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UTILITY AND NON-OPERABILITY STANDARDS IN BIOTECHNOLOGY PATENT PROSECUTION: CAFC PRECEDENT VERSUS PTO PRACTICE

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I. Introduction

Human recombinant insulin and blood clot-dissolving drug tissue plasminogen activator (tPA) are two unqualified success stories of the emerging biotechnology [n.1] industry. The availability of intellectual property protection, most commonly in the form of a patent, is an important component in the ultimate success of this industry. Without the protection of a patent, most companies cannot afford to risk capital *204 assets to develop a promising technology into a commercially useful product. It is imperative, therefore, that the biotechnology industry and the patent bar monitor how the Patent and Trademark Office (PTO) applies the patent laws during prosecution.

Recently, industry leaders and the patent bar criticized the PTO on its interpretation of what constitutes statutorily useful and operable inventions. Leaders in the biotechnology industry and patent practitioners charged that the examiners in Group 1800 have uniformly misapplied the patent laws to inventions that claimed human therapeutic uses. The most serious charge was that examiners in Group 1800 routinely rejected applications which encompassed a human therapeutic use under 35 U.S.C. § § 101 and 112, first paragraph, for lack of utility, and therefore nonenablement. The practitioners argued that the PTO's routine § § 101 and 112 rejections were the result of Group 1800 Examiners applying a higher standard for utility and enablement than other art groups. Practitioners argue this standard directly conflicts with the United States patent code.

This article will first review the historical underpinnings of the utility and enablement standards developed through case law. Second, it will analyze case law and the PTO's reaction to the case law. Third, it will show how and where the PTO has deviated from these standards. Fourth, it will examine the supporting arguments of the patent bar and the PTO positions on these standards. Fifth, it will discuss the PTO's proposed changes to the examination procedures in Group 1800. Finally, the author will argue for the formation of a joint PTO-industry advisory committee to proactively identify and resolve future PTO deviations from judicial precedent.

II. Background: Economic Factors and Statutory Considerations

A. The Birth of Biotechnology

Several commentators trace the origins of the biotechnology industry to the 1973 discovery by Dr. Herbert Boyer and Dr. Stanley Cohen of a method of isolating certain human genes from DNA and replicating those genes in a bacterial host. [n.2] The Cohen-Boyer invention was *205 patented [n.3] and licensed. The ground breaking work of Cohen and Boyer in the 1970s spawned the formation of hundreds of biotechnology companies dedicated to the development of new human recombinant products. According to one commentator, " t he lastdecade 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.'" [n.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 percent over 1990-91. [n.5] Additionally, the total revenues for the biotechnology industry in 1991-92 were 8.1 billion dollars, an increase of 28 percent. [n.6]

Protection of intellectual property in the biotechnology business sector is vital for the survival and growth of both start-up and established companies. According to Dr. Ronald E. Barks, it takes between five and ten years to commercialize a biomedical technology invention. In general, the process of commercialization 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." [n.7] The development costs for a single product can be between 50-200 million dollars. [n.8] Given the 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.

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. Also, more established biotechnology companies will not risk their own *206 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. In theory, it is a quid pro quo method used by the government to encourage early and complete disclosure of inventions that meet the statutory criteria for patentability. Specifically, 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." [n.9] The patent law, codified in Title 35 of the United States Code, 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." [n.10] 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." [n.11]

C. PTO--The Administrative Agency Charged with Implementing the Constitutional Mandate

Congress delegated its responsibility to the PTO for determining the patentability of inventions. 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." [n.12] The statutory authority for examination of patent applications is found in 35 U.S.C. § 131. [n.13] According to the Manual of *207 Patent Examining Procedure (MPEP), " t he main conditions precedent to the grant of a patent to an applicant are set forth in 35 U.S.C. § § 101-103." [n.14]

Accordingly, major hurdles to patentability include the requirements that an invention be useful, [n.15] novel, [n.16] nonobvious, [n.17] and comply with 35 U.S.C. § 112, first paragraph. [n.18]

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

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

In September, 1994, the Commissioner published a notice of public hearing and request for comments on patent protection for biotechnological inventions. [n.19] The members of the Biotechnology Industry Organization (BIO) drafted a 163 page response to the Commissioner's request. [n.20] In the BIO position paper, industry leaders and the patent bar presented their opinion that the high turn-over rate of examiners in the PTO and their lack of legal training result in unfavorable prosecution outcomes, and diminishes competition in the biotechnology industry. According to BIO, universities and smaller start-up companies are vulnerable because they often do not have the resources to provide the clinical data required by examiners for inventions that encompass human *208 therapeutic uses. [n.21]

As will be examined in detail, there are several issues that define the biotechnology industry's concern about their PTO patent application examinations. These issues include:
. The PTO's misapplication of the § § 101 and 112, first paragraph, rejection creates a de facto requirement that claims which encompass a human therapy must disclose clinical data.

. The PTO misapplies the Supreme Court's Brenner decision to biotechnology applications.

. 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 decisions of the Board of Patent Appeals and Interferences (Board) and the Court of Appeals for the Federal Circuit (CAFC), the PTO has 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. Therefore, the PTO asserts that it must require demonstration of safety and efficacy in human clinical trials for pharmaceutical claims.

In December 1994, Bruce A. Lehman, Commissioner of Patents and Trademarks, acknowledged the PTO's misapplication of the utility standards to biotechnology inventions. [n.22] According to the draft guidelines:

*209 . Any credible utility identified by an applicant satisfies § 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, "[o]ur 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. [n.23]

Commissioner Lehman also proposed several other administrative and management changes worthy of note:

. The examining corps will be effectively trained to ensure that the new guidelines are fully understood and implemented.

. The new guidelines are to be incorporated into the initial training regime of new examiners.

. Examiners will be given legal training.

. Supervisors will be trained in accordance with the new guidelines. In addition, supervisors will be trained how to effectively review examiner office actions.

. The PTO will make more effective use of supervisors in reinforcing the new guidelines.

. 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. [n.24]

*210 IV. Historical Precedent: Practical Utility

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

Several of the early § § 101 and 112 patent cases decided by the United States Court of Customs and Patent Appeals (CCPA) [n.25] concerned the patentability of steroids or intermediates in the steroid synthesis process. In In re Nelson, the CCPA 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. [n.26]

In Nelson, the appellants appealed the Board's [n.27] affirmation of the examiner's rejection of claims to novel intermediates in the preparation of steroids. The examiner rejected the claims because the applicants failed to show how the claimed compounds were converted to products having known useful purposes. In response, the applicants argued that their novel compounds were useful to researchers in need of cheaper and shorter routes of synthesis for steroids having therapeutic or similar utility.

The CCPA concluded that the Board and the examiner confused the evaluation of the appellants' 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." [n.28] The CCPA 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." [n.29] Finally, the court said:

> [m]uch confused thinking on this matter has resulted from a failure to separate the requirement of § 101 that an invention be useful from the § 112 requirement that the specification shall so explain 'the manner *211 and processes of ... using' the invention as to 'enable any person skilled in the art ... to ... use the same. [n.30]

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 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 intended to put those skilled in the art in possession of sufficient information to allow them to use and to practice the claimed invention. In contrast, the Nelson court, upholding the Bremner rule [n.31] 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. [n.32]

B. § 101 is a Low Hurdle to Patentability--Proof of Safety and Efficacy is not Required

In another early case, the CCPA considered the PTO's rejection of a patent application for "Glycosides of the Pyridone Series." [n.33] In this case, the appellants claimed several glycosidic compounds with pharmaceutical applications including anti-inflammatory activity, anti-bacterial activity, and effectiveness in decreasing vascular permeability. According to the CCPA, the issue in In re Krimmel was whether a test restricted to a laboratory animal is sufficient to satisfy the statutory utility requirement 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." [n.34]

*212 The Krimmel court reversed the Board, holding:

[w]hen 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. 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. [n.35]

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:

[i]t 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. [n.36]

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:

[t]here 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. [n.37]

C. Brenner v. Manson: The Practical Utility Requirement

Five years after Krimmel, 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 that process. [n.38] The Brenner case *213 came to the Supreme Court by way of a request for an interference proceeding [n.39] during the prosecution of Manson's application. The disputed invention concerned a novel process for making certain known steroids. [n.40] 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. Manson requested that an interference be declared. The examiner, however, 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. The Board considered a reference cited by Manson that disclosed 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." [n.41]

Manson appealed to the CCPA which overturned the Board's decision. The CCPA 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.'" [n.42]

The Commissioner then 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 ...." [n.43] The "running dispute" over the definition of utility was *214 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" [n.44] and the CCPA's interpretation that "it is sufficient that a process produces the result intended and is not detrimental to the public interest." [n.45]

D. "Substantial Utility" is Required--The Supreme Court's Decision

The Supreme Court held in a 7-2 decision that a chemical process that produces the intended product or yields a compound that belongs to a class of compounds that are the subject of serious scientific investigation does not make the process "useful" under 35 U.S.C. § 101. [n.46] The Supreme Court described the quid pro quo contemplated by the U.S. Constitution as a practical economic interaction between the government and inventors. The Court required a patent applicant to disclose a "substantial utility" for his or her invention, i.e., a utility "where specific benefit exists in currently available form." [n.47] The Court 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." [n.48]

The Supreme Court stated that its holding was equally applicable to process claims and product-by-process claims:

We 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 usetesting, a different set of rules was meant to apply to the process which yielded the unpatentable product." [n.49]

Under Brenner v. Manson, an applicant must present evidence sufficient for a finding of substantial utility, e.g., that a specific benefit exists in a currently available form, in order to obtain an allowance for a process claim. Clearly, evidence that structurally similar compounds have a pharmacological effect in an animal model is insufficient.

