University of Georgia Law

Journal of Intellectual Property Law

Volume 2 | Issue 2 Article 3

March 1995

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Recommended Citation
David G. Perryman & Nagendra Setty, *The Basis and Limits of the Patent and Trademark Office's Credible Utility Standard*, 2 J. Intell. Prop. L. 509 (1995).
Available at: https://digitalcommons.law.uga.edu/jipl/vol2/iss2/3

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THE BASIS AND LIMITS OF THE PATENT AND TRADEMARK OFFICE'S CREDIBLE UTILITY STANDARD

David G. Perryman and Nagendra Setty***

INTRODUCTION

"Our starting point is the proposition, neither disputed nor disputable, that one may patent only that which is 'useful.' "[1] Justice Fortas' oft quoted admonishment from *Brenner v. Manson* identifies one of the three statutory requirements[2] for obtaining patent protection, but provides little else as guidance for the patent practitioner faced with the sufficiency of alleged utility in a particular case. The *Brenner* Court further characterized the amorphous utility requirement in the following admission: "[a]s is so often the case, however, a simple everyday word can be pregnant with ambiguity when applied to the facts of life."[3]

Fully cognizant of the "pregnant" ambiguity that practitioners and the Patent and Trademark Office alike face in dealing with utility in the context of chemical patent applications, the Court conspicuously failed to render true or insightful direction.[4] All that is plain from the decision is that an invention must have a "practical utility" to satisfy the statute.[5] Only in the wake of the Court's failing has the Patent and Trademark Office interpreted the *Brenner* language and the underlying statute, 35 U.S.C. § 101.

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[1] Brenner v. Manson, 383 U.S. 519, 528-29, 148 U.S.P.Q. (BNA) 689 (1966). The Court's opinion was based upon the statutory language contained in 35 U.S.C. § 101 1964. *See infra* note 6.

[2] *See* 35 U.S.C. §§ 101, 102 & 103 (1988).

[3] *Brenner*, 383 U.S. at 529.

[4] The Court's failing is reflected by the numerous scholarly works criticizing *Brenner*. *See* DONALD C. CHISUM, CHISUM ON PATENTS, § 4.02[2], at 4-11 n.18 (1994).

[5] *Brenner*, 383 U.S. at 529.

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Examiners,[6] the Board,[7] and the courts have varied drastically in their interpretations of *Brenner* and what a "practical utility" is, or should be. The Patent and Trademark Office has been highly criticized for applying an overly harsh utility standard.[8] In response to this criticism, new Patent and Trademark Office guidelines on utility have been adopted to give Examiners guidance on this issue.[9]

This paper addresses the problems associated with the application of an overly harsh utility requirement. The authors also analyze the inconsistencies in the case law concerning the proper standards and evidentiary proofs for satisfying the utility requirement in a patent application. A comparison of the various case law standards to the new Utility Guidelines, and a discussion of their practical effects, follows. Finally, the limits of the application of the new "credible" evidence standard are addressed.

I. DEFINING THE PROBLEM

In the past decade, the United States government, universities, and numerous other research foundations (collectively referred to as "non-profit institutions") have taken a decided turn toward promoting the transfer of technology from the public sector to the private sector and have used an aggressive patent strategy to achieve that goal.[10] The reasoning of those institutions - that patents are essential to the facile transfer of technology - is buttressed by the fact that unpatented technology often does not provide sufficient market exclusivity to justify the expense that the private sector would incur in developing and marketing an invention. Thus, the public derives little benefit from such unprotected technology.

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[6] U.S. Patent and Trademark Office Examiners ("Examiners").

[7] The Board of Patent Appeals and Interferences ("Board").

[8] *Patenting of Biotechnological Inventions: Public Hearing Before the United States Department of Commerce Patent and Trademark Office*, San Diego, California, October 17, 1994.

[9] The Patent and Trademark Office Examiner Guidelines for Examination of Applications for Compliance with the Utility Requirement (hereinafter "Utility Guidelines"), 60 Fed. Reg. 97, 98 (1995).

[10] *See generally* Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (codified as amended in scattered sections of 15 U.S.C.).

A. NON-PROFIT INSTITUTIONS

The primary axiom held by researchers at universities, government agencies and other non-profit organizations has been "publish or perish." Because this concept has been endemic in academia for many years, landmark scientific findings and incremental forward steps alike have led to immense growth in the scientific literature. Non-profit institutions take great pride in the scientific literature generated by their researchers, and the notoriety linked to such publications contributes to the severe pressure on basic scientists to publish results or risk advancement along a path of academic success.

As a result of this pressure, it has become increasingly important for the institutions' technology transfer offices[11] to instill in researchers an understanding of the severe price paid for premature notoriety. Foreign patent rights are substantially destroyed by public disclosure of research findings, because most foreign countries require patent applications to be filed before any public disclosure of the invention. As such, technology transfer offices now teach the virtues of the "patent, then publish" approach. The result of these teachings has been that non-profit institutions file patent applications as early as possible in the course of research, thereby allowing post-filing disclosure of preliminary results at conferences, seminars and the like.

Publication of preliminary results is particularly important to non-profit institutions that seek to license their discoveries. By licensing biotechnologies[12] to the private sector, further testing and marketing of biotechnology resulting from non-profit research is made possible.[13] Private sector licensees undertake those developmental functions and, through their royalty payments,

[11] A technology transfer office is responsible for encouraging faculty researchers to file patent applications on their basic science invention and managing the transfer of the invention to private industry.

[12] This paper uses biotechnology to mean any process which occurs in a cell or any molecule derived from a cell. However, since the utility principles overlap, traditional small molecule pharmaceuticals will be included in biotechnology.

[13] Many charters of non-profit organizations do not allow, and they often do not have the desire or facilities to undertake, the further testing and marketing of biotechnology resulting from non-profit research.

provide much needed capital that cycles back to further commercially viable basic research. Since the inventors, and the laboratory or department from which a particular invention emanates, often take a large share of license proceeds, a proper incentive is created for the inventor to disclose commercially viable inventions to his/her technology transfer office. To the authors, this system fosters goals that are in line with society's interests.

B. SMALL BIOTECHNOLOGY COMPANIES

Small or start-up biotechnology companies also need to patent early, but for different reasons. Few investors, whether venture capitalists, individual investors or large companies, will invest in a small biotechnology company with neither patents nor patent applications having a short and predictable course to issuance. Attracting such investments requires full disclosure, and the risk of such disclosure prior to filing patent applications is prohibitively high. Because small companies have usually "bet the farm" on a few products, they have a strong desire to file patent applications early in the inventive process.

