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"PRACTICAL UTILITY" IS A USELESS CONCEPT

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ARTICLE

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INTRODUCTION

To repeat what have become little more than platitudes, the purpose of the patent system is “to promote the progress of science and the *useful* arts,”¹ and inventors or discoverers of a “*useful* . . . composition of matter, or any new and *useful* improvement thereof, may obtain a patent therefore”² The trivialization of these tenets is regrettable, for it has allowed a change in the meaning of “useful” to go largely unnoticed. In common parlance, a thing “having util-

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1. U.S. CONST. art. I, § 8, cl. 8 (emphasis added).

2. 35 U.S.C. § 101 (1982) (emphasis added).

ity" is, by definition, "useful."³ When dealing with chemical compounds, however, the judiciary has not equated these expressions. A compound meets the "utility requirement" only if its uses are acceptable to the court. Insofar as acceptable uses are not capable of rigid definition, a decision that a compound has "utility" is effectively a legal conclusion,⁴ distinct from the question of whether it is "useful" in the lay sense.⁵

The purpose of this Article is to explain why "useful," a term with a widely accepted common meaning, should not be singled out for this treatment—the result of which is judges (or Patent & Trademark Office examiners) substituting their judgment of what is a permissible use for that of the inventor. This Article will show that this construction finds no basis in precedent, logic, or the language of 35 U.S.C. § 101. Not surprisingly, the statute means what it says.⁶

I. "USEFUL" IS TO BE GIVEN ITS LAY MEANING

A. History

The guidelines for interpretation of 35 U.S.C. § 101 appear in its history.⁷ Two early decisions defined "useful" as a negative rather than as a positive averment, holding that the term stood in distinct contrast to that which is mischievous or immoral.⁸ For any given

3. See WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY (1984) (defining "useful" as capable of being put to a use, serviceable, having utility).

4. A determination of "utility" is only *effectively* a legal conclusion—i.e. it is analyzed as such. Courts have stated, however, that it is a determination of fact. See, e.g., *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956, 220 U.S.P.Q. 592, 596 (Fed. Cir. 1983) (citing *Wilden Pump v. Pressed & Welded Prods. Co.*, 655 F.2d 984, 988, 213 U.S.P.Q. 282, 285 (9th Cir. 1981)) (holding that oven's utility was question of fact), *cert. denied*, 469 U.S. 835 (1984); *Nickola v. Peterson*, 580 F.2d 898, 911, 198 U.S.P.Q. 385, 399 (6th Cir. 1978) (finding utility of fuel meter was question of fact), *cert. denied*, 440 U.S. 961 (1979); *Gross v. General Motors Corp.*, 521 F.2d 45, 49, 186 U.S.P.Q. 433, 435 (1st Cir. 1975) (holding lack of utility was factual question).

5. In some ways "useful" is like the term "functional" in trademark law, although the latter term has been used both in the lay sense and to denote a legal conclusion. See *In re Morton-Norwich Prods., Inc.*, 671 F.2d 1332, 1337, 213 U.S.P.Q. 9, 12-13 (C.C.P.A. 1982).

6. See *Markey, Why Not the Statute?*, 65 J. PAT. OFF. SOC'Y 331, 331-36 (1983). Chief Judge Markey of the Federal Circuit noted the predisposition of courts (and lawyers) to give unintended meanings to certain terms in other patent statutes. For example, some read "property" as "monopoly," "invention" as "idea," some infer a special standard to "combinations" in contravention of 35 U.S.C. § 103, while others state: "is obvious" "is not obvious" "would be obvious," "would not be obvious," instead of "would have been obvious at the time the invention was made." *Id.*

7. See *In re Kirk*, 376 F.2d 936, 954, 153 U.S.P.Q. 266, 272 (C.C.P.A. 1967) (Rich, J., dissenting) (stating that "true 'legislative materials' necessarily consist only of [§ 101's] long history of construction and repeated reenactment without change").

8. See *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C. Mass. 1817) (No. 8568) (defining "useful" as set forth in the accompanying text); *Bedford v. Hunt*, 3 F. Cas. 37, 137 (C.C. Mass. 1817) (No. 1217) (stating that law only required that invention be capable of use not prohibited by sound morals or policy); see also D. CHISUM, PATENTS § 4.02[1] (1986) (tracing Justice Story's view of utility of invention's purpose in *Lowell* and *Bedford*); W. ROBINSON, THE

subject matter the question was twofold. First, does it have a potential use? Second, is the use in the forbidden class? The second inquiry did not raise a question of law as much as command a moral judgment of things patentable.⁹ Thus, under the precedent, the examination of the proposed use was limited to a determination of whether society would condone it. This Article will examine why inquiry into morality is the only type of "use examination" which is supported by precedent, or logic.