*215 E. Examiners Misapply 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 with no human clinical information. In general, examiners have used Brenner to support the rule that where an invention embodies a potential use as a human therapeutic, yet the application discloses only in vitro or animal data in support of such utility, the claims are unpatentable under § 101 or § 112, first paragraph. This type of rejection by the PTO is tantamount to a requirement that the invention be actually reduced to practice, i.e., that it be in a commercially viable condition as of the filing date.

In applying Brenner, the examiners must remember that the Supreme Court decision was limited to the facts as developed in the prosecution and appeal. Specifically, Manson's specification did not disclose any utility for his claimed invention. Rather, he relied on the known properties of structurally similar compounds to make an analogy between the utility of his compound and the prior art. Therefore, the Brenner decision does not stand for the proposition that lack of human clinical data renders a claim not useful under § 101.

Additionally, the Supreme Court's language does not explain the problem of process claims or a product-by-process claims for which there is evidence of a utility in the form of a research use or animal data which 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? [n.50] Another unanswered question is whether a claim should be allowed for a compound whendata from an animal model or an in vitro experiment 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." [n.51]

*216 F. Brenner Applied--The Relationship Between the Utility and Enablement Standards

A year later, the CCPA applied the Brenner decision in two concurrent cases. [n.52] In both cases, the applicants claimed compounds useful as intermediates in the production of other compounds. Relying heavily on the Brenner decision, the CCPA stated: "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, the presently claimed intermediates, are useful." [n.53] In In re Joly, the court stated: "it is not enough 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." [n.54]

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 *217 would know how to use the compounds for that purpose. [n.55] The CCPA 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. [n.56]

The CCPA also criticized the applicants' general reference to "biological activity" or "biological properties" displayed by the claimed compounds. According to the CCPA, "it is what the compounds are disclosed to do that is determinative here." [n.57] The CCPA described the interrelationship 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." [n.58] Although general reference to the "biological properties" of a claimed compound is not sufficient to overcome the utility hurdle of § 101, the CCPA acknowledged that animal data suggestive of therapeutic properties may be sufficient to overcome the utility requirement for composition of matter claims. [n.59]

*218 G. Animal Data may be Sufficient to Overcome the Utility Hurdle

In 1970, the Second Circuit decided a patent infringement suit where a key issue turned on whether a patentee's claims to a new chemical compound are valid when they claim a therapeutic use based solely on data generated from an animal model. [n.60] The Second Circuit held that:

> [o]ne 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. [n.61]

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 overcome 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). [n.62] The Carter-Wallace court 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." [n.63] Rather, the Supreme Court's opinion in Brenner left this question open.

According to the Carter-Wallace court, however, the Krimmel decision answered the same question five years earlier: "the statutory *219 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." [n.64]

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. § 101 by claiming properties of therapeutic value that were adequately demonstrated through tests on standard experimental animals." [n.65]

H. Proof of Pharmacological Activity may be Sufficient to Establish Practical Utility

Ten years after the Second Circuit decided Carter-Wallace, the CCPA confronted a similar situation in Nelson v. Bowler. [n.66] 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 CCPA 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. The Board, however, ruled that Nelson's evidence of the 16-phenoxy prostaglandin's effect on gerbil colon smooth muscle tissue and rat blood pressure failed to recite practical utility. The Board, therefore, awarded priority to Bowler.

The CCPA 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." [n.67] The CCPA reasoned that " s ince it is crucial to *220 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." [n.68]

In accordance with the Carter-Wallace decision, the CCPA 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. One skilled in the art, therefore, would be "reasonably certain" that Nelson's compounds had practical utility. In reversing the Board, the CCPA concluded 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." [n.69]

I. The Utility Standard--A Two-Step Analysis

Five years after the Nelson decision, the CAFC decided Cross v. Iizuka. [n.70] In this interference case, the CAFC confronted 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 requirement of 35 U.S.C. § 112, first paragraph. [n.71]

The Board concluded Iizuka was entitled to the benefit of his *221 Japanese priority application. Relying on In re Bundy [n.72] and Nelson v. Bowler, [n.73] the Board held that "tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use." [n.74] The Board also said that:

> [k]nowledge 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. [n.75]

In affirming the Board's decision, the CAFC 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 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." [n.76]

According to the CAFC, 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 A2 biosynthesis. The CAFC concluded that "evidence of any utility is sufficient when the applicant does not recite any particular utility." [n.77]

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 *222 available form-- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." [n.78] 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 Cross court observed that the Nelson court had recognized that the actual testing disclosed was insufficient to establish an actual reduction to practice. Nonetheless, the Nelson court found that the extensive in vivo testing was routine in nature and not an indicator that extensive research was required. The Cross court stated: "it is well settled that if the courts do not specify any particular use, evidence proving substantial utility for any purpose is sufficient to establish an actual reduction to practice." [n.79]

Finally, the Cross court determined whether the inhibitory effect on thromboxane synthetase and bovine microsomes, i.e., in vitro utility, sufficiently complied with the practical utility requirements of 35 U.S.C. § 101. According to the Cross court, "[a]dequate proof of any pharmacological activity constitutes a showing of practical utility." [n.80] In addition, the Cross 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." [n.81]

Cross, the defendant, 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 CAFC agreed with the Board that there was "a reasonable correlation *223 between the disclosed in vitro utility and an in vivo activity, and therefore a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonably based on the probative evidence." [n.82] The Cross 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." [n.83]

The CAFC 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 Cross court found that the invention claimed a pharmacological activity, not a specific human therapeutic use and agreed with the Board that the applicant's failure to disclose a dosage range was not fatal to enable the invention. Specifically, the CAFC ruled that one skilled in the art, without inventive skill or undue experimentation, could determine the proper dosage ranges for the claimed invention. The Cross 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 the compounds. [n.84] 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 lower than for pharmaceutical (human therapeutic) claims.

K. The Two-Step Analysis Applied

Eight years after the Cross case, the CAFC considered another case where the PTO rejected an application under 35 U.S.C. § § 101 and 112, first paragraph. [n.85] In In re Ziegler, the Board sustained the examiner's *224 rejection of the claims on three grounds: (1) under 35 U.S.C. § 102(g); [n.86] (2) under 35 U.S.C. § 102(e) [n.87] in view of a prior art reference because the German priority application failed to comply with 35 U.S.C. § 112; and (3) under 35 U.S.C. § 112, first paragraph, for an inadequate written description.

The issue of interest was whether the examiner and the Board correctly concluded that Ziegler was not entitled to the priority date of his German application under 35 U.S.C. § 119 [n.88] because "that application failed to disclose a practical utility for, and because it failed to contain a written description of, the claimed polypropylene." [n.89] Citing Cross v. 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." [n.90] 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." [n.91]

Specifically, the CAFC found that the disclosure in Ziegler's German application that "a polymer is plastic-like" was an insufficient assertion of utility. [n.92] According to the CAFC:

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. [n.93]

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

*225 [w]e 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. [n.94]

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 U.S. Supreme Court in Brenner v. Manson. [n.95] The foregoing case law demonstrates 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 Court's language that substantial utility must exist in currently available form does not provide 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.

