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PTO EXAMINATION GUIDELINES ON UTILITY REQUIREMENT

60 FR 36263

Patent and Trademark Office

[Docket No. 950706172–5172–01]

Utility Examination Guidelines

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The Patent and Trademark Office (PTO) is publishing the final version of guidelines to be used by Office personnel in their review of patent applications for compliance with the utility requirement. Because these guidelines govern internal practices, they are exempt from notice and comment and delayed effective date rulemaking requirements under 5 U.S.C. 553(b)(A).

EFFECTIVE DATE: July 14, 1995.

FOR FURTHER INFORMATION CONTACT: Jeff Kushan by telephone at (703) 305–9300, by fax at (703) 305–8885, by electronic mail at kushan@uspto.gov, or by mail marked to his attention addressed to the Commissioner of Patents and Trademarks, Box 4, Washington, DC 20231.

SUPPLEMENTARY INFORMATION:

I. Discussion of Public Comments

Forty-four comments were received by the Office in response to the request to public comment on the proposed version of utility guidelines published on January 3, 1995 (60 FR 97). All comments have been carefully considered. A number of changes have been made to the examining guidelines and the legal analysis supporting the guidelines in response to the comments received.

Many of the individuals responding to the request for public comments suggested that the Office address the relationship between the requirements of 35 U.S.C. 112, first paragraph, and 35 U.S.C. 101. The Office has amended the guidelines to provide a clarification consistent with these requests. The guidelines now specify that any rejection based on a "lack of utility" under section 101 should be accompanied by a rejection based upon section 112, first paragraph. The guidelines also specify that the procedures for imposition and review of rejections based on lack of utility under section 101 shall be followed with respect to the section 112 rejection that accompanies the section 101 rejection.

A suggestion was made that the guidelines should be modified to provide that an application shall be presumed to be compliant with section 112, first paragraph, if there is no proper basis for imposing a section 101 rejection. This suggestion has not been followed. Instead, the guidelines specify that section 112, first paragraph, deficiencies other than those that are based on a lack of utility be addressed separately from those based on a lack of utility for the invention.

Several individuals suggested that the guidelines address how section 101 compliance will be reviewed for products that are either intermediates or whose ultimate function or use is unknown. The Office has amended the guidelines to clarify how it will interpret the "specific utility" requirement of section 101.

Some individuals suggested that the guidelines be amended to preclude Examiners from requiring that an applicant delete references made in the specification to the utility of an invention which are not necessary to support an asserted utility of the claimed invention. The guidelines have been amended consistent with this suggestion.

One individual suggested that the legal analysis be amended to emphasize that any combination of evidence from *in vitro* or *in vivo* testing can be sufficient to establish the credibility of an asserted utility. The legal analysis has been amended consistent with this recommendation.

A number of individuals questioned the legal status of the guidelines, particularly with respect to situations where an applicant believes that a particular Examiner has failed to follow the requirements of the guidelines in imposing a rejection under section 101. The guildeines and the legal analysis supporting the guidelines govern the internal operations of the Patent and Trademark Office. They are not intended to, nor do they have the force and effect of law. As such they are not substantive rules creating or altering the

rights or obligations of any party. Rather, the guidelines define the procedures to be followed by Office personnel in their review of applications for section 101 compliance. The legal analysis supporting the guidelines articulates the basis for the procedures established in the guidelines. Thus, an applicant who believes his or her application has been rejected in a manner that is inconsistent with the guidelines should respond substantively to the grounds of the rejection. "Non-compliance" with the guidelines will not be a petitionable or appealable action.

Some individuals suggested that the guidelines and legal analysis be amended to specify that the Office will reject an application for lacking utility only in those situations where the asserted utility is "incredible." This suggestion has not been adopted. The Office has carefully reviewed the legal precedent governing application of the utility requirement. Based on that review, the Office has chosen to focus the review for compliance with Section 101 and Section 112, first paragraph, on the "credibility" of an asserted utility.

Some individuals suggested that the guidelines be amended to address how a generic claim that covers many discrete species will be assessed with regard to the "useful invention" requirements of sections 101 and 112 when one or more, but not all, species within the genus do not have a credible utility. The guidelines have been amended to clarify how the Office will address applications in which genus claims are presented that encompass species for which an asserted utility is not credible. The legal analysis makes clear that any rejection of any claimed subject matter based on lack of utility must adhere to the standards imposed by these guidelines. This is true regardless of whether the claim defines only a single embodiment of the invention, multiple discrete embodiments of the invention, or a genus encompassing many embodiments of the invention. As cast in the legal analysis and the guidelines, the focus of examination is the invention as it has been defined in the claims.

Some individuals questioned whether the guidelines and the legal analysis govern actions taken by Examining Groups other than Group 1800 or the Board of Patent Appeals and Interferences. The guidelines apply to all Office personnel, and to the review of all applications, regardless of field of technology.

In addition to the changes made in response to comments from the public, the Office has amended the guidelines to clarify the procedure to be followed when an applicant has failed to identify a specific utility or an invention. The guidelines now provide that where an applicant has made no assertion as to why an invention is believed useful, and it is not immediately apparent why the invention would be considered useful, the Office will reject the application as failing to identify any specific utility for the invention. The legal analysis has also been amended to address evaluation of this question.

II. Guidelines for Examination of Applications for Compliance With the Utility Requirement

A. Introduction

The following guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any application for compliance with the utility requirements of 35 U.S.C. 101 and 112. The guidelines also address issues that may arise during examination of applications claiming protection for inventions in the field of biotechnology and human therapy. The guidelines are accompanied by an overview of applicable legal precedent governing the utility requirement. The guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The guidelines and the legal analysis do not alter the substantive requirements of 35 U.S.C. 101 and 112, nor are they designed to obviate review of applications for compliance with this statutory requirement.

B. Examination Guidelines for the Utility Requirement

Office personnel shall adhere to the following procedures when reviewing applications for compliance with the "useful invention" ("utility") requirement of 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph.

1. Read the specification, including the claims, to:

(a) Determine what the applicant has invented, noting any specific embodiments of the invention;

(b) Ensure that the claims define statutory subject matter (e.g., a process, machine, manufacture, or composition of matter);

(c) Note is applicant has disclosed any specific reasons why the invention is believed to be "useful."

2. Review the specification and claims to determine if the applicant has asserted any credible utility for the claimed invention:

(a) If the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., a "specific utility") and that assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility. Credibility is to be assessed from the perspective of one of ordinary skill in the art in view of any evidence of record (e.g., data, statements, opinions, references, etc.) that is relevant to the applicant's assertions. An applicant must provide only one credible assertion of specific utility for any claimed invention to satisfy the utility requirement.

(b) If the invention has a well-established utility, regardless of any assertion made by the applicant, do not impose a rejection based on lack of utility. An invention has a well-established utility if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties of a product or obvious application of a process).

(c) If the applicant has not asserted any specific utility for the claimed invention and it does not have a well-established utility, impose a rejection under section 101, emphasizing that the applicant has not disclosed a specific utility for the invention. Also impose a separate rejection under section 112, first paragraph, on the basis that the applicant has not shown how to use the invention due to lack of disclosure of a specific utility. The sections 101 and 112, rejections should shift the burden to the applicant to:

—Explicityly identify a specific utility for the claimed invention, and
—Indicate where support for the asserted utility can be found in the specification.

Review the subsequently asserted utility by the applicant using the standard outlined in paragraph (2)(a) above, and ensure that it is fully supported by the original disclosure.

3. If no assertion of specific utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a well-established utility, reject the claim(s) under section 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under section 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The section 112, first paragraph, rejection imposed in conjunction with a section 101 rejection should incorporate by reference the grounds of the corresponding section 101 rejection and should be set out as a rejection distinct from any other

rejection under section 112, first paragraph, not based on lack of utility for the claimed invention.

To be considered appropriate by the Office, any rejection based on lack of utility must include the following elements:

(a) A prima facie showing that the claimed invention has no utility.

A *prima facie* showing of no utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific utility asserted by the applicant for the claimed invention. A *prima facie* showing must contain the following elements:

(i) A well-reasoned statement that clearly sets forth the reasoning used in concluding that the asserted utility is not credible;

(ii) Support for factual findings relied upon in reaching this conclusion; and

(iii) Support for any conclusions regarding evidence provided by the applicant in support of an asserted utility.

(b) Specific evidence that supports any fact-based assertions needed to establish the prima facie showing.

Whenever possible, Office personnel must provide documentary evidence (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) as the form of support used in establishing the factual basis of a *prima facie* showing of no utility according to items (a)(ii) and (a)(iii) above. If documentary evidence is not available, Office personnel shall note this fact and specifically explain the scientific basis for the factual conclusions relied on in sections (a)(ii) and (a)(iii).

