UTILITY/NONOPERABILITY STANDARDS IN BIOTECHNOLOGY PATENT PROSECUTION: FEDERAL CIRCUIT PRECEDENT VS. PTO PRACTICE

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by:

Kevin C. Hooper

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Approved:

Professor Thomas G. Field
Faculty Project Advisor

Professor Chistopher E. Blank
Faculty Project Co-Advisor

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I. Introduction:

Human recombinant insulin and the blood clot-dissolving drug tissue plasminogen activator (tPA) are two of the unqualified success stories of the emerging biotechnology[1] industry. The availability of intellectual property protection, most commonly in the form of a patent grant, is an important component in the ultimate success of the biotechnology industry. Without the protection of a patent most companies cannot afford to risk the capital assets needed to develop a promising technology into a commercially useful product. Therefore, it is imperative that the biotechnology industry, as well as the patent bar, monitor how the Patent and Trademark Office (PTO) applies the patent laws during prosecution.

Recently, the PTO was attacked over its interpretation of what constitutes statutorily useful and operable inventions. Leaders in the biotechnology industry and patent practitioners charged that the Patent Examiners (Examiners) in group 1800 were uniformly misapplying the patent laws to inventions that claimed a human therapeutic use. The most serious charge was that the Examiners in group 1800 routinely gave a rejection under 35 U.S.C. §§ 101/112, first paragraph for lack of utility and therefore nonenablement for any application which encompassed a human therapeutic use.

The practitioners argued that the PTO's routine §§101/112 rejections for human therapeutic use inventions were the result of group 1800 Examiners applying a different, e.g., higher, standard for utility/enablement than the rest of the art groups, and that this standard applied by group 1800 was in direct conflict with the United States patent code. This paper will review the historical underpinnings, developed though case law, of the utility and enablement standards. Through the case law analysis and the PTO's response, this paper will show where and how the PTO deviated from the law. Next, the arguments of the patent bar and the PTO in support of their respective positions will be presented. This paper will then present the PTO's proposed changes to the examination procedures in Group 1800. Finally, an argument will be made that a joint PTO-industry advisory committee is needed in order to pro-actively identify and resolve future deviations by the PTO from judicial precedent.

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[1]The Office of Science Technology Policy has defined "biotechnology" as "the use of various biological processes, both traditional and newly developed to make products and perform services from living organisms or their components." Office of Science and Technology Policy, Exercise of Federal Oversight Within the Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6,753 (1992). The Office of Technology Assessment defines biotechnology as including "any technique that uses living organisms (or parts of organisms) to make or modify products, to plants or animals, or to develop micro-organisms for specific uses ... Biotechnology is the most recent phase in a historical continuum of the use of biological organisms for practical purposes." Commercial Biotechnology: An International Analysis (Washington, D.C.: U.S. Congress, Office of Technology Assessment, OTA-BA-218 January 1984) at 3.

II. Background: Economic Factors and Statutory Considerations

A. The Birth of Biotechnology

Several commentators have traced the origins of the biotechnology industry to the 1973 discovery by Drs. Herbert Boyer and Stanley Cohen of how to isolate certain human genes from DNA and then to replicate those genes using a bacterial host.[2] The Cohen-Boyer invention was patented[3] and licensed out on a non-exclusive basis. From the ground breaking work of Cohen and Boyer in the 1970's, hundreds of biotechnology companies have been formed to develop new human recombinant products.

According to one commentator, "[t]he last decade has seen enormous progress in this technology. In fact, the advent of biotechnology has been compared to 'a second revolution in pharmaceutical innovation, akin to the discovery of antibiotics in the 1940s.'"[4] The biotechnology industry is becoming an economic force to be reckoned with. For example, in 1992 the market capitalization in the biotechnology industry was about 50 billion dollars, an increase of 43% over 1990-1991.[5] In addition, the total revenues for the biotechnology industry in 1991-92 were 8.1 billion dollars, an increase over the previous year of 28%.[6]

Clearly, the protection of intellectual property in the biotechnology business sector is vital for the survival and growth of start-up, as well as, established companies. According to Dr. Ronald E. Barks, in the area of biomedical technology it takes between five to ten years to commercialize an invention. In general, the process of commercialization itself is expensive in terms of time and money: "[f]or every $1 of research, $10 are needed for development, and $100 to take a product to market."[7] In the biotechnology industry, the development costs of a single product can be 50-200 million dollars.[8] Given this high cost of taking an idea from the lab to the consumer, intellectual property protection, especially in the form of patents, is essential for the continued development of this emerging industry.

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[2]*See e.g.*, Sandra H. Cuttler, *The Food and Drug Administration's Regulation of Genetically Engineered Human Drugs*, 1 J. Pharmacy & Law 191 (1992) *citing* John E. Barkstrom, *Recombinant DNA and the Regulation of Biotechnology: Reflections on the Asilomar Conference, Ten Years After*, 19 Akron L. Rev. 81, 84 (1985).

[3]*See*, U.S. Patents 4,740,470; 4,468,464; and 4,237,224. *See also*, Cohen SN, Chang AC, Boyer HW, and Helling RB, *Construction of biologically functional bacterial plasmids in vitro*, PNAS 70(11): 3240-4 (Nov. 1973) and Morrow JF, Cohen SN, Chang AC, Boyer HW, and Helling RB, *Replication and transcription of eukaryotic DNA in Escherichia coli*, PNAS 71(5): 1743-7 (May 1974).

[4]J. Pharmacy & Law at 193, *citing* Joan C. Hamilton et al., Biotech: America's Dream Machine, 3254 Bus. Wk., March 2, 1992, at 66.

[5]Ernst and Young, Biotech 93: Accelerating Commercialization 20 (1992).

[6]*Id.*

[7]Presentation of Dr. Ronald E. Barks, "Government Licensing," Franklin Pierce Law Center Advanced Licensing Institute, July 1994.

[8]Michael W. Glynn, "Pharmaceutical/Biotechnology Licensing," Franklin Pierce Law Center Advanced Licensing Institute, July 1994.

Without early and broad patent protection for new biotechnology research, venture capitalists will not risk the money it takes to allow a start-up company to bring promising research results to the market place. In addition, more established biotechnology companies will not risk their own money on promising research unless they are able to forge a favorable patent position early in the development process.

B. Constitutional Underpinnings of the Patent System

The patent system is as old as the United States Constitution and in theory is simply a *quid pro quo* method used by the government to encourage early and complete disclosure of inventions that meet the statutory criteria for patentability. The constitutional language found in Article I, Section 8, Clause 8 commands that Congress shall have the power to "promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[9] Therefore, the patent law, codified in 35 U.S.C., is based on a constitutional grant of power to Congress. According to Robert L. Harmon, "the exclusive right, constitutionally derived was for the national purpose of advancing the useful arts — the process today called technological innovation."[10] In addition, Mr. Harmon concludes that the "[p]atent system encourages inventors to invent and disclose ...[and] also encourages corporations and investors to risk investment in research, development, and marketing without which the public could not gain full benefit of the patent system."[11]

1. PTO – The Administrative Agency Charged With Implementing the Constitutional Mandate

Congress delegated its responsibility to the PTO for determining the patentability of inventions. Under 35 U.S.C. § 6(a) the Commissioner of the Patent and Trademark Office (Commissioner) may "establish regulations, not inconsistent with law, for the conduct of proceedings in the Patent and Trademark Office."[12] The statutory authority for examination of

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[9]The power to grant copyrights to authors is for the promotion of "Science" whereas the power to grant patents is for the promotion of the "useful Arts". *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 U.S.P.Q.2d 1057 (Fed Cir. 1988).

[10]Robert L. Harmon, Patents and the Federal Circuit §1.2, pg. 8, 3rd ed. (1994).

[11]*Id.*

[12]The PTO is in the Department of Commerce and the Commissioner is appointed by the President of the United States with the advice and consent of the U.S. Senate. 35 U.S.C. §3(a) (1994). The Commissioner is an Assistant Secretary of Commerce and reports to the Secretary of Commerce. 35 U.S.C. §§ 3(d) and 6(a).

patent applications is found in 35 U.S.C. § 131.[13] According to the Manual of Patent Examining Procedure (M.P.E.P.), "[t]he main conditions precedent to the grant of a patent to an applicant are set forth in 35 U.S.C. 101, 102, 103."[14]

Therefore, major hurdles to patentability include the requirements that an invention be useful[15], novel[16], nonobvious[17], and comply with requirements of 35 U.S.C. §112, first

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[13]The Commissioner shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Commissioner shall issue a patent therefor.

[14]Manual of Patent Examining Procedure § 701 5th ed. (August 1993). The M.P.E.P. is published by the U.S. government to provide Examiners, applicants, patent attorneys and agents, etc. with a reference work on the practices and procedures of the PTO for the examination of patent applications. However, the M.P.E.P. does not have the force of law, but it is entitled to notice [s]o far as it is an official interpretation of statutes or regulations with which it is not in conflict. *Syntex (U.S.A.) Inc. v. United States PTO*, 882 F.2d 1570, 11 U.S.P.Q.2d 1866 (Fed Cir. 1989).

[15]35 U.S.C. § 101. Inventions Patentable:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[16]35 U.S.C. § 102. Conditions for Patentability; Novelty and Loss of Right to Patent

A person shall be entitled to a patent unless—

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

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

(c) he has abandoned the invention, or

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

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371 (c) of this title before the invention thereof by the applicant for patent, or

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

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

[17]§103. Conditions for Patentability; Non-Obvious Subject Matter

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

paragraph[18]. However, this paper will focus on the lack of utility and therefore nonenablement rejections used by the examiners in group 1800 to deny patent protection to biotechnology claims that may encompass human therapeutic uses.

III. Industry and Patent Bar Concerns and the PTO's Response

A. BIO's Argument – The PTO Is Not Following the Law

In September of 1994, the Commissioner published a notice of public hearing and request for comments on patent protection for biotechnological inventions.[19] In approximately one month, the members of the Biotechnology Industry Organization (BIO) drafted a 163 page response to the commissioner's request.[20] In the BIO position paper, industry leaders and the patent bar presented their belief that the high turn-over rate in the PTO and the Examiners lack of legal training are responsible for unfavorable prosecution outcomes that are diminishing the ability of the biotechnology industry to compete. According to BIO, universities and smaller start-up companies are especially vulnerable because they may not have the resources to provide the human clinical data that the Examiners seem to require for inventions which have claims that may encompass human therapeutic use.[21]

As will be developed in the case law *infra*, there are several issues that define the biotechnology industry's concern over how their patent applications are examined by the PTO:

- The PTO's misapplication of the §§101/112, first paragraph rejection has lead to a *de facto* requirement that claims which may encompass a human therapy must disclose human clinical data.
- The PTO misapplies the Supreme Court's *Brenner* decision to biotechnology applications.

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

[18]§112. Specification
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. ...

[19]59 F.R. 169, 45267-45271 (September 1, 1994).

[20]Biotechnology Industry Organization, "Critical Synergy: The Biotechnology Industry and Intellectual Property Protection," Hearing of the U.S. Patent and Trademark Office, San Diego, California, October 17, 1994.

[21]*See, e.g.*, Testimony of Kenneth J. Widder, Chairman and CEO of Molecular BioSciences and William Rastetter, President and CEO of IDEC Pharmaceuticals Corporation.

- The PTO must examine the invention as claimed, not as the Examiner interprets the disclosure.
- The PTO must recognize that there is a difference between pharmacological and pharmaceutical claims.

B. The PTO's Traditional Response and the Commissioner's New Guidelines

In Board decisions and appeals before the Federal Circuit, the PTO defended its position by reference to its duty to protect the U.S. public. According to the PTO, the public views the issuance of a patent as the Government's approval that the invention is safe and effective for use by the U.S. public. Therefore, the PTO is correct to require disclosure of safety and efficacy in human clinical trials for pharmaceutical claims.

In December of 1994, Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks acknowledged the PTO's misapplication of the utility standards to biotechnology inventions in his Announcement of Draft Examining Guidelines for Utility.[22] According to the draft guidelines:

- Any credible utility that is identified by an applicant will satisfy §101.
- §101 rejections will be made and reviewed according to consistent and correct legal standards.
- Applicants will no longer be placed in the catch-22 dilemma of having to provide human clinical data to support utility. Rather, if an applicant can show that an asserted utility is credible using any kind of evidence, it will be sufficient to satisfy §101. According to Commissioner Lehman, "Our examiners will no longer impose unrealistic and unattainable evidentiary requirements on patent applicants."
- The new guidelines "reestablish" the proper level of deference that must be given to expert opinions.

