Proposed Utility Examination Guidelines

Department of Commerce
Patent and Trademark Office
[Docket No. 941259-4359]
Request for Comments on Proposed Utility Examination Guidelines

Agency: Patent and Trademark Office, Commerce

Action: Notice and request for public comments.

Summary: The Patent and Trademark Office (PTO) requests comments from any interest member of the public on proposed internal guidelines that will be used by patent examiners in their review of patent applications for compliance with 35 U.S.C. §101. Because these guidelines govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. §553(b)(A).

Dates: Written comments on the proposed guidelines will be accepted by the PTO until February 24, 1995.

Addresses: Written comments should be addressed to the Commissioner of Patents and Trademarks, marked to the attention of Jeff Kushan. Comments submitted by mail should be sent to Commissioner of Patents and Trademarks, Box 4, Patent and Trademark Office, Washington, D.C. 20231. Comments may also be submitted by telefax at (703) 305-8885 and by electronic mail through the Internet to “comments-biotech@uspto.gov.” Written comments should include the following information:

— name and affiliation of the individual responding;

— an indication of whether comments offered represent views of the respondent’s organization or are the respondent’s personal views; and

— if applicable, information on the respondent’s organization, including the type of organization (e.g., business, trade group, university, non-profit organization) and general areas of interest.

Parties presenting written comments are requested, where possible, to provide their comments in machine readable format. Such submissions may be provided by electronic mail messages sent over the Internet, or on a 3.5” floppy disk formatted for use in either a Macintosh or MS-DOS based computer. Machine-readable submissions should be provided as unformatted text (e.g., ASCII or plain text).

Written comments will be available for public inspection on or about March 1, 1995, in Room 902 of Crystal Park Two, 2121 Crystal Drive, Arlington, Virginia. In addition,
Supplementary Information

I. 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 Examiners when examining applications for compliance with the utility requirement of 35 U.S.C. §101. 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.

B. Guidelines for Examination of Applications for Compliance With 35 U.S.C. §101

Examiners must adhere to the following procedures when examining applications for compliance with 35 U.S.C. §101.

1. Determine what the applicant has claimed as his or her invention. This done to:

a) ensure that the applicant has claimed statutory subject matter (e.g., a process, a machine, a composition or a manufacture); and

b) ascertain what the invention is for purposes of determining whether it is “useful.”

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

a) If the applicant has asserted that the claimed invention is useful for any particular purpose and that assertion would be considered credible by a person of ordinary skill in the art, the Examiner should not impose a rejection based on §101. 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.
b) If the applicant has not asserted that the claimed invention is useful for a particular purpose but such a use would be readily apparent to a person of ordinary skill in the art, the Examiner should not impose a rejection under §101.

3. If the applicant has not asserted any credible utility for the claimed invention or a utility would not be readily apparent to one of ordinary skill in the art, reject the claims under §101. To be considered appropriate by the Office, a rejection under §101 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 of ordinary skill in the art would not consider credible any utility for the claimed invention that has been asserted by the applicant. Where no utility has been asserted in the disclosure, the prima facie showing must support a finding that a person of ordinary skill would not be able to ascertain any use for the claimed invention. A prima facie showing must contain:

i) a well-reasoned statement by the Examiner that clearly sets forth the reasoning used in reaching his or her conclusions;

ii) support for factual findings relied upon by the Examiner in reaching his or her conclusions; and

iii) support for conclusions of the Examiner that evidence provided by the applicant to support an asserted utility would not be considered persuasive to a person of ordinary skill in the art.

b) Evidence that supports any factual assertions relied upon by the Examiner in establishing the prima facie showing. Whenever possible, the Examiner must provide documentary evidence that supports the factual basis of a prima facie showing of no utility (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents). If documentary evidence is not available, the Examiner should note this fact and specifically explain the scientific basis for his or her conclusions.