4. A rejection based on lack of utility should not be maintained if an asserted utility for he claimed invention would be considered credible by a person of ordinary skill in the art in view of all evidence of record.

Once a *prima facie* showing of no utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration

Published by THE BUREAU OF NATIONAL AFFAIRS, INC., Washington, D.C. 20037

under 37 CFR 1.132 or a printed publication, that rebuts the basis or logic of the *prima facie* showing. If the applicant responds to the *prima facie* rejection, Office personnel shall review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments and any new reasoning or evidence provided by the applicant in support of an asserted utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not credible should a rejection based on lack of utility be maintained.

If the applicant satisfactorily rebuts a *prima facie* rejection based on lack of utility under section 101, withdraw the section 101 rejection and the corresponding rejection imposed under section 112, first paragraph, per paragraph (3) above.

Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

III. Additional Information

The PTO has prepared an analysis of the law governing the utility requirement to support the guidelines outlined above. Copies of the legal analysis can be obtained from Jeff Kushan, who can be reached using the information indicated above.

Dated: July 3, 1995.

Bruce A. Lehman,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

Legal Analysis Supporting Utility Examination Guidelines

I. General Principles Governing Utility Rejections

The Office must examine each application to ensure compliance with the "useful invention" or utility requirement of 35 U.S.C. § 101. In discharging this obligation, however, Office personnel must keep in mind several general principles that control application of the utility requirement.

As interpreted by the Federal courts, 35 U.S.C. § 101 has two purposes.[1] First, § 101 defines which categories of inventions are eligible for patent protection. An invention that is not a machine, an article of manufacture, a composition or a process cannot be patented.[2] Second, § 101 serves to ensure that patents are granted on only those inventions that are "useful." This second purpose has a Constitutional footing — Article I, Section 8 of the Constitution authorizes Congress to provide exclusive rights to inventors to promote the "useful arts."[3] Thus, to satisfy the requirements of § 101, an applicant must claim an invention that is statutory subject matter and must show that the claimed invention is "useful" for some purpose, either explicitly or implicitly. Application of this latter element of § 101 is the focus of these guidelines.

Deficiencies under the "useful invention" requirement of § 101 will arise in one of two forms. The first is where it is not apparent why the applicant believes the invention to be "useful."[4] This can occur when an applicant fails to identify any specific utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. The second type of deficiency arises in

[1] The utility requirement is found in § 101 of title 35, United States Code, which reads:

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

[2] *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980); *Diamond v. Diehr*, 450 U.S. 175, 209 USPQ 1 (1981).

[3] *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991).

[4] Courts have found an application deficient under the "usefulness" portion of § 101 where the applicant has not identified any "specific" utility for the invention. Such situations arise rarely; namely where an applicant fails entirely to indicate why the claimed invention is useful. For example, in *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966), the Supreme Court affirmed a finding by the Office that a method of producing a particular class of steroids was deficient under § 101 because the applicant did not explain why the compounds produced by the claimed process were useful. The process in question was patented by another who had disclosed a utility for the invention. The Court refused to consider sufficient a general assertion, not made in the application as filed but instead made by the applicant during an interference proceeding, that the compounds in question were structurally similar to others and therefore *might* possess a particular biological activity in common with those other compounds. Thus, the Court focused on the fact that the applicant failed to identify any "specific utility" for the claimed invention in his application. A more recent case involved an assertion that a disclosure that a substance was "plastic-like" and could be pressed into films was insufficient to satisfy § 101. *In re Ziegler*, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993). As the court stated:

> 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."

Id. at 1203, 26 USPQ2d at 1605. Thus, the failure of the applicant to either identify any use for the invention or to disclose features of the invention that would make uses of it readily apparent, was found to render the claimed invention deficient under § 101.

the rare instance where an assertion of specific utility for the invention made by an applicant is not credible.

A. The Utility Requirement Requires that a Claimed Invention Have a Specific "Usefulness" with "Real World" Value

To satisfy § 101, an invention must be "useful." [5] Courts have used the labels "practical utility" or "specific utility" to refer to this aspect of the "useful invention" requirement of § 101. As the Court of Customs and Patent Appeals stated in *Nelson v. Bowler*:

> "Practical utility" is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public. [6]

Practical considerations require the Office to rely on the inventor's understanding of his or her invention in determining whether and in what regard an invention is believed to be "useful." Because of this, Office personnel should focus on and be receptive to specific assertions made by the applicant that an invention is "useful" for a particular reason. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it *is* considered useful. [7] Assertions falling within the former category are sufficient to identify a specific utility for the invention. Assertions that fall in the latter category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a "useful" invention *may* arise from what has been disclosed by the applicant. [8]

Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific utility based on the setting in which the invention is to be used. Inventions that are to be used exclusively in a research setting (i.e., "research tools") illustrate the problem. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the specific invention is in fact "useful" in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified utility and inventions whose specific utility requires further research to identify or reasonably confirm. Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific utility for the invention.

Office personnel also must be careful not to interpret the phrase "immediate benefit to the public" or similar formulations in other cases [9] to mean that products or services based on the claimed invention must be "currently available" to the public in order to satisfy the utility requirement. Rather, *any* reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a "specific" utility.

B. Wholly Inoperative Inventions Are Not "Useful" Inventions Under 35 U.S.C. § 101; "Incredible" Utility

An invention that is "inoperative" (i.e., it does not operate to produce the results claimed by the patent applicant) is not a "useful" invention in the meaning of the patent law. [10] However, as the Federal Circuit has stated, "[t]o violate § 101 the claimed device must be *totally incapable of achieving a useful result.*" [11] If an invention is only *partially* successful in achieving a useful result, a rejection of the claimed invention as

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[5] Courts have recognized that the term "useful" used with reference to the utility requirement can be a difficult term to define. *Manson*, 383 U.S. At 529, 148 USPQ at 693 (simple, everyday word like "useful" can be "pregnant with ambiguity when applied to the facts of life."). Where an applicant has set forth a specific utility, courts have been reluctant to uphold a rejection under § 101 solely on the basis that the applicant's opinion as to the nature of the specific utility was inaccurate. For example, in *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980), the CCPA reversed a finding by the Office that the applicant had not set forth a "practical" utility under § 101 despite the fact that the applicant asserted that the composition was "useful" in a particular pharmaceutical application and provided evidence to support that assertion.

[6] *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

[7] For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. The latter would be sufficient to identify a specific utility for the compound.

[8] *Knapp v. Anderson*, 477 F.2d 588, 590, 177 USPQ 688, 690 (CCPA 1973).

[9] *See, e.g., Brenner v. Manson*, 383 U.S. At 534-35, 148 USPQ at 695-96.

[10] *See, e.g., Newman v. Quigg*, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989); *In re Harwood*, 390 F.2d 985, 989, 156 USPQ 673, 676 (CCPA 1968) ("An inoperative invention, of course, does not satisfy the requirement of 35 U.S.C. § 101 that an invention be useful.").

[11] *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992) (emphasis added). *See also E.I. du Pont DeNemours and Co. v. Berkley and Co.*, 620 F.2d 1247, 1260 n.17, 205 USPQ 1, 10 n.17 (8th Cir. 1980) ("A small degree of utility is sufficient .... The claimed invention must only be capable of performing some beneficial function .... An invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely ... A commercially successful product is not required .... Nor is it essential that the invention accomplish all its intended functions ... or operate under all conditions, ... partial success being sufficient to demonstrate patentable utility .... In short, the defense of non-utility cannot be sustained without proof of total incapacity" (citations omitted).).

a whole based on a "lack of utility" is *not* appropriate. [12]

Situations where an invention is found to be "inoperative" and therefore lacking in utility are rare, and rejections maintained solely on this ground by a Federal court even rarer. In many of these cases, the utility asserted by the applicant was thought to be "incredible in the light of the knowledge of the art, or factually misleading" when initially considered by the Office. [13] Other cases suggest that on initial evaluation, the Office considered the asserted utility to be inconsistent with known scientific principles or "speculative at best" as to whether attributes of the invention necessary to impart the asserted utility were actually present in the invention. [14] However cast, the underlying finding by the court in these cases was that, based on the factual record of the case, it was clear that the invention could and did not work as the inventor claimed it did. Indeed, the use of many labels to describe a single problem (e.g., an assertion regarding utility that is false) has led to some of the confusion that exists today with regard to a rejection based on the "utility" requirement. Examples of such cases include: an invention asserted to change the taste of food using a magnetic field, [15] a perpetual motion machine, [16] a flying machine operating on "flapping or flutter function," [17] a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field, [18] uncharacterized compositions for curing a wide array of cancers, [19] a method of controlling the aging process, [20] and a method of restoring hair growth. [21] Thus, in view of the rare nature of such cases, Office personnel should not label an asserted utility "incredible," "speculative" or otherwise unless it is clear that a rejection based on "lack of utility" is proper.

