

# ARTICLE

## A CALL FOR RECONSIDERATION OF THE STRICT UTILITY STANDARD IN CHEMICAL PATENT PRACTICE

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## I. INTRODUCTION

The strict utility requirement in chemical and biotechnology<sup>1</sup> patent cases has been the subject of considerable criticism and controversy.<sup>2</sup> Section 101 of the patent code provides:

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.<sup>3</sup>

In addition, the first paragraph of section 112 of the patent code provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.<sup>4</sup>

Sections 101 and 112 combine to create two separate utility requirements under the patent statute. First, the applicant must demonstrate a practical utility for the invention under section 101. Second, the applicant's disclosure must instruct those who read the patent how to use this new invention.<sup>5</sup>

In mechanical and electrical applications, the utility requirement is usually not problematic because both the "practical utility" and the "how

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1. Unless otherwise indicated, for the purposes of this article the term "chemical" as used in phrases such as "chemical research" and "chemical invention" is intended to encompass the field of biotechnology as well. The field of biotechnology is generally considered to encompass "the use of data and techniques of engineering and technology for the study and solution of problems concerning living organisms." WEBSTER'S NEW WORLD DICTIONARY 143 (2nd college ed. 1982). The subject matter of biotechnical inventions generally includes material that is capable of direct or indirect self-replication, as well as nucleotide sequences and/or amino acid sequences. See U.S. DEPT. OF COMMERCE, PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE §§ 2401, 2403 (Rev. 16, March 1994) [hereinafter MPEP].

2. See Eric P. Mirabel, *Practical Utility is a Useless Concept*, 36 AM. U. L. REV. 811, 822-23 (1987) (summarizing the negative consequences in the chemical and biotechnology fields which flow from a strict utility requirement which denies patents to inventions with uncertain uses); G. Kenneth Smith and Denise M. Kettelberger, *Patents and the Human Genome Project*, 22 AM. INTEL. PROP. L. ASS'N Q.J. 27, 60-62 (1994) (discussing recent proposals and bills introduced to Congress requesting amendment of the U.S. patent statute for separate requirements for biotechnology protection); Comment, *Utility Requirement in Chemical Patents*, 35 GEO. WASH. L. REV. 809, 817 (1967) (the strict utility requirement for chemical inventions will work a hardship on chemical researchers).

3. 35 U.S.C. § 101 (1988).

4. 35 U.S.C. § 112 (1988).

5. 35 U.S.C. § 112. In a sense the § 101 requirement establishes a standard against which the *invention* must be measured. On the other hand, § 112 creates a standard against which the *inventor's disclosure* must be measured.

to use" requirements are usually easily ascertainable from a description or diagram of the invention itself. Utility in chemical applications, however, is often more elusive because a mere description or diagram of a new chemical compound does not usually reveal its utility.<sup>6</sup> If an invention's utility is not revealed by mere descriptions or drawings, the applicant must assert and support a "practical utility" for the compound, as summarized in the following passage from the Manual of Patent Examining Procedure:

If the asserted utility of a compound is believable on its face to persons skilled in the art in view of the contemporary knowledge in the art, then the burden is upon the examiner to give adequate support for rejections for lack of utility under [Section 101]. On the other hand, incredible statements or statements deemed unlikely to be correct by one skilled in the art in view of contemporary knowledge in the art will require proof on the part of the applicants for patents.<sup>7</sup>

Mechanical and electrical inventions are ordinarily prospectively designed with a particular use in mind, and utility is usually evident.<sup>8</sup> Likewise, many chemical inventions are designed in response to a certain problem in a particular art, and the utility requirement is easily satisfied. For example, a propellant composition may be specifically developed to produce nontoxic combustion gases that inflate an automobile air bag in the event of a collision. Meeting the utility requirements of the patent law for such prospectively designed and specifically applied chemical inventions is routine, paralleling application procedures for mechanical and electrical inventions.

In contrast to most mechanical and electrical inventions, many chemical inventions evolve without a readily discernible utility. Instead, chemical inventions may arise out of research efforts wherein future utility is far less certain or even unknown. For example, an AIDS research foundation may synthesize a new compound during the course of developing a potential vaccine. The foundation may hope that this new compound is useful as part of the desired vaccine, but it may not know the ultimate composition of the drug and how the new compound will fit in that puzzle. Chemical inventions may also be derived from an accidental discovery, in which case the new compound does not even

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6. Indeed, it is noteworthy that the Manual of Patent Examination Procedure devotes what is essentially a one sentence passage to mechanical invention utility. MPEP, *supra* note 1, at § 608.01(p). On the other hand, the Manual devotes an extensive section to chemical utility, entitled "Guidelines for Considering Disclosures of Utility in Drug Cases." *See id.* (citations omitted).

7. *Id.*

8. *See, e.g., id.* ("A complete disclosure should include a statement of utility. This usually presents no problem in mechanical cases.")

have a hoped-for use.<sup>9</sup> In such a case, the new compound may then be the simple object of fundamental use-testing. In contrast, even though accidental uses may arise for mechanical or electrical inventions, the mechanical or electrical device itself is almost always originally created with a particular use in mind.

A chemical invention, therefore, may not have a clear utility initially, but may still be beneficial to society in one of two ways: (1) as an object of scientific research (for example, as a possible building block to a potential vaccine), or (2) as an object of use-testing (for example, as its own starting point in finding some use for somebody). Such research uses for new chemical discoveries have increasing relevance in the field of biotechnology. Currently, scientists are obtaining gene sequence fragments known as cDNA fragments.<sup>10</sup> While only complete cDNA sequences may code for specific proteins, partial fragments of these cDNA sequences also may aid biotechnology research by (1) mapping chromosomes, (2) identifying tissue types, and (3) identifying gene regions associated with diseases.<sup>11</sup>

In *Brenner v. Manson*,<sup>12</sup> the United States Supreme Court responded to a series of inconsistent cases in the area of chemical utility by strictly construing sections 101 and 112. Commentators dispute<sup>13</sup> the wisdom and rationale of the Court's holding in *Manson* that a process yielding a product which either has no known use, or is useful only in the sense that it may be an object of scientific research, is not patentable.<sup>14</sup> In dicta, the Court also suggested that the product itself is not useful if the disclosed utility merely relates to research.<sup>15</sup> The following year, the Circuit Court of Customs and Patent Appeals (CCPA), which preceded the current Court of Appeals for the Federal Circuit (CAFC), embraced *Manson* in the companion cases of *In re Kirk*<sup>16</sup> and *In re Joly*.<sup>17</sup> In *Kirk*, the CCPA expanded the narrow holding of *Manson* to rule that compounds whose

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9. See Bob Gatty, *Mishaps that Mothered Invention: Products Created by Accident*, 75 NATION'S BUS. 58 (1987); *Metro Collects Scientific Cream of the Crop: 11 Nobel Winners Here to Honor U of T's Polyani*, Toronto Star, Oct. 31, 1994, at A1 (Announcing a lecture by Michael Smith, a University of British Columbia professor and the 1993 Nobel Prize winner in chemistry: "Smith says his lecture will stress the importance of funding pure academic research as the most socially and economically beneficial form of scientific activities. Most important scientific discoveries, his own included, are made by accident in the course of searching for something else," he said.) (emphasis added)).

10. See generally, Smith and Kettelberger, *supra* note 2, at 39-46.

11. ROBERT P. MERGES, PATENT LAW AND POLICY 159 (1992).

12. 383 U.S. 519 (1966).

