
IN RE DANE K. FISHER: AN EXERCISE IN UTILITY

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ABSTRACT

Article I, Section 8, Clause 8 of the United States Constitution provides for exclusive rights to inventors in order to “promote the Progress of Science and useful Arts.” The United States Court of Appeals for the Federal Circuit in the recent decision of *In re Dane K. Fisher and Raghunath V. Lalgudi*, 421 F.3d 1365 (Fed. Cir. 2005) denied patentability to expressed sequence tags (ESTs) because they were “only tools to be used along the way in the search for a practical utility” and, therefore, lacked “an immediate real world benefit” requisite to a finding of “substantial” utility considered mandatory under 35 U.S.C. § 101. This holding misconstrues legal precedent and threatens the patentability of many inventions, the benefit of which may be immediate but not fully appreciated until much later. Instead, where the application includes “an assertion of utility and an indication of the use or uses intended” as tools for research, statutory utility should be acknowledged. Patentability based on the benefit of such subject matter should be evaluated under the statutory requirement of non-obviousness under 35 U.S.C. § 103, which has its roots in early, broad interpretations of the phrase “new and useful” that first appeared in Section 1 of the Patent Act of 1793.

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INTRODUCTION

Utility, or usefulness, has existed as a statutory requirement in patent law since the Patent Act of 1790.¹ Distinct notions of “substantial novelty,” also referred to as “comparative or relative utility,” as a measure of the merit of invention, and “positive utility,” that connoted only capability of use not contrary to “sound morals or policy,” developed from the phrase “new and useful” that appears in Section 1 of the Patent Act of 1793.²

Upon enactment of the Patent Act of 1952,³ “substantial novelty” became codified as separate requirements of novelty under 35 U.S.C. § 102, and non-obviousness under 35 U.S.C. § 103. The phrase “new and useful” continued under 35 U.S.C. § 101 and questions of compliance generally were limited to assertions of intended use as understood by one skilled in the art reading the specification. Several decisions by the Court of Customs and Patent Appeals prior to *Brenner v. Manson*⁴ held that statements of use of a chemical compound as an object of research were adequate to meet the requirement under 35

¹ Patent Act of 1790, ch. 7, 1 Stat. 109-12 (April 10, 1790) (repealed 1793).

² Patent Act of 1793, ch. 11, 1 Stat. 318-23 (Feb. 21, 1793) (repealed 1836).

³ Patent Act of 1952, ch. 950, § 1, 66 Stat. 798 (July 19, 1952).

⁴ *Brenner v. Manson*, 383 U.S. 519 (1965).

U.S.C. § 101. As argued strenuously by Judges Rich and Smith, in dissenting opinions to *In re Kirk*⁵ and *In re Joly*,⁶ respectively, the Supreme Court in *Brenner*, despite broad dicta, decided only that a specification supporting a claim to a process must make a disclosure or “showing” of utility of the product formed by the claimed process, and expressly reserved the question of usefulness in research as a valid utility. Nevertheless, based on the language of the *Brenner* opinion, usefulness in research subsequently was deemed to be an inadequate basis for establishing “substantial” utility, absent demonstration of a “specific benefit in currently available form,” or an “immediate real world benefit.”

The United States Court of Appeals for the Federal Circuit, in *In re Dane K. Fisher and Raghunath V. Lalgudi*,⁷ reaffirmed the general understanding of *Brenner* by holding that expressed sequence tags (ESTs), which are short sequences of nucleic acids derived from a particular genomic source, are “only tools to be used along the way in the search for a practical utility.”⁸ Consequently, the claimed ESTs lacked a “specific benefit” that “exists in currently available form” which is the “basic quid pro quo contemplated by the Constitution and the Congress for granting the patent monopoly [as] the benefit derived by the public for an invention with substantial utility.”⁹ Despite the holding by the Federal Circuit, the court acknowledged Fisher’s ESTs as “noteworthy contributions to biotechnology research.”¹⁰

In his dissent from the majority opinion in *Fisher*, Judge Randall Rader argued that the utility requirement should not be used “to reject inventions that may advance the ‘useful arts,’ but not sufficiently to warrant the valuable exclusive right of a patent.”¹¹ Moreover, as noted by Judge Rader, there was never any contention by the board that Fisher’s ESTs were “unable to perform” the utilities asserted.¹² Judge Rader requested the United States Patent and Trademark Office to “seek ways to apply the correct test... , namely inventive step

⁵ *In re Kirk*, 376 F.2d 936 (C.C.P.A. 1967).

⁶ *In re Joly*, 376 F.2d 906 (C.C.P.A. 1967).

⁷ *In re Dane K. Fisher and Raghunath V. Lalgudi*, 421 F.3d 1365 (Fed. Cir. 2005).

⁸ *Id.* at 1376.

⁹ *Id.* at 1371.

¹⁰ *Id.* at 1376.

¹¹ *Fisher* at 1382 (Rader, J., dissenting).

¹² *Id.* at 1381 (Rader, J., dissenting) (“In so ruling, the Board did not reject Fisher’s utilities on the basis that the ESTs were *unable to perform* the purported utilities.”).

or obviousness.”¹³

Judge Rader is not alone in believing that technological advancements should be assessed as a function of obviousness. Scholarship dating back to the early nineteenth century cautioned against confusing “positive utility” and its “degree.”¹⁴ Also, Judge Rich, in his extensive dissent from the majority decision in *Kirk*, stated that “one must be alert, in order to escape mental elephant pits, to avoid being confused by opinions which are dealing not with *utility* per se, but with the *non-obviousness* issue... in terms of *degree* of utility as an *indication* thereof.”¹⁵ Properly construed, under the standard provided for determining obviousness by the Supreme Court and advocated by a recent petition for writ of certiorari and briefs by amici in *Teleflex v. KSR Int’l.Co.*,¹⁶ whereby invention is assessed, not according to the so-called “teaching-suggestion-motivation test” of the Federal Circuit, but in consideration of “one having ordinary skill in the art,” ESTs, as well as other inventions, the “immediate real world benefit” of which may not currently be appreciated, can be evaluated in a manner that is capable of acknowledging in a meaningful way Fisher’s contribution to the “useful Arts.”

I. The Historical Requirement of Utility

A. Early Jurisprudence

Bedford v. Hunt et al.,¹⁷ is an early case making explicit a threshold requirement of practical utility of a patented invention. Circuit Justice Story, paraphrasing Section 1 of the Patent Act of 1793¹⁸ stated: “No person is entitled to a patent under the act of congress unless he has invented some new and useful art, machine, manufacture, or composition of matter, not known or used before.”¹⁹ Justice Story then specified the meaning of “useful” under the statute:

By useful invention, in the statute, is meant such a one as may be applied to some beneficial use in society, in contradistinction to an invention, which is injurious to the morals, the health, or the good order of society. It is not

¹³ *Id.*

¹⁴ *See infra* Section II.A. and accompanying text.

¹⁵ *Kirk*, 376 F.2d at 955 (C.C.P.A., 1967)(Rich, J., dissenting).

¹⁶ *Teleflex, Inc. v. KSR, Int’l Co.*, No. 04-1152 (slip opinion) (Fed. Cir. 2005).

¹⁷ *Bedford v. Hunt*, 3 F. Cas. 37 (C.C.D. Mass. 1817).

¹⁸ Patent Act of 1793, ch. 11, 1 Stat. 318-23 (Feb. 21, 1793) (repealed 1836) (current version at 35 U.S.C. § 101 (2000)).

¹⁹ *Bedford*, 3 F. Cas. at 37.

necessary to establish, that the invention is of such general utility, as to supersede all other inventions now in practice to accomplish the same purpose. It is sufficient, that it has no obnoxious or mischievous tendency, that it may be applied to practical uses, and that so far as it is applied, it is salutary. If its practical utility be very limited, it will follow, that it will be of little or no profit to the inventor; and if it be trifling, it will sink into utter neglect.²⁰

Justice Story concluded that satisfaction of the statutory threshold does not rely upon a degree of utility, but rather that it be “capable of use,” and not contrary to “sound morals and policy.”²¹

Justice Story employed the same reasoning in *Lowell v. Lewis*,²² which, in turn, was relied upon in *Kneass v. Schuylkill Bank*.²³ *Kneass* was an infringement suit challenging the patentability of a method for printing both sides of bank notes.²⁴ The court in *Kneass*, in response to defendant’s allegation that the invention was not patentable because it was worthless, posed the question in reverse: “If the plaintiff’s invention correspond substantially with the thing used by the defendants, how can the latter be permitted to say, that the thing so discovered and used is worthless?”²⁵ Therefore, use by defendants was evidence of utility. The court then recited Justice Story’s criteria for utility, whereby an invention meets the statutory requirement if it is not “frivolous or injurious to the well being, good policy, and sound morals of society.”²⁶ Accordingly, early interpretation of the word “useful,” as a qualification for patentability, required only that the invention not be frivolous, mischievous or immoral, and use by the public was evidence that the invention was not, in fact, worthless.

Through the nineteenth century, jurisprudence was essentially in accord with the standard for statutory utility set forth by Justice Story. For example, Phillips, in his 1837 treatise, compared Justice

²⁰ *Id.*

²¹ *Id.* (“The law, however, does not look to the degree of utility; it simply requires, that it shall be capable of use, and that the use is such as sound morals and policy do not discountenance or prohibit.”).

²² *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D. Mass 1817).

²³ *Kneass v. Schuylkill Bank*, 14 F. Cas. 746 (Cir. Ct. Penn., 1820).

²⁴ *Id.*

²⁵ *Id.* at 748.

²⁶ *Id.* (“In the case of *Lowell v Lewis* [Case No. 8568], Mr. Justice Story, commenting upon this subject, lays it down, that the law only requires that the invention should not be frivolous or injurious to the well being, good policy, and sound morals of society.”).

Story's construction of statutory utility with that of Justice Washington, whom Phillips quoted as stating:

Admit, for the sake of argument, that Perkins's machine, (the one infringed upon,) in the form in which it came from his hands, was so far inferior to the nail machines then in use as to deprive it of all intrinsic value; yet if another person can superadd to that invention something which will remove all its defects, and render it useful, it immediately becomes valuable, not on account of its own qualities, but because of its capacity to receive the improvement, and with its aid to become useful. The original discovery and the improvement become articles of traffic between the two discoverers as soon as the improvement was made, which it was their mutual object to give value to.²⁷

However, in Justice Story's "more restrained sense," which Phillips cast as "now universally adopted in the United States,"²⁸ an invention that is "pernicious," cannot be made useful absent the presence of an improvement that "diverts the invention into a different channel clear of the objection."²⁹ In other words, the invention without the improvement does not meet the statutory requisite of utility in the view of Justice Story's construction, despite the view of Justice Washington:

But in the more restrained sense, according to the construction of Mr. Justice Story, which is now universally adopted in the United States, the improvement on an invention that is not useful, or in other words, that is pernicious, or in the words of the English statute of monopolies, "mischievous to the state or generally inconvenient," cannot be useful, unless it diverts the invention into a different channel clear of the objection; and in this restrained sense the invention cannot be considered useful according to the doctrine of Mr. Justice Washington in the above case, on the ground that it is capable of being rendered so by an improvement.³⁰

Therefore, an invention that is "pernicious" is unpatentable as lacking

²⁷ W. PHILLIPS, *THE LAW OF PATENTS FOR INVENTIONS; INCLUDING THE REMEDIES IN LEGAL PROCEEDINGS IN RELATION TO PATENT RIGHTS* (American Stationers' Co. 1837) at 141 (quoting *Gray & Osgood v. James & others*, 1 Pet.C.C.R. 480, 481).

²⁸ *Id.* at 141-42.

²⁹ *Id.*

³⁰ *Id.*

utility despite the fact that improvements of the invention are not so afflicted.

“Usefulness” is explained by Phillips as being “sometimes contrasted with frivolousness.”³¹ As stated by Phillips, an invention may be frivolous in the sense of “being so obvious” as not to be a discovery, or, alternatively, “it may be trivial or frivolous in respect to its effect upon industry and production.”³² Specifically, obviousness voids the patent as lacking an invention, while an invention that has a “trivial or frivolous” effect upon industry “is still a subject of a patent, since it is not the province of the court to go into the question of the extent or degree of usefulness.”³³

Similarly, a distinction between invention and utility is made by Curtis in his 1849 treatise.³⁴ In Chapter I, entitled “Novelty and Utility,” Curtis paraphrases Section 6 of the Patent Act of 1836,³⁵ and bifurcates the phrase, “new and useful”:

§ 1. The Patent Act now in force in this country requires that the subject of every patent should be “new and useful,” whether it be an art, machine, manufacture, or composition of matter, or an improvement on any of these things. The inquiry that meets us on the threshold is, what constitutes novelty, and what constitutes utility, in the sense of the statute?³⁶

Curtis then cites legal precedent, specifically quoting Mr. Justice

³¹ See *Phillips*, *supra* note 27, at 142.

³² *Id.*

³³ *Id.* Phillips stated at *id.*:

The requisite of usefulness has been sometimes contrasted with frivolousness, and the multiplicity of patents for trivial subjects has been occasionally deprecated by judges. An invention may be slight and trivial as being so obvious and apparent that it cannot be considered a discovery, or it may be trivial or frivolous in respect to its effect upon industry and production. A defect in the first sense renders the patent void as being for a subject that is not an invention. But an invention of a very slender character in the latter sense is still the subject of a patent, since it is not the province of the court to go into the question of the extent or degree of usefulness. It is enough that the invention is useful; how useful it may be is immaterial.

³⁴ G. T. CURTIS, TREATISE OF THE LAW OF PATENTS FOR USEFUL INVENTIONS IN THE UNITED STATES OF AMERICA (Charles C. Little and James Brown, 1849)[hereinafter *Curtis I*].

³⁵ Patent Act of 1836, ch. 357, 5 Stat. 117 (July 4, 1836) (repealed 1870) (current version at 35 U.S.C. § 101 (2000)).

³⁶ See *Curtis I*, *supra* note 34, at 3.

Story in *Earle v. Sawyer*³⁷ where he distinguished the manner of invention from utility as a matter of law:

“It is of no consequence whether the thing be simple or complicated; whether it be by accident, or by long, laborious thought, or by an instantaneous flash of the mind that it is first done. The law looks to the fact, and not to the process by which it is accomplished. It gives the first inventor, or discoverer of the thing, the exclusive right, and asks nothing as to the mode or extent of the application of his genius to conceive or execute it. It must also be useful, that is, it must not be noxious or mischievous, but capable of being applied to good purposes; and perhaps it may also be a just interpretation of the law, that it meant to exclude things absolutely frivolous and foolish. But the degree of positive utility is less important in the eye of the law, than some other things, though in regard to the inventor, as a measure of the value of the invention, it is of the highest importance.”³⁸

Curtis characterized this dictum, as well as that of Sir N.C. Tindel, C.G. in *Crane v. Price*,³⁹ as requiring that an invention be “substantially new”:

§ 6. It is often laid down, that provided the invention is substantially new, it is of no consequence whether a great or small amount of thought, ingenuity, skill, labor, or experiment has been expended, or whether it was discovered by accident.⁴⁰

Curtis then inverts the reasoning of the law of utility and applies it to the concept of novelty, whereby the possibility of “design, thought, or ingenuity... becomes one test of the sufficiency of invention”:

Still it is sometimes necessary to ascertain what bearing the amount of thought, design, or ingenuity that may have

³⁷ 8 F. Cas. 254 (D. Mass, 1825).

³⁸ Cortio I. at 5, n. 1 (quoting Earle at 256).

³⁹ *Crane v. Price*,. Webster’s Pat. Cas., 409. Curtis quotes Sir Tindal, as follows:

But in point of law, the labor of thought or experiment, and the expenditure of money, are not the essential grounds of consideration on which the question, whether the invention is or is not the subject-matter of a patent ought to depend. For if the invention being new and useful to the public, it is not material whether it be the result of long experiment and profound search, or whether by some sudden or lucky thought, or mere accidental discovery. *Id.*

⁴⁰ See *Curtis I*, *supra* note 34, at 5.

been expended, has upon the question of novelty. It may not be necessary that there should be positive evidence of design, thought, or ingenuity; but if it is necessary that the possibility of these qualities having been exercised should not be excluded by the character of the supposed invention, then such possibility becomes one test of the sufficiency of invention.⁴¹

According to Curtis, because “a patent should be something that has not substantially existed before,” the lack of possibility of design or study in the “production” of an “alleged invention” is “proof” of frivolousness.⁴²

Curtis extends this reasoning to “mere colorable variations, or slight and unimportant changes”:

So, too, mere colorable variations, or slight and unimportant changes, will not support a patent; as the immersion of cloth in a steam bath, with the view of damping it, instead of immersing it in hot water; and the substitution of steam as the means of heating hollow rollers over which wool was to be passed, instead of heating them by the insertion of hot iron bars. In such cases, if the consequences resulting from the change are unimportant, and the change consists merely in the employment of an obvious substitute, the discovery and application of which

⁴¹ *Id.* at 6.

⁴² *Id.* Curtis specifically stated:

While the law does not look to the mental process by which the invention has been reached, but to the result, it may still require that the result should be such as not to exclude the possibility of some skill or ingenuity having been exercised. It requires this, because it requires that the subject-matter of a patent should be something that has not substantially existed before. While such a thing may have been produced by mere accident, and not by design, yet it may also have been the fruit of design and study. If, however, the character of the alleged invention be such, that no design or study could by possibility have been exercised in its production, then its character is strong proof that it does not differ substantially from what had been produced before. We must look, therefore, to the character and purposes of invention, and not to the actual process by which it was produced, in order to see that the possibility of thought, design, ingenuity, or a labor having been exercised, is not excluded.

