and design patent protection for the same type of subject matter, and it is possible this is still the case. Furthermore, it was pointed out that species excluded from the Plant Parent Act, namely, tuber-propagated plants, and species excluded from the Plant Variety Protection Act, namely hybrids and the six species referred to as the "soup vegetables," should be claimable under 35 USC 101. Several members of the Committee indicated that they would probably be filing plant applications under 35 USC 101 in the near future.

The possibility of obtaining generic claims to plants under the Utility Statute was also discussed.[2]

The PTC section of the ABA reported at the 1981 New Orleans meeting that "the expected PTO treatment of §101 patent applications directed to plants was discussed with PTO officials." Martin Brown's report continued:

Under the Chakrabarty decision, the PTO is intending to consider patent applications without reference to whether or not the claimed subject matter is living, at least unless the latter involves a higher life form. Similarly, whether a plant is reproduced sexually or asexually or is a tuber propagated plant or a first generation hybrid would be of no consequence. As far as the PTO is concerned there must, however, be an element of human intervention in developing a new variety for it to be patentable.

At present, and at least from the standpoint of internal jurisprudence, there seems to be no particular concern with there being overlapping or alternative areas of patent-type coverage available for plants. Thus, although one might obtain a certificate on a given sexually-reproduced plant, he could choose to obtain a §101 patent. It is not clear whether one could obtain both §101 and §161 patents on a given asexually-reproduced

[2] ABA (PTC Section) 1981 Committee Reports at 71.

plant; or whether one could obtain both a PVP certificate and a §101 patent on a sexually-reproduced plant. Moreover, under Article 2(1) of the UPOV Convention, the granting state can issue either special titles of protection or patents. However, where the national law allows for both types of protection, it "may provide only one of them for one and the same botanical genus or species." Because of this provision, it is not clear how applications originating in the United States for asexually reproduced plants will be treated under UPOV since in certain cases, the same "genus or species" is apparently protectable as a patent under 35 USC 101 and as a PVP certificate. Further deliberation on these aspects are needed.

In any §101 application, the provisions of §112 and §103 must be satisfied and like microorganism cases this may require a deposit to fully comply with §112 and insure that when the patent expires, the public will have the capability of practicing the invention.

The ATCC is accepting deposits of plant germ plasm in a frozen state; however, it is uncertain whether this technique is satisfactory with respect to some plants since freezing may alter the capability of the germ plasm to reproduce the plant. This may also be the situation with respect to tubers.

Barry Grossman of the Commissioner's Office informed the APLA Plant Variety Protection Committee that the PTO "would begin to accept and examine applications covering plants under 35 U.S.C. §101. . . ." Grossman indicated that there are still some problems that are not resolved. For example, if the deposit of propagation material is required to meet 35 U.S.C. §112, where will the material be stored?"[3]

In *Chakrabarty,* the dissenters argued that if a "composition of matter" under the general patent statute could be a living thing, then there would have been no need for Congress to amend the statute in 1930 to provide specifically for the protection of novel and distinct varieties of plants. Essentially, they heeded the canon of statutory construction that forbids one to construe a legislative enactment so as to render it nugatory. Clearly, this argument has greater force when applied to

[3] APLA Bulletin 48 (January-February 1981).

an application for, say, a "semi-dwarf hybrid sunflower seed," than to one for a multiple plasmid-bearing bacterium.

The majority agreed that new and distinct varieties of plants were not protected under the prior law. They reasoned, however, that this was because it was then thought impossible to provide an adequate disclosure of the new variety, rather than because the term "composition of matter" was deemed incapable of applying to plants at all. The Plant Patent Act specifically excused "substantial compliance" with the disclosure requirements of the general patent statute insofar as plant patents were concerned.

Thanks to a legal innovation—the patent deposit—it is now possible to disclose a new variety of plant in a manner which fully complies with the present disclosure requirement, Section 112.

In an influential APLA monograph, C.H. Neagley, D.D. Jeffrey and A.B. Diepenbrock argued that "in terms of statutory construction, Section 101 protection for plants does not mandate nullification or repeal of the specific plant statutes, nor is it irreconcilable with the specific statutes; rather, Section 101 opens the way to alternative forms of protection."[3.1]

The PTO has, in fact, issued several patents with claims covering plant varieties. Several of these patents are discussed below.

Rutger, U.S. Patent No. 4,351,130, *Recessive Tall—A Fourth Genetic Element to Facilitate Hybrid Cereal Production* (1982) is primarily directed to a cereal crop breeding process. However, it contains two product-by-process claims (claims 6 and 9), as well as a genuine product claim to "a recessive tall plant having elongated upper internode" (claim 10).

Mehra-Palta, U.S. Patent No. 4,377,921, *Method for the In Situ Activation of the Needle Fascicles of Gymnosperms and for the Clonal Propagation of Gymnosperms and the Clones Produced Thereby* (1983) claims "A gymnosperm clone produced by a process comprising the steps of contacting the terminal portion of a stem of said gymnosperm with between about 0.01 to 20 mg of a cytokinin to activate the needle fasci-

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3.1 Section 101 Plant Patents—Panacea or Pitfall?, AIPLA Select Legal Papers, Vol. II, No. 2 (January 1984).

cles to elongate into shoots; excising the shoots from said stem; and rooting said shoots" (claim 21).

Finally, Johnson, U.S. Patent No. 4,378,655, *Semi-Dwarf Hybrid Sunflower Seed and Plant and Method of Producing Seed* (1983) contains the most elaborate set of product claims to be found in these three examples. Unlike the two patents noted above, it takes advantage of one of the principal advantages of obtaining utility patent protection of a plant variety—the opportunity to cover the plant variety with both generic and specific claims. This is illustrated by claims 20-22 of the Johnson patent:

> 20. A first generation semi-dwarf hybrid sunflower plant of reduced internode length, the hybrid sunflower plant having been grown from the seed from the cross pollination of a pair of parent plants (P^1 and P^3) wherein in at least one parent substantially all of the pollen is nonfunctional and at least one parent has gametes with nuclei which carry at least one dominant gene for reduced internode length (Df).
>
> 21. A semi-dwarf sunflower plant as described in claim 20 wherein the internode length is reduced by about 10%-35% as compared to hybrids having standard internode length.
>
> 22. A semi-dwarf hybrid sunflower plant as described in claim 20 wherein the internode length is about 75 mm.

These claims were supported by the disclosure of Imperial Experimental Hybrid 310, produced by Cms HA89 × IR-10 cross-pollination. The height, internode length, flower number, color and blooming time, stem diameter and color, leaf number and size, seed color, disease resistance, and pollen of this hybrid were characterized in the specification.

Sunflower hybrids which are "distinct" from Imperial Experimental Hybrid 310, within the meaning of the Plant Variety Protection Act or the Plant Patent Act, by virtue of differing, say, in flowering time, may yet infringe Johnson's claim 20. Such are the benefits of utility patent protection of plant varieties.

Two of the three applicants for the aforementioned utility patents on plant varieties made a deposit of the seed. Thus, Rutger deposited seeds C.I. 11055 in the USDA Germ Plasm

Resource Laboratory; while Johnson deposited seed from inbred line IR-10 at the USDA National Seed Storage Laboratory.

The National Seed Storage Laboratory is part of the National Plant Germplasm System. The NSSL holds the base collections for the System. The working collections are maintained at several regional Plant Introduction Stations, at the Northwest Clonal Repository, and at the Fruit and Nut Germplasm Laboratory. There are also a number of independent collections, such as the Maize Genetics Cooperative Stock Center, based at the University of Illinois.[3.2]

The question has arisen as to whether seed deposits are actually necessary in order to comply with §112, given the present level of skill in the plant genetics art.

In terms of predictability, classical plant breeding may be said to fall midway between mutation-selection techniques and genetic engineering techniques in terms of reproducibility. In the case of genetic engineering, there is no doubt as to the working of the restriction endonucleases, ligases, or reverse transcriptases. EcoRI will always cut G'AATTC. The main uncertainty is at the beginning, when one is trying to obtain a complete cDNA transcript of the gene of interest, or identify the operator region of a regulon one wishes to modify. In certain operations, of course, there is uncertainty; the orientation of an inserted fragment for example, but these uncertainties do not dominate the construction process.

In the case of mutation-selection, there is great uncertainty as to the type of mutation, and as to its locus and effect. While repeating the process may result in mutations of similar effect, they are not likely to be of identical origin.

Classical plant breeding may be said to be statistically reproducible. Thus, Johnson remarks, "if at least one of the two dominant genes involved is required to produce reduced internode length in sunflower, then the ratio of semi-dwarf to nonsemi-dwarf in F^2 would be fifteen semi-dwarf plants to one nonsemi-dwarf plant."

Unfortunately, statistical reproducibility was offered (and

[3.2] G. Wilkes, Current Status of Crop Plant Germplasm, CRC Critical Reviews in Plant Science, 1:133 (1983).

apparently deemed insufficient) in Merat (see §6.03) so it is unwise to rely upon it too heavily.

The aforementioned patent claims were all allowed by Examiner Robert Bagwill, and seemingly reflected a liberal interpretation of *Chakrabarty*. However, on October 17, 1984, the PTO told the Japanese Patent Association that life forms other than microorganisms and certain plants would be denied protection under the utility patent laws: "Any subject matter protectable under either the plant patent law or the Plant Variety Protection Act is preempted by that law and cannot be protected under the general patent law." This was later confirmed by Assistant Commissioner Rene Tegtmeyer.[3.3] As Neagley noted in his monograph, a special statute does not impliedly overrule a general one unless there is an irreconcilable conflict between the two statutes. To the extent that the various exemptions in the PVPA present a possible conflict, the conflict can be resolved by construing the patent grant in the case of a utility patent on a plant to be subject to these exemptions. This would give effect to both statutes.

The PTO specifically stated that a plant obtainable by recombinant DNA technology or by cell fusion can only be protected under the general patent law if "the sexually reproducible plant cannot be protected under the PVPA or the asexually reproducible plant cannot be protected under 35 U.S.C. 161."

The PTO generously extended its preemption arguments to plant cells. Their argument is that "a plant cell capable of differentiation and useful only for reproductive purposes would be considered as no more than an expression of and tantamount to the plant itself." Even a legal scholar sympathetic to the PTO's preemption arguments might shudder upon reading this passage. There is no doubt that the plant cells, per se, cannot be protected under the PPA or the PVPA. They are nonstatutory subject matter insofar as those acts are con-

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3.3 "Section 101 Plant Patents—Preemption," A Report of the AIPLA Plant Variety Protection Committee (L-7), submitted December 7, 1984, by Anthony Diepenbrock, Chairman, to William H. Elliot. It is interesting to note that the PTO is engaging increasingly in the practice of "luncheon law," a field pioneered by the Intellectual Property Section of the DOJ Antitrust Division.

cerned. If they are "tantamount to the plant itself," then why doesn't the PTO allow claims to plant cells or plant parts under the PPA?

While the PTO was willing to permit 35 U.S.C. § 101 claims to tuber-propagated plants (as excluded from the Plant Patent Act) and to first-generation hybrids (as excluded from the PVPA), this was hardly satisfactory protection for plant biotechnology.

In *Ex parte Hibberd,*[3.4] the Board of Patent Appeals and Interferences held that claims to seeds, plants, and tissue cultures were proper under 35 U.S.C. § 101.

The Examiner had acknowledged that in *Diamond v. Chakrabarty,*[3.5] the Supreme Court had held that "Section 101 includes man-made life forms, including plant life." Indeed, the Examiner had allowed claims drawn to hybrid seeds and hybrid plants. Rather, the Examiner argued that the plant-specific acts provide the exclusive forms of protection for plant life covered by those acts.

As the Board pointed out, nothing in the legislative histories suggested that plant life was to be "carved out" of §101 when the Plant Patent Act and the PVPA were enacted. In fact, the Senate Report on the PVPA specifically stated that it "does not alter protection currently available within the patent system."

The Board placed considerable relevance on the maxim of statutory construction that "repeals by implication are not favored," and that "when two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective."

This leads directly to the question of when are two statutes in irreconcilable conflict. Here, the Examiner enumerated several distinctions between the utility patent law and the plant-specific acts. These, the Board viewed as falling short of "conflict."

The Board did not really analyze these differences and compare them with those considered in other statutory construction cases; rather, it contented itself with a conclusory

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[3.4] 227 USPQ 473 (BPAI 1985).

[3.5] 447 U.S. 303 (1980).

declaration of their failings. The closest it came was a general reference to *In re Yardley,*[3.6] which held that copyrights and design patents might both be available for certain designs.

The Examiner also placed misguided reliance on Article 2 of UPOV, an executive agreement. Article 2(1) says that the right of the breeder may be recognized by either a patent or a "special title of protection" (e.g., a PVP certificate), not both for the same botanical genes or species. However, under Article 37, the United States gave notice that it intended to provide *both* forms of protection.[3.7]

While this point was overlooked by the Board, it still was unimpressed by the Examiner's attempt to use an executive agreement to chip away at an Act of Congress. The Board reversed the Examiner's 35 U.S.C. §101 rejections as based on an erroneous interpretation of that provision.

With respect to the tissue culture claims, the Board reversed the rejection for the additional reason that tissue cultures are not "plants" within the purview of 35 U.S.C. §161, relying on the CCPA's vacated 1979 *In re Bergy*[3.8] decision.

These issues are treated again, from a somewhat different vantage point, in §9.05.

§ 6.01A Utility Patent Protection of Plant Breeding and Genetic Engineering Methods

Even before the *Chakrabarty* decision paved the way for utility patent protection of novel plant varieties, per se, the utility patent laws served as a useful adjunct to the plant patent laws. While the plants themselves were not protectible, plant breeding methods are routinely protected under §101. For example, Lawrence, U.S. Patent No. 4,326,358, *Hybrids* (1982), presents the following claim:

> 1. A process for rapidly developing hybrids and commercially producing hybrid seeds, comprising (a) selecting a first parent plant and a second parent plant; (b) crossing said first parent

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[3.6] 493 F.2d 1389 (CCPA 1974).

[3.7] UPOV Notification 17.

[3.8] 596 F.2d 952 (CCPA 1979).

plant with said second parent plant to obtain original-parent-derived hybrids that are phenotypically uniform; (c) cloning said first parent plant to produce a first cloned parental line; and (d) crossing plants of said first cloned parental line with said second parent plant or with a second parental line produced therefrom to obtain hybrid seeds that are phenotypically uniform, provided that when said second parent plant is heterozygous and a second parental line produced therefrom is used in the crossing of step (d), the second parental line must be produced by cloning.

The protection of plant genes, or of vectors capable of replicating in plants, does not present legal issues which differ significantly from those presented by attempts to protect other genes or vectors (see Chapter 4). There are, of course, formidable scientific hurdles, raised by our ignorance of plant molecular biology as of the time of this writing.

One example of a plant molecular biology patent claim should suffice. Howell, U.S. Patent No. 4,407,956 (1983) claims a "recombinant cauliflower mosaic virus capable of propagation and movement, said movement comprising replication and systemic infection, said virus or a parent thereof having received in vitro an insertion of foreign DNA at the intergenic region between reading frames VI and I, a site non-essential to such movement."

§ 6.02 Utility Patent Protection of Animal Varieties—The Constitutional Mandate

In *Bergy,* the Board of Appeals expressed its fear that "[i]f we were to adopt a liberal interpretation of 35 U.S.C. §101, new types of insects, such as honeybees, or new varieties of animals produced by selective breeding and cross-breeding would be patentable.[4] In *Chakrabarty,* the Board elaborated on this theme by saying that if §101 encompasses genetically-engineered microorganisms, "why would not 35 U.S.C. §101 encompass living multicellular organisms (including human beings) which have been modified by the physical incorpora-

[4] Tr. 63.

tion (as by artificial transplants) of additional organs such as the liver or heart?[5] And Gerald Bjorgy, arguing *Chakrabarty* for the Office, said that while his children's cat might be "a better mousetrap," it surely should not be patentable.[6]

The PTO apparently expected that these comments would send shock waves of revulsion up and down the patent community. It had perhaps forgotten that Glascock,[7] Rossman,[8] Dienner,[9] Parker,[10] Thorne,[11] Walker,[12] and the A.B.A.[13] had all applauded efforts to protect the contributions of the animal husbandman. (And the Fifth and Fourteenth Amendments surely would frustrate any attempt to patent human beings, even genetically engineered human beings.[14])

Walker gave testimony at the 1906 Hearing on H.R. 18851, "horticultural patent" bill. An interesting colloquy was initiated by Congressman Chaney of Indiana.[15]

> Mr. Chaney: If you proposed to do this in horticulture, might you not authorize a man breeding horses to get out a patent on an improved breed of horses?

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[5] Tr. 95.

[6] Oral Argument, *Chakrabarty*, Pat. Appl. No. 77-535 (argued on December 5, 1977, before the CCPA).

[7] Glascock and Stringham, *Patent Soliciting and Examining* 591 (1934) citing Rossman, "The Preparation and Prosecution of Plant Patent Applications," 17 JPOS 632, 643-644 (1935): "The plant law should . . . logically be extended to all forms of plants. . . . The next step would be to enact a law for patenting novel types of animal life."

[8] Id.

[9] Dienner, "Patents for Biological Specimens and Products," 35 POS 286, 289-900 (1935).

[10] Hearings Before the Committee on Patents, House of Representatives on H.R. 11372, A Bill to Provide for Plant Patents, 71st Cong. 2nd Sess., at 4 (April 9, 1930): "Col. Francis W. Parker . . . felt that someday the patent law would be amended so as to give to the man who developed new forms of plant or animal life an opportunity to control reproduction."

[11] Thorne, "Relation of Patent Law to Natural Products," 6 POS 23, 27-28 (1923).

[12] Arguments Before the Committee on Patents of the House of Representatives on H.R. 1885, 59th Cong. at 18 (May 17, 1906).

[13] 1966 Resolution 22 of the PTC Section of the ABA.

[14] Brief for Appellant, *Chakrabarty*, 21-22.

[15] *See* Argument, *supra* note 12.

Mr. Walker: The difference is very marked. In horticulture you produce new varieties, while in animals you do not. If somebody could produce an animal that had the speed of the horse, the patience of the ox, the intelligence of the dog, and the wisdom of the elephant all combined, then perhaps he ought to have a patent on that animal.

Mr. Southall: Then you would give a man a patent on a mule?

Mr. Walker: Yes, although the patent on the mule would have expired by now.

The Chairman: But in the first instance you would give a patent on a mule?

Mr. Walker: Yes, we would on that principle give the man who bred together the horse and the ass a patent on the animal produced; that was undoubtedly a benefit to mankind.

Mr. Chaney: The late Mr. Ingalls would object, because he said that the mule has neither pride or ancestry nor hope of posterity.

H.R. 18851 did not become law. But interest in biological patents did not die with it. In 1928 [John Dienner] conferred with Secretary Arthur A. Hyde, then Secretary of Agriculture, with a view to providing legislation granting broad protection like that of a patent to all originators of plants and animals and products thereof, such as fruits, roots, eggs, leaves, seeds, etc. Secretary Hyde was enthusiastic, but the movement was kidnapped and disguised as the 1930 Plant Patent Act.[16]

The Plant Patent Act appeased the Luther Burbanks of this country, but not the Robert Bakewells.[17] In 1966, the Patent, Trademark, and Copyright section of the American Bar Association approved a resolution calling for "the application of all principles of the Patent System to all the agricultural arts (including all plants, sexual seed breeding, micro-organisms, and animal husbandry).[18]

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[16] *See* Dienner, *supra* note 9.

[17] Robert Bakewell was the first of the scientific breeders (though working without a knowledge of Mendelian genetics), and developed several valuable breeds of cattle.

[18] 1966 Committee Reports 76-77; 1966 Summary of Proceedings 59, 74.

Even an opponent of life form patents, Sheldon Krimsky, foresees patents on animals:

> If we genetically modify the germ plasm of a bull to qualify as a product of manufacture, can we patent the germ plasm? Does the patent extend to all of the progeny? Presently, a single bull can provide the sperm for hundreds or thousands of offspring. Someone can own the bull and sell the sperm, but there is no entitlement to the ownership of the progeny.
>
> Let us suppose that in addition to genetically modifying the bull's germ plasm (whereby progeny cows provide a higher yield of milk), we learn how to duplicate the genes in unlimited quantity. The patenting of this product could be tantamount to owning the genetic strain of a species. Moreover, we might be able to achieve monoherds, the livestock counterpart to monocultures. But by narrowing the genetic variation of livestock to improve upon certain qualities and to promote uniformity, we could be duplicating the hazards faced worldwide in agriculture where the variety of crops has been dramatically reduced. Genetic homogeneity, whether in crops or in animals, is vulnerable to a single catastrophic event that a variegated genetic pool could overcome. Recently, scientists at the University of Geneva reported the successful cloning of a mammal. The New York Times story on the event told of some researchers who want to mass-produce prize livestock by the nucleus transplantation technique that gave rise to the mouse clones. The confluence of cloning, engineering genes, and patenting higher life forms may not be too far off.[19]

Norton Zinder, unlike Krimsky, finds "no difference either intellectually or morally between the registering of dogs, prize bulls, and thoroughbred horses and the patenting of life."[20]

Patent protection of new animal breeds would "promote the progress of the useful arts," among which animal husbandry certainly must be numbered. Dienner has rightly decried the "pattern of thinking" of those who believe that only tradi-

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[19] S. Krimsky, Patenting of Microorganisms and Higher Life Forms: Social and Ethical Concerns, in ASM, Patentability of Microorganisms: Issues and Questions 17, 20 (1981).

[20] N. D. Zinder, Genetic Engineering and Patenting, Id., 4-5 (1981).

tional manufactures can be patented.[21] This pattern of thinking has throttled agricultural innovation: "While agriculture was making slow progress in the development of new plants and animals and products thereof, the industrial system under patent protection forged ahead with astonishing speed.[22]

When new plants and animals have been developed, they have changed the course of history. The Maginogion, the Welsh book of legends, tells that when Prince Gwydion learned that Pryderi, one of the rulers of the Welsh Hades, had received a new kind of animal as a gift, Gwydion stole these wondrous beasts—pigs—for "(a) new race of beasts might prove precious to Gwynedd," his kingdom.[23]

The invention of the stirrup made mounted shock combat possible, but a new breed of horse was needed to bear the heavily armored knight. Deliberate selective breeding for the chivalric market began at least as early as 1341.[24] The new war horses contributed to the development of the institution of feudalism.

In more recent times, pack mules made possible the construction of the transcontinental railroads.[25]

A very large number of animals have been domesticated. A partial list would include dogs, cats, goats, cattle, sheep, horses, pigs, chickens, rabbits, camels, reindeer, mink, elephants, bees, and silkworms.[26] These domesticated animals differ greatly from their wild ancestors.

> The wild ancestors of cattle gave no more than few hundred grams of milk; the best milk cow now can yield 12,000 to 15,000 liters of milk during its lactation period. . . . In the ancestors of domestic sheep, wool consisted mainly of thick rough hairs and a small amount of down; the total weight of wool never reached one kilogram. The wool of present day fine-fleeced sheep consists of uniform, thin down fibers; the yearly total weight may reach twenty kilograms. . . . Even at the initial

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[21] Dienner, *supra* note 9 at 289.

[22] Id., 291.

[23] C. Squire, *Celtic Myth and Legend* 306-311 (1975).

[24] L. White, Jr., *Medieval Technology and Social Change*, 62 and n.1 (1962).

[25] S. Davenport, *Domesticated Animals and Plants* (1910).

[26] 5 *Encyclopedia Brittanica* 940 (1975). And *see generally* F. E. Zeuner, *A History of Domesticated Animals* (1963).

> stages of domestication, some morphological changes in animals and plants are apparent. In mink, for example, which became the objects of breeding for fur in about 1920, there have already appeared more than twenty different variations of fur color and several variations in fur texture.[27]

Domestication accelerates evolution, adapting wild creatures to serve man's needs and desires.

In short, utility patent protection for "new" animals (and plants) is entirely consonant with the Constitutional purpose of the patent System—the promotion of the progress of the useful arts. Since 35 U.S.C. §101 does not expresssly exclude them from protection as new manufactures, such protection should be accorded by the Courts, even under present law.

However, as applicants for utility (35 U.S.C. §101) patents must strictly comply with the requirements of §112, it behooves us to consider whether the patent law as presently constituted in fact offers any incentive to the development of new and useful multicellular organisms (other than sexually reproduced plants). The flaws of the present system can, once recognized, be eliminated by carefully drafted reformatory legislation.

The only U.S. decision dealing directly with claims to an animal per se is *In re Merat.* This decision is discussed in great detail in the next section, since the claim in question was rejected under 35 U.S.C. §112. According to the CCPA opinion,

> The examiner rejected the claims solely under 35 USC 101 as directed to nonstatutory subject matter. The board affirmed this rejection and entered two new rejections under 35 USC 103 and 112, second paragraph. We affirm on the Section 112 rejection.[27.1]

The argument of the Board was that if §101 were interpreted broadly enough to encompass a new breed of animals, it would be "broad enough to include breeding plants also. Thus obviating the need for 35 U.S.C. 161." The CCPA declared that in view of the correctness of the Board's 112 rejection, it was "unnecessary to discuss the other grounds of rejection."

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[27] Ency. Britt. Id. 941.

[27.1] In re Merat, 519 F.2d 1390 (CCPA 1978).

In *Bergy I,* the majority cautioned that the CCPA was not deciding "whether any living things other than microorganisms are within Section 101." As the dissent pointed out, this was a "gratuitous distinction."

Finally, in *Diamond v. Chakrabarty,* the majority stated, "the relevant distinction is not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions." It read the Plant Patent Act as a reaction to a perceived disclosure problem, rather than as an attempt to extend the scope of statutory subject matter.

It thus appears that novel animal breeds should be considered patentable subject matter under §101. The "nonstatutory subject matter" arguments advanced by the Board with respect to the *Merat* application were soundly criticized by the Supreme Court in *Chakrabarty.* The dissenters in *Bergy I* admitted that there was no rational distinction between "microorganisms" and "honeybees" so far as §101 is concerned. Finally, there is no doubt that a novel animal breed may be, in Chief Justice Burger's words, "the result of human ingenuity and research," and not merely "nature's handiwork."

Dr. Jorge Goldstein has pointed out that support for this interpretation is offered by an obiter dictum in the Canadian *Abitibi-Price* decision.[27.2] The Commissioner specifically suggested that a new and nonobvious insect which preys on the spruce bud worm might be "every much a new tool of man as a microorganism," and hence patentable. While Dr. Goldstein is correct in stating that this decision is not legal precedent in the United States, I would hesitate to say as he does that it is "of no legal significance." In areas of legal controversy in which there are no applicable American opinions, a court may well look to a Canadian decision for guidance. (The Canadian patent statute is modelled after our own.)[27.3]

Rene Tegtmeyer, the Assistant Commissioner for Patents, declared in October 1984 that "life forms other than microorganisms and certain plants will be denied protection under the general patent laws. A genetically modified animal was a given

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[27.2] In re Abitibi-Price, Inc., 1 Biotechnology Law Reports 48 (Can. Commr. Pats., March 18, 1982.

[27.3] J.A. Goldstein, From Pseudomonas to the Birds: Are Animals Patentable?, Recombinant DNA Technical Bulletin 6: 57, 59-60 (June 1983).

example. While there was no declared reason for the exclusion of animals, that exclusion seems premised on a narrow interpretation of Chakrabarty as limited to microorganisms."[27.4]

It is true that the Supreme Court stated at the outset, "we granted certiorari to determine whether a live, human-made microorganism is patentable subject matter. . . ." However, even the dicta of the Supreme Court should be given considerable weight. The Supreme Court approvingly quoted the 1952 Committee Reports, which stated that the general patent law included "anything under the sun that is made by man."

The PTO's position was inconsistent with its own, publicly announced reading of *Diamond v. Chakrabarty.* Section 2105 of the Manual of Patent Examining Procedure states:

> 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 is whether the living matter is the result of human intervention.

Under that test of human intervention, genetically engineered animals are clearly patentable subject matter under §101.

The *Ex parte Hibberd*[27.5] decision left the PTO in a poor position to maintain that animals are unpatentable per se. Certainly, a transgenic animal is something "under the sun that is made by man." With plants, at least, the PTO had a plausible statutory construction argument for denying protection under 35 U.S.C. §101. The PTO's continued rejection of patents on animals appeared to be founded more on vitalistic grounds than upon any rational analysis of the statute.

This last refuge of vitalism was challenged by *Ex parte*

27.4 "Section 101 Plant Patents—Preemption," A Report of the AIPLA Plant Variety Protection Committee (L-7), submitted December 7, 1984, by Anthony Diepenbrock, Chairman, to William H. Elliot. It is interesting to note that the PTO is engaging increasingly in the practice of "luncheon law," a field pioneered by the Intellectual Property Section of the DOJ Antitrust Division.

27.5 227 USPQ 473 (BPAI 1985).

Allen.[27.6] The contested claims were to "polyploid Pacific oysters" produced by applying hydrostatic pressure to oyster zygotes to induce polyploidy and then cultivating the polyploid zygotes. The Board considered itself bound by the expansive interpretation of "manufacture" and "composition of matter" adopted by the Supreme Court in *Chakrabarty:* "anything under the sun that is made by man." The Section 101 rejection was accordingly reversed.

Subsequently, the Commissioner announced, in April 1987, that the P.T.O. would consider nonnaturally occurring nonhuman multicellular living organisms, including animals, to be patentable subject matter under 35 U.S.C. 101.[27.7]

On April 12, 1988, the U.S. Patent and Trademark Office issued a patent with the following main claim:[27.8]

> 1. A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.

It will be noted that this claim is not limited to any particular species of mammal. Animals of the type claimed were disclosed to be useful in testing possible carcinogens because of their extreme propensity toward the development of tumors.

§ 6.03 Drafting Patent Applications for Animal Varieties

Animal husbandmen may have trouble satisfying the enablement requirement of §112, as *Merat* and *Rote Taube* (RED DOVE) show that it is very difficult to satisfy this requirement by means of a phenotypic selection system.[28]

[27.6] 2 U.S.P.Q. 2d 1425, 1427 (BPAI 1987).