13. See *In re Kirk*, 376 F.2d 936, 955 (C.C.P.A. 1967) (Rich, J., dissenting).

14. *Manson*, 383 U.S. at 535.

15. *Id.*

16. 376 F.2d 936 (C.C.P.A. 1967).

17. 376 F.2d 906 (C.C.P.A. 1967).

sole disclosed utility lay as an intermediate for the production of other compounds, which in turn have no present known use other than as objects of chemical research, did not satisfy the practical utility requirement of section 101.<sup>18</sup> In *Joly*, the CCPA extended *Kirk* to cover process claims, holding that processes which yield chemical intermediates are also unpatentable where the intermediates are used only to create end products with no known use.<sup>19</sup>

Following these cases, the United States Patent and Trademark Office (Patent Office) adopted a rigorous practical utility policy for chemical inventions.<sup>20</sup> However, while not directly disputing or questioning *Manson*, the CCPA/CAFC apparently allowed certain cracks to appear in the wall of the strict practical utility standard in *Nelson v. Bowler*<sup>21</sup> and *Cross v. Iizuka*.<sup>22</sup> In *Bowler*, the CCPA characterized knowledge of "pharmacological activity" of any compound as being "obviously beneficial to the public"<sup>23</sup> and applied a more relaxed section 112 standard of proving an actual reduction to practice than the Patent Office had been using.<sup>24</sup> In *Iizuka*, the Federal Circuit upheld the patentability of a chemical compound shown only to inhibit certain enzymes in vitro (in a test tube) even though no evidence was presented to show that the claimed compound worked in vivo (in a living being), implicitly approving a suggestion in the Patent Office Board of Interference's opinion that tests showing pharmaceutical activity may satisfy section 101 even where no specific therapeutic use for the compounds have been established.<sup>25</sup> Thus, even if the practical utility of an invention is research-oriented in the sense that pharmacological results are produced only in a laboratory setting, the invention may nevertheless pass both utility requirements where sufficient section 112 instructions regarding how to achieve those results are included in the application.

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18. *Kirk*, 376 F.2d at 945.

19. *Joly*, 376 F.2d at 908.

20. See MPEP, *supra* note 1, at § 608.01(p) ("Utility must be definite and in currently available form; not merely for further investigation or research.").

21. 626 F.2d 853 (C.C.P.A. 1980).

22. 753 F.2d 1040 (Fed. Cir. 1985).

23. *Bowler*, 626 F.2d at 856.

24. Specifically, the court recognized an in vivo rat blood pressure test and an in vitro gerbil colon smooth muscle test as sufficiently manifesting the practical utility of substituted prostaglandins and intermediates for preparing these compounds in contradistinction to previous rigorous Patent Office reduction to practice standards. *Bowler*, 626 F.2d at 855-57. See Kenneth D. Sibley, *Practical Utility: Evolution Suspended?*, 32 IDEA 203, 219, n. 92.

25. *Cross*, 753 F.2d at 1043.

Despite these limited cracks in the strict utility requirement, *Manson's* broad dictate remains the law.<sup>26</sup> This Article calls for a reexamination of the strict utility requirement in chemical and biotechnology patent cases. Although *Manson* attempted to bring uniformity and predictability to the law of chemical utility, its demanding standard is inconsistent with the policies underlying the patent statute. These policies recognize that the public benefits from wide dissemination of information in all fields of technology. The current state of the law under *Manson* inhibits the dissemination of information in the chemistry and biotechnology fields by imposing the same rigorous utility standard required of mechanical and electrical inventions before a patent is granted: the standard of development to a point where a "specific benefit exists in currently available form."<sup>27</sup>

This Article critically examines the history of the utility requirement in American patent jurisprudence, and concludes that the strict holding in *Manson* was not inevitable in light of the patent statutes and case precedents and was certainly not necessary to achieve the Constitutional aim to "promote the progress . . . of the useful arts."<sup>28</sup> Unlike their electrical and mechanical counterparts, chemical inventions are beneficial to society in a two-step process, the first step being the discovery or development of a compound with no definitive use and the second step being the discovery or development of a definitive use for that compound. Each step is essential in producing beneficial products for society and, therefore, each step should be the subject of patent incentive and reward. In the chemical and biotechnological arts, then, the patent system should foster progress in a two-step quid pro quo.<sup>29</sup>

This Article further examines the strict chemical utility requirement in light of international patent protection and harmonization considerations.<sup>30</sup> These concerns dictate a need for a relaxed utility standard in the United States allowing scientific research and use-testing as valid utilities under section 101. Germany, Japan, and other nations do not share the stringent chemical utility requirements of the United States. Most other nations recognize research as a valid use for purposes of patentability.<sup>31</sup> Moreover, the chemical utility standard in the United States creates difficulty in obtaining meaningful international protection

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26. See *In re Ziegler*, 992 F.2d 1197, 1203 (Fed. Cir. 1993) ("The utility of a chemical compound may not reside in 'its potential role as an object of use testing.'") (citing *Manson*, 383 U.S. at 535).

27. *Manson*, 383 U.S. at 534-35.

28. U.S. CONST. art. I, § 8, cl. 8.

29. See discussion *infra* Part III.A.

30. See discussion *infra* Part III.B.

31. See STEPHEN A. BENT, ET AL., *INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY WORLDWIDE* 146 (1987).

for inventors from all over the world due to the United States' inconsistent position relative to most of the world.

Finally, this Article introduces the new concept of "best utility" disclosures as a means to implement a relaxed United States patent utility standard in the chemical arts, either as a separate statutory requirement or as a section 112 "best mode" interpretation.<sup>32</sup>

## II. HISTORICAL DEVELOPMENT OF THE PRESENT CHEMICAL UTILITY STANDARD IN THE UNITED STATES

### A. Case Law Prior to *Manson*

The origins of the judicial interpretation of the utility standard in patent law can be traced to Justice Story, who construed the requirement liberally and viewed a finding of lack of utility as the exception. Justice Story's inclusive standard defined utility in contradistinction to frivolity and immorality:

All that the law requires is, that the invention should not be frivolous or injurious to the well being, good policy, or sound morals of society. The word "useful," therefore, is incorporated in the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention.<sup>33</sup>

Other early commentators also viewed utility as an insignificant hurdle.<sup>34</sup> Exemplary of the liberal construction of utility by the judiciary in the first half of the twentieth century was *Potter v. Tone*,<sup>35</sup> a case in which the patent application demonstrated a general utility for the claimed chemical compound by describing the composition's characteristics—a reducing agent and a nonconductor of electricity. The court held that a description of such characteristics was sufficient to satisfy the utility requirement.<sup>36</sup> The court refused to require a commercial application for the chemical invention, which the court felt should be the subject of a separate patent.<sup>37</sup>

Patent Office practice generally agreed with the courts' interpretation. For example, in *Ex parte Watt*<sup>38</sup> the Patent Office Board of Patent Appeals suggested that a composition whose sole use was as an

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32. See discussion *infra* Part III.C.

33. *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568).

34. See CURTISON PATENTS § 28 (1849) (explaining degree of utility is irrelevant).

35. 36 App. D.C. 181, 184 (D.C. Cir. 1911).

36. *Id.* at 184-85.