§ 7. Thus, if an alleged invention is absolutely frivolous and foolish, though it may have the element of novelty, in one sense, it is not the subject of a patent. *Id.*

could not have involved the exercise of the inventive faculty, in any considerable degree, then the change is treated as merely a colorable variation, or a double use and not as a substantive invention.⁴³

This threshold determination of patentability is then applied by Curtis to two lines of cases, the first being a new application of known machinery or apparatus, wherein he concluded:

§ 10. In these cases the subject of each invention was not the particular machinery or apparatus by which the new application was to be made available, but it was the new application itself of certain known substances or agents, to produce a particular result, differing either in the process or in the article produced, from the former methods of producing the same thing, and thereby producing a better article, or producing it by superior and cheaper processes. It is obvious that the result, in such cases, furnishes a complete test of the sufficiency of inventions; because the importance of the result shows that whether actually exercised or not, the possibility of the exercise of thoughts, design, ingenuity, and skill is not excluded. The merit is the same, whether the invention was the fruit of accident or design; because the merit consists in having realized the idea and carried it out in practice. But if the idea and the practice involve no beneficial results, superior to what had been before attained, there could have been no scope for the exercise of the inventive faculty, because the result excludes the supposition of its having been exercised.⁴⁴

The other line of cases involved patents to “a particular instrument or machine, or combination of machinery.” Here, Curtis quoted extensively from *Brunton v. Hawkes*,⁴⁵ in which the subject patent was directed to two inventions, one for an improvement in the construction of chain cables and the other for an improvement in the construction of anchors. This case was decided under English common law, and made a distinction between the inventiveness of the cable and that of the anchor based on obviousness. As stated by Circuit Justice Abbott and quoted in a footnote of Curtis’ treatise:

“And yet there can be no doubt that the invention of the cable, was of a much higher order than in the anchor.

⁴³ *Id.* at 6-7.

⁴⁴ *Id.* at 9-10.

⁴⁵ *Brunton v. Hawkes*, 4 B. & Ald. (1821) 540, 550.

The improvement in the cable, was the carrying out into practice, certain important principles respecting the action of forces, by the substitution of a broad-headed for the pointed stay, in a link of a particular form. The improvement in the anchor, was the avoiding the welding, by means well known, and practiced in cases extremely similar. There was originality of idea in the application of the broad-headed stay, as subsidiary to the principles for the improvement of the chain cable, as laid down in the specification, but there was no originality of idea or of method, in avoiding the welding, this being borrowed from cases which would obviously and immediately present themselves.”⁴⁶

English common law is summarized by Curtis as predicating “the amount of invention” on the “utility” of the result obtained:

§ 14. It appears then, according to the English authorities, that the amount of invention may be estimated from the result, although not capable of being directly estimated on a view of the invention itself.

§ 15. The utility of the change is the test to be applied for this purpose. As there cannot be a decidedly useful new result, without some degree of invention in producing the change which effects that result, when a real utility is seen to exist, a sufficiency of invention may be presumed. And it is said that whenever utility is proved to exist in a very great degree, a sufficiency of invention to support a patent must be presumed.⁴⁷

With respect to United States law, Curtis distinguished “new” from “useful,” even under the Patent Act of 1793:

Our statute requires that the subject of a patent should be “new and useful.” The word “useful” is not supposed to be used, for the purpose of establishing general utility as the test of a sufficiency of invention to support a patent. It had been held, upon the use of the same word in the same connection in the old Patent Act of 1793, that it was used merely in contradistinction to what was frivolous or mischievous to society. This term was held to be satisfied, if the alleged invention was capable of use, and was not injurious to the well-being, good policy or sound morals of

⁴⁶See *Curtis I*, *supra* note 34, at 13, n.1. (quoting *Brunton*, 4 B. of Ald. 540, 550).

⁴⁷*Id.* at 14.

society.

§ 17. But the subject of a patent must not only be “useful,” in the sense, that is, capable of use and not mischievous, but it must also be a “new” art, machine, manufacture, or composition of matter, or “a new improvement” upon one of these things, “discovered or invented” by the patentee, and “not known or used by others” before.⁴⁸

Curtis draws from the statutory requirement that the subject matter of a patent be “new,” that “sufficiency of invention” lies in “substantial difference” from things “previously known or used”:

It is obvious, therefore, that the subject matter of a patent must be something substantially different from anything that has been known or used before; and this substantial difference, in all cases where analogous or similar things have been previously known or used, must be the measure of a sufficiency of invention to support the particular patent.⁴⁹

A parallel is then made by Curtis between “utility” as construed in English courts, and the statutory requirement of “novelty” in the United States:

§ 18. Our courts have, in truth, without using the same terms, applied the same tests of the sufficiency of invention, which the English authorities exhibit, in determining whether alleged inventions of various kinds possess the necessary element of novelty. That is to say, in determining this question, the character of the result, and not the apparent amount of skill, ingenuity or thought exercised, has been examined; and if the result has been substantially different from what had been effected before, the invention has been pronounced entitled to a patent; otherwise, the patent has failed.⁵⁰

“Utility” in the United States, according to Curtis, requires that the “subject matter of a patent must not be injurious or mischievous to society, or frivolous or insignificant.” An invention must, therefore, be “to a certain extent, beneficial to the community.”⁵¹ The degree of benefit, however, “is not a subject for consideration, in determining whether the invention will support a patent.”⁵²

⁴⁸ *Id.* at 14-15.

⁴⁹ *Id.* at 15.

⁵⁰ *Id.* at 16.

⁵¹ See *Curtis I*, *supra* note 34, at 25.

⁵² *Id.* Curtis wrote:

§ 28. The doctrine in relation to utility, being, in this country, that the subject-matter of a patent must not be injurious or mis-

In the fourth edition of Curtis' treatise, published in 1873,⁵³ after enactment of the Patent Act of 1870,⁵⁴ he reiterates the distinction between "new" and "useful" made in the first edition, in 1849. Just as Phillips contrasted usefulness and frivolousness, wherein usefulness determined whether a patent was "void as being for a subject that is not an invention," while frivolousness "of an invention of a very slender character... is still the subject of a patent,"⁵⁵ Curtis distinguished between "positive utility," which was "a mere description of a class of inventions," and "comparative or relative utility," which was a test of "novelty, or of substantial difference of structure or mode of operation":

§ 105. The remaining quality essential to a patentable invention is, that it shall be "useful." Care must be taken, however, to discriminate between what may be called the positive utility of an invention, which is made by the statute a mere description of the class of inventions which can be the subjects of valid patents, and that comparative or relative utility which is sometimes applied as one of the tests of novelty, or substantial difference of structure or mode of operation. We have already seen in what manner this test of comparative utility may be applied to distinguish one invention from another. But this is not the usefulness which the statute contemplates when it describes the subject for which a patent may be granted as a "new and *useful* invention."⁵⁶

Therefore, by at least 1873, the term "new" was equated with "comparative and relative utility," and was interpreted to require a "substantial difference" from prior art, while the term "useful" was characterized as "positive utility," which mandated only a "description of a class of inventions which can be the subject of valid patents."

In the early part of the twentieth century, the standard for utility

chievous to society, or frivolous or insignificant: it follows that every invention, for which a patent is claimed, must be, to a certain extent, beneficial to the community; it must be capable of use, for some beneficial purpose; but when this is the case, the degree of the utility, whether larger or smaller, is not a subject for consideration, in determining whether the invention will support a patent. *Id.*

⁵³ G. T. CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS, (Little, Brown and Co., 4th ed., 1873)[hereinafter, *Curtis II*].

⁵⁴ Patent Act of 1870, ch. 230, 16 Stat. 198-217 (July 8, 1870) (revised 1874).

⁵⁵ *Phillips* at 142.

⁵⁶ See *Curtis II*, *supra* note 53, at 110.

described by Curtis was being applied sporadically. In some cases, utility was employed only as a means of identifying patentable subject matter as a class "capable of use." For example, in *Potter v. Tone*,⁵⁷ a "brown vitreous product" claimed in a patent application involved in an interference proceeding was described in the specification of the junior party, Tone. As quoted by the court, the asserted utility of the claimed compound was as "a nonconductor of electricity," as a "reducing agent," and "useful in operations where silicon and aluminum are now employed."⁵⁸ The Court of Appeals of the District of Columbia found these assertions to "show utility sufficient to support a patent," and quoted with approval from the decision of the Examiners-in-Chief:

"In order to be patentable, an invention must possess utility; and it may be noted that prior to the declaration of this interference it was determined that the specification of the Tone application described a patentable invention; yet all that is stated therein in regard to its utility is that it is a nonconductor of electricity, that it is a reducing agent, and can be used in operations where silicon and aluminum are now employed.

All of these facts are found in both the Thebaud and the Mott reports, or are deducible therefrom. If they show utility sufficient to support a patent, they would seem to be sufficient to demonstrate utility when ascertained by actual test.... , if it was known how it could be produced at will, and some utility had been demonstrated, the invention would seem to have been reduced to practice."⁵⁹

The opinion of the Examiners-in-Chief implied a distinction similar to that between "positive utility," which was described by Curtis as requiring "a mere description of the class of inventions which can be the subjects of valid patents," and "comparative or relative utility which is sometimes applied as one of the tests of novelty, or a substantial difference of structure of mode of operation."⁶⁰ As stated by the Examiners-in-Chief, and as also quoted by the District Court:

"To hold that it must be shown to be capable of use in some commercial process, and that process must have been successfully practiced, would seem to amount to holding that the inventor must make a second invention, which might be the

⁵⁷ *Potter v Tone*, 36 App. D.C. 181 (D.C. Cir., 1911).

⁵⁸ *Id.* at 184.

⁵⁹ *Id.*

⁶⁰ See *Curtis II*, *supra* note 53, at 110.

subject of another patent, and reduce that to practice before he could claim a reduction to practice in the original invention.”⁶¹

The Examiners-in-Chief made clear that the legal threshold for “utility” required only a description of characteristics suggestive of uses “sufficient to assist in promoting the progress of the useful arts and to establish the utility of the invention.”⁶² The court adopted the reasoning of the Examiners-in-Chief and stated that the utility set forth in the specification, as a nonconductor of electricity and as a reducing agent, constituted an “apparent usefulness” sufficient to establish utility of the novel compound.⁶³

In other cases, “use” was relied upon for patentable distinction over the prior art. For example, *Smokador Mfg. Co., Inc. v. Tubular Products Co.*,⁶⁴ was an infringement action based on U.S. Patent No. 1,646,086 directed to an improved ash stand that had a base serving both as a support and as a waste-receiving receptacle. The improvement was the use of glass as the waste-receiving receptacle as a time and labor saving convenience. With respect to patentability, the court invoked “use and wont” as the standard of the ordinary artisan, thereby basing patentable distinction on the advantage of convenience:

But the glass construction disclosed in this specification has manifest advantages. It renders the contents of the receptacle at once visible, without removal of the jar.... The device manifestly saves time and labor. Moreover, a frangible substance like glass would not, we think, readily suggest itself for a receptacle, and such a substance never seems to have

⁶¹ *Potter*, 36 App. D.C. at 184-85.

⁶² *Id.* at 185. The court quoted the Examiners-in-Chief as stating:

The issues in this interference do not cover the use of the material in question for any specific purpose, but the production of a novel material of described characteristics, which characteristics may suggest many uses to subsequent inventors. Its value for educational purposes in demonstrating to chemists the character and properties of “the long-sought silicon monoxid”; its use as a reducing agent in chemical reactions, and the fact that it is a nonconductor of electricity, -- are sufficient to assist in promoting the progress of the useful arts and to establish the utility of invention.
Id.

⁶³ *Id.* (“Such apparent usefulness of the newly discovered compound being shown, nothing more was requisite. If additional uses may hereafter be discovered, rendering it of additional value commercially, Tone will be entitled to their benefit.”).

⁶⁴ *Smokador Mfg. v. Tubular Products, Inc.*, 31 F.2d 255 (2d Cir. 1929).

been used for the purpose prior to the time when Fleming embodied the idea in the patent in suit. Indeed, the first thought of such a receptacle might well have been negative by the consideration that glass would expose to view the dirty contents of receptacles in stands that had been used since cleaning. The ordinary artisan thinks in terms of “use and wont.” To substitute glass for a prior, and what we may justly regard as a more obvious, form of container, and to shield it from sight, except when the stand is turned up for examination, seems to us a patentable step. If the advantages of doing what Fleming accomplished had been already apprehended, the means to attain them would perhaps be too simple to deserve the name of invention. But the apprehension of the labor-saving, convenient, and neat device disclosed in the patent in suit involved more than the work of a routine mind.⁶⁵

In another example, the word “utility” specifically is used as the measure of patentability, distinct from “useful” and apart from suitability for an intended use. The Court of Customs and Patent Appeals (C.C.P.A.) in *In re Holmes*⁶⁶ held that a pipe that is the product of a patentable process is not itself patentable absent some advantage over conventional pipe; the fact that the pipe was useful for its intended purpose, according to the court, was not sufficient to meet the requirements of Section 4886 of the Revised Statutes because the language of the statute “clearly requires that, in order to obtain a patent, the *invention* must be useful.”⁶⁷ In other words, in response to the appellant’s contention that “it is not necessary that the product claimed shall have utility over the other articles of the prior art,”⁶⁸ the court stated that, although the degree of usefulness is “immaterial upon the question of patentability,”⁶⁹ there must be “utility in the par-

⁶⁵ *Id.* at 256.

⁶⁶ *In re Holmes*, 63 F.2d 642 (C.C.P.A. 1933).

⁶⁷ *Id.* at 643 (“Section 4886 of the Revised Statutes (35 USCA § 31) provides that “Any person who has invented or discovered any new and useful art, machine, manufacture or composition of matter . . .’ may obtain a patent This language clearly requires that, in order to obtain a patent, the *invention* must be useful.”).

⁶⁸ *Id.* (“Appellant earnestly contends that to render the claims patentable it is not necessary that the product claims shall have utility over the other articles of the prior art.”).

⁶⁹ *Id.* (“We are in accord with the views expressed in the cases cited that, if an invention be useful in itself, it is immaterial upon the question of patentability

particular form of the structure which appellant claims is invention.”⁷⁰
The Board of Appeals was quoted with approval by the court:

“Applicant’s pipe is no stronger than, cannot be made cheaper than, nor has any use or advantage over, any other pipe of commerce. It has no special utility nor is it particularly adapted for any use other than that to which any pipe would be commonly put.”⁷¹

The court concluded that the seams of the pipe themselves had no utility because no advantages were conferred on the pipe as a consequence that would render the pipe patentably distinct:

It is our view that the seams found in the products claimed, distinguishing the pipe from the prior art, are but an incident of the method of manufacturer, and in themselves have no utility In other words, in so far as utility of the product is concerned, nothing can be ascribed to a pipe having the seams of appellant’s claimed product which renders such a pipe patentably distinct from a pipe having no such seams.⁷²

Regardless of whether the opinion in *Holmes* is consistent with Curtis’ distinction under United States case law between “positive utility” and “comparative or relative utility,” the court in *Holmes* applied a standard of “utility” for “invention” that, statutorily, mandated more than simple novelty and a statement of suitability for an intended use.

***In re Bremner* and Its Legacy: Assertion of Utility and Indication of Use**

*In re Bremner, Taylor, and Jones*⁷³ was an appeal from a decision by the Board of Appeals of the Patent Office to the United States Court of Customs and Patent Appeals. The patent application at issue included claims directed to a process for production of polymers and a claim directed to a product, polydihydropyran. The polymer prod-

whether the invention be of greater or less usefulness than like devices or products shown in the prior art.”).

⁷⁰ *Id.* The court stated:

The difficulty with appellant’s position is that he assumes that, inasmuch as the pipe constructed in accordance with the claims is useful, it follows that utility of the invention is established. The fact is that the pipe so constructed may be useful, but there may be no utility in the particular form of the structure which appellant claims is invention. *Id.*

⁷¹ *Id.* at 643-44.

⁷² *Id.* at 644.

⁷³ *In re Bremner, Taylor, and Jones*, 182 F.2d 216 (C.C.P.A. 1950).

uct, as summarized by the primary examiner, was disclosed only as a resin, the color and melting point of which being set forth in the various examples describing production of embodiments of the invention. As stated by the primary examiner:

(4) Applicants disclose a process of polymerizing dihydropyran in the presence of certain Friedel-Crafts catalysts. The polymers are described on page 3, lines 13-19 as varying from viscous liquids to hard brittle solids. Example 1 describes the production of a golden colored viscous liquid. Example 2 produces a hard resinous polymer. Example 3 produces an almost colorless resin melting at 84.50°C. Example 4 produces a resin melting at 95°C. Example 5 produces a resin melting at 60°C, and in example 6 is described a process of producing several different resins, one melting at 91°C and the rest melting above 200°C.⁷⁴

The court agreed with the board that the polymer formed was novel, and did not question the identification of the polymer.⁷⁵ Nevertheless, the Patent Office found that the patentability of the claimed subject matter was not considered because the specification identified “no use for the products claimed to be developed by the processes.”⁷⁶ The court affirmed the decision of the Patent Office, referencing the United States Constitution, the predecessor statutes to 35 U.S.C. § 101 (R.S. 4886) and 35 U.S.C. § 112 (R.S. 4888), and the immediate legal precedent discussed *supra*:

[W]e 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.