To understand and apply the Brenner court's holding, the examiners must understand the context of the Court's decision, including 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. This encourages 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 the U.S. Constitution. [n.96] The PTO's utility and 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. *226 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 states that the utility requirement requires that the claimed invention have "real world value." [n.97] After reviewing the Brenner v. Manson and Nelson v. Bowler decisions, the PTO now believes 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." [n.98] Thus, the PTO has retreated from its view that inventions claiming a human therapeutic use must overcome a higher utility threshold. [n.99]

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." [n.100] According to the PTO, "wholly inoperative inventions are not useful inventions under 35 U.S.C. § 101." [n.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., a perpetual motion machine. [n.102]

*227 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 CAFC, "[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 affect the object proposed.'" [n.103] The Federal Circuit interprets the 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." [n.104]

As early as 1967, the CCPA ruled that commercial viability is not a prerequisite to patent protection. [n.105] In In re Chilowsky, the issue was whether the applicant's disclosure sufficiently enabled a skilled artisan to construct an operable device 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." [n.106] 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." [n.107]

The CCPA 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 generally alleged that the invention might not work because of theoretical difficulties that might arise during construction. The CCPA stated that the PTO's principles for determining operativeness and sufficiency of disclosure should be uniform, but also stated:

*228 [t]he 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. [n.108]

In reversing and remanding the case, the Chilowsky court reminded the PTO that an application must be judged on what is claimed, not by the supposed mental state of the applicant at the time the application is filed. [n.109] If the disclosure is sufficient to enable a skilled artisan to practice the invention, it simply does not matter whether the applicant understands or explains 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. The CCPA 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." [n.110]

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 are not appropriate. [n.111] Finally, the Chilowsky court emphasizes that the principal underlying operativeness under § 112 must 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 *229 method of making claims and more evidence for method of use claims.

B. An Applicant's Claims are Prima Facie Useful, Unless they are Unreasonable on their Face

Eleven years after Chilowsky, the CCPA once again found that the PTO inappropriately tried to ratchet up the amount of evidence needed to show patentability in chemical cases. [n.112] The application contained composition of matter and method of use claims for isoflavone compounds useful for treating vascular, inflammatory, and vitamin-P deficiency disorders.

Interpreting prior case law as requiring proof of usefulness, [n.113] 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." [n.114] 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 supplied to humans and animals suffering from vascular disorders." [n.115] While arguing that his specification contained sufficient evidence of usefulness, the applicant submitted affidavits describing the clinical use of one of the claimed compounds in treating vascular disorders. The examiner sustained his rejection stating that the record demonstrated that the claimed compounds were not safe and effective for all of the alleged uses. The Board agreed in substance with the examiner's arguments.

On appeal, the CCPA reminded the PTO that the "amount of evidence required depends on the facts of each individual case." [n.116] In addition, the CCPA said that " i n the absence of any apparent reason why the compounds disclosed will not sofunction, or of any evidence showing that they actually do not, the statements in the application are generally deemed sufficient." [n.117] Therefore, the CCPA reversed the *230 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." [n.118] In its decision, the CCPA makes it clear that the PTO has the initial burden to demonstrate that an applicant's claims [n.119] 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." [n.120] According to the new guidelines, examiners should be guided by the principle of "credibility" while 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." [n.121]

According to the new guidelines, the examiner determines credibility by ascertaining whether one skilled in the art would consider the applicant's assertions 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.

*231 VI. § § 101 and 112 Rejections: Inoperative Inventions Lack Utility

A. Evidentiary Support for Examiner Rejections is Required

In another chemical case, the CCPA set forth how the PTO should evaluate claims under § 112, first paragraph. [n.122] 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 CCPA told the PTO that its concern should be over the truth of the applicant's assertion. The CCPA stated:

[a]s a matter of Patent Office practice, ... 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. [n.123]

The Marzocchi court's interpretation of the examiner's initial burden is consistent with In re Chilowsky and In re Gazave. A specification is enabled unless there is reason to doubt the objective truth of the statements contained therein. In new areas of technology, however, 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:

*232 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 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. [n.124]

However, the CCPA 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." [n.125] 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 asserts that the inability of a skilled artisan to predict the result of chemical reactions may be sufficient to doubt the objective truth of a specification. In addition, the Marzocchi court imposes a relatively low evidentiary burden on the examiner; an argument that is inconsistent with the contested statement. The Marzocchi court's

decision defines the boundaries of the battlefield between an applicant and the PTO over what constitutes an examiner's prima facie case of nonenablement. 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 CCPA 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 Determines the Scope of the Disclosure

In a case decided the same year as In re Marzocchi, the CCPA considered another § § 101 and 112, first paragraph, case in the chemical arts and upheld the PTO's rejection of the applicant's claims because they were incredible. [n.126] According to the Fouche court, the examiner and the Board doubted whether the claimed compounds were useful for *233 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." [n.127]

According to the Fouche court, the applicant need not disclose examples to enable one skilled in the art to use the claimed invention. The applicant, however, must disclose that quantum of 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. [n.128] The CCPA held that the examiner justifiably asserted that the applicant's claims were incredible and that the applicant failed to meet his burden of showing that his disclosure of how to use the claimed compounds for therapeutic purposes was true. [n.129]

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

Ten years after the Marzocchi decision, the CCPA presided over another enablement case in the chemical arts. In In re Bundy, the CCPA considered an applicant's appeal from the Board's affirmation 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, such as dosage information, for the claimed compounds. The applicant, however, did disclose that the claimed compounds possessed activity similar to the known E-type prostaglandins. Nevertheless, 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." [n.130] The issue before the CCPA therefore was whether the applicant's disclosure that the claimed compounds were useful, and used in the same manner as known prostaglandins, sufficiently satisfied the how-to-use requirement of § 112, first paragraph.

*234 In deciding the case, the Bundy court referred to In re Gardner [n.131] 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 shifts to the applicant to provide rebuttal evidence. The CCPA found that the applicant disclosed some activity for 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 CCPA focused its analysis on whether the applicant enabled the skilled artisan to use the claimed compounds.

The Bundy court held that the skilled artisan could 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 complied with the how-to-use requirement of § 112 and that:

> [e]arly 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. [n.132]

D. Lack of Utility and Therefore Non-Operability Rejections

In In re Jolles, the PTO had rejected claims to pharmaceutical compositions and methods of treating acute myeloblastic leukemia in humans. [n.133] 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 in the file history disclosed data for seven of the claimed compounds in mice for sub-acute toxicity activity against sarcoma 180 tumors and activity against leukemia L1210.

The examiner rejected both the composition of matter and method of use claims under §§ 101 and 112, first paragraph, for lack of proof of utility, and therefore, non-operability. The examiner stated that there was "insufficient evidence of operativeness in the record that *235 the various compositions were safe and effective to treat acute myeloblastic leukemia in human patients." [n.134] The examiner further asserted that the "instant claims are directed to an incredible utility." [n.135] 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." [n.136]

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 compounds encompassed by the claims was sufficiently disclosed in the specification by analogy to structurally similar compounds 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]." [n.137]

Although the claims stood rejected under § § 101 and 112, the CCPA considered the case to turn on the utility issue. According to the CCPA, 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." [n.138] 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 *236 correct." [n.139] 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," i.e., 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: what the skilled artisan would accept as correct.

The Jolles court told the Board that its reliance on In re Krimmel was misplaced because, in appropriate circumstances, animal data is predictive of success in humans. Citing two prior CCPA cases, the Jolles court reiterated that animal data may be sufficient for a demonstration of utility in human therapeutic claims. [n.140] The Jolles court summarized the Board finding that:

> 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 derivatives to the derivative in allowed claims 15 and 35 when considered with the Maral animal tests. [n.141]

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

Retreating from its initial position, the PTO's new guidelines embrace the federal courts' interpretation of a proper utility analysis. Recognizing that the claimed invention is the proper focus of the utility analysis, the PTO guidelines state: "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." [n.142] Citing In re Krimmel, the PTO further states that "examiners should be especially careful not to read into a claim *237 unclaimed results, limitations or embodiments of an invention." [n.143]

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." [n.144] If the examiner cannot find an explicit statement of utility in the specification, the examiner must then determine whether a utility would be readily apparent to one skilled in the art from the disclosure or from the characteristics of the invention.