37. *Id.*

38. 63 U.S.P.Q. 163 (Pat. Off. Bd. of App. 1942).

intermediate in the production of other compounds satisfied the utility requirement:

Regardless of whether applicant's compounds could or could not be used in a froth flotation process we are of the opinion that they could be regarded as intermediates in the preparation of other compounds, since it is obvious that any organic compound can be so used.<sup>39</sup>

This relaxed standard in chemical utility cases remained until 1950, when a series of cases, beginning with the CCPA case *In re Bremner*, questioned this liberal standard.<sup>40</sup> The application in *Bremner* claimed compositions and processes for producing hard resins, but the specification did not assert particular uses for the inventions.<sup>41</sup> The application merely disclosed physical characteristics of the compound, just as the *Potter* application did.<sup>42</sup> Nevertheless, the *Bremner* court required some showing of actual utility for the claimed compound:

It is our view that no "hard and fast" ruling properly may be made fixing the extent of disclosure of utility necessary in an application, but we feel certain that the law requires that there be in the application an assertion of utility and an indication of the use or uses intended.<sup>43</sup>

Extending this conclusion to the process claims as well, *Bremner* held that a claimed process must also produce a useful product in order to be patentable.<sup>44</sup> The Patent Office quickly adopted the "assertion of utility" requirement as promulgated by the court in *Bremner*.<sup>45</sup>

Although ostensibly construing section 112 rather than section 101,<sup>46</sup> the Court of Appeals for the District of Columbia expanded the *Bremner* ruling in *Petrocarbon, Ltd. v. Watson*.<sup>47</sup> In this case, the applicant claimed a process for producing a new polymer compound which could form a "film" on a cool surface.<sup>48</sup> The court rejected the application because the face of the application did not teach how to use the invention as required by section 112:

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39. *Id.* at 165.

40. 182 F.2d 216 (C.C.P.A. 1950).

41. *Id.* at 217.

42. Compare *Bremner*, 182 F.2d at 217 (no patent "granted upon a . . . process producing a product, unless such product be useful.") with *Potter*, 36 App. D.C. at 185 (patent upheld even though no specific use disclosed for resulting product).

43. *Id.* at 217 (emphasis in original).

44. *Id.*

45. See, e.g., *Ex parte Tolkmith*, 102 U.S.P.Q. 464, 465-66 (Pat. Off. Bd. App. 1955).

46. *Petrocarbon* illustrates the somewhat blurry line created by the courts between the be useful requirement of section 101 and the "how to use" disclosure requirement of section 112. The court may just as well have rejected the application under section 101 on the grounds that the film did not do anything, but instead rejected the application under section 112 on the grounds that the applicant did not teach a person of ordinary skill in the art "how to use" the product of the claimed invention.

47. 247 F.2d 800 (D.C. Cir. 1957), *cert. denied*, 355 U.S. 955 (1958).

48. *Id.* at 801.

The examples [disclosed in the application for use of the film] do not indicate whether or not this film adheres to the object on which it forms, whether it falls off in the form of a powder, whether it is detachable in the form of a film-like substance . . . whether the film itself would have to be subjected to further processing before it could form a useful object or fluid, and so on. Some such further indication, it seems to us, should have been given to enable readers of the application to understand how the product is to be used.<sup>49</sup>

Despite the rising momentum toward a strict chemical utility standard, the CCPA reaffirmed the relaxed standard in the 1960 case of *In re Nelson*.<sup>50</sup> In *Nelson*, the applicant claimed steroid compounds asserted to be useful as intermediates in the preparation of other steroids, at least some of which had therapeutic properties.<sup>51</sup> The court held that these intermediate steroid compounds satisfied the utility requirement of section 101.<sup>52</sup> Although commentators have disputed the breadth of the holding in *Nelson*,<sup>53</sup> the court's policy-based rationale suggests that the applicant was not required to specify a use for the final product in order to demonstrate that the intermediate was useful:

We have never received a clear answer to the question "Useful to whom and for what?" Surely a new group of steroid intermediates is useful to chemists doing research on steroids, and in a "practical" sense too. Such intermediates are "useful" under section 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.<sup>54</sup>

Thus, *Nelson* recognized that in the chemical industry, pure research often has an intrinsic utility despite no immediate use for the fruits of the

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49. *Id.*

50. 280 F.2d 172 (C.C.P.A. 1960).

51. *Id.* at 180.

52. *Id.* at 180-81.

53. Compare, Note, *Requirements for Patenting Chemical Intermediates: Do They Accomplish the Statutory Goals?*, 29 ST. LOUIS U. L.J. 191, 193 (1984) (interpreting *Nelson* as not requiring that the final product also have a use) with, Note, *Do Chemical Intermediates Have Patentable Utility?*, 29 GEO. WASH. L. REV. 87, 98 (1960) (interpreting *Nelson* narrowly as requiring the product of the subject intermediate to have a known utility). In *Manson*, the Supreme Court followed the former interpretation of *Nelson* by quoting *Nelson* as holding that "a process yielding chemical intermediates [is] 'useful to chemists doing research on steroids,' despite the absence of evidence that any of the steroids thus ultimately produced were themselves 'useful.'" *Manson*, 383 U.S. at 530.

54. 280 F.2d at 180-81.

research. As a result, the court construed utility under section 101 to include utility to the chemical researcher.<sup>55</sup>

*Nelson* also provided guidance with respect to the separate roles of sections 101 and 112 in the utility inquiry.<sup>56</sup> More specifically, it noted that a two-step inquiry is required in determining utility under these different sections:

[It is necessary 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 so as to "enable any person skilled in the art . . . to use the same."<sup>57</sup>

According to the court, section 112 "is not directed to the *existence* of usefulness but to what an inventor must disclose as a quid pro quo for patent protection."<sup>58</sup> The court explained that "in exchange for and as a condition of the patent protection, it secures a full disclosure of the invention."<sup>59</sup> Discussing section 101, the court concluded that the existence, rather than the degree, of utility was the critical inquiry.<sup>60</sup> As the court noted, "[t]he seemingly little advances are the bread and butter of progress and sometimes turn out to be of much greater importance than at first thought."<sup>61</sup>

Finally, the CCPA in *Nelson* explicitly rejected the D.C. Circuit's decision in *Petrocarbon*.<sup>62</sup> The court took exception to *Petrocarbon* primarily because the specification described a use for film that was not too broad, because one of ordinary skill in the art would understand the use described by the specification.<sup>63</sup> Thus, in addition to clarifying and differentiating the section 101 and 112 utility requirements, the *Nelson* court applied a more relaxed standard for interpreting both of these sections than did *Bremner* and *Petrocarbon*.

In addition to the confusion between sections 101 and 112, courts appeared confused over the distinction between product claims and process claims. Courts provided little clarification regarding the utility requirements and the differences between product and process claims until the 1963 case of *In re Wilke*.<sup>64</sup> *Wilke* explained that section 112

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55. *Id.*

56. *Id.* at 184.

57. *Id.*

58. *Id.*

59. *Id.* at 182.

60. *Id.* at 178.

61. *Id.* at 182.