B. *The Errors of the Modern Trend*

In more recent decisions, the courts ignored morality. Instead, the courts categorized which uses for compounds, if present, warranted their protection. To avoid absurdities such as "this use is not 'useful,'" the court spoke of "utility,"¹⁰ often prefaced with the modifiers "practical,"¹¹ "substantial,"¹² or "specific."¹³ The prob-

LAW OF PATENTS FOR USEFUL INVENTIONS § 340 (1890) (urging courts to consider total effects of invention upon maker, operator, and consumer before granting patent); H.C. MERWIN, THE PATENTABILITY OF INVENTIONS 75-76 (1883) (stating that *Lowell* definition of "useful" is construed so liberally that patents rarely are denied); Cohen & Schwartz, *Do Chemical Intermediates Have Patentable Utility?*, 29 GEO. WASH. L. REV. 87, 89-91 (1960) (tracing courts' definitions of utility).

9. See W. PHILLIPS, THE LAW OF PATENTS FOR INVENTIONS § 14, at 140 (1837) (quoting *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C. Mass. 1817) (No. 8568) ("[f]or instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention").

10. See *In re Jolles*, 628 F.2d 1322, 1327, 206 U.S.P.Q. 885, 890 (C.C.P.A. 1980) (discussing human utility of cancer drug in patent application); *Kvalnes v. Wright*, 183 F.2d 193, 195, 86 U.S.P.Q. 403, 405 (C.C.P.A. 1950) (discussing utility specified for hosiery dye in patent application).

11. See, e.g., *Cross v. Iizuka*, 753 F.2d 1040, 1046, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985) (analyzing pharmacological products' practical utility as required by 35 U.S.C. § 101); *Nelson v. Bowler*, 626 F.2d 853, 856, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) (holding pharmacological tests demonstrated practical utility although specific therapeutic use not established); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1382-83, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974) (stating court must determine practical utility of drug); *Anderson v. Natta*, 480 F.2d 1392, 1397, 178 U.S.P.Q. 458, 461 (C.C.P.A. 1973) (holding that patent applicant failed to prove practical utility because of insufficient product testing); *Yasuko Kawai v. Metlesics*, 480 F.2d 880, 886, 178 U.S.P.Q. 158, 163 (C.C.P.A. 1973) (holding product's practical utility must be shown when such utility is not obvious); *In re Joly*, 376 F.2d 906, 908, 153 U.S.P.Q. 45, 47 (C.C.P.A. 1967) (stating practical utility of compound is essential element of patentability) (quoting *In re Kirk*, 376 F.2d 936, 945, 153 U.S.P.Q. 48, 56 (C.C.P.A. 1967)); cf. *In re Nelson*, 280 F.2d 172, 180-81, 126 U.S.P.Q. 242, 250 (C.C.P.A. 1960) (defining "practical utility" as thing having some use to any class of persons).

12. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 534, 148 U.S.P.Q. 689, 695 (1966) (arguing that both Congress and Constitution intended quid pro quo for giving patent is substantial utility and benefit to public from invention); see also *Cross v. Iizuka*, 753 F.2d 1040, 1046, 224 U.S.P.Q. 739, 744 (Fed. Cir. 1985) (holding that substantial utility and benefit to public are proper considerations in granting patent); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1385, 181 U.S.P.Q. 453, 456 (C.C.P.A. 1974) (denying drug had substantial utility as tranquilizer); *Anderson v. Natta*, 480 F.2d 1392, 1395, 178 U.S.P.Q. 458, 460 (C.C.P.A. 1973) (stating evidence establishing substantial utility for any purpose is sufficient to show reduction to practice); *Knapp v. Anderson*, 477 F.2d 588, 590, 177 U.S.P.Q. 688, 690 (C.C.P.A. 1973) (finding evidence of substantial utility proves actual reduction to practice if particular use is not speci-

lem is that these modifiers are not in the statute, nor can they be found in the dictionary under "useful." The courts' approach ignores the mandate that *a verbis legis non est recedendum*.¹⁴

A more important reason why "useful" should have no special connotation relates not so much to law or statutes as to chemistry and chemicals. An inventor of a new device builds that device with a use in mind. In fact, an inventor builds a device because that potential use exists and the device is designed specifically for that use. In contrast, the maker of a new compound often will have no conception of the compound's ultimate use. The inventor may have set out to find the cure for cancer or, perhaps more to date, AIDS, and may discover something of no value for that application but of great importance elsewhere.¹⁵ Although the developer may be unaware of the "real" use until some time after production, the compound inherently possesses its "useful" properties from the moment of its creation.¹⁶ In the courts' view, however, that a compound *may have* greater "utility" than those wondrous things sought by alchemists of old is insufficient. Courts read section 101 as though "known to be" appeared before each occurrence of "useful."¹⁷ In light of the way

fied); *Campbell v. Wettstein*, 476 F.2d 642, 646-47, 177 U.S.P.Q. 376, 379 (C.C.P.A. 1973) (finding that tests on laboratory animals are adequate to show substantial utility and reduction to practice).

13. See *Brenner v. Manson*, 383 U.S. 519, 534, 148 U.S.P.Q. 689, 695 (1966) (noting that monopoly of knowledge results when inventor does not detail chemical's specific utility); see also *Anderson v. Natta*, 480 F.2d 1392, 1399, 178 U.S.P.Q. 458, 463 (C.C.P.A. 1973) (rejecting claim because specification of "plastic-like" did not establish substantial specific utility).