The standard model for a "start-up" is to identify innovation at a non-profit institution and base the company upon the patent applications claiming the innovation. The patent portfolio then becomes a major tool for raising the capital upon which the biotechnology company would be formed. Such a model has been the cornerstone of the competitiveness that has allowed the United States to distinguish itself from other countries. Without the availability of patent protection for early and innovative discoveries, the model for start-up biotechnology companies disappears and carries with it our global competitiveness.

Another important consideration for all entities, regardless of size, is the cost of patent protection. If patent applicants are required to provide data that is convincing to a person skilled in the art, which from the Examiner's viewpoint was most often clinical data, then the applicant is in the unenviable position of not being able to forecast its patent potential until lengthy, expensive clinical trials are completed. The private sector would then not be motivated either to form a company around, or perhaps even invest in, technology lacking clinical data. As a result, non-profits would

not be motivated to file patent applications on a discovery prior to obtaining clinical data, and patent rights could be lost through publication. Thus, the purpose of the Federal Technology Transfer Act of 1986 would be defeated.

As to small and large companies, the result of requiring clinical data to prove utility is the tremendous cost of extended prosecution and the loss of investment. This reduces the amount of capital available to those companies to spend on the research and development of further improved therapeutics which would be beneficial both to society as a whole and the United States' global competitiveness. Without a clear course to patent protection, even large companies will not pursue moderately promising compounds that, with further development, could turn out to be of therapeutic importance.

II. STANDARDS OF PROOF

The precise standard of proof required to satisfy the utility requirement is unclear from the case law. The CCPA[14] seems to apply a standard that requires an applicant claiming a compound, or method of using a compound, to demonstrate efficacy that is "convincing to one skilled in the art." While at odds with the original CCPA "convincing" standard, the utility standard has evolved, in the hands of the CAFC[15], into what the authors believe is a better standard: that evidence of utility must show "a reasonable correlation" with the utility stated in an application. A review of case law relevant to the authors' conclusion follows.[16]

A. THE CCPA STANDARD OF PROOF

In *In re Buting*,[17] the applicant disclosed methods of treating a malignant condition in humans using certain sulfones. Confirmation of the activity in human subjects was alleged.[18] Evidence of

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[14] Court of Customs and Patent Appeals (CCPA).

[15] Court of Appeals for the Federal Circuit (CAFC).

[16] For a more general recent review of the cases relating to utility, see *PTO's Examiner Guidelines for Biotech Applications*, 49 Pat. Trademark & Copyright J. (BNA) 234 (1995).

[17] 418 F.2d 540, 163 U.S.P.Q. (BNA) 689 (C.C.P.A. 1969).

[18] *Id.* at 542.

efficacy against a variety of tumors in mice was provided, as well as results from two humans - one with Hodgkin's disease and the other with myelogenous leukemia - both of whom improved in condition.[19] The CCPA held that the evidence presented by the applicant, which was "limited to one compound and two types of cancer," was not commensurate with the scope of utility asserted and claimed, and suggested the applicant should either limit his claims or submit evidence refuting the limitation.[20] The *Buting* court applied the "convincing" standard, relying on *In re Irons* for support.[21] In *In re Irons*,[22] the CCPA first articulated the requirement that an "[applicant's] proofs of [alleged] utility should be *convincing* to one skilled in the art."[23] The amount of evidence required depends on the facts of each individual case,[24] and the character of evidence needed may vary depending on whether the alleged utility appears to accord with or to contravene established scientific principles and beliefs.[25]

In *Irons*, the applicant claimed certain new anti-guanidine polypeptide factors and methods of using them in the treatment of arthritis.[26] In response to the Examiner's rejection of his *five clinical case histories* under § 101, Irons submitted letters from rheumatoid arthritis specialists who administered the claimed compounds to their patients and achieved a high degree of success in eradicating arthritic pain. The Examiner maintained his rejection because the specialists had not conducted their trials according to "double-blind" techniques set forth by Johns Hopkins Hospital, and required evidence from *controlled* studies.[27] The Board affirmed this result, and the matter was appealed to the CCPA.

Speaking for the CCPA, Judge Almond reasoned that "proofs of utility should be *convincing* to one skilled in the art,"[28] but that

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[19] *Id.* at 543.
[20] *Id.* at 544.
[21] *Id.* at 543.
[22] 340 F.2d 974, 978, 144 U.S.P.Q. (BNA) 351 (C.C.P.A. 1965).
[23] *Id.*
[24] *In re* Gazave, 379 F.2d 973, 977-78, 154 U.S.P.Q. (BNA) 92 (C.C.P.A. 1967).
[25] *In re* Chilkowsky, 229 F.2d 457, 462, 108 U.S.P.Q. (BNA) 321 (C.C.P.A. 1956).
[26] *In re* Irons, 340 F.2d at 975.
[27] *Id.* at 976-77.
[28] *Id.* at 978 (emphasis added).

the Court could not agree with the degree of proof required by the Examiner and the Board.[29] Even though the CCPA reversed the Board's decision as to the sufficiency of evidence of utility in Irons' application, cases for nearly fifteen years followed the rule that evidence of utility had to be "*convincing* to one skilled in the art."[30]

The CCPA ruled in *In re Langer*[31] that the utility asserted in a patent application and supported with evidence from the application must be commensurate with the scope of a claim for the claim to issue. *Langer* concerned stannous chelates that were to be incorporated into dentifrices,[32] which would allegedly facilitate the binding of stannous or bivalent tin (Sn^{2+}) to tooth enamel to form an insoluble stannous phosphate layer.[33] The claimed compounds were thus alleged to aid in the prevention of tooth decay.

The claims were supported with human and animal *in vivo* data, but were rejected by the Examiner because the cited literature taught that the claimed compounds would not work either in the manner alleged in the *Langer* application or with the alleged beneficial result of creating an insoluble layer.[34] Because of the conflict between the asserted utility and the art of record, the Examiner required that the applicant demonstrate utility with "clear and convincing evidence commensurate in scope with the allegation and claims."[35]

After a series of Examiner rejections and responses supported by

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[29] *Id.* at 977-78.

[30] *Id.* at 978. *See supra* notes 17-21 and accompanying text (applying "convincing" standard, but recognizing its limited value in determining how much evidence is "convincing"); *In re* Jolles, 628 F.2d 1322, 1326, 206 U.S.P.Q. (BNA) 885 (C.C.P.A. 1980) (applying "convincing" standard).