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

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 under 37 CFR §1.132 or a printed publication, that rebuts the prima facie showing. Once a response has been received by the Examiner, he or she should 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 that the Examiner recognize, fully consider and respond to each substantive element of any response to a rejection under §101.
Examiners are reminded that they must treat as true credible statements made by an applicant or a declarant in the specification or in a declaration provided under 37 CFR §1.132, unless they can show that one of ordinary skill in the art would have a rational basis to doubt the truth of such statements. Thus, not accepting the opinion of a qualified expert that is based on an appropriate factual record would clearly be improper.

II. Additional Information

The PTO has prepared an analysis of the law governing 35 U.S.C. §101 to support the guidelines outlined above. Interested members of the public are invited to comment on the legal analysis as well as the guidelines. Copies of the legal analysis can be obtained from Jeff Kushan, who can be reached using the information indicated above.

Dec. 23, 1994

BRUCE A. LEHMAN

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks

Overview of Legal Precedent Governing the Utility Requirement

I. General Principles Governing Utility Rejections

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

As interpreted by the Federal courts, the utility requirement has two purposes. 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. Second, §101 serves to ensure that patents are granted on only those inventions which 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.” 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

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1. The utility requirement is found in section 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.


“useful” for some purpose, either explicitly or implicitly. Application of this latter element of the utility requirement is the focus of these guidelines.

A. The Utility Requirement Requires that the Claimed Invention Have “Real World Value”

To satisfy §101, an invention must be “useful.”¹⁴ The Court of Customs and Patent Appeals (CCPA) and other courts have used the term “practical utility” as one measure of this concept. As the court 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.⁵

Examiners must be careful not to interpret the phrase “immediate benefit to the public” or similar formulations in other cases⁶ to mean that products or services based on the claimed invention must be “currently available” to the public in order to satisfy §101. Rather, the Examiner should accept as sufficient any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit.


An invention that is inoperative (e.g., the invention does not operate to produce the results claimed by the patent applicant) is not a “useful” invention in the meaning of the patent law.⁷ However, as the Federal Circuit has stated, “[t]o violate §101 the claimed device must be totally incapable of achieving a useful result.”⁸ If an invention is only

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¹⁴Courts have recognized that the term “useful” used with reference to the utility requirement can be a difficult term to define. Brenner v. Manson, 383 U.S. 519, 529, 148 USPQ 689, 693 (1966) (simple everyday word like “useful” can be “pregnant with ambiguity when applied to the facts of life.”). Despite this, courts readily find inventions “useful.” For example, in Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881 (CCPA 1980), the CCPA held that a composition was “useful” because it had been shown to possess a particular pharmacological activity.


⁶See e.g., Brenner v. Manson, 383 U.S. at 534-535, 148 USPQ at 695.

⁷See, 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.”).

⁸Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992) (emphasis added). See also, E.I. du Pont De Nemours and Co. v. Berkley and Co., 620 F.2d 1347, 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
partially successful in achieving a useful result, a rejection of the claimed invention as a whole under §101 is not appropriate. 9

Cases decided by a Federal court in which a claimed invention was held to lack utility under §101 because it was “inoperative” have been rare. Uniformly, in these cases the utility asserted by the applicant was “incredible in the light of knowledge of the art, or factually misleading” 10 when initially considered by the Examiner.

Examples include: an invention asserted to change the taste of food using a magnetic field, 11 a perpetual motion machine, 12 a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field, 13 uncharacterized compositions for curing cancer 14 and a method of restoring hair growth. 15 In view of the rare nature of such cases, Examiners should not label an asserted utility “incredible” unless it is clearly appropriate to do so.

C. Therapeutic or Pharmacological Utility 16

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. 17 As such, pharmacological or therapeutic inventions that provide any “immediate benefit to the public” satisfy §101.

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 nonutility cannot be sustained without proof of total incapacity” [citations omitted].).

9 In such cases, a rejection under 35 U.S.C. §112 may be appropriate. See, 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).