[27.7] 1077 O.G. 24, 33 P.T.C.J. 664.

[27.8] Leder, U.S. 4,736,866.

[28] In re Merat, 519 F.2d 1390 (CCPA 1975); Ex parte Schreiner (Red Dove), 1 Int'l Rev. Indus. Prop. & Copyright L. 136 (1970). Here it is perhaps necessary to define certain terms commonly employed by animal breeders. A typical animal mating system involves some combination of inbreeding and outbreeding. Inbreeding is the mating of individuals more closely related

Merat first crossed "females of a cooking breed of poultry having good growth and fattening characteristics with cocks of small size which carry" a dwarfism gene. He then inbred the crossbred chickens, and selected from their progeny the dwarf hens. Finally, he crossed these dwarf hens with "any desired breed of normal heavy meat cocks, thereby obtaining, as an industrial product, a chick to be raised as a cooking chicken of normal heavy meat size.[29]

The first problem with Merat was its definition of "normal." If the dwarfism gene ("nr") was recessive, then NrNr and Nrnr chickens would both appear to be normal. "Since the claim language is not precise enough to indicate which kind of cock to use to produce the result required by the claims, it fails to comply with §112, second paragraph.[30]

The CCPA also felt that the claim suggested that all of the final product chickens would be "normal," when in fact some would be "normal," some would be "subnormal," and some would be "dwarf."[31] The CCPA's reasoning was faulty; it does not require 100 percent yields in chemical cases, and it would have been obvious to any person of ordinary skill in the com-

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than the average members of the population. It increases the appearanceof unfavorable as well as favorable traits. (Line breeding is a mild form of inbreeding.) Outbreeding is the mating of individuals less closely related than the average members of the population. An outbred animal will possess, to some degree, the superior traits of each of its parents, and thanks to "hybrid vigor," it may be somewhat superior overall. (Crossbreeding is a synonym for outbreeding.) Backcrossing is the crossing of crossbred offspring with one of the parental breeds.

Once the mating scheme is chosen, the breeding animals must be selected, for the breeder is well advised to match "best with best." Currently, phenotypic selection systems are used: the breeding animals are examined for their possession of the particular trait (color, weight, milk production, speed, etc.). The breeder wishes to enhance or transfer. The breeding pairs are then selected on the basis of either their own performance, or the performance of their parents, progeny, or siblings. 1 Ency. Britt. 905-6 (1975). And *see generally* L. Lush, *Animal Breeding Plans* (1945).

[29] 519 F.2d at 1593.

[30] Id. 1396. Though a heterozygous animal's recessive gene in some cases causes its phenotype to be intermediate in nature, *e.g.*, "subnormal" though not "dwarf."

[31] Id.

mercial poultry art (who would presumably be familiar with Mendelian genetics) that the yield would not be 100 percent.

Finally, the CCPA pointed to the fact that:

> [A]ppellant's invention cannot be practiced unless chickens with the nr gene are available. Cf. In re Argoudelis; 434 F.2d 1390, 58 CCPA 769 (1970); Feldman v. Aunstrup, 517 F.2d 1351 (CCPA 1975). The specification contains no disclosure of where chickens having the nr gene may be obtained, nor does it indicate that breeding stocks of nr-bearing chickens are presently being maintained.[32]

In Rote Taube, the single German patent claim was directed to a:

> Method for breeding a dove with red plumage, which is considerably larger with respect to other doves of the same color, has a considerably larger wingspread, the colors of the plumage of the wings being considerably more beautiful and more intense, and having a craw which is extremely large in relation to the size of the body, in which an *Altdeutsche Kropfer* is crossed in the first step of the process with a *Rote Romertaube*, the doves resulting from this crossing are selected according to size and color; a selected product of said crossing is bred in the second step with a *Roter HessenKropfer*, of the doves thus obtained *one* again is selected and bred in the third step with an *Aldeutscher Kropfer*.[33]

The claim was rejected on grounds akin to those espoused by the CCPA in *Merat*. The *Bundesgerichtschof* concluded:

> In the present case, as is evident from the findings of the Patent Office, the method for breeding a dove. . . is not repeatable. . . . [T]he disclosure of the breeding method in the patent specification and its characterization in the claim [will] not ensure a genetically identical repetition of such breeding method and under no circumstances can it be assumed that the same genetic results would be obtained with a high degree of certainty. The initial animal species are characterized in a general man-

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[32] Id. n.9.

[33] 1 IIC 136 (Bundesgerichtshof, March 27, 1966).

ner according to their kind without indicating individual hereditary characteristics. Therefore, in attempting to repeat the breeding method, a person skilled in the art would be required to use such animals that might correspond to the described kind with respect to their looks. The two-step selection is directed to two characteristics which, however, are defined only in general terms (size and color). Carrying out the steps of selection thus still leaves room for many variations, also because the phenotypical approach does not promise a sufficiently predetermined result. The above reasons do not permit the conclusion with certainty that the breeding method can be repeated, particularly since we are here concerned with breeding an animal in the upper range of the evolutionary scale, and having complex hereditary characteristics.[34]

Those responsible for drafting patent applications directed to new breeds of animals would be well advised to (1) state where the required breeding stocks (or sperm and egg banks) are *available;* (2) use a *genotypic* selection scheme if possible; (3) use a *quantitative* selection rule if a phenotypic selection scheme is used; and (4) claim that the breeding method is *statistically* reliable.

The reason, of course, why the selection scheme is so important, is that we cannot asexually reproduce the new animal breed from a cell culture, as we might a new strain of microorganism. Animal husbandmen cannot fully exploit the *Argoudelis*[35] route to enablement until cloning technology is perfected. Any cell holds within it the blueprint of the entire organism, and it is theoretically possible to grow a clone goose, horse, or elephant.

Biologists have removed the nucleus from an unfertilized Vermont Spotted Leopard Frog egg, and inserted the nucleus from an "immature" (undifferentiated) cell of the mottled Kandiyohi mutant frog. The cloned egg developed into an adult, fertile frog with the characteristic pigmentation of the

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[34] Id., 141-142.

[35] *See* In re Argoudelis, 434 F.2d 1390, 1392-1393 (CCPA 1970); D. G. Daus, Conditionally Available Cultures; An Appraisal of In re Argoudelis; 54 JPOS 187 (1972); C. M. Behr, The Prescient Microbe, Or, Where to Deposit a Foreign Body, 57 JPOS 26 (1975).

Kandiyohi mutant.[36] Similar nuclear transplantation experiments have been successfully carried out with other species of amphibia, as well as with the ubiquitous fruit fly, and even in two animal species of commercial interest, the honeybee[37] and the golden carp.[38]

Theoretically, therefore, a new species of amphibian could be developed by traditional techniques (controlled breeding) and the resulting new variety cloned. The cell culture could be kept in a repository and nucleus transplanted to enucleated eggs whenever there was a demand for an adult. Development could be halted and some cells preserved in order to replenish the cell culture on file. Arguably, the deposit of a cell culture in this repository would satisfy the requirements of 35 U.S.C. §112.

There are certain problems in proceeding from nuclear transplantation in amphibia to mammalian cloning:

> What is needed for mammalian cloning? A source of eggs; an enucleation procedure, a supply of donor cells, a technique to put egg and donor nucleus together, and a means of culturing the developing clone until it can survive on its own are the essential prerequisites.[39]

McKinnell suggests hormone-induced ovulation as a source of eggs; removal of the nucleus with lasers or chemical agents; *in vitro* fertilized eggs as a source or embryos, use of the Sendai virus to increase the likelihood of cell fusion, and foster motherhood of the embryo.[40]

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[36] *See generally* R. G. McKinnell, *Cloning—Nuclear Transportation in Amphibia* (1978).

[37] Du Praw, The Honeybee Embryo in *Methods of Developmental Biology* 183-217 (F. H. Witt & N. K. Wessell eds. 1967).

[38] 118 Sci. News 214 (1980) displayed a photograph of a four-month old four-inch long carp produced by scientists at the Chinese Institute of Hydrobiology by transferring a nucleus from a blastula (immature cell) to an enucleated unfertilized egg. Fifty-nine nuclear transplantations were needed to reach the "adult" stage. Among 169 attempted transplants, only two fish developed to the "fry" stage. Id. at 72. 117 Sci. News [5] (1980) reported Soviet scientist Mikhelson's proposal to activate a long-frozen mammoth nucleus by implantation in an elephant oocyte in an elephant's uterus.

[39] R. G. McKinnell, Cloning—A Biologist Reports 79 (1979).

[40] Id. at 80-93.

It therefore appears that true animal cell culture repositories, which can provide cloned cells that will mature into adult animals, are indeed technically feasible. The sooner a test case is brought, the sooner the agricultural community will begin to experience the full benefits of the patent system.

One commentator has suggested that "cloning is perhaps scientifically far-fetched for animals."[40.1] However, Figure 10 in McKinnell's book shows "a cloned frog produced from an enucleated egg of a Vermont spotted leopard frog and an inserted nucleus of a Minnesota Kandiyohi mutant embryo donor."[40.2] The cloned frog expressed the Kandiyohi characteristic. Moreover, the cloning of a goldfish by Chinese scientists was reported in 1981.[40.3]

The enablement problem attaches mainly to animals produced by traditional breeding methods. Animals produced by cloning should be patentable without difficulty. However, until cloning becomes *de rigeur,* animal husbandmen will need legislative relief of some kind. Such relief could easily take the form of an extension of 35 U.S.C. §162 to animal patents.[41]

A second §112 problem for animal husbandmen is the requirement that the applicant "particularly point out and distinctly claim" the subject matter which he regards as his invention. If an applicant claims, for example, a "new breed of dove," he may run into some serious trouble. "Breed" is one of those words which virtually defy definition. The various animal pedigree associations, who are the experts in distinguishing breeds, do not always see eye-to-eye when confronted with what is allegedly a new breed of cat, dog, horse or cow. In any biological patent legislation, Congress would be well advised to make use of the term "novel variety," which is defined in the Plant Variety Protection Act as a variety having characteristics as follows:

[40.1] J.A. Goldstein, From Pseudomonas to the Birds: Are Animals Patentable?, Recombinant DNA Technical Bulletin 6: 57, 61 (June 1983).

[40.2] *Supra* note 36, at 39.

[40.3] Science News, 72 (August 2, 1980).

[41] "No plant patent shall be declared invalid for noncompliance with §112 of this title if the description is as complete as is reasonably possible."

(1) Distinctness in the sense that the variety clearly differs by one or more identifiable morphological, physiological or other characteristics . . . from all prior varieties. . . .
(2) Uniformity in the sense that any variations are describable, predictable and commercially acceptable; and
(3) Stability in the sense that the variety, when sexually reproduced or reconstituted, will remain unchanged with regard to its essential and distinctive characteristics with a reasonable degree of reliability commensurate with that of varieties of the same category in which the same breeding method is employed.[42]

While this definition was drafted to serve the purposes of the Plant Variety Protection Act of 1970, it is remarkably similar to Article 31 of the 1969 Hungarian Patent Regulations, which, though it refers to "plant varieties," applies *mutatis mutandis* (under Article 36) to "animal breeds."[43]

Article 31 (re Article 67 of the Law):

(1) [An animal] variety is new if it differs from known breeds in at least one essential characteristic morphologically, physiologically or in other respects.
(2) [An animal] variety is homogeneous if the essential characteristics of its members—having regard to its sexual or asexual propagatory properties—are identical.
(3) [An animal] variety is relatively stable if in the course of propagation by natural or artificial means or in the course of a propagatory cycle its essential characteristics agree with those in the description.

Even if multicellular organisms were thought patentable under 35 U.S.C. §101, most applications would fall afoul of 35 U.S.C. §112. If the devisers of new forms of multicellular life are to be accorded the benefits of the patent system, and

[42] 7 U.S.C. §2401.

[43] 2C Sinnott, World Patent Law and Practice at Hungary-39 (1977). Article 31 was amended in 1983, apparently to accommodate the UPOV requirements, but its general thrust is unchanged.

thereby encouraged to benefit the public,[44] it would be best to amend 35 U.S.C. §161 to read:

> Whoever invents or discovers, and reproduces, any novel variety of living organism (including viruses, but excluding man) may obtain a patent therefor

and apply 35 U.S.C. §§162-164, *mutatis mutandis,* to living organisms generally.

The acquisition of protection of animal varieties under the utility patent law will require a creative approach.

> The challenge for scientists and industry in emerging areas of "living" inventions will be to create a depository system that can be used to accommodate samples of the "living" invention and to make them available to the public upon the grant of the patent. Just as the late Harvey Edelblute ingeniously started the march to Peoria for microorganism patents, equal or greater creativity will be necessary to establish depository systems for new inventions.[45]

§ 6.04 Design Patent Protection of Ornamental Features of Animals and Plants

Peter Trzyna has suggested that nonfunctional, ornamental features of plants can be protected by design patents.[46] An example would be a distinctive variegated leaf pattern. Karl Bo-

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[44] The importance of patents as an incentive to the commercial exploitation of scientific discoveries is best shown by two articles remarking on its sluggishness in fields in which patents are less available. *See* Time, April 20, 1970, at 46 (lithium carbonate as a chemotherapy for mania) and Chemical & Engineering News, October 6, 1975 at 21 (bacteria and viruses as "biological controls"). *See also* Dr. Betsy Ancker-Johnson's testimony in the Hearings before the Subcomm. on Health and Environment of H. Comm. on Interstate & For Comm. (95th Cong. 1st Sess.) on the "Recombinant DNA Research Act of 1977" at 239-240 re the development of penicillin.

[45] H. C. Wegner and C. A. Wendal, Post-*Chakrabarty* Patent Questions, in ASM, Patentability of Microorganisms: Issues and Questions 28, 30 (1981).

[46] Trzyna, "Are Plants Protectable Under the Design Patent Act?" JPTOS, 487 (Sept. 1987).

zicevic later commented that animal coats with a significant ornamental character might likewise be protectable.[47]

§ 6.05 Protection of Genetically Engineered Animals Under European Patents

Article 53 of the European Patent Convention states

> European patents shall not be granted in respect of . . .
>
> (b) Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

At present, the parties to the Convention are Austria, Belgium, France, the Federal Republic of Germany, Luxembourg, Greece, Switzerland (and Lichtenstein), Sweden, Spain, the United Kingdom, Italy and Monaco.

Seemingly, Art. 53(b) interposes an insuperable barrier to the patenting of animals in Europe. However, the prohibition of Article 53(b) is by no means as broad as it appears to the untrained eye. Special attention must be given to the meanings of the terms "varieties," "essentially biological processes," "microbiological processes" and "products." While it is too soon to say that the question is settled, the odds are good that those engaged in the genetic manipulation of animals by rDNA techniques will be able to obtain meaningful animal patent claims in Europe without waiting for any kind of statutory change.

The decision of the EPO Technical Board of Appeal in *Propagating material/CIBA-GEIGY* (July 26, 1983) was revolutionary in its implications. Appeal had been taken from a rejection of a claim to "propagating material for cultivated plants, treated with an oxime derivative according to formula I of claim 1." The Examiner was of the opinion that the claimed subject matter was barred from protection since it comprised chemically treated plant varieties.

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[47] Letter to the Editor, JPTOS, 651 (Nov. 1987).

The Board carefully distinguished "plants" and "plant varieties." According to the Board, plant varieties were excluded from European patent protection mainly because they were already protected by special titles of protection (similar to Plant Variety Protection Certificates in the United States). These special titles of protection were harmonized by the International Convention for the Protection of New Varieties of Plants (UPOV), which defined "plant varieties" as groups of plants meeting certain requirements of distinctness, homogeneity and stability.

As the Board noted, the subject matter of the appealed claims was "not an individual variety of plant distinguishable from any other variety" as "treatment with an oxime derivative is not a criterion which can be characteristic of a plant variety." Thus, the claimed plant material would not have satisfied the "distinctness" requirement for plant variety protection. Moreover, the treatment could be carried out on propagating material which did not meet the homogeneity or stability requirements either. Thus, the claimed plant material was not entitled to protection as a "plant variety" under UPOV.

The Board declared that the exclusion of Art. 53(b) is restricted to "cases in which plants are characterized precisely by the genetically determined peculiarities of their natural phenotype," *i.e.*, to plant varieties protectable under UPOV, but that "innovations which cannot be given the protection afforded to varieties are still patentable if the general prerequisites are met."

On March 27, 1986, the Swiss Federal Intellectual Property Office amended its guidelines for the examination of patent applications in the field of biotechnology. It declared:

> With respect to inventions relating to *plants*, only new *varieties* as such are not patentable since they are eligible for plant variety protection, a system specially designed for them and which may not be cumulated with patent protection on the same subject matter. The following claims will be admitted in the future:
>
> — Product claims relating to whole plants or their propagating material (seeds, tubers, cuttings, etc.) but in which no *variety* is specified, i.e., claims containing only characters

that are valid for several varieties (for example a whole genus). In this context the variety notion must be interpreted as in the Plant Variety Protection Law. . ., i.e., by reference to the criteria of homogeneity, stability and distinctness from other plant varieties. . . .

— Product claims relating to other botanical material, in particular structural elements that may not be regenerated into whole plants such as cell lines, modified cells, genes, plasmids, etc.

With respect to inventions relating to animals, the applicable criteria will be the same as for plants.

(See Swiss Patents, Designs and Trademarks Gazette, Ed. A, March 27, 1986, quoted in UPOV document CAJ/XVII/8, April 14, 1986, Annex; boldface added).

Thus, in Switzerland at least, if one introduces a foreign gene into an animal by microinjection, and claims the resulting genetically engineered animal without limitation to any particular variety (breed) of animal, the claim would be potentially patentable.

I would suggest that transgenic animals which were incapable of transmitting the new genetic information to their offspring (*i.e.*, animals in which the foreign gene was borne only by somatic cells and not by germ cells) would be especially likely to be considered outside the compass of "animal varieties," as the genetic characteristic imparted by the foreign gene could not then be considered "stable."

Besides arguing that one is claiming an "animal" and not an "animal variety," one may contend that the transgenic animal is the "product" of a "microbiological process." The EPO interprets the term "microbiological process" as encompassing not only methods of using microorganisms (*i.e.*, fermentation processes), but also methods of producing new microorganisms. (*See* EPO Guidelines for Examination, Ch. IV, 3.5.) The EPO seemingly considers a microbiological process to be one in which there is direct human manipulation of the genome at a cellular level, whether that manipulation involves classical mutation-selection techniques or "gene splicing." For this reason, genetically engineered plant and animal cells are already

treated as patentable in Europe, even though plant and animal cells are not "microbial" cells.

While Article 53(b) does not do so explicitly, the EPO seems to take the position that the *product* of an "essentially biological process" is unpatentable; thus, it sets up a dichotomy between "biological" and "microbiological" processes. In the production of a transgenic animal, the initial steps are at a cellular level: the isolation of the desired gene; the coupling of the gene to a suitable promoter; and the microinjection of the recombinant DNA into a suitable host cell. If the host cell is a somatic cell of a developed animal, it is clear that the resultant transgenic animal is entirely the product of what EPO considers to be "microbiological processes." On the other hand, if the host cell is a single cell embryo, it could be argued that the reimplantation of that cell into the uterus and its development into a whole animal is a "biological process." Such a transgenic animal is the product of both "microbiological" and "biological" events. I would contend, however, that since the microbiological steps gave it the desired novel characteristics, it would be appropriate to say that it was not the product of an *essentially* biological process.

In responding to a WIPO questionnaire, the European Patent Office stated its position on the patentability of certain forms of plant and animal biotechnology:

> **Question 1.2.10—new hybrid seed of a plant variety.**
>
> No. Since the product of an essentially biological process is involved the exclusion contained in Article 53(b) EPC, at the end, does not apply. The seed is furthermore considered a plant variety with genetically defined characteristics, the patentability of which is ruled out by Article 53(b) EPC. . . .[T]he EPC does not distinguish between varieties eligible for protection as a plant variety and those not eligible.
>
> **Question 1.2.12—A mouse embryo cell containing a particular additional foreign gene.**
>
> Yes. Animal variety is not involved here; the cell is the product of a microbiological process.
>
> **Question 1.2.21—plant variety having the properties of a particular known variety with an additional particular characteristic**

introduced by transferring a gene encoding that characteristic into a plant cell and regenerating the plant from that cell.

Uncertain. Before the EPO this product may be considered to be a new—non-patentable—variety or the result of a patentable microbiological process. In the latter case, the products of microbiological processes would be deemed not to be covered by the exclusion from patentability of plant varieties. This matter is currently being examined by the EPO.

Question 1.2.22—cell of a particular known plant variety containing a particular additional gene.

Yes, cells are not considered to be plant varieties but the products of microbiological processes (Article 53(b), second part of the sentence).

Question 1.2.24—plant of genus x, containing a foreign gene for resistance to a particular herbicide.

Uncertain. The answer would be yes if the plant were considered to be a product of a microbiological process. On the other hand, the fact that it is a genus and not a variety may be regarded as insufficient to prevent it being excluded under Article 53(b) EPC, as a genus comprises a limited number of varieties.

Question 1.2.25—pigs containing in their hereditary material a foreign gene accelerating their growth.

Uncertain, see 1.2.24. The reply depends on whether or not a pig is considered to be an animal variety.

Question 1.2.26—seed of wheat treated with a particular chemical.

Uncertain for the same reasons as 1.2.21 (second sentence).

Question 1.2.27—plant x treated with microorganism y to improve its resistance.

Yes, if they are plants in general and not individual varieties.

While these answers hardly promise protection of transgenic plants and animals, they make it clear that the EPO will not deny such protection in a "kneejerk" fashion. It will consider whether the claim is directed to a "variety" and whether the organism is the product of a "microbiologicial process."

CHAPTER 7

Ownership of Biotechnology Patent Rights

§ 7.01 Research, Patents and the University

Most universities have found it necessary to evolve policies with regard to the university's interest in inventions developed by professors, with regard to the involvement of professors in commercial activities, and with regard to the university's commercial exploitation of technological developments made under its auspices.[1]

In determining whether the University has title to the invention, the first question is whether there was any express assignment of inventions in the professor's contract with the university. An example is the invention assignment agreement signed by Dr. Cook in *Iron Ore Co. of Canada v. Dow Chemical Co.*[2] Even in the absence of an express contract, employees specifically hired to engage in research and development work may be bound to assign their inventions to their employer.[3]

The university may also acquire a lesser interest in the invention, a so-called "shop right," or nonexclusive license, aris-

[1] Cf. DNA Science, Inc., "Will Genetic Engineering Corrupt the Campus?" (1981) for a look at another aspect of biotechnology in "academe."

[2] 177 USPQ 34, 48 (D. Utah 1972), aff'd on other grounds 500 F.2d 189 (10th Cir. 1974).

[3] Standard Parts Co. v. Peck, 264 U.S. 52, 59-60 (1924).

ing from use of the employer's time, materials, or facilities.[4]

If the university acquires title in the invention, it may (1) dedicate it to the public, (2) make it available, for a modest royalty on a nonexclusive basis, or (3) make it available, for a higher royalty, on an exclusive basis.

These questions of interest become quite complex when a university professor is engaged in related research at both the university and with a commercial concern. If the research bears fruit, it is likely to carry the bitter aftertaste of litigation.

In 1984, a North Carolina appellate court ruled that university researchers were not entitled to have a constructive trust imposed on trade secret royalties received by their university in connection with the secret process which they had developed there as the process belonged to the school under the "hired to invent" doctrine.[5]

§ 7.02 Government Efforts to Encourage Research Joint Ventures

On October 21, 1980, President Carter signed S. 1250 into law as the "Stevenson-Wydler Technology Innovation Act of 1980." The basic purposes of the new Act are to establish funding and cooperation between industries and universities for generic research (*e.g.*, research in basic areas such as materials) and to improve dissemination of federal technology.

To attain the desired cooperation for generic research, the bill establishes "centers of industrial technology." These will be universities or other non-profit host organizations which submit a satisfactory plan for research activity in cooperation with industry. The emphasis will be in areas of generic research and other areas where the technology is likely to benefit the U.S. economy. If the plan is approved, Government funding of up to 75 percent of cost can be obtained. Nineteen million dollars has been allocated for establishing such centers

[4] United States v. Dubilier Condenser Corp., 289 U.S. 178, 188-189 (1933).

[5] Speck v. North Carolina Dairy Foundation, Inc., 28 BNA PTCT 757 (Oct. 25, 1984, decision rendered August 28, 1984).

in 1981 with the amount increasing to $60 million for 1984 and 1985.

The new Act thus appears to allow corporations to cooperate in funding research by mutually using a university center. Its proponents envisioned something similar to the Japanese arrangement by which the government encourages corporations to share in both the cost and benefits of generic research. This was previously difficult to do because of antitrust prohibitions. Section 6(e) permits the Secretary of Commerce to request that the Attorney General render an *advisory* opinion within 120 days as to whether the proposed joint research activities of a Center would violate any of the antitrust laws. This opinion is not binding, and cannot be used as a defense, but the legislators expect that it will have a beneficial influence on a court's attitude toward a joint research venture. The Department of Justice has indicated that it will try to promote innovation through the Centers, not discourage it.

The Center may acquire title to the invention under specified conditions. It may be compelled to license a patent if it is necessary for proper development of the invention. Royalties from the patent must either be given to the inventor or used for educational and research activities.

To disseminate information to state and local governments and private industry, the Act establishes "research and technology application offices" at each federal laboratory. It also establishes a center for utilization of federal technology. Similar programs have been actively pursued in the past by NASA and the Department of Agriculture. These earlier programs were not as successful as hoped for because the Government would not give an exclusive license in the technology developed with federal funds. Industry was generally unwilling to invest in the costly development and marketing of a new product if it could be sold by anyone afterward. A new statute, authorizes Government agencies to grant either exclusive or partially-exclusive licenses if it is necessary to induce investment in research and development. Congress hopes that the combination of the new federal patent licensing law and the Innovation Act's funding of joint research centers will significantly increase the commercialization of technology developed with federal funds.

While the Technology Innovation Act remains a potential statutory vehicle for encouraging innovation, it has remained a "Potemkin village," so far as any practical assistance to research is concerned, because of a lack of funding.

Hopefully, the National Cooperative Research Act of 1984 will have a greater practical effect. The new statute mandates "rule of reason" antitrust analysis for certain research and development joint ventures. In other words, these ventures cannot be considered per se violations of the antitrust laws. Moreover, even if an antitrust violation is found, recovery is limited to actual damages (the usual antitrust recovery being treble damages).

§ 7.03 University Research, Patents, and the Government

A significant amount of recombinant DNA research has been financed by DHEW. Consideration of the government's interest in recombinant DNA research inventions developed under DHEW support is therefore desirable.

In 1976, several universities, including Stanford and the University of California, sought a formal advisory opinion by NIH on the patenting of recombinant DNA research inventions developed under NIH support. NIH solicited comments, and decided that its existing institutional Patent Agreements (IPAs) were acceptable. The IPAs gave the United States a royalty-free license, and restricted the university's right to license the patent on an exclusive basis. It also restricted the university's right to share royalties with the inventor. The university's right to exploit the invention as a trade secret was essentially subject to government pleasure, the government having the right to disclose the invention. It also has the right to compel licensing of patented inventions which have not been "worked" by the university.

§ 7.04 Effect of Public Law 96-517 on Interests of Universities, Foundations, and Small Businesses

Public Law 96-517, signed by President Carter on December 12, 1980, materially changes current law and practice with regard to the acquisition of patent rights in inventions made under contract with the Federal Government, and with regard to the licensing of U.S.-owned patents. In the Senate debate on the bill, Senator Robert Dole of Kansas said that the answer to foreign competition lies in increasing productivity, not in higher tariffs. He pointed out that 95 percent of the 28,000 inventions funded by the Government have yet to be put to work. The new law is intended to take Government inventions off the shelf and into the marketplace.

The provisions of the original House bill applied to all federal contractors, including large corporations. However, the chances of passage of that bill through the Senate were very slim as the Senate had limited the contractor provisions on its own bill to small businesses and non-profit organizations. Therefore, in the interest of getting the bill enacted prior to President-elect Reagan's inauguration, the House limited its own bill to small business and non-profit organizations.

Effective July 1, 1981, the Act gives title to inventions made under federal contract to the small business or non-profit contractor who made them, while retaining a non-exclusive worldwide license for the Federal Government and those practicing the invention on its behalf.

Federal contracts will provide that: the contractor must disclose the invention to the contracting agency, and elect to retain title in the invention, within a "reasonable time" after the invention is made; any U.S. patent application filed by the contractor must disclose the Government's rights and be filed within a reasonable time; and the contractor must periodically report to the agency on its progress in developing the information.

If a Federal employee is a coinventor, the agency is "authorized" to assign to the contractor the rights it acquired from its employee. A funding agreement cannot allow the agency to require the licensing of third parties without specific justification by the agency head.

Non-profit contractors (1) cannot assign the invention, other than to a patent management company, (2) cannot grant long-term exclusive licenses to parties other than small business firms without first obtaining Federal approval, and (3) must share any royalties with the inventor and use their own share of the royalties for research and development or educational purposes.

Exclusive licensing of rights to a licensee who will not be manufacturing pertinent products "substantially in the United States" is forbidden, unless the agency is shown that reasonable but unsuccessful attempts have been made to similarly license domestic manufacturers, or that domestic manufacture is not commercially feasible.

The contracting agency may *compel* licensing of the invention, under "terms that are reasonable under the circumstances," if the agency determines that such action is necessary

(a) [B]ecause the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
(b) [T]o alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or other licensees;
(c) [T]o meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
(d) [B]ecause the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

Unlike the provisions relating to Federal contractors, the provisions of the new legislation relating to licensing Federal patents apply to large corporations as well as small businesses and non-profit organizations. In order to encourage corporations to develop federally-owned inventions, the bill authorizes the granting of exclusive or partially-exclusive licenses if the interests of the public are best served thereby and if it is

necessary to induce investment of risk capital. However, even in this portion of the new statute, small businesses will be given priority if it appears that their development plans are within their capabilities. A license cannot be obtained without submitting a plan, and licensees who will be manufacturing pertinent products "substantially in the U.S."