[31] 503 F.2d 1380, 183 U.S.P.Q. (BNA) 288 (C.C.P.A. 1974).

[32] "[M]outh washes, tooth pastes, tooth powders and chewing gums. . . ." *Id.* at 1381.

[33] *Id.* at 1381-83.

[34] Although there was human data, it was perfunctory, consisting of human subjects being fitted with dental bridges bearing small slabs of human teeth and being asked to chew gum containing varying concentrations of stannous acetate for fifteen minutes, three times a day for one week. Analysis of the slabs for stannous tin concentration showed that there had been some uptake. *Id.* at 1385. The human data did not, however, demonstrate that the claimed compounds and methods helped retard tooth decay. That is the disputed link the Examiner argues is lacking in the application and contrary to the teachings of the cited references. The human data was thus not commensurate with the scope of the claims. *Id.* at 1389.

[35] *In re Langer*, 503 F.2d 1380, 1388.

affidavits, the applicant appealed the final rejection, and the Board affirmed. The Board found that the cited references "provided an adequate basis for 'skepticism' " as to the asserted utility and ruled that the applicant "had the burden of supplying 'evidence as to clinical testing which would resolve the issue in a simple manner.' "[36] The Board stated that it "cannot consider *in vitro* tests alone to evidence actual utility" because of the great disparity between endogenous species of bacteria and other microorganisms present in rats and humans.[37]

The CCPA found that the Examiner had constructed from the references a *prima facie* case of lack of utility, but stopped short of ratifying the Board's ruling that only clinical data would rebut the *prima facie* case.[38] The court held that "[f]ull scale clinical trials in humans . . . may be necessary to establish 'commercial usefulness' . . . [but are] not required to establish 'usefulness' within the meaning of § 101."[39] The CCPA ruled that the applicant's evidence of utility was sufficient to rebut the Examiner's *prima facie* case of lack of utility and "to prove utility to one skilled in the art."[40] Thus, the standard that the CCPA applied may have been a new standard other than the "convincing" standard, the boundaries of which were undefined.

In *In re Jolles*,[41] the applicant disclosed compositions and methods of their use in the treatment of acute myeloblastic leukemia in humans. The Examiner rejected these claims for lack of proof of utility, and the Board affirmed.[42] During prosecution, the applicant submitted two declarations indicating positive results from one of the claimed compounds in treating humans. Another two declarations were submitted demonstrating seven of the claimed compounds were effective in treating cancers in mice. The Examiner alleged that the applicant was asserting "incredible utility" and that the human trials with the one compound could not

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[36] *Id.* at 1390.
[37] *Id.* at 1391.
[38] *Id.* at 1392.
[39] *Id.* at 1392 (citing *In re* Anthony, 414 F.2d 1383, 162 U.S.P.Q. (BNA) 594 (CCPA 1969)).
[40] *In re Langer*, 503 F.2d 1380, 1388.
[41] 628 F.2d 1322, 206 U.S.P.Q. (BNA) 885 (C.C.P.A. 1980).
[42] *Id.* at 1325-26.

be used to support utility for any of the other compounds.[43] Further, the Examiner stated that she was not convinced that the evidence submitted as to the one compound used in the human trials was persuasive. The Board sustained the rejections to all of the compounds except the one used in the human trials. However, the Board ignored the animal data because it reasoned the applicant restricted itself to human utility and not utility in mice.[44]

Citing *In re Buting* as support for the proposition that animal data was customarily used as a basis for the efficacy of anti-cancer agents in humans, the CCPA reversed the Board decision and allowed the applicant's broad class of compositions and methods of applying them to humans.[45] The court reasoned that an applicant alleging utility of a compound with efficacy in humans must present proof "convincing to one of ordinary skill in the art"[46] and found that the applicant's animal data would have convinced such a hypothetical person.

B. THE CAFC STANDARD OF PROOF

In *Cross v. Iizuka*,[47] the Federal Circuit finally tackled, in the context of an interference proceeding, the difficult issue of what data is sufficient proof to support the utility of new compositions. Iizuka claimed certain novel and nonobvious imidazole derivatives alleged to be useful in inhibiting thromboxane synthetase, an enzyme associated with a cascade of compounds involved in platelet aggregation.[48] Relying on *In re Bundy*[49] and *Nelson v. Bowler*,[50] the Board held that Iizuka's data disclosed the pharmacological activity of the compounds, and that the practical utility require-

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[43] *Id.* at 1325.

[44] *Id.* at 1325-26. The mouse data at issue consisted of the results of seven specific, claimed compositions in experimental tests for sub-acute toxicity, activity against sarcoma 180 tumors, and activity against leukemia L 1210. The Board found that the mouse data was "not relevant to establish the claimed human utility." *Id.* at 1327.

[45] *In re Jolles*, 628 F.2d 1322, 1327-28.

[46] *Id.* at 1326.

[47] 753 F.2d 1040, 224 U.S.P.Q. (BNA) 739 (Fed. Cir. 1985).

[48] *Id.* at 1042.

[49] 642 F.2d 430, 209 U.S.P.Q. (BNA) 48 (C.C.P.A. 1981).

[50] 626 F.2d 853, 206 U.S.P.Q. (BNA) 881 (C.C.P.A. 1980).

ment was satisfied by the inhibitory action demonstrated *in vitro*.[51]

The Federal Circuit affirmed the Board's decision in finding that the practical utility requirement was satisfied by Iizuka's *in vitro* data because there was no controverting evidence.[52] The court stated that:

> Presumably this is the accepted practice in the pharmaceutical industry inasmuch as Cross has not proffered any evidence refuting . . . [the evidence of record], and we note that this practice has an inherent logical persuasiveness. *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 *reasonable correlation therebetween*.[53]
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> . . . We, however, find ourselves in agreement with the Board that, based upon the relevant evidence as a whole, there is a *reasonable correlation* between the disclosed *in vitro* utility and an *in vivo* activity, and therefore a rigorous correlation is not necessary where the disclosure of the pharmacological activity is *reasonable based upon the probative evidence*.[54]
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> . . . .
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> . . . We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may

[51] *Cross*, 753 F.2d at 1043.
[52] *Id.* at 1050.
[53] *Id.* (emphasis added).
[54] *Id.* (emphasis added).