10 In re Citron, 325 F.2d 248, 253, 139 USPQ 516, 520 (CCPA 1963).


12 Newman v. Quigg, 877 F.2d at 1581, 11 USPQ2d at 1340.

13 In re Ruskin, 354 F.2d 395, 148 USPQ 221 (CCPA 1966).

14 In re Citron, 325 F.2d 248, 139 USPQ 516 (CCPA 1963).

15 In re Ferens, 417 F.2d 1072, 163 USPQ 609 (CCPA 1969).

16 The CCPA in Nelson used the term “pharmacological” utility. Examiners should rely on the guidance of Nelson and other cases in evaluating therapeutic, prophylactic, or pharmacological utility.

17 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
Courts have repeatedly found that the mere identification of a pharmacological activity of a compound relevant to an asserted pharmacological use provides an “immediate benefit to the public” and thus satisfies §101. As the CCPA held in Nelson v. Bowler:

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 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 an 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 (1967)).
Knowledge\textsuperscript{18a} of the pharmacological activity of any compound is obviously beneficial to the public. It is 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.\textsuperscript{19}

Similarly, courts have found utility despite that 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.\textsuperscript{20} Accordingly, Examiners should not construe §101, under the logic of “practical” utility or otherwise, as requiring an applicant to demonstrate that a therapeutic agent based on a claimed invention is a safe or fully effective drug for humans.\textsuperscript{21} 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,\textsuperscript{22} there is no basis for an Examiner to challenge such a claim on the grounds that it lacks utility under §101.

II. Procedural Considerations Related to Rejections for Lack of Utility

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

As noted above, the claimed invention is the focus of the assessment of whether an applicant has satisfied the utility requirement of §101. 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 rejection under §101.\textsuperscript{23}

\textsuperscript{18a} Nelson v. Bowler, 626 F.2d at 856, 206 USPQ at 883.
\textsuperscript{19} The Federal Circuit, in Cross v. Iizuka, 753 F.2d 1040, 1051, 224 USPQ 739, 747-748 (Fed. Cir. 1985), commented on the significance of data from \textit{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, \textit{in vitro} testing, may establish a practical utility for the compound in question. Successful \textit{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 \textit{in vivo} utility.

\textsuperscript{20} 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).
\textsuperscript{21} See section II.B. regarding evaluation of an asserted utility.
It is common for an applicant to identify several uses for an invention, particularly where the invention is a product (e.g., a machine, an article of manufacture or a composition of matter). However, irrespective of the category of invention that is claimed (e.g., product or process), an applicant need only disclose one credible utility for the claimed invention to satisfy §101. If one asserted utility is credible, utility for the claimed invention as a whole is established.

Examiners should be especially careful not to read into a claim unclaimed results, limitations or embodiments of an invention. 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 Readily Apparent Utility for the Claimed Invention?

After identifying what the claimed invention is, the Examiner should review the specification to ascertain 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. Such statements can be detailed statements of why an invention is believed to be useful by the applicant. They can also take the form of more general assertions of useful applications of the invention.

Some degree of specificity is needed in identifying utility. For example, a statement that a composition has an unspecified “biological activity” without any explanation of why the composition with that activity would be considered useful should not be viewed as a specific assertion of utility.

If the Examiner cannot find any statements asserting utility for the claimed invention in the specification, he or she should then query whether a utility would be readily apparent to a person of ordinary skill from either the disclosure or from the characteristics of the invention. The result of this initial evaluation determines the next step for the Examiner in the review for compliance with utility.

1991) (“It is not required that a particular characteristic set forth in the prosecution history be achieved in order to satisfy §101.”).

24 See, e.g., 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”).

25 See, e.g., Gottlieb, 328 F.2d at 1019; 140 USPQ at 668. In re Malachowski, 530 F.2d 1402, 189 USPQ 432 (CCPA 1976); Hoffman v. Klaus, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988).


27 In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967); In re Joly, 376 F.2d 906, 153 USPQ 45 (CCPA 1967).
1. An Asserted Utility Creates a Presumption of Utility. An applicant’s assertion of utility creates a presumption of utility that will be sufficient, in most cases, to satisfy the utility requirement of 35 U.S.C. §101. 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.

To overcome this presumption, the Examiner must establish that it is more likely than not that one of ordinary skill in the art would doubt the truth of the statement of utility. In other words, the Examiner must show that the asserted utility is not credible.