An important caveat with regard to the new statute is that it does not create any defenses to actions under the antitrust laws. All licenses (and refusals to grant licenses) will be subject to the usual antitrust scrutiny.

§ 7.05 Patent Term Extension

The Drug Price Competition and Patent Term Restoration Act (S. 1538) was signed into law by President Reagan on September 24, 1984. Title I provides for

(1) Certification of the patent status of approved drugs to FDA,
(2) Inclusion in ANDAs of pertinent patent status information in ANDAs, with the effective date of ANDA approval being dependent on the patent status,
(3) Notification of the patent and NDA holders if the ANDA applicant asserts that the pertinent patent is invalid or noninfringed, with the holder having forty-five days to institute a suit for patent infringement in order to stay the ANDA approval, and
(4) A complex scheme of limited exclusivity for certain NDA and supplemental NDA approvals, regardless of patent status (*i.e.*, a form of "data rights" protection).

Title II provides for restoration of up to five years of the term of a product of process patent on a human drug, a human biologic, a medical device, or a food or color additive to compensate for regulatory delays.

The patent may be extended only if an eligible product covered by the claims of the patent received its first approval for commercial use during the original patent term, and if an application for extension is filed within sixty days after that

approval. Only uses approved for the approved product during the original term will be covered by the patent as extended.

Let us examine several common situations in drug development. The easiest case is when a company develops and patents a novel chemical entity which it recognizes has a human drug use. It conducts preclinical studies, and then, after approval of its IND (investigational new drug) application, clinical studies on the drug entity. Based on the data thus collected, it files an NDA (new drug application). Once its NDA is approved by FDA, it may market the chemical as a drug. Presumably, the company would apply for extension of the term of its product patent on the chemical. The company's rights in the extension term would cover only the use of the approved chemical for indications approved during the original term, and would not cover other uses, or unapproved chemicals within the scope of the patent's generic claims.

Next, suppose that the chemical is itself an old one, patented by another, and that you have obtained a patent on a medicinal use of the chemical. After the approval of your NDA for that chemical entity, do you have the right to apply for the extension of your use-patent? Only if you hold the first approved NDA for that chemical entity. Thus, if all you have done is obtained approval for a new therapeutic use for the drug, you are not entitled to an extension. On the other hand, if the previous uses of the chemical were nondrug uses, you would be entitled to a patent term extension.

Another situation which may arise is that you have discovered a new way of producing a drug entity first produced by another. If your method of manufacturing the product "primarily uses recombinant DNA technology in the manufacture of the product," you may still apply for an extension on your process patent after obtaining regulatory approval for your process even if the drug entity had received a previous regulatory approval. Process patents claiming more conventional manufacturing methods are extendable only in the usual "first approval" situation.

According to the Dingell Report on H.R. 3605,

> The Committee's bill requires extensions to be based on the

first approval of a product because the only evidence available to Congress showing that patent time has been lost is data on so called class I, new chemical entity drugs. These drugs had been approved by the Food and Drug Administration (FDA) for the first time. An exception was allowed for products made through recombinant DNA techniques because this innovative, new technique is being employed to improve already improved drugs.

There is no definition of recombinant DNA technology in the Act.

The regulatory renewal period comprises a clinical testing period (IND or IDE) and an application for premarketing approval period (PLANDA, PMA, or PDP). Half credit is given for the testing period and full credit for the application period. (No credit is given for time lost while FDA reviews a 510(k) submission.)

The total regulatory review period is not necessarily compensated for in its entirety. Extensions are subject to a number of additional limitations. If we were to plot the maximum possible extension on the y axis and the time of approval, in years after the patent issued, on the x axis, the broken line representing the maximum extension would start at (0,0), move horizontally to (3,0), and then as a diagonal line with a slope of 1.0 to (8,5). In the case of preenactment patents on products under regulatory review on the enactment date, there is a two-year maximum extension.

The extension is also reduced, according to a complex formula, if due diligence was lacking during the regulatory review period.

Responsibility for the administration of Title II is divided between the PTO and FDA. The PTO determinies whether a patent is eligible for extension and whether the application for extension complied with formalities. The FDA determines the allowable extension.

In applying for a patent term extension, it is essential that the application be filed in a timely manner, *i.e.*, within sixty days after the approval of the NDA. This means that patent attorneys and regulatory compliance personnel should be in communication on a more regular basis than is now the prac-

tice. It is also important that eligibility for the extension of the patent be clearly demonstrated in the application. The statute does not permit one to supplement or amend the application later to show eligibility. According to the statute, the application must identify the approved product, the pertinent regulatory statute, the patent to be extended, and the pertinent claims of that patent; enable the PTO to determine the eligibility of the patent for extension; and enable the PTO and FDA to determine the period of the extension; and briefly describe the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities. More specific guidelines addressing the contents of the application were published at 1047 TMOG 19–20 (October 9, 1984).

The determination of the PTO and FDA regarding the application for extension is published in the Federal Register. A third party may petition the FDA to hold a hearing to inquire into whether the applicant had acted with due diligence during the regulatory review period. The petition must be filed within 180 days of notice. This means that companies in the field will want to monitor the Federal Register for notices of determinations under the Act so that they point out the applicant's misdeeds in time to forestall issuance of the certificate of extension. The fee for applying for an extension was set at $750.00 on September 25, 1984. It may be revised in the final regulations implementing the Act.

CHAPTER 8

Plant Patent Protection

§ 8.01 Development and Propagation of New Plant Varieties

Attorneys new to this field may not be familiar with the many ways in which a new variety may come into existence. Plant breeders classically obtain new varieties by controlled pollination, *i.e.*, by taking advantage of the fact that plants engage in sexual reproduction, a common biological scheme

for gene recombination. (The precise technique will vary depending on whether the plant normally relies on self-pollination or not.) If the outbred genotype offers desirable phenotypic characteristics, it will then be inbred to obtain a pure line that breeds true.

A second method is the alteration of the number of chromosomes ("ploidy"). Polyploidy is associated with changes in plant size. Several chemicals, *e.g.*, colchicine, induce polyploidy.

A third method is the exploitation of mutations. Since most plants are multicellular organisms, mutations fall into two broad categories. First, the mutation may affect the genetic makeup of a sex cell. Second, it may affect a somatic cell (one not a part of the plant's reproductive apparatus). Depending on the particular tissues affected, the plants may be referred to as "chimeras" and "bud sports."

A fourth method is protoplast fusion. A protoplast is a plant cell stripped of its cell walls. Protoplasts of different species may be induced to fuse, to regenerate a cell wall, and to proliferate, the culture eventually growing into an entire plant. A related technique is the transfer of plant organelles, some of which are autonomous packets of genetic information (plastids).

A fifth method is the transfer of exogenous DNA into the

plant cell by means of bacterial plasmid, plant virus or viroid vectors.

Plants may be propagated by a variety of means:[1]

I. Sexual
   A. Propagation by seed—annuals, biennials, and many perennial plants.

II. Asexual (vegetative)
   A. Propagation by apomictic embryos—citrus
   B. Propagation by runners—strawberries
   C. Propagation by suckers—red raspberry, blackberry.
   D. Layering
      (1) Tip—trailing blackberry, black raspberry
      (2) Simple—honeysuckle, spires, filbert
      (3) Trench—apple, pear, cherry
      (4) Mound or stool—gooseberry, apple
      (5) Air (pot or Chinese)—India rubber plant, lychee
      (6) Compound or serpentine—grape, honeysuckle
   E. Separation
      (1) Bulbs—hyacinth, lily, narciccus, tulip
      (2) Corms—gladiolus, crocus
   F. Division
      (1) Rhizomes—canna, iris
      (2) Offsets—houseleek, pineapple, date
      (3) Tubers—Irish potato
      (4) Tuberous roots—sweet potato, dahlia
      (5) Crowns—everbearing strawberry, phlox
   G. Propagation by cuttings
      (1) Root cuttings—red raspberry, horseradish
      (2) Stem cuttings
         (a) Hardwood—fig, grape, gooseberry, quince, rose, forsythia
         (b) Semi-hardwood—lemon, olive, camellia, holly
         (c) Softwood—lilac, forsythia, weigela

[1] Hartmann & Kester, *Plant Propagation: Principles and Practices* 2-3 (3d ed. 1975).

(d) Herbaceous—geranium, coleus, chrisanthemum

(3) Leaf cuttings—*begonia rex, Bryophyllum, Sansevieria,* African Violet

(4) Leaf-bud cuttings—blackberry, hydrangea

H. Grafting

(1) Root grafting

(a) Whip or tongue graft—apple and pear

(2) Crown grafting

(a) Whip or tongue graft—Persian walnut

(b) Cleft graft—camellia

(c) Side graft—narrow leaved evergreens

(3) Top grafting

(a) Cleft graft—various fruit trees

(b) Saw-kerf or notch graft—various fruit trees

(c) Bark graft—various fruit trees

(d) Side graft—various fruit trees

(e) Whip or tongue graft—various fruit trees

(4) Approach grafting—mango

I. Budding

(1) T-budding—stone and pome fruit trees, rose

(2) Patch budding—walnut and pecan

(3) Ring budding—walnut and pecan

(4) I-budding—walnut and pecan

(5) Chip budding—grape, mango

J. Micro-propagation

(1) "Meristem" culture—orchid, carnation

(2) Tissue culture—tobacco

(3) Embryoids—tobacco

(4) "Embryo" culture—orchid

[(5) "Callus" culture]

The term "cultivar" is a contraction of the phrase "cultivated variety," and differs from a "botanical variety." "Variety" and "cultivar" are synomymous. Cultivars have been classified as follows:[2]

Asexually reproduced cultivars:

[2] Id., 15.

(a) A *clone* is a group of plants originating from a single individual and reproduced by vegetative means, such as by cuttings, layers, or grafts. Examples of clones are 'Elberta' peach, 'King Alfred' daffodil, and 'Bliss Triumph' potato.
(b) *Apomictic* cultivars (or apomicts), are biologically unique kinds of plants that reproduce by seed but are asexual because of complete or partial apomixis.

Sexually reproduced cultivars: These are propagated by seed, and specific production programs geared to the genetic characteristics of individual cultivars may be necessary to maintain their genetic identity.

(a) A *line* cultivar is a group of self-fertilizing plants that maintains its genetic identity from generation to generation naturally. Examples are 'Rosy Morn' petunia, 'Marglobe' tomato, and 'Marquis' wheat.
(b) An *inbred line* is a group of naturally cross-fertilizing lines through artificial restraints on cross-pollination. These are generally used to produce hybrid cultivars.
(c) *Hybrid cultivars* are groups of plants grown from seed produced by cross-pollinating two or more parental breeding stocks which are maintained either as inbred lines or as clones. Examples of hybrid cultivars are "Granex" onion, derived from crossing two onion inbred lines, and "U.S. 13" corn, produced by consecutive crossing involving four inbred lines.
(d) A cultivar may consist of a *seedling mixture* of cross-fertilized individuals which, as a group, may be more or less variable genetically, but which possess one or more common phenotypic characteristics. For example, *Phlox drummondi* 'Sternenzauber' is a mixture of different color forms, but all have the same star-like corolla shape.
(e) *Synthetic cultivars* are a special category of seedling mixture in which separately developed seedling lines are combined . . . An example is 'Ranger" alfalfa, a cultivar derived from inter-crossing among five seed-

propagated lines which were previously developed and maintained in isolation.

Depending on its source, seed is classified as breeder seed, foundation seed, registered seed, and certified seed. Several seed depositories ("germplasm banks") exist, though their use has been less critical from a legal point of view than that of type culture collections of microorganisms.

§ 8.02 The Plant Patent Act

Early in the twentieth century, a plant breeder wrote:

> I have been for years in correspondence with leading breeders, nurserymen, and Federal officials and I despair of anything being done at present to secure to the plant breeder any adequate returns for his enormous outlays of energy and money. A man can patent a mousetrap or copyright a nasty song, but if he gives to the world a new fruit that will add millions to the value of the earth's annual harvests he will be fortunate if he is rewarded by so much as having his name connected with the result. Though the surface of plant experimentation has thus far only been scratched and there is so much immeasurably important work waiting to be done in this line, I would hesitate to advise a young man, no matter how gifted or devoted, to adopt plant breeding as a life work until [Congress] takes some action to protect his unquestioned rights to some benefit from his achievements.[3]

These pessimistic words were penned by Luther Burbank, who gave the world the Shasta daisy, the Chrimson Winter rhubarb, the Burbank potato, and some 800 other new varieties. Reacting to such complaints,

> In 1928 [John Dienner] conferred with Secretary Arthur A. Hyde, then Secretary of Agriculture, with a view to providing legislation granting broad protection like that of a patent to all originators of plants and animals and products thereof, such as fruit, roots, eggs, leaves, seeds, etc. Secretary Hyde was en-

[3] H.R. Rep. No. 1129, 71st Cong., 2d Sess (1930) at 2.

thusiastic, but the movement was kidnapped and disguised as the 1930 Plant Patent Act.[4]

The Act was amended in 1952, as part of the general codification of the patent laws, and again in 1954.

The statute, as presently codified, is so short that it may be quoted below:

§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 title. (Amended September 3, 1954, 68 Stat. 1190.)

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

§162. Description, Claim

No plant patent shall be declared invalid for noncompliance with § 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.

§163. Grant

In the case of a plant patent the grant shall be of the right to using the plant so reproduced.

§164. Assistance of Department of Agriculture

The President may by Executive order direct the Secretary of Agriculture, in accordance with the requests of the Commissioner, 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 Commissioner officers and employees of the Department.

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[4] Dienner, Patents for Biological Specimens and Products, 35 JPOS 286, 289-290 (1935).

§ 8.03 Protected and Unprotected "Plants" Under the Plant Patent Act

[1] Bacteria

In 1938, Cornelius F. Arzberger unsuccessfully applied for a plant patent on, "Bacteria herein described and designated as *Clostridium saccharo-butyl-acetonicum-liquefaciens.*"[5] Two years later, the CCPA ruled that bacteria, though "plants" in a strict botanical sense, were not "plants" within the meaning of the Plant Patent Act.[6] The infirmities of this holding are discussed in this author's article, *Arzberger Under the Microscope.*[7]

The *Arzberger* holding was ignored by the Board in *Ex parte Solomons,* reversing the examiner's rejection of a claim to a microfungus:

> A novel non-toxic fungi Fusarium graminearum as described in the foregoing specification which has been deposited with the Commonwealth Mycological Institute and identified as Fusarium graminearum Schwabe I.M.I. 145425.[8]

In 1966, a resolution passed by the PTC Section of the ABA appeared to favor plant patent protection of microorganisms. In 1976, its Plant Patent Committee drafted a resolution expressly favoring amendment of the Plant Patent Act to include microorganisms. Questions were raised when the resolution was debated as to the applicability of the "asexual reproduction" requirement to microorganisms, and as to whether inclusion was "100 percent essential" in order to come within the Union for the Protection of New Varieties of Plants (UPOV). A motion to delete was carried.

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[5] In re Arzberger, 46 U.S.P.Q. 32 (CCPA 1940).

[6] Id.

[7] Cooper, Arzberger Under the Microscope—A Critical Reexamination of the Exclusion Bacteria from Plant Patent Protection, 78 Patent and Trademark Rev. 59 (Feb. 1980) and 7 Rutgers J. Computers, Tech. & Law 367 (1980). *See also* Daus, Bond & Rose, Microbiological Plant Patents, 10 IDEA 87 (1966).

[8] 201 U.S.P.Q. 42 (POBA 1978).

[2] Tuber-Propagated Plants

According to the legislative history of the Act:

> The bill excepts from the right to a patent the invention or discovery of a distinct and new variety of a tuber-propagated plant. The term "tuber" is used in its narrow horticultural sense as meaning a short, thickened portion of an underground branch. It does not cover, for instance, bulbs, corms, stolons, and rhizomes. Substantially, the only plants covered by the term "tuber-propagated" would be 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.[9]

All member states of the Union for the Protection of New Varieties protect tuber-propagated plants.

In 1969 and 1976, the PTC Section of the ABA passed resolutions favoring the abrogation of this exemption.

[3] Newly Found Plants Versus Newly Created Plants

The original plant patent bill provided that the statutory concept of "invention" and "discovery" encompassed "finding a thing already existing and reproducing the same . . ."[10] This provision was criticized on constitutional grounds by Commissioner Robertson:

> It may be doubted whether a valid patent can be granted for a plant even if it is a new variety, when that new plant is *reproduced by operation of nature,* aided only by the act of the patentee in grafting it by the usual methods, and a very serious question arises as to whether the definition given to the words "invention" and "discovery" in the proviso in the bill, namely, that they shall be interpreted "in the sense of finding a thing already existing and reproducing the same as well as in the sense of creating," does not go beyond the power which the

[9] H. Rept. No. 1129, 71st Cong. 2d Sess. (1930).

[10] S. 3530, 71st Cong., 2d Sess. (January 6, 1930).

Constitution grants to Congress.[11]

Robertson would have limited protection to new varieties produced, "for example, by cross pollination resulting from human efforts."[12]

Commissioner Robertson did not refer in his letter to the fact that "a plant which reproduces itself without human aid" was excluded from plant patent protection, a provision which seems to answer his objection as quoted above.

A second bill was introduced by Senator Townsend in the Senate (S.4015) which did nothing to allay his concerns, as it protected "any distinct and newly found variety of plant" and deleted the exclusion referred to above.

Shortly thereafter, Congressman Purnell introduced H.R. 11372, which did not refer one way or another to the patentability of newly found plants. The House Committee Report, however, stated that:

> *The bill does not provide for patents upon varieties of plants newly found by plant explorers or others, growing in an uncultivated or wild state.*[13]

The final sections of the reports presented an impassioned defense of the constitutionality of the bill.

> The only question is, is the new variety a discovery and is the originator or discoverer an inventor?
>
> There is a *clear and logical distinction* between the discovery of *a new variety of plant* and of certain inanimate things, such, for example, as a new and useful natural mineral. The mineral is created wholly by nature unassisted by man and is likely to be discovered in various parts of the country; and, being the property of all those on whose land it may be found, its free use by the respective owners should of course be permitted. On the other hand, a plant discovery *resulting from cultivation is unique,* isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man, and such discoveries

[11] Arzberger Rec. at 82.

[12] Id., 83.

[13] H. Rept. No. 1129, 71st Cong., 2d Sess. (1930).

can only be made available to the public by encouraging those who own the single specimen to reproduce it asexually and thus create an adequate supply.

It is obvious that nature originally creates plants but it cannot be denied *that man often controls and directs the natural processes* and produces a desired result. In such cases the part played by nature and man cannot be completely separated or weighed or credited to one or the other. Nature in such instances, unaided by man, does not reproduce the new variety true to type.

Furthermore, there is no apparent difference, for instance, between the part played by the plant originator in the development of new plants and the part played by the chemist in the development of new compositions of matter which are patentable under existing law. Obviously, these new compositions of matter do not come into being soley by act of man. The chemist who invents the composition of matter must avail himself of the physical and chemical qualities inherent in the materials used and of the natural principles applicable to matter. . . .

. . .

The same considerations are true of the plant breeder. He avails *himself of the natural principles of genetics and of seed and bud varieties.* He cultivates the plants in his own laboratory under his own eye. He may test and experiment with them on a variety of proving grounds. He may promote natural cross-pollination by growing the parent plants in juxtaposition. For instance, because of manual difficulties artificial hand pollination is impractical in the production of seed of the genus compositae, including such species as dahlias, chrysanthemums, asters, daisies, and the like, and also in the case of many of the small fruits. In other cases hand pollination is unnecessary; natural pollination does equally well. On the other hand, if the periods of the bloom of the plants differ, hand pollination and the camel's-hair brush must be used. Again, orchids, avocados, grapes, and most orchard fruits are subjected to hand pollination. In the case of sports, the plant breeder *not only cultivates the plants but may subject them to various conditions of cultivation to encourage variations,* as, for example, in some recent developments, the subjection of the plants to the effects of *x-rays* or to *abnormal fertilization.* Finally, the plant breeder must recognize the new and appreciate its possibilities either

for public use or as a basis for further exercise of the art of selection.[14]

The Committee also pointed out that at the time of the adoption of the Constitution, the term "inventor" was still used in the sense of "one who finds out," as corroborated by the use in the Patent and Copyright Clause of the term "discovery."[15] Finally, the Committee noted the expansiveness with which the Supreme Court interpreted the constitutional terms "commerce" and "writings."[16]

A patent office decision, discussed *infra,* nonetheless questioned the applicability of the act to seedlings found in a cultivated area. Despite the objections of Commissioner Watson, a 1954 amendment expressly extended protection to "cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant found in an uncultivated state."[17]

§ 8.04 What is a Variety

According to the 1930 Committee Reports:

> New and distinct varieties fall into three classes—sports, mutants, and hybrids.
>
> In the first class of cases, the sports, the new and distinct variety results from bud variation and not seed variation. A plant or portion of a plant may suddenly assume an appearance or character distinct from that which normally characterizes the *variety or species.*
>
> In the second class of cases, the mutants, the new and distinct variety results from seedling variation by self pollination of species.
>
> In the third class of cases, the hybrids, the new and distinct variety results from seedlings of cross pollenization of two spe-

[14] S. Rept. 315, 71st Cong., 2d Sess. (April 2, 1930) at 9-10.
[15] Id., 10-11.
[16] Id., 11-12.
[17] 68 Stat. 1190 (September 3, 1954).

cies, two varieties, or of a species and a variety. In this case the word "hybrid" is used in its broadest sense.[18]

The term "variety," a disfavored one in modern botanical circles, is not defined by the Act. The 1930 Committee Reports state that "(i)t is not necessary that the new variety be a new species,"[19] but this negative rule does not carry us very far. In *Yoder Bros., Inc. v. California Florida Plant Corp.*, we are told that:

> Several definitions of the term "variety" of chrysanthemum were offered at trial. Mr. Duffett, Yoder's head breeder, defined a variety as a group of individual plants which, on the basis of observation by skilled floriculturists and according to reasonable commercial tolerances, display identical characteristics under similar environments. Cal-Florida defined variety in its complaint as a "subspecies or class of chrysanthemums distinguishable from other subspecies or classes of chrysanthemums by distinct characteristics, such as color, hue, shape and size of petal or blossom or any of them."[20]

Another definition was offered in *Pan-American Plant Co. v. Matsui:*

> A "variety" of chrysanthemum plant is a group of plants which exhibit similar essential characteristics and which are distinguishable from other groups of plants by the presence of significant differences with respect to one or more such characteristics.[21]

In 1978, the Plant Patent Committee of the ABA (PTC Section) proposed the following resolution:

> RESOLVED, that the Section of Patent, Trademark and Copyright Law favors in principle constructing the term "variety" in 35 U.S.C. §161 to refer to a group of individual plants which, on the basis of observations by persons possessing ordinary skill

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[18] S. Rept. at 4.
[19] Id., 5.
[20] 193 U.S.P.Q. 264, 268 (5th Cir. 1976).
[21] 198 U.S.P.Q. 462, 463 (N.D. Cal. 1977).

and experience in the field, and subject to reasonable commercial tolerances, display identical characteristics when commonly exposed to any given set of environmental conditions, and which are distinguishable from individual plants of other varieties when exposed to environmental conditions in which such distinguishing features will be manifested.[22]

In support of this resolution, the Committee declared:

The meaning of the term "variety" is fundamental to interpretation of 35 U.S.C. §161, but is not defined in the statute or in the science of taxonomy. The range of variations between separate clones of asexually reproduced plants of some species extends from miniscule differences lacking commercial or horticultural import, and observable, if at all, only by a scientist under laboratory analysis, to dramatic differences in horticultural performance, appearance and other characteristics of major industrial significance. The Proposed Resolution is intended to foster the patenting only of varieties which represent a meaningful departure from existing stock. In addition, the Proposed Resolution recognizes that horticultural treatment affects the observable characteristics of plants, and that under some circumstances a patent should be extended to a new development whose advantage lies primarily in the ability of the plant to withstand adverse growing conditions *(e.g.,* heat or drought tolerance, color or form retention of a flowered crop under conditions which damage the appearance of otherwise similar existing plants, etc.).[23]

The reference to a "meaningful departure from existing stock" might easily be misunderstood. The legislative history of the 1930 Act makes it clear that:

In order for the new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties, and it is immaterial whether in the judgment of the Patent Office the new characteristics are inferior or superior to those of existing varieties. Experience has shown the absurdity of many views held as to the value of new varieties at the time of

[22] 1978 Committee Repts. at 70.
[23] Id., 70-71.

their creation.[24]

The 1978 proposed ABA resolution was not, of course, the first recognition of the semantic problems with the term "variety." In 1937, R. C. Cook called for "(c)larification of variety definition in the law:"

> If patent varieties are clones, that should be clearly stated. If a broader definition is attempted, there seems to be no reason why the law should be limited to asexually reproduced varieties.[25]

§ 8.05 A "Novel" Variety

By force of the second paragraph of 35 U.S.C. §161, 35 U.S.C. §102 is fully applicable to plant patent applications. *In re LeGrice,* however, essentially held that information published about a new variety of plant would not trigger §102(b) (technically, a "loss of rights") if it did not enable horticulturists to *produce* the variety question. The disclosure in question contained sufficient information to *identify* the new variety:

> Charming Maid (Flor.). Trial Ground No. 624. Reg. No. 269. Dainty Maiden x Mrs. Sam McGredy. Raiser and Distributor E.B. LeGrice, North Walsham. Vigorous growing variety with deep glossy green foliage 16. Freedom from disease 16. Large single flowers borne in small clusters. Freedom of flowering 16. General effect 6. Fragrance 5. Gold Medal Provincial Show, 1953.[26]

The CCPA discussed the general rule that a "prior publication" must enable the reader to construct and use the invention.

The CPAA recognized that 35 U.S.C. §162 might permit an *applicant* to regard this as an adequate disclosure, but declared: "*No such allowance has been made in 35 U.S.C. §102(b)*

[24] S. Rept. at 6.

[25] R. C. Cook, The First Plant Patent Decision, 19 JPOS 187, 192 (March 1937).

[26] 133 U.S.P.Q. 365, 368 (CCPA 1962).

with reference to the sufficiency of the description of new plant varieties in printed publications." In essence, then, a plant patent applicant cannot lose his rights through public description of the new variety so long as he does not make the stock available for propagation by the public.

The *LeGrice* case may be compared with *Mancy, supra,* which held that knowledge of the bioactivity of related strains of bacteria did not enable bacteriologists to make and use Mancy's *novel* microbe.

Perhaps prophetically, Judge Smith remarked in *LeGrice* that "(c)urrent studies to 'break the chromosome code' may also add to the knowledge of plant breeders so that they may someday secure possession of a plant invention by a description in a printed publication. . . ."[27]

"Novelty" was also at issue in *Nicholson v. Bailey,* involving a claim to:

> A new and distinct variety of navel orange tree substantially as described, characterized particularly by its much heavier juice content; its larger amount of acidity; its absence of dry juice-cells and ability to hold its juices; its higher ratios of sugars to acids; its higher content of soluble solids; its different flavor; its shorter maturing period after flowering, which is six to six-and-one-half months; and its higher rate of productivity on sour orange rootstock; all as compared with the Washington navel orange.[28]

An ingenious but unsuccessful argument was made to the effect that the parent tree's existence in a small citrus grove for twenty-five to thirty years prior to its discovery by plaintiff "constituted 'knowledge or use by others' or such 'public use' as to make U.S. Plant Patent 625 invalid."[29] Denying defendant's motion for summary judgment, the *Nicholson* court held that the "mere existence" of the parent tree did not defeat the claim in the absence of any evidence "that its distinctive character and its value were appreciated by anyone prior to its discovery by plaintiff." The court relied on cases distinguishing "accidental" use from knowing or repeated

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[27] 133 USPQ at 374 n.7.
[28] 125 USPQ 157, 158 (S.D. Fla. 1960).
[29] Id.

use.[30]

§ 8.05A A "Distinct" Variety

The requirement of distinctness is closely related to the problem of detecting infringement. Such techniques as electrophoresis and electron microscopy are becoming significant in plant identification. Naturally, attempts have been made to claim plants by their analytical profiles.

> [O]ne certificate of protection had been granted under UPOV based solely on electrophoresis data. The PTO representative [at an ABA/APLA meeting] said that in the U.S. unless a distinguishing characteristic is visually observable the patent will be denied. U.S. practice does not permit electrophoresis data to form the sole basis for patent.[30.1]

Distinctions observable only by chemical analysis may, of course, be the basis for a utility patent on a chemical. Indeed, in cases where the molecular formula of a chemical is unknown, the PTO has permitted applicants to claim the chemical by reciting its physical and chemical characteristics, including characteristics of the kind measured by electrophoresis (molecular weight and charge). Such claims are known as "fingerprint" claims (see §4.02[2][a]).

In this author's opinion, there is no basis in the language of the statute or in the legislative history for the PTO's requirement of "visual observability." (Since the smears on an electrophoretic gel are visually observable, it is evident that the PTO is using the term in a very restrictive and none too well defined sense.)

The legislative history of the Act states that "in order for the new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties." Note that there is nothing about visual observability here. It is true that elsewhere the Committee deprecated variations "observable,

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[30] Id.

[30.1] 1984 ABA (PTC Section) Committee Report 75.

if at all, only by a scientist under laboratory analysis." However, in the next breath the Committee stated that the intent was, instead, to foster the development of varieties representing "a meaningful departure from existing stock." Certainly, the particular chemical composition of a plant may have a bearing on its food value. Electrophoretic analysis is indicative of the plant's chemical makeup. Since characteristics relating to food value may be, to borrow another phrase from the committee report, of "major industrial significance." A plant may also contain chemicals of therapeutic value which may be extracted from its tissues. Would the PTO argue that the first person to cultivate the cinchona tree could not assert that its quinine content was a characteristic sufficient to render it a "distinct variety?"