> establish a practical utility for the compound in question. Successful *in vitro* testing will marshal resources and direct the expenditures of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an *in vivo* utility.[55]

In *In re Brana*,[56] the Federal Circuit reversed a Board decision finding insufficient utility for the claimed dione compounds based on *in vitro* data and a correlation with existing *in vivo* data. The original application disclosed *in vitro* activity of the diones against unspecified human tumor cells and referenced a computer analysis of the anti-tumor activity of structurally related compounds in leukemia *in vivo* murine assays used by the National Cancer Institute. Based on the *in vitro* data and comparison to structurally similar compounds with proven *in vivo* efficacy, Brana *et al.* argued that their claimed diones had sufficient utility.

Despite the *in vitro* data and *in vivo* correlation, the Board affirmed the Examiner's rejection because the applicants allegedly failed to prove that the claimed compounds are useful.[57] The Board argued that based on several cited references, "the tests offered by applicants to prove utility were inadequate to *convince* one of ordinary skill in the art that the claimed compounds are useful antitumor agents."[58]

In considering the Board's position, the court employed an apparent two-part test to determine if an invention satisfies § 101. First, the PTO must provide evidence "showing that one of ordinary skill in the art would *reasonably doubt* the asserted utility."[59] Second, if the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility, the burden shifts "to the applicant to provide rebuttal evidence *sufficient to convince* such a person of the invention's asserted

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[55] *Id.* at 1051.
[56] 51 F.3d 1560, 34 U.S.P.Q.2d (BNA) 1436 (Fed. Cir. 1995).
[57] *Id.* at 1565, 1566.
[58] *Id.* at 1566 (emphasis added).
[59] *Id.* at 1566 (emphasis added).

utility."[60]

The court held that the PTO had not met its initial burden because neither the references cited by the PTO nor "the nature of applicant's invention alone would cause one of skill in the art *to reasonably doubt* the asserted usefulness."[61] The court went on to hold that "even if one skilled in the art would have reasonably questioned the asserted utility . . . applicants proffered sufficient evidence *to convince* one of skill in the art of the asserted utility."[62]

C. THE BOARD'S STANDARD

The claimed invention in *Ex parte Aggarwal*[63] was a method of using recombinant lymphotoxin glycoproteins to treat tumors in animals including humans.[64] The Examiner found the claims broad enough to cover homogenous lymphotoxins,[65] which were supported by animal data, and heterogenous lymphotoxins,[66] which were not supported by such data. The Examiner rejected the claims under § 101 and the Board affirmed.

The Board held that the animal data did not provide sufficient evidentiary support under § 101 "with regard to *human* lymphotoxin itself."[67]

The court found that:

> [t]here is no question that the appellants have made an important discovery with regard to chemical compounds (proteins) which are the subject of serious scientific investigation but of unverified and speculative utility. Appellants urge that in such situations it is in the public's interest that patent applications

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[60] *Id.* at 1566 (emphasis added).

[61] *In re Brana*, 51 F.3d 1560, 1566 (emphasis added).

[62] *Id.* at 1566, 1567 (emphasis added).

[63] 23 U.S.P.Q.2d (BNA) 1334 (Bd. Pat. App. & Inter. 1992).

[64] *Id.* at 1335.

[65] Lymphotoxins used in and obtained from the same species (*e.g.* obtained from a mouse and used in a mouse).

[66] Lymphotoxins used in and obtained from different species (*e.g.*, obtained from a human but used in a mouse or *vice versa*).

[67] *Id.* at 1339 (emphasis in original).

> be filed early rather than waiting for what might be a long period of experimentation.[68]

Despite this seemingly persuasive argument, the Board followed its interpretation of *Brenner v. Manson* and required human or *in vivo* data predictive of human efficacy.[69] Due to the lack of scientific data supporting the utility of administering human lymphotoxins, the applicant was precluded from protecting the novel and nonobvious discovery.

In *Ex parte Balzarini*,[70] the applicant claimed a novel unit dosage of a composition and methods of its use in the treatment of AIDS and AIDS-related diseases.[71] The claims were supported with *in vitro* data demonstrating the anti-viral activity of the two active ingredients of the composition, the cytopathogenic effect on HIV in human T-lymphocytes, and the inhibitory effects of the active ingredients on HIV in infected human cells.[72] It was "apparent" from the specification that the primary utility alleged was in the treatment of HIV-positive humans.[73] The Board stated that:

> [i]t is the inclusion of such human efficacy in the treatment of these diseases that forms the basis of the examiner's questioning of the utility and enablement of the claimed invention.[74]

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[68] *Id.*

[69] *Id.* at 1339.

[70] 21 U.S.P.Q.2d (BNA) 1892 (Bd. Pat. App. & Inter. 1991). A distinction between method and composition claims is reflected by the following language from the Board:

> [t]he appealed claims are drawn to compounds and not to a method of treatment. Generally speaking, utility in treating a single disease is adequate basis for the patentability of a pharmaceutical compound under 35 U.S.C. § 101.

Ex parte Krepelka, 231 U.S.P.Q. (BNA) 746, 747 (Bd. Pat. App. & Inter. 1986). *See generally Ex parte* Chwang, 231 U.S.P.Q. 751, 752 (Bd. Pat. App. & Inter. 1986) (holding method cases not applicable to compound cases); *In re Irons*, 340 F.2d 974 (C.C.P.A. 1965) (suggesting method of use is separate factor from compound itself).

[71] *Balzarini*, 21 U.S.P.Q.2d at 1894.

[72] *Id.*

[73] *Id.*

[74] *Id.*

Although the application alleged utility commensurate in scope with the claims, the Examiner disputed such allegations based on references stating that successful *in vitro* testing was not associated with the *in vivo* treatment of AIDS.[75] Citing *Langer*, the Board ruled that "while we are not requiring human clinical trials, it may very well be that in 1987 or even now *those skilled in this art would not accept* anything short of such human clinical trials."[76]

From both *Aggarwal* and *Balzarini* it is apparent that recent Board cases are not applying the reasonable correlation standard set forth in *Cross*. Rather, the Board appears to be applying the "convincing" standard promulgated by the CCPA. Despite the *Cross* court's recognition of the true value and role of *in vitro* testing in the real world of biotechnology research, the Board required convincing clinical data to support claims that cover human uses. If the Board had applied a "reasonable correlation" standard in *Aggarwal* and *Balzarini*, both cases would likely have been decided differently.

III. THE SUPERIORITY OF THE *CROSS* STANDARD

The U.S. Constitution requires only that the patent laws foster the "useful arts," and the Federal Circuit's insight in *Cross* seems to be wholly consistent with that goal. *In vitro* testing actually plays the role in the biotechnology industry to which the *Cross* court alluded: it represents the first tier of testing, *in vivo* animal testing being the second tier and clinical testing the third. Thus, requiring only a reasonable correlation between *in vitro* testing and *in vivo* efficacy fosters the "useful arts."