2. When is an Asserted Utility Not “Credible”? Compliance with §101 is a question of fact. Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by an Examiner as being “wrong,” even when the Examiner may believe the assertion is not accurate beyond a reasonable doubt. Rather, the Examiner must determine if the assertion of utility is credible. If it is, the Examiner should not reject the claimed invention under §101.

To assess credibility, the Examiner should determine if one of ordinary skill in the art would consider the assertions of the applicant to have any reasonable scientific basis. If they do, they should not be challenged as not being credible. Only where they do not (e.g., if the assertion is “incredible in view of contemporary knowledge”), should the Examiner challenge the statement as not being credible. In making credibility determinations, the Examiner must consider the full record of evidence related to the asserted utility, including any data and reasoning provided by the applicant in the specification and any references cited by the applicant to support utility. The Examiner must also consider information that is generally known in the art regarding the asserted utility.

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28 See, e.g., In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); In re Irons, 340 F.2d 974, 111 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).


30 The evidentiary standard used throughout ex parte examination is a preponderance of the evidence. 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).

31 Raytheon v. Roper, 724 F.2d at 956, 220 USPQ at 596.
As noted above, rejections under §101 have been rarely sustained by Federal courts. Generally speaking, in these rare cases, the §101 rejection was sustained because the applicant 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. The phrase “incredible utility” has come to be associated with such cases. “Incredible utility,” however, is a conclusion, not a starting point for analysis under §101. A conclusion that an asserted utility is “incredible” thus can be reached only after the Examiner has evaluated both the assertions of the applicant regarding utility and any evidentiary basis for those assertions. An Examiner should be particularly careful not to start with the presumption that an asserted utility is per se “incredible” and then proceed to base a rejection under §101 on that presumption.

Special care should be taken when assessing the credibility of an asserted therapeutic utility for a claimed invention. In such cases, a previous lack of success in treating a disease or condition, or the absence of a proven animal 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.

3. No Statement of Utility for the Claimed Invention in the Specification Does Not Negate Utility. Occasionally, an applicant will not explicitly state in the specification or otherwise assert a specific utility for the claimed invention. In such cases, if a person of ordinary skill would recognize a utility for the claimed invention if provided with the specification at the time of its filing, no rejection under §101 should be imposed. 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 under §101.

C. Initial Burden Is on the Examiner to Establish Prima Facie Case and Provide Evidentiary Support Thereof

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32 In re Gazave, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967), 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.

33 In re Folkers, 344 F.2d 970, 145 USPQ 390 (CCPA 1965).
To properly reject a claimed invention under 35 U.S.C. §101, the Examiner 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.34 If the Examiner 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.35

The prima facie showing must be set forth in a well-reasoned statement. In the statement, the Examiner 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 or that one of ordinary skill would not recognize utility for the claimed invention if unstated. The statement should specifically identify the scientific basis of the Examiner’s conclusions. 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, the Examiner must provide evidentiary support for the prima facie case. In most cases, the Examiner can and should provide documentary evidence (e.g., articles in scientific journals, or excerpts from patents or scientific treatises) that supports his or her factual conclusions. 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 Examiners use specificity in setting forth an initial rejection under §101 and support their factual conclusions. For example, the Examiner 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 Examiner in setting forth rejection and will be able to address those assumptions properly.

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

34In 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.”).

35See, e.g., In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) (“[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 section 101); In re Piasecki, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984).
As the courts have recognized, in appropriate situations the Office may require an applicant to substantiate an asserted utility for a claimed invention. However, requests for additional evidence should be imposed rarely, and only if necessary to support the scientific credibility of the asserted utility (e.g., if the asserted utility is not consistent with the evidence of record and current scientific knowledge). As the CCPA stated in In re Isaacs, “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.” Whenever possible, Examiners should identify the nature of evidence which, if provided, would be persuasive in establishing the credibility of an asserted utility.