A number of characteristics are enumerated by the Committee which are less "visually observable" than is electrophoretic behavior. "Flavor" and "perfume" are hardly visually perceivable. This author hopes that the PTO will soon recognize the error of its ways.

R. S. Allyn has raised an interesting issue relating to "loss of rights" under 35 U.S.C. §102(b):

> Is the grant of a patent on a tree applied for after two years sale of the fruit barred? If the plant was sold before the passage of the Plant Act is it patentable?[31]

On the one hand, the fruit per se is not protectible under the Plant Patent Act as presently interpreted by the PTO.[32] On the other hand, the fruit might be used as propagative material.[33] This is one of several unresolved "statutory bar" issues.

The distinction between "experimental" and "commercial" use has double-edged significance. First, purely *experimental* use by or on behalf of the *patent owner* does not start the clock of the "loss of rights" provision, 35 U.S.C. §102(b).[34] Second, it has been urged that the patent laws are not meant to discour-

[31] R. S. Allyn, Plant Patent Queries, 15 JPOS 180 (March 1933).

[32] MPEP § 1610.

[33] Id.

[34] City of Elizabeth v. American Nicholson Pavement Co., 97 U.S. 126 (1878).

age experimentation, hence, experimental use by *another researcher* does not constitute infringement.[35]

In 1976, the ABA/PTC Plant Patent Committee proposed a resolution calling for the amendment of 35 U.S.C. §162 (first paragraph) to read:

> 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, *nor shall experimental growing for test purposes constitute an invalidating public use under section 102 so long as the variety was not sold in this country for commercial growing more than one year before the application for patent on it was actually filed in this country.*[36]

The supporting report explained:

> Since it is common to test-grow all new varieties to determine their stability, homogeneity, and characteristics, and this normally occurs in open fields, there is some risk that convential testing may be regarded as public use, under Section 102. Some members thought it well to place a period after "section 102" and cancel the rest of the proposed addition. Some thought that putting the new variety "on sale" should be mentioned, as in section 102. Others disagreed, noting that catalogues of varieties newly perfected are often mailed to this country long before the actual plants are made available here. A catalogue of plants is not an enabling disclosure.[37]

Turning to consider the characteristics which might distinguish a new variety, the 1930 Committee Reports are helpful:

> The characteristics that may distinguish a new variety would include, among others, *those of habit; immunity from disease; resistance to cold, drought, heat, wind, or soil conditions; color of flower, leaf, fruit, or stems; flavor; productivity, including ever-bearing qualities in case of fruits; storage qualities; perfume; form;* and *ease of asexual reproduction.* Within any one of the above or other classes of characteristics the differences

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[35] Chesterfield v. United States, 159 F.Supp. 371, 375-376, 118 U.S.P.Q. 445 (Ct. Cl. 1958).

[36] ABA (PTC) 1976 Committee Reports 113-114.

[37] 1976 Committee Rept. at 114.

which would suffice to make the variety a distinct variety, will necessarily be differences of degree. While the degree of difference sufficient for patentability will undoubtedly be a difficult administrative question in some instances, the situation does not present greater difficulties than many that arise in the case of industrial patents.[38]

A related statute speaks of "distinctness" as:

Distinctness in the sense that the variety clearly differs by one or more identifiable morphological, physiological or other characteristics (which may include those evidenced by processing or product characteristics, for example, milling and baking characteristics in the case of wheat) as to which a difference in genealogy may contribute evidence, from all varieties of public knowledge at the date of determination within the provisions of section 42.[39]

"Distinctness" was considered briefly in *Yoder,* which defined it "as the aggregate of the plant's distinguishing characteristics."[40]

In *Pan-American Plant Co. v. Matsui,* the court agreed with plaintiff, relying on the legislative history, that "immunity from disease and ease of sexual production [are] characteristics which may distinguish a new variety."[41] However, finding "noninfringement," it declined to rule on the issue of validity.

§ 8.06 "Nonobvious" Variety

In *Yoder Bros., Inc. v. California-Florida Plant Corp.* 35 U.S.C. §103 was awkwardly applied to plant patents. The Fifth Circuit struggled to fit plant patents into the *Graham* mold. Unable to find a "meaningful way to [ascertain] the level of ordinary skill in the art," or to "give obviousness an indepen-

[38] S. Rept. 315, 71st Cong. 2d Sess. (1930) at 6.

[39] 7 U.S.C. § 2401(a)(1) [Plant Variety Protection Act, Sec. 41].

[40] Yoder Bros., Inc. v. Cal.-Fla. Plant Corp, 193 USPQ 264, 291 (5th Cir. 1977).

[41] Pan-American Plant Co. v. Matsui, 198 USPQ 462, 465 (1977).

dent meaning" apart from distinctness, it resorted to the "constitutional standard [of] invention"[42] —whatever *that* means. What it meant to the Fifth Circuit was a measurement of the extent to which the new variety was more useful than the prior art varieties:

> If the plant is a source of food, the ultimate question might be its nutritive content of its prolificacy. A medicinal plant might be judged by its increased or changed therapeutic value. Similarly, an ornamental plant would be judged by its increased beauty and desirability in relation to the other plants of its type, its usefulness in the industry, and how much of an improvement it represents over prior ornamental plants, taking all of its characteristics together.[43]

It is difficult to decide which flaw in this reasoning to attack first. First, patent law traditionally ignores the *degree* of utility of a new invention, so long as it is usable for some purpose, even if it is more expensive or less effective than a prior invention. Second, the new standard is certain to be capriciously applied, and is therefore pernicious. Third, the level of skill in the art of horticulture may be ascertained as readily as the level of skill in any of the "useful arts." Fourth, the court ignored the precedent of *In re Mancy* [, 182 USPQ 303 (CCPA 1974)], holding that use of a new variety of microorganism in a process already practiced with similar varieties is not prima facie obvious, as the new variety was not previously available to those skilled in the art. Fifth, the court failed to realize that the requirement of "obviousness" might well be subsumed in the requirement of distinctness, even though it was willing to declare that "(f)or plant patents, the requirement of distinctness replaces that of utility."[44]

Mancy suggests that a new and distinct variety is necessarily "nonobvious."[45] Others might temper this suggestion by requiring the claimant to show that horticulturalists had tried and failed to obtain and asexually reproduce a variety having

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[42] 193 U.S.P.Q. at 292.
[43] Id., 292-93.
[44] Id., 291.
[45] 499 F.2d 1289, 1292 (CCPA 1974).

its distinctive characteristics, *i.e.*, to present objective evidence of nonobviousness.[46] This author would not hesitate, however, to reject *Yoder's* peculiar graft of 35 U.S.C. §103 upon the body of plant patent law.

An interesting evidentiary question was raised in *Yoder.* Cal-Florida had offered evidence that the patented sports Gold Marble, Promenade, and Red Torch were "recurring" in nature. According to the Fifth Circuit, "(t)he only possible probative value of the sport recurrence evidence would be to show that a sport of a particular size, shape, color, or other trait is predictable from a given variety of parent plant."[47] (A conclusion of "obviousness" might be drawn from the predictability of the sport.) The Court held that Congress did not intend to exclude "recurring sports."

> Although we are willing to assume for purposes of this argument that some mutations may appear that would have been genetically impossible before—*i.e.*, that a fundamental change in the biochemical structure of the chromosome may take place —by far the majority of mutations and sports of chrysanthemums are predictable to some extent for those skilled in the field. For example, the testimony at trial indicated that a yellow sport could be expected from a white chrysanthemum. Indeed, part of the skill required of a chrysanthemum breeder is to know what to look for and to take steps immediately to preserve it by asexual reproduction if the desired trait appears. Given that fact, we think that the purpose of the Plant Patent Act would be frustrated by a requirement that only those rare, never-before-seen, if not genetically impossible sports or mutations would be patentable. That purpose was "to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry, and thus assist in placing agriculture on a basis of economic equality with industry." S. Rep. 315, supra. To make it significantly more difficult to obtain a plant patent than another type of patent would frustrate that purpose.[48]

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[46] Graham v. John Deere & Co., 383 U.S. 1, 17-18 (1966).
[47] 193 U.S.P.Q. at 294.
[48] Id., 294-95.

The Court also turned aside a possible Constitutional objection:

> We do not think that sport recurrence would negate invention, however. An infinite number of a certain sized sport could appear on a plant, but until someone recognized its uniqueness and difference and found that the traits could be preserved by asexual reproduction in commercial quantities, no patentable plant would exist. An objective judgment of the value of the sport's new and different characteristics—*i.e.*, nutritive value, ornamental value, hardiness, longevity, *etc.*—would not depend in any way on whether a similar sport had appeared in the past, or whether that particular sport was predictable.[49]

Thus far, the PTO has taken the position that a new variety which satisfies the §161 "distinctness" requirement also satisfies the §103 "nonobviousness" requirement. Under U.S. practice, if a new variety displays a distinguishing characteristic, it is patentable. Recent UPOV guidelines, however, define "distinctness" as the existence of a "minimum distance," taxonomically speaking, between the novel variety and prior varieties. The "minimum distance" concept gives a false air of mathematical exactitude to what is really an imprecise art of taxonomic comparison. In any event, "PTO representatives have said that the 'minimum distance' guideline will not apply to U.S. examining practice when examining domestic applications or those under the UPOV."[49.1]

§ 8.07 "Asexually Reproduced" Variety

The plant patent right, as defined by 35 U.S.C. §163, is an exclusive right to propagate the plant by asexual reproduction, rather than by seeds. To obtain a plant patent, the applicant must establish that he has asexually reproduced it. Mere preservation of the plant is not enough. In other words, "asexual reproduction" is a central concept of the plant patent law.

In re Arzberger involved a plant patent claim to a new strain

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[49] Id., 295.

[49.1] 1984 ABA (PTC Section) Committee Reports 73–74.

of bacteria. Arzberger's bacterium reproduced asexually by binary fission. One of the bases for rejection of his claim was the "asexual reproduction" requirement. The Examiner stated:

> It is noted that asexual reproduction is defined in the Reports as by grafting, budding, cutting, layering, division, and the like. For definition of these methods of plant propagation, attention is drawn to the Thompson publication, pages 291 to 294, 297, 304, and 313. If bacteria were within Congressional intent it is not seen how the above methods of asexual reproduction could be applied thereto.[50]

The Examiner recognized that bacteria reproduce asexually, but objected that "bacteria divide themselves." The examiner felt that the *quid pro quo* for the patent right included "the aid of man [in reproduction) as expressed by manual effort."[51] Commentators Daus, Bond, and Rose accept the "manual art" requirement, but argue that modern fermentors use mechanical agitators to break off clumps of microbial cells." (Large concentration of cells secrete substances which inhibit cell division.) Daus, Bond, and Rose reason that this agitation is division by human agency.[52]

Arzberger did not concede a need for the direct "aid of man":

> A large number of different types of higher plants reproduce asexually in nature, without man's aid, by various processes, such as corm separation, rooting of stolons or branches, or the formation of aerial shoots from roots, rhizomes, or mycelia. Thus, a gladiolus such as that of Plant Patent No. 77 may reproduce asexually by corm separation, without man's intervention; vines or berry bushes, such as the grape vine of Plant Patent No. 195, or the dewberry of Plant Patent No. 4, may reproduce asexually by layering, without man's intervention,

(*Text continued on page 8-23*)

[50] 46 U.S.P.Q. 32, 34 (CCPA 1940).

[51] Id.

[52] Microbiological Plant Patents, 10 IDEA 87, 92 (1966).

by root formation at the end of a branch in contact with the ground; hybrid poplars, such as that of Plant Patent No. 207, may reproduce asexually, without man's intervention, by the formation of aereal shoots from roots near the surface of the ground; sugar cane, such as the sugar cane of Plant Patent No. 203 may reproduce asexually, without man's help, by the formation of aerial shoots from the rhizomes, or by rooting at the joints of a fallen cane; the mushroom of Plant Patent No. 27 reproduces asexually by division, without man's intervention, with the formation of aereal bodies from the dividing mycelia below the surface of the ground; and strawberries, such as the strawberry of Plant Patent No. 60, reproduce asexually, without man's aid, by root formation on the stolons. In all of these cases the plant in nature brings forth offspring by asexual methods and without the aid of man.[53]

Arzberger suggested that the applicant need only place such plants in an environment favorable for reproduction.[54]

The strict interpretation is espoused by Deller's treatise:

> [A]sexual reproduction is the heart of the present plant patent system: the whole key to the "invention" of a new plant is the discovery of new traits *plus* the foresight and appreciation to take the step of asexual reproduction.[55]

It is supported by a passage in the reports suggesting that the Act was meant to encourage breeders to help plants to reproduce asexually which could not do so on their own:

> [W]ithout asexual reproduction there would have been but one true McIntosh or Greening apple tree. These varieties of apple could not have been preserved had it not been through human effort in the asexual reproduction of the two original trees. They could not have been reproduced true to the type by nature through seedlings. The bill, therefore, proposes to afford through patent protection an incentive to asexually reproduce new varieties. Many varieties of apples equally as valuable as the McIntosh or Greening have undoubtedly been created and disappeared beyond human power of recovery because no at-

[53] Rec., 27.
[54] Arzberger Br. 20-21.
[55] Id., 21.

tempt was made to asexually reproduce the new varieties. The present bill by its patent protection proposes to give the necessary incentive to preserve new varieties.[56]

The strict interpretation of the "asexual reproduction" requirement might nonetheless defeat the purpose of the Act. It is clear from a comparison of H.R. 9765 with H.R. 11372 that plants which are *capable* of reproducing asexually without human aid are protectable. Congress deliberately deleted the original proviso excluding "a plant which reproduces itself without human aid."[57] The Senate report noted "(t)hat the present measure is substantially the same as the original bill except for . . . the granting of patents irrespective of the fact that the plant may, under some conditions, reproduce itself without human aid."[58] The liberal interpretation of the "asexual reproduction" requirement is necessary if plants such as strawberries, blackberries, tulips, and pineapples are to receive protection.

§ 8.08 A Variety Found in a "Cultivated State"

In *Ex parte Foster*, the Board denied a plant patent to a plant hunter who obtained two unusual syngonium plants from a garden in the city of Barranquilla, Colombia, cultivated them in Florida, determined that they were of a new and useful variety, and asexually reproduced them.[59] The Board, relied on the legislative history: (1) express protection of "any distinct and newly found variety of plant" was stricken from S.4015 to eliminate "patents for varieties of plants which are newly found by plant explorers but exist in an uncultivated or wild state," (2) a broad definition of "invention and discovery" was deleted from H.R. 1765, and (3) Congressman Purcell's remark that the revised bill did not give "the man who runs over into his neighbor's yard and finds an unusual plant of some kind an opportunity to exploit it."

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[56] 1129, 71st Cong., 2d Sess. (1930) at 45.
[57] S. Rept. at 5.
[58] Id., 3-4.
[59] 90 U.S.P.Q. 16 (POBA 1951).

In 1954, § 161 was amended to read:

> 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 title (amended September 3, 1954, 68 Stat. 1190).

The House Report stated that the amendment was enacted to "remove any doubt" as to the "legislative intent." (It may be remarked parenthetically that the overruled *Foster* decision was supported by far stronger evidence of legislative intent than were the dissenters' opinions in *Bergy* and *Chakrabarty.)*

§ 8.09 Inventorship and Ownership

Miller had "noticed a small peach tree growing in his yard," and cultivated it. Moore recognized that it was a new variety and, with Miller's permission, asexually reproduced it. The Board held that Moore was properly considered the one who "discovered" the "new variety," since Miller's contribution alone would have done "nothing to preserve the variety." Sophistically, it failed to ask whether Moore could have perpetuated the new variety if Miller had allowed it to perish a decade before. The Board deemed it unnecessary to entertain the speculation that Miller and Moore were joint inventors.[60]

In *Kluis, J* and *A* declared that they were the "joint inventors and asexual reproducers" of a rose; *J* having discovered it and *A* having asexually reproduced it. Holding that joint inventors need not be in "each other's presence like "Siamese twins" at each stage in the development of the invention or . . . jointly perform every act" required, the court deemed the oaths "peculiar" but "sufficient."[61]

In *Mix v. Newland,* the Oregon Supreme Court held that a

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[60] Ex parte Moore, 115 U.S.P.Q. 145 (POBA 1957).

[61] Ex part Kluis, 70 U.S.P.Q. 165 (POBA 1945).

nursery owner *owns* any new variety found in his nursery, even if another actually recognized the new variety.[62]

§ 8.10 Conception and Reduction to Practice

"Conception" and "reduction to practice," insofar as they apply to plant patent prosecution, were defined in *Dunn v. Ragin*. *Dunn* declared that "conception" required more than that inventor "[become] aware of [the] existence" of the new variety; "he must be certain that it is a new variety."[63] "Reduction to practice" was said to occur "when the new variety is actually reproduced [asexually] and it is determined that the progeny in fact posses the characteristic or characteristics which distinguish it as a new variety."[64] *Dunn* deemed "constructive" reduction to practice (by filing a patent application) to be precluded by the statutory asexual reproduction requirement,[65] and declared that the behavior of living organisms was so unpredictable that conception and reduction to practice were necessarily concurrent.[66]

§ 8.11 Disclosure Requirements

In 1930, Patent Office Commissioner Robertson criticized S. 3530, the original plant patent proposal, because:

> [T]here at once arises the difficulty of defining in a written document which must be printed, both as constituting part of the patent and as constituting a publication available for search and distribution, the differences which identify a new variety from previously known varieties. For example, if that difference exists only in the color of the bloom, then in order to describe that difference it would seem that a colored print of some sort would have to constitute a part of the patent.

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[62] 196 U.S.P.Q. 506 (Ore. 1975).
[63] 50 U.S.P.Q. 472, 475 (Pat. Off. Bd. Interf. Exam. 1941).
[64] Id., 474.
[65] Id.
[66] Id., 475.

If it is not possible by ordinary description or the physical qualities of the plant, or the fruit, or the bloom, or all three, to so accurately define this new variety and from all subsequently created new varieties, then it is difficult to see how a patent to be granted would comply with the other provisions of the statutes, namely, that the inventor must describe his invention in full, clear, concise, and exact terms (R.S. 4888).

In other words, section 4888, Revised Statutes, requires one who obtains a patent to file in the Patent Office "a written description of the same, and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains . . . to make, construct, compound, and use the same."

In many instances (if not all) it may be found that no description could be written that would enable anyone to identify so as to reproduce from that description (without the extraneous aid or physical cuttings or slips grafted in accordance with the usual methods) the new variety, as the only way asexually reproduced varieties can be reproduced is from a physical cutting or slip from the new variety itself. To state the matter in another way, if after the new variety were produced, and then reproduced asexually, an application for patent was filed with the most explicit description that it is possible to furnish, and all the plants containing such a new species were destroyed, as for example by fire, then there would be no other way whatever of reproducing this new species. The written description filed in the Patent Office would be useless and hence could not satisfy the conditions of section 4888, Revised Statutes.[67]

Accordingly, when Congress enacted the Plant Patent Act, it provided a saving clause 35 U.S.C. §162:

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.

[67] Arzberger Rec., 83.

Read together, 35 U.S.C. §§ 112, 113, 161 (sec. para.), and 162; 37 C.F.R. §§ 1.161-1.167, and MPEP §§ 1601-1610 suggest that applicants should:

(1) State the distinctive characteristics of the new variety as compared to:
   (a) Its antecedents
   (b) Related known varieties
   in accepted botanical terms.
(2) Provide an artistically executed drawing disclosing all the distinctive characteristics of the plant which may be represented visually.
(3) When color is a distinctive feature of the plant, positively identify the color by reference to a color dictionary, and by providing a color drawing of the plant.
(4) State the origin or parentage of the plant.
(5) Point out where and in what manner the plant was asexually reproduced.
(6) When the plant is newly found, point out the location and character of the area where the plant was discovered.
(7) On demand, provide specimens for official inspection.
(8) On demand, provide affidavits from qualified agricultural or horticultural experts regarding the novelty and distinctness of the variety.
(9) Avoid unwarranted advertisement in the specification of the drawing.
(10) Avoid laudatory expressions.
(11) Claim the entire plant, not its fruit or flower, and title the invention accordingly.

Executive Order No. 5464 and 35 U.S.C. §163 provide for the submission of plant patent application files to the Department of Agriculture for examination for distinctiveness by the Agricultural Research Service. For this reason, 37 C.F.R. §1.163 requires that two copies of the specification be submitted to the PTO.

Presumably relying on the second paragraph of 35 U.S.C. §162, 37 C.F.R. §1.164 states that more than one claim is not permitted.

In re LeGrice held that there is "no requirement for any how-to-make disclosure in the application for a plant patent."[68] The CCPA, after examining the plant patent grant (35 U.S.C. §163), concluded that a "how-to-asexually reproduce" disclosure requirement existed, and this holding was adopted in 37 C.F.R. §1.163(a), a PTO rule which presumably has force of law.

In re Greer involved a rejection of the following claim:

> A new and distinct variety of BERMUDA GRASS PLANT, substantially as shown and described, characterized particularly by its outstanding reproductive properties, its large, glossy rhizomes, its high level of resistance to common Bermuda grass diseases and the large percentage of above ground stolons which remain green in freezing weather.[69]

This claim was rejected under 35 U.S.C. §112, based on the Department of Agriculture report:

1. The claimed grass is reported as superior to five other varieties of bermuda grass in its ability to withstand freezing weather. No comparative data were included in the application to show the relative winter survival for the claimed grass vs. other varieties. In addition to the lack of survival data, it [is] not clear from the application that all varieties were planted and managed in the same fashion.
2. The claimed grass is reported to have a high level of resistance to common bermuda-grass diseases. It is stated, however, that no disease was noted on bermuda grass varieties grown at the same locations as the claimed grass. This information does not support the claim for disease resistance as the named varieties differ greatly in their reaction to disease (from highly susceptible to highly resistant).
3. It is stated that the rhizomes of the claimed gross penetrate to a greater depth than those of Coastal bermuda

[68] 133 U.S.P.Q. at 378.

[69] 179 U.S.P.Q. 301, 302 (CCPA 1973).

grass. This comparison should include Zimmerly Select as this was the original source of the claimed grass.

4. No comparative measures of rhizome diameters are included because comparable material was not available in test plots. Since diameter or rhizomes is a distinguishing characteristic of the claimed grass, comparative plots should be established to obtain these data.
5. A larger percentage of stolons of the claimed grass apparently stay green in freezing weather, in comparison with widely distributed bermuda grass varieties. The conditions under which these observations were made should be described. All varieties must be grown under comparable conditions, *i.e.*, age of stand, irrigation, soil fertility, and clipping or grazing practice. Information on stolon color for the claimed grass and bermuda grass varieties could be given either as a percentage of stolon length or as percentage of stolons that remain green. The description of the claimed grass is not adequate to determine if it differs from other named bermuda grasses.[70]

Both the Board and the CCPA, in affirming this rejection, relied on a passage from the Senate Committee Report of April 2, 1930:

> Modern methods of identification, together with such amplification thereof as may reasonably be expected, will render it possible and practicable to describe clearly and precisely the characteristics of a particular variety. When this cannot be done by an applicant for a patent, the variety is not clearly distinguishable as a distinct variety, and no patent would issue.[71]

In *Jessel v. Newland,* a claim to a "Copper Anne" sport was rejected under 35 U.S.C. §112 for failure to enumerate in the specification the characteristics distinguishing the instant variety over related known varieties such as "Bronze Princess Anne." The application was amended to overcome this rejec-

[70] Id., 302-303.
[71] Id., 303.

tion. After the application was placed in interference, the Board of Patent Interferences decided that the amendment added "new matter," contrary to 35 U.S.C. §132. While holding that 35 U.S.C. §132 must be applied to plant patents as it is to utility patents, despite the language of 35 U.S.C. §162, the Commissioner held that the color reproduction of the plant, which accompanied the original application, supplied the antecedent bases for the detailed written description of the comparative color characteristics of the plant supplied by amendment.[72]

§ 8.12 Claims for Plant Products

In 1933, R. S. Allyn raised the question,

> Is a rose blossom or a peach, a berry or a mushroom or a nut—a "plant" within the law?
>
> Does a United States "Plant" Patent give its owner the right to exclude others from importing or dealing in flowers, fruits or nuts, and if not, why not? Does the patent cover both plant and fruit or flower—or is a Plant Patent like a machine patent limited to the producer and must we have an amendment to the Act to cover the product of the new Plant?[73]

This was not an idle question. The claim of Plant Patent No. 2 could be viewed as covering a rose blossom, rather than the entire plant. Allyn added, "Query—can we safely reproduce the plant or can the owner enjoin a florist who sells cut flowers in New York which were grown in New Jersey by someone else?" Plant Patent No. 47 claimed a pecan nut, not the tree. Allyn concluded:

> It doesn't seem to me that the flower or fruit necessarily goes with the plant, nor do I think Congress intended to protect the product of the plant. The question is, of course, enormously important. Process and machine patents do not protect the

[72] 195 U.S.P.Q. 678 (Comm'r 1977).
[73] Allyn, 15 JPOS at 180.

products. If it is possible to asexually reproduce the plant from the flower (or such part of the plant as goes with the flower) that is quite another question.[74]

The same year, H. C. Robb agreed:

> [O]ne thing is certain and that is that the law was intended to cover new varieties of plants, not the blossoms, fruit, or nuts thereof. Those features may be in any instance the evidence of the novelty and hence it is proper to claim the plant by the characteristics of distinctiveness shown by these products.[75]

John Dienner, on the other hand, had favored the application of the patent law to "biological products," such as "fruits, roots, eggs, leaves, seeds."[76] His attempt to obtain this broad spectrum of protection was "fruitless." The Committee Report speaks of patenting plant varieties, not plant products; the PTO insists that the claim be directed to the plant variety. MPEP 1605 states: "A plant patent is granted on the entire plant." MPEP 1610 warns "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 fruit."

In 1976, the ABA/PTC Section adopted a resolution calling for the application of plant patents to "all parts of patented plants, such as cut flowers," by amending 35 U.S.C. §163 to read:

> In the case of a plant patent the grant shall be of the right to exclude others from [asexually] reproducing the plant or selling or using the plant so reproduced, or any part thereof.[77]

Its sponsor, Mr. Klein, explained that:

> [O]ne of the big problems with our plant patent protection was

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[74] Id., 186.

[75] H. C. Robb, Plant Patents, 15 JPOS 752, 757 (October 1933).

[76] J. A. Dienner, Patents for Biological Specimens and Products, 35 JPOS 286, 290 (April 1953).

[77] 1976 Committee Reports at 114-115.

the ease with which the original plant could be bootlegged, shipped out of the country (for example to Mexico or Brazil), and reproduced in huge quantities. The blooms are then shipped back here to compete with local florists. They undersell those who have to pay royalties on the plants in this country. Committee 111 unanimously believed that the creation of the plant should entitle the creator to the uses to which it was put. They therefore considered that the inventor of the plant patent should be given the right to exclude parts of plants just as well as the asexual reproduction of the plant themselves. This was the current law in France and Denmark. Mr. Klein was not sure whether it was formally adopted in Britain. Mr. Robertson had thought the committee should go even farther and specify fruits. There was no debate on the matter and a vote was taken. The motion to adopt carried. Resolution 24 was adopted.[78]

This resolution was discussed in 1981, when the pertinent subcommittee noted "a steadily increasing volume of importation of flowers." It suggested an analogy between an unrooted cutting (found to infringe in *Yoder)* and a cut flower (a possible reproductive material), in support of its contention that control of the sale of cut flowers was proper "from the standpoint of rational enforcement of patent rights."[79]

In 1984, the Section adopted a similar resolution, noting the "ever increasing flow of foreign cut flowers into the United States grown from patented varieties on which the patentee receives no return." The ABA committee report supporting the resolution sadly observed that "under the present state of the art a patented plant cannot be propagated from all of its parts," and thus imported cut flowers would escape the reach of the plant patent laws even under *Yoder's* liberal interpretation of the scope of the grant.[79.1]

In the absence of legislative assistance, the plant patent owner may be able to take advantage of certain limited avenues of relief. First, if the plant material is imported, a §337

[78] 1976 Summary of Proceedings at 95-96.
[79] 1981 ABA (PTC Section) Committee Reports 69-70.
[79.1] 1984 ABA (PTC Section) Committee Reports 71–72.

action may be filed.[80] That is, the importation of parts of a plant patented in the United States might be considered an unfair act in the importation of goods under §337 of the Trade Act of 1974. Admittedly, since the plant patent covers only the whole plants, while only the plant parts are imported, the unfair act is not, literally, one of patent infringement. However, the International Trade Commission has stated that "while the Commission often looks to domestic patent law for guidance in determining what constitutes an unfair method of competition or unfair act, it is clear that our jurisdiction is not limited to the strict application of analogous laws."[80.1] Second, if the vended material (the flower or fruit) is *at all capable* of acting as a propagative material, the sale of this material might be considered active inducement to infringe or contributory infringement.[81] Third, a prudent plant patent applicant might also seek an "article of manufacture" patent on the plant material *(but see* discussion of the "product of nature" doctrine, Ch. 3, *supra).*

§ 8.13 Number and Breadth of Claims

According to the Fifth Circuit, the task of the patent solicitor—"claiming enough but not too much"—calls "for a precision and a prescient forecast encountered in few other facets of law."[82] As an ameliorative, utility patent applications are permitted to present several claims of varying scope, rather than a single claim.

The PTO has taken the position that a plant patent cannot present more than one claim (37 C.F.R. § 1.164) because a plant patent is granted only on the entire plant. The PTO is correct in ruling that subsidiary claims cannot be presented to cover the blossoms, fruit, or nuts, per se. But commentators

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[80] *See generally* PRG, *International Trade Commission Patent Practice* (1979).

[80.1] In re Certain Apparatus for the Production of Copper Rod, 214 USPQ 892, 895 (ITC 1980).

[81] *See* 35 U.S.C. §271 (b) and (c).

[82] Topliff v. Topliff, 145 U.S. 156, 171 (1892); Reed v. Parrack, 276 F.2d 784, 788 (5th Cir. 1960).

have rightly criticized the PTO's stance insofar as it reflects on "genus" and "species" claims to the plant varieties themselves.