C. Therapeutic or Pharmacological Utility

Inventions asserted to have utility in the treatment of human or animal disorders are subject to the same legal requirements for utility as inventions in any other field of technology. [22] As such, pharmacological or therapeutic inventions that provide *any* "immediate benefit to the public" satisfy § 101. [23]

Courts have repeatedly found that the mere *identification* of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides an "immediate benefit to the public" and thus satisfies the utility requirement. [24] As the CCPA held in *Nelson v. Bowler*:

> Knowledge of the pharmacological activity of any compound is obviously beneficial to the public. It is

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[12] *See In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA), *reh'g denied*, 480 F.2d 879 (CCPA 1973); *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971).

[13] *In re Citron*, 325 F.2d 248, 253, 139 USPQ 516, 520 (CCPA 1963).

[14] *E.g., In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977).

[15] *Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 USPQ 848 (Fed. Cir. 1985).

[16] *Newman v. Quigg*, 877 F.2d 1575, 11 USPQ2d 1340 (Fed. Cir. 1989).

[17] *In re Houghton*, 433 F.2d 820, 167 USPQ 687 (CCPA 1970).

[18] *In re Ruskin*, 354 F.2d 395, 148 USPQ 221 (CCPA 1966).

[19] *In re Citron*, 325 F.2d 248, 139 USPQ 516 (CCPA 1963).

[20] *In re Eltgroth*, 419 F.2d 918, 164 USPQ 221 (CCPA 1970).

[21] *In re Ferens*, 417 F.2d 1072, 163 USPQ 609 (CCPA 1969).

[22] *In re Chilowsky*, 229 F.2d 457, 461-2, 108 USPQ 321, 325 (CCPA 1956) ("There appears to be no basis in the statutes or decisions for requiring any more conclusive evidence of operativeness in one type of case than another. The character and amount of evidence needed may vary, depending on whether the alleged operation described in the application appears to accord with or to contravene established scientific principles or to depend upon principles alleged but not generally recognized, but the degree of certainty as to the ultimate fact of operativeness or inoperativeness should be the same in all cases"); *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967) ("Thus, in the usual case where the mode of operation alleged can be readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned, and no further evidence is required.").

[23] The utility being asserted in *Nelson* related to the a compound with "pharmacological" utility. *Nelson*, 626 F.2d at 856, 206 USPQ at 883. Office personnel should rely on *Nelson* and other cases as providing general guidance when evaluating the utility of an invention that is based on any therapeutic, prophylactic, or pharmacological activities of that invention.

[24] In *Nelson v. Bowler*, the CCPA addressed the practical utility requirement in the context of an interference proceeding. Bowler challenged the patentability of the invention claimed by Nelson on the basis that Nelson had failed to sufficiently and persuasively disclose in his application a practical utility for the invention. Nelson had developed and claimed a class of synthetic prostaglandins modeled on naturally occurring prostaglandins. Naturally occurring prostaglandins are bioactive compounds that, at the time of Nelson's application, had a recognized value in pharmacology (e.g., the stimulation of uterine smooth muscle which resulted in labor induction or abortion, the ability to raise or lower blood pressure, etc.). To support the utility he identified in his disclosure, Nelson included in his application the results of tests demonstrating the bioactivity of his new substituted prostaglandins relative to the bioactivity of naturally occurring prostaglandins. The Court concluded that Nelson had satisfied the practical utility requirement in identifying the synthetic prostaglandins as pharmacologically active compounds. In reaching this conclusion, the court considered and rejected arguments advanced by Bowler that attacked the evidentiary basis for Nelson's assertions that the compounds were pharmacologically active.

In *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980), an inventor claimed protection for pharmaceutical compositions for treating leukemia. The active ingredient in the compositions was a structural analog to a known anti-cancer agent. The applicant provided evidence showing that the claimed analogs had the same general pharmaceutical activity as the known anti-cancer agents. The Court reversed the Board's finding that the asserted pharmaceutical utility was "incredible," pointing to the evidence that showed the relevant pharmacological activity.

In *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), the Federal Circuit affirmed a finding by the Board of Patent Appeals and Interferences that a pharmacological utility had been disclosed in the application of one

inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility. [25]

Similarly, courts have found utility for therapeutic inventions despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition. [26] Accordingly, Office personnel should not construe § 101, under the logic of "practical" utility or otherwise, to require that an applicant demonstrate that a therapeutic agent based on a claimed invention is a safe or fully effective drug for humans. [27]

These general principles are equally applicable to situations where an applicant has claimed a process for treating a human or animal disorder. In such cases, the asserted utility is usually clear — the invention is asserted to be useful in treating the particular disorder. If the asserted utility is *credible*, there is no basis to challenge such a claim on the basis that it lacks utility under § 101.

D. Relationship Between §112 First Para. and §101

A deficiency under § 101 also creates a deficiency under § 112, first paragraph. [28] For example, the Federal Circuit recently noted, "[o]bviously, if a claimed invention does not have utility, the specification cannot enable one to use it." [29] As such, a rejection properly imposed under § 101 should be accompanied with a rejection under § 112, first paragraph. It is equally clear that a rejection based on "lack of utility," whether grounded upon § 101 or § 112, first paragraph, rests on the same basis (i.e., the asserted utility is not credible). To avoid confusion, any rejection that is imposed on the basis of § 101 should be accompanied by a rejection based on § 112, first paragraph. The § 112, first paragraph, rejection should be set out as a separate rejection that incorporates by reference the factual basis and conclusions set forth in the § 101 rejection. The § 112, first paragraph, rejection should indicate that because the invention as claimed does not have utility, a person skilled in the art would not be able to use the invention as claimed, and as such, the claim is defective under § 112, first paragraph. A § 112, first paragraph, rejection should not be imposed or maintained unless an appropriate basis exists for imposing a rejection under § 101 under these guidelines. [30] In particular, the factual showing needed to

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party to an interference proceeding. The invention that was the subject of the interference count was a chemical compound used for treating blood disorders. Cross had challenged the evidence in Iizuka's specification that supported the claimed utility. However, the Federal Circuit relied extensively on *Nelson v. Bowler* in finding that Iizuka's application had sufficiently disclosed a pharmacological utility for the compounds. It distinguished the case from cases where only a generalized "nebulous" expression, such as "biological properties," had been disclosed in a specification. Such statements, the court held, "convey little explicit indication regarding the utility of a compound," 753 F.2d at 1048, 224 USPQ 745 (citing *In re Kirk*, 376 F.2d 936, 941, 153 USPQ 48, 52 (CCPA 1967)).

[25] *Nelson*, 626 F.2d at 856, 206 USPQ at 883.

[26] The Federal Circuit, in *Cross v. Iizuka*, 753 F.2d 1040, 1051, 224 USPQ 739, 747-48 (Fed. Cir. 1985), commented on the significance of data from *in vitro* testing that showed pharmacological activity:

> We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question. Successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an *in vivo* utility.

Recently, the Federal Circuit reiterated that therapeutic utility sufficient under the patent laws is not to be confused with the requirements of the FDA with regard to safety and efficacy of drugs to be marketed in the United States.

> FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. *Scott* [*v. Finney*], 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 [(Fed. Cir. 1994)]. Usefulnes in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

In re Brana, 51 F.3d at 1568, 34 USPQ2d at 1442-1443.

[27] *See, e.g., In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Anthony*, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969); *In re Watson*, 517 F.2d 465, 186 USPQ 11 (CCPA 1975).

[28] See *In re Brana*, 51 F.3d at 1564, 34 USPQ2d at 1436; *In re Jolles*, 628 F.2d 1322, 1326 n.10, 206 USPQ 885, 889 n.11 (CCPA 1980); *In re Fouche*, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971)("[I]f such compositions are in fact useless, appellant's specification cannot have taught how to use them."). Courts have also cast the §101-§112 relationship such that § 112 presupposes compliance with § 101 compliance. *See In re Ziegler*, 992 F.2d at 1200-01, 26 USPQ2d at 1603 ("The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention. . . . If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112."); *In re Kirk*, 376 F.2d 936, 942, 153 USPQ 48, 53 (CCPA 1967)("Necessarily, compliance with § 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention.").