14. See BLACK'S LAW DICTIONARY 124 (5th ed. 1979) (from "the words of a statute there must be no departure").

15. History is replete with examples of such "accidental" discoveries. For example, the composition nitroglycerin, originally developed as an explosive, was later found useful in treating heart ailments. The Supreme Court also acknowledged this precept in *Brenner v. Manson*, 383 U.S. 519, 536, 148 U.S.P.Q. 689, 696 (1965), when it stated that "we are [not] blind to the prospect that what now seems without 'use' may tomorrow command the grateful attention of the public."

16. See, e.g., *In re Folkers*, 344 F.2d 970, 974, 145 U.S.P.Q. 390, 393 (C.C.P.A. 1965) (finding utility of chemical compound is invariably manifestation of that compound's properties); *In re Papesch*, 315 F.2d 381, 391, 137 U.S.P.Q. 43, 51 (C.C.P.A. 1963) (holding that compound and all its properties are inseparable); *In re Kirchner*, 305 F.2d 897, 901, 134 U.S.P.Q. 324, 328 (C.C.P.A. 1962) (stating that "[a]ctual utility . . . is an inherent characteristic of every chemical compound"). Note also that the similarity of structure of new compounds to known ones has often permitted an inference of similarity of use. This doctrine is an implicit acknowledgement that the uses for the new compounds are inherently the same as for the old. E.g., *Ciric v. Flanigen*, 511 F.2d 1182, 1186, 185 U.S.P.Q. 103, 106 (C.C.P.A. 1975) (analyzing known uses for crystalline zeolites); *Silvestri v. Grant*, 496 F.2d 593, 601, 181 U.S.P.Q. 706, 708 (C.C.P.A. 1974) (holding new form of old drug ampicillin made utility obvious), *cert. denied*, 420 U.S. 928 (1975); *In re Adams*, 316 F.2d 476, 478, 137 U.S.P.Q. 333, 335 (C.C.P.A. 1963) (holding new property of known hormone need not be specified for patent). But see *In re Kirk*, 376 F.2d 936, 942, 153 U.S.P.Q. 48, 53 (C.C.P.A. 1967) (requiring steroid maker to specify useful properties to obtain patent).

17. Although the term "useful" in § 101 entails no element of knowledge, it may seem that the "real" use must be known so that it can be described in a manner that complies with

compounds are developed this proposition is unsupported by reason.

More disturbing than the disregard of these self-evident truths is that the ordained "utility" is a shifting target. The standard is moving further from the common definition of "useful," namely, things which are "capable of being put to a use" and closer to a commandment that the use be advantageous.¹⁸ That edict not only ignores the adage that the degree of utility is immaterial,¹⁹ but also requires judicial examination of whether the use is of value to a mythical person working in the field. The judiciary seems undeterred even though the most knowledgeable chemists often disagree on the objectives of their own technology.²⁰ The similarity between 35 U.S.C. §§ 101 and 112 is doubtless partially responsible for the erroneous construction of "useful."

II. CONTRASTING "USEFUL" IN 35 U.S.C. § 101 WITH THE "HOW-TO-USE" REQUIREMENT OF 35 U.S.C. § 112

Turning to the precedents, the court in *In re Bremner*²¹ announced that a chemical patent application must include an "assertion of utility and an indication of the use or uses intended."²² In analyzing

35 U.S.C. § 112. This section demands "a written description of the invention and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art . . . to make and use the same" 35 U.S.C. § 112 (1982). This supposition appears enticing, yet it ignores § 112's language ordering description of "the manner . . . of . . . using." This wording indicates that *any* use which is known to the inventor, whether or not it ultimately turns out to be the "real" use, is sufficient. If nothing else is known, describing its use as a paper weight would seem to satisfy the literal requirements. *Contra In re Kirk*, 376 F.2d 936, 942, 153 U.S.P.Q. 48, 53 (C.C.P.A. 1967) (stating that Congress intended § 112 to pre-suppose full satisfaction of the requirements of § 101).

18. Compare *In re Nelson*, 280 F.2d 172, 181, 126 U.S.P.Q. 242, 250 (C.C.P.A. 1960) (holding that compounds for use as intermediates satisfied requirements of § 101) with *In re Kirk*, 376 F.2d 936, 942, 153 U.S.P.Q. 48, 54 (C.C.P.A. 1967) (stating that chemical compound was not presumed useful under § 101 merely because it was similar to other useful compounds) and *In re Joly*, 376 F.2d 906, 908, 153 U.S.P.Q. 45, 47 (C.C.P.A. 1967) (holding that use of subject compounds as intermediates to produce other compounds which had no adequately established use was insufficient). Accord *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1384, 181 U.S.P.Q. 453, 455 (C.C.P.A. 1974) (holding compound producing pupil dilation upon administration not sufficient to establish reduction to practice); *Anderson v. Natta*, 480 F.2d 1392, 1397, 178 U.S.P.Q. 458, 461 (C.C.P.A. 1973) (finding that process of producing co-polymers was insufficient reduction to practice in absence of structural testing of product). But see *In re Iirani*, 487 F.2d 924, 926, 180 U.S.P.Q. 44, 46 (C.C.P.A. 1973) (finding that claimed compound, disclosed as capable of conversion to acid with known uses, had practical utility); *Nelson v. Bowler*, 626 F.2d 853, 856-57, 206 U.S.P.Q. 881, 884 (C.C.P.A. 1980) (distinguishing *Rey-Bellet* and holding pharmacological activity of smooth muscle stimulation and blood pressure modulation were practical utilities).