62. *Id.* at 186. The CCPA in *Nelson* made no attempt to distinguish the *Petrocarbon* case, stating instead that one of ordinary skill in the plastics art would know how to use the disclosed film in *Petrocarbon* in light of the film's disclosed properties. *Id.*

63. *Id.*

64. 314 F.2d 558 (C.C.P.A. 1963).

imputes different requirements on product and process claims. For a process claim, the applicant is only required to teach how to use the process, and is not required to teach a use for the product of the claimed process.<sup>65</sup> On the other hand, for product claims section 112 requires a disclosure of both the manner of making the claimed product and the manner of using the claimed product.<sup>66</sup> Thus, *Wilke* and *Nelson* combined to turn back the strict holding of *Brenner*. Despite *Wilke* and *Nelson*, chemical researchers still had reason to be uncertain regarding the status of the utility requirement until 1966.

## B. The *Manson* Decision

In 1966 The United States Supreme Court entered the chemical utility debate in *Brenner v. Manson*.<sup>67</sup> *Manson* was a patent applicant who sought an interference<sup>68</sup> with a previously issued patent.<sup>69</sup> Specifically, both parties claimed a process that yielded a steroid product used in cancer research.<sup>70</sup> The original examiner refused to declare an interference, asserting that *Manson's* application failed to disclose any utility for the chemical research compound produced by the process.<sup>71</sup> Appealing the examiner's rejection, *Manson* attempted to demonstrate utility by referring to a publication which disclosed that other steroids that were homologs<sup>72</sup> to the steroids *Manson's* process created were

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65. *Id.* at 565-66. *Accord, In re Adams*, 316 F.2d 476 (C.C.P.A. 1963), and *In re Szwarc*, 319 F.2d 277 (C.C.P.A. 1963).

66. *Wilke*, 314 F.2d at 562.

67. 383 U.S. 519 (1966).

68. The patent office may hold an interference hearing when a current patent application overlaps in scope with a pending application or an unexpired patent. 35 U.S.C. § 135 (1988). The interference seeks to resolve the issue of priority of invention between the parties. *Id.*

In *Manson*, Howard Ringold and George Rosenkranz applied for a U.S. patent in December 1957, claiming priority as of December 1956 when they filed for a Mexican patent. *Manson*, 383 U.S. at 520-21. *Manson* filed his U.S. application in January 1960, claiming that he discovered the process before December 1956. *Id.* *Manson* requested an interference hearing to resolve the competing priority claims. *Id.*

Judges examining the *Manson* decision have disagreed about the significance of the interference setting of the case. Compare *In re Kirk*, 376 F.2d 936, 944 (for purposes of determining utility differences between ex parte hearing and interference are "highly technical procedural ones") with *Kirk*, 376 F.2d at 953 (even for utility inquiries these two situations "differ by more than 'highly procedural aspects' ") (Rich, J., dissenting).

69. *Id.* at 521.

70. *Id.* at 520-22.

71. *Id.* at 521.

72. The Applicant's "homolog utility" argument seemed sensible, especially in light of the modern test of obviousness for chemical inventions announced three years earlier in *In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963). Although *Papesch* ended the era in which the Patent Office typically determined obviousness simply because of a similar structural formula to a composition disclosed in the prior art, a difference in properties was

effective in inhibiting tumors in mice.<sup>73</sup> The Patent Office Board of Patent Appeals rejected this argument, concluding that the utility of a product could not be demonstrated merely by its close relation to another useful compound.<sup>74</sup> The CCPA reversed the Patent Office Board of Appeals in view of *Nelson*, noting that for process claims utility need not also be demonstrated for the product of the process so long as the product is not "detrimental to the public interest."<sup>75</sup>

The Supreme Court not only reversed the CCPA,<sup>76</sup> but rejected the standard in *Nelson*. Instead, the Court required process patent applications to demonstrate the utility of the products produced by the process.<sup>77</sup> The product of the process patent must exhibit a practical utility itself and not simply be "an object of scientific research" or "an object of use testing."<sup>78</sup>

As a rationale for its holding, the Court skeptically portrayed the disclosure of information in patents as being of dubious quality which does not entice others to search for a use for an invention.<sup>79</sup> More importantly, the Court feared that a process whose product is not precisely delineated by a specific practical utility would effectively "block off whole areas of scientific development" because of the uncertain scope of this monopoly grant.<sup>80</sup> As a result of these concerns, the Court required a showing of "substantial"<sup>81</sup> utility as the quid pro quo for receiving a patent. Therefore, a novel process does not merit a patent monopoly unless a "specific benefit exists in currently available form" for the products of the claimed process.<sup>82</sup> Whereas *Nelson* defined utility to include utility to the chemical researcher,<sup>83</sup> *Manson* held that a process

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nevertheless required in order to demonstrate the unobviousness of the invention as a whole when the prior art was a homolog of the invention. Conversely, it follows that it might be ordinarily expected that homologs would have a similar utility, as asserted by the applicant, based on similar properties.

73. 383 U.S. at 522.

74. *Id.*

75. The Supreme Court characterized this as an "extreme proposition." *Id.* at 530.

76. *Id.* at 536.

77. *Id.* at 534-35.

78. *Id.* at 535.

79. *Id.* at 534. The Court noted the "highly developed art of drafting patents so that they disclose as little information as possible." *Id.* at 534. Furthermore, any incentives to future research created by the patent disclosure are undercut by the patent-holder's ability to enforce the patent. *Id.*

For a discussion of the "dubious quality" of disclosure in patent applications see Sibley, *supra* note 24, at 216.

80. 383 U.S. at 534 (citing *Monsanto Chemical Co. v. Coe*, 145 F.2d 18, 21-24 (D.C. Cir. 1944)).

81. *Id.* at 534.

82. *Id.* at 534-35.

83. *Nelson*, 280 F.2d at 181. See *supra* notes 50-63 and accompanying text.

whose sole utility is in research does not satisfy the utility requirement.<sup>84</sup> In dicta, the Court further suggested that a product whose sole use was in research could also not be protected by a product patent.<sup>85</sup> The Court treated products and processes alike, centering its analysis on the disclosed use; if the use is merely for research, then the invention is unpatentable, regardless of whether the invention is a product or a process.<sup>86</sup>

### C. The CCPA's Response to *Manson*: *Kirk & Joly*

The CCPA in the companion cases of *In re Kirk*<sup>87</sup> and *In re Joly*<sup>88</sup> extended the *Manson* holding by embracing the dicta in *Manson* which suggested that the Court's reasoning would be similarly applicable to product claims for chemical research intermediates.<sup>89</sup> *Kirk* and *Joly* both involved product claims for intermediates used to synthesize other compounds that had no known utility. Specifically, *Kirk* involved intermediate steroids used in preparing "biologically active compounds."<sup>90</sup> The CCPA held that if a process is not useful, then the claimed intermediates used in the process are not useful, and sections 101 and 112 are thus not satisfied.<sup>91</sup> In *Joly*, the CCPA also affirmed the Examiner's rejection for insufficient disclosure of utility.<sup>92</sup> The court explained that "[a] useless product does not become useful by conversion into another useless product."<sup>93</sup>

In his dissenting opinion in *Kirk*, Judge Rich criticized the wisdom of the policies enunciated in *Manson* as extended by the majority in *Kirk* and *Joly*.<sup>94</sup> He also distinguished *Manson*, viewing it as having much

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84. *Manson*, 383 U.S. at 535-36.

85. *Id.* at 535 ("these arguments . . . would apply equally to the patenting of the product produced by the process").

86. *Id.*

87. 376 F.2d 936 (C.C.P.A. 1967).

88. 376 F.2d 906 (C.C.P.A. 1967).