The Federal Circuit's two-tier test set forth in *Brana* is of potential concern to the public. The concern relates to the level of evidence required by the PTO to "reasonably doubt" an asserted utility. To be consistent with *Cross*, any evidence applicants present which "reasonably correlates" with the asserted utility could not reasonably be doubted. It is only when the evidence of record does not "reasonably correlate" with the asserted utility that applicant must show "convincing evidence" of the asserted utility.

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[75] *Id.* at 1895.

[76] *Balzarini*, 21 U.S.P.Q.2d (BNA) at 1897 (emphasis added).

Under this interpretation of *Brana*, it would be the rare case where applicants would be required to show data convincing to the skilled artisan. If, however, *Brana* allows the PTO to routinely assert "reasonable doubt," then the case does not go far enough in easing the utility standard because "convincing" evidence will be routinely required of applicants. Thus, the lower standard of *Cross*, which does not require that an applicant show "convincing evidence," represents the better standard.

The benefits of applying the lower standard of *Cross* clearly outweigh any detriments to the public. The rigorous evidence needed to satisfy the "convincing" utility standard results in the misallocation of resources within non-profit organizations. Clinical data is not the goal of non-profits and is often prohibitively expensive for government agencies and small biotechnology companies. The negative incentives promulgated by the "convincing" utility standard result in a failure to file patent applications or to pursue patent applications that would be rejected under 35 U.S.C. § 101. Without such patent applications, the private sector will not invest in the technology, and the public does not benefit from the ultimate product or its use. Thus, any research discoveries will enter the public domain without effect.

The rigorous "convincing" standard also misallocates resources within biotech companies. Maintaining patent applications during the process of gathering convincing clinical data requires large expenditures which drain resources that could otherwise be invested in research. The loss of resources for research results in lost benefits to the public. The harsh utility standard also falsely redirects large pharmaceutical companies' resources only to the top tier pharmaceutical candidates.

Small or start-up companies are further harmed because the "convincing" standard results in the inability to raise capital since investors often insist on issued patents or applications with a reasonable time-line to issuance. This puts young companies in a "catch 22" because they need capital to obtain clinical data, but cannot obtain capital without clinical data; the very existence of young companies is placed at risk. Thus, the "convincing utility" standard endangers the continuing development of the U.S. biotechnology industry and its present global competitive advantage.

The public faces minimal risk of harm by an issued patent on a composition or method which ultimately does not work in humans as alleged.[77] The Patent and Trademark Office appears to act for society by preventing the creation of monopolies of knowledge. However, if the *in vitro* or animal *in vivo* testing in a particular case proves not to predict efficacy in humans, society has lost little value. If claimed novel compositions or novel uses of known compositions do not work effectively and safely in humans, they will never pass Food & Drug Administration muster.

The potential detriment to society of a therapeutic patent on a compound based soley on *in vitro* data is that, if the composition does not prove useful *in vivo*, then others would be precluded from using the compound for the life of the patent. However, if the compound is not useful as described by the patent, it is unlikely that it will be found to have unrelated important activities. Furthermore, in the rare circumstance where the compound is not useful as alleged in the patent, but is later found to have some other use, the compound is not actually out of the public domain because the patent is invalid for lack of utility and can be proven such by the discoverer of the later use. In addition, the same patent which discloses the compound for which the utility is not ultimately supported, may, as the patent system intends, be responsible for leading to the later discovered true utility. Finally, since the patent system already allows for protection of a compound based on alternative and commercially unimportant utilities, little additional harm can occur by the issuance of a composition claim based only on *in vitro* data.

Because the utility requirement would only be lowered to require a "reasonable correlation" between *in vitro* evidence of *in vivo* efficacy, cases of poor *in vitro* evidence would still not satisfy 35

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[77] In balancing the standard of utility cases, Professor Wegner states:

> One must ponder what *harm* it does if the PTO grants a claim to a compound that, in the end, does prove[s] [sic] to have only minimal clinical worth? Since the patent right is entirely exclusionary in nature, the patentee in this situation gains nothing from his grant. For every new area of technology that emerges in the pharmaceutical arts, the areas that the university professor or small business typically works in, these are areas that can least afford patent-focused clinical testing, yet these are the areas that are routinely attacked at the PTO.

Wegner, *Patent Law*, § 435 at 365.

U.S.C. § 101. Thus, the likelihood of the *in vitro* data ultimately not correlating with *in vivo* efficacy in an issued patent would be reduced.

IV. RECENT PATENT AND TRADEMARK OFFICE GUIDELINES

A. BACKGROUND

Over the last five years, the Patent and Trademark Office has caused many of the problems discussed above by applying an overly harsh utility standard. While the Patent Office examining corps has been inconsistent, it generally has required evidence which would be convincing to one skilled in the art.[78] To convince individual Examiners of utility often required human clinical data, where human therapy was either claimed or asserted as a utility for claimed compositions.

In response to a hailstorm of criticism, the Patent and Trademark Office recently issued proposed Guidelines for Examining Applications for Compliance with the Utility Requirement.[79] The new guidelines adopt a much more reasonable approach to the utility requirement, which is in line with the goals of the patent system.

Rather than waiting for legislative action or appeals to the CAFC, the Commissioner held public hearings and determined that many of the problems discussed above had in fact occurred.[80] The Commissioner's solution was to set forth a utility standard taking a rational approach to the utility issue. While the standard selected by the Commissioner could be challenged based on the CCPA precedent discussed above, the new Patent and Trademark Office standard is the proper legal standard.

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[78] *Balzarini*, 21 U.S.P.Q.2d at 1894.

[79] The proposed Guidelines, while subject to public comment, were slated to take effect upon their proposal in December 1994. *Bioworld Today*, December 23, 1994. The effort was spearheaded by Jeff Kushan, Attorney Advisor; Commissioner of Patents and Trademarks, Box 4, Washington, D.C. 20231.

[80] *Patenting of Biotechnological Inventions: Public Hearing Before the United States Department of Commerce Patent and Trademark Office*, San Diego, California, October 17, 1994.