Citing several federal court decisions, [n.145] 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 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." [n.146]

The PTO now appears to recognize 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. [n.147] In particular, the PTO guidelines state:

[s]pecial 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 model for testing the effectiveness of drugs for treating *238 a disorder in humans, should not, standing alone, serve as a basis for challenging the asserted utility under § 101. [n.148]

Procedurally, the initial burden is on the examiner to establish a prima facie case of lack of utility and to provide evidentiary support thereof. [n.149] 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 their conclusion of 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. [n.150]

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. [n.151]

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 if the asserted utility is not consistent with the evidence of record and current 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." [n.152]

Once the examiner properly rejects an invention for lack of utility, the burden shifts to the applicant to rebut the examiner's prima facie case. The applicant has several tools for rebutting the examiner's prima facie case, including amending the claims and submitting a 37 C.F.R. § 1.132 declaration. 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 *239 that the character and amount of evidence needed to support an asserted utility varies 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." [n.153] Finally, the guidelines recognize that examiners must provide evidentiary support for their conclusions. Blanket conclusions of unpatentability, without clear evidentiary support, are not a sufficient basis for a rejection.

VII. Human Therapeutic Cases

A. Human Safety and Efficacy Data Usually is not Necessary to Comply with § 101

Lack of safety and efficacy is a recurring theme in the PTO's rejections of many of the applications cited in the case law. 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 do not meet the unpublished PTO standards. The federal courts, however, have continuously reminded the PTO that safety and efficacy are not elements of 35 U.S.C. § § 101 or 112, firstparagraph. [n.154]

As early as 1962, the CCPA 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. [n.155] In In re Hartop, the applicants claimed a "therapeutic composition" to a 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. He was of the opinion that vascular damage at the site of the injection was a possibility. Despite the applicants' disclosure of the invention's safety and efficacy in rabbits, the examiner rejected the *240 claims under § 101. The examiner stated and the Board agreed that:

[a]pplicants 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. [n.156]

The CCPA 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 applicants' 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. [n.157]

The CCPA concluded that the FDA, 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 FDA 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 FDA, not the PTO, Determines when a Drug is Safe for the Commercial Market

The CCPA in In re Anthony, again held that the FDA, not the PTO, is charged with determining whether drugs are sufficiently safe and effective for the commercial market. [n.158] The issue in In re Anthony was *241 whether the PTO correctly required the applicant to overcome 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 CCPA 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. [n.159]

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." [n.160] 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." [n.161] 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. [n.162]

The Anthony court's analysis makes sense when one considers exactly what a patent conveys: the right to exclude others from making, using, or selling the claimed invention for a statutorily prescribed amount of time. [n.163] The patent grant does not give the patentee the right to make, use, or sell the claimed invention. By granting a patent on an *242 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 nonobvious as defined by the patent statute. Whether the patented invention is safe and effective for use in humans is determined by another agency, the FDA.

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 stated:

> '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. [n.164]

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:

> [t]he 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. [n.165]

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

[a]lthough 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 *243 for believing that the drug is unsafe, and shall be accepted if it establishes a reasonable probability of safety. [n.166]

C. Commercial Usefulness is not the Utility Standard Under § 101

Several years after In re Anthony, the CCPA considered another chemical case in which the examiner rejected the applicant's claims for lack of proof of utility because the disclosure failed to provide human clinical data. [n.167] 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 mouth washes, tooth pastes, and other related products.

The examiner rejected all claims for lack of proof of utility because "those skilled in the art would not accept applicant's allegation as obviously valid and correct." [n.168] The CCPA 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." [n.169]

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. [n.170]

*244 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.

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. [n.171]

The Langer court interpreted the PTO's insistence on human clinical data as tantamount to a requirement that 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

Two years after In re Langer, the CCPA 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. [n.172] The examiner argued that the applicant's invention was not per se believable without proof and that the burden was on the applicant to provide evidence to support the alleged utility. [n.173]

*245 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, stating:

> [p]roof 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. [n.174]

The CCPA 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 CCPA stated that the "amount of evidence required to overcome a § 101 rejection depends on the facts of each case." [n.175] The CCPA held:

> [s]imilarly, 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. [n.176]

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 *246 and the asserted utility." [n.177] The new guidelines make it clear that the applicant does not need to

demonstrate that there is a statistically proven correlation between the characteristics of a compound and an asserted therapeutic use. Also, the applicant does not needto 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." [n.178]

According to the new guidelines, if a specification contains in vitro, animal data or both, "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." [n.179] The guidelines state this procedure must be followed whether or not the tests or animal models 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." [n.180]

Citing Ex parte Balzarini, [n.181] 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." [n.182] Human clinical trials are prerequisites for FDA approval not patentability. [n.183] As a general rule, however, if an applicant initiates human clinical trials for a product or process to treat an *247 indication, the subject matter of that trial meets the "reasonably predictive of utility" burden. [n.184]

The new PTO guidelines specifically recognize that "other agencies of the government," e.g., the FDA, are responsible for enforcing standards established by statute for the advertisement, use, sale, or distribution of drugs. Citing several cases, [n.185] 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." [n.186]

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." [n.187] 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 differentiation between claims which treat a symptom of a disease and claims which are directed to curing the disease itself. Finally, the guidelines state that "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." [n.188]

F. In re Brana: The CAFC's Latest Word on Human Therapeutic Utility

In March 1995, the CAFC reaffirmed its earlier decisions that proof of human therapeutic utility is not a condition precedent to a pharmaceutical patent. [n.189] In In re Brana, the Board adopted the *248 examiner's position that the specification failed to describe any specific disease against which the claimed compounds were active and that the prior art tests and the tests disclosed in the applicants' specification were insufficient to establish a reasonable expectation that the claimed compounds had a practical utility. While explaining that the rejection could also have been sustained under § 101 for failure to disclose a practical utility, the Board affirmed the examiner's rejection of the claimed compounds under § 112, first paragraph, for lack of an enabling disclosure.

The CAFC reconsidered an applicant's evidentiary burden for determining whether an invention has practical utility or is useful. Citing several cases, Judge Plager chastised the Commissioner for appealing this case when he wrote, "[t]his is not a new issue; it is one which we would have thought had been settled by case law years ago." [n.190]

The Commissioner's first argument was that "the applicant's specification failed to disclose a specific disease against which the claimed compounds are useful, and therefore, absent undue experimentation, one of ordinary skill in the art was precluded from using the invention." [n.191] The CAFC disagreed with the Commissioner's argument that the applicants did no more than make a general assertion that the claimed compounds possessed biological activity. The CAFC found that the applicants' specification contained an assertion that the claimed compounds had "a better action and a better action spectrum as antitumor substances" than other prior art compounds. [n.192] The CAFC concluded that the tumor models [n.193] used by the applicants represented a specific *249 disease against which the claimed compounds were alleged to be effective and, consequently, that the applicants' specification contained a sufficiently specific use.

Alternatively, the Commissioner argued that even if the specification alleged a specific use, "the tests offered by the Applicants to prove utility were inadequate to convince one of ordinary skill in the art that the claimed compounds are useful as antitumor agents." [n.194] Referring to In re Marzocchi, the CAFC reminded the Commissioner "that the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." [n.195] Also, referring to In re Bundy, the CAFC stated:

> [o]nly after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility. [n.196]

Based on the record, the CAFC concluded that the PTO did not meet its initial burden. The CAFC did not find the evidentiary proof submitted by the PTO to be persuasive in establishing that one of ordinary skill in the art would reasonably doubt the applicants' assertions of utility. The CAFC stated: "[t]he purpose of treating cancer with chemical

compounds does not suggest an inherently unbelievable undertaking or involve implausible scientific principles." [n.197] Accordingly, the CAFC concluded that the "applicants should not have been required to substantiate their presumptively correct disclosure to avoid a rejection under the first paragraph of § 112." [n.198]

The CAFC argued that its decision was further buttressed by a declaration submitted by the applicants that demonstrated that several of the compounds within the scope of the claims exhibited significant antitumor activity against the L1210 murine model in vivo. The CAFC summarized the PTO's position as follows:

> The Commissioner counters that such in vivo tests in animals are only preclinical tests to determine whether a compound is suitable for processing in the second stage of testing, by which he apparently means in *250 vivo testing in humans, and therefore are not reasonably predictive of the success of the claimed compounds for treating cancer in humans. [n.199]

Referring to Scott v. Finney, [n.200] the CAFC concluded that the Commissioner and the Board confused the standards for patentability with the requirements of FDA approval. The CAFC stated:

> FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer. [n.201]

Although the Brana decision is neither new nor revolutionary, it is important for its reaffirmation of the proposition that the PTO has the initial burden of proof to provide sufficient evidence that one of ordinary skill in the art would reasonably doubt an applicant's asserted utility. In addition, the CAFC unequivocally states that the standards for a patent and FDA approval are different. Finally, the CAFC recognizes the PTO's continued application of safety and efficacy standards for pharmaceutical-type inventions is not only contrary to established case law, but runs the risk of seriously inhibiting the incentives to compete among biotechnology companies and, therefore, jeopardizes the very existence of the industry.