Commissioner Lehman also proposed several other administrative changes that are worthy of note:

- The examining corps will be effectively trained to ensure that the new guidelines are fully understood and implemented.
    1. The new guidelines are to be incorporated into the initial training regime of new examiners.
    2. Examiners will be given legal training.
- Several management changes have also been proposed.
    1. Supervisors will be trained in accordance with the new guidelines. In addition, supervisors will be trained how to effectively review Examiner office actions.

[22]Remarks for Press Conference on Utility Guidelines, Version 1.0 (December 20, 1994).

2. The PTO will make more effective use of supervisors in reinforcing the new guidelines.
3. Two or more Quality Assurance Experts will be assigned to Group 1800. These experts will review a "significant" proportion of office actions before they issue from the office to ensure that they are consistent with the guidelines.

IV. Historical Precedent: Practical Utility

A. The Utility and Enablement Standards Are Different, Although Related

The early §§ 101/112 patent cases decided by the United States Court of Customs and Patent Appeals (C.C.P.A.)[23] concerned the patentability of steroids or intermediates in the steroid synthesis process. In *Application of Nelson*, the C.C.P.A. held that intermediates may be useful in some situations and, therefore, disclosure of novel compounds useful for steroid research complied with the enabling requirement of §112.[24]

In *Application of Nelson*, the appellants appealed the Patent Office Board of Appeals (Board)[25] affirmance of the Examiner's rejection of their claims to novel intermediates in the preparation of steroids. The Examiner rejected the claims because the applicants failed to show how the claimed compounds could be converted to products having known useful purposes. The applicants argued that their novel compounds were useful, as defined by the statute, to researchers who were searching for cheaper and shorter routes of synthesis for steroids having therapeutic or similar utility.

The C.C.P.A. concluded that the Board and the Examiner confused the evaluation of the appellant's invention by combining the requirements of utility under §101 and operability under §112, first paragraph. The court stated that the PTO "has taken the position that appellants have not complied with §112, but it has not shown why this is so except by objection to the kind of utility disclosed, which presents an issue under §101 rather than §112."[26] The C.C.P.A. also said, "[w]hat the Patent Office is really trying to insist on here has nothing to do with the 'how to use' provision of §112. It is demanding some different, or greater, or more commercial or more mundane use than the one disclosed."[27] Finally, the court said, "[m]uch confused thinking on this matter has resulted from a failure to separate the requirement of section 101 that an invention be useful from the section 112 requirement that the specification shall so explain 'the manner and

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[23] The C.C.P.A. was the precursor to the Court of Appeals for the Federal Circuit (C.A.F.C.).
[24] *Application of Nelson*, 280 F.2d 172, 126 U.S.P.Q. 242 (1960).
[25] The term "Board" as used herein refers to the Patent of Board of Appeals and its successor, the Board of Patent Appeals and Interferences (B.P.A.I.).
[26] 280 F.2d at 177.
[27] *Id.* at 183.

processes of ... using' the invention as to 'enable any person skilled in the art ... to ... use the same.'"[28]

These statements by the *Nelson* court indicate that, as early as 1960, the PTO did not understand the standards for utility and enablement under §§101 and 112, first paragraph. The *Nelson* court found that the PTO applied a different, e.g., higher standard, to applications in the chemical arts when human therapeutic use was claimed as a possible utility. According to the *Nelson* court, the enablement requirement under §112, first paragraph is to put those skilled in the art in possession of sufficient information to allow them to use and practice the claimed invention. In contrast, the *Nelson* court, in upholding the *Bremner* rule[29] said that an applicant must indicate a use for his or her new composition but that:

> ...compliance with the law does not necessarily require specific recitations of use but may be inherent in description or may result from disclosure of a sufficient number of properties to make a use obvious; and where those of ordinary skill in the art will know how to use, the applicant has a right to rely on such knowledge. If it will not be sufficient to enable them to use his invention, he must supply the know-how.[30]

B. §101 Is a Low Hurdle to Patentability – Proof of Safety and Efficacy Is Not Required

In another early case, the C.C.P.A. considered the PTO's rejection of a patent application entitled, "Glycosides of the Pyridone Series."[31] In this case, the appellants claimed several glycosidic compounds that had pharmaceutical applications including anti-inflammatory activity, anti-bacterial activity, and effectiveness in decreasing vascular permeability. According to the C.C.P.A., the issue in *Krimmel* was whether "a test restricted to a laboratory animal is sufficient to satisfy the utility requirement of the statute when a patent application discloses that claimed compounds are useful in the treatment of a condition which can occur both in man and in lower animals, and it is agreed that the disclosure does not exclude the treatment of man."[32]

In reversing the Board, the *Krimmel* court held that:

> ...when an applicant for a patent has alleged in his patent application that a new and unobvious chemical compound exhibits some useful pharmaceutical property and when this property has been established by statistically significant tests with 'standard experimental animals,' sufficient statutory utility for the compounds has been presented.

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[28] *Id.* at 184

[29] *Application of Bremner*, 182 F.2d 216, 37 C.C.P.A. 1032 (C.C.P.A. 1950).

[30] 280 F.2d at 184-85.

[31] *Application of Krimmel*, 292 F.2d 948, 130 U.S.P.Q. 215 (1961).

[32] *Id.* at 952.

> By 'standard experimental animals,' we mean whatever animal is usually used by those skilled in the art to establish the particular pharmaceutical application in question.[33]

The *Krimmel* court acknowledged that the treatment of humans fell within the "pharmaceutical application" language, but nonetheless reversed the PTO's rejection of the claims, because the court interpreted the utility requirement of §101 as a fairly low hurdle to patentability. Specifically, the Court said:

> ...it is our firm conviction that one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment of humans.[34]

The *Krimmel* court dismissed the argument that the grant of a patent "gives a kind of official imprimatur to the medicine in question" when it concluded that:

> There is nothing in the patent statute or any other statutes called to our attention which gives the Patent Office the right or duty to require an applicant to prove that compounds or other materials which he is claiming, and which he has stated are useful for 'pharmaceutical applications,' are safe, effective, and reliable for use with humans. It is not for us or the Patent Office to legislate and if the Congress desires to give this responsibility to the Patent Office, it should do so by statute.[35]

C. *Brenner v. Manson*: The Practical Utility Requirement

Five years after *Krimmel* was decided by the C.C.P.A., the United States Supreme Court in *Brenner v. Manson*, decided whether the practical utility of a compound produced by a chemical process is an essential element to establish a *prima facie* case of patentability for the process.[36] The *Brenner* case came to the Supreme Court by way of a request for an interference proceeding[37] during the prosecution of Manson's application.

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[33] *Id.* at 953.
[34] *Id.*
[35] *Id.* at 954.
[36] 383 U.S. 519, 86 S.Ct. 1033, 148 U.S.P.Q. 689 (1966). A second important issue decided by the *Brenner* Court was whether the U.S. Supreme Court had *certiorari* jurisdiction upon petition of the Commissioner (e.g., Edward J. Brenner) to review decisions of the C.C.P.A. The Supreme Court concluded that the C.C.P.A was an Article III court and that "the orderly administration both of our *certiorari* jurisdiction and of the patent laws requires that ultimate review be available in this Court, regardless of the route chosen by the litigants."
[37] *See*, 35 U.S. C. § 102(g), nt. 16, *supra*..

Briefly, the disputed invention concerned a novel process for making certain known steroids.[38] A U.S. patent (Ringold patent) was issued to two inventors (Howard Ringold and George Rosenkranz) on the process. The inventors claimed a U.S. priority date of December 17, 1956, the date on which they filed a Mexican patent application.

In January 1960, Manson filed a U.S. patent application on the same process and asserted that he discovered the process before the December 17, 1956 priority date of the Ringold patent. Manson requested that an interference be declared. However, the Examiner denied Manson's request and rejected his application for failure to disclose any utility for the compounds produced by the claimed process.

Manson appealed to the Board and was denied again. The Board considered a reference cited by Manson which disclosed a utility, e.g., tumor inhibition in mice, for compounds of similar chemical structure. However, the Board concluded that, "the statutory requirement of usefulness of a product cannot be presumed merely because it happens to be closely related to another compound which is known to be useful."[39]

Manson appealed to the C.C.P.A which overturned the Board's decision. The C.C.P.A. held that Manson was entitled to an interference proceeding because "'where a claimed process produces a known product it is not necessary to show utility for the product,' so long as the product 'is not alleged to be detrimental to the public interest.'"[40] The Commissioner petitioned for a *writ of certiorari* to the Supreme Court. The Supreme Court granted the *writ* to "resolve this running dispute over what constitutes 'utility' in chemical process claims...." The "running dispute" over the definition of "utility" in chemical process claims was between the PTO's view that "it was never intended that a patent be granted upon a product, or a process producing a product, unless such a product be useful"[41] and the C.C.P.A.'s interpretation that "it is sufficient that a process produces the result intended and is not detrimental to the public interest."[42]

D. The Supreme Court's Decision – "Substantial Utility" Requirement

The Supreme Court held in a 7:2 decision, that a chemical process produces the intended product or that the compound yielded belongs to a class of compounds which is the subject of

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[38]The applicants described the products of their process as "2-methyl dihydrotestosterone derivatives and esters thereof as well as 2-methyl dihydrotestosterone derivatives having a C-17 lower alkyl group. The products of the process of the present invention have a useful high anabolic-androgenic ratio and are especially valuable for treatment of those ailments where an anabolic or antiestrogenic effect together with a lesser androgenic effect is desired." *See*, 383 U.S. at 521, nt. 1.

[39]383 U.S. at 522.

[40]*Id.*

[41]*See e.g.*, 182 F.2d at 217.

[42]*See e.g.*, 333 F.2d 234, 238, 52 C.C.P.A. 739 (C.C.P.A. 1964); 280 F.2d 172.

serious scientific investigations does not make the process "useful" under 35 U.S.C. §101.[43] The Supreme Court described the *quid pro quo* contemplated by the U.S. Constitution as a practical economic interaction between the government and inventors. Specifically, the Supreme Court required a patent applicant to disclose a "substantial utility" for his or her invention, e.g., a utility "where specific benefit exists in currently available form."[44] The Supreme concluded that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. A patent system must be related to the world of commerce rather than the realm of philosophy."[45]

The Supreme Court clearly stated that its holding was equally applicable to process claims as well as product-by-process claims: "[w]e find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product."[46] Under the *Brenner v. Manson* decision, in order for an applicant to obtain an allowance for a process claim, he or she must present evidence sufficient for a finding of substantial utility, e.g., that a specific benefit exists in currently available form. Clearly, evidence that compounds of a similar structure have a pharmacological effect in an experimental animal model is insufficient.

E. Examiner's Misapplication of the "Substantial Utility" Requirement

The Examiners in Group 1800 have improperly used the Supreme Court's language in *Brenner* as the basis for rejecting claims to human therapies with *in vitro* or *in vivo* support but no human clinical information. In general, the Examiners have used *Brenner* to make the argument that because an invention embodies a potential use as a human therapeutic and the application discloses only *in vitro* or animal data to support the claimed utility, the claims are unpatentable for lack of operativeness under §§101/112, first paragraph for failure to disclose evidence that a specific benefit exists in a currently available form. This rejection by the PTO is tantamount to a requirement that the invention be actually reduced to practice, e.g., that it be in a commercially viable condition as of the filing date. The Examiners must remember that the Supreme Court was limited to the facts as developed in the prosecution and appeal. Specifically, Manson's specification did not disclose <u>any</u> utility for his claimed invention. Rather, he relied on the known properties of structurally similar compounds to make an analogy between utilities. The *Brenner*

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[43] 383 U.S. at 535.
[44] *Id.*
[45] *Id.* at 536.
[46] *Id.*

decision does not stand for the proposition that lack of human clinical data renders a claim not useful under §101.