[29] *In re Brana*, 51 F.3d at 1564; 34 USPQ2d at 1439.

[30] In other words, Office personnel should not impose a § 112, first paragraph, rejection grounded on a "lack of utility" basis unless a § 101 rejection is proper.

Published by THE BUREAU OF NATIONAL AFFAIRS, INC., Washington, D.C. 20037

impose a rejection under § 101 as outlined in these guidelines must be provided if a rejection based on § 112, first paragraph, is to be imposed on "lack of utility" grounds.

It is important to recognize that § 112, first paragraph, addresses matters other than those related to the question of whether or not an invention lacks utility.[31] These matters include whether the claims are fully supported by the disclosure, whether the applicant has provided an enabling disclosure of the claimed subject matter, whether the applicant has provided an adequate written description of the invention and whether the applicant has disclosed the best mode of practicing the claimed invention. The fact that an applicant has disclosed a specific utility for an invention and provided a credible basis supporting that specific utility does not provide a basis for concluding that the claims comply with all the requirements of § 112, first paragraph. For example, if an applicant has claimed a process of treating a certain disease condition with a certain compound and provided a credible basis for asserting that the compound is useful in that regard, but to actually practice the invention as claimed a person skilled in the relevant art would have to engage in an undue amount of experimentation, the claim may be defective under § 112, but not § 101. To avoid confusion during examination, any rejection under § 112, first paragraph, based on grounds other than "lack of utility" should be imposed separately from any rejection imposed due to "lack of utility" under § 101 and § 112, first paragraph.

[31] The court has sustained rejections under §112 when the scope of protection sought by the applicant fails to bear a reasonable correlation to the scope of enablement provided by the specification. *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991). Further, under § 112 an applicant must provide an enabling disclosure, which must teach one of ordinary skill in the art "how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The factors that are relevant in determining what constitutes undue experimentation have been set forth in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986)). These factors include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

An application may also be deficient under §112 if it fails to disclose the "best mode" of practicing the claimed invention known to the inventor at the time the application was filed. *Chemcast Corp. v. Arco Industries Corp.*,913 F.2d 923, 927-928, 16 USPQ2d 1033, 1036-37 (Fed. Cir. 1990). *See also Transco Products Inc. v. Performance Contracting Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994; *Glaxo Inc. v. Novopharm Ltd.* 52 F.3d 1043, 34 USPQ2d 1565 (Fed. Cir. 1995). Note, however, that applications are rarely subjected to a rejection under § 112 on the grounds of lack of disclosure of the best mode due to the subjective nature of this inquiry.

II. Procedural Considerations Related to Rejections for Lack of Utility

A. The Claimed Invention is the Focus of the Utility Requirement

The claimed invention is the focus of the assessment of whether an applicant has satisfied the utility requirement. Each claim (i.e., each "invention"), therefore, must be evaluated on its own merits for compliance with all statutory requirements. Generally speaking, however, a dependent claim will define an invention that has utility if the claim from which it depends has defined an invention having utility.[32] Where an applicant has established utility for a species that falls within a identified genus of compounds and presents a generic claim covering the genus, as a general matter, that claim should be treated as being sufficient under § 101.[33]

It is common and sensible for an applicant to identify several specific utilities for an invention, particularly where the invention is a product (e.g., a machine, an article of manufacture or a composition of matter). However, regardless of the category of invention that is claimed (e.g., product or process), an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy § 101 and § 112; additional statements of utility, even if not "credible" do not render the claimed invention lacking in utility.[34] Thus, if applicant makes one credible assertion of utility, utility for the claimed invention *as a whole* is established.

Statements made by the applicant in the specification or incident to prosecution of the application before the Office cannot, standing alone, be the basis for a "lack of utility" rejection under § 101 or § 112.[35] An

[32] An exception to this general rule is where the utility specified for the invention defined in a dependent claim differs from that indicated for the invention defined in the independent claim from which the dependent claim depends.

[33] Only where it can be established that other species clearly encompassed by the claim do not have utility, using the standards set forth in these guidelines, should a rejection be imposed on the generic claim. In such cases, the applicant should be encouraged to amend the generic claim so as to exclude the species that lack utility. A claim that raises this question is likely to be deficient under § 112, second paragraph, in terms of accurately defining the genus to encompass species that are sufficiently similar to constitute the genus.

[34] See, *e.g.*, *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown."); *In re Gottlieb*, 328 F.2d 1016, 1019, 140 USPQ 665, 668 (CCPA 1964) ("Having found that the antibiotic is useful for *some* purpose, it becomes unnecessary to decide whether it is in fact useful for the other purposes 'indicated' in the specification as possibly useful."); *In re Malachowski*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Int. 1988).

[35] *Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft m.b.H.*, 945 F.2d 1546, 1553, 20 USPQ2d 1332, 1338 (Fed. Cir. 1991) ("It is not required that a particular characteristic set forth in the prosecution history be achieved in order to satisfy § 101.").

applicant may include statements in the specification whose technical accuracy cannot be easily confirmed if those statements are not necessary to support the patentability of an invention with regard to any statutory basis. Thus, the Office should not require an applicant to strike non-essential statements relating to utility from a patent disclosure, regardless of the technical accuracy of the statement or assertion it presents. Office personnel should also be especially careful not to read into a claim unclaimed results, limitations or embodiments of an invention. [36] Doing so can inappropriately change the relationship of an asserted utility to the claimed invention and raise issues not relevant to examination of that claim.

B. Is There an Asserted or Well-Established Utility for the Claimed Invention?

Upon initial examination, the Examiner should review the specification to determine if there are any statements asserting that the claimed invention is useful for any particular purpose. A complete disclosure should include a statement which identifies a specific utility for the invention.

1. An Asserted Utility Must Be Specific, Not General

A statement of specific utility should fully and clearly explain why the applicant believes the invention is useful. Such statements will usually explain the purpose of or how the invention may be used (e.g., a compound is believed to be useful in the treatment of a particular disorder). Regardless of the form of statement of specific utility, it must enable one ordinarily skilled in the art to understand why the applicant believes the claimed invention is useful.

Except where an invention has a well-established utility, the failure of an applicant to specifically identify why an invention is believed to be useful renders the claimed invention deficient under § 101 and § 112, first paragraph. In such cases, the applicant has failed to identify a "specific utility" for the claimed invention. For example, a statement that a composition has an unspecified "biological activity" or that does not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." [37] In contrast, a disclosure that identifies a particular biological activity of a compound and explains how that activity can be utilized in a particular therapeutic application of the compound does contain an assertion of specific utility for the invention.

Situations where an applicant either fails to indicate why an invention is considered useful, or where the applicant inaccurately describes the utility should rarely arise. One reason for this is that applicants are required to disclose the best mode known to them of practicing the invention at the time they file their application. An applicant who omits a description of the specific utility of the invention, or who incompletely describes that utility, may encounter problems with respect to the best mode requirement of § 112, first paragraph.

2. No Statement of Utility for the Claimed Invention in the Specification Does Not Per Se Negate Utility

Occasionally, an applicant will not explicitly state in the specification or otherwise assert a specific utility for the claimed invention. If no statements can be found asserting a specific utility for the claimed invention in the specification, Office personnel should determine if the claimed invention has a well-established utility. A well-established utility is one that would be immediately apparent to a person of ordinary skill based upon disclosed features or characteristics of the invention, or statements made by the applicant in the written description of the invention. If an invention has a well-established utility, rejections under § 101 and § 112, first paragraph, based on lack of utility should not be imposed. [38] For example, if an application teaches the cloning and characterization of the nucleotide sequence of a well-known protein such as insulin, and those skilled in the art at the time of filing knew that insulin had a well-established use, it would be improper to reject the claimed invention as lacking utility solely because of the omitted statement of specific utility.

If a person of ordinary skill would not immediately recognize a specific utility for the claimed invention (i.e., why it would be useful) based on the characteristics of the invention or statements made by the applicant, the Examiner should reject the application under § 101 and under § 112, first paragraph, as failing to identify a specific utility for the claimed invention. The rejection should clearly indicate that the basis of the rejection is that the application fails to identify a specific utility for the invention. The rejection should also specify that the applicant must respond by indicating why the invention is believed useful and where support for any subsequently asserted utility can be found in the specification as filed.

If the applicant subsequently indicates why the invention is useful, Office personnel should review that assertion according to the standards articulated below for review of the credibility of an asserted utility.

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[36] *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961).