It was never intended that a patent be granted upon a product, or a process producing a product, unless such product be useful. See subsection 8 of section 8 of Article I, United

⁷⁴ *Id.* at 216-17.

⁷⁵ *Id.* at 217 (“In the brief for appellants before us it is said, in substance, that the tribunals of the Patent Office did not question the production of a new chemical polymer by the process disclosed by appellants, and that those tribunals did not question the identification of such polymer.”).

⁷⁶ *Id.*. As stated by the court:

The statement so made in the brief for appellants is accurate, but the matters suggested as not being questioned by the tribunals of the Patent Office were not considered by those tribunals on their *per se* patentable merits, because they held that no use for the products claimed to be developed by the processes had been shown in the specification. *Id.*

States Constitution; R.S. 4886 (35 U.S.C. 31); R.S. 4888 (35 U.S.C. 33); also decisions *Potter v. Tone*, 1911 C.D. 295, 36 App. D.C. 181; *Scovill Mfg. Co. v. Satler*, 21 F.2d 630; *Smokador Mfg. Co. v. Tubular Products Co.*, 31 F.2d 255 [1 USPQ 158]; and *In re Holmes*, 20 C.C.P.A. (Patents) 899, 63 F.2d 642, 16 USPQ 399....

There is nothing in the application which asserts utility nor any thing indicating what use of the product may be made.⁷⁷

Therefore, according to the court in *Bremner*, both the claimed product and the method by which the product is made could not be patented based on a specification that failed to articulate that the product had utility and “what use of the product may be made,” despite acknowledgement of novelty and that the product was adequately described.

In an early test of *Bremner*, the Board of Patent Appeals in *Ex parte Tolkmith*⁷⁸ affirmed a rejection by the examiner of a claim directed to a chemical compound, O-(2, 4, 5-trichlorophenyl) methanephosphonic chloride, for lack of proper disclosure of utility because the specification described the compound only as “an intermediate for the preparation of more complex phosphorous derivatives and as a constituent of parasiticide compositions.”⁷⁹ In response to the appellants’ contention that the requirement of *Bremner*, whereby an application need only include “an assertion of utility and an indication of the use or uses intended,” was met⁸⁰, the board found that, in view of the unpredictable and highly specific nature of toxic action in living organisms, no specific enabling embodiment was provided.⁸¹ The

⁷⁷ *Id.*

⁷⁸ *Ex parte Tolkmith*, 102 USPQ 464 (Pat. Off. Bd. App., 1954).

⁷⁹ *Id.* at 465.

⁸⁰ *Id.* As stated by the board:

Appellant further contends that he has complied with the requirements for utility indicated in the decision in *In re Bremner et al.*, relied upon by the examiner in his rejection. The court in this decision stated that the law requires that there be in the application an assertion of utility and an indication of the use or uses intended. *Id.*

⁸¹ *Id.* at 466. The board concluded:

Since toxic action to living organisms is a highly specific and, in most cases, unpredictable one, we think the determination of a useful application of this compound might well require considerable experimentation In our opinion the minimum requirement to satisfy 35 U.S.C. § 112 and Rule 71 on this aspect of the invention would be a specific embodiment of the composition in a

board held that utility must be more than conjecture or suggestion; it “must presently exist”:

We believe that the utility necessary to support a patent for a new compound must presently exist and that this requirement is not satisfied by conjecture or suggestions only of the inventor or possible applications based on some similarity in chemical structure with old compounds of established utility.⁸²

A year later, in another decision by the Board of Appeals, *Ex parte Ladd, Harvey, Cable, and Szayna*,⁸³ a rejection of claims on the basis of lack of utility in view of the presence of only broad statements of use in the specification was reversed. The claims at issue were rejected because, according to the examiner, the following passage in the specification was insufficient to show utility:

The unsaturated compounds obtainable by the method of our invention are particularly useful in the preparation of new halogen-containing addition polymers and interpolymers. Moreover, these compounds likewise serve as intermediates for a variety of organic syntheses including such reactions as halogenation, hydration and alkylation.⁸⁴

The board reversed because, in view of the prior art:

[I]t is well known how to polymerize the compounds in question and that the resulting polymers may well be expected to possess a wide variety of uses, because these [prior art] patents [of record] show that polymers having a variety of uses have been made from very closely related positioned isomers and homologs of the claimed compounds.⁸⁵

With respect to enablement, the board made a very similar statement:

We are of the opinion that when a newly discovered compound belongs to a class of compounds the members of which have become well recognized to be useful for a particular purpose, and it is evident from the prior art that it is

parasitical composition with a disclosure of how it is to be applied and to what parasite. Since the specification falls far short of this requirement we conclude that it is not sufficient to satisfy the requirement of the aforesaid section of the code. *Id.*

⁸² *Id.*

⁸³ *Ex parte Ladd, Harvey, Cable, and Szayna*, 112 USPQ 337 (Pat. Off. Bd. App., 1955).

⁸⁴ *Id.* at 338.

⁸⁵ *Id.*

within the skill of the art to use the claimed compound for this purpose, the disclosure that the claimed compound may be so used is sufficient to meet the requirement of Sec. 35 U.S.C. § 112 that: “The specification shall contain a written description of the invention, and of the manner and process of using it***.”⁸⁶

Therefore, within a year, the board decided both in favor of, and contrary to, rejections made by examiners of claims directed to specific compounds, where the specification in each case made only general reference to applications to which the compounds could be put. In both *Tolkmith* and *Ladd*, the inventor had made conjectures of “possible applications based on some similarity in chemical structure with old compounds of established utility.”⁸⁷ However, the deciding factor in both cases was whether there were “presently existing” or expected” uses by one skilled in the art. The distinction between *Tolkmith* and *Ladd* was that “parasiticides” were not considered by the board in *Tolkmith*, as were the polymers in *Ladd*, to be a “a class of compounds the members of which have become well recognized to be useful for a particular purpose.”⁸⁸

At the district court level, the United States Court of Appeals District of Columbia Circuit in *Petrocarbon, Ltd. v. Watson*⁸⁹ held that a patent specification supporting a claimed invention directed to a process of forming “new and useful polymers” which, according to examples in the specification, exhibited heat and acid resistance and formed “films,” was inadequate under 35 U.S.C. § 112, first paragraph.⁹⁰ Specifically, despite the appellants’ assertion that the disclosure was adequate under *Bremner* as “an assertion of utility and an indication of the use or uses intended,”⁹¹ statements of heat and acid resistance of the polymers were not reflective of the properties of the film, nor did they explain how the film was to be used. As stated by the court:

If the specification had indicated a particular use for the film, and if the question before us was whether the language used was sufficient to explain this use to one skilled in the art, then testimony of experts might well have been received. But the present specification, while indicating

⁸⁶ *Id.*

⁸⁷ *Tolkmith*, 102 U.S.P.Q. at 466.

⁸⁸ *Ladd*, 112 U.S.P.Q. at 338.

⁸⁹ *Petrocarbon Ltd. v. Watson*, 247 F.2d 800 (D.C. Cir. 1957).

⁹⁰ *Id.*

⁹¹ *Id.* at 801.

useful properties of the new polymers (hear [sic] and acid resistance), makes no such statement as to the film, or explains how the film is to be used. Since the word "film" by itself does not connote a particular use, the specification is defective as a matter of law.⁹²

In re Nelson,⁹³ was an appeal from the Patent Office Board of Appeals in which Judge Rich, for the Court of Customs and Patent Appeals, held, similarly to the board in *Ladd*,⁹⁴ that novel intermediate compounds that are useful "in well known reactions to produce steroids of a class at least some members of which are known to have useful therapeutic properties,"⁹⁵ meet the statutory requirement of utility.⁹⁶ Further, the court in *Nelson* disputed any requirement that statutory utility must be a "presently existing 'practical' usefulness":

The Patent Office position seems to have been that there must be a presently existing "practical" usefulness to some undefined class of persons. 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 101.⁹⁷

This reasoning by the court extended to an argument made by the Patent Office that was interwoven into the utility rejection, whereby the specification, by failing to provide a presently existing practical utility, failed to enable the claimed invention under § 112. Specifically, the board stated, as quoted by the court in *Nelson*:

"There is no assertion in appellant's specification that they are able to synthesize an *active* digitalis glycoside from their intermediate, nor any other specific *physiological active* steroid having a hydroxyl group in the 14-position or with a 14, 15-double bond." [Emphasis ours.]

".... there is no evidence before us that... appellants ever produced a *useful* steroid from their... intermediates." [Emphasis ours.]

"35 U.S.C. [§] 112 requires an applicant to fully de-

⁹² *Id.*

⁹³ *In re Nelson*, 280 F.2d 172 (C.C.P.A. 1960).

⁹⁴ *Ladd*, 112 U.S.P.Q. at 338.

⁹⁵ *Nelson*, 280 F.2d. at 180.

⁹⁶ *Id.* at 181 ("We conclude that the claimed compounds are 'useful' within the meaning of section 101 and that there is disclosure of the utility in the specification.").

⁹⁷ *Id.* at 180.

scribe how to make and *use* the invention and to set forth the best mode contemplated of carrying it out. Clearly appellants have failed to do that in this case because they have not shown how their intermediate may be used to prepare a single useful steroid. We are unable to conclude that a method for doing this would be obvious to one skilled in the art.” [Board’s emphasis.]⁹⁸

The court stated that, in effect, the Patent Office was imposing a requirement that was not based on the “‘how to use’ provision of § 112,” but, rather, a higher threshold of a demonstration of a physiologically active embodiment:

What the Patent Office is really trying to insist on here has nothing to do with the “how to use” provision of § 112. It is demanding some different, or greater, or more commercial or more mundane use than the one disclosed. Just what kind of use, we have been unable to discover although it is apparent that the Patent Office would have been satisfied if the new compounds, or their steroids made therefrom, had possessed *therapeutic* activity.⁹⁹

The court held that previous decisions by the board, such as in *Tolk-mith*, were contrary to legal precedent, namely *Bremner*:

Essentially the reason given by the board for its decision affirming the rejection seems to be that appellants have not shown the production from their new androstenes of a single *physiologically active* steroid. While the board itself has rendered some decisions tending to support its view that this is necessary, notably *Ex parte Tolk-mith*,..., the only higher authority cited which is in [sic] point is the opinion of this court in the *Bremner* case, *supra*.¹⁰⁰

Further, although Judge Rich asserted that the basis for the decision in *Bremner* was the predecessor statute to 35 U.S.C. § 112,¹⁰¹ the predecessor statute to 35 U.S.C. § 101 was cited by the court in *Bremner* in the same passage.¹⁰² Moreover, the court quoted

⁹⁸ *Id.* at 176-77.

⁹⁹ *Id.* at 183.

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 183 (“The *Bremner* case, 182 F.2d 216, 217, 37 C.C.P.A. 1032, decided by this court in 1950, sustained a rejection on the ground that the specification failed to comply with RS 4888 (35 U.S.C., 1946 ed., 33, the predecessor statute to 35 U.S.C. § 112).”).

¹⁰² *Bremner*, 182 F.2d at 217 (“It was never intended that a patent be granted upon a product, or a process producing a product, unless such product be useful. See subsection 8 of section 8 of Article I, United States Constitution; R.S.

Bremner as requiring “an assertion of utility and an indication of the use or uses intended,”¹⁰³ and that appellants’ claimed steroid compounds met the so-called “‘rule’ of *Bremner*”:

It is clear to us that the above “rule” of the *Bremner* case has been fully met in appellant’s application. They have *asserted* that the new steroid compounds are useful and they have *indicated* that the intended use is in the field of steroid [sic] chemistry wherein they have utility as intermediates in synthesizing other steroid compounds. Nothing in the *Bremner* case requires more.¹⁰⁴

Therefore, despite Judge Rich’s statement regarding the statutory basis for the decision in *Bremner*, the “rule” of *Bremner*, as characterized by Judge Rich, was limited to a requirement of making an *assertion* of usefulness and an *indication* of intended use, as opposed to providing enablement under 35 U.S.C. § 112. Even the “assertion” requirement was minimized by Judge Rich. The court, in a footnote, stated that “mere assertion” of utility was a “meaningless formality” in view of the fact that even filing a patent application constituted an assertion that an invention is new and useful:

n. 4. The first law point discussed in the *Bremner* opinion was that a patent specification is required by law to assert “utility” and the factual finding was that it did not. We find on review of the record that the court was mistaken in saying that there was no assertion of utility, for the opening statement of the *Bremner*, et al. specification was that the invention was “new *and useful*.” Upon reflection, we are now of the opinion that a *mere assertion* of utility in a specification is a meaningless formality and no more required by law than an assertion of novelty. We think it only reasonable to infer from the fact of filing an application that the applicant asserts that the invention is new and useful, for unless it is both he has no right to a patent. 35 U.S.C. § 101.¹⁰⁵

The court in *Nelson* specifically stated that their decision was consistent with *Bremner* and differed in the holding because of the facts

4886 (35 U.S.C. 31); R.S. 4888 (35 U.S.C. 33).”). R.S. 4886 stated, in part: “That any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . may . . . obtain a patent therefore.”

¹⁰³ *Nelson*, 260 F.2d at 183.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.* at 183.

in each case.¹⁰⁶ In particular, Judge Rich found that disclosure of the products described in *Bremner* as “resins,” is “to a chemist... broad enough to include a wide variety of diverse materials and... has no definite meaning.”¹⁰⁷ As viewed the court, asserting that a “resin” is inherently useful, as argued by the appellants, on the basis that it is solid at room temperatures and melts at a higher temperature and therefore can be molded, “no more indicates or suggests a use than stating that big pieces of material can be cut up into little pieces.”¹⁰⁸

Nevertheless, the decision rendered in *Nelson* was not a holding that all compounds are inherently useful:

We are not holding that *all* compounds are inherently useful as “intermediates.” ... What the *Bremner* rule requires is that an application shall make known to those skilled in the art something that can be done with the new compound and not, through silence, leave the matter entirely to speculation or independent investigation.¹⁰⁹

Further, the court declined to accept the holding in *Petrocarbon*, which failed to find statutory utility in use of claimed polymers to form a ‘film,’ because, according to Judge Rich, and contrary to the holding in *Petrocarbon*, one skilled in the “plastics art, ... would know of many possible uses for the polymers and how to use them.”¹¹⁰

Judge Worley dissented from the majority opinion on policy grounds, namely, that granting a patent in this case would be an “un-earned monopoly” that would prevent others from experimentation on pain of infringement:

Patent rights are valuable rights and should be earned by those who seek patent monopolies. But the net effect of granting a patent here will be to give appellants an un-earned monopoly on a substantial area in the field of chemistry, and prevent others, unless they are willing to risk infringement, from also experimenting in a field which should remain open to all.¹¹¹

Judge Kirkpatrick also dissented, but on the basis that, absent a showing in the specification, the invention could be frivolous:

¹⁰⁶ *Id.* at 185 (“We believe our decision in this case to be consistent with the opposite result reached in the *Bremner* case because of the differences in the facts.”).

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 183.

¹⁰⁹ *Id.* at 185.

¹¹⁰ *Id.* at 186.

¹¹¹ *Id.* at 190 (Worley, J., dissenting).

At the very least, even by Justice Story's standard, [applicant] must show that [the invention] is neither frivolous nor injurious to the "well being *** of society." I do not suppose that this applicant's product is injurious to the well being of society but for all that he tells us in his specification it could be, and, though it may well be that he has spent time and labor in a sincere effort to create something which would be a benefit, one could call the result frivolous despite its impressive formula if it should turn out to have no use of any kind.¹¹²

In *In re Wilke*,¹¹³ Judge Smith reversed a Patent Office Board of Appeals decision and held that, although a *product* claim failed to comply with 35 U.S.C. § 112, first paragraph, for failure to sufficiently describe "how to use two of the four addition products grouped in claim 36,"¹¹⁴ claims directed to a *process* of forming such products in the same application were adequately supported under the same statute.¹¹⁵ Judge Smith stated for the majority in *Wilke* that there was no evidence of Congressional intent to support an interpretation by the Patent Office of *Bremner*, whereby "the specification must teach a use for the product of a claimed process":

¹¹² *Id.* at 191 (Kirkpatrick, J., dissenting).

¹¹³ *In re Wilkie*, 314 F.2d 558 (C.C.P.A. 1963).

¹¹⁴ *Id.* at 564. The court stated:

Thus, we are unable to find *any* description of *how to use* two of the four addition products grouped - claim 36. We therefore affirm the rejection of claim 36 under 35 U.S.C. § 112 as being based on an insufficient description of how to use the claimed products. *Id.*

¹¹⁵ *Id.* at 565. The court stated:

We pass now to an analysis of process claims 18-27, inclusive, to ascertain whether they are in fact directed to an invention which is adequately supported in the specification to meet the requirements of 35 U.S.C. § 112. These claims are each *process claims* directed to certain process steps disclosed in the specification to produce the products disclosed therein.

When so considered, we find that claims 18-27, inclusive, are sufficiently supported by the specification. Referring to these claims it will be seen claim 18 recites the conditions for a process which involves a reaction using from 1-4 molecules of maleic acid anhydride. The process produces a product which is described as being an intermediate in the production of a plasticizer. *Id.*

It is our opinion, therefore, that claims 18-27, inclusive, define the steps of the process disclosed in the specification and that such steps are disclosed in the specification sufficiently to teach one of ordinary skill in this art how to carry out the *claimed processes*. This is a sufficient compliance with 35 U.S.C. § 112. We decline to apply to these process claims the statement in the *Bremner* case from which the Patent Office has extracted the so-called “rule of *Bremner*,” i.e., that the specification must teach a use for the product of a claimed process. Had this been the intent of Congress, we are certain that it would have been so stated in 35 U.S.C. § 112. Instead, the language of 35 U.S.C. § 112 where applied to a *process* requires no more than has been here disclosed.¹¹⁶

However, the distinction of the facts in *Wilkie* from those in *Bremner* was that in *Bremner* there was no statement of use of the *product*. Judge Smith did not need to apply the “rule of *Bremner*” because there was never any determination in *Wilkie* that a statement of use under 35 U.S.C. § 101 of products was lacking, but rather only that the how-to-use requirement of 35 U.S.C. § 112 was not satisfied as applied to those products.