19. *In re Ruskin*, 354 F.2d 395, 397, 148 U.S.P.Q. 221, 222 (C.C.P.A. 1966); *In re Nelson*, 280 F.2d 172, 178, 126 U.S.P.Q. 242, 248 (C.C.P.A. 1960).

20. See *In re Nelson*, 280 F.2d 172, 180, 126 U.S.P.Q. 242, 250 (C.C.P.A. 1960) (stating that judiciary has never received clear answer to question "Useful to whom and for what?").

21. 182 F.2d 216, 86 U.S.P.Q. 74 (C.C.P.A. 1950).

22. *Id.* at 217, 86 U.S.P.Q. at 75.

Bremner, the court in *In re Nelson*²³ concluded that the first requirement was a "meaningless formality and no more required by law than an assertion of novelty."²⁴ As to the requisite indication of use, the court noted that

[m]uch confused thinking on this matter has resulted from a failure to separate the requirement of section 101 that an invention be useful from the section 112 requirement that a specification shall so explain "the manner and process of . . . using" the invention as to "enable any person skilled in the art . . . to . . . use the same."²⁵

The "confused thinking" was reinstated by a later ruling that a lack of utility can lead to rejection under either section 101 or 112.²⁶

Confusion has arisen also because the "how-to-use" constraint of section 112 is a question of law²⁷ properly determined by studying the patent application.²⁸ In contrast, determining whether a compound is "useful" necessitates exploration of the compound *itself*.²⁹ Nevertheless, the courts always have looked solely to what is written in determining the product's utility.³⁰ Because the decision can be based solely on examination of documents, judges naturally tend to

23. 280 F.2d 172, 126 U.S.P.Q. 242 (C.C.P.A. 1960).

24. *Id.* at 183 n.4, 126 U.S.P.Q. at 252 n.4.

25. *Id.* at 184, 126 U.S.P.Q. at 252-53.

26. *In re Fouché*, 439 F.2d 1237, 1243, 169 U.S.P.Q. 429, 434 (C.C.P.A. 1971).

27. See *Cross v. Iizuka*, 753 F.2d 1040, 1044 n.7, 224 U.S.P.Q. 739, 742 n.7 (Fed. Cir. 1985) (stating that how-to-use requirement is question of law); *Quaker City Gear Works, Inc. v. Skil Corp.*, 747 F.2d 1446, 1453-54, 223 U.S.P.Q. 1161, 1166 (Fed. Cir. 1984) (stating that enablement requirement of § 112 is question of law), *cert. denied*, 105 S. Ct. 2676 (1985); *Carter-Wallace Inc. v. Otte*, 474 F.2d 529, 547, 176 U.S.P.Q. 452, 453 (2d Cir. 1972) (stating that court determines question of patent applications' disclosure based on application of legal standard to complex facts), *cert. denied*, 412 U.S. 929 (1973).

28. See generally *In re Adams*, 316 F.2d 476, 478, 137 U.S.P.Q. 333, 335 (C.C.P.A. 1963) (holding that how-to-use disclosure of application need not be as complete for method claims as for product claims) (citing *In re Wilke*, 314 F.2d 558, 136 U.S.P.Q. 435 (C.C.P.A. 1963)); *In re Nelson*, 280 F.2d 172, 184, 126 U.S.P.Q. 242, 251 (C.C.P.A. 1960) (deciding compliance with § 112 based on examination of patent specification); 35 U.S.C. § 112 (1982) (stating that patent's specification shall contain written description of invention and of manner and process of using it).

Note that while ultimately determining proper "enablement" from the specification, extraneous evidence often is allowed to support factual questions raised along the way. For example, extraneous evidence was allowed in support of these questions. Are dosage levels in human subjects needed to teach how-to-use? *Cross v. Iizuka*, 753 F.2d 1040, 1051, 224 U.S.P.Q. 739, 748 (Fed. Cir. 1985); *In re Gardner*, 427 F.2d 786, 789, 166 U.S.P.Q. 138, 141 (C.C.P.A. 1970). Do slight structural differences between known compounds and those claimed allow a conclusion of opposite pharmacological effects? *In re Bundy*, 642 F.2d 430, 432, 209 U.S.P.Q. 48, 51-52 (C.C.P.A. 1981). Is undue experimentation required to practice the invention? *In re Kirk*, 376 F.2d 936, 942, 153 U.S.P.Q. 48, 53 (C.C.P.A. 1967).

29. See *supra* note 16 and accompanying text (discussing proposition that uses are inherent).

30. See, e.g., *Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985) (stating that where constructive reduction to practice is involved, invention's practical utility is determined through reference to disclosures of application).

make a legal conclusion, viz "lack of utility," and can avoid adjudging a compound's potential uses, which by definition do not appear on the documents' face.