[37] *Brenner v. Manson*, 383 U.S. at 531, 148 USPQ at 694 (general assertion of similarities to compounds known to be useful without sufficient, corresponding explanation why claimed compounds are believed to be similarly useful insufficient under § 101); *In re Ziegler*, 992 F.2d at 1201, 26 USPQ2d at 1604 (disclosure that composition is "plastic-like" and can form "films" not sufficient to identify specific utility for invention); *In re Kirk*, 376 F.2d 936, 945-46, 153 USPQ 48, 56 (CCPA 1967)(indication that compound is "biologically active" or has "biological properties" insufficient standing alone). *See also In re Joly*, 376 F.2d 906, 908, 153 USPQ 45, 46-47 (CCPA 1967); *Kawai v. Metlesics*, 480 F.2d 880, 890, 178 USPQ 158, 165 (CCPA 1973)(contrasting description of invention as sedative which did suggest specific utility to general suggestion of "pharmacological effects on the central nervous system" which did not).

[38] *In re Folkers*, 344 F.2d 970, 145 USPQ 390 (CCPA 1965).

C. Evaluating the Credibility of an Asserted Utility

1. An Asserted Utility Creates a Presumption of Utility

In most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. § 101.[39] As the CCPA stated in *In re Langer*:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented *must* be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter *unless* there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.[40]

Thus, *Langer* and subsequent cases direct the Office to presume that a statement of utility made by an applicant is true.[41] For obvious reasons of efficiency and in deference to an applicant's understanding of his or her invention, when a statement of utility is evaluated, Office personnel should not begin by questioning the truth of the statement of utility. Instead, any inquiry must start by asking if there is any reason to question the truth of the statement of utility. This can be done by simply evaluating the logic of the statements made, taking into consideration any evidence cited by the applicant. If the asserted utility is credible (i.e., believable based on the record or the nature of the invention), a rejection based on "lack of utility" is not appropriate. Clearly, Office personnel should not begin an evaluation of utility by assuming that an asserted utility is likely to be false, based on the technical field of the invention or for other general reasons.

Compliance with § 101 is a question of fact.[42] Thus, to overcome the presumption of truth that an assertion of utility by the applicant enjoys, Office personnel must establish that it is more likely than not that one of ordinary skill in the art would doubt (i.e., "question") the truth of the statement of utility.[43] To do this, Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. Of course, a person of ordinary skill must have the benefit of both facts and reasoning in order to assess the truth of a statement. This means that if the applicant has presented facts that support the reasoning used in asserting a utility, Office personnel must present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the applicant's assertion of utility.[44] The initial evidentiary standard used during evaluation of this question is a preponderance of the evidence (i.e., the totality of facts and reasoning suggest that it is more likely than not that the statement of the applicant is false).

2. When is an Asserted Utility Not "Credible"?

Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong," even when there may be reason to believe that the assertion is not entirely accurate. Rather, Office personnel must determine if the assertion of utility is *credible* (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (a) the logic underlying the assertion is seriously flawed, or (b) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility.

One situation where an assertion of utility would not be considered credible is where a person of ordinary

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[39] *See, e.g., In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (1965); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977).

[40] *In re Langer*, 503 F.2d at 1391, 183 USPQ at 297 (emphasis in original). The "Langer" test for utility has been used by both the Federal Circuit and the CCPA in evaluation of rejections under § 112, first paragraph, where the rejection is based on a deficiency under § 101. The Federal Circuit explicitly adopted the CCPA's formulation of the "Langer" standard for § 112, first paragraph, rejections:

> [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.

In re Brana, 51 F.3d at 1566, 34 USPQ2d at 1441 (quoting *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971)) (emphasis in *Brana*).

[41] *See In re Langer*, 503 F.2d at 1391, 183 USPQ at 297; *In re Malachowski*, 530 F.2d at 1404, 189 USPQ at 435; *In re Brana*, 51 F.3d at 1566, 34 USPQ2d at 1441.

[42] *Raytheon v. Roper*, 724 F.2d at 956, 220 USPQ at 596.

[43] The evidentiary standard to be used throughout *ex parte* examination in setting forth a rejection is a preponderance of the totality of the evidence under consideration. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) ("After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument."); *In re Corkill*, 771 F.2d 1496, 1500, 226 USPQ 1005, 1008 (Fed. Cir. 1985). A preponderance of the evidence exists when it suggests that it is more likely than not that the assertion in question is true. *Herman v. Huddleston*, 459 U.S. 375, 390 (1983).

[44] The Federal Circuit recently addressed the presumption of utility standard in *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). In *Brana*, the Office rejected an application as being deficient under § 112, first paragraph. The Office asserted that the compounds were not useful because they would not work in treating a particular tumor type, given the well known failure of other compounds in the same class to effectively treat tumors. The Office also provided a reference that criticized the human predictive value of the models used by Brana to illustrate utility (i.e., certain murine anti-tumor models). The Federal Circuit did

skill would consider the assertion to be "incredible in view of contemporary knowledge" and where nothing offered by the applicant would counter what contemporary knowledge might otherwise suggest. Office personnel should be careful, however, not to label certain types of inventions as "incredible" or "speculative" as such labels do not provide the correct focus for the evaluation of an assertion of utility. *"Incredible utility" is a conclusion, not a starting point for analysis under § 101.* A conclusion that an asserted utility is "incredible" can be reached only after the Office has evaluated both the assertion of the applicant regarding utility *and* any evidentiary basis of that assertion. The Office should be particularly careful not to start with a presumption that an asserted utility is *per se* "incredible" and then proceed to base a rejection under § 101 on that presumption.

Rejections under § 101 have been rarely sustained by Federal courts. Generally speaking, in these rare cases, the § 101 rejection was sustained either because the applicant failed to disclose any utility for the invention or asserted a utility that could only be true if it violated a scientific principle, such as the second law of thermodynamics, or a law of nature, or was *wholly* inconsistent with contemporary knowledge in the art. [45] Special care therefore should be taken when assessing the credibility of an asserted therapeutic utility for a claimed invention. In such cases, a previous lack of success in treating a disease or condition, or the absence of a proven animal model for testing the effectiveness of drugs for treating a disorder in humans, should *not*, standing alone, serve as a basis for challenging the asserted utility under § 101.

D. Initial Burden is on the Office to Establish a Prima Facie Case and Provide Evidentiary Support Thereof

To properly reject a claimed invention under 35 U.S.C. § 101, the Office must (a) make a *prima facie* showing that the claimed invention lacks utility, and (b) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. [46] If the Office cannot develop a proper *prima facie* case *and* provide evidentiary support for a rejection under § 101, a rejection on this ground should not be imposed. [47]

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not find either of these grounds persuasive. It first noted, in *In re Brana*, 51 F.3d at 1566, 34 USPQ2d at 1441:

> The purpose of treating cancer with chemical compounds does not suggest an inherently unbelievable undertaking or involve implausible scientific principles. *In re Jolles*, 628 F.2d at 1327, 206 USPQ at 890. Modern science has previously identified numerous successful chemotherapeutic agents. In addition, the prior art, specifically Zee Cheng *et al.*, discloses structurally similar compounds to those claimed by the applicants which have been proven *in vivo* to be effective as chemotherapeutic agents against various tumor models.
>
> Taking these facts — the nature of the invention and the PTO's proffered evidence — into consideration we conclude that one skilled in the art would be without basis to reasonably doubt applicants' asserted utility on its face. The PTO thus has not satisfied its initial burden. Accordingly, applicants should not have been required to substantiate their presumptively correct disclosure to avoid a rejection under the first paragraph of § 112. *See In re Marzocchi*, 439 F.2d at 224, 169 USPQ at 370.

The Federal Circuit then criticized the Office for failing to evaluate evidence provided by the applicant with the proper level of deference. It found that a person of ordinary skill would have considered the evidence offered by the applicant, in combination with success by others that was documented in the literature, persuasive in support of the applicant's assertions of utility. It then rebuked the Office for requiring a higher standard for proof of therapeutic utility. As it stated, in *In re Brana*, 51 F.3d at 1567, 34 USPQ2d at 1442 (footnote omitted):

> 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 vivo* testing in humans, and therefore are not reasonably predictive of the success of the claimed compounds for treating cancer in humans. The Commissioner, as did the Board, confuses the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption. *See Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994) ("Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings.").

Given this strong indication by the Federal Circuit, the Office must be careful not to impose an unreasonably high standard of proof for applicants to establish a therapeutic utility.