In re Adams was a subsequent decision¹¹⁷ which held that claims directed to steroids and methods for preparing them met the “how-to-use” requirement of the first paragraph of 35 U.S.C. § 112 because, although the specification made reference only to “biological properties,”¹¹⁸ they were analogues of known compounds that one skilled in the art, taking the entire disclosure as a whole, would be enabled to use.¹¹⁹ The court further stated that the utility of the claimed compounds, which were described in specification as being of the “androstanane and pregnane series,” need not be “conclusively predicted.”¹²⁰ With respect to claims directed to the method of forming the claimed compounds, the court generalized the holding of *Wilkie* as imposing only a reduced standard for claims directed to a method of making a product, relative to that required to adequately describe how to use a

¹¹⁶ *In re Wilkie*, 314 F.2d at 565-66.

¹¹⁷ *In re Adams*, 316 F.2d 476 (C.C.P.A. 1963).

¹¹⁸ *Id.* at 477.

¹¹⁹ *Id.* at 478. (“We are of the opinion that when the *entire* disclosure, taken as a whole, is considered, one skilled in the art would be enabled to use the compounds.”).

¹²⁰ *Id.* (“Contrary to the statement of the examiner referred to by the board, it need not be ‘conclusively predicted’ that androgenic or progestational activity is present in order to enable one skilled in the art to use the invention.”).

claimed product produced by the method.¹²¹

Judge Martin, concurring in part and dissenting in part, objected to the holding on the basis that “there is a high degree of unpredictability in the steroid field and that this unpredictability would render an assumption of related biological activity based on a similarity of structure of various steroid derivatives incorrect.”¹²² Judge Martin concluded that “it does not seem apparent to me that a steroid chemist would know how to use the claimed compounds from the information disclosed in appellants’ application.”¹²³

In yet another case directed to an appeal from the Patent Office Board of Appeals, Judge Worley in *In re Diedrich*,¹²⁴ held that a German patent specification could not be relied upon by appellants for a filing date because an intervening U.S. patent application in the series that was abandoned by the appellants did not adequately disclose how to use the claimed products.¹²⁵ As with *Tolkmith*, the court held that general allegations of use can be overly broad.¹²⁶ As in previous decisions, a general statement of utility was held by the court to provide insufficient guidance to enable one skilled in the art to use the invention, contrary to the statutory mandate of 35 U.S.C. § 112.¹²⁷

The majority opinion in *In re Szwarc*,¹²⁸ held, like the court in *Wilke*, that “a specification which teaches those skilled in the art how to use the [claimed] process, i.e., by disclosing the manipulative steps of the process, the required operating conditions and the starting materials so that the [claimed] process may be used by a person skilled in the art, meets the requirements of 35 U.S.C. § 112.”¹²⁹ Judge Smith, who wrote the opinion, asserted that “[i]t is not necessary to specify the intended uses for the product produced therein.”¹³⁰ He explicitly stated that there had “been ‘a modification of the control-

¹²¹ *In re Adams*, 316 F.2d at 478 (“The disclosure of how the product is used is not required to be as complete in order to show how to use the method of making the product as it is with product claims. *In re Wilke*, 314 F.2d 558 . . .”).

¹²² *Id.* at 479 (Martin, J., concurring in part and dissenting in part).

¹²³ *Id.* at 480 (Martin, J., concurring in part and dissenting in part).

¹²⁴ *In re Diedrich*, 318 F.2d 946 (C.C.P.A. 1963).

¹²⁵ *Id.* at 948.

¹²⁶ *Id.* at 951 (“To say merely that an invention is useful as a pharmaceutical, even coupled with the recitation of certain properties, falls far short of satisfying the precise demands of section 112.”).

¹²⁷ *Id.* (“We agree with the board that one skilled in this art would not know how to use the compounds in issue on the basis of the disclosure of appellant’s parent application, hence it fails to satisfy the demands of 35 U.S.C. § 112.”).

¹²⁸ *In re Szwarc*, 319 F.2d 277 (C.C.P.A. 1963).

¹²⁹ *Id.* at 286.

¹³⁰ *Id.*

ling legal principles' as to the proper interpretation of 35 U.S.C. § 112 as applied to process claims since the *Bremner* decision in 1950.¹³¹

As in *Wilkie*, there was no determination that the specification lacked an adequate statement of intended use of the products formed by the claimed process.¹³² Therefore, just as in *Wilkie*, there was no need for Judge Smith to make reference to *Bremner* in *Szwarc* because, as discussed above, the *Bremner* decision did not extend to process claims in a specification where "an assertion of utility and an indication of the use or uses intended"¹³³ of the resulting product had been made but not in an enabling manner, since, in *Bremner*, no assertion of utility of the product had been made at all. In short, the holding by the court in *Bremner* did not apply to the facts in *Szwarc*.

Judge Smith also wrote the majority opinion in *In re Manson*¹³⁴ in which he stated that the only issue was "whether an applicant for a patent on a *new process* for making a *known compound* must establish a utility for such a *compound*, in order to satisfy the requirements of Rule 204(b) preparatory to having an interference declared between his application and a prior patent."¹³⁵ In essence, Judge Smith addressed the question of whether satisfaction of the utility requirement, as applied to a claimed process, mandated an assertion in the specification of a utility for the product formed by the process.

Holding in the negative, thereby reversing the decision by the board, the court in *Manson* acknowledged that *Wilkie* was limited to 35 U.S.C. § 112, but, as in *Szwarc*, the basis for the court's holding was a characterization of the reasoning in *Wilkie* that purported to overrule *Bremner*:

It seems clear from the present record that the Patent Office refused to accept appellant's affidavits on the philosophical basis that unless a compound is known to be useful, a process for making the compound is not useful under section 101 and hence not patentable. Thus the case of *In re Wilkie and Pfohl*, 314 F.2d 558, 50 CCPA 964, cited by appellant and argued by both parties, is not directly controlling here since it dealt with the adequacy of the specification with respect to a disclosure of "how to use" under section 112.

As to whether a specification must show *how to use* the

¹³¹ *Id.*

¹³² *Id.* at 284.

¹³³ *Bremner*, 182 F.2d at 217.

¹³⁴ *In re Manson*, 333 F.2d 234 (C.C.P.A. 1964).

¹³⁵ *Id.* at 235.

product of a claimed *process*, however, our holding in *Wilkie* made it abundantly clear that it is not necessary so to do. In the present case, our holding that where a claimed process produces a known product it is not necessary to show utility for the product eradicates, as to the process claims, whatever remained of the so-called “rule of *Bremner*” subsequent to our decision in *Wilkie*. See also *In re Szwarc*, 319 F.2d 277, 50 CCPA 1571.¹³⁶

However, as discussed above, the court in *Wilkie* did not overrule *Bremner*. Rather, Judge Smith in *Wilkie* merely declined to extend 35 U.S.C. § 112, first paragraph, to a description in the specification of how to use the product of a claimed process. As also described above, the decision in *Wilkie* was not inconsistent with *Bremner*, in that, contrary to *Bremner*, there was no question in *Wilkie* of whether the specification included “an assertion of utility and an indication of the use or uses intended,” of the product formed by the process claimed. Further, the court in *Szwarc*, as in *Wilkie* did not question whether the specification provided a sufficient statement of utility under 35 U.S.C. § 101.¹³⁷

Unlike *Wilkie* and *Szwarc*, Judge Smith in *Manson*, by holding that a patent specification need not establish utility of a known product formed by a claimed process, did overrule *Bremner* because, unlike *Wilkie* and *Szwarc*, satisfaction of the requirement under 35 U.S.C. § 101 was specifically at issue. In other words, whereas the court in *Bremner* held that “the law requires that there be in the application an assertion of utility and an indication of the use or uses intended,”¹³⁸ and that “[i]t was never intended that a patent be granted upon a product, or a process producing a product, unless the product be useful,”¹³⁹ the court in *Manson* held that a claimed “process is ‘useful,’ as a matter of law, if it operates as disclosed to produce its intended result or perform its intended function and if it is not, in operation or result, detrimental to the public interest.”¹⁴⁰

Judge Smith, in essence, abrogated at least the portion of the holding in *Bremner* that required “an assertion of utility and an indication of the use or uses intended”¹⁴¹ of the product of a claimed process. The basis for holding contrary to *Bremner* was a narrow reading of

¹³⁶ *Id.* at 237.

¹³⁷ *Szwarc*, 319 F.2d at 284-5.

¹³⁸ *Bremner*, 182 F.2d at 217.

¹³⁹ *Id.*

¹⁴⁰ *Manson*, 333 F.2d at 237-38.

¹⁴¹ *Bremner*, 182 F.2d at 217.

35 U.S.C. § 101 that limits the statute, in the case of formation of a known product, to operability of the process of its formation, independent of any assertion of utility of the product formed:

As there defined [in 35 U.S.C. § 101], a process is a separate category of patentable invention. Clearly, a process which operates as disclosed to produce a known product is “useful” within the meaning of section 101. To add to this section the further requirement that such a process is “useful” only when a “use” for a known end product is disclosed seems to us to be an improper arrogation of the authority delegated to Congress by the Constitution. Had such a restriction been intended by Congress, we believe it would have been directly stated either in section 101 or in the definition of a process found in section 100(b). We take the omission of any such requirement to be determinative of the issue here.¹⁴²

C. *Brenner v. Manson*: The Modern Standard for Statutory Utility

On appeal, in *Brenner v. Manson*,¹⁴³ the Supreme Court broadened the scope of the issue in *Manson* beyond that of establishing use of end products that are known.¹⁴⁴ As stated by Justice Fortas, two issues were to be decided in *Brenner*:

This case presents two questions of importance to the administration of the patent laws: First, whether this Court has certiorari jurisdiction, upon petition of the Commissioner of Patents, to review decisions of the Court of Customs and Patent Appeals; and second, whether the practical utility of the compound produced by a chemical process is an essential element in establishing a *prima facie* case for the patentability of the process.¹⁴⁵

The first issue was decided in the affirmative.¹⁴⁶ In addressing the

¹⁴² *Manson*, 333 F3d. at 236.

¹⁴³ *Brenner v. Manson*, 383 U.S. 519 (1966).

¹⁴⁴ 383 U.S. at 530-31. n.16. The Court stated:

Respondent couches the issue in terms of whether the process yields a ‘known’ product. We fail to see the relevance of the fact that the product is ‘known,’ save to the extent that references to a compound in scientific literature suggest that it might be a subject of interest and possible investigation. *Id.*

¹⁴⁵ *Id.* at 520.

¹⁴⁶ *Id.* at 528 (“We therefore conclude that § 1256 authorizes the grant of certiorari in the present case.”).

second issue, that of “whether the practical utility of a compound produced by a chemical process is an essential element in establishing a *prima facie* case for the patentability of the process,” the Court responded to three points of argument presented by the respondent (Manson). The first point was an assertion that the steroid formed by the claimed process had an adjacent homologue known in the art to have “tumor-inhibiting effects in mice, and that this discloses the requisite utility.”¹⁴⁷ The court rejected this argument on the basis of lack of predictability in the field of the steroids.¹⁴⁸

The second and third points raised by the respondent were presented by the Court as questions: “Is a chemical process ‘useful’ within the meaning of § 101 either (1) because it works—i.e., produces the intended product? or (2) because the compound yielded belongs to a class of compounds now the subject of serious scientific investigation?”¹⁴⁹ To answer these questions, the Court spoke to the “general intent” of Congress and policy considerations.¹⁵⁰

¹⁴⁷ *Id.* at 531. Justice Fortas summarized the first argument as follows:

[Respondent] begins with the much more orthodox argument that his process has a specific utility which would entitle him to a declaration of interference even under the Patent Office’s reading of § 101. The claim is that the supporting affidavits filed pursuant to Rule 204(b), by reference to Ringold’s 1956 article, reveal that an adjacent homologue of the steroid yielded by his process has been demonstrated to have tumor-inhibiting effects in mice, and that this discloses the requisite utility. *Id.*

¹⁴⁸ 383 U.S. at 531-32. The Court explained:

Even on the assumption that the process would be patentable were respondent to show that the steroid produced had a tumor-inhibiting effect in mice, we would not overrule the Patent Office finding that respondent has not made such a showing. The Patent Office held that, despite the reference to the adjacent homologue, respondent’s papers did not disclose a sufficient likelihood that the steroid yielded by this process would have similar tumor-inhibiting characteristics. Indeed, respondent himself recognized that the presumption that adjacent homologues have the same utility has been challenged in the steroid field because of ‘a greater known unpredictability of compounds in that field.’ *Id.*

¹⁴⁹ *Id.* at 532.

¹⁵⁰ *Id.* As stated by the Court:

These contentions present the basic problem for our adjudication. Since we find no specific assistance in the

With respect to the first question, the Court stated that, where an inventor has not established a “specific utility” for a process, the policy of disclosing new discoveries was out-weighed by the “more compelling consideration” of the prospect of granting monopolies that would “block off whole areas of scientific development, without compensating benefit to the public”:

Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public.¹⁵¹

According to the Court, prerequisite to granting a patent on a process, the *quid pro quo* of benefit to the public mandated that the utility of the invention be “substantial,” and that the process be developed to the point where benefit derived by the public is “specific” and “exists in currently available form”:

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.¹⁵²

With respect to the second question, of whether a chemical process is “useful” if “the compound yielded belongs to a class of compounds now the subject of serious scientific investigation,” the Court stated that the potential for benefit as the subject of scientific research was

legislative materials underlying § 101, we are remitted to an analysis of the problem in light of the general intent of Congress, the purposes of the patent system, and the implications of a decision one way or the other. *Id.*

¹⁵¹383 U.S. at 534.

¹⁵²*Id.* at 534-35.

an inadequate basis in support of “utility.”¹⁵³ The Court relied on three decisions to support this proposition, stating that, “the decisions of the C.C.P.A. are in accord with the view that a product may not be patented absent a showing of utility greater than any adduced in the present case.”¹⁵⁴ Oddly, the three cases relied on by the Court, *In re Bergel*,¹⁵⁵ *In re Nelson*,¹⁵⁶ and *In re Folkers*,¹⁵⁷ all found that the utility requirement had been met. Further, with regard to *Nelson*, and as discussed above, the utility requirement had been found to be met with respect to a claimed product because it belonged to a class of compounds, androstenes, which Judge Rich characterized as being “of a type which steroid chemists can use in well-known reactions to produce steroids of a class at least some members of which are known to have useful therapeutic properties.”¹⁵⁸ Nevertheless, the Court in *Brenner* found that a “potential role as an object of use testing,” was an inadequate basis for “utility” either for the product or the process “which yielded the unpatentable product.”¹⁵⁹ The Court stated that to do so would be to equate a patent with a hunting license: “But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. ‘[A] patent system must be related to the world of commerce rather than to the

¹⁵³ *Id.* at 535.

¹⁵⁴ *Id.*

¹⁵⁵ *In re Bergel*, 292 F.2d 955, 958 (C.C.P.A. 1961). The court stated:

That appellants’ compounds actually do inhibit the growth of the transplanted cancer strain is not questioned. In our opinion, that achievement is sufficient to satisfy the express language of section 101, and is in harmony with the basic constitutional concept of promoting the progress of science and the useful arts. *Id.*

¹⁵⁶ *Nelson*, 280 F.2d at 181 (“We conclude that the claimed compounds are ‘useful’ within the meaning of section 101 and that there is a disclosure of utility in the specification.”).

¹⁵⁷ *In re Folkers*, 344 F.2d 970, 975 (C.C.P.A. 1965) (“We think appellants have made a contribution to the art by inventing a new and unobvious composition of matter and have complied with the requirement of 35 U.S.C. § 101 that their invention be useful.”). *Id.*

¹⁵⁸ *Nelson*, 280 F.2d at 180.

¹⁵⁹ *Brenner*, 383 U.S. at 535. As stated by the Court:

We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole ‘utility’ consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. *Id.*

realm of philosophy....”¹⁶⁰ Therefore, the Court reversed Judge Smith’s decision in the lower court and held, with respect to the second issue in the case, that “the practical utility of a compound produced by a chemical process is an essential element in establishing a *prima facie* case for the patentability of the process.”¹⁶¹

The Court also commented extensively on legal precedent at the C.C.P.A., beginning with Judge Rich’s opinion in *Nelson*. The Court characterized the holding in *Nelson* as the beginning of a trend by the C.C.P.A. to move “sharply away from *Bremner*,”¹⁶² because the majority opinion in *Nelson* found that claimed chemical intermediates were considered “‘useful to chemists doing research on steroids,’ despite the absence of evidence that any of the steroids thus ultimately produced were themselves ‘useful.’”¹⁶³ The Court in *Brenner* further described the “trend” purportedly initiated by *Nelson* as having “accelerated, culminating in the present case where the court held it sufficient that a process produces the result intended and is not ‘detrimental to the public interest.’”¹⁶⁴ The acceleration noted by the Court was attributed to *Wilkie*, *Adams* and *Szwarc*. With reference to *Wilkie* and *Adams*, the Court referenced holdings that 35 U.S.C. § 112 “was satisfied even though the specification recited only the manner in which the process was to be used and not any use for the products thereby yielded.”¹⁶⁵

As discussed above, in *Wilkie*, the court determined that the rejections by the board were based solely on 35 U.S.C. § 112; there was no rejection under 35 U.S.C. § 101.¹⁶⁶ As a question of enablement, the court merely declined to apply *Bremner* as interpreted by the Patent Office, whereby claims directed to a method of making a product

¹⁶⁰ *Id.* at 536.