In addition, the Supreme Court's language does not illuminate the problem of applications that claim either a process or a product made by a process for which there is evidence of a utility either in the form of a research use or animal data that suggests a potential human therapeutic use. For example, should a patent issue on a claim for the use of a partial amino acid sequence as a research tool or as a component in a kit for identifying whether a particular protein is present in a blood, urine, or tissue sample?[47] In addition, should a claim be allowed for a compound in which data from an animal model or *in vitro* experiments suggests a human therapeutic utility? The limitations of the majority holding were described by Justice Harlan in his dissenting opinion: "The further argument that an established product use is part of 'the basic *quid pro quo*' for the patent or is the requisite 'successful conclusion' of the inventors' search appears to beg the very question whether the process is 'useful' simply because it facilitates further research into possible product uses."[48]

F. *Brenner* Applied – The Interrelationship Between the Utility and Enablement Standards

A year later, the C.C.P.A. had the opportunity to apply the *Brenner* decision in two cases decided concurrently.[49] In both cases, the applicants claimed compounds useful as intermediates in the production of other compounds. The C.C.P.A., relying heavily on the *Brenner* decision said, "it seems clear that, if a process for producing a product of only conjectural use is not itself 'useful' within section 101, it cannot be said that the starting materials for such a process, – i.e., the presently claimed intermediates – are useful."[50] In *In re Jolly*, the court said, "it is not enough

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[47] *But see*, R. Eisenberg, "Technology Transfer and the Human Genome Project: Some Problems with Patenting Research Tools," *in*, The Future of Intellectual Property Protection for Biotechnology: An International Conference, Washington Law School Foundation (Oct. 21-23, 1993).

[48] 383 U.S. at 537.

[49] *In re Jolly*, 376 F.2d 906, 153 U.S.P.Q. 45 (1967) and *In re Kirk*, 376 F.2d 936, 153 U.S.P.Q. 48 (1967). *In re Jolly* was an appeal from the decision of the Board affirming the Examiner's rejection of product and process claims of application Serial Number 81,272 entitled "Esters of 2-Enols of DELTA super 1 Steroids and Preparations Thereof." *In re Kirk* was an appeal from the decision of the Board affirming the Examiner's rejection of an invention that claimed novel 1 dehydro- derivatives which the applicant claimed were useful because of their biological properties or as intermediates in the preparation of compounds with useful biological properties (e.g., steroids). In both cases, the PTO rejected all the claims for failure to comply with 35 U.S.C. §§ 101/112, first paragraph, e.g., the "how to use" component of §112, first paragraph, and the legal adequacy of the assertions of usefulness under §101.

[50] 153 U.S.P.Q. at 47. In *In re Jolly*, the applicant's specification disclosed the production of intermediates which could be used to make two named 2,3 diketo steroids. The applicants only disclosed that the two 2,3 diketo steroids were similar in structure to the known compounds cortisone and prednisone. The applicant's argument was that the disclosure of a steroid useful as an intermediate to make other steroids by specific reactions is an adequate disclosure for utility purposes under §101.

that the specification disclose that the intermediate exists and that it 'works,' reacts, or can be used to produce some intended product of no known use. Nor is it enough that the product disclosed to be obtained from the intermediate belongs to some class of compounds which now is, or in the future might be, the subject of research to determine some specific use."[51]

Similarly in *In re Kirk*, the applicants argued that their specification was adequate to comply with the requirements of §101 and §112, first paragraph because they disclosed intermediate compounds in the process for producing end-products with useful biological properties, e.g., steroids. Specifically, the applicants argued that their compounds had utility as intermediates in the production of aromatic steroidal hormones and "other biologically useful compounds," and that one skilled in the art would know how to use the compounds for that purpose.[52] The C.C.P.A. held that it was not the intention of the

> ... statutes to require the PTO, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.[53]

The C.C.P.A. also criticized the applicant's general reference to "biological activity" or "biological properties" displayed by the claimed compounds. According to the C.C.P.A., "it is what the compounds are disclosed to do that is determinative here."[54] The C.C.P.A. described the inter-relationship between the utility requirement of §101 and the enablement requirement of §112, first paragraph when it said that "Congress intended §112 to pre-suppose full satisfaction of the requirements of §101. Necessarily, compliance with §112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention."[55] Although general reference to the "biological properties" of a claimed compound is not sufficient to overcome the utility hurdle of §101, the C.C.P.A. acknowledged that animal data which demonstrates that a claimed composition of matter has therapeutic properties may be sufficient to overcome the utility requirement.[56]

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[51] *Id.*
[52] 153 U.S.P.Q. at 51.
[53] *Id.* at 53.
[54] *Id.* at 52.
[55] *Id.* at 53.
[56] *Id.* at 56. *See also*, n. 7, where the court acknowledges that *In re Hitchings*, 342 F.2d 80, 144 U.S.P.Q. 637 (C.C.P.A. 1965), *In re Krimmel*, *In re Dodson*, 292 F.2d 943, 130 U.S.P.Q 224 (C.C.P.A. 1961), and *In re Bergel*, 292 F.2d 955, 130 U.S.P.Q. 206 (C.C.P.A. 1961) support the proposition that "usefulness of compositions of

G. Animal Data May Be Sufficient to Overcome the Utility Hurdle

In 1970, the Second Circuit decided a patent infringement suit in which a key issue in the case turned on whether the patentee's claims to a new chemical compound where valid when they claimed a therapeutic use based solely on data generated from an animal model.[57] The Second Circuit held that:

> ... one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment of humans.[58]

According to the *Carter-Wallace* court, submission of testing information to the PTO in support of an invention's claimed utility is optional. Data must be submitted to over-come a lack of utility rejection by the PTO only when the asserted utility of a compound is not believable on its face to a person skilled in the art. In addition, the *Carter-Wallace* court, consistent with *In re Krimmel*, said that to require the PTO to make findings on the safety of a drug for human use would work a serious overlapping of the jurisdictions of the PTO and the Food and Drug Administration (FDA).[59] The Carter-Wallace court specifically found that the Supreme Court's decision in *Brenner* did not stand for the proposition that "when an inventor seeks a patent on a chemical compound intended for therapeutic use, he must produce evidence of tests on humans sufficient to establish the safety of the drug for human use."[60]

Rather, the Supreme Court's opinion in *Brenner* left this question open. However, the C.C.P.A. in *In re Krimmel* answered the same question five years earlier when it held "that the statutory requirement of utility is satisfied when the inventor reveals a novel compound with therapeutic properties whose utility has been demonstrated through tests on standard experimental animals." The Second Circuit concluded, "that Carter-Wallace possessed a valid patent on the compound in question, having satisfied the statutory requirement of utility found in 35 U.S.C.

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matter under §101 may be established by an appropriate demonstration that the composition has useful properties or activities when tested in laboratory animals."

[57] *Carter-Wallace, Inc. v. Riverton Laboratories, Inc.*, 433 F.2d 1034, 167 U.S.P.Q. 656 (2nd Cir. 1970). *Carter-Wallace* was an appeal from the district court's determination that the patent of the appellee, Carter-Wallace for a pharmaceutical compound known as meprobamate, was valid and infringed. The Carter-Wallace patent covered three organic compounds used as tranquilizers and in the treatment of muscle spasms. The claim of anti-convulsive properties was supported by reference to tests conducted on mice and the claim of a paralyzing action by reference to pharmacological studies on unnamed animals.

[58] 433 F.2d at 1039.

[59] *Id.* at 1039-40. *See also*, 21 U.S.C. §§ 301-394.

[60] *Id.* The *Carter-Wallace* Court defined the therapeutic property of a compound as its "ability to heal or cure in whole or significant part, a disorder in a human being or in any form of plant or animal life."

§101 by claiming properties of therapeutic value that were adequately demonstrated through tests on standard experimental animals."[61]

H. Proof of Pharmacological Activity May Be Sufficient to Establish Practical Utility

Ten years after the Second Circuit decided *Carter-Wallace*, the C.C.P.A. confronted a similar situation in *Nelson v. Bowler*.[62] This interference centered on claims that described 16-phenoxy-substituted prostaglandins which were structurally related to known, naturally occurring prostaglandins designated as PGF 2 and PGE 2. The issue before the C.C.P.A. was whether Nelson, the junior party, demonstrated sufficient utility for his invention prior to the critical date of Bowler, the senior party. Substantively, the issue was whether Nelson sufficiently demonstrated "practical utility" for his 16-phenoxy prostaglandins by disclosing their ability to stimulate gerbil colon smooth muscle tissue and modulate blood pressure in rats.

The Board found that Nelson conceived and prepared the compounds within the scope of the disputed claims prior to Bowler's critical date. However, the Board ruled that Nelson's evidence, e.g., the 16-phenoxy prostaglandin's effect on gerbil colon smooth muscle tissue and rat blood pressure failed to recite practical utility. Therefore, the Board awarded priority to Bowler.

The C.C.P.A. reversed the Board's decision because "the board erred in not recognizing that tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use."[63] The C.C.P.A. reasoned that "[s]ince it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility."[64]

In accordance with the *Carter-Wallace* decision, the C.C.P.A. concluded that knowledge of a pharmacological use of a compound is beneficial to the public. Nelson's disclosure of blood pressure modulation and smooth muscle cell stimulation by the 16-phenoxy prostaglandins provided a pharmacological use. Therefore, one skilled in the art would be "reasonably certain" that Nelson's compounds had practical utility. In reversing the Board, the C.C.P.A. concluded

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[61] *Id.* at 1040.

[62] 626 F.2d 853, 206 U.S.P.Q. 881 (C.C.P.A. 1980). Nelson arose in the context of an interference proceeding between the Upjohn Company, the assignee of Nelson, and the Imperial Chemical Industries, Ltd., the assignee of Bowler. This appeal is from the decision of the Board awarding priority of invention on four counts to Bowler.

[63] *Id.* at 856. The C.C.P.A. defined practical utility as a "short hand" way of attributing "real world value" to the claimed subject matter. In other words, the C.C.P.A. interpreted "practical utility" to mean that one skilled in the art would be able to immediately use the claimed invention in such a way so as to benefit the public.

[64] *Id.*

that "a rigorous correlation [between the pharmacological activity and the tests run] is not necessary where the test for pharmacological activity is reasonably indicative of the desired response."[65]

I. The Utility Standard – A Two-Step Analysis

Five years later, the C.A.F.C. expanded on the *Nelson v. Bowler* decision.[66] In another interference case, the C.A.F.C. was confronted with three issues: (1) whether tests evidencing a pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use; (2) whether the Board erred in finding that the utility disclosed in a Japanese priority application was sufficient to meet the practical utility requirement of 35 U.S.C. §101; and (3) whether the Board erred in finding that the Japanese priority application contained sufficient disclosure to satisfy the enablement, e.g., how to use, requirement of 35 U.S.C. §112, first paragraph.

The Board concluded Iizuka was entitled to the benefit of his Japanese priority application. Relying on *In re Bundy*[67] and *Nelson v. Bowler*[68], the Board held that "tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use."[69] The Board also said that:

> knowledge of the pharmaceutical activities of compounds is beneficial to the medical profession, and requiring Iizuka to have disclosed *in vivo* dosages in the Japanese priority application would delay and frustrate researchers by failing to provide an incentive for early public disclosure of such compounds, thereby failing to further the public interest.[70]

In affirming the B.P.A.I.'s decision, the C.A.F.C. described a proper utility analysis under 35 U.S.C. §101:

> a thorough analysis of the utility issue requires first, a determination as to what utility is disclosed, i.e., the stated utility, for the invention claimed in the application. Only after the stated utility has

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[65] *Id.*

[66] *Cross v. Iizuka*, 753 F.2d 1040, 224 U.S.P.Q. 739 (Fed Cir. 1985). This appeal was from the decision of the Board awarding priority on a single phantom count to Iizuka, the senior party. This case arose in the context of an interference proceeding in which each party moved to be accorded the benefit of a foreign priority application. The disputed invention described imidazole derivative compounds which inhibit the synthesis of thromboxane synthetase, an enzyme which leads to the formation of thromboxane A_2, a highly unstable, biologically active compound which is convertible to the stable thromboxane B_2 by the addition of water.

[67] *See*, 642 F.2d 430, 209 U.S.P.Q. 48 (C.C.P.A. 1981) where the C.C.P.A. said that how the utility requirement is applied depends on the type of claim. The court held that claims which are not drawn to particular uses, e.g., composition of matter and method of making claims, require a lower evidentiary burden.

[68] *See*, nt. 61, *supra*.

[69] 753 F.2d at 1043.