Allyn was the first to inveigh against the "single claim" doctrine:

> An interesting question of infringement may also arise as to two cherry tree patents. The fruit of Patent No. 29 ripens from ten days to two weeks *later* than the true Montmorency and No. 30 ripens ten days to two weeks *earlier* than the Montmorency. As the ripening period, of course, depends upon the soil and climate it would appear necessary to grow a true Montmorency alongside of the alleged infringement in order to make the rather nice comparison.[83]

Magnuson "found no logical reason or explanation offered for such limitation except perhaps that a plant is considered as a single, inseparable entity and cannot be broken down into component parts on which to issue separate patents."[84]

Another critic was H. C. Robb:

> The writer does not approve of the Patent Office restriction to a single claim and from the beginning argued against it, but

(*Text continued on page 8-35*)

[83] 15 JPOS at 184-185.

[84] Magnuson, A Short Discussion on Various Aspects of Plant Patents, 30 JPOS 493, 504 (July 1948).

until this matter can be settled at the instance of an applicant willing to make the test, the restriction must be abided by. As is well known, courts will not decide a moot question.[85]

In support of the PTO's position on the issue of whether more than one claim to a plant variety is permissible, reference may be made to 35 U.S.C. § 162: "The *claim* in the specification shall be in formal terms to the plant shown and described." This language was not added to the Code, however, until well after the single claim practice was established. The legislative history does not address this point, so it is impossible to say whether Congress meant to ratify the established PTO practice.

Turning to the issue of generic claiming, the best argument in support of the PTO position is that advanced by D. D. Jeffery:

> As to the scope or breadth of plant patents, members of the horticultural industry have for some time expressed the desire to "generically" protect sports arising out of a patent variety. This would be particularly desirable where varieties are known to be susceptible to sporting, either naturally or by conventional radiation techniques. This "generic" coverage would give broader protection in terms of infringement and would avoid the necessity of having to obtain a separate patent covering each sport variety. However, under existing law, this "generic" protection is not possible. The Plant Patent Act makes asexual reproduction of a new and distinct variety a prerequisite for patenting, and thus precludes the present patenting of expected future sports.[86]

But this agreement is not without flaws. The requirement of "asexual reproduction" in the plant patent area may be compared with the "utility" requirement for mechanical, chemical, and electrical patents. It is well settled that a disclosure of a single utility, even a minor or commercially impractical one,

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[85] 15 JPOS at 757.

[86] D. D. Jeffery, The Patentability and Infringement of Sport Varieties: Chaos or Clarity?, 59 JPOS 645, 657 (October 1977).

is sufficient to satisfy this requirement.[87] Similarly, it may be argued that asexual reproduction of a single *specimen* of a variety is sufficient to satisfy 35 U.S.C. §161. It must be remembered that it is the "variety"—which may be claimed broadly —which is patentable. The 1930 Committee Reports state: "(i)t is not necessary that the new variety be a new species, but the bill does not exclude a new and distinct species from being patented.[88] A claim to a new plant species would, of course, be a generic claim.

Efforts are still being made to obtain a liberalization of plant patent claim practice, thus far without success. Inevitably, some attorneys are now considering taking advantage of the recent *Chakrabarty* ruling, and filing a *utility* patent claim, in generic terms, on the new plant variety.

§ 8.14 Plant Patent Infringement: Introduction

The touchstone of plant patent infringement litigation is 35 U.S.C. §163: "In the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so produced." The original plant patent bills (S. 3530, H.R. 9765) did not contain any special language of grant, *i.e.*, the plant patent owner received the same exclusive right to make, use, or sell his invention as did the owner of a utility patent. Commissioner Robertson pointed out:

> [T]hat in order to avoid any doubt as to the scope of the protection that a patent of this kind would give to the patentee, the bill should provide that the grant of the exclusive right to make, use, and sell, as provided for in section 4584 Revised Statutes should be construed to cover the reproduction of the plant. This suggestion is made because the word "make" in the statute is usually understood to mean the construction by human activity whereas those plants are reproduced by growth, a person only putting the graft or scion, for example, in such a position in the

[87] *See* Brenner v. Manson, 383 U.S. 519 (1965).
[88] S. Rept. at 5-6.

tree to be grafted upon, that it will grow.[89]

As enacted, the Act provided that the patentee's exclusive patent *included* "in the case of a plant patent the exclusive right to asexually reproduce the plant." This was, as is evident, an imperfect resolution of the point raised by Commissioner Robertson, and in 1952 Congress enacted the present "grant" provision.[90]

The nature of the plant patent right is further delimited in the 1930 Committee Reports:

> Whether a new variety is a sport, mutant, or hybrid, the patent right granted is a right to propagate the new variety by asexual reproduction. It does not include the right to propagate by seeds. . . . The present bill by its patent protection proposes to give the necessary incentive to preserve new varieties. On the other hand, it does not give *any patent protection to the right of propagation of the new variety by seed*, irrespective of the degree to which the seedlings come true to type.[91]

§ 8.15 Derivation as an Element of Infringement

In utility patent law, there is no requirement that the patentee prove that the accused infringer benefited from the teachings of the patent or copied the plaintiff's commercial unit. Even an "independent discoverer" may be an infringer.[92]

Plant patent law, more closely resembles copyright or trade secrets law, which require proof of the accused's access to the allegedly appropriated subject matter.[93]

In the first plant patent decision, plaintiff failed to establish appropriation of his "Berberis Thungerbi Pluniflora Execta."

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[89] Arzberger Rec., 83.

[90] 66 Stat. 792 (1952).

[91] S. Rept. at 5.

[92] Eastern Oil Well Survey Co. v. Sperry-Sun Well Survey Co., 131 F.2d 884, 887, 56 U.S.P.Q. 5 (5th Cir. 1943).

[93] Yoder Bros., Inc. v. California-Florida Plant Corp., 537 F.2d 1347,1380, 193 U.S.P.Q. 264 (5th Cir. 1976); Ex parte Weiss, 159 U.S.P.Q. 122, 124 (POBA 1967).

The charge is that the defendants obtained their plants from cuttings of the plaintiff's, because that constitutes asexual reproduction, and in no other way could the alleged infringing plants have been produced.

From a consideration of all the evidence upon the subject, I feel unable to say that it would be impossible to reproduce or duplicate substantially the character of the plant of the plaintiff without cuttings from the Horvath plants. Conceding that the plants of the plaintiff and or the defendants have similar characteristics, the proof is not clear and convincing that the plaintiff must have appropriated plants or cuttings belonging to Horvath or his assignee.[94]

R. C. Cook, editor of the *Journal of Heredity,* interpreted this passage as holding:

[T]hat if cuttings or other propagation material were not obtained from the plants covered by the patent, no infringement existed. That is, it would seem to be the view of the court in this case that plant patents under the present statute represent in effect clones, *i.e.*, the asexual progeny of a given plant. If this reasoning is upheld in later decisions it follows that a plant patent under the existing act represents a ***biological entity rather than a verbal abstraction*** outlined with doubtful completeness in the specification and almost defying exact definition.

It has already been suggested that this "clone" view represented about the only practical and workable method of plant patent administration.[95]

H. C. Robb was one of the early supporters of the "derivation" requirement:

Of course, it must be understood that the infringing plant will necessarily be a propagated reproduction of the original patented plant. There is much misunderstanding of this phase of the law. Simply because I cross a Paul's Scarlet with a Gruss an

[94] Cole Nursery Co. v. Youdath Perrenial Gardens, Inc., 31 U.S.P.Q. 95, 96 (N.D. Ohio 1936).

[95] R. C. Cook, The First Plant Patent Decision, 19 JPOS 187, 189 (March 1937).

> Teplitz, I cannot, by securing a patent for the result, prevent someone else from crossing these same varieties, for nature does not twice perform exactly the same and the product would be recognizably different, certainly in some of the various features, I believe.[96]

In discussing the status of "sports" which happen to closely resemble a patented plant, H. C. Robb commented:

> So far as the question of possible accusation of infringement of the patent is concerned, the owner of the unpatented plant has the defense by way of proof that his variety is not a propagation of the patented plant.
>
> Now, of course, if a propagator can independently (with the assistance of nature) produce a duplication of a patented variety, he is free to do so, but the patent law has prevented the flagrant piracy and hijacking of horticultural developments that heretofore discouraged all but the few incorrigible optimists.[97]

In *Armstrong Nurseries, Inc. v. Smith,* Chief Judge Sheehy found eight patents valid and infringed without entering findings of "derivation." He referred to the infringing plants as being "characterized" by certain features "substantially as shown and described" in the asserted patents.[98] *Kim Bros. v. Hagler,* on the other hand, absolved the defendant as:

> There is no credible evidence that the appearance of the branch on what we called, at the trial, the "accused tree," in an orchard other than that of defendant, and situated across the road from his, was the result of any grafting or budding of a branch or bud from the plaintiff's patented tree. There is a hearsay statement quoting Joseph E. Hunter, the owner of the orchard in which the "accused tree" was found, as saying that two persons, Robert Milton Riesner and Roy Milton Reisner, *"may have done it."* But they, when called as witnesses by the defendant, testified under oath that *they were not on the Hunter Ranch in 1954* at the time the alleged branch first appeared, carrying the new variety which the defendant claims as a sport

[96] 15 JPOS at 757.
[97] Id., 762.
[98] 130 U.S.P.Q. 220 (E.D. Tex. 1958).

and which he has patented. Indeed, they testified that the first time they went on the place was a year later. Their testimony stands uncontradicted.

. . .

(W)e are of the view that the plaintiff has failed to prove that the trees grown by the defendant were the result of the appropriation by the defendant of the plaintiff's *Sun Grand* patent or that, to be more specific, during the year 1955 the defendant grafted Sun Grand nectarine scions on other fruit trees, or that in the year 1956 he budded trees of the same variety covered by the plaintiff's patent.[99]

The "derivation" issue was not of significance in the next plant patent infringement suit, *Nicholson v. Bailey,* as it was undisputed that defendant had purchased two Dream Navel Orange trees from plaintiff.[100]

The commentators did not agree, any more than the courts of Texas and California, as to whether "derivation" was a part of the gravamen of the suit. R. A. Magnuson declared:

In the case of a *Plant Patent,* it would seem that *the test of infringement is* whether there was a *reproduction* of substantially the same plant as covered by the patent by any means *other than by seed.*[101]

P. F. Langrock criticized this approach:

What test is to be used in infringement proceedings to show an invasion of the patentee's exclusive right to reproduce asexually his patented plant? It is necessary that there be some sort of a physical appropriation from one of the patent plants. It is only when there is such a physical appropriation that the rights of the patentee are invaded. Another person can develop a similar or even identical plant on his own and not only would he be free from a charge of infringement but might be entitled to a patent of his own. The test set out by Magnuson calling for only a showing of an asexual reproduction of "substantially the same

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[99] 120 U.S.P.Q. 210, 212 (S.D. Cal. 1958).
[100] 125 U.S.P.Q. 157, 159 (S.D. Fla. 1960).
[101] 30 JPOS 493, 508.

plant" misses the narrow confinement of the protection afforded to plant patents. It is not substantially the same plant that is patented but one particular plant that has one particular chromosome structure and when reproduced asexually will produce plants that have an absolute genetic identity with the parent plant.[102]

He admitted, however, that "(i)t is often difficult or even impossible to show the actual appropriation where the burden of proof is on the patentee charging infringement.[103]

To overcome this difficulty, Langrock suggested that it was:

> [T]ime for the law to create a presumption that an infringement has occurred upon the showing by the patentee that a defendant's allegedly infringing plants are substantially the same as the patented plant and that the defendant has had at least a minimum opportunity to make an actual physical appropriation. The burden would then shift to the defendant to show that he developed the plant independently and without making a physical appropriation from the patentee's patented stock. This seems to be the only fair and sensible solution when the position of the defendant is considered; he is in a position far superior to the plaintiff to dispel any doubts about the origin of his allegedly infringing plant, and if he is in fact innocent of the infringement it should be a relatively easy thing for him to show.[104]

While Langrock does not draw the analogy, a prima facie case of copyright infringement is established by proof of access to the allegedly infringed work and at least substantial similarity between the two works.[105]

In a somewhat confused opinion, the Fifth Circuit adopted Langrock's reasoning:

> Asexual reproduction is literally the only way that a breeder can

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[102] P. F. Langrock, Plant Patents—Biological Necessities in Infringement Suits, 41 JPOS 787, 788-789 (December 1959).

[103] Id., 789.

[104] Id., 789-790.

[105] Granite Music Corp. v. United Artists Corp., 532 F.2d 718 (9th Cir. 1976).

be sure he has reproduced a plant identical in every respect to the parent. It is quite possible that infringement of a plant patent would occur only if stock obtained from one of the patented plants is used, given the extreme unlikelihood that any other plant could actually infringe. . . . If the alleged infringer could somehow prove that he had developed the plant in question independently, then he would not be liable in damages or subject to an injunction for infringement.[106]

Langrock would no doubt be troubled by the "weasel" words, "extreme unlikelihood" and "quite possible" in the passage quoted above, which blunt the force of his reasoning. The murkiness of the Fifth Circuit's reasoning prompted D. D. Jeffery to comment:

Although derivation was not an issue in *Yoder* due to the admissions of CFPC, the Court would appear to require proof of derivation of the patented plant before infringement would be established. However, the Court subsequently implies that the facts of a particular case may require the alleged infringer to prove independent development.[107]

Emphasizing, perhaps, the difference between Northern and Southern California, San Francisco Judge Renfrew paid scant attention to the *Kim* decision in Fresno when he rejected the "derivation" requirement in *Pan American Plant Co. v. Matsui:*

Defendant moved for summary judgment on the ground that the alleged infringing plant in this case was not asexually reproduced from the patented plant. Defendant contended that the Plant Patent Act prohibits only the sale of plants grown from plant material cloned directly from the patented plant. The Court concluded that defendant's interpretation of the Plant Patent Act is incorrect, and that the Act bars the asexual reproduction and sale of any plant which is the same variety (i.e., has the same essential characteristics) as the patented plant, whether or not the infringing plant was originally cloned from the patented plant. Since plaintiff's claim of infringement will be

[106] *Yoder*, 193 U.S.P.Q. at 293.
[107] 59 JPOS at 650-651.

denied on other grounds, however, there is no need to discuss the asexual reproduction question in detail.[108]

The ABA (PTC Section) Plant Patent Committee's 1978 Report took a similar view:

> Certain court decisions appear to impose the requirement as a condition to finding infringement of a plant patent that the patentee prove derivation of the infringing plant from the plant material which gave rise to the application. That concept can be found in such decisions as Yoder Brothers, Inc. v. California-Florida Plant Corporation, 537 F.2d 1347 (5th Cir. 1976); Cole Nursery Co. v. Youdath Perennial Gardens, 17 F. Supp. 665 (S.D. Cal. 1958), aff'd 276 F.2d 259 (9th Cir. 1960). The requirement of proof of derivation can add significantly to the complexity of plant patent infringement litigation, and, particularly where a plant patent has been issued for a newly discovered mutation, may significantly reduce or destroy the value of the patent. Neither the wording of the plant patent law (35 U.S.C. §§161-164) nor its legislative history require proof of derivation, and judicial imposition of such a requirement is inconsistent with the Congressional objective of rewarding and motivating the originators of new plant varieties. It may be noted in passing that the Proposed Resolution does not address itself to the claim of the plant patent, since as required by 35 U.S.C. §162, the claim is simply "in formal terms to the plant shown and described."[109]

The Committee proposed the following resolution, which the full section permitted to rest as a Committee Report in view of the small number of informed members:

> RESOLVED, that the Section of Patent, Trademark and Copyright Law favors in principle that the determination of applicability of a plant patent to, and the infringement or non-infringement of such a patent by, a particular accused plant or crop of plants be based upon a comparison of the depiction and description of the variety as set forth in the patent to the characteristics of the accused plant or crop, and that

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[108] 198 U.S.P.Q. at 463 n.2.

[109] 1978 Committee Reports at 71-72.

the exclusionary right under 35 U.S.C. §163 not be confined to plants horticulturally derived from the plant material upon which the application for patent was based.[110]

§ 8.16 Distinctness and Infringement

We consider now the scope of the protection afforded by a plant patent. A utility patent covers not only the structures or substances literally reached by the claims but also unimportant variations which perform substantially the same function in substantially the same way to obtain the same result. A design patent covers all designs which, in the eyes of an ordinary observer of reasonable attentiveness, are substantially the same as the patented design.[111] As Robb has pointed out, plant patent claims which refer back to the specification of the patent for disclosure of the distinctive characters are similar to design patent claims.[112] Robb was unwilling, however, "to concede that in a plant case the patentee must be limited to the extent that the infringing plant must be a Chinese copy or reproduction of the patent disclosure."[113] Robb, a proponent of the "derivation" requirement, explained away the seeming contradiction in his position by pointing to the 1930 Committee Reports, which stated:

> Of course, allowance must be made for those minor differences in characteristics, commonly called fluctuations, which follow from variations in methods of cultivation or environment and are temporary rather than permanent characteristics of the plant.[114]

Elaborating on this point, P. F. Langrock remarked:

> There are environmental factors that may result in a plant that is genetically identical having characteristics that vary from the

[110] Id., 71; 1978 Summary of Proceedings at 58-59.
[111] Gorham Mfg. Co. v. White, 81 U.S. (14 Wall.) 511 (1872).
[112] 15 JPOS at 757.
[113] Id.
[114] S. Rept. at 6.

parent plant, much as identical twins will develop more and more individual characteristics as the minor variations in their environments take their toll. Thus there can be an infringement even where there is a diversity in the superficial characteristics between the parent and the infringing plants, where these differences are the result of environmental factors.[115]

A similar conclusion is reached by D. D. Jeffery:

Regarding infringement, where it can be proved that the plants are identical and that defendant derived, directly or indirectly, the patented plant material from plaintiff, there is infringement, as in *Yoder*. This would also be true if minor differences exist which can be shown to be due to differing growing conditions.[116]

In assembling evidence of infringement, the patent attorney must be cognizant of the importance of environmental conditions. As Allyn said, comparing cherry plant varieties distinguished on the basis of the ripening period:

As the ripening period, of course, depends upon the soil and climate it would appear necessary to grow a true Montmorency alongside of the alleged infringement in order to make the rather nice comparison.[117]

The first case to consider the equivalency of an accused plant to a patented variety was *Kim Bros. v. Hagler.* Plant Patent 974 claimed:

A new distinct variety of nectarine tree substantially as described and illustrated bearing yellow fleshed freestone fruit characterized by ripening period between the white fleshed John Rivers and Grower varieties; approximately two weeks earlier than the yellow fleshed Kim or Bim varieties; and approximately three weeks earlier than the yellow fleshed Le Grand variety; its firm flesh; its relatively larger size; and its

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[115] 41 JPOS at 789.
[116] 59 JPOS at 655.
[117] *Allyn, supra,* 15 JPOS at 185.

superior shipping and eating qualities.[118]

The Court found that the patent was not infringed:

> I am satisfied that the credible evidence warrants the conclusion that the nectarine grown by the defendant differs in coloration from that of the plaintiff. An examination of the actual fruit and the photographs introduced shows clearly the difference in coloration between the defendant's fruit which is reddish, and the plaintiff's fruit, which is orange. There is similar difference in coloration in the pit cavity of the fruit, the defendant's fruit having a reddish color around the pit. The fruits differ in size and shape as do also the pits. And there are also marked differences in the leaves as to shape, color and the glands on them. Because only two crops of the defendant's fruit have been harvested, the evidence as to earlier ripening could not be established with the same certainty with which the ripening period of an older variety could be established. However, I am convinced that, on the whole, the evidence sustains the conclusion that the defendant's variety ripens five or six days earlier than the fruit of its parent variety *Le Grand*, as claimed in the defendant's patent.[119]

This conclusion was buttressed by the fact that the Patent Office, by issuing a patent to *defendant*, had recognized defendant's tree as a new and distinct variety:

> [W]hen they, with the knowledge of the field and of the prior art were satisfied that, in the crowded field of nectarines, the defendant had developed, from a sport or mutant, a nectarine which had sufficient new characteristics to amount to invention, their finding should be given due weight.[120]

The Court concluded that there was "ample proof" that the plants grown by defendant were a "sport" or "mutant" form of plaintiff's plant.[121]

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[118] 120 U.S.P.Q. at 212.
[119] Id., 213.
[120] Id.
[121] Id., 213-214.

The question of "equivalency" arose again in *Pan-American Plant Co. v. Matsui*, involving a claim to:

> A new and distinct variety of chrysanthemum plant, substantially as herein shown and described, characterized by its very large, bright yellow blooms, its excellent production or well formed flowers, flowering with a very even eleven-week response and producing very few culls.[122]

The Court held that the "Sunshine" variety asexually reproduced and sold by defendant was not the "same variety" as the mutant chrysanthemum developed by Danielsen of Plant American.

> It is undisputed that before Plant Patent No. 3486 was ever granted, the Danielson plant material became diseased and produced blossoms that were 50 to 60 percent culls. It is also undisputed that the Sunshine chrysanthemum does not suffer the same problems. The Court finds that Sunshine's ability to be asexually reproduced with a far smaller percentage of culls than the Danielson plant material is a significantly different characteristic which makes it a different variety. Sunshine "is substantially different from plaintiff's patented [plant] and hence does not infringe." Kim Bros. v. Hagler, 276 F.2d 259, 261, 125 USPQ 44, 45-46 (9th Cir. 1960).
>
> The Court is not persuaded that the high percentage of culls was a temporary characteristic of the Danielson plant material. Pan-American is unable to say for certain that it could have eliminated the disease, because it destroyed *all* the Danielson plant material in the United States without even attempting to cure the defect.[123]

The Court declared (referring to yet another chrysanthemum variety) that "(I)f two plants have significantly different characteristics, they are two different varieties within the meaning of the Plant Plant Act."[124]

As a general rule, the burden of proof on the issue of patent

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[122] 198 U.S.P.Q. at 464.
[123] Id., 465.
[124] Id., 466.

infringement is the traditional civil standard, "the preponderance of the evidence.[125] *Cole Nursery Co. v. Youdath Perennial Gardens, Inc.*, however, declared that the proof of "derivation" was "clear and convincing."[126] This standard was subsequently applied to the "distinctness" issue in *Kim Bros. v. Hagler.*[127] The statutory or judicial authority for this stringent standard was not clearly delineated.

§ 8.17 Marking of Protected Varieties

The present 35 U.S.C. §287 provides:

> Patentees, and persons making or selling any patented article for or under them, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.," together with the number of the patent, or when, from the character of the article, this cannot be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

By virtue of the second paragraph of 35 U.S.C. § 161, this "notice" provision is applicable to plant patents.

The "notice" requirement has been strictly construed, and the marking of only a fraction of the patented articles distributed by the patentees or its licensees is inadequate.[128] In 1948, R. A. Magnuson commented:

> It would seem that in infringement suits, a patentee would be

[125] Bene v. Jeantet, 129 U.S. 683 (1889).

[126] 31 U.S.P.Q. at 96.

[127] 120 U.S.P.Q. at 213.

[128] Hazeline Corp. v. Radio Corp. of America, 20 F. Supp. 668 (S.D.N.Y. 1937).

unable to recover unless he could prove that he had marked his patented products and that the defendant was duly notified of his infringement(s) of plaintiff's patent rights but continued after such notice to make, use or vend the article so patented. The patenteee should therefore place a plate or tag containing the patent notice on every patented plant or tree. Merely "posting" an orchard or garden would appear to be insufficient marking for protection in view of decisions regarding patented articles other than plants.[129]

"Marking" and "actual notice of infringement" were at issue in *Nicholson v. Bailey:*

It is an undisputed fact that on or about February 21, 1948, the plaintiff sold two Dream Navel orange trees to the defendant. In his affidavit in support of his motion, the defendant states, however, that these two trees or the package in which they might have been contained were not marked or labelled so as to give notice of the patent. The defendant further states that he has not asexually reproduced, sold or used plants covered by U.S. Plant Patent 625 after any notice of infringement or since the filing of this suit. This statement by the defendant is countered by the plaintiff in the following manner: In plaintiff's answer to requests for admissions Nos. 1 and 3, the plaintiff states that "he admits that he did not physically affix to the plant or containers the word "patent," but states that he did adequately inform purchasers, the defendant and other nursery men of the fact that his said plant was patented." In the deposition taken subsequently, the plaintiff deposed that the above answers were, in part, incorrect, that the two trees sold to the defendant on or about February 21, 1948, had metal tags attached to them with the wording "Dream Navel Orange—U.S. Plant Patent 625," and that to that extent the plaintiff was mistaken in his said answers. This testimony is repeated in plaintiff's affidavit filed in opposition to the motion for summary judgment. In all three documents, i.e., the answers to the requests for admissions, the deposition and the affidavit, the plaintiff alleges that he orally informed the defendant at the time of the sale of the two trees, subsequently and prior thereto, that the trees were patented and that they could not be asexual-

[129] 30 JPOS at 508.

ly reproduced or sold without the plaintiff's permission.[130]

The Court accepted the patentee's belated declaration that he tagged the plants and that he orally informed defendant that he owned a patent on the plants at the time of the purchase and that certain future acts would constitute an infringement. It is not clear whether the Court's qualification of its interpretation of the "notice" provision ("especially in a plant patent case") was intended to suggest that the provision should be more liberally applied in the case of plant patents.

§ 8.18 Active Inducement and Contributory Infringement

In *Armstrong Nurseries, Inc. v. Smith*, a rose patent case, the Court entered a finding that:

> Defendant Hood was unaware when he first budded the aforesaid 73,000 rose plants that any of them were of the aforesaid patented varieties. Later when the crop came on and Defendant Hood questioned Defendant Dyess in respect of the varieties of said patented rose plants, Defendant Dyess told Defendant Hood that those plants which were in fact of the variety shown and described in the Plant Patent No. 792 and commonly known as "Forty-Niner" were a new variety known as "Fifty-Five"; that those plants which were in fact of the variety shown and described in Plant Patent No. 1280 and commonly known as "Roundelay" were a new variety known as "Roustabout"; that those plants which were in fact of the variety shown and described in Plant Patent No. 823 and commonly known as "New Yorker" were a variety known as "Mirros"; and that those which were in fact of the variety shown and described in Plant Patent No. 484 and commonly known as "Pinocchio" were a variety known as "Pinecastle."
>
> At the time Defendant Dyess furnished Defendant Hood the aforesaid budwood Defendant Dyess did not possess a current valid growing license or sublicense from the holders of the aforesaid Plant Patent Nos. 484, 792, 823, and 1280 respectively, and by his dealings with Defendant Hood in respect of said

[130] 125 U.S.P.Q. at 159.

budwood and the roseplants subsequently grown by Defendant Hood, he actively induced the infringement of said Plant Patents by Defendant Hood and is an infringer of the rights of said patentees under said respective plant patents.[131]

Presumably, the "contributory infringement" provision [35 U.S.C. §271(b)] is, likewise, applicable to plant patent litigation.

§ 8.19 Plant Patent Term Restoration

The present Patent Term Restoration Act applies to drugs (including biologics), medical devices, and food and color additives. It does not apply to plants, even though imported plants are in fact subject to a regulatory review period somewhat analogous to that undergone by veterinary biologics. As an ABA committee noted recently:

> Plant materials of new varieties are imported to the United States from a foreign country and are frequently subject to quarantine procedures of the Department of Agriculture pursuant to Section 7 of the Plant Quarantine Act (7 U.S.C. 160) and Section 106 of the Plant Pest Act (7 U.S.C. 150ee). During the quarantine period plant material cannot be marketed to the United States. When the U.S. plant patent issues during the quarantine period the owner is frequently deprived of a portion of his term (sometimes 3–5 years of the term is lost).[132]

§ 8.20 Changes in Plant Patent Protection Under UPOV

The Union for the Protection of New Varieties of Plants (UPOV) is discussed in detail in §9.06. The United States became a party to this 1978 Convention on December 8, 1981. As a result of this treaty ratification, it is necessary, as a condition for receiving a plant patent, to register a variety name for the plant. Under UPOV Convention Article 13, the examiner

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131 120 U.S.P.Q. at 224.

132 1984 ABA (PTC Section) Committee Reports 74.

must determine whether the proposed variety name is identical with or confusingly similar to other variety names utilized in UPOV member countries. The examiner must also be wary of proposed names which might mislead the consumer as to the characteristics, value or identity of the patented plant.[133]

The implementation of the variety naming requirement is still the subject of controversy within the Union. The UPOV Administrative and Legal Committee, despite the opposition of the U.S. delegation, has advocated a system under which identical names for new varieties belonging to different genera would be denied.[134] Under U.S. practice, however, the proposed variety name will only be compared with the names utilized for the same or for closely related species.[135]

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[133] MPEP §1612 (5th ed., August 1983).

[134] 1984 ABA (PTC Section) Committee Reports 73.

[135] *See* note 133, *supra*.

CHAPTER 9

The Plant Variety Protection Act and the UPOV

§ 9.01 Obtaining Protection Under the Plant Variety Protection Act

The Plant Variety Protection Act was enacted in 1970 to encourage the development of novel varieties of sexually produced plants and to make them available to the public.[1] Consequently, it is mainly of interest to breeders and farmers of such sexually reproduced crops as wheat, alfalfa, soybeans, cotton, corn, lettuce, and watermelon, as opposed to orchardmen and horticulturalists. It was amended in 1980 to harmonize it with the UPOV, an international convention.[2]

Under the Act, "Plant Variety Protection Certificates" may be issued by the Plant Variety Protection Office or the Department of Agriculture[3] to "the breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hyprius) who has so reproduced the variety, or his

[1] 82 Stat. 1542 (preamble).

[2] The text of the UPOV can be obtained from the World Intellectual Property Organization (WIPO).