¹⁶¹ *Id.* at 520.

¹⁶² *Id.* at 530.

¹⁶³ *Brenner*, 383 U.S. at 530. Interestingly, and as later commented upon by Judge Rich in his dissent in *In re Kirk*, 376 F.2d 939 (C.C.P.A. 1967), the Court in *Brenner* misstated the claimed subject matter in *Nelson* as a process rather than a product. (“There [in *Nelson*], the court reversed the Patent Office’s rejection of a claim on a *process* yielding chemical intermediates ‘useful to chemists doing research on steroids,’ despite the absence of evidence that any of the steroids thus ultimately produced were themselves ‘useful.’” *Id.* at 530 (emphasis added)).

¹⁶⁴ *Id.*

¹⁶⁵ *Id.* at n.15.

¹⁶⁶ *Wilkie*, 314 F.2d at 562 (“Despite the present effort of the solicitor to bring 35 U.S.C. § 101 into this appeal, we agree with the board that the rejection of the appealed claims is based solely on appellants’ failure to disclose their invention as required by 35 U.S.C. § 112.”).

required a description of how to use the product formed. Instead, it was sufficient that there be “an assertion of utility and an indication of the use or uses intended,” which, with respect to the facts of *Wilkie*, apparently had been met (or at least was not the basis for rejection of the claims by the board, as determined by the court) because the specification, according to the court, described the product formed by the claimed process as “an intermediate in the production of a plasticizer.”¹⁶⁷ However, since *Bremner* only stated that “the law requires that there be in the specification an assertion of utility and an indication of the use or uses intended,” and that “[i]t was never intended that a patent be granted upon a product, or a process producing that product, unless such product be useful,”¹⁶⁸ there is no explicit requirement in *Bremner* mandating that, beyond an assertion of utility and an indication of the use or uses intended for a product formed by a process, that there be also an enabling description of how to use that product in order to adequately support process claims. Therefore, the court’s decision in *Wilkie* to decline applying the “rule of *Bremner*” as interpreted by the Patent Office, rather than being a trend away from *Bremner*, as characterized by the Court in *Bremner*, could instead be seen as an overstatement of *Bremner* by the Patent Office in that *Bremner* never clearly stated that, in addition to including “an assertion of utility and an indication of the use or uses intended,”¹⁶⁹ an application need also describe an enabling method of how to use a product formed by a claimed process.

Adams, like *Wilkie*, was concerned only with the enablement requirement of 35 U.S.C. § 112 as applied to a claimed product and a claimed process for forming that product. With respect to the claimed process, the court relied on *Wilkie* for the proposition that the “disclosure of how the product is used is not required to be as complete in order to show how to use the method of making the product as it is with product claims.”¹⁷⁰ With respect to both the product and the process claims, the court held that, upon consideration of the entire disclosure “taken as a whole,” one skilled in the art would be enabled to use the compounds.¹⁷¹ Therefore, as with *Wilkie*, where the utility requirement of 35 U.S.C. § 101 was met, and the only question

¹⁶⁷ *Id.* at 565 (“When so considered, we find that [process] claims 18-27, inclusive, are sufficiently supported by the specification The process produces a product which is described as being an intermediate in the production of a plasticizer.”).

¹⁶⁸ *Bremner*, 182 F.2d at 217.

¹⁶⁹ *Id.*

¹⁷⁰ *Adams*, 316 F.2d at 478.

¹⁷¹ *Id.*

was of satisfaction of the enablement requirement under 35 U.S.C. § 112, satisfaction of that requirement as applied to the process claims did not require an enabling disclosure of how to use the product formed by the claimed process.

The Court in *Brenner* also noted that the majority opinion in *Szwarc* “acknowledged that its view of the law respecting utility of chemical processes had changed since *Brenner*.”¹⁷² However, as also discussed above, although Judge Smith in *Szwarc* specifically stated that the “so-called ‘rule of *Brenner*’ as applied to process claims, no longer exists in this court,”¹⁷³ the specification in *Szwarc* met the requirements of U.S.C. § 101; the only question to be decided by the court in *Szwarc* was whether process claims must be supported by a specification that provides an enabling description of how to use the resulting product formed by the claimed process. Therefore, *Szwarc*, like *Wilkie* and *Adams*, and contrary to Judge Smith’s suggestion in *Szwarc*, did not, in fact, overrule *Brenner*, but only the “rule of *Brenner*” established by the Patent Office as its interpretation of *Brenner*, wherein, as stated in *Wilkie*, “the specification must teach a use for the product of a claimed process,” sufficient to meet the requirements of 35 U.S.C. § 112.¹⁷⁴

The holding by the Court in *Brenner*, whereby 35 U.S.C. § 101 mandates a “practical utility of the compound produced by a chemical process” as “an essential element in establishing a *prima facie* case for the patentability of the process,”¹⁷⁵ is consistent with *Wilkie*, *Adams*, and *Szwarc*, and clarifies the holding in *Brenner*; there is no requirement in this holding, despite the *dicta* recited above, requiring an enabling disclosure of how to use the product of the claimed process. Instead, it only overruled Judge Smith’s decision in the lower court in *Manson* that no assertion of utility or indication of the use or uses intended for a product is required to support a claim to a process for forming that product.

Justice Harlan concurred with the portion of the majority decision regarding certiorari jurisdiction, but dissented from the holding with respect to patentability.¹⁷⁶ The basis for his dissent stemmed from the policy considerations asserted by the majority concerning the *quid pro quo* of disclosure and the utility of research:

The further argument that an established product use is part

¹⁷² *Brenner*, 383 U.S. at 530, n.15.

¹⁷³ *Szwarc*, 319 F.2d at 285.

¹⁷⁴ *Wilkie*, 314 F.2d at 566.

¹⁷⁵ *Brenner*, 383 U.S. at 519.

¹⁷⁶ *Id.* at 536 (Harlan, J., concurring in part and dissenting in part).

of “[t]he basic *quid pro quo*”... for the patent or is the requisite “successful conclusion” ... of the inventor’s search appears to beg the very question whether the process is “useful” simply because it facilitates further research into possible product uses.¹⁷⁷

Justice Harlan strongly suggested that the fact that a product may be the subject of research may indeed be a sufficient utility:

What I find most troubling about the result reached by the Court is the impact it may have on chemical research. Chemistry is a highly interrelated field and a tangible benefit for society may be the outcome of a number of different discoveries, one discovery building upon the next. To encourage one chemist or research facility to invent and disseminate new processes and products may be vital to progress, although the product or process be without “utility” as the Court defines the term, because that discovery permits someone else to take a further but perhaps less difficult step leading to a commercially useful item. In my view, our awareness in this age of the importance of achieving and publicizing basic research should lead this Court to resolve uncertainties in its favor and uphold the respondents’ position in this case.¹⁷⁸

In re Folkers, et al.,¹⁷⁹ was decided in 1965, after *Manson*, but before the decision on appeal to the Supreme Court in *Brenner*. Judge Worley for the Court of Customs and Patent Appeals held that description of the physical properties of newly described compounds was sufficient to satisfy the requirements of 35 U.S.C. § 101¹⁸⁰ and 35 U.S.C. § 112.¹⁸¹ In particular, the court found that a statement within the specification that the compounds were “involved” in “electron transport activity”¹⁸² was a sufficient statement of utility under 35 U.S.C. § 101:

The question here is not whether the property of electron transfer is a use, but whether knowledge of that property necessarily and implicitly renders it readily apparent to one of ordinary skill that the present compounds are useful. We think logic and reason require an affirmative answer to the

¹⁷⁷ *Id.* at 537 (Harlan, J., concurring in part and dissenting in part).

¹⁷⁸ *Id.* at 539 (Harlan, J., concurring in part and dissenting in part).

¹⁷⁹ *In re Folkers*, 344 F.2d 970 (C.C.P.A. 1965).

¹⁸⁰ *Id.* at 974.

¹⁸¹ *Id.* at 976.

¹⁸² *Id.* at 971, n.3 (“This material is also named Coenzyme Q in later publications. It is involved in the electron transport activity of mitochondria.”).

latter question.

On the facts of this case, we are of the view that appellants have satisfied the requirements of Section 101 by setting forth the fact their compounds are hydroquinones and quinones, and reciting that the compounds possess the property of electron transport activity.¹⁸³

The court further stated that the claimed compounds of the invention were useful because they belonged to a class of compounds which were “well recognized as useful for a particular purpose because of a particular property.”¹⁸⁴

Also, like the court in *Nelson*, Judge Worley premised utility, at least in part, on usefulness of the claimed compounds in “the study of enzyme systems which are responsible for and necessary to the life function of metabolism, the conversion of food to energy.”¹⁸⁵ The policy considerations by Judge Rich in *Nelson* and by Judge Worley in *Folkers* when considering satisfaction of the utility standard under 35 U.S.C. § 101 are essentially identical. For example, in *Nelson*, Judge Rich stated:

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.

We conclude that the claimed compounds are “useful” within the meaning of section 101 and that there is a disclosure of utility in the specification.¹⁸⁶

Judge Worley, in *Folkers*, stated, in turn:

Other compounds of the quinone nature, but further removed in chemical structure from Q-275 than the presently claimed compounds, had no effect in restoring succinxi-

¹⁸³ *Id.* at 974.

¹⁸⁴ *In re Folkers*, 344 F.2d at 975 (“Since appellants’ newly discovered compounds belong to a class of compounds, the members of which have become well recognized as useful for a particular purpose because of a particular property, the only reasonable conclusion is that the new compounds, also possessing that property, are similarly useful.”).

¹⁸⁵ *Id.* at n.9 (“We also agree with appellants that their compounds are useful to the biochemist in the study of enzyme systems which are responsible for and necessary to the life function of metabolism, the conversion of food to energy.”).

¹⁸⁶ *Nelson*, 280 F.2d at 181.

dase activity when added to the extracted mitochondria in concentrations comparable to that used for Q-275, hence were of no further use *in the study of that particular enzyme system*. On the other hand, appellants have effectively stated in their specification that their compounds have the activity of Q-275 and are of use in maintaining cellular succinoxidase activity in an *in vitro* system.

We think appellants have made a contribution to the art by inventing a new and unobvious composition of matter and have complied with the requirement of 35 U.S.C. § 101 that their invention be useful.¹⁸⁷

Similarly, the court in *Folkers* parallels the analysis made by Judge Rich in *Nelson* with respect to satisfaction of the enablement requirement under 35 U.S.C. § 112. Specifically, Judge Rich in *Nelson* stated:

In other words, compliance with the law does not necessarily require specific *recitations* of use but may be inherent in description or may result from disclosure of a sufficient number of properties to make a use obvious; and where those of ordinary skill in the art will know *how* to use, the applicant has a right to rely on such knowledge. If it will not be sufficient to enable them to use his invention, he must supply the know-how.¹⁸⁸

Judge Worley applied a parallel argument in *Folkers*:

The fact that the claimed compounds are derivatives related in chemical structure and significant properties to the "common and well known" family of hydroquinone and quinone compounds argues strongly for the proposition that those skilled in the chemical arts would, without more, know how to use them.¹⁸⁹

Therefore, as late as 1965, subsequent to the decision by the Court of Customs and Patent Appeals in *Manson*, but prior to the decision by the Supreme Court of the *Manson* decision on appeal in *Brenner*, satisfaction of the utility requirement under 35 U.S.C. § 101 required only a statement of a property of a claimed compound sufficient to warrant some usefulness, such as usefulness in research. Also, the enablement requirement under 35 U.S.C. § 112 mandated only that one skilled in the art understand that the claimed compound falls within a class of compounds "that those skilled in the chemical arts

¹⁸⁷ *Folkers*, 344 F.2d at 975.

¹⁸⁸ *Nelson*, 280 F.2d at 184.

¹⁸⁹ *Folkers*, 344 F.2d at 976.

would, without more, know how to use....”¹⁹⁰

The first major tests of *Brenner* were *In re Kirk*¹⁹¹ and *In re Joly*,¹⁹² which were decided on the same day. Chief Judge Worley delivered the majority opinion in *Kirk*, while Judge Almond delivered the opinion in *Joly*. Both Judges Rich and Smith filed respective dissenting opinions in *Kirk* and *Joly*. The claims in *Kirk* were on appeal from the rejection by the Patent Office for failure of the specification “to comply with 35 U.S.C. §§ 101 and 112.”¹⁹³ They were directed to steroid compounds described in the specification as “often possessing high biological activity,” as being “of value on account of their biological properties or as intermediates in the preparation of compounds with useful biological properties,” and “of value in steroid technology, in the furtherance of steroidal research and in the application of steroidal materials to veterinary or medical practice”¹⁹⁴ Specific compounds within the scope of the rejected claims were identified as being “of value as intermediates in the preparation of 6-methylated aromatic steroidal hormones,” “as intermediates in the preparation of biologically active compounds and in some cases on account of their biological properties,” and “as intermediates in the preparation of compounds with valuable biological properties such as progestational properties or properties associated with the adrenocortical hormones or as intermediates in the preparation of compounds with useful biological properties.”¹⁹⁵

The contention by appellants in *Kirk* that the specification met the requirements of both 35 U.S.C. § 101 and § 112 because “one skilled in the art would know how to use the compounds of the claims to take advantage of their presently-existing biological activity,” and because the compounds “have use as intermediates in the production of aromatic steroidal hormones and other biologically useful compounds,” which “one skilled in the art would know how to use for that purpose” was rejected by Judge Worley.¹⁹⁶ The court held that “nebulous expressions” of “biological activity” or “biological properties” were inadequate to satisfy the requirements of §§ 101 and 112.¹⁹⁷ Specifically, the court found that, although five of eighteen disclosed androstanes were claimed, the specification did not identify

¹⁹⁰ *Id.*

¹⁹¹ *Kirk*, 376 F.2d 936 .

¹⁹² *Joly*, 376 F.2d 906.

¹⁹³ *Kirk*, 376 F.2d at 937.

¹⁹⁴ *Id.* at 938.

¹⁹⁵ *Id.* at 939.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at 941.

which androstanes were useful or what biological properties they possessed:

It is what the compounds are *disclosed* to do that is determinative here. In that regard, it is appropriate to note that the specification does not even intimate that the claimed compounds of the spirostane and pregnane series themselves have “biological activity,” much less the specific progestational, glucocorticoid or anti-inflammatory activities mentioned in the affidavit. With respect to the eighteen androstanes that are disclosed, five of which are claimed here, it is said they “are of value... *in some cases* on account of their biological properties.” There is no suggestion *which* androstanes are of value for that reason, or *what* biological properties make them useful.¹⁹⁸

The court held that the assertions made of “biological” activity as recited in the specification did not meet the requirements of 35 U.S.C. § 101 or § 112.¹⁹⁹

With respect to use of the claimed compounds as intermediates in research, the court in *Kirk* viewed *Nelson* as being overruled by *Brenner*:

The decision in *Nelson* might well control here—*if* that decision were still viable precedent. The question remains, however, whether the majority view in *Nelson*—that steroid chemical compounds may be useful under § 101 if they are useful to chemists doing research on steroids and can be used to produce steroids which are members of a general class some members of which are known to have useful therapeutic properties—can possibly remain the law in view of *Brenner v. Manson*.²⁰⁰

The court in *Kirk* dismissed the sufficiency of general allegations of utility in research as being rejected by the Supreme Court.²⁰¹ Moreover, the reasoning by the Supreme Court in *Brenner* was extended by the court in *Kirk* to hold that starting materials for a process that does not produce a “useful” product also cannot meet the re-

¹⁹⁸ *Kirk*, 376 F.2d at 941.

¹⁹⁹ *Id.* at 942 (“We conclude that appellants’ specification does not comply with § 101 and § 112 merely on the statements of ‘biological’ activity recited therein.”).

²⁰⁰ *Id.* at 944.

²⁰¹ *Id.* at 945 (“There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of ‘useful in research’ or ‘useful as building blocks of value to the researcher’ was recognized, and clearly rejected by the Supreme Court . . .”).

quirements of 35 U.S.C. § 101.²⁰² The court further held that, contrary to Judge Worley's decision in *Folkers*, just months before *Brenner*, inclusion of a product, obtained from a claimed intermediate, in a class of compounds that is considered useful, also is inadequate as a statement of use under 35 U.S.C. § 101.²⁰³ The court concluded that preceding decisions found to be inconsistent with the majority's interpretation of *Brenner* were overruled. Decisions expressly overruled were *Nelson*, *Wilkie*, *Adams* and *Szwarc*.²⁰⁴

Judge Rich wrote an extensive dissent in which he asserted that the decision in *Brenner* was limited to the narrow holding that:

[F]or the purposes of provoking an interference with a process claim in an issued patent an applicant for a patent must disclose that the patent on the same claim must disclose that the process produces a "useful" product, that it is not enough to assert the use of the product is obvious to the applicant, but some specific use must be mentioned (as *Brenner* said), at least in the absence of evidence that a specific use would be obvious.²⁰⁵

Fundamental to Judge Rich's interpretation of *Brenner* is the specific failure by the Supreme Court to overrule the holding in cases, including *Nelson* and *Folkers* where the utility requirement was met on the basis of statements of properties of compounds in common with a class of compounds known to be useful, or membership of compounds in such a class. As stated by Judge Rich, a "showing of utility" was absent in *Brenner* (referred to by Judge Rich as "Manson") and, therefore, statements made by the Supreme Court alluding to requirements of "practical utility," or "some specific use," necessary to meet the requirement under 35 U.S.C. § 101, as relied upon by the majority in *Kirk*, must be dicta:

What the majority makes out of [*Brenner v.*] *Manson* by

²⁰² *Kirk*, 376 F.2d at 945 ("It seems clear that, if a process for producing a product of only conjectural use is not 'useful' within § 101, it cannot be said that the starting materials for such a process -- i.e., the presently claimed intermediates -- are 'useful.'").