89. *Kirk*, 376 F.2d at 945 ("just as the practical utility of the compound produced by a chemical process 'is an essential element' . . . the practical utility of the compound, or compounds produced from a chemical 'intermediate' . . . is an essential element in establishing patentability of that intermediate"); *Joly*, 376 F.2d at 908 (quoting *Kirk*).

90. *Kirk*, 376 F.2d at 939.

91. *Id.* at 945, 942 (discussing sections 101 and 112).

92. *Joly*, 376 F.2d at 909.

93. *Id.* at 907.

94. *Kirk*, 376 F.2d at 957-59 (Rich, J., dissenting). However, the extension of the *Manson* holding to ex parte proceedings in *Kirk* and *Joly* is actually not surprising, given the broad language and strong dicta in *Manson*. A narrow interpretation of *Manson* by the CCPA—for example, by restricting the stringent utility requirement to a reduction of practice inquiry in an interference context—would not be in the spirit of the expansive policy-based reasoning of the Supreme Court.

narrower applicability.<sup>95</sup> Specifically, Rich questioned the line drawing issues surrounding the concept of practical utility.<sup>96</sup> He noted that these so called "useless" products were commonly used and sold within the chemical research industry.<sup>97</sup> According to Rich, the best rule "from the practical, administrative standpoint" was a per se finding of utility for new chemical compounds.<sup>98</sup> As a result of the majority decisions, Rich called for Congressional action to reverse the tide of judicial rulemaking.<sup>99</sup>

Judge Rich also criticized the Supreme Court's disregard—that the CCPA majority in *Kirk* and *Joly* followed—for the precedential value of prior judicial and legislative interpretations of utility.<sup>100</sup> Finally, Judge Rich quotes extensively from a memorandum sent by a large chemical company to its patent counsel.<sup>101</sup> The memo indicates that the researchers often asserted artificial utilities for their newly developed products because the testing for their "true utility" was too time-consuming.<sup>102</sup>

#### D. The Chemical Utility Requirement Today: The Progeny of *Manson*, *Kirk*, and *Joly*

Although *Manson* rejected the inclusion of chemical research into the utility definition under sections 101 and 112, *Carter-Wallace v. Riverton*<sup>103</sup> held that a patent for a new compound satisfied the utility requirement by claiming potential human therapeutic value evidenced by laboratory animal tests.<sup>104</sup> While the compound was intended for human

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95. *Id.* at 949 (1967) (Rich, J., dissenting). Judge Rich distinguished *Manson* as a case where an applicant in an interference hearing produced no evidence of utility. *Id.* at 948. On the other hand, *Kirk* involved an "admitted disclosure of the compounds as intermediate to make certain steroids." *Id.* at 949. Thus, for Rich, the difference was that between zero disclosure and some disclosure.

Rich also would limit *Manson* to an interference setting, whereas *Kirk* and *Joly* involved *ex parte* proceedings and thus required different rules. *Id.* at 953. In an interference, the utility requirement is arguably more challenging because of the necessity to establish actual reduction to practice in order to prove priority of invention. *Id.*

Nevertheless, the interference distinction Rich suggests may simply be a mechanism he employed to attempt to limit the scope of the questionable policy considerations created by the Supreme Court, whose decisions were binding upon the CCPA.

96. *Id.* at 957.

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.* at 950-955.

101. *Id.* at 959.

102. *Id.* at 960.

103. 433 F.2d 1034 (C.C.P.A. 1970). The claims at issue were three organic compounds in the class of 2,2-disubstituted-1, 3-propanediol, one of which was generically known as meprobamate.

104. *Id.* at 1039-40.

use, at the time of the patent application tests had been conducted only on mice and other laboratory animals.<sup>105</sup> Whether the drug could ever be used to treat humans, however, remained unproven. Thus *Carter-Wallace* refines *Manson* by essentially measuring utility by the degree of research. In effect, *Carter-Wallace* finds utility where laboratory testing indicates that the new compound has a chance of being useful.

The court further refined the quantity and quality of testing necessary to show utility in *Nelson v. Bowler*<sup>106</sup> and *Cross v. Iizuka*.<sup>107</sup> In *Bowler*, the court held that "pharmacological activity" evidence shown through testing on animals constituted a practical utility even though such testing did not establish a specific therapeutic value.<sup>108</sup> In reaching its decision, the court expressly recognized that providing incentive for disclosure of compounds yet unproven as to their usefulness to humans nonetheless benefited the public. The *Iizuka* opinion noted, "[I]t 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."<sup>109</sup>

In *Iizuka*, the court held that *in vitro* testing of a claimed compound coupled with *in vivo* testing of structurally similar compounds was sufficient evidence of pharmacological activity to meet the utility requirement.<sup>110</sup> *Iizuka* extended *Bowler*, holding that a patent applicant may show the utility of a new compound without testing the new compound on laboratory animals, thus lessening the degree of research needed to meet the utility requirement.

In biotechnology research, the utility of cDNA fragments<sup>111</sup> has recently been at issue during the course of the multinational Human Genome Project. Craig Venter, formerly affiliated with the National Institutes of Health (NIH), filed a patent application in 1991 claiming as products partial cDNA fragments sequenced at NIH.<sup>112</sup> The application claimed full length cDNA sequences as well as complementary variants thereof, all of which NIH asserted could be obtained without undue

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105. 433 F.2d at 1036.

106. 626 F.2d 853 (C.C.P.A. 1980).

107. 753 F.2d 1040 (Fed. Cir. 1985).

108. 626 F.2d at 856.

109. *Id.*

110. 753 F.2d at 1050.

111. The term "cDNA" signifies complementary DNA, which matches the genetic messenger or messenger RNA (mRNA). Of the many DNA sequences in human genetic material or the human genome, only the cDNA sequences encode operational proteins. It is estimated that only about 3% of DNA in the human genome actually codes for a useful protein. See, *MERGES*, *supra* note 11, at 158.

112. See, e.g., Edmund L. Andres, *U.S. Seeks Patent on Genetic Codes Setting Off Furor*, N.Y. TIMES, Oct. 21, 1991, at A1.

experimentation.<sup>113</sup> Although Venter and other advocates of the NIH application argued that allowing patents for partial cDNA sequences promotes technology, the NIH ultimately allowed the application to be abandoned in early 1994.<sup>114</sup> Thus, officially, the patentability of the cDNA fragments remains an unresolved issue.<sup>115</sup> Unless patents for the cDNA fragments are ultimately granted, the prosecution histories will remain secret.<sup>116</sup>

Commentators have noted, however, that in view of *Manson*, *Kirk*, and *Joly*, partial cDNA fragments apparently do not meet the utility standard adopted by the courts.<sup>117</sup> The ultimate utility for a cDNA sequence is to determine the protein produced by the gene. Although an inventor of a partial cDNA fragment may assert nominal utilities, such as uses as genetic markers, PCR primers, and tissue typing probes, these utilities probably would not meet the *Manson* standard of a "substantial" utility, and would instead be construed as uses for "purely research purposes."<sup>118</sup>

### III. RECONSIDERING THE STRICT UTILITY STANDARD IN CHEMICAL PATENT PRACTICE

#### A. A Criticism of *Manson*: Chemical Research Benefits Society in a Two-Step Quid pro quo, Each Step Being Crucial in Promoting the Progress of the Useful Arts

At the core of the Supreme Court's reasoning in *Brenner v. Manson* were fundamental notions of the purposes of patent law as expressed in the Constitution and in the Patent Act of 1952: "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived from an invention with substantial utility."<sup>119</sup> From this axiom the Court concluded that "[u]nless 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."<sup>120</sup> Inherent in this logical progression, however, is the embedded conclusion that any compound whose "specific benefit" does not "exist in currently available form" would not be beneficial to society such that it merits

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113. *Id.*

114. Smith and Kettelberger, *supra* note 2, at 51.

115. *Id.* at 63.