[70] *Id.*

> been determined can a proper analysis be undertaken to determine if the stated utility complies with the 'practical utility' requirement of §101. ... these questions regarding utility are factual in nature, and are to be determined in the first instance by the PTO, the agency with the expertise in this regard."[71]

The C.A.F.C. disclosed a two-step analysis to determine statutory utility: first, determine what utility is disclosed in the applicant's specification; and second, determine if the utility disclosed meets the statutory criteria for "practical utility" under 35 U.S.C. §101.

According to the C.A.F.C., the Board found that the Japanese application disclosed a utility for the claimed imidazole derivatives as agents for inhibiting thromboxane synthetase in human or bovine platelet microsomes and as therapeutically active agents that prevented the deleterious conditions of thromboxane A_2 biosynthesis. The C.A.F.C. concluded that "evidence of any utility is sufficient when the count does not recite any particular utility."[72] The starting point of any "practical utility" determination is the Supreme Court's decree that 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.[73] Under *Nelson v. Bowler*, the disclosure of a pharmacological activity of a compound was found to be beneficial to the public and that adequate proof of any such utility constituted a showing of practical utility.

J. *Nelson v. Bowler* Reaffirmed – *In Vitro* Utility May Be Predictive of *In Vivo* Activity

The C.A.F.C. found that the *Nelson* court, while observing that the actual testing disclosed was not sufficient to establish an actual reduction to practice, nonetheless found that the extensive *in vivo* testing done was routine in nature and was not, therefore, to be construed as an indicator that extensive research, i.e., inventive skill and/or undue experimentation, was required to resolve complex difficulties related to the utilization of the compound for the particular activity. Citing *Knapp v. Anderson*, the court said, "it is well settled that if the counts do not specify any particular use, evidence proving substantial utility for any purpose is sufficient to establish an actual reduction to practice."[74]

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[71] *Id.* at 1044 n. 8 [citations omitted].
[72] *Id.* at 1045. *See also*, 626 F.2d at 856; *Rey-Bellet v. Englehardt*, 493 F.2d 1380, 181 U.S.P.Q. 453 (C.C.P.A. 1974); *Knapp v. Anderson*, 477 F.2d 588, 177 U.S.P.Q. 688 (C.C.P.A. 1973); and *Blicke v. Treves*, 241 F.2d 718, 112 U.S.P.Q. 472 (C.C.P.A. 1957).
[73] 383 U.S. at 535.
[74] 241 F.2d 718 *citing* 477 F.2d 588, 177 U.S.P.Q. 688 (C.C.P.A. 1973).

Finally, the *Iizuka* court determined whether the inhibitory effect on thromboxane synthetase and bovine microsomes, e.g., *in vitro* utility, was sufficient to comply with the practical utility requirements of 35 U.S.C. §101. According to the Iizuka court, "[a]dequate proof of any pharmacological activity constitutes a showing of practical utility."[75] In addition, the *Iizuka* court said that "*in vitro* testing, in general, is relatively less complex, less time consuming, and less expensive than *in vivo* testing. Moreover, *in vitro* results with respect to the particular pharmacological activity are generally predictive of *in vivo* test results, i.e., there is a reasonable correlation there between."[76]

Cross argued that there must be a strong correlation between the *in vitro* tests described in a specification and the claimed *in vivo* utility in order to establish a practical utility. Iizuka, however, argued that successful demonstration of an *in vitro* activity establishes a sufficiently strong probability that *in vivo* testing will be successful. The C.A.F.C. agreed with the Board that there was "a reasonable correlation between the disclosed *in vitro* utility and an *in vivo* activity, and therefore a rigorous correlation [was] not necessary where the disclosure of pharmacological activity is reasonably based on the probative evidence."[77] The *Iizuka* court concluded that "[w]e perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question."[78]

The C.A.F.C. held that Iizuka's priority Japanese patent application disclosed sufficient information to enable one skilled in the art to use the invention under 35 U.S.C. §112, first paragraph. The Iizuka court found that the invention claimed a pharmacological activity, not a specific human therapeutic use. The Iizuka court agreed with the Board that the applicant's failure to disclose a dosage range was not fatal to enabling the invention. Specifically, the C.A.F.C. ruled that one skilled in the art, without inventive skill or undue experimentation, could determine the proper dosage ranges for the claimed invention. The Iizuka court made it clear that its enablement analysis would have been different if Iizuka had claimed a therapeutic use rather than a pharmacological activity for its compounds.[79] It is settled law that a specification must enable the claimed invention. Therefore, the quanta of evidence sufficient to meet the enablement threshold for pharmacological claims, is by definition different, e.g., lower than for pharmaceutical (human therapeutic) claims.

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[75] 753 F.2d at 1050.
[76] *Id.*
[77] *Id.*
[78] *Id.* at 1051.
[79] *See e.g., In re Gardner*, 427 F.2d 786, 166 U.S.P.Q. 138 (1970).

K. The Two-Step Analysis Applied

Eight years after the *Iizuka* case, the C.A.F.C. had another opportunity to consider the PTO's rejection of an application under 35 U.S.C. §§101/112, first paragraph.[80] In *In re Ziegler*, the Board sustained the Examiner's rejection of the claims on three grounds: (1) under 35 U.S.C. §102(g)[81]; (2) 35 U.S.C. §102(e)[82] in view of a prior art reference because the Germany priority application failed to comply with 35 U.S.C. §112; and (3) 35 U.S.C. § 112, first paragraph for an inadequate written description.

The issue of interest herein was whether the Examiner and the Board were correct to conclude that Ziegler was not entitled to the priority date of his German application under 35 U.S.C. §119[83] because "that application failed to disclose a practical utility for, and because it failed to contain a written description of, the claimed polypropylene."[84] Citing *Iizuka*, the *Ziegler* court stated that "[t]he how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. §101 that the specification disclose as a matter of fact a practical utility for the invention."[85] According to the *Ziegler* court, "[i]f the application fails as a matter of fact to satisfy 35 U.S.C. §101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. §112."[86]

The *Ziegler* court applied the two-pronged utility analysis announced in Iizuka. Specifically, the C.A.F.C. found that the disclosure in Ziegler's German application that "a polymer is plastic-like" was an insufficient assertion of utility.[87] According to the C.A.F.C.:

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[80] *In re Ziegler*, 992 F.2d 1197, 26 U.S.P.Q.2d 1600 (Fed Cir. 1993). In this case Karl Ziegler appealed the Board's affirmance of the Examiner's rejection of a claim to polypropylene. On August 3, 1954 Ziegler filed a German patent application entitled "Process for Polymerization and Copolymerization of Olefins." On June 8, 1955 Ziegler filed an analogous application in the United States claiming the August 3, 1954 priority date of the original German application. Because of the pendency of an interference, the PTO suspended the prosecution of the U.S. application for a number of years. The final rejection of Ziegler's claims was considered and sustained by the C.A.F.C. in *In re Ziegler*, 833 F.2d 1024 (Fed Cir. 1987). On October 15, 1987 Ziegler filed the application at issue in this case as a continuation-in-part of the parent application.

[81] *See*, n. 16, *supra*.

[82] *Id.*

[83] 35 U.S.C. §119 states that "An application for an invention filed in this country by any person who has ... previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed..."

[84] 992 F.2d at 1200 [text added].

[85] *Id.*

[86] *Id.* at 1201.

[87] In a prior interference proceeding involving the Ziegler application, the C.C.P.A. made this holding, therefore Ziegler was collaterally estopped from making a contrary argument in this case. *See*, *Anderson v. Natta*, 480 F.2d 1392, 1399, 178 U.S.P.Q. 458, 463 (C.C.P.A. 1973).

> Ziegler did not assert any practical use for the polypropylene or its film, and Ziegler did not disclose any characteristics of the polypropylene or its film that demonstrated its utility. Ziegler did not even assert that the polypropylene was useful in applications where any of the solid plastics were used. Rather, Ziegler said the polypropylene was 'plastic-like.' And we have already adjudicated that that assertion is insufficient.[88]

In upholding the PTO's decision to reject Ziegler's claimed priority date, the C.A.F.C. described a possible pitfall if the utility requirements of §101 was lowered. The C.A.F.C concluded:

> We are convinced that, at best, Ziegler was on the way to discovering a practical utility for polypropylene at the time of the filing of the German application; but in that application Ziegler had not yet gotten there. It would be unlawful as well as unfair to permit Ziegler to 'file an application for a promising chemical compound in a foreign country, ... have up to one year to determine a practical utility before filing in the United States and yet claim an earlier date of invention under 35 U.S.C. §119.[89]

L. The Utility Dynamic – Analysis of the Invention As Claimed

The legal standard for utility is clearly stated in 35 U.S.C. §101 and interpreted by the United States Supreme Court in *Brenner v. Manson*. The foregoing case law indicates that the PTO must evaluate the claimed invention for its utility. It is also clear that the threshold for utility is dynamic – rising or falling – with the character of the claim. Human clinical data is simply not the utility standard for all biotechnology inventions. The Supreme Court's language that substantial utility must exist in currently available form does not give group 1800 Examiners the authority to ratchet up the utility standard for all biotechnology inventions whether they are compositions of matter, method of making, or method of use claims.

In order to understand and apply the *Brenner* court's holding, the Examiners must understand the context of the Supreme Court's decision, e.g., its procedural history and the relevant case law. Interpreted as a whole, the federal case law indicates the utility requirement is, and has traditionally been, a low standard. In addition, there is a constitutional mandate that patents are to be granted to promote the useful arts, e.g., encourage early and complete disclosure to the public in exchange for a commercial advantage of exclusivity in the market place for a fixed amount of time. By establishing a uniform requirement of *in vivo* (human clinical) data for any claim that may have a potential human therapeutic use, the PTO disregards case law, the plain meaning of §101, and the mandate of Article 1, Section 8, Clause 8 of the U.S. Constitution. The

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[88] 992 F.2d at 1203.

[89] *Id., quoting, Yasuko Kawai v. Metlesics*, 480 F.2d 880, 886, 178 U.S.P.Q. 158, 163 (C.C.P.A. 1973).

PTO's utility/enablement requirements for claims that have potential human therapeutic application seem to be evolving into a standard of commercial viability because of its repeated attempts to require human clinical data and safety and efficacy results. This trend has evolved into a *de facto* actual reduction to practice standard for claimed inventions with potential human applications.

M. Practical Utility – The PTO's Response in the New Proposed Guidelines

In the supplementary information provided by the PTO in its request for comments on the new proposed utility examination guidelines, the PTO stated that the utility requirement requires that the claimed invention have "real world value."[90] After reviewing the *Brenner v. Manson* and *Nelson v. Bowler* decisions, the PTO now states that "practical utility" and similar phrases mean that "the Examiner should accept as sufficient any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit."[91] In so stating, the PTO has retreated from its view that inventions that claim a human therapeutic use must over-come a higher utility threshold.[92]

Case law clearly demonstrates and the PTO now formally recognizes that "[t]o violate §101, the claimed device must be totally incapable of achieving a useful result."[93] According to the PTO, "wholly inoperative inventions are not useful inventions under 35 U.S.C. §101. In addition, the PTO concedes that Examiners should not label an asserted utility of an invention as "incredible" unless "it is clearly appropriate to do so," e.g., unless the invention is, for example a perpetual motion machine.[94]

V. Proof of Operability for Human Therapeutic Inventions

A. Rejections Must Be Based On Evidence – Not Examiner Speculation

According to a recent decision of the C.A.F.C., "[t]o meet the utility requirement, the Supreme Court has held that a new product or process must be shown to be "operable" – that is, it must be 'capable of being used to effect the object proposed.'"[95] The courts have interpreted the

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[90] 60 F.R. 97, Docket No. 941259-4359 (January 3, 1995).
[91] *Id.*
[92] *See e.g.*, 282 F.2d 172 and 292 F.2d 948.
[93] *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 24 U.S.P.Q.2d 1401, 1412 (Fed Cir. 1992).
[94] 60 F.R. 97, *supra,* note 90.
[95] *Stiftung v. Renishaw, plc.*, 945 F.2d 1173, 20 U.S.P.Q.2d 1094, 1100 (Fed Cir. 1991) *quoting, Mitchell v. Tilghman*, 86 U.S. (19 Wall.) 287, 396 (1873).