²⁰³ *Id.* ("Nor is it enough that the product disclosed to be obtained from the intermediate belongs to some class of compounds which now is, or in the future might be, the subject of research to determine some specific use.").

²⁰⁴ *Id.* at 946 ("It is impossible to reconcile the reasoning and conclusion of the majority in *Nelson*, *Wilkie*, *Adams* and *Szwarc* with the majority view in *Brenner v. Manson*. Therefore, to the extent that those decisions are inconsistent with *Brenner v. Manson* and the views expressed herein, they must be, and are, overruled.").

²⁰⁵ *Id.* at 955 (Rich, J., dissenting).

way of a test for utility under 35 U.S.C. § 101 is that the compound must have “practical utility,” or “some specific use.” This is its summation of what is to be found in the [*Brenner v.*] *Manson* passages quoted by the majority. My own summary of that dictum would be that there must be specific, substantial utility which provides specific benefit in currently available form. One reason for characterizing this as dictum is that the opinion also refers to decisions of this court, including *Nelson*, listed in footnote 23 and left undisturbed, which have required “a showing of utility greater than any adduced in the present case,” which, it will be remembered, was zero in [*Brenner v.*] *Manson*. The distinction which must be born in mind is that between *some* disclosure of utility and *none*. The most significant aspect of *Manson*’s patent application and his Rule 204(b) affidavits is that they disclosed *no utility whatever* for the compounds produced by his claimed process.²⁰⁶

Interestingly, Judge Worley’s own opinion, in *Folkers*, was also recited in Footnote 23 in *Brenner* as an example of a decision by the C.C.P.A. “in accord with the view that a product may not be patented absent a showing of utility greater than any adduced in the present case.”²⁰⁷ Judge Rich noted in his dissent that Judge Worley’s opinion in *Folkers*, which was not among those cases Judge Worley overruled in his majority opinion in *Kirk*, was indistinguishable from *Potter v. Tone*, in that both cases based utility on usefulness in research:

Although the [*Brenner v.*] *Manson* opinion makes an argumentative assumption that “Congress intended that no patent be granted on a chemical compound whose sole ‘utility’ consists of its potential role as an object of use testing,” there is no citation of prior decisions or legislative history in support of that assumption, I know of none, that is not the case here, and the statement appears to be inconsistent with the action taken by the Court in [*Brenner v.*] *Manson* footnote 17. See *Potter v. Tone*, 36 App. D.C. 181 (1911), which is an overlooked part of the history of utility law and a case relied on by Chief Judge Worley in his opinion in *In re Folkers*, 344 F.2d 970, 52 (C.C.P.A. 1269),... a case I find indistinguishable from this one but in which he found statutory utility with the unanimous support of the court, which case he has not overruled. The Supreme Court itself

²⁰⁶ *Id.* at 948 (Rich, J., dissenting).

²⁰⁷ *Brenner*, 383 U.S. at 535.

in footnote 23 of [*Brenner v.*] *Manson*, acknowledged the *Folkers* case as being one having a showing of utility “greater than any adduced” by [*Brenner v.*] *Manson*.²⁰⁸

As noted by Judge Rich, footnote 17 of *Brenner* suggests that the question of patentability of compounds known only to be useful in research was to be reserved.²⁰⁹

Judge Rich also alluded to the policy considerations, made by the Supreme Court linking an exchange of patent monopoly for “substantial utility,” that were relied upon by Judge Worley in *Kirk*.²¹⁰ Specifically, Judge Rich stated that failure to understand that the degree of utility is not part of the *quid pro quo* for obtaining a patent monopoly was a “mental elephant pit” of confusion between the utility requirement under 35 U.S.C. § 101 and non-obviousness under 35 U.S.C. § 103:

In considering this case-law history one must be alert, in order to escape mental elephant pits, to avoid being confused by opinions which are dealing not with *utility* per se, but with the *non-obviousness* issue (or its predecessors, the presence of “invention,” or “inventive level” as Stringham calls it) in terms of *degree of utility* as an *indication* thereof. The same precaution is called for in deciding the patentability issue in current cases so as not to confound the requirement of section 101 with that of section 103. It has been pointed out time and again since the days of Justice Story, as fully discussed in *Nelson*, that *degree of utility* is

²⁰⁸ *Kirk*, 376 F.2d at 949 (Rich, J., dissenting).

²⁰⁹ *Brenner*, 383 U.S. at 531, n. 17 (“In light of our disposition of the case, we express no view as to the patentability of a process whose sole demonstrated utility is to yield a product shown to inhibit the growth of tumors in laboratory animals.”).

²¹⁰ In support of his statement that “[t]here can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of ‘useful in research’ or ‘useful as building blocks of value to the researcher’ was recognized, and clearly rejected, by the Supreme Court,” Judge Worley quoted the Supreme Court, in part, as follows:

The basic *quid pro quo* contemplated by the Constitution and the Congress for granting that 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.

Kirk, 376 F.2d at 945 (quoting *Brenner*, 383 U.S. at 534-35).

of no *public* concern whatsoever. This elementary principal appears not to have gotten through to those who still talk of *utility* in terms of “quid pro quo” for a patent. The *only* quid pro quo demanded by statute is *full disclosure* of a new and unobvious invention which is of *some* use to someone. If it is of very little *use*, the patent will correspondingly be of very little *value* to the patentee, who has never been called on either to know or to explain all potential uses of his invention. The hard fact is he almost never knows the full extent of the utility until years after he makes his invention. Uses evolve *after* inventions are disclosed.²¹¹

Regarding the standard laid out by the majority in *Kirk*, as derived from *Brenner*, Judge Rich stated:

But then we come to the practical problem posed by the rule being promulgated by the majority—a rule of great vagueness and no definite limits by reason of reliance on the terms “practical,” “substantial,” “specific” and “currently available.” They are nothing but trouble makers as time will amply demonstrate.²¹²

According to Judge Rich, as a policy matter, patentability is “of vast practical economic importance” and is attendant on the ability of inventors of new chemical compounds to “serve the ends of science—to push back the frontiers of chemistry,” by “[giving] the compounds to the world”:

The issue in these cases is of vast practical economic importance to the public, chemical and medical research, and the chemical industry as a whole. The simple question involved, to borrow a phrase from Mr. Justice Douglas, really is at what point the inventors of new chemical compounds “serve the ends of science—to push back the frontiers of chemistry.” My view, like that of Justices Harlan and Douglas, is that they do it when they are in a position to give the compounds to the world.²¹³

Judge Almond in the majority opinion of *Joly*, like *Kirk*, held that “the mere disclosure that a claimed chemical compound may be used as an intermediate to make other compounds, *without regard* for the

²¹¹ *Id.* at 955. (Rich, J., dissenting).

²¹² *Id.* at 960 (Rich, J., dissenting).

²¹³ *Id.* at 962-63. (Rich, J., dissenting) (Quoting *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 154 (1950) (Douglas, I., concurring)).

usefulness of the latter compounds,” was inadequate under 35 U.S.C. § 101.²¹⁴ In dissent, Judge Smith expanded upon Judge Rich’s assessment of the utility of research tools:

Judge Rich in his *Kirk* dissent demonstrates that chemists of ordinary skill in the art would have no difficulty in using new and unobvious chemical products and processes once they are disclosed as required by section 112. They are “useful,” under section 101, as tools, just as other professions have their particular “tools” with which to work.²¹⁵

Further, Judge Smith reiterates Judge Rich’s admonition against confusing utility under 35 U.S.C. § 101 and non-obviousness under 35 U.S.C. § 103 in that, failure to make this distinction will prompt holdings that, at least in retrospect, may appear absurd. Specifically, Judge Smith, also relying on Justice Douglas’ concurring opinion in *Great Atlantic & Pacific Tea Co.*,²¹⁶ stated:

Justice Douglas’ observation, while directed to the old requirement for “invention” which Congress subsequently replaced by the section 103 requirement for non-obviousness is based on the recognition that the patentability of inventions is to be judged by reference to what it contributes to those skilled in the art involved.

....

The Supreme Court in the [*Brenner v.*] *Manson* dictum advances as one test that judges look to the “objects” of the invention in determining what the invention is useful for. Yet in the same opinion we are told that “objects of scientific inquiry” are, as a matter of law, not “useful.” Thus, allegedly because of [*Brenner v.*] *Manson*, the majority here and in *Kirk* find that we are dealing with “objects of scientific inquiry” which, under the [*Brenner v.*] *Manson* dictum, are not “useful” as a matter of law.²¹⁷

As an example of the confusion that can ensue between these two statutes, whereby utility is judged by the degree of contribution, as “practical,” “substantial” and “specific” usefulness, Judge Smith stated that the first powered flight of the Wright brothers would likely have failed the threshold requirement for utility derived from *Brenner* by the majority opinions in *Kirk* and *Joly*:

²¹⁴ *Joly*, 376 F.2d at 908.

²¹⁵ *Id.* at 914 (Smith, J., dissenting).

²¹⁶ *Great Atlantic & Pacific Tea Co.*, 340 U.S. at 154-58 (1950).

²¹⁷ *Joly*, 376 F.2d at 915 (Smith, J., dissenting).

Under the majority decision here, and its extension of the dictum in [*Brenner v.*] *Manson*, an inventor, contrary to the law as it has existed since 1790, is not entitled to a patent in the chemical field until he can assert and prove that it has a “practical,” “substantial” and “specific” usefulness which confers a “specific benefit” which must exist in “currently available form.”

It is fortunate indeed that such a view did not prevail in the past. Under such a test I seriously doubt whether the present majority would find the first powered flight of the Wright Brothers to be “useful.” Since it lasted but 12 seconds, traversed but 120 feet, and reached a maximum height of but 10 feet, it cannot be said to have had a “practical” or “substantial” utility or that it made powered flight practical or substantial in a then “currently available form.” Under the majority view such a flight would indeed be “useless.”²¹⁸

Judge Smith extended this analogy to other fundamental innovations:

For that matter, Morse’s first attempts at electric telegraphy, Bell’s first telephone, Hall’s first production of aluminum, Edison’s first incandescent lamp and a host of other pioneering inventions did not possess any “practical” or “substantial” utility nor did they yield a specific benefit “in currently available form” until many years after the first primitive tests. By the tests of the majority here all are seemingly “useless” and hence unpatentable. But history shows the usefulness of these inventions was found sufficient for patentability.²¹⁹

According to Judge Smith, the majority decisions in *Joly* and *Kirk* are assumptions of uselessness of chemical compounds, contrary to the standards applied to other classes of inventions, and this distinction should be remedied by Congress:

The majority decision here, as well as in *Kirk*, proceeds to its conclusion by an unquestioning *assumption* that we are concerned with “useless” chemical products. This concept carries over and pervades its decision here not only as to the product claims but also as to the process claims directed to the making of these products. Such unwarranted *fact* assumptions at the appellate level suggests that policywise, Congress should enact into law the solution sug-

²¹⁸ *Id.* at 917 (Smith, J., dissenting).

²¹⁹ *Id.* (Smith, J., dissenting).

gested Judge Rich in *Kirk*, supra, the rule which prevailed prior to the misapplication of the *Brenner* decision after 1950, i.e., that all chemical compounds are useful per se within the meaning of 35 U.S.C. § 101. Chemists know how they can use chemical compounds, and particularly so here when they are told about their chemical structures and specific processes are disclosed for their use. They are, in fact, the “tools” of chemical research and development. Are they inherently less “useful” than are the other tools of research?²²⁰

Later cases, such as *In re Fouche*,²²¹ asserted that failure to establish utility must imply lack of adequate disclosure of how to use the claimed invention for that utility:

It appears that the examiner and the board doubted that compositions having heterocyclic moieties would be useful at all for therapeutic purposes. While this position could have led to a rejection under § 101, it also leads to a rejection under the how-to-use provision of § 112, since if such compositions are in fact useless, appellant’s specification cannot have not taught how to use them.²²²

Another case, *In re Jolles*,²²³ was reflective of *Brenner* and an earlier case, *Ladd*,²²⁴ discussed above, in that the court found that utility under 35 U.S.C. § 101 *can* be met for claimed compounds in view of structural similarity with compounds of known utility *if* there is sufficient expectation that the claimed compounds will behave in the same manner as known compounds. For example, as stated by the court in *Jolles*:

The similarities of the claimed derivatives to each other are represented in the tabulation of differences provided *supra* for the eight compounds tested by Dr. Maral. The Maral declarations established that the eight compounds have substantial activity against experimental tumors in mice. The board found that the successful clinical tests in humans of the one derivative shown in Jacquillat declarations sufficiently established utility for claims 15 and 35. The claimed compounds have a close structural relation-

²²⁰ *Id.* at 929 (Smith, J., dissenting).

²²¹ *In re Fouche*, 439 F.2d 1237 (C.C.P.A. 1971).

²²² *Id.* at 1243.

²²³ *In re Jolles*, 628 F.2d 1322 (C.C.P.A. 1980).

²²⁴ *Ex parte Ladd*, Harvey, Cable and Szayna, 112 U.S.P.Q. 337 (Pat. Bd. App., 1955).

ship to daunorubicin and doxorubicin, both known to be useful in cancer chemotherapy. Considering these facts and the record before us, we conclude that one of ordinary skill in the art would accept the appellants' claimed utility in humans as valid and correct.²²⁵

Similarly, the court in *Cross v. Iizuka*,²²⁶ held that practical utility under 35 U.S.C. § 101 was met by *in vitro* testing of claimed compounds, and by demonstration of *in vitro* and *in vivo* pharmacological activity of structural similar compounds.²²⁷ With respect to the "how-to-use" requirement of 35 U.S.C. § 112, the court found that failure of a Japanese priority application to disclose dosages was not fatal, since one of ordinary skill in the art could determine appropriate dosages.²²⁸

The Federal Circuit in 1993 held, in *In re Ziegler*²²⁹ that a priority claim under 35 U.S.C. § 119 was inadequate because the prior German application did not disclose a practical utility for the claimed

²²⁵ *Jolles*, 628 F.2d at 1327-28.

²²⁶ *Cross v. Iizuka*, 753 F.2d 1040 (Fed. Cir. 1985).

²²⁷ *Id.* at 1051. The court stated:

Today, under the circumstances of the instant case, where a Japanese priority application discloses an *in vitro* utility, i.e., the inhibition of thromboxane synthetase in human or bovine platelet microsomes, and where disclosed *in vitro* utility is supplemented by the similar *in vitro* and *in vivo* pharmacological activity of structurally similar compounds, i.e., the parent imidazole and 1-methylimidazole compounds, we agree with the Board that this *in vitro* utility is sufficient to comply with the practical utility of § 101. *Id.*

²²⁸ *Id.* at 1051-52. As explained by the court:

We agree with the Board, however, that this deficiency in the Japanese priority application is not fatal The Board found that there was sufficient credible evidence that one skilled in the art, without the exercise of inventive skill or undue experimentation, could determine the IC₅₀ dosage level for the imidazole derivatives of the phantom count in the microsome environment. . . . We do not believe that the Board erred in arriving at this conclusion.

Accordingly, we are satisfied that the how-to-use requirement of § 112 has been complied with by the disclosures of the Japanese priority application. *Id.* at 1051-52.

²²⁹ *In re Ziegler*, 992 F.2d 1197 (Fed. Cir. 1993).

polypropylene.²³⁰ The basis for this rejection was the “how to use” requirement of 35 U.S.C. § 112 which, according to the court “incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention.”²³¹ The court reasoned that an application, as a matter of law, cannot enable one of ordinary skill in the art to use an invention under 35 U.S.C. § 112 if, as a matter of fact, the application fails to meet the requirements of 35 U.S.C. § 101.²³² With respect to the utility requirement, the court in *Ziegler* compared the description of the claimed polypropylene as “plastic-like” in that “[t]he granular solid polypropylene obtained may be pressed at 140°C to yield flexible foils which appear transparent in thin films and opaque in thick layers,”²³³ with other cases, including *Petrocarbon*,²³⁴ discussed above, wherein description of the claimed product as a “film” was held to be an insufficient statement of utility.²³⁵ The court commented that the limited comprehension at the time of the German application of the “plastic-like” nature of the claimed polypropylene was, at best, a basis for subsequent discovery of a practical utility:

When Ziegler filed the application in Germany almost 40 years ago, it was a time of competition surrounding the polymerization of polypropylene.... Ziegler’s German application states that propylene had never been previously transformed into a “genuine” plastic, yet then describes the polymers therein including polypropylene as “plastic-like.” We are convinced that, at best, Ziegler was on the way to discovering a practical utility for polypropylene at the time of the filing of the German application; but in that application Ziegler had not yet gotten there.²³⁶

The Federal Circuit relied on *Brenner* to assert that “[t]he utility of a

²³⁰ *Id.* at 1203 (“Because Ziegler’s German application did not disclose a practical utility for polypropylene, Ziegler may not claim the benefit of that application’s filing date under 35 U.S.C. § 119.”).