[3] PVPA Secs. 1, 3, 82.

successor in interest. . . ."[4]

According to the PVPA of 1970:

> The term "novel variety" may be represented by, without limitation, seed, transplants, and plants, and is satisfied if there is:
>
> (1) Distinctness in the sense that the variety clearly differs by one or more indentifiable morphological, physiological or other characteristics (which may include those evidenced by processing or product characteristics, for example, milling and baking characteristics in the case of wheat) as to which a difference in genealogy may contribute evidence, from all prior varieties of public knowledge at the date of determination within the provisions of section 42; and
>
> (2) Uniformity in the sense that any variations are describable, predictable, and commercially acceptable; and
>
> (3) Stability in the sense that the variety, when sexually reproduced or reconstituted, will remain unchanged with regard to its essential and distinctive characteristics with a reasonable degree of reliability commensurate with that of varieties of the same category in which the same breeding method is employed.[5]

Note that this alleviates much of the confusion surrounding the term "variety" in the Plant Patent Act of 1930.

The "inventorship" questions which arose under the 1930 Act also are resolved more clearly by the PVPA, *via* a definition of the term "breeder":

> The term "breeder" shall mean the person who—(1) directs the final breeding creating the novel variety, or (2) discovers the novel variety.[6]

Somewhat shortsightedly, the PVPA defines the term "sexually reproduced" as including "any production of a variety by

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[4] PVPA Sec. 42.

[5] PVPA Sec. 41(a). *See* Byrne, The Agritechnical Criteria in Plant Breeders' Rights Law, Industrial Property 293 (October 1983).

[6] PVPA Sec. 41(e).

seed,"[7] which arguably would not include varieties produced by cell fusion or by "gene splicing."

A statutory bar arises (cp. 35 U.S.C. §102(b)) if the new variety was "sold" or "used" ". . . or existing in and publicly known in this country" for more than a year prior to the effective filing date of the PVPA application on the new variety.[8] However, "use" and "sale" do not include experimental use or "sale" for other than seed purposes of seed or other plant material produced as the result of testing."[9]

The bar also may arise if, at such time, the "variety" was "effectively available to workers in this country."[10] This concept, arguably a departure from the interpretations of 35 U.S.C. §102(b) under the Plant Patent Act of 1930, mandates that:

> A variety described in a publication as specified in section 42(a)(1)(B) is "effectively available to workers in this country" if a source from which it can be purchased is indicated in such publication or readily determinable or if such publication teaches how to produce the Variety from source-material effectively available to workers in this country.

Similar rules apply to whether a bar similar to 35 U.S.C. §102(a) arises.[11]

Another departure from traditional patent law appears in Section 42 (a)(3), the PVPA counterpart to 35 U.S.C. §102(g). The bar arises if another was the "first-to-determine that the variety has been sexually reproduced with recognized characteristics" and:

> [S]uch other (A) has a certification of plant variety protection hereunder or (B) has been engaged in a continuing program of development and testing to commercialization, or (C) has within six months after such earlier date of determination adequately described the Variety by a publication reasonably deemed a

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[7] PVPA Sec. 42(f).
[8] PVPA Secs. 41(i), 42(a)(1)(A).
[9] PVPA Sec. 41, Subsecs. (h) and (i).
[10] PVPA Sec. 42 (a)(1)(B).
[11] PVPA Sec. 41(j).

part of the public technical knowledge in this country which description must include a disclosure of the principal characteristics by which the variety is distinguished.[12]

The regulations originally promulgated under the PVPA prohibited the protection of foreign varieties for which an application for plant variety protection had been made in a foreign country more than one year prior to applying for protection in the United States.[12.1] In order to comply with UPOV treaty requirements, the regulations were amended in 1983 to provide for protection of foreign varieties which have not been marketed in a foreign country for more than six years in the case of vines and trees, or four years in the case of all other plants.[12.2] The PVPA application must contain the name of the variety, a "description of the variety setting forth its novelty and a description of the genealogy and breeding procedure, when known."[13] According to the PVPO, the following exhibits are normally required:

(1) Exhibit A—Origin and Breeding History of the Variety,
(2) Exhibit B—Novelty Statement,
(3) Exhibit C—Objective Description or the Variety, and
(4) Exhibit D—Additional Description of the Variety.[14]

The examiner may require the submittal of drawings, photographs, or specimens.[15]

The applicant may freely add to or correct the description before the certificate issues, upon a showing that the description is "retroactively accurate."[16]

The application also must contain a statement of the basis of

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[12] PVPA Sec. 42(3).

[12.1] 7 C.F.R. §180.7 (1972). THe PVPO was permitted to extend this grace period in up to four one-year increments to allow for growing-out tests officially required in the foreign country. However, the term of American protection was reduced by the cumulative length of these extensions.

[12.2] 7 C.F.R. §180.7 (1983).

[13] PVPA Sec. 52.

[14] A sample application is available from the PVPO.

[15] PVPA Sec. 52(2).

[16] Id.

applicant's ownership[17] and

> A declaration that a viable sample of basic seed necessary for propagation of the variety will be deposited and replenished periodically in a public repository in accordance with regulations to be established hereunder. This declaration may be added by amendment.[18]

The reader will note the analogy between this requirement and the microbiological depository requirement discussed *infra.* Curiously, no seed depository regulations have been promulgated, other than a fee for late replenishment.[19]

If the application is rejected, the examiner is required to "cite the reasons the application was denied"; (t)he pertinence of each reason if not obvious, shall be clearly explained."[20] The applicant may request reconsideration by the Commissioner.[21] Appeal from the latter's decision may be taken to the Secretary of Agriculture.[22] The Secretary has the benefit of the advisory opinion of the Plant Variety Protection Board, an expert panel.[23] Appeal from the Secretary's decision may be taken to the Court of Customs and Patent Appeals or mandamus may be sought from the U.S. District Court for the District of Columbia.[24]

On a voluntary basis, an applicant with a pending application may permit the PVPO to publish a description of his variety in the latter's *Official Journal.* Permission is usually granted.[25]

The Secretary of Agriculture has the power to declare "a protected variety open to use," for "a reasonable royalty," when "necessary in order to insure an adequate supply of

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[17] PVPA Sec. 52(4).

[18] PVPA Sec. 52(3). Note that the applicant *as filed* need *not* contain this declaration. Note also PVPA Sec. 83(c), terminating plant variety protection if seed is not replenished within three months of notice under Sec. 101(d).

[19] 7 CFR §180.175(1).

[20] 7 CFR §180.105.

[21] 7 CFR §180.106.

[22] 7 CFR §180.300.

[23] PVPA Sec. 7 and 7 CFR §180.2.

[24] PVPA Secs. 71, 72 CP. USC §§145, 146.

[25] 7 CFR §180.800.

fiber, food, or feed in this country" at a "fair price."[26] The regulations indicate that this power is exercised after an *ex parte* determination, not after a public hearing.[27]

The penultimate provision of the PVPA as enacted in 1970 was the so-called "soup vegetable" exemption:

> The provisions of this Act shall not apply to the seeds, plants, or transplants of okra, celery, peppers, tomatoes, carrots, and cucumbers.[28]

This exemption was adopted at the urging of the Senate Committee on the Judiciary, to protect the segment of the vegetable industry which was "not engaged in research to develop new varieties for sale in commercial seed channels."[29] The exemption was reconsidered in 1980. Report. No. 96-1115 states:

> An analysis of breeding programs for the six excluded vegetables indicates not only far less development of new varieties, but a concentration of the limited development in hybrid varieties.
>
> The lack of protection for open pollinated varieties of the six excluded vegetables is the direct cause of the concentration of research efforts for these plants in hybrid varieties. The discrimination against breeders of varieties of these crops must be terminated, if American agriculture is to receive the best seeds available for all crops.

The exemption was repealed.[30]

§ 9.02 The Scope of Plant Variety Protection

Plant Variety Protection Certificates, as issued, are announced in the Plant Variety Protection Office Official Jour-

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[26] PVPA Sec. 44.
[27] 7 CFR §180.700.
[28] PVPA Sec. 144.
[29] S. Rept. No. 91-1246, 41st Cong., 2d Sess. (1970).
[30] P.L. 96-574.

nal, which gives the certificate number, varietal name, issue date, and owner for each newly protected variety. It also describes the distinct characteristics asserted by the applicant. Thus, for "Maverick" alfalfa, we are told that it is "most similar to 'Roamer,' however, 'Maverick' has an insignificant percentage of creeping-rooted plants whereas 'Roamer' is classified as a creeping-rooted alfalfa. Also, 'Maverick' has 27% fewer purple, 15% more variegated, and 6% more yellow flowers than 'Roamer'." (Certificate No. 8100064). "CS24" soybeans are distinguished by their "excellent emergence from a depth of 10 cm at 25 deg. C." (No. 8100133). "Red King" radishes are resistant to "clud root, race 6," whereas "Fancy Red" is susceptible. (No. 8300024).

The 1970 Act is not a model of legislative clarity when it comes to explaining the rights accorded by a plant variety protection certificate. Section 83 purports to delimit the exclusive rights conferred by this certificate, but these rights are not coterminous with Section 111, defining acts of infringement. The 1970 Act thus departs from the fundamental legal principle *ubi jus, ubi remedium.* As the House report admits, Section 111 "is broader than Section 83 in some respects and narrower in others. . . . [T]he enforceable rights conferred by the bill are governed by Section 111."

Under Section 83 of the 1970 Act, the "term of plant variety protection" normally expired seventeen years from the date of issue. (This was changed by the 1980 amendment to eighteen years.) Unlike the Patent Act, the PVPA allows the Secretary to *shorten* the term "by the amount of delay in the prosecution of the application" attributable to the applicant if the certificate is not issued within three years from the effective date.

The term also expires if the applicant totally disregards his obligation to replenish the seed of his variety in a public depository.

It appears from the wording of PVPA Secs. 111 and 127 that protection is available for novel varieties properly marked "propagation prohibited" even before the PVP certificate is issued. This is confirmed by the House Report on Section 111, which states

> Infringement can occur before a certificate of plant variety

protection is issued when a novel plant variety has been distributed with notice that propagation is prohibited. This more resembles copyright than patent law. Justification for this may be found in the fact that infringement is expected almost never to be by independent work, but by willful reproduction starting from the protected variety itself.

The following acts of infringement are enumerated in PVPA Sec. 111

(1) Sell the novel variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it;
(2) Import the novel variety into, or export it from, the United States;
(3) Sexually multiply the novel variety as a step in marketing (for growing purposes) the variety; or
(4) Use the novel variety in producing (as distinguished from developing) a hybrid or different variety therefrom; or
(5) Use seed which had been marked "propagation prohibited" or progeny thereof to propagate the novel variety; or
(6) Dispense the novel variety to another, in a form which can be propagated, without notice as being a protected variety under which it was received; or
(7) Perform any of the foregoing acts even in instances in which the novel variety is multiplied other than sexually, except in pursuance of a valid United States plant patent; or
(8) Instigate or actively induce performance of any of the foregoing acts.

There are a number of pecularities of this provision which warrant comment. First, there is the distinction between "producing" and "developing" in (4), above. Suppose *A* crossed *B*'s protected variety *X* with variety *Y* to obtain a different variety Z which could be further multiplied by inbreeding Z. This use of *X* in the development of *Z* is permissible. But

suppose that *Z* was a sterile or genetically unstable hybrid, *i.e.*, whenever *A* wished to obtain *Z* he needed to use *B's* stock variety *X*. This would be use of *X* in "producing" *Z*, and would infringe. Second, suppose *A* has a plant variety protection certificate on variety *X* and *B* has a plant patent on it. (This is possible if *A* first bred the new variety but *B* was the first to asexually reproduce it). If so, *B* and *B's* licensees may asexually reproduce and sell *X* without *A's* permission, though both *A* and *B* may enjoin its asexually reproduction by others. Attention should also be called to Section 102, making diversion of sexually reproducible plant material from authorized testing actionable.

Additionally, if a description is revised prior to issue, the "Courts shall protect others from any injustice which would result."

There are a number of interesting exemptions to Section 111.

Section 113, a verbose and oblique paragraph, applies only to persons "whose primary farming occupation is the growing of crops for sale for other than reproductive purposes," *i.e.*, "crop farmers." Suppose crop farmer *A* obtained the seed of the protected variety *X* from its owner for seeding purposes. When he raises the crop, he can save some of the seed of variety *X* he has just produced on his farm, sell his crop (for other than reproductive purposes) and

(A) Use the saved seed to produce another crop for use on his farm;
(B) Use the saved seed to produce another crop for sale for other than reproductive purposes;
(C) Sell the saved seed to crop farmer *B* for "reproductive purposes";
(D) Sell the saved seed to *anyone* for "other than reproductive purposes," but any purchaser of this seed who diverts it to seeding purposes infringes the PVP certificate.

It may be argued that the proper interpretation of the first sentence of Section 113 is that the saved seed may be sold, but not used to sexually multiply the protected variety (save by

another crop farmer) or to produce a different variety. The provision, frankly, is unclear.

Section 114 simply authorizes the "use and reproduction of a protected variety for plant breeding or other bona fide research," and thus is related to the proviso Section 111(4) above.

Section 115 exempts carriers and persons in the advertising business.

Section 112 is a grandfather clause, exempting persons who developed and produced the variety more than one year prior to the effective filing date of another's application for plant variety protection over that variety.

In addition, there is the usual limitation on damages when the protected subject matter is not marked. The marking requirement is more lenient than that provided for by the patent laws in that notice is effective if "physically associated" with the seed itself. The patent laws require "affixation." The label may bear the words "Propagation Prohibited" so long as (1) the variety is under testing, (2) an application has been filed, or (3) a "statement" of "reasonable basis" is filed with the Secretary and the variety was first sold less than one year ago. In case (1), the label should read "Unauthorized Propagating Prohibited —For testing (or Increase) Only." [*See* 7 CFR §180.140.] In case (2), the label should read "Unauthorized Propagation Prohibited—U.S. Variety Protection Applied For." [*See* 7 CFR §180.140.] Case (3) is discussed only in PVPA Sec. 128, without any explanation of the term "reasonable basis," or of whether the "sale" referred to is a sale in this country.

The stature of limitations for PVPA infringement actions requires that they be brought "within six years after the infringement (or within three years after the owner learns of the infringement). "Damages are normally "the higher of adequate compensation or a reasonable royalty," and may be trebled in an appropriate case. On the other hand, damages might not be awarded against an innocent infringer whose wrongful acts occurred before a certificate was issued.

§ 9.03 Application of the PVPA in the Courts

On June 10, 1980, a complaint was filed in *Helena Chemical Company v. Southern Chemical and Seed Co.*,[30.1] The plaintiff was enforcing a Plant Variety Protection Certificate on the "Wilstar 790" soybean variety. The defendant company had been formed by several former employees of plaintiff. The subsequent history of the case is not known to this author. However, it is believed to be the first action instituted under the Plant Variety Protection Act.

The second case to be brought under the PVPA was *North American Plant Breeders v. Haynes*.[31] The jury verdict awarded plaintiff $7,051.55 in compensatory damages. Punitive damages and attorney's fees were denied:

> There was no evidence of "bad faith or inequitable conduct" by the defendants. In fact, when first informed by the plaintiff that there was a question of infringement, the defendants offered to stop sales of "CRUD," and in fact did not sell LUD under the "CRUD" label or any other guise. In addition, due to the dearth of authority construing the Plant Variety Protection Act, what constitutes infringement and what qualifies under the "exceptions" are still open and unresolved questions. In these circumstances, I find no bad faith or inequitable conduct that would merit the imposition of increased damages or attorney's fees.[32]

In 1983, the Fifth Circuit rendered a decision interpreting the scope of the farmers' exemption.[32.1] *Delta* held a PVP certificate on "Deltapine 41" cottonseed. *Peoples' Gin Co.* was a nonprofit agricultural cooperative with approximately fifty farmers as members. The cooperative "ginned" its members' cotton, thus separating out the cottonseed. What was done with the cottonseed varied from instance to instance. It might be

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[30.1] Civil Action No. DC80-89-WK-O.

[31] Civ. No. 78-974 (D. Ore.), jury verdict (Sept. 25, 1980), judgment (December 3, 1980).

[32] Order (December 3, 1980).

[32.1] Delta and Pine Land Co. v. Peoples' Gin Co., 694 F.2d 1013 (5th Cir. 1983), aff'g, 546 F. Supp. 939 (N.D. Miss. 1982).

(1) Saved for the farmer who provided it;
(2) Saved for another member of the cooperative;
(3) Held by *People* for anyone who expressed an interest, later, in buying it; or
(4) Sold by the farmer to an outsider who had asked *People* whether any of its members had seed available.

Thus, *People* functioned as an intermediary for arranging the transfer of seed from a member farmer to another farmer, member or not. It did not actually sell seed itself.

The Fifth Circuit held that *People* had infringed *Delta's* PVP certificate. It held that the farmers' exemption was applicable only to sales made by one farmer to another without any marketing assistance by a third party such as an agricultural cooperative. Since the "farmer exemption" was "at odds with the primary purpose of the Act," the court felt that it should be narrowly construed so as not to unduly lessen the incentive for the development of new strains: "Although it may appear that the broadest reading of the exemption would benefit farmers today, it could be detrimental to their interests tomorrow."

As the trial court had persuasively reasoned, a broad reading of the crop exemption could have serious economic repercussions for breeders. "Absent active participation by a third party, a farmer's awareness of prospective sellers and purchasers is necessarily limited by his own initiative and personal efforts. . . . Where a third party . . . acts as agent . . ., the volume of such sales is likely to increase according to the aggressiveness and size [of the agent]."

The court was not willing to draw a distinction between the situation in which the cooperative actively solicited potential buyers and sellers, and that in which it merely let it be known that it holds seed for purchase by unidentified buyers. In either case, said the court, the cooperative has arranged the sale. Only the practice of allowing *Peoples'* to save seed for a particular member specified by the producer was sanctioned by the court.

Infringement of a Plant Variety Protection Certificate was

established in *Heart Seed Co. v. Seeds, Inc.*[32.2] The certificate was to a variety of Kentucky bluegrass.

In seeking the Certificate, Heart Seed presented evidence of the "distinctness" of its variety. This evidence took two forms. First, Heart Seed observed the form and structure of the plant and its parts, and compared these morphological characteristics to those of other varieties of *Poa pratensis.* Second, seeds were treated with phenol, and the nature and distribution of melanin coloring was evaluated. At trial, however, Heart Seed also presented evidence of the electrophoretic similarity of the protected Argyle variety and of the grass sold by the defendant. The court held that electrophoresis was a "valid and acceptable technique" of determining similarity.

The "Argyle" Kentucky bluegrass variety attained notoriety for other reasons as well. A protest proceeding[32.3] requesting the withdrawal of the Certificate was instituted by various individuals, one of whom was a named defendant in *Heart Seed Co. v. Seeds, Inc.* Numerous grounds were stated. One was lack of stability. The PVPO noted that "Argyle" appeared stable in field trials form 1981-1985 and that no seed control agency has accused it of instability. On the issue of distinctness, it was asserted that "Argyle" was not distinct from "South Dakota" or "Pomeroy" Kentucky bluegrass. These varieties were distinguished, however, on the basis of the larger "panicles" of "Argyle." Other petitioners urged that "Argyle" should have been classified as a "rough bluegrass" (*Poa trivialis*), based, for example, on "Argyle" 's lack of "basal webbing"; this contention was also unsuccessful.

(*Text continued on page 9-13*)

[32.2] 4 U.S.P.Q.2d 1324 (E.D. Wash. 1987).

[32.3] In re Certificate of Protection for "Argyle" Kentucky Bluegrass, 4 U.S.P.Q.2d 1320 (PVPO 1987).

As then Commissioner Leese told the American Patent Law Association in 1980,

> The Plant Variety Protection Office has been in operation since 1970, has eight examiners (five Ph. D's and three Masters'), and operates on an annual budget of $359,000. Searches are conducted by machine, and the Office also helps in providing varietal names for varieties applied upon. It has a data bank of over 20,000 variety descriptions. . . . The total number of applications since 1978 stands at 1,178 with a total number of 833 granted. Of this 833 granted, 733 have been for agriculture crops and 90 have been for flowers. The most popular varieties to date have been soybeans (168), peas (90), wheat (84), beans (76), lettuce (41), marigolds (20), and rye grains (20). With respect to depositing seed, Leese indicated that the PVP Office requires 2500 viable seeds. He also indicated that seed could be identified by both chemical and protection analysis. The major rejection made by the office is on the basis that the applicant is unable to describe and identify his variety.[33]

The APLA has recently discussed the advisability or joint administration of the PPA and the PVPA:

> It was concluded that the general concept of combining the administration of the two statutes is a good one. However, there is still disagreement as to where joint administration should occur. The Patent and Trademark Office feels that since it examines almost as many or more applications than the Plant Variety Protection Office, with one Examiner as opposed to eight, that its operation is more efficient. On the other hand, the Plant Variety Protection Office feels that in view of its mechanized search, and the fact that it has a bank of varietal names and the capability of giving variety names, it would best administer the Acts.[34]

[33] APLA Bulletin 794-95 (December, 1980).
[34] Id., 795.

§ 9.05 Comparison of the Three Avenues of Plant Variety Protection

The United States has three systems under which new varieties of plants may be protected:

(1) The Plant Patent Act of 1930 (as amended in 1954) protects asexually reproduced varieties (with certain exceptions).
(2) The Plant Variety Protection Act of 1970 (as amended in 1980) protects sexually reproduced varieties (with certain exceptions).
(3) The Patent Statute of 1952 protects "manufactures" and "compositions of matter" which are not "products of nature," and thus, arguably, protects genetically engineered plants.

The systems differ in many respects: standards of protectability; scope and terms of protection; and disclosure and deposit requirements. These distinctions will be developed in this section.

	35 U.S.C. §101	*35 U.S.C. §161*	*7 U.S.C. §2321*
Subject Matter	Living organisms of a genotype not found in nature; pure cultures of naturally occurring organisms	Asexually reproduced varieties of plants, excluding uncultivated or tuber-propagated plants, possibly excluding bacteria and fungi, but including cultivated sports, mutants and hybrids	Sexually reproduced (esp. by seed) varieties of plants excluding bacteria fungi and first-generation hybrids
Substantive Conditions For Protection	Novelty Utility Nonobviousness	Novelty/Distinctness Nonobviousness (see Yoder) Discovery in Cultivated State Asexual Reproduction	Distinctness Uniformity Stability Novelty Sexual Reproduction
Claims	Multiple, Generic Claims Permitted	Single Varietal Claim to Whole Plant Only	Single Varietal Claim Only
Disclosure Requirements	Best Mode; How-to-Use; How-to-Make; (Deposit of Novel Organism to Assure Reproducibility	"Substantial compliance" only; no formal deposit requirement; drawing requirement	Description of novel characteristics, genealogy, and breeding procedure; deposit of seeds, replenished as

	35 U.S.C. §101	*35 U.S.C. §161*	*7 U.S.C. §2321*
	by Others—Argoudelis)		needed
Administered By	PTO (Commerce Dep't)	PTO (Commerce Dep't)	PVPO (Agriculture Dep't)
Time Bars For Filing Application	One year from first public written disclosure anywhere, first application in U.S. by applicant to same invention, or first public (nonexperimental) use or sale in U.S.	Same, but written disclosure not a bar if plant not yet available	One year from first public nonexperimental use or sale of the new variety in the U.S. for said purposes, or one year from first time the variety is effectively available to workers in this country
Infringement	Doctrine of Equivalency Experimental Use and Exhaustion Defenses	"Derivation" Requirement "Whole Plant" Requirement	Crop and Research Exemptions Sale of Propagation Material Infringes
Term of Protection	17 years	17 years	18 years, with possible limitations.
Costs			
Filing & issue	$800 ($400)	$450 ($225)	$1500
Maintenance	$2400 ($1200)	—	—

(Parenthesized costs are for small entities.)

The question has arisen as to whether these routes of protection are exclusive.

Article 2(1) of the 1978 UPOV Convention provides that

> each member state of the Union may recognize the right of the breeder provided for in this Convention by the grant either of a special title of protection or of a patent. Nevertheless, a member State of the Union whose national law admits of protection under both these forms may provide only one of them for one and the same botanical genus or species.

However, Article 37 permits a state just joining the Convention to give notice that it intends to provide a dual system of protection for the same genera or species. In ratifying the UPOV Convention, the United States gave notice that it would apply the provisions of Article 37 with respect to "protection of the same genus or species under different forms and also in regard to the period of protection applicable to normally asexually produced varieties." Thus, the U. S. treaty obligations do

not require that these forms of protection be exclusive, and indeed the language of the American instrument of ratification suggests that they are not. The "plant variety protection certificate" is not a patent, but rather a "special title of protection" under the Treaty.

When a breeder seeks both a utility patent and a plant patent, there is a possibility of "double patenting." The patent statute declares that whoever invents patentable subject matter may obtain "a patent therefor." Historically, the use of the singular in this expression has been regarded as significant; two valid patents for the same invention cannot be granted. Moreover, one cannot have two valid patents where one claims an obvious variation on the subject matter of the other.

It is now fairly clear that the two patents in question need not be utility parents. *In re Thorington*[35] involved an applicant for a utility patent on a helicoidal lamp who already held a design patent on the ornamental appearance of such a lamp. The applicant argued unsuccessfully that application of the double patenting doctrine was inappropriate in view of the differences in statutory origin, subject matter protected, and tests for infringement. These are, of course, the very arguments that might be raised to avoid a double patenting rejection in a plant-utility conflict.

Of course, the fact that a double patenting rejection is possible does not mean that it is appropriate merely because the same applicant has sought both plant and utility patent protection. In *Carman Industries v. Wahl*,[36] the Federal Circuit noted that "double patenting is rare in the context of utility versus design patents;" presumably it would feel the same way about the utility-plant context. It went on to hold that for a "double patenting" rejection to be appropriate, the claims of the two patents must "cross-read;" that is, the claimed subject matter of each patent must be obvious in the view of the subject matter of the other.

In view of the well-established body of law relating to the design-utility patent context, the "authority for overlapping trademark and design patent protection for the same orna-

[35] 418 F.2d 528 (CCPA 1969).

[36] 724 F.2d 932 (Fed. Cir. 1983).

mental design"[37] is unlikely to have any impact on the plant-utility patent double patenting issue.

It seems to this author that double patenting rejections are likely to be more frequent in plant-utility situations than in design-utility situations, because the subject matter protected is likely to be more similar.

So long as the utility patent and plant patent applications are not drawn to identical subject matter, after one issues, a double patenting rejection against the other application may be overcome by a terminal disclaimer.[38] A terminal disclaimer forfeits the portion of the second patent's term which would extend beyond the term of the first patent.

Applicants may wish to request the simultaneous issue of their utility and plant applications and thus obviate the "terminal disclaimer" requirement. This is possible if both applications have been allowed.[39]

In a related vein, let me note that one may file a utility patent application with generic claims covering a plant variety, and, if these claims are rejected as obvious, file a plant patent continuation application. The latter would have the benefit of the filing date of the original application and would not be subject to any de facto deposition requirement.[40]

§ 9.06 Plant Variety Protection in UPOV Countries

In 1961, the Union for the Protection of New Varieties of Plants (UPOV) was created. The 1961 Convention was ratified, or acceded to, by Belgium, Denmark, France, the Federal

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[37] Noted in Neagley, Jeffrey and Diepenbrock, Section 101 Plant Patents —Panacea or Pitfall?, AIPLA Select Legal Papers, Vol. II, No. 2 (January 1984). This case law is, however, relevant to any challenge against dual patent act/plant variety protection act protection. Similarly, one can rely on cases like In re Yardley, 493 F.2d 1389 (CCPA 1974), which held that an application for patent does not constitute a "contract" or "election" not to seek copyright protection. And *cf.* Straus, Patent Protection for New Varieties of Plants Produced by Genetic Engineering—Should "Double Patenting" Be Prohibited, 15 IIC 426 (No. 4, 1984).

[38] *See* 35 U.S.C. §253; In re Robeson, 331 F.2d 610 (CCPA 1964).

[39] 974 O.G. 16 (August 25, 1978).

[40] Ex parte Solomons, 201 USPQ 42 (POBA 1978).

Republic of Germany, Israel, Italy, Netherlands, South Africa, Sweden, Switzerland, and the United Kingdom. Structural changes were made through a 1972 amendment. In 1978, the UPOV Convention was revised, and the United States became a signatory. The 1978 Convention, the "Geneva Act," is expected to supersede the 1961 Convention, "the Paris Act" (not to be confused with the Paris Convention). Consequently, this Treatise will focus its attention on the Geneva Act. The list of states to which the Act applies is published every year in the January issue of *Industrial Property.*

The substantive provisions of the Geneva Act are Articles 1 through 13, 37, and 38.

According to Article 5, the breeder's prior authorization is required for "the production for purposes of commercial marketing," marketing or offer for sale of the "reproductive or vegetative propagating material, as such, of the variety," including whole plants, and parts of ornamental plants not normally marketed for propagation purposes. Authorization is not required for experimental use of the variety but is required for the commercial use of the protected variety in the production of another variety. Under Article 8, the period of protection is not less than eighteen years for "vines, forest trees, fruit trees and ornamental trees" and not less than fifteen years for other plants.

The UPOV "may be applied to all botanical genera and species." Article 6 sets forth the conditions required for protection:

(a) Whatever may be the origin, artificial or natural, of the initial variation from which it has resulted, the variety must be clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common knowledge at the time when protection is applied for. Common knowledge may be established by reference to various factors such as: cultivation or marketing already in progress, entry in an official register of varieties already made or in the course of being made, inclusion in a reference collection, or precise description in a publication. The characteristics which permit a variety to be defined and

distinguished must be capable of precise recognition and description.

(b) At the date on which the application for protection in a member State of the Union is filed, the variety

(i) Must not—or, where the law of that State so provides, must not for longer than one year—have been offered for sale or marketed, with the agreement of the breeder, in the territory of that State, and

(ii) Must not have been offered for sale or marketed, with the agreement of the breeder, in the territory of any other State for longer than six years in the case of vines, forest trees, fruit trees and ornamental trees, including, in each case, their rootstocks, or for longer than four years in the case of all other plants.

Trials of the variety not involving offering for sale or marketing shall not affect the right to protection. The fact that the variety has become a matter of common knowledge in ways other than through offering for sale or marketing shall also not affect the right of the breeder to protection.