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[45] *In re Gazave*, 379 F.2d at 978, 154 USPQ at 96 (footnotes omitted), provides a good perspective on rejections for lack of utility. In reversing the Board's rejection for lack of utility where the applicant had asserted a specific utility, the CCPA held:

> Appellant's discovery here does not appear to us to be of such a "speculative," abstruse or esoteric nature that it must inherently be considered unbelievable, "incredible," or "factually misleading." Nor does operativeness appear "unlikely" or an assertion thereof appear to run counter "to what would be believed would happen by the ordinary person" in the art. Nor does appellant's field of endeavor appear to be one where "little of a successful nature has been developed" or one which "from common knowledge has long been the subject matter of much humbuggery and fraud." Nor has the examiner presented evidence inconsistent with the assertions and evidence of operativeness presented by appellant.

[46] *In re Gaubert*, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975) ("Accordingly, the PTO must do more than merely question operability — it must set forth *factual reasons* which would lead one skilled in the art to question the objective truth of the statement of operability.").

[47] *See, e.g., In re Oetiker*, 977 F.2d at 1445, 24 USPQ2d at 1444 ("[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant .... If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent."). *See also Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 USPQ 848 (Fed. Cir. 1985) (applying *prima facie* case law to § 101); *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984).

The *prima facie* showing must be set forth in a well-reasoned statement. The statement must articulate sound reasons why a person of ordinary skill in the art would conclude that it is *more likely than not* that an asserted utility is not *credible*. The statement should specifically identify the scientific basis of any factual conclusions made in the *prima facie* showing. The statement must also explain why any evidence of record that supports the asserted utility would not be persuasive to one of ordinary skill.

In addition to the statement setting forth the *prima facie* showing, Office personnel must provide evidentiary support for the *prima facie* case. In most cases, documentary evidence (e.g., articles in scientific journals, or excerpts from patents or scientific treatises) can and should be cited to support any factual conclusions made in the *prima facie* showing. Only when documentary evidence is not readily available should the Examiner attempt to satisfy the Office's requirement for evidentiary support for the factual basis of the *prima facie* showing *solely* through an explanation of relevant scientific principles.

It is imperative that Office personnel use specificity in setting forth an initial rejection under § 101 and support any factual conclusions made in the prima facie showing. For example, Office personnel should explain why any *in vitro* or *in vivo* data supplied by the applicant would not be reasonably predictive of an asserted therapeutic utility from the perspective of a person of ordinary skill in the art. By using specificity, the applicant will be able to identify the assumptions made by the Office in setting forth the rejection and will be able to address those assumptions properly.

E. Evidentiary Requests by an Examiner to Support an Asserted Utility

In appropriate situations the Office may require an applicant to substantiate an asserted utility for a claimed invention.[48] The purpose for this authority is to enable an applicant to cure an otherwise defective factual basis for the operability of an invention. Because this is a curative authority (e.g., evidence is requested to enable an applicant to support an assertion that is inconsistent with the facts of record in the application), Office personnel should indicate not only why the factual record is defective in relation to the assertions of the applicant, but also, where appropriate, what type of evidentiary showing can be provided by the applicant to remedy the problem.

Requests for additional evidence should be imposed rarely, and only if necessary to support the scientific credibility of the asserted utility (e.g., if the asserted utility is not consistent with the evidence of record and current scientific knowledge). As the Federal Circuit recently noted, "[o]nly after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility."[49] As courts have stated, "it is clearly improper for the Examiner to make a demand for further test data, which as evidence would be essentially redundant and would seem to serve for nothing except perhaps to unduly burden the applicant."[50]

F. Consideration of a Response to a Prima Facie Rejection for Lack of Utility

If a rejection under § 101 has been properly imposed, along with a corresponding rejection under § 112, first paragraph, the burden shifts to the applicant to rebut the *prima facie* showing.[51] An applicant can do this using any combination of the following: amendments to the claims, arguments or reasoning, or new evidence[52] submitted in an declaration under 37 CFR 1.132, or in a printed publication.

Once a response has been provided, Office personnel must review the complete record, including the claims, to determine if it is appropriate to maintain the rejections under § 101 and § 112. If the record as a whole would make it more likely than not that the asserted utility for the claimed invention would be considered credible by a person of ordinary skill in the art, the Office cannot maintain the rejection.[53]

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[48] *See In re Pottier*, 376 F.2d 328, 330, 153 USPQ 407, 408 (CCPA 1967) ("When the operativeness of any process would be deemed unlikely by one of ordinary skill in the art, it is not improper for the examiner to call for evidence of operativeness."). *See also In re Jolles*, 628 F.2d at 1327, 206 USPQ at 890; *In re Citron*, 325 F.2d 248, 139 USPQ 516 (CCPA 1963); *In re Novak*, 306 F.2d 924, 928, 134 USPQ 335, 337 (CCPA 1962).

[49] *In re Brana*, 51 F.3d at 1566, 34 USPQ2d at 1441 (citing *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981)).

[50] *In re Isaacs*, 347 F.2d 887, 890, 146 USPQ 193, 196 (CCPA 1965).

[51] *In re Oetiker*, 977 F.2d at 1445, 24 USPQ2d at 1444 ("The examiner bearsthe initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant ... After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.").

[52] New evidence provided by an applicant must be relevant to the issues raised in the rejection. For example, declarations in which conclusions are set forth without establishing a nexus between those conclusions and the supporting evidence, or which merely express opinions, are of limited probative value with regard to rebutting a *prima facie* case. *In re Grunwell*, 609 F.2d 486, 203 USPQ 1055 (CCPA 1979); *In re Buchner*, 929 F.2d 660, 18 USPQ2d 1331 (Fed. Cir. 1991). *See also Manual of Patent Examining Procedure*, § 716 (Rev. 16, 1994).

[53] As the CCPA stated in reference to review of an applicant's response to a *prima facie* showing of obviousness in *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976):

> When prima facie obviousness is established and evidence is submitted in rebuttal, the decisionmaker must start over ... An earlier decision should not, as it was here, be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only on its knockdown

G. Evaluation of Evidence Related to Utility

There is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted utility, therapeutic or otherwise. Rather, the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed,[54] and whether the asserted utility appears to contravene established scientific principles and beliefs.[55] Furthermore, the applicant does *not* have to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt."[56] Nor must an applicant provide evidence such that it establishes an asserted utility as a matter of statistical certainty.[57] Instead, evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is *more likely than not true.*

III. Special Considerations for Asserted Therapeutic or Pharmacological Utilities

The Federal courts have consistently reversed rejections by the Office asserting a lack of utility for inventions claiming a pharmacological or therapeutic utility where an applicant has provided evidence that reasonably supports such a utility. In view of this, Office personnel should be particularly careful in their review of evidence provided in support of an asserted therapeutic or pharmacological utility.

A. A Reasonable Correlation Between the Evidence and the Asserted Utility is Sufficient

As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a *reasonable* correlation between the activity in question and the asserted utility.[58] An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof. The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted. Instead, as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use.[59]

B. Structural Similarity to Compounds with Established Utility

Courts have routinely found evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility as being supportive of an assertion of therapeutic utility for a new compound.[60] Such evidence should be given appropriate weight in determining whether one skilled in the art would find the asserted utility credible. Office personnel should evaluate not only the existence of the structural relationship, but also the reasoning used by the applicant or a declarant to explain why that structural similarity is believed to be relevant to the applicant's assertion of utility.

C. Data from In Vitro or Animal Testing Is Generally Sufficient to Support Therapeutic Utility

If reasonably correlated to the particular therapeutic or pharmacological utility, data generated using *in vitro* assays, or from testing in an animal model or a combination thereof almost invariably will be sufficient to establish therapeutic or pharmacological utility for a compound, composition or process.[61] In *no* case has a Federal court required an applicant to support an asserted utility with data from human clinical trials.

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ability. Analytical fixation on an earlier decision can tend to provide that decision with an undeservedly broadened umbrella effect. Prima facie obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself ... [S]uch finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached by an earlier board upon a different record.

[54] In *Ex parte Ferguson*, 117 USPQ 229 (Bd. App. 1957), the applicant asserted that a drug would provide relief from the pain of ulcers. The Examiner rejected the claims on the basis that the applicant had not shown that the drug was effective in curing ulcers. The Board reversed the Examiner and indicated that the evidence necessary to support the asserted utility merely had to demonstrate that the subjects felt better after using the drug.

[55] *In re Gazave*, 379 F.2d at 978, 154 USPQ at 96; *In re Chilowsky*, 229 F.2d at 462, 108 USPQ at 325.

[56] *In re Irons* 340 F.2d at 978, 144 USPQ at 354.