²³¹ *Id.* at 1200.

²³² *Id.* at 1201 (“If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112.”).

²³³ *Id.*

²³⁴ *Petrocarbon Ltd. v. Watson*, 247 F.2d 800 (D.C. Cir. 1957).

²³⁵ *Ziegler*, 992 F.2d at 1203 (“Like . . . applicant in *Petrocarbon*, . . . Ziegler did not assert any practical use for the polypropylene or its film, and Ziegler did not disclose any characteristics of the polypropylene or its film that demonstrated its utility.”).

²³⁶ *Id.*

chemical compound may not reside in its ‘potential role as an object of use-testing.’”²³⁷ The court further quoted from *Brenner* in stating that “[t]o satisfy 35 U.S.C. § 101, to be able to serve as a predicate for a section 119 claim, the disclosure must assert a ‘specific benefit... in currently available form.’”²³⁸ Despite being “cognizant of Ziegler’s noteworthy contributions to polymer chemistry,” the court was constrained by its interpretation of *Brenner*, whereby usefulness in research was held to be an inadequate basis for patent protection.²³⁹

In a case decided in 1995, *In re Brana*,²⁴⁰ the Federal Circuit again maintained that absence of utility “can be the basis of a rejection under both 35 U.S.C. § 101 and § 112, ¶ 1.”²⁴¹ Specifically, with respect to a decision by the board that “applicant’s specification failed to disclose a specific disease against which the claimed compounds are useful, and therefore, absent undue experimentation, one of ordinary skill in the art was precluded from using the invention,”²⁴² the court stated that favorable comparisons in the specification by applicants to a prior art reference was a sufficient statement of specific use.²⁴³ The Federal Circuit also reversed a second basis for rejection of the claimed compounds by the board wherein, as paraphrased by

²³⁷ *Id.* (quoting *Brenner* at 383 U.S. at 535).

²³⁸ *Id.* (quoting *Brenner*, 383 U.S. at 534-35).

²³⁹ *Id.* (“While we are cognizant of Ziegler’s noteworthy contributions to polymer chemistry, we must nevertheless abide by the principle underlying 35 U.S.C. § 101 that a patent ‘is not a reward for the search, but competition for its successful conclusion.’” (quoting *Brenner* at 536)).

²⁴⁰ *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995).

²⁴¹ *Id.* at 1564, n.12. The court, in a footnote, stated:

This court’s predecessor has determined that absence of utility can be the basis of a rejection under both 35 U.S.C. § 101 and § 112 ¶ 1. *In re Jolles*, 628 F.2d 1322, 1326 n. 11, 206 USPQ 885, 889 n. 11 (C.C.P.A. 1980); *In re Fouche*, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (C.C.P.A. 1971) (“[I]f such compositions are in fact useless, appellant’s specification cannot have taught how to use them.”). Since the Board affirmed the examiner’s rejection based solely on § 112 ¶ 1, however, our review is limited only to whether the application complies with § 112 ¶ 1. *Id.*

²⁴² *Id.*

²⁴³ *Id.* at 1565 (“We conclude that these tumor models represent a specific disease against which the claimed compounds are alleged to be effective. Accordingly, in light of the explicit reference to Paull, applicant’s specification alleges a sufficiently specific use.”).

the Federal Circuit, “even if the specification did allege a specific use, applicants failed to prove that the claimed compounds are useful.”²⁴⁴ In response, the Federal Circuit held that the board was required to provide “evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility,” and did not do so.²⁴⁵ Further, the court stated that even if the Patent Office had “met its initial burden thereby shifting the burden to the applicants to offer rebuttal evidence, applicants proffered sufficient evidence to convince one of skill in the art of the asserted utility” by providing declarations “showing that several compounds within the scope of the claims exhibited significant anti-tumor activity... *in vivo*.”²⁴⁶ The court held that “the prior art further supports the conclusion that one skilled in the art would be convinced of the applicant’s asserted utility,” because “evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility.”²⁴⁷ The court stated that “in view of all the foregoing, we conclude that applicant’s disclosure complies with the requirement of 35 U.S.C. § 112 ¶ 1.”²⁴⁸

II. *Fisher*

A. *Ex parte Fisher*

*Ex parte Fisher*²⁴⁹ was a non-precedential decision by the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences that affirmed rejections of a single claim of a patent application under 35 U.S.C. § 101 for lack of utility and under 35 U.S.C. § 112, first paragraph, “for lack of enablement based on the finding of lack of utility.”²⁵⁰ The rejected claim of the affected patent application, 09/619,643, is as follows:

1. A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of

²⁴⁴ *Id.* at 1565-66.

²⁴⁵ *Id.* at 1566.

²⁴⁶ *Id.* at 1567.

²⁴⁷ *Id.*

²⁴⁸ *Id.* at 1568.

²⁴⁹ *Ex parte Fisher*, 72 U.S.P.Q. 2d 1020 (Bd. Pat. App. Int. 2004) (hereinafter *Fisher I*).

²⁵⁰ *Id.* at 1021.

SEQ ID NO: 1 through SEQ ID NO: 5.²⁵¹

Generally, and as described in the specification, expressed sequence tags (ESTs) “are short sequences of randomly selected clones from a cDNA (or complementary DNA) library which are representative of the cDNA inserts of these randomly selected clones.”²⁵² The ESTs claimed were obtained from a complementary DNA library generated from a particular strain of maize.²⁵³ As described by the board, “the claimed nucleic acid molecules having the sequences identified as SEQ ID NO: 1 through SEQ ID NO: 5, represent five randomly selected nucleic acid molecules isolated from pooled leaf tissue at the time of anthesis.”²⁵⁴ “Anthesis” is the flowering period in plants.²⁵⁵

Utilities for the claimed nucleic acid sequences, as summarized by the examiner, were several, but held by the examiner to be inadequate to meet the requirements either of 35 U.S.C. § 101 or § 112, first paragraph, because they were all “nonspecific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acids being claimed.”²⁵⁶ The examiner summarized the utilities identified in the specification as follows:

The specification teaches that the nucleic acids may be used to produce a plant containing reduced levels of a protein (pg. 11), determining an association between a polymorphism and a plant trait (pg. 11), isolating a genetic region or nucleic acid (pg. 11), determining a level or pattern in a plant cell of a protein in a plant (pg. 11), determining a mutation in a plant whose presence is predictive of a mutation affecting a level or a pattern of a protein (pg. 13), as molecular tags to isolate genetic regions, isolate genes, map genes, and determine gene function (pg. 14), and identifying tissues (pg. 14) [.] The specification states that the nucleic acid ESTs of the present invention can enable the acquisition of molecular markers, which can be used in breeding schemes, genetic and molecular mapping and cloning of agronomically significant genes (pg. 31).²⁵⁷

According to the examiner, “determining whether the claimed nucleic

²⁵¹ *Id.*

²⁵² *Id.*

²⁵³ *Id.*

²⁵⁴ *Ex parte* Fisher, 72 U.S.P.Q. 2d at 1027.

²⁵⁵ *McGraw Hill Dictionary of Scientific and Technical Terms* (6th ed., 2003).

²⁵⁶ *Ex parte* Fisher, 72 U.S.P.Q. 2d at 1022.

²⁵⁷ *Id.*

acids have or do not have a polymorphism would require determining whether there was a polymorphism within such a sequence and then determining how to use this information in a patentably meaningful way.”²⁵⁸

On appeal to the board, appellants emphasized use of the nucleic acid molecules claimed “to identify the presence or absence of a polymorphism in a population of maize plants,” and “to isolate nucleic acid molecules of other plants and organisms.”²⁵⁹ In taking up the appeal, the board stated with respect to polymorphisms that, although there was description in the specification as to “how one would go about determining the existence of a polymorphism,” there was none directed to why the claim sequences would be useful in doing so.²⁶⁰ The board did not delineate how much information about the claimed sequences would be necessary to satisfy a threshold of “substantial utility,” but stated that the specification lacked any information linking those sequences to polymorphisms and, therefore, the specification presented only an “insubstantial use”:

In other words, appellant’s position is that an EST by definition possesses patentable utility because it can be used by itself in determining whether populations share a common genetic heritage. While that may be a “utility,” we do not find that it is a *substantial* utility.

Without knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence or a polymorphism provides the barest information in regard to genetic heritage.... In contrast, at the other end of the “utility spectrum” would be information gleaned from detecting the presence or absence of a poly-

²⁵⁸ *Id.*

²⁵⁹ *Id.*

²⁶⁰ *Id.* at 1026. The board stated that:

“a. *Polymorphisms*

This utility is *discussed* at pages 35-42 of the specification in terms of what polymorphisms are and how one would go about determining the existence of a polymorphism. The discussion in this portion in the specification, however, is not specific to the nucleotide molecules depicted in SEQ. ID NO: 1 through SEQ ID NO: 5 . . .

..The specification does not explain why any of the 32,236 nucleotide molecules disclosed in the specification, more specifically, the five nucleotide molecules depicted in SEQ ID NO: 1 through SEQ ID NO: 5, would in fact be useful in detecting polymorphisms.

Ex parte Fisher, 72 U.S.P.Q. 2d at 1026.

morphism when it is known what effect the gene from which the EST is derived has in the development and/or phenotype of the plant. Somewhere between having no knowledge (the presence circumstances) and having complete knowledge of the gene and its role in the plant's development and/or phenotype lies the line between "utility" and "substantial utility." We need not draw the line or further define it in this case because the facts in this case represent the lowest end of the spectrum, i.e., an insubstantial use.²⁶¹

As applied to use of the sequences as probes or as a source of primers, the board stated that, although the sequences could be employed "to isolate nucleic acid molecules of other plants and organisms," as asserted by appellants, in the absence of "any property in terms of plant trait, or phenotype to any of the nucleotide molecules set forth in SEQ ID NO: 1 through SEQ ID NO: 5.... using the claimed molecules to isolate other molecules, which themselves lack substantial utility, does not represent a substantial utility."²⁶² In essence, the board hinged utility on a reasonable expectation of success in fulfilling stated objectives, such as identification of polymorphisms associated with a plant trait, or phenotype:

The specification does not provide any expectation of successfully using any of the 32,236 nucleic acid molecules disclosed in the specification, or more specifically the five nucleic acid molecules depicted as SEQ ID NO: 1 through SEQ ID NO: 5, to isolate promoters of tissue enhanced, tissue specific, cell-specific, cell-type, developmentally or environmentally regulated expression profiles....

....

Accordingly, despite appellant's assertion to the contrary, there is no reasonable expectation that any of the claimed nucleic acid molecules would be capable of isolating a promoter that was only active in leaves at the time of anthesis.²⁶³

The court relied on *Brenner* to conclude that the utility requirement of 35 U.S.C. § 101 had not been met:

We recognize appellants' argument [that] "[a]n invention may be 'less effective than existing devices but nevertheless meet the statutory criteria for patentability.'"... While

²⁶¹ *Id.*

²⁶² *Id.*

²⁶³ *Id.* at 1027.

we agree with appellants' statement, we fail to see how it applies to appellants' claimed invention, wherein there is no evidence or expectation that the claimed nucleic acid molecules would be "effective" at all. In this regard, we remind appellants that an invention does not have utility sufficient to satisfy § 101 until it is "refined and developed" to the point of providing a specific benefit in currently available form. See e.g., *Brenner*, 383 U.S. at 434, 148 USPQ at 695.²⁶⁴

Moreover, in response to appellants' argument, as stated by the board, that "the claimed nucleic acids are useful because those of skill in the art could experiment with them and figure out for themselves what any observed experimental results might mean,"²⁶⁵ the board drew a parallel with *Brenner*, stating that "[j]ust as the process claimed in *Brenner* lacked utility because the specification did not disclose how to use the end-product, the products claimed here lack utility, because even if used in gene expression assays, the specification does not disclose how to use SEQ ID NO: 1 – [5] specific gene expression data."²⁶⁶ The board further found that, unlike "EST databases, clone sets or microarrays," appellants' claimed nucleotide sequences would each provide only a single data point and, as such, do not constitute a "substantial use."²⁶⁷ Further, because appellants argued that the rejection for lack of enablement under 35 U.S.C. § 112 should be reversed for the same reasons the examiner's rejection under 35 U.S.C. § 101 should be reversed, the board affirmed the enablement rejection on the same basis that the rejection under 35 U.S.C. § 101 was affirmed.²⁶⁸ A rejection by the examiner for lack

²⁶⁴ *Id.* at 1027-28.

²⁶⁵ *Ex parte* Fisher, 72 U.S.P.Q. 2d at 1029.

²⁶⁶ *Id.*

²⁶⁷ *Id.* As stated by the board:

Appellants argue that ESTs have real world value as seen from the "growth of a multimillion dollar industry in the United States premised on the usefulness of ESTs" . . . Suffice it to say, the claims on appeal are not directed to EST databases, clone sets and/or microarrays. Again, it is not seen that the one data point which may be provided by using the uncharacterized nucleic acid molecules of SEQ ID NO: 1 through SEQ ID NO: 5 in such devices represents a substantial use." *Id.*

²⁶⁸ *Ex parte* Fisher, 72 U.S.P.Q. 2d at 1029. The board stated: Appellants assert this rejection [under 35 U.S.C. § 112, first paragraph, for lack of enablement] should be reversed for the same reasons set forth in their arguments

of written description under 35 U.S.C. § 112, first paragraph, was reversed by the board.²⁶⁹

B. *In re Fisher*

On appeal to the Federal Circuit, the decision by the board was affirmed by a panel that included Chief Judge Michel, and Circuit Judges Bryson and Rader.²⁷⁰ Judge Rader dissented.²⁷¹ Writing for the majority, Chief Judge Michel stated that the position of the government, and of *amici* in support of the government, was that “general and speculative” research plans do not provide “a specific and substantial benefit in currently available form.”²⁷² As summarized by the majority, *amici* advocated that, because the claimed ESTs are only “objects of further research aimed at identifying what genes of unknown function are expressed during anthesis and what proteins of unknown function are encoded by those genes,” and “[u]ntil the corresponding genes and proteins have a known function,... the claimed ESTs lack utility under § 101 and are not patentable.”²⁷³ The court agreed with the government and *amici*, stating that the Supreme Court in *Brenner* “announced a more rigorous test”²⁷⁴ than that of simply determining “whether the invention in question is ‘frivolous and insignificant’” and consequently “allowing the patenting of any invention not positively harmful to society.”²⁷⁵ As interpreted by the court in *Fisher II*, the test announced by the Court in *Brenner* was that of a *quid pro quo* in exchange for patent monopoly of substantial utility, whereby the claimed invention provides a specific benefit:

The Supreme Court observed that Justice Story’s definition “sheds little light on our subject,” on the one hand framing the relevant inquiry as “whether the invention in question is ‘frivolous and insignificant’” if narrowly read, while on the other hand “allowing the patenting of any invention not positively harmful to society” if more broadly read. In its

regarding the rejection under 35 U.S.C. § 101. Thus our conclusion with respect to the § 101 issue will also apply to this aspect of the § 112 (enablement) issue. On this basis, we affirm the rejection of claim 1 under the enablement provision of 35 U.S.C. § 112, first paragraph. *Id.*

²⁶⁹ *Id.* at 1030.

²⁷⁰ *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005) (hereinafter *Fisher II*).

²⁷¹ *Id.* at 1379 (Rader, J., dissenting).

²⁷² *Id.* at 1370.

²⁷³ *Id.*

²⁷⁴ *Id.* at 1371.

²⁷⁵ *Id.*

place, the Supreme Court announced a more rigorous test, stating:

The basic *quid pro quo* contemplated by the Constitution and the Congress for granting the 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.²⁷⁶

Judge Michel then recited the Utility Examination Guidelines,²⁷⁷ incorporated by the Patent and Trademark Office into the Manual of Patenting and Examining Procedure (MPEP) stating that: “[u]tilities that require or constitute carrying out further research to identify or reasonably confirm a ‘real world’ context of use are not substantial utilities.”²⁷⁸ The court also characterized “research tools,” as “a term often given to inventions used to conduct research,” and then quoted the MPEP as a caution by the PTO against patenting inventions “useful only in a research setting” because there is a distinction the PTO must make “between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm.”²⁷⁹ The court found that, “[t]he PTO standards for assessing whether a claimed invention has a specific and substantial utility comport with this court’s interpretation of the utility requirement of § 101.”²⁸⁰

The court concluded that Fisher did not establish a substantial utility because none of the seven described uses of the claimed ESTs had been proven to be successful.²⁸¹ Neither did Fisher establish a “specific” utility under § 101 because Fisher did not distinguish the five claimed ESTs “apart from the more than 32,000 ESTs disclosed in the ‘643 application or indeed from any EST derived from any organ-

²⁷⁶ *Id.* (quoting *Brenner*, 383 U.S. at 534-35) (emphasis added in *Fisher II*).

²⁷⁷ *Utility Examination Guidelines*, 66 Fed. Reg. 1092 (January 5, 2001).

²⁷⁸ *Fisher II*, 421 F.3d at 1372 (quoting (MPEP § 2107.01, 8th ed. 2001, rev. May 2004)).