116. *Id.*

117. See, e.g., *id.* at 53.

118. *Id.*

119. *Manson*, 383 U.S. at 534.

120. *Id.*

patent rights. This conclusion is questionable when applied to inventive processes in the chemical arts.

The *Manson* decision is fundamentally flawed in that it assumes that all chemical research benefits society via the same one-step quid pro quo that society experiences with mechanical and electrical inventions. It is a virtual tautology that mechanical and electrical inventions are created with a use in mind: a nose cone for a jet airplane is produced with the airplane in mind; an electrical amplifier is created with the need for an amplified electrical output in mind. The creation of invention "X", and the useful application of invention "X", are inherently unified. The invention process applies technology to address a perceived need or to improve a current application. Society benefits in a one-step quid pro quo: in exchange for a patent, the inventor discloses to society an operative electrical/mechanical innovation—that innovation is almost always inherently useful/beneficial by its electrical or mechanical nature.<sup>121</sup>

On the other hand, many chemical inventions benefit society in a two-step, rather than a one-step, progression. The first step is the creation of a compound with new characteristics and the second step is the finding of a use for that compound and its properties. Professor Merges summarizes the two-step nature of chemical research in the following passage:

Because of the unique nature of chemical research, chemists often develop a chemical compound without a particular purpose in mind. Often a chemist works with a family of related compounds, trying to synthesize one which, because of the properties it shares with other compounds in the family, is thought likely to be useful for something. The chemist might have a particular goal when she sets out, such as the discovery of a compound that will treat a particular disease. Alternatively, she may be exploring a general class of compounds whose properties suggest they might eventually serve some as yet unspecified purpose. Either way, chemists often synthesize compounds which they believe might be useful someday for something.<sup>122</sup>

Following this first step comes the second step of finding a use for the synthesized compound. Under the *Manson* decision and its progeny, only inventors who achieve the second step may obtain a patent for their

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121. While it is difficult to imagine otherwise, Professor Merges puts forth the following example of a non-useful mechanical invention:

[O]ne might perhaps imagine a "machine" with working parts that did not really do anything; perhaps it just spins around, or oscillates back and forth for no particular purpose. Such a machine would fail the test of utility under § 101 of the patent code. Note that machines that serve only to amuse or entertain are deemed useful under the patent code.

MERGES, *supra* note 11, at 147.

122. *Id.* at 149.

efforts. In other words, only if a use for a newly discovered compound is known, or if a use is discovered for an existing compound which previously had no known use, can a patent be obtained for that compound.

Despite *Manson's* implications to the contrary, both the (1) "creation" step and the (2) "finding an application" step in the progress of chemical development are beneficial to society, and *each* should be rewarded independently of the other. Thus, the creation of a new chemical compound and its disclosure to society, even if its use is not yet known, should be encouraged and rewarded by the patent process. The premise of the above assertion is, of course, that society does benefit from the disclosure of compounds with no known use. This assertion demonstrates complete consistency with the present allowance of "method of use" claims for patented compounds reciting nominal use, or a vastly different use, in their original patent disclosures.<sup>123</sup> It is well known that if an inventor finds a novel, nonobvious use for a known compound, she may obtain a patent for that method of use. With this in mind, consider the following hypothetical.

Assume that a composition claim has been granted to inventor A on a new compound X, with the disclosed utility being to kill mosquitoes. Assume that inventor B reads the patent disclosure for compound X and decides that compound X might be useful for something other than killing mosquitoes. It is well-known under novelty and obviousness principles that if the new use was similar to killing mosquitoes (for example, killing flies), there would be a reduced chance of obtaining a method-of-use patent under sections 102 and 103.<sup>124</sup> If, however, the new use were completely unrelated to killing mosquitoes (for example, a cure for cancer), a patent on the new method-of-use would probably be granted.<sup>125</sup>

The purpose of the above hypothetical is to show that the patent laws already recognize that the disclosed use of a new compound may just be the tip of the iceberg for that compound. More importantly, the laws already recognize that it may be the tip of some *other* iceberg: the less obvious a new use is in light of the original compound patent disclosure, the more willing the patent laws are to reward the new-use

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123. 35 U.S.C. § 100 includes in the definition of a patentable "process" the "new use of a known process, machine, manufacture, composition of matter, or material," establishing the basis for "method of use" claims as a "process" claim under 35 U.S.C. § 101. 35 U.S.C. §§ 100, 101 (1988).

124. See generally, MPEP, *supra* note 1, at § 706.02 (In section entitled "Rejection on Prior Art," the patent office reviews standards for anticipation rejections under 35 U.S.C. § 102 and obviousness rejections under 35 U.S.C. § 103.).

125. *Id.*

inventor.<sup>126</sup> It is the job of subsequent inventors to find uses which are as nonobvious as possible in light of the compound's original disclosure. Why, then, must the original compound have any recited use at all? Or, alternatively, why should products with nominal utilities receive patents while those with unknown, but potentially great, utilities go unrewarded? The patent law machinery is already in place to allow society to benefit from the disclosure of new compounds with no known use.

Currently, there is a large inconsistency between the benefits society receives from patented "nominal-use" compounds and those received from non-disclosed, non-patented, no-known-use compounds. In the former case, the product patent is granted even where only a nominal use is disclosed, and society fully benefits as new inventors scurry to find novel, nonobvious uses for that compound. In sad contrast, a compound with no known use will remain undisclosed, as its inventor will not disclose the compound through a patent until she finds at least a nominal use for the compound.<sup>127</sup> There is no rational reason for such an artificial distinction, created by *Manson* and its lower-court progeny, to remain. It is clear that society would benefit from step one of the two-step quid pro quo because society already benefits where only nominal uses are initially disclosed. There is no practical difference in the promotion of the useful arts between inventions with no known use and those with a mere nominal use. Therefore, each step of the two-step quid pro quo should be independently encouraged by the patent system. When a subsequent use is found for a claimed compound, a subsequent inventor may file "method-of-use" claims, and a resulting cross-licensing arrangement between the product-claim owner and the method-of-use claim owner can ensure beneficial use by all and a proportionate sharing of the rewards of creation by the two patent holders.

In light of the benefit to society of disclosing a compound with no known use or with a known use only in research, the Supreme Court's reasoning in *Manson* is questionable. The founding fathers provided Congress with the opportunity to establish a patent system in order to "promote the progress of science and the useful arts."<sup>128</sup> However, the *Manson* Court doubted the significance of a benefit to the public in receiving the applicant's disclosure of new compounds with uncertain uses, because the Court explained that in claim drafting, the applicant discloses as little information as possible.<sup>129</sup> Congress has explicitly and

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126. *Id.*

127. *Manson* disagrees on this point, claiming that inventors who cannot determine a use for their inventions will have "every incentive to make [their] invention[s] known to those able to do so." *Manson*, 383 U.S. at 534.