In summary, the similarity of terminology and evidence examined makes the source of confusion between "useful" and "manner of using" understandable. The most egregious examples of construing "useful" as a legal conclusion, however, came about due more to a misunderstanding of the objectives of patent law than because of statutory misinterpretation.

III. USE AS INTERMEDIATES

The court in *In re Nelson* reasoned that "practical" usefulness, urged as a requirement by the Patent Office, was met by a new group of steroid intermediates that scientists claimed were "useful to chemists doing research on steroids."³¹ The court's analysis demonstrates that "practical" use does not mean "carrying judicial imprimatur," but is equivalent to "useful" in the lay sense.³²

In *In re Manson* the United States Court of Customs and Patent Appeals (CCPA) again refused to construe "useful" as a legal conclusion.³³ The court summarized the Board of Patent Appeals' position as one requiring an applicant to demonstrate that he knew of a "utility for the compound produced by the process at the time he invented the process," before he may have claims to the process placed in interference to decide priority of invention under 35 U.S.C. § 135.³⁴ The court did not comment on the Board's reference to "utility," and simply held that "a process which operated as disclosed to produce a known product is 'useful' within the meaning

31. 280 F.2d 172, 180, 126 U.S.P.Q. 242, 250 (C.C.P.A. 1960).

32. *Id.* at 180-81, 126 U.S.P.Q. at 250. As the court stated in *In re Nelson*:

Such intermediates are "useful" under [s]ection 101. They are often actually placed on the market before much, if anything, is known as to what they are "good" for, other than experimentation and the making of other compounds in the important field of research. Refusal to protect them at this stage would inhibit their wide dissemination, together with the knowledge of them which a patent disclosure conveys, which disclosure the potential protection encourages. This would tend to retard rather than promote progress.

The new androstenes, being *useful to research chemists* for the purposes disclosed by appellants, are clearly useful to society and their invention contributes to the progress of an art which is of great potential usefulness to mankind. They are new steroids which in known ways can be made into other steroids, thus furthering the development of this useful art.

Id.; see also *In re Folkers*, 344 F.2d 970, 975, 145 U.S.P.Q. 390, 393 (C.C.P.A. 1965) (holding that § 101 requirements were met because compounds were useful to biochemists studying enzyme systems).

33. 333 F.2d 234, 236, 142 U.S.P.Q. 35, 35 (C.C.P.A. 1964), *rev'd*, 383 U.S. 519, 148 U.S.P.Q. 689 (1966).

34. *Id.* at 235, 142 U.S.P.Q. at 36.

of section 101."³⁵ The court went on to emphasize that "utility" means only that the claimed invention operates, produces the intended result, and is not contrary to sound morals and policy.³⁶

The Supreme Court reversed the CCPA, and enunciated their definition of "useful":

The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with *substantial utility*. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.³⁷

Thus, a conclusion of "substantial utility" is reached only when the use is approved by the Court. Although it is conceded that the Supreme Court Justices are as equipped as anyone to identify pornography—thus justifying the famous "I know it when I see it" standard—their backgrounds do not serve as well to identify which uses will serve to "promote the progress of science and the useful arts."³⁸

Having said that, the *Manson* Court spoke of "useful" inventions,³⁹ referring by implication only to those with "substantial utility." Ever since, "useful" has encompassed only those compounds and intermediates which have "substantial," "specific," or "practical" utility,⁴⁰ even though that interpretation leads to the absurd and self-contradictory corollary that *use as an intermediate to prepare "useless" things is not a "useful" use*. As ludicrous as this is on its face, it is even more incredible if one considers that the common meaning of "useful" is, "capable of being put to a use."⁴¹ Under this definition there is no limitation on what that latent use may be: use

35. *Id.* at 236, 142 U.S.P.Q. at 36.

36. *Id.* at 238, 142 U.S.P.Q. at 38. This pronouncement is comparable to the early decisions wherein "utility" raised moral questions but did not justify broad-based use examination. See *supra* note 8 (discussing early cases).

37. *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966) (emphasis added).

38. U.S. CONST. art. I, § 8, cl. 8; see also *In re Kirk*, 376 F.2d 936, 954-57, 153 U.S.P.Q. 266, 272-76 (C.C.P.A. 1967) (Rich, J., dissenting) (criticizing dicta in *Manson* as contrary to legislative history and beyond facts); Rushforth, *The Patentability of Chemical Intermediates*, 56 CALIF. L. REV. 497, 510-14 (1968) (arguing that public benefits from research advances resulting from unmarketable compounds).

39. *Brenner v. Manson*, 383 U.S. 519, 535-36, 148 U.S.P.Q. 689, 695-96 (1966).

40. See *In re Kirk*, 376 F.2d 936, 945, 153 U.S.P.Q. 48, 56 (C.C.P.A. 1967), where after referring to the "practical utility" requirement of *Manson*, the court stated, that if a process for producing a product of only conjectural use is not inherently "useful" within § 101 then the materials initiating the process, (the claimed intermediates) also cannot be deemed "useful"; see also *supra* notes 11-13 and accompanying text (defining terms).