B. THE STANDARD

The standard of proof promulgated by the Utility Guidelines depends on whether the patent applicant "has disclosed or asserted any credible utility for the claimed invention."[81] A rejection under 35 U.S.C. § 101 should not be made if an asserted utility would be considered "credible" by one of ordinary skill in the art in view of all the evidence of record.[82]

The Utility Guidelines give meaning to the "credible" standard by stating that "to assess credibility, the Examiner should determine if one of ordinary skill in the art would consider the assertions of the applicant to have *any* reasonable scientific basis."[83] This statement is consistent with the common dictionary meaning of credible: "entitled to belief or trust."[84]

While the credible standard appears to be clear on its face, a more detailed reading of the Utility Guidelines raises ambiguity. The Utility Guidelines state that an Examiner's *prima facie* showing of no utility must contain:

> [s]upport for conclusions of the Examiner that evidence provided by the applicant to support an asserted utility would not be considered *persuasive* to a person of ordinary skill in the art.[85]

The requirement of "persuasive" evidence appears to be inconsistent with applicants merely having to show "credible" evidence. This occurrence in the Guidelines of "persuasive" should be changed to "credible" for clarity and consistency with the new standard.

A related issue is the sufficiency of evidence an applicant must present to establish a credible utility. The Utility Guidelines state that:

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[81] Request for Comments on Proposed Utility Examination Guidelines, 60 Fed. Regs. 97 (Dept. Comm. 1995) [hereinafter Proposed Guidelines] at Supplementary Information § I. B. 2.

[82] Proposed Guidelines at Supplementary Information § I. B. 4.

[83] Proposed Guidelines at Overview of Legal Precedent Governing the Utility Requirement § II. B. 2. (emphasis in original).

[84] WEBSTER'S NEW TWENTIETH CENTURY DICTIONARY 428 (2d ed. 1967).

[85] Proposed Guidelines at Supplementary Information § I. B. 3. (a)(iii) (emphasis added).

> Examiners are reminded that they must treat as true credible statements made by an applicant or a declarant in the specification or in a declaration provided under 37 C.F.R. 1.132, unless they can show that one of ordinary skill in the art would have a rational basis to doubt the *truth* of such statements.[86]

Here again, the Utility Guidelines seem to contradict the requirement that applicants must show merely credible evidence, rather than evidence which is more likely than not true. This occurrence of "truth" should be changed to "credibility" for clarity and consistency with the new standard.[87]

If these inconsistencies are nonetheless adopted in the Utility Guidelines, Examiners should not view these two apparently inconsistent provisions as an excuse to continue with excessively harsh prior standards. To eliminate this possibility, the Utility Guidelines should be modified accordingly.

As noted above, *Cross v. Iizuka* adopted a standard that only a reasonable correlation between *in vitro* utility and *in vivo* activity need be shown, and that a rigorous correlation is not necessary where the disclosure of the pharmacological activity is reasonable based upon probative evidence.[88] As also noted above, the Utility Guidelines adopt a credible standard for utility. However, the Utility Guidelines also address the reasonable correlation and reasonably predictive standard they contain as a special consideration for asserted therapeutic or pharmacological utilities.[89]

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[86] Proposed Guidelines, at Supplementary Information § I. B. 4. (emphasis added).

[87] The apparent inconsistency in the Utility Guidelines possibly can be explained by the application of the "persuasive" and "truth" standards to the facts on which an ultimate determination of credibility is based. Any facts presented in applicant's showing of utility must be persuasive to one of ordinary skill in the art such that the hypothetical person would not have a reasonable basis to doubt their truth.

[88] 753 F.2d 1040, 1050 (Fed. Cir. 1985).

[89] Proposed Guidelines at Overview of Legal Precedent § III. The Utility Guidelines read:

> A. A Reasonable Correlation Between Evidence and Asserted Utility is Sufficient
>
> As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a *reasonable* correlation between the activity in question and the asserted utility. (emphasis in original)
>
> * * *

While one can logically distinguish pharmacological utilities from other utilities, the ultimate standard should be whether an asserted pharmacological utility is "credible." One can assess credibility by determining if there is either a "reasonable correlation" between the evidence presented and the claimed invention or if the evidence presented is reasonably predictive of the claimed invention. Thus a "credible" standard encompasses both the "reasonable correlation" and "reasonably predictive" standards.[90] While it may be useful to analyze a particular pharmaceutical utility using the reasonable correlation standard, the standard for pharmacological utilities does not differ from the credible standard.

As noted above, public policy should dictate the utility standard. Thus, even in view of *Brana*, credible evidence of utility is all that should be required to satisfy § 101. However, at most, *Brana* should be interpreted consistently with *Cross* and the Utility Guidelines to require only "credible" evidence to rebut a PTO allegation of reasonable doubt as to the asserted utility. Thus, applicants should be required to show convincing evidence only when rebutting the PTO's *prima facie* showing of a lack of credible evidence.

The origins of the "credible utility" standard deserve some

C. Data from *In Vitro* and Animal Testing is Generally Sufficient to Support Therapeutic Utility

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If an applicant provides data from *in vitro* and animal tests to support an asserted utility, 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. (second emphasis added)

* * *

F. Treatment of Specific Disease Conditions

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Thus, affidavit evidence from experts in the art indicating that there is a reasonable expectation of success, supported by sound reasoning, usually should be sufficient to establish that such a utility is *credible*. (emphasis in original)

[90] Determination of credibility may require a two-step process for an alleged pharmaceutical utility which is based on *in vitro* data of a pharmacological activity. First, the credibility of *in vivo* pharmacological activity must be determined based on the *in vitro* pharmacological data, *i.e.*, does the *in vitro* pharmacological activity reasonably correlate with *in vivo* pharmacological activity. Second, it must be determined whether it is credible that the *in vivo* pharmacological activity will be effective in treating the condition associated with the pharmacological activity; *i.e.*, does the pharmacological activity reasonably correlate with therapeutic activity.

exploration. The Utility Guidelines themselves purport to be based on case law, including the CAFC's decision in *Cross v. Iizuka*, but the "credible" standard of evidence for practical utility does not directly appear anywhere in *Cross* or the CCPA cases.[91] As noted above, there is a conflict between the Utility Guidelines/*Cross* standards and the CCPA's requirement that there be evidence "convincing to one skilled in the art" even when the PTO has not set forth a *prima facie* case of inadequate utility. Thus, in selecting the "credible" standard, the Patent and Trademark Office has followed the *Cross* precedent, even though that precedent did not specifically overrule CCPA precedent requiring a "convincing" utility. Given the existence of inconsistent standards in the case law, the Patent and Trademark Office could follow either standard. However, since the Utility Guidelines follow the legal standard consistent with public policy, the application of a "credible" standard should withstand any challenge based on CCPA precedent or the second tier test of *Brana*.[92]

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[91] The "credible" standard of the new Utility Guidelines appears to be crafted from whole cloth, and is not a mere codification of the *Cross* pronouncements. *Cross* speaks only in terms of "reasonable correlations" between the evidence of utility in an application and the claimed therapeutic use. *Cross v. Iizuka*, 753 F.2d 1040, 1050-51 (Fed. Cir. 1985). Indeed, there is no discussion in *Cross* or virtually all of the earlier cases of the "credible" utility standard.