(c) The variety must be significantly homogeneous, having regard to the particular features of its sexual reproduction or vegetative propagation.

(d) The variety must be stable in its essential characteristics, that is to say, it must remain true in its description after repeated reproduction or propagation or, where the breeder has defined a particular cycle of reproduction of multiplication, at the end of each cycle.

(e) The variety shall be given a denomination as provided in Article 13.

Article 9 permits compulsory licensing of the protected variety if the breeder receives equitable remuneration.

Article 10(2) provides that:

> The right of the breeder shall become forfeit when he is no longer in a position to provide the competent authority with reproductive or propagating material capable of producing the

variety with its characteristics as defined when the protection was granted.

Further disclosure requirements are imposed by Article 12, parts (1) and (2), and Article 13.

Article 37 makes it possible for the United States to ratify UPOV without abrogating its plant patent legislation [compare Article 2(1)].

Article 2 provides that a member state may limit the applicability of UPOV to "varieties with a particular manner of reproduction or multiplication, or a certain end use."

The UPOV has assembled a "Collection of the Texts of the Convention and Other Important Documents Established by UPOV." It is obtainable from the Union Internationale pour la Protection des Obtentions Vegetales, 34, chemins des Columbettes, 1211 Geneve 20, Suisse.

Member States, As of January 1, 1981, of the International Union for the Protection of New Varieties of Plants (UPOV)

Member State	*Starting Date*	*Date Bound by 1972 Act*	*Date Bound by 1978 Act*
Belgium	Dec. 5, 1976	Feb. 11, 1977	(signed)
Canada	———	———	(signed)
Denmark	Oct. 6, 1968	Feb. 11, 1977	Nov. 8, 1981
France	Oct. 3, 1971	Feb. 11, 1977	Mar. 17, 1983
Germany (F.R.)	Aug. 10, 1968	Feb. 11, 1977	(signed)
Hungary	Apr. 16, 1983	———	Apr. 16, 1983
Ireland	Nov. 8, 1981	———	Nov. 8, 1981
Israel	Dec. 12, 1979	Dec. 12, 1979	Apr. 12, 1984
Italy	July 1, 1977	July 1, 1977	(signed)
Japan	Sept. 3, 1982	Sept. 3, 1982	(signed)
Mexico	———	———	(signed)
Netherlands	Aug. 10, 1968	Feb. 11, 1977	Aug. 2, 1984
New Zealand	Nov. 8, 1981	———	Nov. 8, 1981
South Africa	Nov. 6, 1977	Nov. 6, 1977	Nov. 8, 1981
Spain	May 18, 1980	May 18, 1980	———
Sweden	Dec. 17, 1971	Feb. 11, 1977	Jan. 1, 1983
Switzerland	July 10, 1977	July 10, 1977	Nov. 8, 1981
United Kingdom	Aug. 10, 1968	July 31, 1980	Sept. 24, 1983
United States	Nov. 8, 1981	———	Nov. 8, 1981*

* Gave notice that it would apply the provisions of Article 37 with respect

to "protection of the same genius or species under different forms and also in regard to the period of protection applicable to normally asexually reproduced plant varieties." (UPOV Notification 17 in January 1981 issue of Industrial Property at 25.)

CHAPTER 10

Protection of Biological Invention Abroad

§ 10.01 Statutory Protection in the Eastern Bloc

Biotechnology is a matter of international scientific and commercial interest. Inevitably, companies engaged in the protection of novel biotechnologies will seek to protect their inventions on a worldwide basis. For this reason, some under-

standing of the international regime for the protection of inventions is desirable. The great international conventions dominate the protection of any invention abroad, including, of course, biological inventions. The most farflung of these multilateral arrangements, the Paris Convention, does not have any provisions which are specifically directed to biological invention. There are, however, a number of provisions which are of interest to the biotechnology community. Article 4 states that the filing of an application in one Convention country, if equivalent to a regular national filing under the patent law of a second Convention country, gives rise to a right of priority in the latter country. The right of priority allows the applicant to treat the date of the first regular filing as his effective filing date on all applications filed in Convention countries within the priority period, which is one year from that first filing date. Article 4 *quater* provides that

> the grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of the patented process is subject to restrictions of limitations resulting from the domestic law.

Finally, Article 5 *quater* provides that

> when a product is imported into a country of the Union where there exists a patent protecting a process of manufacture of the said product, the patentee shall have all the rights, with regard to the imported product, as are accorded him by the domestic law of the country of the importation, on the basis of the process patent, with respect to products manufactured in that country.

The reader is warned that a few countries, notably, the People's Republic of China and the Republic of Taiwan, are not parties to the Paris Convention.

The second most important international arrangement is the Patent Cooperation Treaty. The purpose of the PCT was to simplify the formalities of applying for patent in several of the member states by providing an accepted "International Application" format, and to assure a proper basis for examina-

tion by providing for the preparation of search reports according to internationally recognized standards. Besides these obvious advantages of filing a PCT application, taking the PCT route permits deferral of foreign filing fees and translation costs until after a search report is received. This search report may provide some inkling as to the chance of obtaining a patent. In addition, late or deficient fees are not necessarily fatal.

On the other hand, transmittal and search fee expenses are added to the costs of the U.S. application, and one cannot amend the designation of states after filing.

Many prominent patent countries are parties to the PCT, such as Japan, the United States, Great Britain, the Federal Republic of Germany, the Benelux countries, the Scandinavian countries, Australia, and the Soviet Union. However, there are some very significant exceptions, such as Italy, Canada, and Mexico. (France does not provide a national title by the PCT route.)

While the PCT does not address substantive patent law, the rules promulgated under the PCT do address the formalities of referring to a deposited microorganism. (See §5.02[17].)

The European Patent Convention was intended to provide for the common examination of applications for a European patent, which may be enforced in any designated member state, according to that state's law of claim interpretation. The official fees are likely to be less than the cost of obtaining national patents in three EPC member countries. Only one set of papers is needed, and only one local attorney. The case may be filed and prosecuted in English, with translation costs being thus deferred until the time of grant.

These are significant advantages to filing under the EPC. However, a European filing does have a few disadvantages. One cannot let maintenance fees lapse in some countries but not in others. The reaction of a national court to a European patent is still unpredictable. Finally, you have all your eggs in one basket if the European Patent Office has an unfavorable opinion of your claims and disclosure. The European Patent Convention specifically addresses the patentability of biological invention (§10.02, infra), and rules promulgated under the

Convention address the depositing of microorganisms. (§5.02 [18].)

The European Patent Organization has deposited an instrument of ratification under the PCT. The practical effect of this action is that applicants may file PCT applications which, after leaving the international stage (when the PCT application is published), enter the national stage as European rather than national applications.

By far the most daring foray into the realm of biological invention is Article 6(2) of the Hungarian Law on the Protection of Inventions by Patents (No. 2 of 1969), which provides that[1]

> (2) Plant varieties and animal breeds and the processes for obtaining them shall be patentable if the variety or breed is new, homogeneous and relatively stable.

In 1983, the Hungarian patent law was amended to bring it into accord with the 1978 UPOV Convention. Article 67 now states that "a plant variety is patentable if it is distinguishable, novel, homogeneous and stable, and if it has been given a varietal name apt for registration." The term of protection for plant varieties is eighteen years for vines and trees and fifteen years for other plants, running from the date of grant. The analogous protection of animal varieties under the Hungarian patent law is for twenty years from the date of filing. The patent controls both sexual and asexual propagating material.[2] Novelty, homogeneity, and stability are defined in the regulations.

The Hungarian definitions, set forth below, may profitably be compared with the provisions of the United States' Plant Variety Protection Act, quoted earlier:

> (1) A plant variety is distinguishable if it definitely differs by one or more important characteristics from any other plant variety whose existence is a matter of common knowledge at the priority date;

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[1] 2C Sinnott, *World Patent Law and Practice*, Hungary-3 (1977).

[2] Id., Art. 68(1), at Hungary-25.

(2) A plant is novel if it has not yet been offered for sale or marketed, with the agreement of the breeder or his successor in title: (a) in the country earlier than one year before the priority date; (b) abroad in case of vines and trees earlier than six years, in case of other plants earlier than four years, before the priority date;

(3) A plant variety is homogeneous if its individuals—having regard to the differences due to the particular features of reproduction—are identical.

(4) A plant variety is stable if the essential characteristics of its individuals, after successive reproduction, or at the end of reproduction cycles specified by the applicant, concur with the description.[3]

Unlike the American plant patent legislation, the Hungarian statute applies to the sale of any part of the plant that may be used for propagation.[4] The existence of an "experimental use" immunity from suit is implicit in the language of grant.[5]

In Romania, a patent (for socialist state organizations) and an inventor's certificate (for the private inventor) may be granted for the invention of "new species of plants, bacteria and mushroom cultures, new species of animals or silkworms, irrespective of the way these inventions have been created."[6] The provision obviously was not drafted by a zoologist—it implies that silkworms are not animals. The final broad stroke of the provision is intriguing, but it is unclear whether it resolves the finder-creator dilemma which the U.S. Congress considered in 1930.

Bulgaria similarly provides "authorship certificates" for "new species or varieties of farming crops or new animal breeder."[7] *Query* whether microorganisms are embraced by this provision.

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[3] Art. 31, Hungarian Patent Regulations, Industrial Property, Hungary, Text 2-007, page 006 (May 1984).

[4] Id., Art. 32.

[5] Art. 68, Hungarian Patent Law, Industrial Property, Hungary Text 2-006, page 013 (May 1984).

[6] 2F Id. Romania-5 (Romanian Law No. 62 on Inventions and Innovations, 1974, Item 14(b)).

[7] 2B Id. Bulgaria-3.

The Soviet Statute on Discoveries, Inventions, and Innovations (1973), on the other hand, states that "new strains of microorganisms shall be considered inventions,"[8] while the Czechoslovak Law on Discoveries, Inventions, Rationalization Proposals limits protection to "microorganisms" used in industrial manufacture.[9] *Query* whether a "single cell protein" source is patentable.

Animal and plant varieties are *not* protectible in Poland; but its statute does not definitively exclude protection for microorganisms.[10]

§ 10.02 Statutory Protection in the Western Bloc

Austria, Belgium, France, the Federal Republic of Germany, the United Kingdom, the Netherlands, Sweden, Switzerland, Italy, Luxemburg, and Liechtenstein are parties to the European Patent Convention, whose Article 53 provides

> European patents shall not be granted in respect of . . .
>
> (b) Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

West German law apparently permits patents on plant varieties not protected by its Law on the Protection of Plant Varieties, and on processes used in breeding these varieties.[11]

Von Pechmann argues that genetic mutation is a "microbiological process" within the meaning of the MPC and that the "result" of this process—a mutated microorganism—would be patentable.[12] Wegner believes that the MPC is concerned only with metabolic, not reproductive, microbiological processes.[13]

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[8] 2G Id. Soviet Union-12.

[9] 2C Id. Czechoslovakia-7.

[10] 2E Id. Poland-2.

[11] Id. West Germany-78.11.

[12] H. C. Wegner, Patenting Nature's Secrets—Microorganisms, 7 IIC 235, 245-246 (1976).

[13] Id.

Lederer argues[14] that microorganisms are not plants or animals within the meaning of the Convention. Whether we adopt von Pechmann's argument or Lederer's, we are led to the conclusion that, as the official Guidelines for Examination, Section C-IV-3.5 states, "patents may be obtained . . . for microorganisms themselves." (Lederer suggests that product-by-process claims would be allowable even if product per se claims were not.) "Repeatability" is an important requirement under European law, and with regard to a microorganism obtained by mutation it can only be achieved by depositing the organism in a culture collection. (This would not necessarily be true if the patent were directed to a "genetically engineered" microorganism.)

Patent Office practice in Japan, and the decisional law in the Federal Republic of Germany, France, United Kingdom, Canada, New Zealand, Ireland, and Australia will be discussed subsequently.

The United States, of course, permits patents on microorganisms. S.621, "A Bill to Provide for Guidelines and Strict Liability in the Development of Research Related to Recombinant DNA," would have provided:

> Notwithstanding any other law, no patent shall be granted on any procedure or organism which results from research on recombinant DNA unless all applicable guidelines have been strictly adhered to, and a full and complete disclosure had been made with regard to such process or organism.[15]

Israeli Patent Law (1967) accords limited protection to biological inventions: ". . . no patents shall be granted for . . . . (2) new varieties or plants and animals, except microbiological organisms *not derived from nature.*"[16]

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[14] *See Generally* F. Lederer, A Perspective on Patenting Microorganisms Under the European Convention: Prospects and Considerations, 7 APLA Q.J. 288, 295-298 (1979).

[15] Introduced by Mr. Bumpers, February 4, 1977 (95th Cong., 1st Sess.).

[16] Sinnott, *supra* at Israel-4.

§ 10.03 Statutory Protection in the Third World

Latin American countries have not welcomed the "New Biology." Article 5(b) of the Cartagena Agreement provides that "vegetable varieties or animal breeds, [or] essentially biological procedures for obtaining them" are "not patentable."[17] Microorganism protection is expressly foreclosed in Brazil, where patents on "varieties or species of microorganisms" were anathematised in 1971.[18] Mexican and Colombia law follow the approach of the Cartagena and Munich agreements.[19]

In Africa and Asia, the laws of Sri Lanka, South Africa, and Nigeria are based on MPC Article 53,[20] as is the Agreement of the African Intellectual Property Organization,[21] and the "Model Law for Developing Countries on Inventions."[22]

According to a 1984 survey conducted by an ABA subcommittee, microorganisms are patentable per se in Turkey, Argentina, Brazil, and the Philippines, though not in Korea, Mexico, or Taiwan.[22.1]

§ 10.04 Plant Patent Protection Outside of the Conventions

As of 1981, the following national laws extended some form of patent protection to some varieties of plants:[23]

Argentina—Law on Seeds and Phytogenetic Creations, 1973.

Belgium—Law on the Protection of New Plant Varieties, of May 20, 1975.

Czechoslovakia—Law Relating to Seeds, 1964.

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17 2G Id. Andean Pact-3.

18 2BV Id. Brazil-4, Article 9(f).

19 2E Id. Mexico-3.

20 Id. Sri Lanka-30; Id. South Africa-11; 2F Nigeria-3.

21 2 Baxter and Sinnott, *World Patent Law and Practice,* 188.25 (1981).

22 2A Baxter and Sinnott, 342-70 [253] *Patent Law and Practice* (1981) (Section 5(a)).

22.1 1984 ABA (PTC Section) Committee Reports at 69.

23 2 Baxter and Sinnott, *World Patent Law and Practice* 26.1, 167.2, 167.3 (1981).

Denmark—Plant Variety Breeders' (Protection of Rights).

France—Law on the Protection of New Plant Varieties, 1970.

Germany, F.R.—Law Relating to Seeds, 1953; Law on the Protection of Plant Varieties, 1968, and Amending Law of 1974.

Italy—Decree No. 974 for the Protection of New Plant Varieties, of August 12, 1975.

Netherlands—Seeds and Planting Materials Act, 1966.

New Zealand—The Plant Varieties Act, 1973.

South Africa—Plant Breeders' Rights Act No. 15 of 1976.

Spain—Law on the Protection of Plant Varieties, No. 12 of 1975.

Sweden—Plant Breeders' Protection Act, 1971.

Switzerland—Law Concerning the Protection of New Plant Varieties, of March 20, 1975 (in force June 1, 1977).

United Kingdom—Plant Varieties and Seeds Act, 1964.

United States—Plant Variety Protection Act, 1970; Plant Patent Act of 1930.

Cuba—Law of 1936, Art. 41(8).

South Korea—Law of 1981.

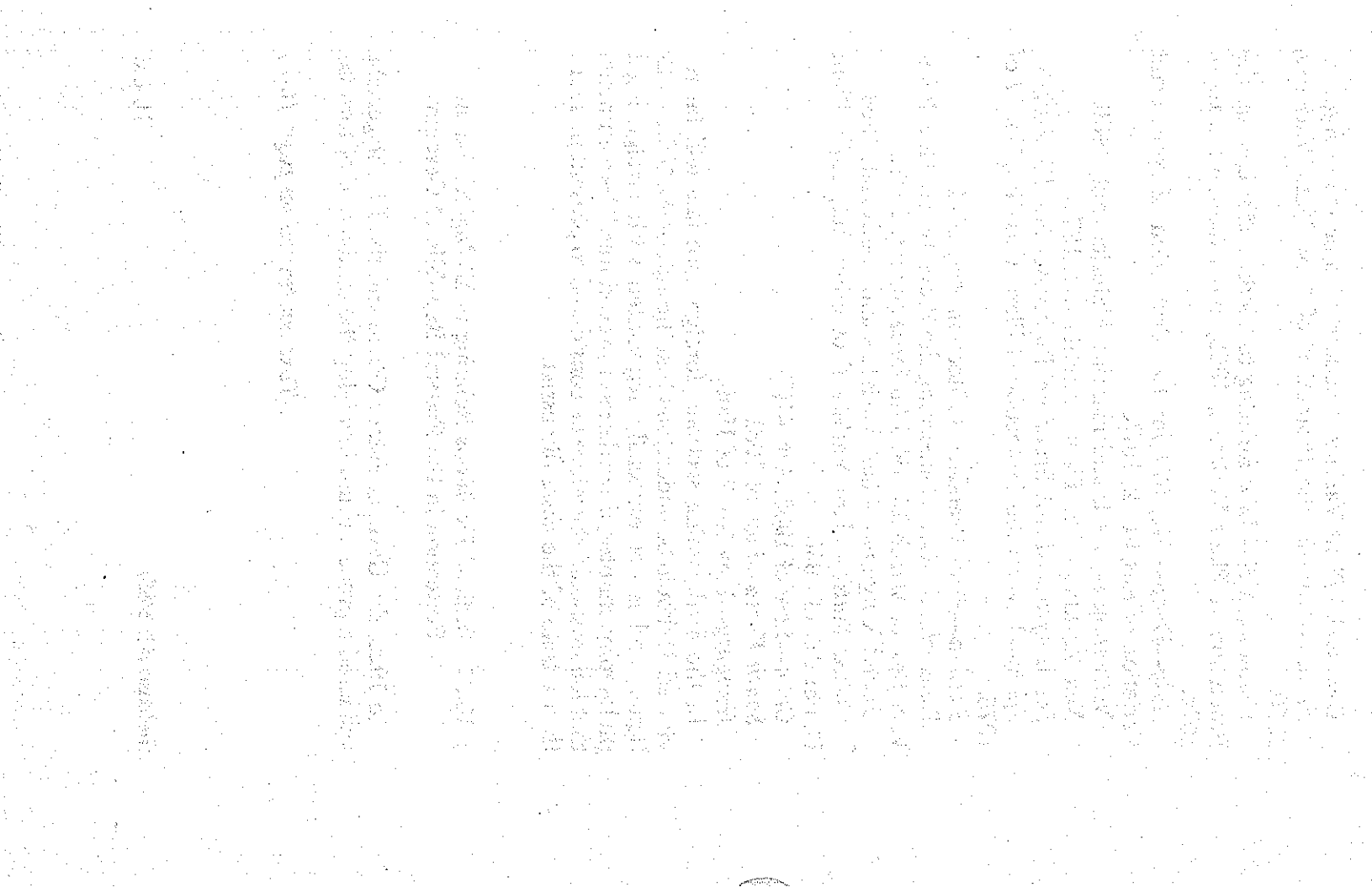
Hungary—Law No. 2 of 1969.

In the forthcoming sections, foreign case law will be reviewed. It should be understood that the author is a U.S. practitioner, and is not especially acquainted with foreign legal philosophy, statutes, precedents or procedures. The comments that follow should therefore be considered to present no more than a taste of the cases discussed.

§ 10.05 Judicial Decisions Relating to Biological Patent Protection in the Federal Republic of Germany

In 1922, the German Patent Office and the Reichtsgericht validated a process claim involving the cultivation of tortoise

(*Text continued on page 10-7*)



tubercles.[24] This may have been the first biotechnology case in Germany; it was certainly not the last.

[1] The "Red Dove" Case

The Federal Republic of Germany has a well-developed body of case law dealing with biological invention. The "Red Dove" case[25] involved a method for "breeding a dove with red plumage" and covered much of the ground discussed in *Bergy, Chakrabarty,* and *Merat.*

The single claim was directed to

> Method for breeding a dove with red plumage, which is considerably larger with respect to other doves of the same color, has a considerably larger wing spread, the color of the plumage of the wings being considerably more beautiful and more intense, and having a craw which is extremely large in relation to the size of a body in which an Altdeutsche Kropfer is crossed in the first step of the process with Rote Romertaube, the doves resulting from this crossing are selected according to size and color, a selected product of said crossing is bred in the second step with a Roter Hessenkropfer, of the doves thus obtained one again is selected and bred in the third step with an Altdeutscher Kropfer.

This claim was rejected on four grounds.

(1) The characteristics designated in the patent claim are too definite to support unambiguous patent protection;
(2) The steps of the breeding method enumerated in the second part of the patent claim are not technical procedures;
(3) Repeatability is questionable, and furthermore,
(4) There is no advance in the art and no inventive level.

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[24] F. Lederer, A Perspective on Patenting Microorganisms Under the European Convention: Prospects and Considerations, 7 APLA Q.J. 288, 289 (1979).

[25] Ex parte Schreiner, file: XZB 15/67 (Bundespatents gericht) decided March 27, 1969; 1969 GRUR 872, in 1 Int'l Rev. Indus. Prop. & Copyright L. (IIC) 136 (No. 1, 1970).

The Federal Supreme Court declared that the "fact that living organisms and in essence the biological forces effective within them are the starting point, the means and the objective of the method for which a patent has been applied, does not in principle exclude the possibility of patenting." Though the basic patent statute had been enacted in 1877, it thought "of little importance what the legislature in 1877 considered to be 'technology.'"

The Court rejected vitalistic arguments against biological patent protection:

> According to current scientific knowledge, living organisms from one-celled bacteria to highly developed creatures have several basic features in common with respect to structure and way of life, as evident from known natural laws. Today prevalent opinion indicates that living organisms consist of a substance constructed of basic elements present on the earth, just as in the case of other material phenomena. Since the discovery in 1828 of a urea synthesis, the possibility for synthetic preparation of organic materials has increased. Prevalent scientific opinion also indicates that the metabolism effecting the material construction and energetic actions of living creatures occurs as a result of reactions which, to the extent that their regularity is known, may be classified within the general principles of physics and chemistry. According to the present state of scientific knowledge, the laws of genetics also originate from complicated physical and chemical procedures. The laws governing biological phenomena and forces as far as they could be determined, permit the conclusion that these phenomena and forces are also to a considerable extent subject to casual relationships that might at least be comparable to the causality of natural events for inanimate matter. Accordingly, no sufficient reason is apparent for excluding methodical utilization of natural biological forces and phenomena from patent protection in principle. It is immaterial whether, and to what extent, such utilization would fall directly under the term "technology" or whether that term can only be indirectly used in connection with biological forces and phenomena. In any event, present-day recognition that certain results can be attributed to biological reactions and thus be predicted and controlled, changes earlier interpretations to the extent that a teaching to methodi-

cally utilize controllable natural forces to achieve a casualperceivable result could be considered patentable, provided that teaching meets the general prerequisites of industrial application, novelty, advance in the art and inventive merit.

The Court classified biological invention into three categories: (1) cultivation of organisms by inanimate means (*e.g.*, chemical treatment of plants; (2) production of inanimate substances by biological processes (*e.g.*, fermentation); and (3) reproductive processes. (Such as was claimed in "Red Dove.") All were considered potentially patentable: "breeding of animals cannot be excluded from patent protection with the argument that the means and also the result are of a biological nature."

However, the "Red Dove" claim could not surmount another obstacle: the "reproducibility" requirement. The description set forth in the specification "does not ensure a genetically identical repetition." The problem of "breeding an animal in the upper range of the evolutionary scale" was compounded by the "general manner" in which the "initial animal species" and the desired characteristics" were specified, which spoiled the promise of the "phenotypical approach." The rejection was therefore affirmed.

While the "Red Dove" case is still of interest because of its kinship to the *Merat* case in the United States, its vitality as a statement of German patent law is extremely dubious, since Germany amended its patent law to bring it into conformity with Article 53 of the European Patent Convention.

[2] The "Baker's Yeast" Case

In the Baker's Yeast case,[26] the Federal Supreme Court upheld the patentability of microbiological processes, and discussed the disclosure of microbiological inventions.

The application in question was directed to the utilization

[26] In re Koninklijke Nederlandsche Gist-en Spiritusfabriek N.V., Case X ZB 4/74 (Bundesgerichtshof, March 11, 1975); in 6 IIC 207 (No. 2, 1975) (Baekerhefe/Baker's Yeast). Discussed by F. Lederer, A Perspective on Patenting Microorganisms Under the European Convention: Prospects and Considerations, 7 APLA Q.J. 288, 292-295 (1979).

of a new mutant of a baker's yeast. After final rejection, the following claims were presented

(1) Baker's yeasts CBS 6128 and CBS 6131.
(2) Process for the production of the baker's yeasts according to Claim 1, characterized in that baker's yeasts CBS 6128 and CBS 6131 are cultivated in the usual way.
(3) Use of the baker's yeasts according to Claim 1 for pressed yeast or active dry yeast.

The Court declared that an invention is "not excluded from patent protection merely because it makes use of a living starting material and utilizes natural biological forces and phenomena, and leads to a living product or use thereof." The official headnote stated that "product protection for a new microorganism is allowable, if the inventor shows a reproducible way to produce the new microorganism." The Court made it clear that it drew no distinctions between patents on microorganisms per se and on propagation process claims.

The applicants described "the selected yeast species according to appearance, spore, and ascus formation, their specific suitability for the fermentation of various substrates, and the required growth factors in synthetic culture media. . . . This description by itself is not sufficient to identify yeast strains."

Nonetheless, the Court declared, the "reproducibility" requirement could be satisfied by depositing the microorganism in a culture collection "at the latest, at the same time as the protection is applied for." At the time the application is laid open for inspection, the deposit must be made irrevocable in a declaration to the "office recognized for the deposition."

The Court rejected the advice of commentators that the deposited organisms not be released to interested third parties until the application is published (triggering "provisional" patent protection), or even as late as the date of expiration of the patent (on the theory that, until then, the culture cannot be used without a license).

The Court declared that an applicant may demand (1) that the requestor furnish his name and address; and (2) that the requester agree not to pass the sample on to other persons or to take it out of German territory.

The Court declined to set a specific post-expiration period during which the availability of the organism need be ensured. "The economic importance of the organism must be taken into account."

It should be noted that the holding of Baker's Yeast—that the organism must be deposited on or prior to the date of filing—is now enshrined in Rule 28(1)(a) under the European Patent Convention. However, under the EPC rule, the deposit becomes irrevocable once the depository institution and accession number are communicated in the application, under Rule 28(2), final paragraph.

[3] The "Rose Mutation" Case

A number of interesting plant variety protection issues are raised in *M. L. Meilland v. J. Derhi,* the "Rose Mutation" case.[27] The German Plant Variety Act provides protection for both "discovered" and "cultivated" varieties. The issuance of a patent right on a cultivated rose sport, "Derliva," was opposed by the applicant's employer, the owner of the patent on the parent variety, "Lovita." The Federal Supreme Court held that new varieties brought about by the spontaneous mutation of cultivated plants are protectible, and that a sport is protectible as new variety if it differs from every known variety in at least one important morphological or physiological characteristic (in this case, "Derliva" had a lighter and brighter color than "Lovita"). The degree of difference was irrelevant.

The Court delved into certain issues which would be raised in an infringement suit. It explained that the "Derliva" patent was not "dependent" on the "Lovita" patent, making it clear that the doctrine of "equivalency" is of little assistance to the owner of a plant variety certificate.

The Court also considered certain ownership questions. It held that the owner of the field on which the plant was grown did not have any patent right. It noted that the applicant had not utilized opposer's trade secrets in recognizing the pres-

[27] M. T. Meilland v. J. Derhi (Bundesgerichtshof, November 27, 1975), in 8 IIC 286 (No. 3, 1977).

ence of a new variety. The issue of whether under contract law the applicant was obligated to transfer the right to the opposer was remanded, as French law governed. (It may be noted that applicant's duties included the discovery and separation of all plants which deviated from the protected plant variety, Lovita.) German law would have required the assignment.

The Court gave conflicting signals with regard to the effect of the legality of the applicant's use of the variety on his ability to obtain and enforce a patent thereon. It appears that applicant had a *right* to a patent but could not "protect" (secure) that right without the cooperation of the owner of the parent variety. (This is similar, perhaps to the treatment of "derivative works under the new U.S. Copyright Act.")

[4] The "6-APA" Case

In a case involving application P. 1805 571.5-44, directed to a microbiological procedure for the manufacture of 6-aminopenicillanic acid (6-APA), the Federal Patent Court reversed the rejection by the German Patent Office.[28] The applicant had apparently failed to supply "declaration of accessibility" from the ATCC, its depository. The Court held, however, that the culture collection's willingness to supply culture collections to the public could be inferred from the issuance of U.S. patent on the process, and from the depository's confirmation of its receipt of the *applicant's* declaration of accessibility. It warned that the applicant had been lucky that it had been able to satisfy the "access" requirement by producing circumstantial evidence of accessibility.

In dicta, the Federal Patent Court elaborated on the deposit requirements. First, "it cannot be left to the depositor to decide whether he wishes to preserve a deposited microorganism after a patent rejection," *i.e.*, the deposit is irrevocable "for the duration of the possible lifetime of the claimed patent plus a prescribed period of time exceeding the patent's duration." Thus, the patent strain is preserved as a part of the prior art.

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[28] Case 16 W. (Pat) 7/71 (Bundespatentgericht, March 22, 1976), in 8 IIC 553 (No. 6. 1977).