41. See WEBSTER'S NINTH COLLEGIATE DICTIONARY 1299 (9th ed. 1984).

as an intermediate is as appropriate as any other.⁴² Nevertheless, if *Manson* is read in its specific factual context and limited accordingly, the decision, as opposed to the court's statements and reasoning, is not wholly unreasonable.⁴³

IV. "USEFUL" AND REDUCTION TO PRACTICE

The primary issue in *Manson* was Manson's right to an interference with an issued patent.⁴⁴ A subsidiary issue was the sufficiency of affidavits, which had no disclosure of use for the product of the claimed process, to show a reduction to practice.⁴⁵

It is axiomatic that some disclosure of some use is necessary to establish reduction to practice. As a first step towards deduction of this tenet, appreciation of some use is necessary inasmuch as the issue is whether the invention was reduced to practice; an invention without a perceived use is a contradiction in terms. The second step asks the question presented to the Court in *Manson*: what level of perception of the use must be proved? *Manson* proffered only that the use was obvious to him; therefore, the Court's conclusion that the proof was insufficient was not erroneous. When an issued patent is in interference, it is reasonable to require a higher standard of proof of "use appreciation" to prevent an applicant from merely copying the use assertion in the patent and then falsely claiming prior conception of the copied use.⁴⁶ Because *Manson* offered no proof and merely alleged that the use was "obvious," he failed to meet the standard for establishing reduction to practice.

In subsequent decisions on reduction to practice, however, the lower courts did not view *Manson* as so limited,⁴⁷ and concluded instead that it sanctioned inquiry into the acceptability of the use. Therefore, the numerous decisions that require "practical utility"⁴⁸

42. *In re Nelson*, 280 F.2d 172, 180-81, 126 U.S.P.Q. 242, 250 (C.C.P.A. 1960).

43. See *In re Kirk*, 376 F.2d 936, 956, 153 U.S.P.Q. 48, 273-74 (C.C.P.A. 1967) (Rich, J., dissenting) (urging limitation of *Manson*).

44. *Brenner v. Manson*, 383 U.S. 519, 532, 148 U.S.P.Q. 689, 694 (1966).

45. *Id.*

46. For similar reasons, such as prevention of false claims, courts have required a higher standard of proof to show compliance with the "description" or "enablement" requirements of 35 U.S.C. § 112 when an issued patent is involved, than that needed to overcome a § 112 rejection during *ex parte* prosecution. See *Snitzer v. Etzel*, 531 F.2d 1062, 1066, 189 U.S.P.Q. 415, 417 (C.C.P.A. 1976) (requiring clear and convincing evidence to prove adequate description and enablement in an interference).

47. In *Knapp v. Anderson*, 477 F.2d 588, 591, 177 U.S.P.Q. 688, 691 (C.C.P.A. 1973), however, the court seemed to recognize the real effect of *Manson* when it stated that, "the disclosure necessary to support patentability . . . is not necessarily relevant to the degree of proof required to support an actual reduction to practice. . . ."

48. See, e.g., *Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985) (requiring disclosed utility to meet practical utility standard); *Nelson v. Bowler*, 626 F.2d 853, 856, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) (equating practical utility with real usability by

or "substantial utility"⁴⁹ to show reduction to practice not only give an unintended meaning to "useful" in 35 U.S.C. § 101, but also misapprehend the crux of *Manson*.⁵⁰

An issue somewhat related to proof of "use appreciation" arose prior to *Manson* in cases where the CCPA required objective proof in support of the asserted use.⁵¹ These decisions, however, deal with sufficiency of the proffered evidence and, thus, provide no precedent for use examination or for elevation of "useful" to legal conclusion status.

V. DOES IT WORK?

In pre-*Manson* decisions involving compositions for curing baldness, the CCPA was concerned particularly that the invention be proved "useful" in the sense that it operate as claimed.⁵² Although some courts held that all medical patents should be granted only with great care and scrutiny following thorough testing by several physicians,⁵³ the CCPA always viewed this grant more liberally. For example, the CCPA held that mere proof of "pharmacological activity" in animals—a standard more easily met than that of "therapeu-

experts in field); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1382-83, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974) (finding that practical utility supports conclusion of actual reduction to practice); *Anderson v. Natta*, 480 F.2d 1392, 1397, 178 U.S.P.Q. 458, 460 (C.C.P.A. 1973) (denying practical utility in absence of structural testing of product's alleged use when reduced to practice).

49. See, e.g., *Anderson v. Natta*, 480 F.2d 1392, 1395, 178 U.S.P.Q. 458, 460 (C.C.P.A. 1973) (establishing substantial use of process and product of process sufficient to show reduction to practice); *Knapp v. Anderson*, 477 F.2d 588, 590, 177 U.S.P.Q. 688, 690 (C.C.P.A. 1973) (proving substantial use for any purpose sufficient to establish reduction to practice if interference counts do not specify use); *Campbell v. Wettstein*, 476 F.2d 642, 646-47, 177 U.S.P.Q. 376, 379 (C.C.P.A. 1973) (showing substantial utility in laboratory animals to prove reduction to practice).