128. U.S. CONST. art. I, § 8, cl. 8.

129. See *supra* note 79 and accompanying text.

clearly promulgated disclosure requirements for an applicant for a patent.<sup>130</sup> While a claim may disclose minimal information, as clearly established by Congress in the patent statute, it must be sufficiently supported by the disclosure to merit the patent rights.<sup>131</sup> It is the role of Congress to determine what disclosure requirements an applicant must meet in exchange for the proprietary interest from the patent. Congress has clearly fulfilled this responsibility. The duty of the patent office is to zealously examine patent applications in accordance with the instructions of Congress.

Further, in *Manson* the Court asserted that fears of secrecy for unpatentable processes were "exaggerated."<sup>132</sup> The majority dismissed the idea that if an inventor cannot find a use for an invention, he would suppress or conceal the invention until such time as a suitable use is discovered. Surprisingly, the Court argued the opposite to be true—an inventor would have "every incentive" to disclose an invention with no known utility so that someone else may determine a use for the invention.<sup>133</sup> Although this may be somewhat true in the confines of academic research,<sup>134</sup> the Court's rationale is in tension with a fundamental premise behind the patent statute: rewarding inventors by granting them the chance at profit encourages dissemination of technological information. Distinct from this premise, the Court implied that research data which has no current "practical utility"<sup>135</sup> will be disseminated more readily in the absence of a proprietary reward, for two reasons. First, if an inventor does not "complete" his invention—for example, by not discovering a practical utility for it—then the inventor would fully disclose the invention in the hope that someone else will complete the invention.<sup>136</sup> Second, the Court asserts that if an inventor could receive a patent for such a product, he probably will disclose as little information as possible to the public and thus impede research efforts to find the elusive use for this product.<sup>137</sup> Although the Court claimed to analyze the "general intent of Congress,"<sup>138</sup> its decision and reasoning run contrary to some of the fundamental concepts of the patent

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130. See generally, 35 U.S.C. § 112; 37 C.F.R. §§ 1.71 - 1.85 (1994).

131. 35 U.S.C. § 112 (1988).

132. *Manson*, 383 U.S. at 534.

133. *Id.* at 534.

134. See, Lawrence R. Velvel, *A Critique of Brenner v. Manson*, 49 J. PAT. OFF. SOC'Y 5, 7 (1967) However, as academic research has taken on a much more competitive nature, notions of academic benevolence may simply be outdated.

135. However, as Judge Rich noted, "practical utility" is a slippery term which justifies conclusions more readily than it provides an analytical structure to face new problems. See *Kirk*, 376 F.2d at 857 (Rich, J., dissenting).

136. *Manson*, 383 U.S. at 534.

137. *Id.*

138. *Id.* at 533.

system. In a dissenting opinion in *Manson*, Justice Harlan highlighted the lack of empirical support for the Court's rationale.<sup>139</sup> Other commentators share this concern and criticize the majority opinion as abstract and reasoned without the necessary facts in the record.<sup>140</sup>

Unsatisfied with the utility of an inventor's mere creation of a new composition, the *Manson* Court feared that granting claims for a new composition with no known use would prevent the public from discovering end uses for such a composition,<sup>141</sup> which the Court presumably found to be the greater contribution to technology. The Court's stringent definition of utility results in a requirement of "substantial" utility, assuring the public of a tangible benefit in exchange for the applicant's proprietary monopoly.<sup>142</sup> Specifically, Justice Fortas concluded that a process which is only useful as an object of scientific research is important, but does not merit a patent.<sup>143</sup> He explained that "a patent is not a hunting license," and is "not a reward for the search, but compensation for its successful conclusion."<sup>144</sup> Once again, however, this assertion simply begs the question because it does not explain why the production of an object of scientific research is not in itself a successful conclusion.

## B. International Considerations Further Compel Abandonment of a Stringent Chemical Utility Requirement

In addition to the questionable policies justifying *Manson*, the evolving international climate also favors relaxing the rigorous utility requirement in the United States. Many key foreign competitors of the United States have not adopted similar stringent chemical utility requirements. Both the European Patent Convention and the Japanese Patent Statute label utility under the alternative concept of "industrial

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139. *Id.* at 538 (Harlan, J., dissenting). Harlan also questioned, in the absence of empirical data to the contrary, the majority's assertion that "useless" new compounds will be readily disclosed by inventors. *Id.* Harlan believed that a first chemist should be encouraged to disseminate his invention by rewarding him with a patent, in the interests of progress, even without a "utility" as defined by the majority. *Id.* at 539. Thereafter, someone else could then take the "further but less difficult step" leading to a commercially useful item. *Id.*

140. *See, e.g., Velvel, supra* note 134, at 56 (encouraging Congress to investigate the facts that are assumed by the Court).

141. 383 U.S. at 534-35.

142. *Id.* at 534. Thus, the strict definition of utility was judicially created; the legislature simply used the broad term "utility" with no indication of a special meaning. A special meaning was implemented by the Court. *See, e.g., Mirabel, supra* note 2, at 814 (arguing that dictionary meaning of "utility" is mandated in the absence of a specific instruction by the legislature and thus "utility" must also encompass any chemical research investigations).

143. *Manson*, 383 at 535-36.

144. *Id.* at 536.

applicability."<sup>145</sup> In these nations, "industrial applicability" includes the use of an invention for pure research purposes.<sup>146</sup> In the United States, chemical research is only a valid utility under narrow circumstances.<sup>147</sup>

The United States' stricter position with respect to chemical utility creates confusion when an inventor seeks international protection. If, for example, an inventor initially files a patent application in a foreign country with a lower utility standard, the inventor may not necessarily secure a priority date in the United States under section 119 of the United States patent code<sup>148</sup> if the rigorous utility standards of *Manson*, *Kirk*, and *Joly* are not met at the time of foreign filing.<sup>149</sup> However, this rule is not surprising and naturally follows from the policy considerations underlying section 119, once the utility standard is established.<sup>150</sup>

An inventor who expects to file an application in the United States based upon a prior foreign application date must meet what may essentially be a much stricter standard than required by the initial foreign application, creating confusion in securing patent protection in multiple countries. *In re Ziegler*<sup>151</sup> exemplifies this uncertainty. In *Ziegler*, the applicant originally filed an application in Germany in 1954 for a process pertaining to propylene. Within twelve months of the German application's filing date, Ziegler filed an application in the United States Patent Office in accordance with section 119. Subsequently, the United States application became involved in an interference, and eventually a continuation application was filed in 1987. The CAFC affirmed the PTO's ruling that the original German application which the applicant relied upon for priority did not explicitly disclose a practical utility under section 112.<sup>152</sup> The CAFC's decision in *Ziegler* was not surprising; it merely prohibited an applicant from circumventing the strict practical

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145. See BENT ET AL, *supra* note 31, at 146 (citing Article 52(1) of the European Patent Convention and Section 29(1) of the Japanese Patent Law).

146. *Id.*

147. See *supra* note 52.

148. 35 U.S.C. § 119 (1988).

149. See generally, *Kawai v. Metlesics*, 480 F.2d 880 (C.C.P.A. 1973). The CCPA held in *Kawai* that a foreign application itself must meet the requirements found in § 112 in order to achieve priority status. *Id.* at 886. The court felt that the statute mandated that in exchange for a right to priority, the foreign application must be treated as if it were filed in the United States on the date that the foreign application is filed. *Id.*

150. *Id.* In *Kawai*, the CCPA analyzed priority in the context of a constructive reduction to practice, which requires proof in the specification of a disclosure of a practical utility. *Id.*

151. 992 F.2d 1197 (Fed. Cir. 1993).