[57] *Nelson v. Bowler*, 626 F.2d 853, 856-57, 206 USPQ 881, 883-84 (CCPA 1980) (reversing the Board and rejecting Bowler's arguments that the evidence of utility was statistically insignificant. The court pointed out that a rigorous correlation is not necessary when the test is reasonably predictive of the response). *See also Rey Bellet v. Engelhardt*, 493 F.2d 1380, 181 USPQ 453 (CCPA 1974)(data from animal testing is relevant to asserted human therapeutic utility if there is a "satisfactory correlation between the effect on the animal and that ultimately observed in human beings").

[58] *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980).

[59] *Nelson v. Bowler*, 626 F.2d at 857, 206 USPQ at 884.

[60] In *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980), the claimed compounds were found to have utility based on a finding of a close structural relationship to daunorubicin and doxorubicin and shared pharmacological activity with those compounds, both of which were known to be useful in cancer chemotherapy. The evidence of close structural similarity with the known compounds was presented in conjunction with evidence demonstrating substantial activity of the claimed compounds in animals customarily employed for screening anti-cancer agents.

[61] A cursory review of cases involving therapeutic inventions where utility (either under § 101 or § 112, first paragraph) was the dispositive issue illustrates the fact that the Federal courts are not particularly receptive to rejections based on inoperability. Most striking is the fact that in those cases where an applicant supplied a reasonable evidentiary

If an applicant provides data, whether from *in vitro* assays or animal tests or both, to support an asserted utility, and an explanation of why that data supports the asserted utility, the Office will determine if the data and the explanation would be viewed by one skilled in the art as being reasonably predictive of the asserted utility. [62] Office personnel must be careful to evaluate all factors that might influence the conclusions of a person of ordinary skill in the art as to this question, including the test parameters, choice of animal, relationship of the activity to the particular disorder to be treated, characteristics of the compound or composition, relative significance of the data provided and, most importantly, the explanation offered by the applicant as to why the information provided is believed to support the asserted utility. If the data supplied is consistent with the asserted utility, the Office cannot maintain a rejection under § 101.

Evidence does not have to be in the form of data from an art-recognized animal model for the particular disease or disease condition to which the asserted utility relates. Data from any test that the applicant reasonably correlates to the asserted utility should be evaluated substantively. Thus, an applicant may provide data generated using a particular animal model with an appropriate explanation as to why that data supports the asserted utility. The absence of a certification that the test in question is an industry-accepted model is not dispositive of whether data from an animal model is in fact relevant to the asserted utility. Thus, if one skilled in the art would accept the animal tests as being *reasonably predictive* of utility in humans, evidence from those tests should be considered sufficient to support the credibility of the asserted utility. [63] Office personnel should be careful not to find evidence unpersuasive simply because no animal model for the human disease condition had been established prior to the filing of the application. [64]

D. Human Clinical Data

Office personnel should not impose on applicants the unnecessary burden of providing evidence from human clinical trials. There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders, [65] even with

showing supporting an asserted therapeutic utility, almost uniformly the utility-based rejection was reversed. *See, e.g., In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436; *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883-84 (CCPA 1980); *In re Malachowski*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1976); *In re Gaubert*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1975); *In re Gazave*, 379 F.2d 973, 154 USPQ 92 (CCPA 1967); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961).

Only in those cases where the applicant was unable to come forward with any relevant evidence to rebut a finding by the Office that the claimed invention was inoperative have utility rejections been affirmed by the court. *In re Citron*, 325 F.2d at 253, 139 USPQ at 519-20 (therapeutic utility for an uncharacterized biological extract not supported or scientifically credible); *In re Buting*, 418 F.2d 540, 543-44, 163 USPQ 689, 690 (CCPA 1969) (record did not establish a credible basis for the assertion that the single class of compounds in question would be useful in treating disparate types of cancers); *In re Novak*, 306 F.2d 924, 134 USPQ 335 (CCPA 1962) (claimed compounds did not have capacity to effect physiological activity upon which utility claim based). Contrast, however, *In re Buting* to *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973), in which the court held that utility for a genus was found to be supported through a showing of utility for one species.

[62] *See, e.g., Ex parte Maas*, 9 USPQ2d 1746 (Bd. Pat. App. & Int. 1987); *Ex parte Balzarini*, 21 USPQ2d 1892 (Bd. Pat. App. & Int. 1991).

[63] A number of decisions have addressed the question of whether animal data provided sufficient evidence of utility. In *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962), the applicant submitted affidavit evidence that the compound tested successfully for therapeutic effectiveness and acute toxicity in the "standard experimental animal." The court held that "inherent in the concept of the 'standard experimental animal' is the ability of one skilled in the art to make the appropriate correlation between the results actually observed with the animal experiments and the probable results in human therapy." Therefore, the court concluded that appellants' claimed solutions were useful within the meaning of 35 U.S.C. § 101.

In *In re Krimmel*, 292 F.2d at 953, 130 USPQ at 219, the court held that when the specification teaches the use of the claimed compound for the treatment of any animal and is not limited to the treatment of humans, and when statistically significant tests with "standard experimental animals" establish that the compound exhibits a useful pharmaceutical property, sufficient statutory utility for the compound has been presented. The court defined "standard experimental animals" as "whatever animal is usually used by those skilled in the art to establish the particular pharmaceutical application in question."

In *Ex parte Krepelka*, 231 USPQ 746 (Bd. Pat. App. & Int. 1986), the Board reversed the Examiner's rejection under 35 U.S.C. § 101 that claims drawn to compounds asserted to be useful in treating human cancer were "incredible" and thus lacked patentable utility. The Examiner did not support the assertions with any evidence to controvert evidence in the applicant's disclosure. The evidence in the disclosure included test results derived from acceptable experimental animals, *i.e.*, results from animals which were known to correlate with pharmacological effects observed in humans, were sufficient to demonstrate the utility of the claimed compounds.

[64] Lack of an appropriate animal model to assess effectiveness of a drug or a treatment modality should not itself preclude a finding that an invention has utility. *See In re Chilowsky*, 229 F.2d at 461, 108 USPQ at 325 ("The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it."); *In re Wooddy*, 331 F.2d 636, 639, 141 USPQ 518, 520 (CCPA 1964) ("It appears that no one on earth is certain as of the present whether the process claimed will operate in the manner claimed. Yet absolute certainty is not required by the law. The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it").

[65] Indeed, in *In re Isaacs*, 347 F.2d 889, 146 USPQ 193 (1963), the CCPA stated:

> No authority has been cited and we have been able to find none which requires that in order to secure a patent,

respect to situations where no art-recognized animal models exist for the human disease encompassed by the claims.[66] Before a drug can *enter* human clinical trials, the sponsor, often the applicant, must provide a convincing rationale to those *especially* skilled in the art (e.g., the Food and Drug Administration) that the investigation may be successful. Such a rationale would provide a basis for the sponsor's expectation that the investigation may be successful. In order to determine a protocol for phase I testing, the first phase of clinical investigation, some credible rationale of how the drug might be effective or could be effective would be necessary. *Thus, as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility.*

E. Safety and Efficacy Considerations

The Office must confine its review of patent applications to the statutory requirements of the patent law. Other agencies of the Government have been assigned the responsibility of ensuring conformance to standards established by statute for the advertisement, use, sale or distribution of drugs.[67] As the Federal Circuit recently held, "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws."[68]

Thus, while an applicant may on occasion need to provide evidence to show that an invention will work as claimed, it is improper for Office personnel to request evidence of safety in the treatment of humans, or regarding the *degree* of effectiveness.[69]

F. Treatment of Specific Disease Conditions

Claims directed to a method of treating or curing a disease for which there have been no previously successful treatments or cures warrant careful review for compliance with § 101.[70] The fact that there is no

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utility of a pharmacologically active substance must be proved by in vivo testing. The mere fact that the claimed invention may have possible utility in vivo does not warrant disregard of in vitro activity where the claims are not limited to in vivo use.

Similarly, in *In re Langer*, 503 F.2d at 1392-93, 183 USPQ at 297 (footnote omitted), the CCPA, after considering the evidence relied upon by the Office in imposing a § 101 rejection stated:

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.

[66] *Ex parte Balzarini*, 21 USPQ2d 1892 (Bd. Pat. App. & Int. 1991) (human clinical data is not required to demonstrate the utility of the claimed invention, even though those skilled in the art might not accept other evidence to establish the efficacy of the claimed therapeutic compositions and the operativeness of the claimed methods of treating humans).