Supreme Court's use of the word "operable" in *Brenner* to mean that "when a properly claimed invention meets at least one stated objective, utility under §101 is clearly shown."[96]

As early as 1967, the C.C.P.A. ruled that commercial viability is not a prerequisite to patent protection.[97] In *Application of Chilowsky*, the issue was whether the applicant's disclosure was sufficient to enable a skilled artisan to construct a device which can operate as described. The Examiner took the position that "it must appear from [the] applicant's disclosure, not that an operative reactor can probably be built, but that an operative reactor can actually be built."[98] The Board generally adopted the Examiner's position on appeal when it stated that, "[t]he present invention is obviously speculative, suggesting a series of proposals which might possibly be used for the stated purpose."[99]

The C.C.P.A. observed that neither the board nor the Examiner pointed out any specific element of the applicant's claims that was shown to be, or, considered inoperative. Rather, the Examiner and board made general allegations that the invention might not work because of several theoretical difficulties that might arise during construction. The C.C.P.A. stated that the PTO's principles in determining operativeness and sufficiency of disclosure should be uniform but:

> The character and amount of evidence may vary, depending on whether the alleged operation described in the application appears to accord with or to contravene established scientific principles or to depend upon principles alleged but not generally recognized; but the degree of certainty as to the ultimate fact of operativeness or inoperativeness should be the same in all cases.[100]

In reversing and remanding the case, the Chilowsky court reminded the PTO that an application must be judged on what it discloses, e.g., what is claimed, not by the supposed mental state of the applicant at the time the application was filed.[101] If the disclosure is sufficient to enable a skilled artisan to practice the invention, it simply does not matter whether the applicant understood or explained all the principles underlying the invention. In addition, the Chilowsky court cautioned the PTO that commercial success is not necessary to support a patent application.

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[96] *Id.*, *See also*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed Cir. 1983), *cert. denied*, 469 U.S. 835 (1984).

[97] *Application of Chilowsky*, 229 F.2d 457, 463, 108 U.S.P.Q. 321 (C.C.P.A. 1956). This case was an appeal from the Board's affirmance of the Examiner's rejections of all claims to a method and apparatus for utilizing thermal energy resulting from the atomic decomposition of uranium and its compounds.

[98] *Id.* at 461.

[99] *Id.*

[100] *Id.* at 462.

[101] *See also, Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 220 U.S.P.Q. 592, 596 (Fed Cir. 1983) where the court said that "[w]hile a patent covering a meritorious invention should not be struck down because the patentee has misconceived the scientific principle of his invention, the error cannot be overlooked when the misconception is embodied in the claim." The *Raytheon* court also said that "[b]ecause it is for the invention as claimed that enablement must exist, and because the impossible cannot be enabled, a claim containing a limitation impossible to meet may be held invalid under §112."

The C.C.P.A. told the PTO that all applicants are "entitled to specific information as to the grounds on which their applications are rejected and should not be met with anything in the nature of a blanket rejection based on the comparatively recent development of the art and the difficulty which has been experienced in producing commercial devices."[102]

Although *Chilowsky* was decided in 1956 and involved atomic energy, its lesson is easily applied to the current clash between the biotechnology industry and the PTO. *Chilowsky* teaches that commercial viability is not a requirement of patentability under §112 and that blanket rejections of claims because the technical area is relatively new, e.g. the current §101/112 rejections, are not appropriate.[103] Finally, the Chilowsky court emphasized that the principal underlying operativeness under §112 should remain uniform; but, the quantum of evidence needed to reach that threshold varies with the invention as claimed, e.g., less evidence for composition of matter and method of making claims and more evidence for method of use claims.

B. Applicants Claims are Prima Facie Useful, Unless They Are Unreasonable on Their Face

Eleven years after *Chilowsky*, the C.C.P.A. decided a chemical case along the same lines, e.g., that the PTO again inappropriately tried to ratchet up the amount of evidence needed to assert patentability, in this case, statutory usefulness under §101.[104] The application contained composition of matter and method of use claims in the specification for isoflavone compounds useful for treating vascular, inflammatory, and vitamin-P deficiency disorders.

Interpreting prior case law as requiring proof of usefulness[105], the Examiner rejected the claims for an "absence of clear, convincing, scientific evidence that the composition is safe and effective for all the purposes intended."[106] In addition, the Examiner found "no showings in the case of statistically significant therapeutic treatments of vascular disorders, by the claimed methods, with lack of toxicity to the patient, when applied to humans and animals suffering from vascular disorders."[107] While arguing that his specification contained sufficient evidence of usefulness, the applicant, in response to the Examiner's rejections submitted affidavits describing

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[102] 292 F.2d at 463.

[103] *See*, 724 F.2d 592, 220 U.S.P.Q. at 599. Lack of enablement cannot coexist with infringement and commercial success: In the context of infringement litigation, evidence that the alleged infringing party used a properly claimed device constitutes proof that the device is enabled because "[p]eople rarely, if ever, appropriate useless inventions." The court also observed that enablement is further supported when there is evidence that the claimed invention has met with commercial success.

[104] *Application of Gazave, 379* F.2d 973, 154 U.S.P.Q. 92 (C.C.P.A. 1967). Gazave appealed the Board's affirmance of the Examiner's rejection of his process and composition claims for lack of proof of therapeutic utility.

[105] *See e.g., In re Krimmel*; *In re Novak*, 306 F.2d 924, 49 C.C.P.A. 1283 (C.C.P.A. 1962); and *Commonwealth Engineering Co. v. Ladd, D.C.*, 199 F.Supp. 51 (D.C.D.C 1961).

[106] 379 F.2d at 975.

[107] *Id.* at 976.

the clinical use of one of the claimed compounds in treating vascular disorders. The Examiner maintained his rejection that the record did demonstrate that the claimed compounds were safe and effective for all of the alleged uses. The Board agreed in substance with the Examiner's arguments.

On appeal, the C.C.P.A. reminded the PTO that the "amount of evidence required depends on the facts of each individual case."[108] In addition, the C.C.P.A. said that "[i]n the absence of any apparent reason why the compounds disclosed will not so function, or of any evidence showing that they actually do not, the statements in the application are generally deemed sufficient."[109] Therefore, the C.C.P.A. reversed the decision of the Board stating that "appellant's assertions of usefulness in his specification appear to be believable on their face and straight forward, at least in the absence of reason or authority in variance."[110] In its decision, the C.C.P.A. made it clear that the PTO has the initial burden to demonstrate that an applicant's claims[111] are not believable on their face with respect to their claimed usefulness. In other words, an applicant's claims are *prima facie* useful, unless they are unbelievable on their face.

C. Proof of Operability for Human Therapeutic Inventions – The PTO's Response in the New Proposed Guidelines

Citing to *In re Chilowsky* and *In re Gazave*, the PTO concedes that "[i]nventions asserted to have utility in the treatment of human or animal disorders are subject to the same legal requirements for utility as inventions in any other field of technology."[112] According to the new guidelines, Examiners should be guided by the principle of "credibility" in examining inventions for utility. The PTO now recognizes that "[i]f the asserted utility is credible, there is no basis for an Examiner to challenge such a claim on the grounds that it lacks utility under §101."[113]

According to the new guidelines, the Examiner determines credibility by determining whether one skilled in the art would consider the assertions by the applicant to have any reasonable scientific basis. In making credibility determinations, the Examiner must consider the full record and any information that is generally known in the art concerning the asserted utility.

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[108] *Id.* at 977; *See also, Bluestone v. Schmerling*, 265 F.2d 948, 121 U.S.P.Q. 417 (C.C.P.A. 1959).
[109] 379. F.2d at 977.
[110] *Id.*
[111] *See, Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 220 U.S.P.Q. 592, 597 (Fed Cir. 1983) *quoting, Environmental Designs, Ltd. v. Union Oil Co. of California*, 713 F.2d 693, 699, 218 U.S.P.Q. 865, 871 (Fed Cir. 1983): "[t]he specification must be sufficiently explicit and complete to enable one skilled in the art to practice the invention, while a claim defines only that which the patentee regards as his invention. The claim, not the specification, measures the invention. The argument that claim 1 must include a limitation found in the specification is thus legally unsound." (citations omitted).
[112] 60 F.R. 97, note 90 *supra.*
[113] *Id.*

VI. §§101/112 Rejections: Inoperative Inventions Which Therefore Lack Utility

A. Evidentiary Support For Examiner Rejections Is Required

In a chemical case, the C.C.P.A. set forth how the PTO should evaluate claims under §112, first paragraph.[114] In discussing the PTO's enablement rejection of the applicant's method of use claims, the *Marzocchi* court chastised the PTO for its concern over the applicant's use of a generic term that encompassed a considerable number of compounds. The C.C.P.A. told the PTO that its concern should be over the truth of the applicant's assertion. The C.C.P.A. stated that:

> As a mater of Patent Office practice, then a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt does exist, a rejection for failure to teach how to make and/or use will be proper on that basis; such a rejection can be overcome by suitable proofs indicating that the teaching contained in the specification is truly enabling.[115]

The *Marzocchi* court's interpretation of the Examiner's initial burden of proof for an enablement rejection is consistent with *In re Chilowsky* and *In re Gazave*. A specification is considered enabled unless there is reason to doubt the objective truth of the statements contained therein. However, in new areas of technology, the *Marzocchi* court found that the PTO may be confronted with assertions made in a specification that are *prima facie* unbelievable simply because the area of science is relatively new and undeveloped. When this happens, a clash occurs between the constitutional mandate that patents be granted to reward inventors for their early and full disclosure of inventions that meet the statutory criteria and the examination procedures and standards used by the PTO to ensure that inventions meet these statutory criteria.

The *Marzocchi* court cautioned the PTO to be conservative when evaluating the objective truth of statements in new areas of technology:

> In the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create doubt as to the accuracy of a particularly broad

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[114] *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (C.C.P.A. 1971). The applicant in this case appealed the Board's affirmance of the Examiner's rejections under 35 U.S.C. §§103 and 112, first paragraph of the applicant's technique for improving the adhesion characteristics between glass and vinyl polymer resins.

[115] *Id.* at 369.

> statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles.[116]

However, the C.C.P.A made it clear that the Examiners have the burden to explain why they doubt the truth or accuracy of an applicant's statements and to support their rejections with either "acceptable evidence" or "reasoning which is inconsistent with the contested statement."[117] Therefore, Examiners have a burden to provide evidence, not just speculation, to support their rejections.

The *Marzocchi* court's conservative enablement analysis of new or complex technologies is manifest in its assertion that the "unpredictability" of chemical reactions, e.g., the relatively low level of understanding by the skilled artisan in the area, may be sufficient to doubt the objective truth of a specification. In addition, the *Marzocchi* court imposed a relatively low evidentiary burden on the Examiner, e.g., an argument that is inconsistent with the contested statement. The *Marzocchi* court's decision defined the boundaries of the battlefield between applicants and the PTO over what constitutes the Examiner's *prima facie* case of enablement. Specifically, applicant's must attack the Examiner's grounds for questioning the accuracy of statements in the specification. The focus of the battle shifts away from the claimed invention to the predictability of the pertinent art. In *Marzocchi*, the C.C.P.A. found the PTO's grounds for questioning the accuracy of the statements in the specification insufficient and overturned the enablement rejection.

B. The Scope of the Claims Determine the Required Scope of Disclosure

In a case decided the same year as *In re Marzocchi*, the C.C.P.A. considered another §101/112, first paragraph case in the chemical arts and upheld the PTO's rejection of the applicant's claims because they were incredible.[118] According to the *Fouche* court, the Examiner and the board doubted whether the claimed compounds would be useful for therapeutic purposes. The *Fouche* court said that "[w]hile this position could have led to a rejection under 101, it also leads to a rejection under the how-to-use provision of 112, since if such compositions are in fact useless, appellant's specification cannot have taught how to use them."[119]

According to the *Fouche* court, the applicant need not disclose examples to enable one skilled in the art to use the claimed invention. However, the applicant must disclose that quanta of

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[116] *Id.* at 369-370.

[117] *Id.*

[118] *In re Fouche*, 439 F.2d 1237, 169 U.S.P.Q. 429 (C.C.P.A. 1971). The C.C.P.A. upheld the Board's affirmance of the Examiner's rejection of the applicant's composition of matter claims to dibenzocycloheptadiene derivatives that have anti-depressant, neuroleptic and tranquilizing properties.