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 identify for the Commissioner any problems and deviations from CAFC precedent. This committee could formulate a proactive response to prosecution problems before serious injury to biotechnology companies occurs.

The Commissioner is statutorily authorized to convene a joint industry-*251 PTO advisory committee. [n.202] In addition, the Federal Advisory Committee Act (FACA) provides rules under which such an industry-PTO advisory committee may function. [n.203] In fact, the PTO already has several advisory committees such as the Public Advisory Committee for Trademark Affairs, the Advisory Committee for Patents, and the Advisory Commission on Patent Law Reform. [n.204]

For example, the Advisory Commission on Patent Law Reform advises 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, i.e., 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 may be to expand the scope of the Biotechnology Technical Advisory Committee (BTAC). In the Department of Commerce's Bureau of Export Administration, the BTAC 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. [n.205] A subcommittee of the BTAC might be formed in order to monitor the PTO's examination procedures.

IX. Conclusion

Prior to the Proposed Utility Guidelines that were 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 and enablement standards for human therapeutic inventions placed the public at risk. A patent, however, does not guarantee that the disclosed invention will ever be practiced. The FDA 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 arts, in the biotechnology and pharmaceutical field, there is a second layer of *252 government standing between the U.S. public and the patented invention.

According to the MPEP, 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 PTO 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. [n.206]

The case law, however, demonstrates that the "Examining Corps" and the Commissioner had a different agenda from that disclosed in the MPEP. [n.207] 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 were paternalistic feelings among examiners to 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 those in Group 1800, must be provided with additional legal education in order to properly apply case law during the examination process.

Several themes are discernible from the case law cited herein. First, 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 is the invention. Second, the Supreme Court's decision in Brenner v. Manson is not a basis for automatically rejecting, for lack of utility and enablement, claims unsupported by human clinical data that might encompass a human therapy. 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. Third, the PTO must distinguish between pharmacological and pharmaceutical claims. The utility dynamic will necessarily be different depending upon thetype of claim. Fourth, 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. Finally, examiners *253 must provide evidence, such as citations to scientific literature, to support their prima facie cases of rejection. Vague allegations of unpatentability because of lack of utility or operability must be avoided.

The new PTO guidelines go a long way toward alleviating the problems described in this article and bring the PTO into conformance with the federal case law. In summary, the new guidelines direct examiners to adhere to the following analysis when examining applications for compliance with § 101. The examiners are directed to:

(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. 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; and

(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. [n.208]

The new proposed PTO guidelines for utility are neither revolutionary nor new. The new guidelines simply attempt to align utility examination procedures with CCPA and CAFC precedent and with the PTO's own internal rules.

Improper examination procedures may lead to unsubstantiated rejections that 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 should be established to identify problem areas, conduct fact finding and legal research, and then report those findings to the Commissioner. The benefits of this joint PTO-industry committee are several. First, the committee may provide early detection of potential examination procedures in conflict with legal precedent. *254 Second, the committee may provide a joint factual and legal analysis of the problems in the examination process which can be submitted to the Commissioner. Third, representatives of this joint PTO-industry committee may 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 death of a particular invention. Therefore, a proactive system, like the proposed joint PTO-industry advisory committee, for identifying problems and providing solutions may be beneficial in heading off years of wasteful litigation.

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[n.1]. The Office of Science and Technology Policy defines "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." 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"; Office of Technology Assessment, Commercial Biotechnology: An International Analysis 3 (Jan. 1984). The use of "biotechnology" herein is consistent with either definition.

[n.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)).

[n.3]. See U.S. Patent Nos. 4,740,470; 4,468,464; and 4,237,224. See also S.N. Cohen et al., Construction of Biologically Functional Bacterial Plasmids in Vitro, PNAS 3240 (1973); J.F. Morrow et al., Replication and Transcription of Eukaryotic DNA in Escherichia coli, PNAS 1743 (1974).

[n.4]. Sandra H. Cuttler, The Food and Drug Administration's Regulation of Genetically Engineered Human Drugs, 1 J. Pharmacy & Law 191, 193 (1992) (citing Frank E. Young, The Reality Behind the Headlines, From Test Tube to Patient: New Drug Development in the United States 4 (1988)).

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

[n.6]. Id.

[n.7]. Dr. Ronald E. Barks, Presentation on Government Licensing at Franklin Pierce Law Center, Advanced Licensing Institute (July 1994).

[n.8]. Michael W. Glynn, Presentation on Pharmaceutical/Biotechnology Licensing at Franklin Pierce Law Center, Advanced Licensing Institute (July 1994).

[n.9]. U.S. Const. art. I, § 8, cl. 8. 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., 548 F.2d 1560, 7 U.S.P.Q.2d (BNA) 1057 (Fed. Cir. 1988).

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

[n.11]. Id.

[n.12]. 35 U.S.C. § 6(a) (1988). 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) (1988). The Commissioner is an Assistant

Secretary of Commerce and reports to the Secretary of Commerce. 35 U.S.C. § § 3(d), and 6(a) (1995).

[n.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." 35 U.S.C. § 131 (1995).

[n.14]. Manual of Patent Examining Procedure § 701 (5th ed. 1993) (MPEP). The MPEP 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. The MPEP does not have the force of law, but it is entitled to notice so 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, 882 F.2d 1570, 11 U.S.P.Q.2d (BNA) 1866 (Fed. Cir. 1989).

[n.15]. 35 U.S.C. § 101 (1994).

[n.16]. 35 U.S.C. § 102 (1994).

[n.17]. 35 U.S.C. § 103 (1994).

[n.18]. 35 U.S.C. § 112 (1994).

[n.19]. Notice of Public Hearings and Request for Comment on Patent Protection for Biotechnological Inventions 59 Fed. Reg. 45,267-271 (1994).

[n.20]. Biotechnology Industry Organization, The Biotechnology Industry and Intellectual Property Protection (Oct. 17, 1994).

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

[n.22]. See Bruce A. Lehman, Remarks for Press Conference on Utility Guidelines: Announcement of Draft Examining Guidelines for Utility 2 (Dec. 20, 1994). See 60 Fed.

Reg. 97 (1995) (Request for Comments on Proposed Utility Examination Guidelines proposed on January 3, 1995). See also Overview of Legal Precedent Governing the Utility Requirement (The PTO's analysis of the law governing 35 U.S.C. § 101 to support the Proposed Utility Examination Guidelines in 60 Fed. Reg. 97 (1995)).

[n.23]. See Bruce A. Lehman, Remarks for Press Conference on Utility Guidelines: Announcement of Draft Examining Guidelines for Utility 1-2 (Dec. 20, 1994).

[n.24]. Id. at 2-4.

[n.25]. The CCPA was the precursor to the Court of Appeals for the Federal Circuit.

[n.26]. In re Nelson, 280 F.2d 172, 126 U.S.P.Q. (BNA) 242 (C.C.P.A. 1960), overruled in part by In re Kirk, 376 F.2d 936, 153 U.S.P.Q. (BNA) 48 (C.C.P.A. 1967).

[n.27]. The term "Board" as used herein, refers to the Patent Board of Appeals and its successor, the Board of Patent Appeals and Interferences (BPAI).

[n.28]. 280 F.2d at 177, 126 U.S.P.Q. (BNA) at 248.

[n.29]. Id. at 183, 126 U.S.P.Q. (BNA) at 252.

[n.30]. Id. at 184, 126 U.S.P.Q. (BNA) at 252.

[n.31]. In re Bremner, 182 F.2d 216, 86 U.S.P.Q. (BNA) 74 (C.C.P.A. 1950).

[n.32]. In re Nelson, 280 F.2d 172, 184, 126 U.S.P.Q. (BNA) 242, 253 (C.C.P.A. 1960).

[n.33]. In re Krimmel, 292 F.2d 948, 130 U.S.P.Q. (BNA) 215 (C.C.P.A. 1961).

[n.34]. Id. at 952, 130 U.S.P.Q. (BNA) at 218.

[n.35]. Id. at 953, 130 U.S.P.Q. (BNA) at 219.

[n.36]. Id.

[n.37]. Id. at 954, 130 U.S.P.Q. (BNA) at 220.

[n.38]. Brenner v. Manson, 383 U.S. 519, 148 U.S.P.Q. (BNA) 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, Edward J. Brenner, to review decisions of the CCPA. The Supreme Court concluded that the CCPA 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."