But there is historical support for the distinction between a merely "credible" utility and a sufficient "practical utility" under 35 U.S.C. § 101. In *Application of Isaacs*, 347 F.2d 887, 889-90, 146 U.S.P.Q. (BNA) 193 (C.C.P.A. 1965), the CCPA noted the Patent Office's view that the applicant's "allegations of success *in vitro*, while not sufficient under section 101, were at least credible." Although the CCPA ultimately did not rule on the purported distinction between a credible utility and a utility sufficient to satisfy § 101, the *Isaacs* case demonstrates that the Patent Office has long believed in a distinction between "credible" and "practical" utilities.

[92] It is unlikely that a defendant in a patent infringement action will raise this inconsistency. That is, one accused of infringing the invention embodied in the claims of a patent would be hard pressed to argue that there is no utility in that invention. From the defendant's use of similar or infringing technology, the "practical utility" of the invention would likely be manifestly obvious at least as a matter of inference.

However, the inquiry into the discrepancy between the CCPA and CAFC/Utility Guidelines standards is not purely academic because the issue could arise during an interference proceeding. In an interference, the litigated issue concerns which party first "invented" the overlapping subject matter contained in the parties' respective applications. "Invention" is commonly defined as a conception and reduction to practice, and each party's patent specification must adequately disclose that invention, including sufficient "practical utility," which is supported by *Cross v. Iizuka*, 753 F.2d 1040, 1044, (Fed. Cir. 1985).

Therefore, one fertile area for dispute in an interference proceeding is the sufficiency of the

V. THE LIMITS OF THE UTILITY STANDARD

The new Utility Guidelines were slated to take effect immediately in December, 1994. Since inception, the new Utility Guidelines have been largely followed by the Examiner corps, with the effect of a much reduced standard of proof.[93] Thus, a reduced Patent and Trademark Office utility standard appears already to have had a positive impact consistent with the goals of the patent system.

A. REJECTIONS UNDER 35 U.S.C. § 101/112

Since the effective date of the Utility Guidelines, patent practitioners have reported that some rejections under 35 U.S.C. § 101 have been converted into rejections under 35 U.S.C. § 112 based on the same factors as the § 101 rejection.[94] The Patent and Trademark Office often rejects patent applications under 35 U.S.C. § 101 and § 112 for the same reasons.[95] The basis for this § 101/112 rejection can be found in *In re Jolles*[96] and *Application of Isaacs*[97],

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parties' specifications in disclosing "practical utility." That was the precise context in which the CAFC issued its decision in *Cross v. Iizuka*. Cross alleged that Iizuka was not entitled to the priority of his earlier Japanese patent application, which was senior to Cross' application, because the Iizuka application allegedly failed to set forth sufficient "practical utility." *Id.*, at 1043. Because the CAFC found that the Iizuka application stated a "pharmacological activity," which the Court then found to be sufficient utility, it ruled that Iizuka was entitled to its priority filing date. But the court in *Cross* did not evaluate the sufficiency of the stated utility under the CCPA's "convincing" standard. For a complete discussion of *Cross*, *see supra* notes 47-55 and accompanying text. To the extent there is a distinction between the standards for proving utility articulated in the CAFC and CCPA cases, the distinction could be argued in the interference context.

[93] In some cases, multiple long-standing rejections have been withdrawn by Examiners, including one application which was on appeal to the Patent Office Board of Appeals and Interferences.

[94] 35 U.S.C. § 112, p 1:

> 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. *Id.*

[95] This type of rejection can be called a § 101/112 rejection.

[96] 628 F.2d 1322, 1325, 206 U.S.P.Q. (BNA) 885 (C.C.P.A. 1980). *See supra* note 41 and accompanying text.

which hold that an application having an inadequately disclosed utility cannot teach someone skilled in the art how to use the invention. Since the utility factors are applied to this type of "how to use" rejection under § 112, the conversion of a utility rejection to a § 112 rejection has the same negative impact on industry and society, and the Patent and Trademark Office should discontinue this type of rejection practice.[98] If Examiners, however, still apply a utility type rejection under § 112, the applicant should be able to overcome it by showing the same evidence that establishes a "credible" utility that satisfies 35 U.S.C. § 101.[99]

This § 101/112 issue was recently considered in *In re Brana*. In *Brana*, the claims on appeal were rejected only under 35 U.S.C. § 112.[100] While the rejection was under 35 U.S.C. § 112, the court noted that the rejection was based only on the issue of whether the compounds had practical utility.[101] The court recognized that a rejection can be maintained under both 35 U.S.C. § 112 and § 101, stating "if a claimed invention does not have utility, the specification cannot enable one to use it."[102]

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[97] 347 F.2d 887, 888-89, 146 U.S.P.Q. (BNA) 193 (C.C.P.A. 1965). *See supra* note 91 and accompanying text.

[98] Naturally, one must still provide an adequate written description for one skilled in the art to make the claimed invention. However, in pharmaceutical applications this can often be satisfied simply by teaching how to make the compound, since determining administration routes and optimizing dosage are typically routine.

[99] *Overview of Legal Precedent Governing the Utility Requirement* I. B. seems to be the basis for Examiners converting § 101 rejections to § 112 rejections. It states that "if an invention is only partially successful in achieving a useful result a rejection of the claimed invention as a whole under § 101 is not appropriate." Footnote 9 in the Utility Guidelines states that "in such case, a rejection under 35 U.S.C. § 112 may be appropriate." (citing *In re Gardner*, 475 F.2d 1389 (C.C.P.A. 1973), and *In re Marzocchi*, 439 F.2d 220 (C.C.P.A. 1971).