[119] *Id.* at 1243.

information sufficient to enable the skilled artisan to practice the entire invention. In other words, the broader the scope of the claims, the more the applicant must disclose, unless such knowledge is already available to the skilled artisan.[120] The C.C.P.A. held that the Examiner was justified in asserting that the applicant's claims were incredible and that the applicant failed to meet his burden, e.g., he failed to show that his disclosure of how to use the claimed compounds for therapeutic purposes was true.[121]

C. Public Policy Encourages Early Disclosure of Novel Compounds With Therapeutic Utility

Ten years after *Marzocchi* was decided, the C.C.P.A. decided another enablement case in the chemical arts. In *In re Bundy*, the C.C.P.A. considered an applicant's appeal from the Board's affirmance of the Examiner's enablement rejection of Bundy's novel composition of matter claim to a new series of analogs of naturally-occurring prostaglandins.

The applicant stated in the specification that the novel prostaglandin analogs were more potent and had a longer biological half-life than the naturally occurring compounds. But, the applicant did not disclose a specific use for the claimed compounds, e.g., dosage information. However, the applicant did disclose that the claimed compounds possessed activity similar to the known E-type prostaglandins. The Examiner rejected the claim under §112, first paragraph "as being inadequately supported by the instant specification, in that not a single example was directed to one of the claimed compounds."[122] The issue before the C.C.P.A. was whether the applicant's disclosure that the claimed compounds were useful and used in the same manner as known prostaglandins was sufficient to satisfy the how-to-use requirement of 35 U.S.C. §112, first paragraph.

In deciding the case, the *Bundy* court referred to *In re Gardner*[123] and *In re Marzocchi* for the proposition that the PTO must have adequate support to challenge the credibility of an applicant's assertions of utility before the burden is shifted to the applicant to provide rebuttal evidence. The C.C.P.A. found that the applicant disclosed some activity of the claimed compounds coupled with knowledge as to the use of the disclosed activity. Because the applicant did not disclose human dosage information or even animal tests with the claimed compounds, the C.C.P.A. focused its analysis on whether the applicant enabled the skilled artisan to use the claimed compounds.

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[120] *Id.* at 1242.
[121] *Id.* at 1243.
[122] *In re Bundy*, 642 F.2d 430, 432-33, 209 U.S.P.Q. 48 (C.C.P.A. 1981).
[123] 475 F.2d 1389, 177 U.S.P.Q. 396 (C.C.P.A. 1973).

The *Bundy* court held that the skilled artisan would be able to determine specific dosages for the claimed compounds. The court observed that the applicant's sole claim was a composition claim; no therapeutic use was claimed. The court concluded that the applicant had complied with the how-to-use requirement of §112 and that:

> Early filing of an application with its disclosure of novel compounds which possess significant therapeutic use is to be encouraged. Requiring specific testing of the thousands of prostaglandin analogs encompassed by the present claim in order to satisfy the how-to use requirement of §112 would delay disclosure and frustrate, rather than further, the interests of the public.[124]

D. Lack of Utility and Therefore Non-Operability Rejections

One year before *Bundy*, the C.C.P.A. decided a case in which the PTO rejected claims to pharmaceutical compositions and methods of treating acute myeloblastic leukemia in human patients.[125] The appellant's application contained declarations reporting that one of the claimed compounds was partially successful in the treatment of patients with acute myeloblastic leukemia during a clinical trial. Two other declarations that accompanied the patent application disclosed data for seven of the claimed compounds in mice for sub-acute toxicity activity against sarcoma 180 tumors and activity against leukemia L 1210.

The Examiner rejected both the composition of matter and method of use claims under §§101/112, first paragraph for lack of proof of utility and therefore nonoperability. The Examiner stated that there was "insufficient evidence of operativeness in the record that the various compositions were safe and effective to treat acute myeloblastic leukemia in human patents."[126] The Examiner further asserted that the "instant claims are directed to an incredible utility."[127] After considering all of the declarations, the Examiner concluded that "it would not be reasonable for a person of ordinary skill in the art to presume that these novel compounds would be safe and effective for the incredible utility alleged in the absence of verified data substantiating the said allegations of use."[128]

On appeal, the Board sustained the Examiner's rejection except with regard to claims 15 and 35 which were directed to the specific compound used in the clinical trial and its method of use. The Board did not accept the applicant's argument that utility for the rest of the novel

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[124] 642 F.2d at 434.

[125] *In re Jolles*, 628 F.2d 1322, 206 U.S.P.Q 885 (C.C.P.A. 1980). The appellant's application contained composition of matter claims to certain naphthacene derivatives useful in treating leukemia and method of use claims for the treatment of leukemia by administering to a human patient the claimed naphthacene derivatives.

[126] *Id.* at 1325.

[127] *Id.*

[128] *Id.*

compounds encompassed by the claims was sufficiently disclosed in the specification by analogy to structurally similar compounds, e.g., daunorubicin and doxorubicin, which where known to be effective in the treatment of acute myeloblastic leukemia. The Board concluded that "the quantum of evidence represented by a single compound falls far short in proving the asserted utility [of all the claimed compounds]."[129]

Although the rejections were under §§101/112, the C.C.P.A. considered the rejections to turn on the utility issue. According to the C.C.P.A. the "dispositive issue is whether the applicant has submitted sufficient evidence to establish his asserted utility of the composition of the rejected claims for the treatment of acute myeloblastic leukemia in human patients."[130] The quantum of evidence sufficient to demonstrate utility under §101 is determined by reference to the level of knowledge of the skilled artisan. The *Jolles* court recognized that the type of claim under review also influences the sufficiency of the evidence for proof of utility. Finally, whether the alleged utility is consistent with, or challenges established scientific principles also influences the character and quantum of evidence required for utility.

The *Jolles* court chastised the PTO for not providing support for its assertion that the applicant's asserted utility was "incredible". The *Jolles* court, consistent with the *Marzocchi* holding, said that "[w]hen utility as a drug, medicant, and the like in human therapy is alleged, it is proper for the Examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the allegations as obviously correct."[131] Although the *Jolles* court did not define the character of the substantiating evidence, in most cases, human clinical data is not required. Reference to what may be called the "utility dynamic," e.g., the type of claim, the level of knowledge in the art, and accordance with accepted principles, will determine the type and amount of evidence required to rebut the Examiner's *prima facie* case. The battle over the patentability of the claimed naphthacene compounds turned on the predictability of the art, or what the skilled artisan would accept as correct.

The *Jolles* court told the Board that its reliance on *In re Krimmel* was misplaced, e.g., that in appropriate circumstances animal data is predictive of success in humans. Citing two prior C.C.P.A. cases, the *Jolles* court clearly stated that animal data may be sufficient for a demonstration of utility in human therapeutic claims.[132] The *Jolles* court held that the Board:

> found the quantum of evidence represented by the single derivative to fall far short in proving the asserted utility for the remaining claimed derivatives. The board erred in this finding by failing to give sufficient weight to the similarity of the remaining claimed

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[129] *Id.* at 1326.

[130] *Id.*

[131] *Id.* at 1327. *See also, In re Novak*, 306 F.2d 924, 134 U.S.P.Q. 335 (1962).

[132] *See e.g., In re Bergel*, 292 F.2d 955, 130 U.S.P.Q. 206 (C.C.P.A. 1961) and *In re Buting*, 418 F.2d 540, 163 U.S.P.Q. 689 (C.C.P.A. 1969).

derivatives to the derivative in allowed claims 15 and 35 when considered with the Maral animal tests.[133]

Similarly, in *In re Ziegler* discussed *supra*, the appellant argued that he was entitled to the priority date of his original German patent application, but the court sustained the PTO's assertion that the German application failed to meet the requirements of §§101/112. The Ziegler court stated that "[t]he how to use prong of §112 incorporates as a matter of law the requirement of 35 U.S.C. §101 that the specification disclose as a matter of fact a practical utility for the invention."[134] With reference to the "utility dynamic," the C.A.F.C. reviewed Ziegler's German application and found that its assertion that the claimed polymer was "plastic-like" was not believable on its face, e.g., the disclosure did not assert a benefit in currently available form. Because Ziegler's German application failed to disclose a practical utility, the application also failed as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. §112, first paragraph and therefore, it was not entitled to the benefit of the foreign priority date under 35 U.S.C. §119.

E. Procedural Considerations – The PTO's Response in the New Proposed Guidelines

Retreating from its initial position, the new guidelines clearly re-embraces the Federal court's interpretation of a proper utility analysis. Recognizing that the claimed invention is the proper focus of the utility analysis, the PTO states, "irrespective of the category of invention that is claimed (e.g., product or process), an applicant need only disclose one credible utility for the claimed invention to satisfy §101. If one asserted utility is credible, utility for the claimed invention as a whole is established."[135] Citing *In re Krimmel*, the PTO states that "Examiners should be especially careful not to read into a claim unclaimed results, limitations or embodiments of an invention."[136]

After determining the scope of the invention by reference to the claims, the Examiner must next determine whether there is an asserted or readily apparent utility. According to the new PTO guidelines, the Examiner "should review the specification to ascertain if there are any statements asserting that the claimed invention is useful for any particular purpose."[137] If the Examiner cannot find an explicit statement of utility in the specification, the Examiner must next determine whether a utility would be readily apparent to one skilled in the art from the disclosure or from the characteristics of the invention.

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[133] 628 F.2d at 1327.
[134] 992 F.2d at 1200, 26 U.S.P.Q.2d at 1603. *See also*, 753 F.2d at 1042-1044, 224 U.S.P.Q at 741-742; 439 F.2d at 1243; and 169 U.S.P.Q. at 434.
[135] 60 F.R. 97, note 90, *supra*.
[136] *Id.*
[137] *Id.*

Citing several Federal court cases[138], the new guidelines acknowledge that an asserted utility creates a presumption of utility. "To overcome this presumption, the Examiner must establish that it is more likely than not than not that one of ordinary skill in the art would doubt the truth of the statement of utility. In other words, the Examiner must show that the asserted utility is not credible."[139]

As stated before, the PTO now recognizes that whether an asserted utility is credible is a question of fact to be evaluated by the Examiner in light of the knowledge of one skilled in the art with reference to the invention as claimed and the specification. Recognizing the holding of *In re Jolles*, the new guidelines state that whether an asserted utility is "incredible" is a conclusion and not a starting point.[140] In particular, the PTO guidelines now state:

> Special care should be taken when assessing the credibility of an asserted therapeutic utility for a claimed invention. In such cases, a previous lack of success in treating a disease or condition, or the absence of a proven animal mode for testing the effectiveness of drugs for treating a disorder in humans, should not, standing alone, serve as a basis for challenging the asserted utility under §101.[141]

Procedurally, the initial burden is on the Examiner to establish a *prima facie* case of lack of utility and to provide evidentiary support thereof.[142] As stated above, a simple declaration that an asserted utility is "incredible" is insufficient. Under the new guidelines, the Examiners must with specificity:

(1) Identify the scientific basis for the conclusion on lack of utility;

(2) Explain why any evidence of record that supports the asserted utility would not be persuasive to one of ordinary skill in the art; and

(3) Provide evidentiary support for the *prima facie* case.

Only when documentary evidence is not readily available should the Examiner attempt to satisfy the PTO's requirement solely through an explanation of the relevant scientific principles.[143]

Evidentiary requests by an Examiner to an applicant in order to support an asserted utility should be the exception rather than the rule. The new guidelines recognize that in "appropriate situations", e.g., if the asserted utility is not consistent with the evidence of record and current

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[138] *See e.g.*, 628 F.2d 1322; *In re Irons*, 340 F.2d 974 144 U.S.P.Q. 351 (1965); 503 F.2d 1380; 566 F.2d 1154, 1159; 60 F.R. 97, note 90, *supra*. It should also be noted that deliberately false statements are grounds for rendering an issued patent unenforceable under 37 C.F.R. §1.156. Threat of rendering a patent unenforceable due to inequitable conduct should alone be sufficient to keep applicants honest in their assertions of e.g., utility.

[139] 60 F.R. 97, note 90, *supra*.

[140] *Id.*

[141] *Id.*

[142] *Id.*

[143] *Id.*

scientific knowledge, the PTO may require an applicant to substantiate a utility for a claimed invention. "However, requests for additional evidence should be imposed rarely, and only if necessary to support the scientific credibility of the asserted utility."[144]

Once the Examiner has properly rejected a claimed invention for lack of utility, the burden shifts to the Applicant to rebut the *prima facie* case. The Applicant has several tools for rebutting the Examiner's *prima facie* case including: amending the claims, submission of a 37 C.F.R. §1.132 declaration, etc. Once the Applicant submits a response, the Examiner must review the complete record, including the claims, to determine if it is appropriate to maintain the lack of utility rejection.