[n.39]. See 35 U.S.C. § 102(g) (1994).

[n.40]. See Brenner v. Manson, 383 U.S. 519, 521 n.1, 148 U.S.P.Q. (BNA) 689, 690 n.1. 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."

[n.41]. 383 U.S. at 522, 148 U.S.P.Q. (BNA) at 690.

[n.42]. Id. at 522, 148 U.S.P.Q. (BNA) at 691.

[n.43]. Id.

[n.44]. See, e.g., In re Bremner, 82 F.2d at 216, 86 U.S.P.Q. (BNA) 74 (C.C.P.A. 1950).

[n.45]. See, e.g., In re Manson, 333 F.2d 234, 238, 142 U.S.P.Q. (BNA) 35, 38 (C.C.P.A. 1964), rev'd, 383 U.S. 519, 148 U.S.P.Q. (BNA) 35 (1965).

[n.46]. Brenner v. Manson, 383 U.S. at 535, 148 U.S.P.Q. (BNA) at 689.

[n.47]. Id. at 534, 148 U.S.P.Q. (BNA) at 695.

[n.48]. Id. at 536, 148 U.S.P.Q. (BNA) at 696.

[n.49]. Id. at 535, 148 U.S.P.Q. (BNA) at 696.

[n.50]. But see Rebecca Eisenberg, Technology Transfer and the Human Genome Project: Some Problems with Patenting Research Tools, The Future of Intellectual Property Protection for Biotechnology (International Conference at Washington Law School Foundation Oct. 21-23, 1993).

[n.51]. Brenner v. Manson, 383 U.S. at 537, 148 U.S.P.Q. (BNA) at 696.

[n.52]. In re Joly, 376 F.2d 906, 153 U.S.P.Q. (BNA) 45 (C.C.P.A. 1967); In re Kirk, 376 F.2d 936, 153 U.S.P.Q. (BNA) 48 (C.C.P.A. 1967). In re Joly was an appeal from the decision of the Board affirming the Examiner's rejection of product and process claims of application Serial No. 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 and § 112, first paragraph, the "how-to-use" component of § 112, first paragraph, and the legal adequacy of the assertions of usefulness under § 101.

[n.53]. In re Joly, 376 F.2d at 945, 153 U.S.P.Q. (BNA) at 47. In In re Joly, the applicant's specification disclosed the production of intermediates which could be used to make two named 2,3-diketo steroids. The applicant only disclosed that the two 2,3-diketo steroids were structurally similar to 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.

[n.54]. In re Joly, 376 F.2d at 945, 153 U.S.P.Q. (BNA) at 47.

[n.55]. In re Kirk, 376 F.2d at 939, 153 U.S.P.Q. (BNA) at 51.

[n.56]. Id. at 942, 153 U.S.P.Q. (BNA) at 53.

[n.57]. Id. at 941, 153 U.S.P.Q. (BNA) at 52.

[n.58]. Id. at 942, 153 U.S.P.Q. (BNA) at 53.

[n.59]. Id. at 945, 153 U.S.P.Q. (BNA) at 56. See also Id.; In re Hitchings, 342 F.2d 80, 144 U.S.P.Q. (BNA) 637 (C.C.P.A. 1965); In re Krimmel, 292 F.2d 948, 130 U.S.P.Q. (BNA) 215 (C.C.P.A. 1961); In re Dodson, 292 F.2d 943, 130 U.S.P.Q. (BNA) 224 (C.C.P.A. 1961); In re Bergel, 292 F.2d 955, 130 U.S.P.Q. (BNA) 206 (C.C.P.A. 1961) (supporting the proposition that "usefulness of compositions of matter under § 101 may be established by an appropriate demonstration that the composition has useful properties or activities when tested in laboratory animals").

[n.60]. Carter-Wallace, Inc. v. Riverton Labs., Inc., 433 F.2d 1034, 167 U.S.P.Q. (BNA) 656 (2d Cir. 1970). Carter-Wallace decided 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 patentee supported the claim of anti- convulsive properties by reference to tests conducted on mice and supported the claim of a paralyzing action by reference to pharmacological studies on unnamed animals.

[n.61]. Carter-Wallace, Inc., 433 F.2d at 1040, 167 U.S.P.Q. (BNA) at 660.

[n.62]. Id. at 1039-40, 167 U.S.P.Q. (BNA) at 660. See also 21 U.S.C. § § 301-394 (1995).

[n.63]. 433 F.2d at 1039, 167 U.S.P.Q. (BNA) at 660. 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." Id.

[n.64]. Id.

[n.65]. Id.

[n.66]. 626 F.2d 853, 206 U.S.P.Q. (BNA) 881 (C.C.P.A. 1980). Nelson arose in the context of an interference proceeding between Upjohn Company, the assignee of Nelson, and 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. Id.

[n.67]. Id. at 856, 206 U.S.P.Q. (BNA) at 883. The CCPA defined practical utility as a "short hand" way of attributing "real world value" to the claimed subject matter. In other words, the CCPA 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.

[n.68]. Id. at 856, 206 U.S.P.Q. (BNA) at 883.

[n.69]. Id.

[n.70]. Cross v. Iizuka, 753 F.2d 1040, 224 U.S.P.Q. (BNA) 739 (Fed. Cir. 1985). This appeal originated 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 sub2 , a highly unstable, biologically active compound which is convertible to the stable thromboxane B sub2 by the addition of water.

[n.71]. Id.

[n.72]. See In re Bundy, 642 F.2d 430, 209 U.S.P.Q. (BNA) 48 (C.C.P.A. 1981) where the CCPA 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.

[n.73]. See supra note 66.

[n.74]. Cross v. Iizuka, 753 F.2d 1040, 1043, 224 U.S.P.Q. (BNA) 739, 741 (Fed. Cir. 1985).

[n.75]. Id.

[n.76]. Id. at 1044 n.8, 224 U.S.P.Q. (BNA) at 742 n.8.

[n.77]. Id. at 1045, 224 U.S.P.Q. (BNA) at 743. See also Rey-Bellet v. Englehardt, 493 F.2d 1380, 181 U.S.P.Q. (BNA) 453 (C.C.P.A. 1974); Knapp v. Anderson, 477 F.2d 588, 177 U.S.P.Q. (BNA) 688 (C.C.P.A. 1973); Blicke v. Treves, 241 F.2d 718, 112 U.S.P.Q. (BNA) 472 (C.C.P.A. 1957).

[n.78]. 753 F.2d at 1046, 224 U.S.P.Q. (BNA) at 774 (citing Brenner v. Manson 383 U.S. at 534, 148 U.S.P.Q. (BNA) at 695).

[n.79]. Cross v. Iizuka, 753 F.2d at 1047, 224 U.S.P.Q. (BNA) at 745 (Fed. Cir. 1985). ((citing Blicke v. Treves, 241 F.2d 718, 112 U.S.P.Q. (BNA) 472 (C.C.P.A. 1957), (citing Knapp v. Anderson 477 F.2d 588, 177 U.S.P.Q. (BNA) 688 (C.C.P.A. 1973))).

[n.80]. 753 F.2d at 1050, 224 U.S.P.Q. (BNA) at 747.

[n.81]. Id.

[n.82]. Id.

[n.83]. Id. at 1051, 224 U.S.P.Q. (BNA) at 748.

[n.84]. See, e.g., In re Gardner, 427 F.2d 786, 166 U.S.P.Q. (BNA) 138 (C.C.P.A. 1970).

[n.85]. In re Ziegler, 992 F.2d 1197, 26 U.S.P.Q.2d (BNA) 1600 (Fed. Cir. 1993). In this case, Karl Ziegler appealed the Board's affirmation of the Examiner's rejection of a claim to polypropylene. On August 3, 1954, Ziegler filed a German patent application, "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 CAFC 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.

[n.86]. 35 U.S.C. § 102(g) (1994).

[n.87]. Id.

[n.88]. 35 U.S.C. § 119 (1994).

[n.89]. In re Ziegler, 992 F.2d at 1200, 26 U.S.P.Q.2d (BNA) at 1602.

[n.90]. Id.

[n.91]. Id. at 1201, 26 U.S.P.Q.2d (BNA) at 1603.

[n.92]. In a prior interference proceeding involving the Ziegler application, the CCPA made this finding. 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. (BNA) 458, 463 (C.C.P.A. 1973).

[n.93]. 992 F.2d at 1203, 26 U.S.P.Q.2d (BNA) at 1605.