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

If an Examiner has properly rejected a claimed invention under §101, the burden shifts to the applicant to rebut the prima facie showing. An applicant can do this using any combination of the following: amendments to the claims, arguments or reasoning, or new evidence submitted in an declaration under 37 CFR §1.132, or in a printed publication.

Once a response has been provided, the Examiner must review the complete record, including the claims, to determine if it is appropriate to maintain the rejection under §101. 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

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36 See In re Potti, 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).

37 In re Isaacs, 357 F.2d 587, 152 USPQ 748 (CCPA 1965).

38 In re Oetiker, 977 F.2d at 1445, 24 USPQ2d at 1444 (“the 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. . . . 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.”).

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, may be 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).
Examiner should not maintain the rejection. If the Examiner concludes otherwise, he or she should maintain the rejection under §101.

F. 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, and whether the asserted utility appears to contravene established scientific principles and beliefs. Furthermore, the applicant does not have to provide evidence sufficient to establish that an asserted utility is true “beyond a reasonable doubt.” Nor must an applicant provide evidence such that it establishes an asserted utility as a matter of statistical certainty. 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

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40 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 decision-maker 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 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. . . . Such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached by an earlier board upon a different record.

41 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.

42 In re Gazave, 379 F.2d at 978, 154 USPQ at 96 (CCPA 1967); In re Chilowsky, 229 F.2d at 462, 108 USPQ at 325.

43 In re Irons 340 F.2d at 978, 144 USPQ at 354.

44 Nelson v. Bowler, 626 F.2d 853, 856-857, 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).
The Federal courts have consistently reversed rejections by the Office asserting a lack of utility under §101 for inventions claiming a pharmacological or therapeutic utility where an applicant has provided evidence supporting such a utility. In view of this, Examiners should be particularly careful in their review of evidence provided in support of an asserted therapeutic or pharmacological utility.

A. A Reasonable Correlation Between Evidence and Asserted Utility Is Sufficient

As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. The applicant does not have to prove that there is a statistically proven correlation between characteristics of a compound and the asserted use, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted.

B. Structural Similarity to Useful Products

The courts have on several occasions found evidence of structural similarity to known compounds with particular therapeutic or pharmacological uses as supporting therapeutic utility of a newly claimed compound. Such evidence, when provided by an applicant in support of an assertion of utility, should be given appropriate weight in determining whether one skilled in the art would find the asserted utility credible.

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

Data generated using in vitro assays and testing in animals almost invariably will be sufficient to support an asserted therapeutic or pharmacological utility. In no case has a

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45 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).

46 In In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980), the claimed compounds were found to have utility based on a close structural relationship to daunorubicin and doxorubicin, 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.

47 The CPA has sustained rejections under §101 for a claimed therapeutic utility in only two instances. In re Citron, 325 F.2d at 253, 139 USPQ at 520 (therapeutic utility for an uncharacterized biological extract not supported or scientifically credible); In re Buting, 418 F.2d 540, 543, 163 USPQ 689, 690 (CCPA 1969) (confusing lack of enablement under §112 for range of species claimed for lack of utility of claimed invention as a whole under §101 because 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 contrast, in the vast majority of cases where §101 was the basis of a rejection, the courts
Federal court required an applicant to support an asserted utility with data from human clinical trials.

If an applicant provides data from in vitro and animal tests to support an asserted utility, the Examiner should determine if the tests, including the test parameters and choice of animal, would be viewed by one skilled in the art as being reasonably predictive of the asserted utility. If so, and the data supplied is consistent with the asserted utility, the Examiner should not maintain a rejection under §101. This approach is to be followed not only in cases where there are art-recognized animal models for assessing utility in human disease and treatment, but also where no such validation of a specific test has been performed. Thus, if one skilled in the art would accept the animal tests as being reasonably predictive of utility in humans, they should be considered sufficient to support the credibility of the asserted utility.

Examiners should be careful not to find evidence unpersuasive have relied on a varying combination of data from in vitro and animal testing, and from structural similarities to known compounds to find credible an asserted utility. See, e.g., 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 (CCPA 1980); 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).