50. The pre-*Manson* cases also do not support a requirement of "practical or substantial" utility to establish a reduction to practice. The applicable decisions merely hold that successful animal experiments are sufficient to establish an actual reduction to practice. See *Archer v. Papa*, 265 F.2d 954, 121 U.S.P.Q. 413 (C.C.P.A. 1959); *Blicke v. Treves*, 241 F.2d 718, 112 U.S.P.Q. 472 (C.C.P.A. 1957).

51. See *In re Ferens*, 417 F.2d 1072, 1074, 163 U.S.P.Q. 609, 611 (C.C.P.A. 1979) (requiring clear and convincing evidence to one of ordinary skill in particular art) (citing *In re Irons*, 340 F.2d 974, 144 U.S.P.Q. 351 (C.C.P.A. 1965)); *In re Oberweger*, 115 F.2d 826, 829, 47 U.S.P.Q. 455, 458 (C.C.P.A. 1940) (requiring convincing proof of utility).

52. *In re Oberweger*, 115 F.2d 826, 829, 47 U.S.P.Q. 455, 458 (C.C.P.A. 1940) (emphasizing importance of utility for hair growth products to prevent fraud on public).

53. See *Isenstead v. Watson*, 157 F. Supp. 7, 9, 115 U.S.P.Q. 408, 410 (D.D.C. 1957) (stating that medical formulas should be thoroughly tested and successfully tried by more than one physician before patent granted); see also *Radoev v. Brenner*, 253 F. Supp. 923, 925, 148 U.S.P.Q. 702, 703-04 (D.D.C. 1966) (considering evidence from specialists in area more probative than other doctors' evidence); *Rudd v. Kingsland*, 94 F. Supp. 569, 570, 88 U.S.P.Q. 418, 419 (D.D.C. 1951) (requiring more than hearsay testimony from two doctors).

tic use"—is sufficient.⁵⁴ Moreover, even when recognizing that the test results could have been caused by the "placebo effect," the CCPA held that "double-blind" tests in human subjects are not needed.⁵⁵

After the decision in *Manson*, however, there was a general tightening of standards. For example, proof that one of the claimed compounds was effective in the treatment of two human subjects was insufficient to support claims to a class of compounds alleged to treat seven classes of tumors.⁵⁶ Nevertheless, just as the Court in *Manson* did not address the *sufficiency* of the proffered evidence—there being none—pre-*Manson* decisions on that issue provide no foundation for examination of the *acceptability* of use undertaken in *Manson* and its progeny.

VI. IS IT SAFE?

Although prior to *Manson* there were indications that a lack of safety meant that a compound was not "useful,"⁵⁷ the two applica-

54. *Nelson v. Bowler*, 626 F.2d 853, 856-58, 206 U.S.P.Q. 881, 883-85 (C.C.P.A. 1980); cf. *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 181 U.S.P.Q. 453 (C.C.P.A. 1974).

For cases where proof of effectiveness in animals was sufficient, see *In re Jolles*, 628 F.2d 1322, 1327, 206 U.S.P.Q. 885, 890 (C.C.P.A. 1980) (stating that testing drugs on animals is relevant to utility for humans); *In re Langer*, 503 F.2d 1380, 1392-93, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974) (ruling that § 101 usefulness does not require full-scale tests on humans); *In re Hitchings*, 342 F.2d 80, 86-87, 144 U.S.P.Q. 637, 642-43 (C.C.P.A. 1965) (accepting inhibition of cancer growth in animals as proof of utility); *In re Ross*, 305 F.2d 878, 880, 134 U.S.P.Q. 320, 321 (C.C.P.A. 1962) (finding proof of effectiveness of compounds on animals was sufficient proof of utility for humans); *In re Krimmel*, 292 F.2d 948, 953, 130 U.S.P.Q. 215, 219 (C.C.P.A. 1961) (finding compound useful that achieves goal of "pharmaceutical applications" in animals); *In re Dodson*, 292 F.2d 943, 947, 130 U.S.P.Q. 224, 227 (C.C.P.A. 1961) (holding that proving usefulness in animals is sufficient even if compound's ultimate purpose is human use); *In re Bergel*, 292 F.2d 955, 958, 130 U.S.P.Q. 206, 209 (C.C.P.A. 1961) (accepting prevention of cancer in rats as sufficient proof of compound's utility for that purpose); *Archer v. Papa*, 265 F.2d 954, 958, 121 U.S.P.Q. 413, 416-17 (C.C.P.A. 1959) (finding success in laboratory experiments sufficient for reduction to practice); *Blicke v. Treves*, 241 F.2d 718, 722, 112 U.S.P.Q. 472, 476 (C.C.P.A. 1957) (ruling that producing desired pharmacological effect in animals established compound's utility). But see *In re Citron*, 325 F.2d 248, 253, 139 U.S.P.Q. 516, 519-20 (C.C.P.A. 1963) (requiring actual proof of effect in humans to establish utility for humans); see also *In re Gottlieb*, 328 F.2d 1016, 1019, 140 U.S.P.Q. 665, 667 (C.C.P.A. 1964) (finding evidence of efficacy of compound as fungicide sufficient to demonstrate utility despite assertions of intended use in human treatment).