[n.94]. Id. (quoting Kawai v. Metlesics, 480 F.2d 880, 886, 178 U.S.P.Q. (BNA) 158, 163 (C.C.P.A. 1973)).

[n.95]. 383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).

[n.96]. See U.S. Const. art. I, § 8, c1. 8.

[n.97]. See Overview of Legal Precedent Governing the Utility Requirement 1 (The PTO's analysis of the law governing 35 U.S.C. § 101 to support the Proposed Utility Examination Guidelines in 60 Fed. Reg. 97 (1995)).

[n.98]. Id.

[n.99]. See, e.g., Grant v. United States, 282 F.2d 165 (2d Cir. 1960); In re Krimmel, 292 F.2d 948, 130 U.S.P.Q. (BNA) 215 (C.C.P.A 1961).

[n.100]. Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571, 24 U.S.P.Q.2d (BNA) 1401, 1412 (Fed. Cir. 1992).

[n.101]. See Overview of Legal Precedent Governing the Utility Requirement 1-2 (The PTO's analysis of the law governing 35 U.S.C. § 101 to support the Proposed Utility Examination Guidelines in 60 Fed. Reg. 97 (1995)).

[n.102]. Id.

[n.103]. Stiftung v. Renishaw PLC, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d (BNA) 1094, 1100 (Fed. Cir. 1991) (quoting Mitchell v. Tilghman, 86 U.S. 287, 396 (1873)).

[n.104]. Id. See also Raytheon Co. v. Roper Corp., 724 F.2d 951, 958, 220 U.S.P.Q. (BNA) 592, 598 (Fed. Cir. 1983), cert. denied, 469 U.S. 835, 225 U.S.P.Q. (BNA) 232 (1984).

[n.105]. In re Chilowsky, 229 F.2d 457, 463, 108 U.S.P.Q. (BNA) 321, 326 (C.C.P.A. 1956). This case was an appeal from the Board's affirmation of the Examiner's rejection of all claims to a method and apparatus for utilizing thermal energy resulting from the atomic decomposition of uranium and its compounds.

[n.106]. Id. at 461, 108 U.S.P.Q. (BNA) at 324.

[n.107]. Id.

[n.108]. Id. at 462, 108 U.S.P.Q. (BNA) at 325.

[n.109]. See also Raytheon Co., 724 F.2d at 951, 220 U.S.P.Q. (BNA) at 596 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."

[n.110]. 229 F.2d at 463, 108 U.S.P.Q. (BNA) at 326.

[n.111]. See 724 F.2d at 952, 220 U.S.P.Q. (BNA) 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." Id. The court also observed that enablement is further supported when there is evidence that the claimed invention has met with commercial success.

[n.112]. In re Gazave, 379 F.2d 973, 154 U.S.P.Q. (BNA) 92 (C.C.P.A. 1967). Gazave is a statutory usefulness case under § 101. Gazave appealed the Board's affirmance of the Examiner's rejection of his process and composition claims for lack of proof of therapeutic utility.

[n.113]. See, e.g., In re Krimmel, 292 F.2d 995, 130 U.S.P.Q. (BNA) 206 (2d Cir. 1960); In re Novak, 306 F.2d 924, 134 U.S.P.Q. (BNA) 335 (C.C.P.A. 1962); Commonwealth Eng'g Co. v. Ladd, 199 F.Supp. 51, 131 U.S.P.Q. 255 (D.D.C. 1961).

[n.114]. 379 F.2d at 975, 154 U.S.P.Q. (BNA) at 94.

[n.115]. Id. at 976, 154 U.S.P.Q. (BNA) at 94.

[n.116]. Id. at 977, 154 U.S.P.Q. (BNA) at 96; See also Bluestone v. Schmerling, 265 F.2d 948, 121 U.S.P.Q. (BNA) 417 (C.C.P.A. 1959).

[n.117]. 379 F.2d at 977, 154 U.S.P.Q. (BNA) at 96.

[n.118]. Id.

[n.119]. See Raytheon Co., 724 F.2d at 957, 220 U.S.P.Q. (BNA) at 597 (quoting Environmental Designs, Ltd. v. Union Oil Co. of California, 713 F.2d 693, 699, 218 U.S.P.Q. (BNA) 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)).

[n.120]. See Overview of Legal Precedent Governing the Utility Requirement 2 (The PTO's analysis of the law governing 35 U.S.C. § 101 to support the Proposed Utility Examination Guidelines in 60 Fed. Reg. 97 (1995)).

[n.121]. Id.

[n.122]. In re Marzocchi, 439 F.2d 220, 169 U.S.P.Q. (BNA) 367 (C.C.P.A. 1971). The applicant in this case appealed the Board's affirmance of the Examiner's rejections of the claimed technique for improving the adhesion characteristics between glass and vinyl polymer resins under 35 U.S.C. § 103 and § 112, first paragraph.

[n.123]. Id. at 223, 169 U.S.P.Q. (BNA) at 369.

[n.124]. Id.

[n.125]. In re Marzocchi, 439 F.2d 223, 169 U.S.P.Q. (BNA) 370 (C.C.P.A. 1971).

[n.126]. In re Fouche, 439 F.2d 1237, 169 U.S.P.Q. (BNA) 429 (C.C.P.A. 1971). The CCPA upheld the Board's affirmance of the Examiner's rejection of the applicant's composition-of-matter claims to dibenzocycloheptadiene derivatives that have antidepressant, neuroleptic, and tranquilizing properties.

[n.127]. Id. at 1243, 169 U.S.P.Q. (BNA) at 434.

[n.128]. Id. at 1242, 169 U.S.P.Q. (BNA) at 434.

[n.129]. Id. at 1243, 169 U.S.P.Q. (BNA) at 434.

[n.130]. In re Bundy, 642 F.2d 430, 432-33, 209 U.S.P.Q. (BNA) 48, 51 (C.C.P.A. 1981).

[n.131]. 475 F.2d 1389, 177 U.S.P.Q. (BNA) 396 (C.C.P.A. 1973).

[n.132]. 642 F.2d at 434, 209 U.S.P.Q. (BNA) at 52.

[n.133]. 628 F.2d 1322, 206 U.S.P.Q. (BNA) 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.

[n.134]. Id. at 1325, 206 U.S.P.Q. (BNA) at 888.

[n.135]. Id.

[n.136]. Id.

[n.137]. Id. at 1326, 206 U.S.P.Q. (BNA) at 889.

[n.138]. Id.

[n.139]. Id. at 1327, 206 U.S.P.Q. (BNA) at 890; See also In re Novak, 306 F.2d 924, 134 U.S.P.Q. (BNA) 335 (C.C.P.A. 1962).

[n.140]. See, e.g., In re Bergel, 292 F.2d 955, 130 U.S.P.Q. (BNA) 206 (C.C.P.A. 1961); In re Buting, 418 F.2d 540, 163 U.S.P.Q. (BNA) 689 (C.C.P.A. 1969).

[n.141]. In re Jolles, 628 F.2d 1322, 1327, 206 U.S.P.Q. (BNA) 885, 890 (C.C.P.A. 1980).

[n.142]. See Overview of Legal Precedent Governing the Utility Requirement 2-3 (The PTO's analysis of the law governing 35 U.S.C. § 101 to support the Proposed Utility Examination Guidelines in 60 Fed. Reg. 97 (1995)).

[n.143]. Id. at 3.

[n.144]. Id.

[n.145]. See, e.g., In re Jolles, 628 F.2d 1322, 206 U.S.P.Q. (BNA) 885; In re Irons, 340 F.2d 974, 144 U.S.P.Q. (BNA) 351 (C.C.P.A. 1965); In re Langer 503 F.2d 1380, 183 U.S.P.Q. (BNA) 288 (C.C.P.A. 1974); In re Sichert, 566 F.2d 1154, 1159, 196 U.S.P.Q. (BNA) 209, 215 (C.C.P.A. 1977). See supra note 22. Under 37 C.F.R. § 1.156 (1994), deliberately false statements are grounds for rendering an issued patent unenforceable. Threat of rendering a patent unenforceable due to inequitable conduct alone should be sufficient to keep applicants honest in their assertions of utility.

[n.146]. See Overview of Legal Precedent Governing the Utility Requirement 3 (The PTO's analysis of the law governing 35 U.S.C. § 101 to support the Proposed Utility Examination Guidelines in 60 Fed. Reg. 97 (1995)).

[n.147]. Id. at 4.

[n.148]. Id.

[n.149]. Id. at 4-5.

[n.150]. Id. at 5.