48 See, e.g., Ex parte Maas, 9 USPQ2d 1746 (Bd. Pat. App. & Inter. 1987); Ex parte Balzarini, 21 USPQ2d 1892 (Bd. Pat. App. & Inter. 1991).

49 A number of decisions have addressed the question of whether animal data provide 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 948, 130 USPQ 215 (CCPA 1961), 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.” 292 F.2d at 953, 130 USPQ at 219.

In Ex parte Krepelka, 231 USPQ 746 (Bd. Pat. App. & Inter. 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
simply because no animal model for the human disease condition had been established prior to the filing of the application.\textsuperscript{50}

\textit{D. Human Clinical Data}

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,\textsuperscript{51} even with respect to situations where no art-recognized animal models existed for the human disease encompassed by the claims.\textsuperscript{52} Examiners should not impose on applicants the unnecessary burden of providing evidence from human clinical trials. Examiners should note that before a drug can enter human clinical trials, the sponsor (e.g., often the applicant) must establish a sufficient basis to those especially skilled in the art (e.g., the Food and Drug Administration) that the drug will be effective to some degree in treating the stated disorder. Thus, as a general rule, if an applicant has initiated human clinical trials for a product or process used for treating an indication, the subject of that trial has met the burden of being reasonably predictive of utility.

derived from acceptable experimental animals, \textit{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.\textsuperscript{50}

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. \textit{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.”); \textit{In re Woody}, 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”).

\textsuperscript{51}Indeed, in \textit{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, utility of a pharmacologically active substance must be proved by in vivo testing. The mere fact that the claimed invention may have possible utility \textit{in vivo} does not warrant disregard of \textit{in vitro} activity where the claims are not limited to \textit{in vivo} use [347 F.2d at 889, 146 USPQ at 195].

Similarly, in \textit{In re Langer}, 503 F.2d at 1393-94, 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.

\textsuperscript{52}In \textit{Ex parte Balsarini}, 21 USPQ2d 1892 (Bd. Pat. App. & Inter. 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).
E. Safety and Efficacy Considerations

The Examiner must confine his or her examination, for purposes of utility, to compliance with 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 of effectiveness.53

F. Treatment of Specific Disease Conditions

53Congress 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 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 35 U.S.C. §§321(g) and (p). Under the FDA, the clinical investigation of a new drug is divided into three distinct phases. The general principles of new drug investigations require the agency to assess the likelihood that the drug will meet 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, an applicant must show the drug is not injurious to health and that there is a reasoned expectation to think the drug will actually work. As a review matter, there must be a rational reason to think that the compound will actually be effective.

If the use approved by the FDA is not set forth in the specification, FDA approval may not satisfy 35 U.S.C. §101. However, if the approved use is one set forth in the specification, the Examiner must be extremely hesitant to challenge utility. In such a situation, the inventor has signed an oath stating a utility (i.e., the application) and experts at the FDA have assessed the likelihood that the drug will be effective for the utility indicated and found it satisfactory. Thus, in challenging utility, the examiner is at odds with those experts designated by Congress to decide the issue and who have assessed the likelihood that the drug will meet the statutory standards of efficacy.

54See In re Sichert, 566 F.2d 1154, 196 USPQ 209 (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. & Inter. 1981).
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. The mere fact that there is no known cure for a disease, however, should not serve as the basis of an Examiner’s conclusion that such an invention lacks utility. Rather, the Examiner should only reject the claims under §101 if he or she can establish a prima facie case that the asserted utility is not credible.

In such cases, the Examiner 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 scientifically 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 scientifically credible by a person of ordinary skill in the art.

In these cases, 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. 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.

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55The credibility of an asserted utility for treating a human disorder may be more difficult to establish where current scientific understanding suggests that such a task would be impossible. Such a determination has always required a good understanding of the state of the art at the time of the invention. 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. & Inter. 1986); Ex parte Krepelka, 231 USPQ 746 (Bd. Pat. App. & Inter. 1986); Ex parte Jovanovics, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981).

56In 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. & Inter. 1957).

57See 21 CFR §§312.80-88.