152. *Id.* at 1203. The applicant attempted to assert that a practical utility was in fact asserted, but the court rejected the applicant's argument following reasoning similar to that of *Petrocarbon*. See *supra* note 23. See also, *Application of Hafner*, 410 F.2d 1403 (1969) (application was rejected in the United States because of a lack of disclosure of utility, while such disclosure was not required in Germany).

utility requirement of *Manson* by filing abroad prior to filing in the United States and then using the interim period to discover a practical utility to satisfy U.S. law while also retaining the prior foreign filing date.

As foreign competition continues to become more challenging, patent harmonization<sup>153</sup> is an ever-increasing possibility that could result from negotiations under the General Agreement of Tariffs and Trade (GATT),<sup>154</sup> through an independent effort by the World Intellectual Property Organization (WIPO), or, less likely, through direct legislation in Congress.

The increasing momentum toward uniformity between patent systems should be extended to lessen the strict chemical utility standard in the United States. This unnecessarily strict standard hampers the development of chemical and biotechnological research in the United States by discouraging the exchange of information about new compositions until a substantial use (as defined in *Manson*, *Kirk*, and *Joly*) has been disclosed. While inventors in the United States are certainly free to read patents from other countries, American inventors may not have practical access to these disclosures until an English translation is available through a U.S. patent application.<sup>155</sup> Thus the actual exchange of information through disclosure will be more active in nations with the lower utility standard.

### C. Introducing "Best Utility" as a Means for Implementing a Relaxed Chemical Utility Standard

An alternative to the strict utility requirement under *Manson* would be to allow research as a viable practical utility while requiring the inventor to disclose her "best utility" at the time of filing a patent claim. "Best utility" is the best use for a new compound known or suspected by an inventor at the time of application. Disclosure of the "best utility" for chemical patents is analogous to the "best mode" requirement for mechanical and electrical inventions under Section 112. A "best utility" requirement would prevent an applicant from asserting mere research utility while concealing a better utility from the public. The present "how to use" requirement of section 112 would be insufficient to prevent concealment because the enablement inquiry is commensurate with the asserted utility. Therefore, under *Iizuka*, if a mere research utility were

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153. See generally, HAROLD WEGNER, PATENT HARMONIZATION (1993).

154. See generally, Bruce A. Lehman, *Intellectual Property Under the Clinton Administration*, 27 GEO. WASH. J. INT'L L. & ECON. 395 (1993).

155. Such concerns motivated Sen. Dennis DeConcini (D-Ariz.) to introduce on September 30, 1994 a new bill (S.2488) providing for the publication of patent applications eighteen months after their filing. 140 CONG. REC. S13,863 (daily ed. Sept. 30, 1994) (statement of Sen. DeConcini), described in *Legislation: Administration Bill on 18-Month Publication of Patents is Introduced*, 48 PAT., TRADEMARK & COPYRIGHT J. 599 (1994).

disclosed, the enablement requirement would be satisfied by simply explaining "how to use" the research while a "better" utility could be suppressed.

The "best utility" requirement would be most effectively implemented if it were codified as a specific requirement for chemical and biochemical patent applications. Codification would clearly distinguish the "best utility" requirement for chemical patents from the "best mode" requirement for mechanical and electrical patents. It would also eliminate any confusion by requiring that an inventor not only state the best embodiments of a claimed compound, but also share the status of her research.

#### IV. CONCLUSION

Congress should reject the policies outlined in *Manson*, *Kirk*, and *Joly* by implementing legislation to the contrary. In view of the disadvantage to chemical and biotechnological researchers in the United States on an increasingly competitive international playing field, Congress should explicitly include research as a satisfactory utility under section 101.

Chemical and biotechnological research are inherently different from electrical and mechanical inventions because discovering a new composition and finding a use for the composition should be the subject of two separate patents with the final commercial product brought to the marketplace through a cross-licensing agreement. Electrical and mechanical cases do not ordinarily create this potential for separate patents because a new invention is inherently connected to its practical utility. Since new chemical or biotechnological creations have potential use in research, these research possibilities should be explicitly codified as sufficient uses in the Patent Statute. The disclosed research utility should meet an analysis similar to the "best mode" requirement of section 112. The applicant would be required to disclose his "best utility" at the time of filing in order to obtain a valid patent.

Although the Supreme Court in *Manson* suggested that obtaining a use for a compound is a greater contribution than actually discovering the compound,<sup>156</sup> obtaining the use is obviously not possible without knowledge of the existence of the compound. Without a proprietary interest, an inventor of a compound has little incentive to provide information about the compound to potential competitors. The Supreme Court's fear that large areas of technology would be blocked off by

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156. See *supra* note 38. The Supreme Court's suggestion may further be attacked because composition claims are clearly the premium form of protection and are unquestionably preferred over method claims, such as those claiming a "method for making" or a "method for using."

granting claims to inventors with no known utility should be alleviated by the concept of "method of use" claims.

Alternatively, federal courts may choose to re-adopt the basic *Nelson* holdings, either by the unlikely avenue of an outright Supreme Court reversal of *Manson*, or, more likely, by a Federal Circuit ruling which confines *Manson* to its facts, as Judge Rich suggests in *Kirk*.<sup>157</sup> In *Nelson*, the Federal Circuit's predecessor court created a compromise wherein research is deemed to fulfill practical utility under section 101 while the inventor must teach someone skilled in the art "how to use" the invention under section 112.<sup>158</sup> *Nelson* struck a proper balance by allowing research to be a viable utility and requiring the applicant to properly disclose and teach the invention in view of the aforementioned fundamental patent law principles. *Nelson* was not as liberal as the earlier chemical utility cases, which essentially disregarded the utility requirement of both sections 101 and 112.

Simply reestablishing *Nelson* as the law would not necessarily be a panacea. An applicant should also be required to disclose the "best utility" in order to preclude the inventor from suppressing an actual use while simply disclosing a research use, and thus gaining the patent monopoly with an incomplete or fraudulent disclosure. One solution to this problem, of course, would be to judicially subsume the "best utility" requirement under the "best mode" requirement. In other words, the section 112 requirement of demonstrating to a person of ordinary skill in the industry how to use the product would require a showing of the best use for the product, including the best avenues of future research.

In conclusion, the *Nelson* approach better encourages the public to invent and also requires the applicant to teach and disclose research utility in accordance with the policies that drive the patent system. The stricter policies announced in *Manson* do not encourage an inventor of a new chemical or biochemical composition or process to disclose the discovery to other researchers who may then further attempt to put the invention to a more commercially practical use. The *Nelson* approach also invites further research and progress by allowing later inventors to file patent applications for novel uses of the products created by their peers. The more liberal interpretation of chemical utility would also aid researchers in the United States by removing the disadvantage in international competition created by the United States' strict position. In view of the foregoing considerations, the current rigorous chemical utility standard in the United States should be relaxed and the *Nelson* approach to the utility requirement for chemical inventions should be reinstated,

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157. See *Kirk*, 376 F.2d at 948-49.

158. *Nelson*, 280 F.2d at 184.

either judicially or legislatively, with the proviso that an applicant must disclose a "best utility" in order to obtain a valid patent.