[n.151]. Id.

[n.152]. Id.

[n.153]. Id. at 6 (emphasis added).

[n.154]. See, e.g., In re Jolles, 628 F.2d 1322, 206 U.S.P.Q. (BNA) 885 (C.C.P.A. 1980); Carter-Wallace Inc. v. Riverton Labs., Inc. 433 F.2d 1034, 167 U.S.P.Q. (BNA) 565 (2d Cir. 1970); In re Gazave, 379 F.2d 973, 154 U.S.P.Q. (BNA) 92 (C.C.P.A. 1967); In re Hartop, 311 F.2d 249, 135 U.S.P.Q. (BNA) 419 (C.C.P.A. 1962); In re Krimmel, 292 F.2d 948, 130 U.S.P.Q. (BNA) 215 (C.C.P.A. 1961).

[n.155]. 311 F.2d at 249, 135 U.S.P.Q. (BNA) at 419.

[n.156]. Id. at 254, 135 U.S.P.Q. (BNA) at 424.

[n.157]. Id. at 257, 135 U.S.P.Q. (BNA) at 426.

[n.158]. In re Anthony, 414 F.2d 1383, 162 U.S.P.Q. (BNA) 594 (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 1- isomers of a-ethyltryptamine and their use for treating depression. During the prosecution of the application, the assignee submitted a declaration to overcome 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. Id.

[n.159]. Id. at 1393, 162 U.S.P.Q. (BNA) at 602.

[n.160]. Id. at 1394, 162 U.S.P.Q. (BNA) at 603.

[n.161]. Id. at 1395, 162 U.S.P.Q. (BNA) at 603.

[n.162]. Id. at 1395, 162 U.S.P.Q. (BNA) at 604.

[n.163]. See 35 U.S.C. § 154 (1995).

[n.164]. In re Anthony, 414 F.2d 1383, 1396, 162 U.S.P.Q. (BNA) 594, 605 (C.C.P.A. 1969).

[n.165]. 414 F.2d at 1398 n.15, 162 U.S.P.Q. (BNA) at 606 n.15.

[n.166]. Id. at 1398 n.18, 162 U.S.P.Q (BNA) at 607 n.18 (quoting Guidelines for Considering Disclosures of Utility in Drug Cases, 3 Off. Gaz. Pat. Office 849 (1968).

[n.167]. In re Langer, 503 F.2d 1380, 183 U.S.P.Q. (BNA) 288 (C.C.P.A. 1974). This appeal is from the decision of the Board, adhered to on reconsideration, affirming the rejection of all claims in an application entitled, "Dentifices 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.

[n.168]. Id. at 1386, 183 U.S.P.Q. (BNA) at 294.

[n.169]. Id. at 1392, 183 U.S.P.Q. (BNA) at 297.

[n.170]. Id.

[n.171]. Id.

[n.172]. In re Malachowski, 530 F.2d 1402, 189 U.S.P.Q. (BNA) 432 (C.C.P.A. 1976). The appellant 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.

[n.173]. In the concurring opinion of In re Malachowski, Judge Markey would have reversed the PTO simply on the procedure: "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 work. The aged concern over the sale of 'patent medicines' may be safely entrusted to the Food and Drug Administration." 530 F.2d at 1406, 189 U.S.P.Q. (BNA) at 436.

[n.174]. Id. at 1404, 189 U.S.P.Q. (BNA) at 434.

[n.175]. Id.

[n.176]. Id. at 1405, 189 U.S.P.Q. (BNA) at 435; See also In re Gottlieb, 328 F.2d 1016, 1019, 140 U.S.P.Q. (BNA) 665, 668 (C.C.P.A. 1964).

[n.177]. See Overview of Legal Precedent Governing the Utility Requirement 6 (The PTO's analysis of the law governing 35 U.S.C. § 101 to support the Proposed Utility Examination Guidelines in 60 Fed. Reg. 97 (1995)).

[n.178]. Id. at 7.

[n.179]. Id.

[n.180]. Id.

[n.181]. 21 U.S.P.Q.2d (BNA) 1892 (BPAI 1991).

[n.182]. See Overview of Legal Precedent Governing the Utility Requirement 7 (The PTO's analysis of the law governing 35 U.S.C. § 101 to support the Proposed Utility Examination Guidelines in 60 Fed. Reg. 97 (1995)).

[n.183]. See, e.g., 21 U.S.C. § § 301-394 (1995); 42 U.S.C. § § 262- 63 (1995).

[n.184]. See Overview of Legal Precedent Governing the Utility Requirement 7 (The PTO's analysis of the law governing 35 U.S.C. § 101 to support the Proposed Utility Examination Guidelines in 60 Fed. Reg. 97 (1995)).

[n.185]. In re Sichert, 566 F.2d 1154, 196 U.S.P.Q. (BNA) 209 (C.C.P.A. 1977); In re Watson, 517 F.2d 465, 186 U.S.P.Q. (BNA) 11 (C.C.P.A. 1975); In re Krimmel, 292 F.2d 948, 130 U.S.P.Q. (BNA) 215 (C.C.P.A. 1961); Ex parte Jovanovics, 211 U.S.P.Q. (BNA) 907 (BPAI 1981).

[n.186]. See Overview of Legal Precedent Governing the Utility Requirement 7 (The PTO's analysis of the law governing 35 U.S.C. § 101 to support the Proposed Utility Examination Guidelines in 60 Fed. Reg. 97 (1995)).

[n.187]. Id. at 7-8.

[n.188]. Id. at 8.

[n.189]. In re Brana, 51 F.3d 1560, 34 U.S.P.Q.2d (BNA) 1436 (Fed. Cir. 1995). The applicants in this case challenged the Board's affirmance of the Examiner's rejection of claims directed to 5-nitrobenzodeisoquinoline-1,3-dione compounds for use as antitumor agents. The compounds differed from prior art compounds because of the presence of a nitro group at the 5-position and an amino group at the 8-position of the isoquinoline ring. The applicants' specification asserted that the claimed compounds with these substitutions "produce a better action and a better action spectrum as antitumor substances" than known prior art compounds. The prior art compounds were evaluated previously in two in vivo murine cancer models. Id. See also Patents: Animal Tests Are Sufficient to Prove Utility in Drug Patents, 49 Pat. Trademark & Copyright J. (BNA) 677 (1995).

[n.190]. 51 F.3d at 1563, 34 U.S.P.Q.2d (BNA) at 1439.

[n.191]. Id. at 1563, 34 U.S.P.Q.2d (BNA) at 1439-40; See also In re Kirk, 376 F.2d 936, 153 U.S.P.Q. (BNA) 48 (C.C.P.A. 1967).

[n.192]. 51 F.3d at 1566, 34 U.S.P.Q.2d (BNA) at 1440. Specifically, the applicants compared the effectiveness of their compounds with structurally similar compounds in the prior art. In addition, the applicants disclosed results in their specification illustrating the cytotoxicity of the claimed compounds against human tumor cells in vitro and concluded that these tests had "a good action."

[n.193]. The specification referred to two murine lymphocytic leukemia tumor models (P388 and L1210) recognized and used by the National Cancer Institute (NCI) to measure a compound's antitumor activity.

[n.194]. 51 F.3d at 1564, 34 U.S.P.Q.2d (BNA) at 1440-41.

[n.195]. Id.

[n.196]. Id.

[n.197]. Id.

[n.198]. Id.

[n.199]. Id. at 1567, 34 U.S.P.Q.2d (BNA) at 1442.

[n.200]. 34 F.3d 1058, 1063, 32 U.S.P.Q.2d (BNA) 1115, 1120 (Fed. Cir. 1994).

[n.201]. In re Brana, 51 F.3d 1560, 1563-64, 34 U.S.P.Q.2d (BNA) 1436, 1442-43 (Fed. Cir. 1995).

[n.202]. 35 U.S.C. § 6 (1988).

[n.203]. See, e.g., 5 U.S.C. app. § 2 (1976). See also 41 C.F.R. § 101 (1995), for the General Services Administration rule on Federal Advisory Committee Management.

[n.204]. For example, in 1989 there were at least 58 advisory committees in the Department of Commerce. See 55 Fed. Reg. 18,649 (1989).

[n.205]. See 57 Fed. Reg. 5,247 (1992).

[n.206]. M.P.E.P. § 608.01(p) (1993).

[n.207]. See supra note 22.

[n.208]. See 60 Fed. Reg. 97, 98 (1995) (Request for Comments on Proposed Utility Examination Guidelines proposed on January 3, 1995).