Second, the deposit becomes obligatory and irrevocable when the German patent application is first laid open for inspection. Third, access to the organism cannot be limited to a specific sphere of persons, other than limiting it to those technically qualified to handle the organism (*e.g.*, a pathogen) safely. Fourth, the Court intimated that the inability to obtain an export license from the depository country might be deemed an obstacle to accessibility. Fifth, the Court implied that applicants should be wary of differences in deposit requirements between nations. Free access at the ATCC commenced under U.S. law when the U.S. patent issued, on October 26, 1971. The German application was laid open on May 14, 1970.

The Court did not penalize the applicant because the German law was unclear until the *Baker's Yeast* decision in 1975. An interesting question was raised as to whether the absence of any third party requests for subcultures during the "inaccessibility" period would be pertinent in a later case.

[5] The "Antamanide" Case

The German Patent Office's 1972 Guidelines for the Examination of Patent Applications state, with regard to "natural substances" that:

> The basic assumption is that products of nature as such are not capable of protection by patent. However, patents may be granted for inventions concerning heretofore unknown forms or isolations of such natural substances. The patentability of synthetically produced substances which also occur in nature will not be recognized, as a matter of principle. . . .

In *C. H. Boehringer Sohn*,[29] the Federal Patent Court reversed a rejection of a claim to a cyclic decapeptide antamanide which was allegedly found in nature, specifically, in the deadly green amanite fungus. The Court declared that this synthetically prepared natural substance was novel in that at

[29] In re C. H. Boehringer Sohn, 16 W (Pat) 64/75 (Bundespatentgericht, July 18, 1977), in 10 IIC 494 (No. 4, 1979).

the time of the application none of those skilled in the art were capable of using the claimed compound, or were aware of its antidotal value. From the factual context, it may be inferred that even if the existence of the compound in the natural source is known, the compound may be patented, since the presence of the antaminide in the fungus had been known for thirty years. Unfortunately, the Court's opinion does not clarify this point.

On the issue of "obviousness," the Court observes that a related compound did not have the desired result and that the claimed antamanide had been ignored by those skilled in the art for thirty years.

The Court declared that there "is no legal requirement to treat natural substances differently with respect to patent law than other chemical substances. . . ." It indicated also that the applicant need not expressly limit this claim to exclude natural substances.

§ 10.06 Judicial Decisions Relating to Biological Patent Protection in Great Britain

[1] Microbiological Processes and Microorganisms Are Patentable; Other Biological Methods Are Not

As in the United States, Dr. Weizmann's acetone production process was the subject of infringement litigation. The main issues were of "originality," "prior invention," and "insufficiency of description," and the patentee prevailed throughout.[30] Judge Romer did not address formally the issue of whether a process utilizing living organisms was patentable, but the *Commercial Solvents* case has been cited in support of this proposition.

Thus in *Virginia-Carolina Chemical Corp.*, it is stated that

> At one time it seems to have been thought that any operation

[30] Commercial Solvents Corp. v. Synthetic Products Co. Ltd., 43 Repts. Pat., Des. & Tmk Cases (RPC) 185 (High Ct. Justice, Chancery Div. 1926) (Romer, J.).

> which involved living organisms was excluded from the definition of invention. That this was unjustified is apparent from the judgment in *Commercial Solvents* , . . . , and from the considerable number of patents granted in respect of the preparation of antibiotics. The increasing use of naturally occurring organisms has wholly outmoded as a rule of thumb quite a restriction of patentability to inanimate matter.[31]

On the other hand, in *N. V. Philips*, Justice Lloyd-Jacob denied an application for a patent for a method of producing a new form of Poinsettia by modifying its growth conditions, holding that this was not a patentable "manner of manufacture" inasmuch as the production of the end product under the modified environmental conditions was the "inevitable result of that which is inherent in the plant."[32]

Similarly, in *Canterbury Agricultural College*,[33] a Hearing Officer refused a patent on a method of improving the wool yield of sheep by an injected preparation, despite the suggestion in the *C & W* case (involving removal of lead from the human bloodstream) that a treatment for animals might be patentable, in view of the established patent office practice of refusing such patents. An exception was noted with regard to the production of vaccines and sera, since claims had been allowed which covered the treatment of an animal in association with a novel process for working-up the immediate product of the treatment.

In *Szuecs*, the Superintending Examiner hesitantly approved a claim to a mushroom cultivation method, classifying it together with microbiological processes employing factory apparatus.[34]

In *General Electric Co. Ltd.*,[35] the Patent Appeal Tribunal disapproved the Office's dividing line between "higher and lower forms of living matter," derived from "a time when the

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[31] In re Virginia-Carolina Chemical Corp. Application, [1958] RPC 35, 36-37 (Pat. App. Trib.) (Lloyd-Jacob, J.).

[32] In re Application of N. V. Philips' Gloeiampen fabriken, 71 RPC 192 (Pat. Appl. Trib. 1954) (Lloyd-Jacob, J.).

[33] [1958] RPC 85.

[34] [1956] RPC 25.

[35] [1961] RPC 21.

many gradations of living forms were not as fully apprehended as is now possible." Nonetheless, Lloyd-Jacobs held that the claim to an electric shock process of mutating lactic streptococcus bacteria was not directed to a "manner of manufacture" but only to a "conditioning procedure." The Superintending Examiner had been of the opinion that "manufacture" included mutants of living organisms specifically associated with a particular manufacturing process.

In a dictum in *Dann's Application*, Lord Wilberforce said, "The priceless strain, being something living, found in nature, cannot be patented: the prosaic process, as applied to the strain, is capable of protection."[36]

The British Patent Office issued a patent to General Electric, UK 1,436,573, on the genetically engineered microorganism developed by Chakrabarty, apparently without raising any patentability issue before the Patent Appeals Tribunal.

Questions regarding the patentability of such organisms have been raised in Parliament.

> Mr. Hooley asked the Prime Minister if she will appoint a special committee of scientific and legal experts to examine the consequences of any decision in the United Kingdom that living organisms can be patented and the impact such a decision would have on scientific research in the field of biotechnology.
>
> The Prime Minister: The recent joint report from the Advisory Council for Applied Research and Development, the Advisory Board for Research Councils, and the Royal Society drew attention to obstacles to the development of biotechnology which can arise from the operation of certain aspects of the patent law. The Government's policy in the field of biotechnology is being reviewed in the light of the recommendations of the ACARD report and these problems will be examined as part of that review. We hope to be able to publish the Government's response to the joint report in the near future.[37]

Despite the flurry of legislative queries, the British Patent

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[36] In re Dann's Application, sub. nom. American Cyanamid Co. v. Upjohn Co., [1970] 3 All ER 785, 799 (House of Lords).

[37] Chartered Institute of Patent Agents (Bulletin) at 504 (July 1980) referring to Hansard Session, June 24, 1980.

Office has continued to issue patents on genetically engineered microorganisms, transfer vectors, and expression vectors.

The reader is reminded that the United Kingdom is a party to the Munich Patent Convention.

[2] Disclosure Requirements

In 1963, the British Patent Office rejected an application, in which the exemplary microbial strains were identified only by a private reference numeral, as insufficient. The examiner suggested that the applicants could have "fully described in their specification the morphological and physiological properties of these strains," or "indicat[ed] in the specification that the particular strains had been deposited in a recognized culture collection." He stressed that the effectiveness of the organisms in the indicated species varied widely from strain to strain, and that the applicant was required to disclose the best method of practicing his fermentation process. The Patent Appeal Tribu-

(*Text continued on page 10-17*)

nal agreed that the specification was insufficient, but ordered that the applicants be permitted to propound explanatory amendments. The examiner refused the amendments, since they did not correct an "obvious mistake" or further describe "matter in substance disclosed." The examiner's action, but not all his reasoning, was approved. Lloyd-Jacobs suggested that if "an appendix to a culture collection catalogue wherein certain of the reference numbers were bracketed with the private laboratory reference numbers or the source from which the cultures were received" had been available to the reader of the specification, an amendment would have been permissible. Subsequently, the applicants suggested that their strain *Torulopsis utilus* No. 812 was shown by their Austrian specification, received by the U.K. Patent Office prior to the publication of the U.K. specification, to have been deposited in the institute of Applied Microbiology of Tokyo University as strain TM-9. However, the examiner and the appeal tribunal agreed in *Kyowa's Application*[38] that the critical date was, at the latest, the date of *filing* of the U.K. application.

The subsequent *Dann's Application* proceeding led to a holding that a patent could not be revoked for an applicant's related failure to deposit organisms in a public culture collection and to instruct the culture collection to permit access to the patent strain. It may therefore be compared with the *Argoudelis* and *Feldman* cases in the U.S. and the "Baker's Yeast" decision in the Federal Republic of Germany.

Claims 1 and 2 are illustrative of the subject matter of Dann's application, assigned to American Cyanamid:

1. A method of producing an antibiotic designated protiromycin which comprises subjecting a protiromycin producing strain of Streptomyces verticillatus to aerobic fermentation and in aqueous nutrient medium containing assimilable sources of carbon, nitrogen, and inorganic salts.
2. A method according to claim 1, in which the strain used

[38] In re Kyowa's Application, [1968] Repts. Pat., Des. & Tmk. Cases (RPC) 101 [UK]; [1969] RPC 259.

is AB 929 (AECC 15 No. 13495), AA 849 (ATCC No. 13538) or AB 286 (ATCC No. 443539).

The application process in Britain begins with the submittal of a "provisional specification." Later, a "complete specification" of the application must be published before a patent can be issued. Certain protective rights are conferred on the applicant when the complete specification is filed. Publication of the specification is a mechanism for subjecting the application to a more deliberate scrutiny on the issue of patentability, *i.e.*, by competitors and not just by an examiner.

The strains in question were deposited with the ATCC in 1959. The complete specification was filed in 1960.

Upon publication of Dann's application in August, 1963, Upjohn attempted to obtain a subculture of the microorganism from the culture collection referred to in the application. The culture repository *refused access.* Upjohn filed an opposition to the sealing of the patent in November, 1963, arguing that under British law the culture had to be available to the public at the time the application was published. American Cyanamid was denied access to the strains until January 5, 1966 (for U.S. requests). American Cyanamid's position is not clearly explained, but it appears that it related to its desire to obtain patent protection in the United States, where the invention originated. On January 13, 1966, Superintending Examiner Mirams adopted Upjohn's position, refusing the grant of the patent.

The Examiner noted that the patent strains could "only be obtained from natural sources as a result of a screening program . . . but organisms not of . . . common occurrence might not be found for a very long time, if found at all." The Examiner held that a mere taxonomic description was inadequate as a disclosure of a starting material not already in common use.[39]

Turning to the issue of *when* the deposit must be made, American Cyanamid suggested that the date of expiration was the critical date, presumably on the theory that there was no public right to *use* the strains until the patent expired. American Cynamid explained that it refused access since release of

[39] For Examiner Mirams' decision, *see* [1966] RPC 532, 533-537.

the culture "would effectively make the applicants' invention available in the United States at a time when it did not have protection in that country." Upjohn pointed out that access to the culture was needed for the public to attack the patent, and that a U.S. application could have been filed to preserve American Cyanamid's rights. The Examiner did not clearly indicate whether it was the date of filing or the date of publication which was critical.

American Cyanamid appealed this decision in March, 1966, and in July Justice Lloyd-Jacobs of the Patent Appeals Tribunal reversed the rejection.[40] In essence, Jacobs declared that the applicant need only give adequate directions for identifying the utilization strains, and for using them to produce the antibiotic. He recognized that this "would not be particularly effective," and that the case law forbade inventors to throw onto the public an unreasonable "burden of experimentation of research," but was not swayed from his conviction that the starting materials were adequately defined. "If, for example, an inventor discovered a new process for the extraction of a metal from an ore which contained, say, less than a stated percentage of that metal, it might well take much experimentation and research to discover the location of ore bodies of the required constitution."

Mr. Jacobs, assuming *arguendo* that Upjohn's position was correct, indicated his willingness to excuse American Cyanamid's refusal of access, when the defect had been remedied and "the reason for non-access explained in a manner which cast no discredit on the bona fides of the applicants."

British Patent 934,853 was sealed on August 23, 1963. Upjohn instituted a proceeding in the Chancery Division of the High Court of Justice to revoke the American Cyanamid patent.

Mr. Justice Graham ordered the revocation of the patent.[41]

Relying on the fundamental principle that "there must be proper and adequate consideration for the grant of a valid

[40] [1966] RPC 532, 537-540.

[41] [1970] RPC 306. The full text of the "complete specification" is given in this decision.

patent," Graham held that there is "clearly lack of consideration for the grant of a claim to a method or process which in fact the public cannot carry out because of an essential and novel material for use in such method or process, which was available to the patentee and which he could have made available to the public, or could have given them sufficient directions to make or obtain, "when nonetheless it was not made available to the public. Graham further held that under British law this consideration must be supplied by the *date of filing* of the "complete specification," since by Section 22 this was also the date of the patent. The disclosure requirement could easily have been met by allowing free access to the culture deposited at the ATCC. (The Court did not discuss what written directions would have been adequate to enable the public to obtain the patent strain without more than "routine research and experimentations.")

In dicta, Graham admitted that microbiological patents are sufficiently akin to plant patents to justify, as a matter of policy, deferring public access to the strains until the date of grant, but declared that this would require an amendment to the law.

The House of Lords held that British law did not impose a deposit requirement.[42]

Lord Reid distinguished between the common law of revocation of a patent and the specific grounds enumerated in Section 32 of the Patents Act of 1949. Reid thought that it would have been contrary to the "general intendment of the Statute of Monopolies" to allow the patent to remain in force unless the patentee had taken "such steps as were necessary to enable others to carry out his invention when his patent expired," including if need be open deposit of the strain in a public repository. Lord Reid felt, however, that it could not be said that "the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed," the only pertinent ground for revocation enumerated in the 1949 Act.

Lord Morris observed that the disclosure problem arises only with newly discovered strains unlikely to be found again in nature by others, and that failure to impose a deposit re-

[42] [1970] 3 All ER 785.

quirement would tend to give the patentee a post-expiration date advantage: "If they [competitors] are not given the tools how can they finish the job?" Nonetheless, he refused to read into the statute a requirement that the patentee make the starting material available.

Lord Guest declared that "lack of consideration" was not a statutory ground for revocation of a patent. He, too, thought that statute required *merely* a "description."

Lord Wilberforce could not see what sense a failure to give access to carefully described strains can be called a failure of description. He also asked "What if the material is in short supply? How much must be supplied? On what terms? For how long? What is the position of assignees?"

The lone dissenting voice was that of Lord Diplock. He took the view that if the claim were to the *endproduct*, the applicant had not taught how to obtain that product unless the specification states "where a culture of the parent microorganism can be obtained by the reader."

The *Dann's Application* decision appears to be mooted by the United Kingdom's accession to the Munich Patent Convention.

§ 10.07 Judicial Decisions Relating to Biological Patent Protection in Other "Statute of Monopolies" Countries

The Statute of Monopolies, enacted in 1624,[43] was the cornerstone of the British patent system. It abolished the existing monopolies on "currants, iron powder, cards, horns, oxshin bones," and other commercial products, but granted fourteen years' protection to the "true and first inventor" of "new manufactures within this realm." In 1790, the United States enacted its first patent statute, which was clearly based on the English precedent. New Zealand, Australia, Ireland, and Canada, are also to be included among the major "Statute of Monopolies" countries.

Mr. Chakrabarty was given a patent in the United Kingdom,

[43] 21 Jac. 1 c.3.

without, however, any court ruling as to the propriety of this interpretation of its patent law. In Australia and Canada the Commissioner of Patents have determined that microorganisms are patentable. In the United States, the question was resolved, in favor of the biotechnology industry, by the Supreme Court itself. The patenting of life forms has been a topic of discussion, at least, in New Zealand. In Ireland, however, the High Court denied patent protection.

[1] Biological Patent Protection in New Zealand

According to Y. M. Cripps, the New Zealand Patent Office has received at least two applications for patents on microorganisms: Ser. No. 187,300, Recombinant DNA Transfer Vectors and Microorganisms Containing a Gene from a Higher Organism (U. Calif. May 17, 1978), and Ser. No. 16,321, Improvements in or Relating to Microorganisms (Ranks, Hovis and McDougall Ltd., April 30, 1971).[44]

Cripps cites the *Swift* case,[45] in which the New Zealand Supreme Court held that a method of tenderizing meat with the aid of enzymes is patentable, "as authority for the patentability of biological processes but the case law does not extend to a discussion of the patentability of organisms."

Cripps suggest that the failure to comply with genetic engineering regulations "would be contrary to law or morality" and hence, under Section 17 of the Patents Act 1953, a patent could be refused on any inventions developed in violation of the regulations.[46] Cripps feels, however, that genetic engineering techniques and genetically engineered organisms are prima facie patentable.[47]

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[44] Y. M. Cripps, Genetic Engineering—A Problem for the Patent Office?, New Zealand Law Journal, June 19, 1979 at 232 n. "g."

[45] Swift & Co. v. Commissioner, [1960] NZLR 775, described id. at 233 n. "i."

[46] Id., 236. The Munich Patent Convention contains a similar provision, Art. 53(a).

[47] Id., 237.

In *National Research Development Corporation v. Commis-*

(*Text continued on page 10-23*)

sioner,[48] the Australian Supreme Court reversed the rejection of claims to herbicidal methods. It rejected the arguments of Douglas in *Funk Bros.* quoting Justice Frankfurther instead. It declared, "The truth is that the distinction between discovery and invention is not precise enough to be other than misleading in this area of discussion. . . . The fallacy lies in dividing up the process that [the applicant] puts forward as his invention." This is, of course, the point made by the U.S. Supreme Court in *Diehr.* It also held that the "everyday concept of manufacture" was too narrow, and that the creation of a weed-free condition on crop-bearing land could be a manner of manufacture. Finally, it held that the fact that the process was used in agriculture rather than in industry was irrelevant to the issue of patentability.

The Australian Commissioner of Patents stated in 1976 that he was "unaware of any Australian decision regarding the patentability of living organisms, in particular microorganisms. Because the number of applications for patents in respect of microorganisms per se, compositions containing microorganisms and processes involving microorganisms seems to be increasing, it is of some importance that clear guidelines be established for the benefit of both applicants and examiners."[49]

The opportunity came when a patent application was filed claiming "Fusarium graminearum Schwabe I-7 deposited with the Commonwealth Mycological Institute and assigned the number I.M.I. 154209." The Commissioner discussed the proper interpretation of the statutory term "manufacturers" in the light of the examiner's objection that "living organisms are not patentable":

> A perusal of the definitions and quotations appearing in the Oxford English Dictionary under "manufacture" will show that the word has always admitted of applications beyond the limits which a strict observance of its etymology would suggest.
> . . .
>
> The truth is that any attempt to state the ambit of s.6 of the

[48] [1960] Aust. L. Repts. (ALR) 114.

[49] In re Ranks Hovis McDougall Ltd., 8 IIC 453, 454 (No. 5, 1977).

> Statute of Monopolies by precisely defining "manufacture" is bound to fail. The purpose of s.6, it must be remembered, was to allow the use of the prerogative to encourage national development in a field which . . . was seen to be excitingly unpredictable. To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound. It would be unsound to the point of folly to attempt to do so now, when science has made such advances that the concrete applications of the notion which were familiar in 1623 can be seen to provide only the more obvious, not to say the more primitive, illustrations of the broad sweep of the concept.
>
> . . .
>
> An objection that a claim to a new microorganism, being something living, is not a manner of manufacture is based, in my opinion, on too restricted a view of the meaning of manufacture in section 6 of the Statute of Monopolies.

The Commissioner held that the production of a "new microorganism which has improved or altered useful properties" by some "man-controlled microbiological process" was a patentable contribution. The mere isolation of a naturally occurring organism was not, however, considered "invention."

[3] Microbiological Patent Protection in Ireland

The Irish Patents Act of 1964, like the 1952 statute in the United States, provides protection for "manufacturers" and "compositions of matter." It differs from U.S. law, however, in that it expressly provides that "where a complete specification claims a new substance the claim shall be construed as not extending to that substance when found in nature." The High Court of Ireland ruled in 1978 that *Fusarium graminearum Schwabs,* as a soil isolate, was an "unaltered substance occurring in nature" and hence unpatentable.[50]

Mr. Justice McWilliam also doubted that the growth of living microorganisms could be considered a form of manufacture.

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[50] Ranks Hovis McDougall Ltd. v. Controller of Patents, 10 IIC 754, [1978] F.S.R. 593.

> It does not follow that, because a substance has been produced by man, it has, necessarily, been manufactured. . . . [T]he words "manufacture" and "composition" must be distinguished from the word "grow" . . . [which] appl[ies] whether the products grown are grown naturally or are artificially assisted to grow. . . . [T]hese microorganisms appear to me to be wholly composed of living cells which have been grown admittedly under very special and complicated conditions, and not to have been "made" or "put together" or "constructed."

The holding is reminiscent of our Commissioner Robertson's statement to Congress that "the word 'make' in the statute is usually understood to mean the construction by human activity whereas . . . plants are reproduced by growth. . . ." The present 35 U.S.C. §163 was enacted in recognition of the difficulty of interpreting the statutory term "make" in a biological context.

This decision appears to foreclose patent protection of living isolates. However, where an organism has been mutated, or, *a fortiori,* when its extrachromosomal elements have been altered by man, the breeder has gone beyond providing artificial assistance to growth, and it may be maintained that the organism has been "constructed."

[4] Microbiological Patent Protection in Canada

In *American Cyanamid Co. v. Charles E. Frost & Co.,*[51] the Exchequer Court of Canada reviewed the evidence as to the taxonomic equivalency of *Streptomyces lusitanum* with *S. aureofaciens.* The Court was quickly made aware of the "differences of opinion in the scientific world in the proper specification of streptomyces." Drs. Backus and Benedict, testifying for plaintiff, emphasized a small number of prominent morphological and cultural characteristics. Dr. Henssen, testifying for defendant, disagreed with plaintiff's experts as to the morphology of the strains. Dr. Cain, another expert witness for

[51] 2 Exchequer Court of Canada Reports (Ex. C.R.) 355 (1964).

defendant, called for an Adansonian approach, but was most impressed by the strains' divergence in growth characteristics on Czopek's agar. It was a "battle of the experts," and the Court gave the nod to the specialists in streptomyces taxonomy.

An "overclaiming" attack was disposed of on the theory that no unworkable strains were known of at the "date of the patent." A "disclosure" challenge was dealt with by Dr. Benedict's testimony that he had isolated and identified three strains of *S. aureofaciens* from Japanese soil, based on the description in the specification. Moreover, the strain was on deposit with the ATCC, and Dr. Cain was given a subculture of a "related" aureofaciens organism capable of producing tetracycline.

On March 18, 1982, the Canadian Commissioner of Patents ruled[51.1] that living organisms—specifically, "a microbial culture system acclimatized to spent sulfite liquor and having five principal components, all fungi"—were patentable "manufactures" or "compositions of matter" under Section 2 of the Canadian Patent Act. These fungi were new strains which had not "existed previously in nature," although they were of species "both old and known." They were not obtained by RDNA techniques. The Commissioner reviewed prior case law in the U.S., Great Britain, and the Federal Republic of Germany, and noted Japanese office practice, but did not discuss the adverse Irish precedent. The Canadian decision was specifically extended to

> all microorganisms, yeasts, molds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa; in fact to all new life forms which are produced en masse as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform propreties and characteristics.[51.2]

[51.1] In re Abitibi-Price, Inc., 1 Biotechnology Law Reports 48 (Can. Commr. Pats., March 18, 1982).

[51.2] A detailed discussion of the Abitibi-Price decision by a Canadian patent attorney is available. See D. Stotland, Canada's Abitibi-Price Decision: Green Light for Bioengineered Organisms? 1 Biotechnology Law Reports 129-32 (August-September 1982).

Strongly criticizing *Bergy I* for its hesitancy, the Commissioner stated:

> If an inventor creates a new and unobvious insect which did not exist before (and thus is not a product of nature), and can recreate it uniformly and at will; and it is useful (for example to destroy the spruce bud worm), then it is every bit as much a new tool as a microorganism. With still higher life forms, it is of course less likely that the inventor will be able to reproduce it at will and consistently, as more complex life forms tend to vary more from individual to individual. But if it eventually becomes possible to achieve such a result, and the other requirements of patentability are met, we do not see why it should be treated differently.

Curiously, in view of this broad language, the Commissioner refused an application for a variety of soybean obtained by cross-breeding. The Federal Court of Appeal[51.3] affirmed. In its view, such a plant does not come within the "common and ordinary meaning" of either a "manufacture" or a "composition of matter." A cross-bred plant "cannot really be said, other than on the most metaphorical level, to have been produced from raw materials or to be a combination of two or more substances united by chemical or mechanical means."

Conceivably, the greater degree of human intervention reflected by rDNA manipulations of plants could lead to a different result. The analogy with a "micro-organism obtained as a result of a laboratory process" in *Abitibi*, would then be stronger.

§ 10.08 Protection of Biological Invention in Japan

In 1976, R. C. Wegner suggested:

> Generally, as pointed out by the German Federal Supreme Court in its [Red Dove] and [Baker's Yeast] decisions, the patentability of a microorganism invention depends upon the question of whether the microorganism invention is patentable

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[51.3] Pioneer Hi-Bred, Ltd. v. Commissioner of Patents and Trademarks ___: 491 (Fed. Ct. App., Mar. 11, 1987).

as a chemical invention. Accordingly, in those countries such as Italy where no patent protection is provided for even the traditionally synthesized organic compound, a fortiori the patenting of a microorganism, per se, would be out of the question. In Japan, the new law of May 29, 1975, provides for the protection of chemical products, per se, for the first time. . . .[52]

The Japanese Patent Office published "Examination Standards for Inventions Concerning Microorganisms and the Fermentation Industry" in 1965, and "Examination Standards for Inventions of the Applied Microbiological Industry" in 1970.[53] The latter declared:

> Inventions of microorganisms, per se, are not patentable because they are industrially inapplicable, since the invention cannot be reproduced, in the same manner that plants and animals are not patentable.[54]

Because Japanese process patents cover the manufactured product, this was not a major limitation.[55]

In 1975, the Japanese Patent Office, in response to a surge of interest generated by the UPOV legislation, published "Examination Standards for the Invention of New Varieties of Plant" (excluding microorganisms). In 1978, the new "Seed and Seedling Law" provided for PVPA-like protection of new plant varieties.[56]

In 1979, not long after the Japanese Patent Law was amended to permit patents on chemical products, the Japanese Patent Office published "Guidelines Relating to the Examination of Inventions of Microorganisms." The guidelines apply to "inventions of newly bred microorganisms per se," but their scope is far greater than the literal meaning would suggest:

> By the term "microorganisms," referred to herein, is meant yeasts, molds, mushrooms, bacteria, actinomycetes, algae, virus-

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[52] Wegner, *supra*, 7 IIC at 236.

[53] I. Hayashi, A Japanese Prospective on Patenting Microorganisms: Prospects and Considerations, 7 APLA QJ 306, 309 (1979).

[54] Id.

[55] Id., 311.

[56] Id., 312.

es, protozoa and the like, and the convenience, cultured tissues of animals and plants as well.

The term "breeding," referred to herein, includes crossing, creating mutants, screening, etc.[57]

The specification will name the microorganism in accordance with accepted biological nomenclatures and state those "microbiological properties" which "characterize" the organism. The claim will give the scientific name of the organism, state those microbiological properties that render the claimed microorganism distinct from prior art, and if the organism was isolated from nature, recite the phrase, "isolated from nature in a substantially pure form."

The Guidelines provide several sample claims:

1. Bacillus subtilis having no sporogenic ability.
2. Saccharomyces cerevisiae which does not ferment galactose and which has a hydrophobic cell membrane.
3. Candida guilliermondii, in the spherical cell form, having a gram-negative and fragile cell wall.
4. Candida lipolytica having a defective cell wall which is gram-positive and has a Mannan content as low as 70 percent or less of that of ordinary Candida guilliermondii.
5. Candida SP No. 100 which does not substantially grow at a pH of lower than 3.0, capable of being stained with Acid Black on its cell surface and having a readily leaking bacterial protein.
6. Brevibacterium ammoniagenes requiring compound A.
7. Brevibacterium ammoniagenes FRI No. X requiring compound A.
8. Brevibacterium ammoniagenes tolerant to compound B having an ability of selectively producing substance P.[58]

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[57] A. Aoki & Associates AIPPI J., Sept. 1979 at 151 (transl.).

[58] I. Hayashi, A Japanese Perspective on Patenting Microorganisms: Prospects and Considerations, 7 Amer. Pat. L. Ass'n Q.J. 306, 314 (1979).

Hayashi has commented on these guidelines, which he helped write.[59]

With regard to the drafting of a microbiological patent claims, Hayashi suggests that a microorganism is like a catalyst, which, in Japanese practice, is defined by its action as well as its composition. Thus, Hayashi suggests claims such as "Microorganisms belonging to Genus A, requiring substance *Y* and capable of selectively producing substance *X*." (Under the prior guidelines, process claims were permitted to recite a genus limitation when the production of *X* by organisms of the genus was unknown.) Hayashi foresees dependent "variant" claims such as "*Saccharomyces cerevisiae* var. *Y* characterized. . . ." Hayashi raises the question of whether an auxotrophic mutant of a patented strain which produces a different metabolite than the parent strain should come within the claim thereon. With regard to "genetically engineered" microorganisms, Hayashi warns that the specification should "clarify concretely means for preventing danger to and ensuring the safety of the public."

§ 10.09 Judicial Decisions Relating to Biological Patent Protection in France

The French Supreme Court *(Cour de cassation)* has held that a vitamin manufacturing patent owned by Societe Merck & Co., which disclosed that fungi "belonging to the classes of Myxomycetes, Schizomycetes, and Fumycetes, particularly to the second of those classes, and within that class, especially to certain kinds of streptomyces grueus," was valid, and infringed by the use of *Propionibacterium freudenreichii*.[60] The Court of Appeals of Paris had declared that

> While it was true that there existed about 100,000 kinds of bacteria from which the appropriate strain had to be chosen, expert testimony . . . had shown that the [LLD] test was

[59] Hayashi at 312-319.

[60] Société Pierrel and Société Végétadrog v. Société Merck & Co., 5 IIC 508 (No. 4, 1972).