The Guidelines improperly rely on these two cases. In *Gardner*, the CCPA expressly stated that "as this court pointed out in *Fouche*, absence of the asserted utility may properly lead to a rejection under either provision [§§ 101 or 112]." 475 F.2d at 1392. That is, the absence of utility may support a rejection under either § 101 or § 112, but that observation by the CCPA does not lead to the conclusion that even though utility is satisfied, § 112 may not be. In fact, the opposite conclusion is closer to the mark of the CCPA's holding: that satisfaction of the § 101 requirements is *a fortiari* a satisfaction of the "how to use" component of § 112. Similarly, the CCPA in *Marzocchi* does not even mention utility or § 101. Thus, the Guidelines' reliance on *Marzocchi* appears to be misplaced.

[100] 51 F.3d 1560, 1564.

[101] *Id.*

[102] *Id.*

The court applied a § 101 utility analysis and did not consider any other requirements of § 112, first paragraph. The court concluded that applicants had satisfied the utility requirements under § 101 and reversed the Examiner's rejection under § 112, first paragraph. Thus, *Brana* is entirely consistent with the proposition that § 101 utility rejections should not be converted to § 112 enablement rejections when § 101 has been satisfied by an adequate showing of practical utility.

B. RESEARCH TOOLS

The Patent and Trademark Office's recent practice often has been to deny protection for certain research tools based on the holding of *Brenner v. Manson*.[103] In *Brenner*, the claims were directed to a novel method of making a certain class of compounds. Since there was no use for the compounds set forth in the application, the court found that there was insufficient utility if the product of the process is useful only as the *object* of scientific research.[104] In other words, the only use of the compounds at issue was to research the compounds' potential uses.

The Patent and Trademark Office has argued, based largely on *dicta* in *Brenner*, that proteins and other molecules that do not have an activity associated with a therapeutic benefit are not useful under 35 U.S.C. § 101. Although a protein can be used to study the cellular mechanisms in which the protein displays its activity, *i.e.*, as a research tool, the Patent and Trademark Office has taken the position that the use does not constitute a presently available utility.[105]

The research tool scenario is, however, distinct from the holding of *Brenner*. In the research tool scenario, the protein itself is not the object of testing, but is, instead, useful as a valuable research tool. Although the result of that research would be unknown at the time of application, it benefits society in the broad sense and may

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[103] 383 U.S. 519 (1966).

[104] *Id.* at 535-36.

[105] For example, a protein is discovered which has an effect in cell proliferation. Unless applicant can show a nexus between the protein and preventing cancer, utility is denied. In other words, the Patent and Trademark Office has argued that using the protein to study cell proliferation is not sufficient utility.

directly lead to valuable therapeutics.[106] Therefore, the Patent and Trademark Office has expanded the holding of *Brenner* to the detriment of the patent system. Allowing such claims can provide significant benefits to society, by furthering the commercial development of these tools and allowing for cost-effective procurement of patents; the downside or cost to society is minimal.

The Utility Guidelines adopt any real world value as satisfying 35 U.S.C. § 101:

> Practical utility is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.[107]
>
> * * *
>
> Examiners must be careful not to interpret the phrase "immediate benefit to the public" or similar formulations in other cases to mean that products or services based on the claimed invention must be 'currently available' to the public in order to satisfy § 101. Rather, 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.[108]

Thus, the only question in a particular application is determining if the use is reasonable. The research tool area should satisfy the reasonable use standard, especially when the research tool is something for which industry will pay. Thus, a protein having a disclosed activity, but no known or suspected therapeutic benefit

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[106] In fact, such research tools are valuable and are an important commercial industry.

[107] *Overview of Legal Precedent Governing the Utility Requirement* I. A. (citing Nelson v. Bowler, 626 F.2d 853, 856, 206 U.S.P.Q. (BNA) 881, 883 (C.C.P.A. 1980)).

[108] *Id.*

satisfies real world value for utility.[109]

The new Utility Guidelines also invite a return to the issue of whether novel DNA fragments satisfy the new real world value requirement.[110] It should be readily apparent that such DNA fragments can be used as primers and probes to locate genes and proteins of real value. That use of such fragments certainly has real world value. Thus, the fragments should satisfy the utility requirement of 35 U.S.C. § 101.[111]

CONCLUSION

There were distinct disadvantages to the overly stringent "convincing" utility standard promulgated by the CCPA and enforced by the Patent and Trademark Office. The standard was satisfied only by applications supported by clinical data, resulting in the lack of protection for much biotechnology and pharmaceutical research.

The CAFC perceived the error of the "convincing" standard and, in *Cross v. Iizuka*, set forth the more tenable "reasonable correlation" standard. Despite the *Cross* guidance, the Board and examining corps continued to apply the "convincing" standard until

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[109] A less clear issue is whether a protein for which any activity has yet to be determined satisfies practical utility. Awarding a patent to such a discovery is consistent with the goals of the patent system of providing motivation to look for such proteins and provide exclusivity such that a non-profit discovery of such a protein can be cost-effectively licensed by private industry if the protein turns out to be commercially relevant. Although similar to *Brenner v. Manson*, this situation can be distinguished from *Brenner* because a purified protein differs from a small molecule in that one knows the protein has some, albeit presently unknown, activity which will have value as a tool in studying cellular function. In addition, the holding of *Brenner v. Manson* has been criticized. *See* DONALD C. CHISUM, CHISUM ON PATENTS, § 4.02[2], at 4-11, n.18 (1994).

[110] The U.S. government through the National Institutes of Health Office of Technology Transfer filed patent applications claiming novel DNA fragments for which no gene, and thus protein, was known. After much criticism from researchers, the National Institutes of Health withdrew those applications.

[111] A less clear issue is the scope of such claims under 35 U.S.C. § 112. Specifically, if the claims are to any nucleic acid comprising the novel fragment such that the gene encoding the fragment would infringe the claim, based on present practice, the Patent and Trademark Office will likely reject the claims based on lack of enablement under 35 U.S.C. § 112, first paragraph. In such a case an applicant should adequately describe how one would go about cloning the entire gene and finding the activity of the encoded protein to increase the likelihood of satisfying 35 U.S.C. § 112, first paragraph.

Commissioner Lehman issued new examination guidelines.

The Guidelines reiterate the role of the *Cross* standard and set forth a "credible" utility standard. By redefining the contours of § 101 and the utility standards, the Guidelines address the real harm dealt to the public by the "convincing" standard.

There is, therefore, little societal benefit achieved by converting a § 101 rejection to a § 112 rejection. Nevertheless, the examining corps continues to espouse the conversion practice to substitute § 112 obstacles for those no longer available under the § 101 rubric. Only time will allow practitioners to evaluate the Guidelines' practical impact on examination of biotechnology and pharmaceutical applications.