55. *In re Irons*, 340 F.2d 974, 977-78, 144 U.S.P.Q. 351, 354 (C.C.P.A. 1965).

56. *In re Buting*, 418 F.2d 540, 544, 163 U.S.P.Q. 689, 691 (C.C.P.A. 1969); see also *Knapp v. Anderson*, 477 F.2d 588, 590, 177 U.S.P.Q. 688, 691 (C.C.P.A. 1973) (finding laboratory test demonstrating limited dispersant characteristics for claimed compound used in lubricating oil insufficient to show reduction to practice when alleged use was for keeping engine clear and sludge-free during operation); *In re Harwood*, 390 F.2d 985, 989, 156 U.S.P.Q. 673, 676 (C.C.P.A. 1968) (upholding rejection for lack of proof of utility because applicant presented no evidence of inference that claimed compositions would not sterilize all insect species encompassed by claims); cf. *In re Sichert*, 566 F.2d 1154, 1158-59 & n.6, 196 U.S.P.Q. 209, 212-13 & n.6 (C.C.P.A. 1977).

57. See *In re Anthony*, 414 F.2d 1383, 1398-99, 162 U.S.P.Q. 594, 607 (C.C.P.A. 1969).

ble holdings went only to the adequacy of proof of safety.⁵⁸ In fact, in both cases the court emphasized that the presence of a certain degree of danger did not mean that the drugs in question were not "useful."⁵⁹ This statement is simply an application of the principle that the degree of utility is immaterial,⁶⁰ and adhering to this principle makes any conclusions regarding acceptability of the use immaterial.

CONCLUSION

To reiterate, there is no basis for judicial use examination. To construe "useful" in section 101 as denoting a legal conclusion causes pernicious consequences. The most deleterious consequence is discouraging or delaying a patent application and, thus, impeding the dissemination of information necessary to "promote the progress of science and the useful arts."⁶¹ Other significant evils are encouraging contrivance of "phony" uses and withholding of information.⁶² All these consequences defeat a primary purpose of the patent law: to disclose inventions "in sufficient detail to enable one skilled in the art to practice [it]."⁶³

As treacherous as these results are to chemistry, use examination could prove more crippling if extended to the budding field of biotechnology. Because of the novelty of this area, the potential uses for many biological products or materials are beyond present comprehension. Use examination in biotechnology, therefore, would be harder to carry out and less justifiable. Because little is known and communication can lead to explosive advancements, providing this disincentive to dissemination of information will stifle progress in

(reversing rejection for "lack of utility" made after applicant's assignee withdrew its new drug application because some patients had developed blood disease).

58. See *id.* (reversing rejection of lack of utility based on examination of safety evidence); *In re Hartop*, 311 F.2d 249, 255-57, 135 U.S.P.Q. 419, 425-26 (C.C.P.A. 1962); see also *In re Krimmel*, 292 F.2d 948, 954, 130 U.S.P.Q. 215, 220 (C.C.P.A. 1961) (stating that Patent Office does not have right or duty to require proof that claimed compounds are "safe, effective, and reliable for use in humans"). For a more recent decision on proof of safety, see *In re Watson*, 517 F.2d 465, 474-76, 186 U.S.P.Q. 11, 19 (C.C.P.A. 1975) (deferring subjective tests of safety to delegated executive agencies).

59. *In re Anthony*, 414 F.2d 1383, 1395, 162 U.S.P.Q. 594, 604 (C.C.P.A. 1969); *In re Hartop*, 311 F.2d 249, 257, 135 U.S.P.Q. 419, 424-25 (C.C.P.A. 1962).

60. See *In re Ruskin*, 354 F.2d 395, 397, 148 U.S.P.Q. 221, 222 (C.C.P.A. 1966) (accepting utility of any process that produces intended result); *In re Nelson*, 280 F.2d 172, 178, 126 U.S.P.Q. 242, 249 (C.C.P.A. 1960).

61. U.S. CONST. art. I, § 8, cl. 8.

62. See *In re Kirk*, 376 F.2d 936, 959-63, 153 U.S.P.Q. 266, 276-78 (C.C.P.A. 1967) (Rich, J., dissenting) (arguing that satisfying § 101 requirements wastes time and inventive brain power).

63. *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484, 61 U.S.P.Q. 382, 388 (1944); *In re Nelson*, 280 F.2d 172, 182, 126 U.S.P.Q. 242, 253 (C.C.P.A. 1960).

this fledgling art more seriously than it does in chemistry, where there exists a far greater pool of knowledge.

Although these negative consequences flow when patent protection is denied for inventions with limited or uncertain uses, there are no negative consequences if patents are granted on such inventions. The holder of such a patent would be taking nothing from the public because the public would not be tempted to make, use, or sell a "useless" invention. These patents would merely disclose information to the public.

It is comforting to know that all the ills associated with use examination can be remedied simply by revoking a privilege that was usurped originally in contravention of precedent and logic. Like Humpty-Dumpty, the judiciary would have "useful" mean "whatever I choose it to mean." If "useful," instead, is given the definition supported by the dictionary, prior case law, and common sense, that is, something "capable of being put to a use," use examination will be abolished in one fell swoop.