[67] Congress has created a special agency to determine both the safety and the effectiveness of new drugs. That agency is the Food and Drug Administration (FDA). According to 21 U.S.C. § 355(a), in order to introduce or deliver for introduction into interstate commerce any new drug, an individual must obtain approval of an application filed with the FDA. The statute defines "drug" extremely broadly and defines "new drug" as any drug not generally recognized as both safe and effective for the use suggested. *See* 21 U.S.C. §§ 321(g) and (p). Under FDA regulations, the clinical investigation of a new drug is generally divided into three distinct phases. The general principles of new drug investigations require the agency to assess the likelihood that investigations will yield data capable of meeting the statutory standards for marketing approval before granting approval of these phases. 21 CFR § 312.22(a). Part of these statutory standards include the requirement that the drug *prove effective*, a higher standard than the utility requirement. 21 U.S.C. § 355(a), 21 CFR § 314.105. *Cf. In re Irons*, 340 F.2d 974, 978, 144 USPQ 351, 354 (CCPA 1965) (reversing the Board of Appeals' utility rejection and pointing out that proof with a double blind test — even where the art recognized a very significant placebo effect — amounted to proof beyond a reasonable doubt, which was not required to comply with 35 U.S.C. § 101). Indeed, the simple request to begin testing the drug requires submission of an explanation of the rationale for the research, as well as information relating to the effectiveness of the drug. 21 CFR §§ 312.23(a)(3)(iv), (5)(iv), (8)(i), and (9)(i). Thus, the FDA pursues a two-prong test to provide approval for testing. Under that test, a sponsor must show that the investigation does not pose an unreasonable and significant risk of illness or injury and that there is an acceptable rationale for the study. As a review matter, there must be a rationale for believing that the compound could be effective.

If the use reviewed by the FDA is not set forth in the specification, FDA review may not satisfy 35 U.S.C. § 101. However, if the reviewed use is one set forth in the specification, Office personnel must be extremely hesitant to challenge utility. In such a situation, experts at the FDA have assessed the rationale for the drug or research study upon which an asserted utility is based and found it satisfactory. Thus, in challenging utility, Office personnel must be able to carry their burden that there is no sound rationale for the asserted utility even through experts designated by Congress to decide the issue have come to an opposite conclusion.

[68] *In re Brana*, 51 F.3d at 1568, 34 USPQ2d at 1442, citing *Scott v. Finney*, 34 F.3d at 1063, 32 USPQ2d at 1120.

[69] *See In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Anthony*, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969); *In re Watson*, 517 F.2d 465, 186 USPQ 11 (CCPA 1975); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961); *Ex parte Jovanovics*, 211 USPQ 907 (Bd. Pat. App. & Int. 1981).

[70] The credibility of an asserted utility for treating a human disorder may be more difficult to establish where current scientific understanding suggests that the such a task would be impossible. Such a determination has always required a good understanding of the state of the art as of the time that the invention was made. For example, in the 1960s, there were a number of cases where an asserted use in treating cancer in humans was viewed as "incredible." *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re. Buting*, 418 F.2d 540, 163 USPQ 689 (CCPA 1969); *Ex parte Stevens*, 16 USPQ2d 1379 (Bd. Pat. App. & Inter. 1990); *Ex parte Busse*, 1 USPQ2d 1908 (Bd. Pat. App. & Int. 1986); *Ex parte Krepelka*, 231 USPQ 746 (Bd. Pat. App. & Int. 1986); *Ex parte Jovanovics*, 211 USPQ 907 (Bd. Pat. App. & Int. 1981).

known cure for a disease, however, cannot serve as the basis for a conclusion that such an invention lacks utility. Rather, Office personnel must determine if the asserted utility for the invention is credible based on the information disclosed in the application. Only those claims for which an asserted utility is not *credible* should be rejected.

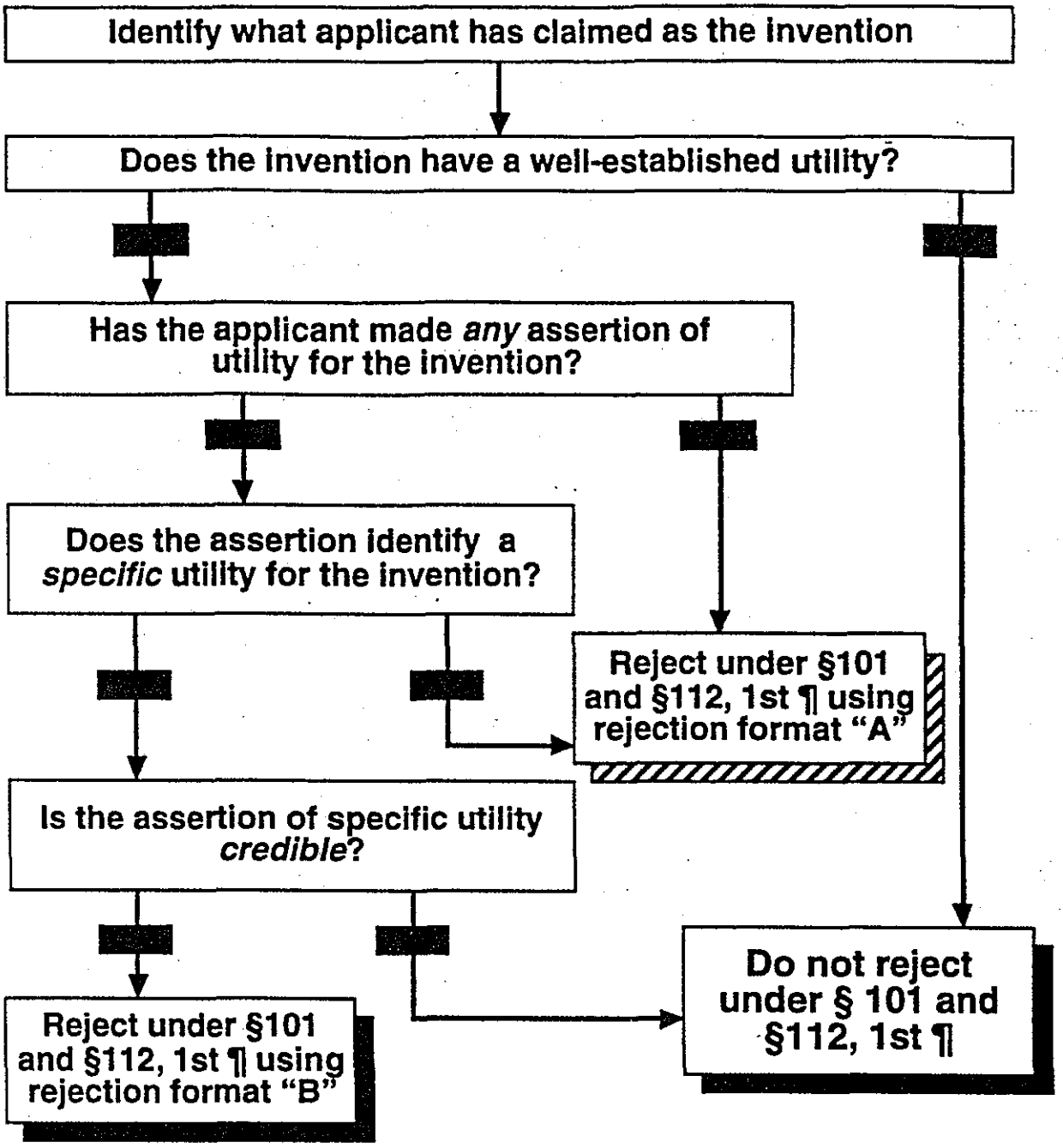
In such cases, the Office should carefully review what is being claimed by the applicant. An assertion that the claimed invention is useful in treating a symptom of an incurable disease may be considered credible by a person of ordinary skill in the art on the basis of a fairly modest amount of evidence or support. In contrast, an assertion that the claimed invention will be useful in "curing" the disease may require a significantly greater amount of evidentiary support to be considered credible by a person of ordinary skill in the art. [71]

It is important to note that the Food and Drug Administration has promulgated regulations that enable a party to conduct clinical trials for drugs used to treat life threatening and severely-debilitating illnesses, even where no alternative therapy exists. [72] Implicit in these regulations is the recognition that experts qualified to evaluate the effectiveness of therapeutics can and often do find a sufficient basis to conduct clinical trials of drugs for "incurable" or previously untreatable illnesses. Thus, affidavit evidence from experts in the art indicating that there is a reasonable expectation of success, supported by sound reasoning, usually should be sufficient to establish that such a utility is *credible*.

[71] *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). *See also Ex parte Ferguson*, 117 USPQ 229 (Bd. Pat. App. & Int. 1957).

[72] *See* 21 CFR §§ 312.80-88 (1994).

Utility Review Flowchart



Rejection Format "A":	Applicant has not disclosed any specific utility for the claimed invention, credibility can't be assessed.
Rejection Format "B":	Applicant has disclosed a specific utility for the claimed invention, but the assertion is not credible.