The new guidelines formally recognize federal case law that holds that the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed. In addition, the new guidelines recognize that "beyond a reasonable doubt" is not the standard for determining whether to accept an asserted utility. Rather, "evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true."[145] Finally, the guidelines recognize that Examiners must provide evidentiary support for their conclusions. Blanket conclusions of unpatentability, without clear evidentiary support, is not a sufficient basis for a rejection.

VII. Human Therapeutic Cases

A. Human Safety and Efficacy Data Is Usually Not Necessary To Comply With § 101

Lack of safety and efficacy is a reoccurring theme in the PTO's rejections of many of the applications cited in the case law summarized *supra*. By its continued reference to whether an invention that claims a therapeutic use is safe and effective, the PTO seems to have an unwritten policy of protecting the U.S. public from inventions that claim a therapeutic utility but do not meet the unpublished PTO standards. However, the Federal courts have continuously reminded the PTO that safety and efficacy are not elements of patentability, e.g., are not elements of 35 U.S.C. §101 or §112, first paragraph.[146]

As early as 1962, the C.C.P.A. in *In re Hartop*, said that safety and efficacy are not required elements of an applicant's specification for claims that may encompass a human therapeutic use.[147] In *In re Hartop*, the applicant's claimed a "therapeutic composition" to a

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[144] *Id.*
[145] *Id.*
[146] *See, e.g.*, 628 F.2d 1322, 206 U.S.P.Q. 885; 433 F.2d 1034, 167 U.S.P.Q. 565; 379 F.2d 973, 154 U.S.P.Q 92; *In re Hartop*, 311 F.2d 249, 135 U.S.P.Q. 419 (1962); and 292 F.2d 948, 130 U.S.P.Q. 215.
[147] 311 F.2d 249, 135 U.S.P.Q. 419.

concentrated, alkaline, water-free, organic solvent of a thiobarbituric acid compound useful as anesthetic and hypnotic agents. The Examiner required the applicants to provide data that demonstrated the claimed invention was safe in humans because he was of the opinion that vascular damage at the site of the injections was a possibility. Despite the applicant's disclosure of the invention's safety and efficacy in rabbits, the Examiner rejected the claims under §101. The Examiner stated and the Board agreed that:

> Applicants have not affirmatively demonstrated the safety in humans of the claimed highly alkaline solutions employed. Tests in animals will not reveal phlebitis or venous thrombosis produced by excessively alkaline materials excepting by autopsy; in humans, pain directs attention to associated symptoms such as inflammation or coolness of the extremity.[148]

The C.C.P.A. reversed the PTO, when it concluded that proof of human safety and efficacy are not the standards for utility under §101 for composition claims that may encompass a human therapeutic use. The court held that the applicant's disclosure that the claimed invention was safe and effective in rabbits was sufficient to meet the utility requirement under §101.

> Bearing in mind that absolute proof of such a proposition as 'safety' of a drug or medicament is impossible and that 'proof' of 'safety' is relative with the degree of 'proof' dependent on the quantity and quality of the available evidence, bearing in mind what evidence of 'safety' has been submitted in the case at bar, and bearing in mind that inherent in the concept of the 'standard experimental animal' is the ability of one skilled in the art to make the appropriate correlations between the results actually observed with the animal experiments and the probable results in human therapy, we hold that appellants' claimed solutions have been shown to be useful within the meaning of 35 U.S.C. §101.[149]

The C.C.P.A. concluded that the F.D.A., not the PTO, is charged with determining whether a drug is safe and effective for the advertisement, use or sale to the U.S. public. The court observed that the standards used by the F.D.A. and the PTO are quite different and that it is not for the courts or the PTO to legislate changes in the utility standards of §101.

B. The F.D.A., Not the P.T.O., Determines When a Drug Is Safe For the Commercial Market

Several years after *In re Hartop*, the C.C.P.A. in *In re Anthony*, held again that the F.D.A., not the PTO, is charged with determining whether drugs are sufficiently safe and effective

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[148] 135 U.S.P.Q. at 424.
[149] *Id.* at 426.

for the commercial market.[150] The issue in *In re Anthony* was whether the PTO was correct when it required the applicant to over-come a lack of utility rejection by requiring evidence that the compounds were both safe and effective. According to the Examiner, because the disclosure did not establish that the compounds were safe and effective, they lacked the utility required by §101. The C.C.P.A. interpreted the PTO's position as follows:

> It is the examiner's position that where a drug, which has a recognized toxic reaction associated with its use coupled with the fact that the nation's safeguarding agent, the Food and Drug Administration, has banned such drug from the market as being unsafe and to date has not lifted such ban; that such drug is not safe for use within the meaning of 35 U.S.C. §101.[151]

While recognizing that safety was traditionally an element in the overall usefulness analysis under §101, the *Anthony* court noted that safety is a relative matter and that "absolute complete proof of safety is realistically impossible."[152] The *Anthony* court took judicial notice that "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."[153] The court continued its analysis of the PTO's use of safety and efficacy arguments in §101 rejections when it stated that Congress clearly gave the statutory authority and responsibility in this area to the FDA not the PTO. In addition, the *Anthony* court observed that the criteria for patentability in the PTO and safety and efficacy in the FDA are fundamentally different.[154]

The Anthony court's analysis makes sense when one considers exactly what a patent conveys, e.g., the right to exclude others from making, using or selling the claimed invention for a statutorily prescribed amount of time.[155] The patent grant does not give the patentee the right to make, use or sell the claimed invention. By granting a patent on an invention that may be useful in human therapy without safety and efficacy data, the PTO is not dodging its responsibility to the U.S. public. Rather, a patent grant tells the public that an invention is useful, novel and

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[150] *In re Anthony*, 414 F.2d 1383, 162 U.S.P.Q. 594, 602, (C.C.P.A. 1969). This case was an appeal from the Board's affirmance of the Examiner's rejection of composition of matter and method of use claims under §101 for lack of utility and §103 for obviousness. The invention claimed the d- and l- isomers of α-ethyltryptamine and their use for treating depression. During the prosecution of the application, the assignee submitted a declaration to over-come the examiner's utility rejection which detailed the clinical trial results of Monase, a compound of the claimed invention. Based on the declaration, the Examiner dropped the utility rejection. Subsequently, the FDA at the assignee's request, suspended further clinical trials because of a finding that Monase was unsafe for use under the test conditions. Thereafter, the examiner reinstated his §101 rejection.

[151] *Id.* at 602.

[152] *Id.* at 603

[153] *Id.* at 603-604.

[154] *Id.* at 604.

[155] *See*, 35 U.S.C. §154.

nonobvious as defined by the patent statute. Whether the patented invention is safe and effective for use in humans is determined by another agency, e.g., the F.D.A.

The requirement of safety and effectiveness data seems to suggest that commercial usefulness is an element of the PTO's §101 analysis. But the *Anthony* court said:

> 'commercial usefulness,' i.e. progress in the development of a product to the extent that it is presently commercially salable in the market place, has never been a prerequisite for a reduction to practice and the subsequent patentability of any of the classes of patentable subject matter set forth in §101, much less the particular class of compositions of matter called drugs.[156]

Furthermore, the *Anthony* court recognized that the constitutional underpinnings of the patent law embody a desire to promote the useful arts by attracting investment capital for further research and development in the area of the invention. The *Anthony* court quotes with approval the appellant's argument that:

> The most important consequence of the grant of a patent in this case is that it would tend to encourage the assignee or a licensee of the assignee to do further work to determine, *inter alia*, whether the claimed invention is in fact responsible for the side effect or whether a New Drug Application can be obtained with due consideration for the possible side effect in spelling out indications for use of the invention. This is the kind of investment the patent system was intended to encourage. This is the kind of investment that will best serve the public in providing safe medications to alleviate mankind's ever present medical problems.[157]

The *Anthony* court reversed the PTO's rejection of the claims under §101 for lack of usefulness. The *Anthony* court stated that the applicant's disclosure met the Commissioner's criteria in the "Guidelines for Considering Disclosures of Utility in Drug Cases":

> Although absolute safety is not necessary to meet the utility requirement under this section (§101), a drug which is not sufficiently safe under the conditions of use for which it is said to be effective will not satisfy the utility requirement. Proof of safety shall be required only in those cases where adequate reasons can be advanced by the examiner for believing that the drug is unsafe, and shall be accepted if it establishes a reasonable probability of safety.[158]

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[156] 414 U.S.P.Q. at 605.

[157] *Id.* at 606, note 15.

[158] *Id.* at 607, note 18, *quoting*, "Guidelines for Considering Disclosures of Utility in Drug Cases," 849 Official Gazette of the U.S.P.T.O. No. 3 (U.S. Department of Commerce, April 16, 1968).

C. Commercial Usefulness Is Not the Utility Standard Under §101

Several years after *In re Anthony* was decided, the C.C.P.A. decided another chemical case in which the applicant's claims were rejected for lack of proof of utility because the disclosure failed to provide human clinical data.[159] The applicant's specification contained both composition and method of use claims to a new source of stannous tin as a cleaning agent for incorporation into e.g., mouth washes, tooth pastes, etc.

The Examiner rejected all claims in the Langer application for lack of proof of utility because "those skilled in the art would not accept applicant's allegation (that the claimed invention was useful in reducing enamel solubility of teeth) as obviously valid and correct."[160] The C.A.F.C summarized the Board's decision to affirm the rejection because the "Examiner's references establish such a strong *prima facie* case for lack of utility ("usefulness") in the entire claimed subject matter that the highest type of evidence (i.e., clinical testing in humans) is required to rebut the *prima facie* case."[161]

The *Langer* court discussed the respective burdens on the applicant and Examiner under the utility requirement of §101:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of §101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope. Assuming that sufficient reason to question the statement of utility and its scope does exist, a rejection for lack of utility under §101 will be proper on that basis; such a rejection can be overcome by suitable proofs indicating that the statement of utility and its scope as found in the specification are true.[162]

The *Langer* court ruled that the Examiner established a *prima facie* case for lack of utility in the entire claimed subject matter because a reference of record provided a basis for one skilled in the art to question the objective truth of the applicant's statement of utility. However, the Langer court disagreed with the Board's ruling that human clinical data was necessary to rebut the Examiner's *prima facie* case. The *Langer* court said:

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[159] *In re Langer*, 503 F.2d 1380, 183 U.S.P.Q. 288 (C.C.P.A. 1974). This appeal is from the decision of the Board, adhered to on reconsideration, affirming the rejection of all the claims in an application entitled, "Dentifrices and Method for Reducing Enamel Solubility" for lack of proof of utility of the claimed subject matter for its intended purpose under 35 U.S.C. §101.

[160] *Id.* at 294.

[161] *Id.* at 297.

[162] *Id.*

> It is not proper for the Patent Office to require clinical testing in humans to rebut a *prima facie* case for lack of utility when the pertinent references which establish the *prima facie* case show *in vitro* tests and when they do not show *in vivo* tests employing standard experimental animals.[163]

The Langer court interpreted the PTO's insistence on human clinical data as tantamount to requiring the applicant establish a commercial usefulness for the claimed invention. The Langer court, referring to its decision in *In re Anthony* reminded the PTO that commercial viability is not the utility standard under §101.

D. How Much Evidence of Utility Is Enough – A Case by Case Analysis

Two years after *In re Langer*, the C.C.P.A. reversed another §101 case in which the Board affirmed the Examiner's rejection of both composition of matter and method of use claims to the treatment of arthritis.[164] The Examiner argued that the appellant's invention was not *per se* believable without proof and that the burden was on the appellant to provide evidence to support the alleged utility.[165]

The Board reversed the Examiner's rejection with respect to the claims to lower animals but affirmed the rejection of the claims to humans. The Board used the Examiner's language in its conclusion:

> Proof of utility must be commensurate in scope with the allegations of utility set forth in the disclosure. Since human use is alleged for the claimed composition, utility commensurate in scope with the disclosed utility is in order. The Examiner is mindful of the fact that utility supporting human use can be adduced with animal tests, but so far as the record of this application is concerned, the tests do not corroborate human usefulness.[166]

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[163] *Id.*

[164] *In re Malachowski*, 530 F.2d 1402, 189 U.S.P.Q. 432 (C.C.P.A. 1976). The appellants claimed compositions of matter directed to a preparation consisting of the ignition residue of anthracite coal to be administered orally. The method claims embodied the administration of the preparation to treat arthritis without limitation as to what kind of animal was treated. The appellant disclosed the use of his invention to treat canines, "alluded" to the treatment of equines, and "contemplated" the treatment in humans at a dosage range of 100-1000 mg/100 lbs of body weight.

[165] In the concurring opinion, Judge Markey would have reversed the PTO simply on procedure, e.g., that the Examiner failed in his *prima facie* case: "The legal principle or theory of the cited cases thus support a §101 rejection when the utility shown by the evidence is not commensurate with the scope of all the claims, i.e., when the claim is of such breadth as to read upon both operative and inoperative applications of compounds or methods. I think that principle is wrong, because such claims will never be applied to or enforced against the inoperative compounds or methods encompassed. No one uses things that don't [sic] work. The aged concern over the sale of 'patent medicines' may be safely entrusted to the Food and Drug Administration." 189 U.S.P.Q. at 436.

[166] *Id.* at 434.

The C.C.P.A. framed the issue as whether composition of matter and method claims drafted so broadly as to encompass lower animal and human uses are patentable under §101 when utility has been shown only in lower animals. In reversing the PTO, the C.C.P.A. stated that the "amount of evidence required to overcome a §101 rejection depends on the facts of each case."[167] The C.C.P.A. held:

> Similarly, with regard to the present appeal, even if proof of utility of the claimed invention as an anti-arthritic agent for human beings is lacking, there remains the proven utility as an anti-arthritic agent for lower animals. Having found that the claimed composition has utility as contemplated in the specification, §101 is satisfied and it becomes unnecessary to decide whether it is in fact useful for the other purposes indicated in the specification as possibilities.[168]

E. Human Therapeutic Cases – The PTO's Response in the New Proposed Guidelines

The new guidelines command Examiners to be "particularly careful" in analyzing assertions of therapeutic or pharmacological utility. As a general rule, the new guidelines provide that a "reasonable" correlation between the evidence of record and an asserted utility is sufficient. According to the new guidelines, "evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility."[169] The new guidelines also make it clear that the applicant need not demonstrate that there is a statistically proven correlation between the characteristics of a compound and an asserted therapeutic use. Nor does the applicant have to provide actual evidence of success in treating humans where such a utility is asserted.

In addition, evidence of structural similarity between a claimed compound and other known compounds with particular therapeutic or pharmacological uses may be a sufficient assertion of utility. Finally, the new guidelines recognize that data from *in vitro* and animal testing is generally sufficient to support a therapeutic utility. The PTO's new guidelines recognize that "[i]n no case has a Federal court required an applicant to support an asserted utility with data from human clinical trials."[170]

According to the new guidelines, if a specification contains *in vitro* and/or animal data, "the Examiner should determine if the tests, including the test parameters and choice of animal, would be viewed by one skilled in the art as being reasonably predictive of the asserted utility."[171] The guidelines state that this procedure must be followed whether or not the tests and/or animal models

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[167] *Id.*
[168] *Id.* at 435. *See also, In re Gottlieb*, 328 F.2d 1016, 1019, 140 U.S.P.Q. 665, 668 (C.C.P.A. 1964).
[169] 60 F.R. 97, note 90, *supra.*
[170] *Id.*
[171] *Id.*

are recognized by the art as predictive of human therapeutic utility. The guidelines conclude that "if one skilled in the art would accept the animal tests as being reasonably predictive of utility in humans, they should be considered sufficient to support the credibility of the asserted utility."[172]

Citing *Ex parte Balzarini*, the PTO guidelines also recognize that "[t]here is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders, even with respect to situations where no art-recognized animal models existed for the human disease encompassed by the claims." Human clinical trials are prerequisites for FDA approval not patentability.[173] However, as a general rule, if an applicant initiates human clinical trials for a product or process to treat an indication, the subject of that trial meets the "reasonably predictive of utility" burden .[174]

The new PTO guidelines now specifically recognize that "other agencies of the government," e.g., the F.D.A., are responsible for enforcing standards established by statute for the advertisement, use, sale, or distribution of drugs. Citing several cases discussed *supra*[175], the new PTO guidelines state that "it is improper for an Examiner to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness."[176]

The new PTO guidelines conclude with the statement that "[c]laims directed to a method of treating or curing a disease warrant careful review for compliance with §101."[177] The fact that there is no known cure for a particular disease may not serve as the basis of rejection for lack of utility. According to the new guidelines, the Examiner must establish a *prima facie* case that the asserted utility is not credible. In analyzing method of treating or curing claims, the new guidelines command the Examiner to carefully review the claims. In particular, the guidelines emphasize the difference between claims which treat a symptom of a disease and claims which are directed to curing the disease itself. Finally, the guidelines state that "affidavits from experts in the art indicating that there is a reasonable expectation of success, supported by sound reasoning, usually should be sufficient to establish that such a utility is credible."[178]

VIII. Industry-PTO Advisory Committee

A joint industry-PTO advisory committee may alleviate the above-described problems. This advisory committee could monitor the PTO's examination of biotechnology applications and

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[172] *Id.*
[173] *See e.g.*, 21 U.S.C. §§301-394 and 42 U.S.C. §§ 262, 263.
[174] 60 F.R. 97, note 90, *supra*.
[175] 566 F.2d 1154; 311 F.2d 249; 414 F.2d 1383; *In re Watson*, 517 F.2d 465, 186 U.S.P.Q. 11 (C.C.P.A. 1975); 292 F.2d 948; *Ex parte Jovanovics*, 211 U.S.P.Q. 907 (Bd. Pat. App. & Inter. 1981).
[176] 60 F.R. 97, note 90, *supra*.
[177] *Id.*
[178] *Id.*

identify for the Commissioner any prosecution problems of similar deviations from C.A.F.C. precedent. In this way, a proactive response to any prosecution problem may be formulated quickly before serious injury to biotechnology companies is felt.

Under 35 U.S.C. § 6, the Commissioner is statutorily authorized to convene a joint industry-PTO advisory committee. In addition, the Federal Advisory Committee Act (F.A.C.A) provides rules under which such an industry-PTO advisory committee may function.[179] In fact, the PTO already has several Advisory Committees, e.g., the Public Advisory Committee for Trademark Affairs, Advisory Committee for Patents, and the Advisory Commission on Patent Law Reform.[180]

For example, the Advisory Commission on Patent Law Reform was formed to advise the Secretary of Commerce through the Commissioner of the PTO, on what, if any changes are needed in the U.S. patent system. A similar advisory commission with a narrower function, e.g., identifying discrepancies between federal case law and patent examination procedures is clearly provided for in the law.

An easy and efficient means to initiate a joint industry-PTO advisory commission might be to expand the scope of the Biotechnology Technical Advisory Committee (B.T.A.C.). In the Department of Commerce's Bureau of Export Administration, the B.T.A.C. currently advises the Office of Technology and Policy Analysis with respect to technical questions that affect the level of export controls applicable to biotechnology and related equipment and technology.[181] A subcommittee of the B.T.A.C might be formed in order to accomplish the goal of monitoring the PTO's examination procedures.

IX. Conclusion

Prior to the new PTO guidelines published on January 3, 1995, the standards for utility and operability in Group 1800 did not correspond with the patent law, its own internal rules, and the constitutional mandate to promote the useful arts. The PTO was under a misconception that relaxing its utility/enablement standards for human therapeutic inventions placed the public at risk. However, a patent does not guarantee that the disclosed invention will ever be practiced. The F.D.A. must approve any human therapeutic composition before it can be advertised, used or sold to the U.S. public. Therefore, unlike other technology areas, e.g., the mechanical or electrical

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[179] *See, e.g.*, 5 U.S.C. app. (1976). See also, 41 C.F.R. part 101-6 for the General Services Administration rule on Federal Advisory Committee Management.

[180] For example, in 1989 there were at least 58 advisory committees in the Department of Commerce. *See*, 55 F.R. 18649 (May 3, 1989).

[181] See, 57 F.R. 5247 (February 13, 1992).

arts, in the biotechnology and pharmaceutical field, there is a second layer of government standing between the U.S. public and the patented invention.

According to the M.P.E.P., Examiners should follow two principles when evaluating the sufficiency of the disclosure of utility in "drug" cases:

> (1) The same basic principles of patent law which apply in the field of chemical arts shall be applicable to drugs, and
>
> (2) The Patent and Trademark Office shall confine its examination of disclosure of utility to the application of patent law principles, recognizing that other agencies of the Government have been assigned the responsibility of assuring conformance to the standards established by statute for the advertisement, use, sale or distribution of drugs.[182]

However, the case law demonstrates that the Examining corps and the Commissioner had a different agenda from that disclosed in the M.P.E.P.[183] The old practices of the PTO had the potential to severely limit the development of the biotechnology industry. The PTO's motivation was unclear; perhaps there was a paternalistic feeling by the Examiners that they must protect the public from potentially dangerous pharmaceuticals; or perhaps, the Examiners had insufficient training in how to interpret and apply the case law. In either case, the Examiners, especially in Group 1800, must be provided with more education, especially legal training, to prepare them to properly apply case law during the examination process.

Several themes are discernible from the case law cited herein: (1) The PTO must examine an application for its utility and enablement based on the claimed invention not what the Examiner might imagine that the inventor really thinks the invention is. (2) The Supreme Court's decision in *Brenner v. Manson* is not a basis for automatically rejecting claims unsupported by human clinical data that might encompass a human therapy for lack of utility and therefore nonenablement. The Examiners must evaluate the invention as claimed with reference to what is disclosed in the specification. In *Brenner v. Manson*, the applicant failed to disclose any utility for the claimed invention. (3) The PTO must distinguish between pharmacological and pharmaceutical claims. The utility dynamic will necessarily be different depending upon the type of claim. (4) Only in situations where a human therapy is specifically claimed may human clinical data be required, and even then, animal data may be an appropriate substitute if the model is accepted by those skilled in the art to be predictive of the human condition. (5) The Examiners must provide evidence, e.g., citations to scientific literature, to support their *prima facie* cases of rejection. Vague allegations of unpatentability because of lack of utility/operability must be avoided.

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[182]M.P.E.P. §608.01(p) at 600-40-600-41 (1993).
[183]*See*, n. 144, *supra*.

The new PTO guidelines go a long way toward alleviating the problems described in this paper and bring the PTO into conformance with the Federal case law summarized *supra*. In summary, the new guidelines direct Examiners to adhere to the following analysis when examining applications for compliance with §101:

(1) Determine what the Applicant claimed as his or her invention;

(2) Review the specification and claims to determine if the Applicant disclosed or asserted any credible utility for the claimed invention;

  (a) Credibility is to be assessed from the perspective of one of ordinary skill in the art in view of any evidence of record that is relevant to the Applicant's assertions;

(3) If the Applicant has not asserted any credible utility for the claimed invention or a utility would not be readily apparent to one of ordinary skill in the art, reject the claims under § 101;

(4) A rejection under § 101 should not be maintained if an asserted utility for the claimed invention would be considered credible by a person of ordinary skill in the art in view of all evidence of record.[184]

The new proposed PTO guidelines for utility are neither revolutionary nor even new. The new guidelines are simply an attempt to reign-in utility examinations that have run amok. The new guidelines bring the utility examination procedures into line with C.C.P.A. and C.A.F.C. precedent and with the PTO's own internal rules.

Improper examination procedures that lead to rejections unsubstantiated by case law are extremely costly in terms of lost time through appeals and lost investment opportunities. To prevent future divergence between PTO examination practices and Federal Circuit case law, a joint PTO-industry committee might be established to identify problem areas, conduct fact finding and legal research and then report those finding to the Commissioner. The benefits of this joint PTO-industry committee are several: First, early detection of potential examination procedures in conflict with legal precedent; second, a joint factual and legal analysis of the problem that can be submitted to the Commissioner; third, representatives of this joint PTO-industry committee might be utilized in the training of Examiners according to the new guidelines. In business sectors like the biotechnology industry, delays in obtaining patent protection can mean the difference between the development or the death of a particular invention. Therefore, a proactive system, like the proposed joint PTO-industry advisory committee, for identifying problems and providing solutions therefor, would be beneficial in heading off years of unneeded litigation and unnecessary expense.

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[184]60 F.R. 97, note 90, *supra*.