²⁷⁹ *Id.*

²⁸⁰ *Id.*

²⁸¹ *Id.* at 1374 (“Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the ‘643 application, we have no choice but to conclude that the claimed ESTs do not have a ‘substantial’ utility under § 101.”).

ism.”²⁸² Commercial success was dismissed as a basis for utility in view of the fact that there was no evidence “that agricultural companies have purchased or even expressed any interest in the claimed ESTs.”²⁸³ With respect to enablement, the court agreed with the PTO that an invention for which utility under § 101 has not been established cannot meet the enablement requirement of § 112.²⁸⁴ The board’s decision, that Claim 1 of the ‘643 patent failed to establish utility under § 101 and was not enabling under § 112, first paragraph, was affirmed.²⁸⁵

²⁸² *Id.* The court stated:

Nothing about Fisher’s seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the ‘643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101.

Fisher II, 421 F.3d at 1374.

²⁸³ *Id.* at 1377-78.

Fisher’s reliance on the commercial success of general EST databases is also misplaced because such general reliance does not relate to the ESTs at issue in this case. Fisher did not present any evidence showing that agricultural companies have purchased or even expressed any interest in the claimed ESTs. And, it is entirely unclear from the record whether such business entities ever will. Accordingly, while commercial success may support the utility of an invention, it does not do so in this case. *Id.*

²⁸⁴ *Id.* at 1378.

We agree with the government. It is well established that the enablement requirement of § 112 incorporates the utility requirement of § 101. The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112.

Id. (quoting *Ziegler*, 992 F.2d at 1200-01).

²⁸⁵ *Fisher II*, 421 F.3d at 1379.

We conclude that substantial evidence supports the Board’s findings that each of the five claimed ESTs lacks a specific and substantial utility and that they are not enabled. Accordingly, the Board’s decision affirming the final rejection of claim 1 of the ‘643 patent for

In his dissent, Judge Rader stated, contrary to the majority opinion, that, as research tools, ESTs have a “specific” and “substantial” utility sufficient to meet the statutory threshold under § 101:

Several, if not all, of Fisher’s asserted utilities claim that ESTs function to study other molecules. In simple terms, ESTs are research tools. Admittedly ESTs have use only in a research setting. However, the value and utility of research tools generally is beyond question, even though limited to a laboratory setting.... Thus, if the claimed ESTs qualify as research tools, then they have a “specific” and “substantial” utility sufficient for § 101.²⁸⁶

Judge Rader specifically noted that neither the board nor the court ever contended that the ESTs were “unable to perform” the utilities that were identified by Fisher in the ‘643 patent application, and thereby deprived Fisher of an “opportunity to provide evidence in rebuttal”:

In addition, this court faults Fisher for not presenting evidence of utility showing that the claimed ESTs “have been used in the real world.” To the contrary, this court misapprehended the proper procedure. Fisher asserted seven different utilities. The Board rejected two of these assertions outright as “insubstantial.”... This summary dismissal deprived Fisher of any chance to proffer evidence. Rather than fault Fisher for not presenting evidence it was prevented from offering, this court should instead observe that the Board did not satisfy its burden of challenging Fisher’s presumptively correct assertion that the ESTs were *capable* of performing those functions. See MPEP § 2107.02(iv) at 21-40 (noting that the initial burden is on the office to establish a *prima facie* case as to lack of utility and to provide evidentiary support thereof); *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (where an applicant has asserted utility in the disclosure, the Patent Office has the initial burden of challenging this presumptively correct assertion of utility).

Abandoning the proper legal procedure, the Board reasoned that the molecules studied with these ESTs showed no particular use, therefore, the ESTs themselves also lacked utility. In so ruling, the Board did not reject

lack of utility under § 101 and lack of enablement under § 112, first paragraph, is affirmed. *Id.*

²⁸⁶ *Id.* at 1379 (Rader, J., dissenting).

Fisher's utilities on the basis that the ESTs were *unable to perform* the purported utilities. Thus, the Board did not establish a *prima facie* challenge to the ESTs' ability to perform these two utilities. Without anything to rebut, Fisher had no obligation or opportunity to provide evidence in rebuttal.²⁸⁷

Judge Rader dissented from affirming the board's decision because the board failed to properly establish "that Fisher did not supply evidence of the ESTs' ability to perform the asserted utilities."²⁸⁸

Judge Michel, in writing for the majority, declined to comment on concerns raised by the Patent Office and *amici* that "allowing EST patents without proof of utility would discourage research, delay scientific discovery, and thwart progress in the 'useful Arts' and 'Science.'"²⁸⁹ Rather, the court stated that:

The concerns of the government and *amici*, which may or may not be valid, are not ones that should be considered in deciding whether the application for the claimed ESTs meets the utility requirement of § 101.... They are public policy considerations which are more appropriately directed to Congress as the legislative branch of government, rather than this court as a judicial body responsible simply for interpreting and applying statutory law.²⁹⁰

The court specifically avoided policy considerations in its conclusion that the Fisher patent application did not meet the utility requirement of 35 U.S.C. § 101.²⁹¹ Judge Rader, nevertheless, imputed, at least to the board, a policy of not granting exclusive rights to subject matter that it views as "contributing 'insubstantially' to the advance to the useful arts":

In truth, I have some sympathy with the Patent Office's dilemma. The Office needs some tool to reject inventions that may advance the "useful arts" but not sufficiently to warrant the valuable and exclusive right of a patent. The Patent Office has seized upon this utility requirement to re-

²⁸⁷ *Id.* at 1381 (Rader, J., dissenting).

²⁸⁸ *Id.* ("Thus, I respectfully disagree with this court's conclusion that the Board's decision can be affirmed on the basis that Fisher did not supply evidence of the EST's ability to perform the asserted utilities."). (Rader, J., dissenting).

²⁸⁹ *Fisher II*, 421 F.3d at 1378.

²⁹⁰ *Id.*

²⁹¹ *Id.* ("Policy reasons aside, because we conclude that the utility requirement of Section 101 is not met, we hold that Fisher is not entitled to a patent for the five claimed ESTs.").

ject these research tools as contributing “insubstantially” to the advance of the useful arts.²⁹²

Judge Rader criticized use of the utility requirement “to reject inventions that may advance the ‘useful arts’ but not sufficiently... because it lacks any standard for assessing the state of the prior art and the contributions of the claimed advance.”²⁹³ Instead, according to Judge Rader, “the proper tool for assessing sufficient contribution to the useful arts is the obviousness requirement of 35 U.S.C. § 103,”²⁹⁴ despite the legal precedent of *In re Deuel*²⁹⁵ that Judge Rader characterized as “[depriving] the Patent Office of the obviousness requirement for genomic inventions.”²⁹⁶ Judge Rader implored the Patent Office to “seek ways to apply to correct test, the test used worldwide for such assessments (other than in the United States), namely inventive step or obviousness.”²⁹⁷ Judge Rader would also have reversed the enablement rejection “because it was a consequence of the finding of lack of utility.”²⁹⁸

C. The Relevance of *In re Deuel*

In re Deuel,²⁹⁹ was an appeal of a decision by the Board of Patent Appeals and Interferences to reject claims directed to specific nucleic acid sequences and to nucleic acid sequences generally encoding specific human and bovine heparin-binding growth factors (HBGFs)³⁰⁰

²⁹² *Id.* at 1381-82 (Rader, J., dissenting).

²⁹³ *Fisher II*, 421 F.3d at 1382 (Rader, J., dissenting).

²⁹⁴ *Id.* (Rader, J., dissenting).

²⁹⁵ *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995).

²⁹⁶ *Fisher II*, 412 F.3d at 1382 (Rader, J., dissenting).

²⁹⁷ *Id.* (Rader, J., dissenting) (“Nonetheless, rather than distort the utility test, the Patent Office should seek ways to apply the correct test, the test used worldwide for such assessments (other than in the United States), namely inventive step or obviousness.”).

²⁹⁸ *Id.* (Rader, J., dissenting).

²⁹⁹ *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995).

³⁰⁰ *Id.* at 1555. The court summarized the scope of the rejected claims, as follows:

Claims 4 and 6 generically encompass *all* isolated/purified DNA sequence (natural and synthetic) encoding human and bovine HBGFs, despite the fact that Deuel’s application does not describe the chemical structure of, or tell how to obtain, any DNA or cDNA except the two disclosed cDNA molecules Claims 5 and 7, on the other hand, are directed to the specifically disclosed cDNA molecules encoding human and bovine HBGFs, respectively. *Id.*

as obvious under 35 U.S.C. § 103.³⁰¹ The examiner had rejected claims over a combination of references, one of which disclosed “heparin-binding brain mitogens,” and suggested that although “brain-specific,” homology may exist among species.³⁰² The other reference employed by the examiner generally described use of gene probes to screen DNA or cDNA libraries.³⁰³ As stated by the court, the examiner’s position was that, in view of the partial, N-terminal sequence of a heparin-binding protein disclosed by the first reference, Bohlen, and the gene cloning technique described in the other reference, Maniatis, it would have been obvious to one of ordinary skill art to clone Deuel’s claimed genes.³⁰⁴ The board affirmed the examiner’s decision as having established a *prima facie* case of obviousness, thereby presenting to the Federal Circuit the issue of patentability of specific nucleic acid sequences employing generally known techniques of gene cloning:

Thus, the appeal raises the important question whether the combination of a prior art reference teaching a method of gene cloning, together with a reference disclosing a partial amino acid sequence of a protein, may render DNA and cDNA molecules encoding the protein *prima facie* obvious under § 103.³⁰⁵

The court reversed the rejection for all of the claims. With respect to specific nucleic acid sequences, the court stated that “[n]ormally a *prima facie* case of obviousness is based upon structural similarity, *i.e.*, an established structural relationship between a prior art com-

³⁰¹ *Id.* at 1555-56 (“During prosecution, the examiner rejected claims 4-7 under 35 U.S.C. § 103 as unpatentable over the combined teachings of Bohlen and Maniatis.”).

³⁰² *Id.* at 1556 (“The Bohlen reference discloses a group of protein growth factors designated as heparin-binding brain mitogens (“HBBMs”) Bohlen teaches that HBBNs are brain-specific, and suggests that proteins may be homologous between species. The reference provides no teaching concerning DNA or cDNA coding for HBBMs.”).

³⁰³ *Id.* (“Maniatis describes a method of isolating DNAs or cDNAs by screening a DNA or cDNA library with a gene probe. The reference outlines a general technique for cloning a gene; it does not describe how to isolate a particular DNA or cDNA molecule.”).

³⁰⁴ *In re Deuel*, 51 F.3d at 1556 (“The examiner asserted that, given Bohlen’s disclosure of a heparin-binding protein and its N-terminal sequence and Maniatis’s gene cloning method, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to clone a gene for HBGF.”).

³⁰⁵ *Id.* at 1557.

pound and the claimed compound,”³⁰⁶ and, as applied to Deuel’s claims directed to particular nucleic acid sequences, “the prior art does not disclose any relevant cDNA molecules, let alone close relatives of the specific, structurally-defined cDNA molecules of claims 5 and 7 that might render them obvious.”³⁰⁷ More generally, the court stated that “[a] prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein.”³⁰⁸ Interestingly, the court contemplated that a “different result might pertain, however, if there were prior art, *e.g.*, a protein of sufficiently small size and simplicity, so that lacking redundancy, each possible DNA would be obvious over the protein.”³⁰⁹ The court succinctly stated: “What cannot be contemplated or conceived cannot be obvious.”³¹⁰

As applied to Deuel’s broader claims to nucleic acid sequences encoding specific human or bovine heparin-binding growth factors, the court stated that, although a claim directed generically to all DNA sequences encoding a particular protein may be obvious in view of a known protein, the Bohlen reference disclosed only a partial amino acid sequence and, therefore, Deuel’s genus claims were not obvious:

Claims 4 and 6 are of a different scope than claims 5 and 7. As is conceded by Deuel, they generically encompass all DNA sequences encoding human and bovine HBGFs. Written in such a result-oriented form, claims 4 and 6 are thus tantamount to the general idea of all genes encoding the protein, all solutions to the problem. Such an idea might have been obvious from the *complete* amino acid sequence of the protein, coupled with knowledge of the genetic code, because this information may have enabled a person of ordinary skill in the art to envision an idea of, and, perhaps with the aid of a computer, even identify all members of the claimed genus. The Bohlen reference, however, only discloses a partial amino acid sequence, and thus it appears that, based on the above analysis, the claimed genus would not have been obvious over this prior

³⁰⁶ *Id.* at 1558.

³⁰⁷ *Id.*

³⁰⁸ *Id.*

³⁰⁹ *In re Deuel*, 51 F.3d at 1559.

³¹⁰ *Id.* at 1558.

art disclosure.³¹¹

Contrary to Judge Rader's broad comment and his dissent from the majority opinion in *Fisher II*, *Deuel* did not preclude finding obviousness in "genomic inventions." Rather, as discussed above, the court in *Deuel* specifically contemplated obviousness in at least two situations; where a protein is sufficiently small and simple, each possible DNA would be obvious over the protein; and where a protein is known, thereby rendering obvious generic claims encompassing all DNA sequences encoding the protein (given the known degeneracy of the genetic code). The holding in *Deuel* is limited to findings of non-obviousness of nucleic acid sequences that depend upon what is known about an encoded protein (e.g., whether the complete sequence or only a partial sequence is known, and the "size and simplicity" of the protein) and in view of claim scope (e.g., whether the claim is generic to all nucleic acid sequences encoding the protein, or a specific nucleic acid sequence). As stated by the Federal Circuit, application of generally known techniques does not necessarily render resulting specific compounds obvious: "The fact that one can conceive a general process in advance for preparing an *undefined* compound does not mean that a claimed *specific* compound was precisely envisioned and therefore obvious."³¹²

III. Analysis of *Fisher*: Of Elephant Pits and Microscopes

Although legal precedent clearly establishes that failure to establish utility under 35 U.S.C. § 101 precludes, as a matter of law, a finding that the application enables one of ordinary skill in the art to use the invention, under 35 U.S.C. § 112, first paragraph,³¹³ the converse also has been true whereby lack of enablement constitutes a basis for finding lack of utility.³¹⁴ The court in *Fisher II* drew a similar conclusion as applied to utility of claimed ESTs: "Consequently, because *Fisher* failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice but to conclude that the claimed ESTs do not have a 'substantial' utility under § 101."³¹⁵

The difference, in fact, between the holding by the Supreme Court in *Brenner*, wherein utility was found lacking with respect to claimed

³¹¹ *Id.* at 1560.

³¹² *Id.* at 1559.

³¹³ *See, for example, Ziegler*, 992 F.2d 1201.

³¹⁴ *See, for example, Brenner*, 383 U.S. at 531-32 ("Indeed, respondent himself recognized that the presumption that adjacent homologues have the same utility has been challenged in the steroid field because of 'a greater known unpredictability of compounds in that field.'").

³¹⁵ *Fisher II*, 421 F.3d at 1374.

steroids, and the majority in *Fisher II*, was that in *Brenner*, there was evidence supporting a finding of lack of predictability among homologues of compounds in the field. Moreover, other cases subsequent to *Brenner*, such as *Jolles*³¹⁶ and *Cross*³¹⁷ did, indeed, hold that the utility requirement under 35 U.S.C. § 101 can be met, despite lack of proof that claimed compounds have been successfully used for an intended purpose. As discussed above, the court in *Brana* also referred to application of 35 U.S.C. § 101 where applicants provided favorable evidence of a sufficiently specific use.³¹⁸

In *Fisher*, no evidence of predictability, or of lack of predictability, was provided to or by the Patent Office. Rather, the board in *Fisher I* and the court in *Fisher II* recognized that in *Jolles* and *Cross* utility had been established by evidence of structural similarity and testing

³¹⁶ *Jolles*, 628 F.2d at 1327-28. The court in *Jolles*, for example, stated:

The Maral declarations establish that the eight [embodiment of the claimed] compounds have substantial activity against experimental tumors in mice The claimed compounds have a close structural relationship to daunorubicin and doxorubicin, both known to be useful in cancer chemotherapy. Considering these facts in the record before us, we conclude that one of ordinary skill in the art would accept appellants' claimed utility in humans as valid and correct. *Id.*

³¹⁷ *Cross*, 753 F.2d 1051. The court in *Cross* stated:

Today, under the circumstances of the instant case, where a Japanese priority application disclosed an *in vitro* utility, i.e., the inhibition of thromboxane synthetase in human or bovine platelet microsomes, and where disclosed *in vitro* utility is supplemented by the similar *in vitro* and *in vivo* pharmacological activity of structurally similar compounds, i.e., the parent imidazole and 1-methylimidazole compounds, we agree with the Board that this *in vitro* utility is sufficient to comply with the practical utility of § 101. *Id.*

³¹⁸ *Brana*, 51 F.3d at 1565-66. The court in *Brana* stated:

The second basis for the Board's rejection was that, even if the specification did allege a specific use, applicants failed to prove that the claimed compounds are useful. Citing various references, the Board found, and the Commissioner now argues, that the tests offered by applicants to prove utility were inadequate to convince one of ordinary skill in the art that the claimed compounds are useful as antitumor agents.¹⁶

16. As noted, this would appear to be a § 101 issue, rather than § 112. *Id.*

that was well recognized in the art to be predictive.³¹⁹ However, reliance by the board on cases where utility was established in view of evidence presented by patent applicants of a reasonable expectation of success does not excuse the board from having to make a *prima facie* case showing that the claimed ESTs lack utility and of providing sufficient evidentiary evidence to support “factual assumptions relied upon in establishing the *prima facie* showing,”³²⁰ as required by the guidelines admitted by the majority opinion to be consistent with the position of the Federal Circuit in *Fisher II*.³²¹

The majority in *Fisher II* also recited the government and amici arguments in support of the government that “Fisher failed to meet the standard [of utility under 35 U.S.C. § 101] because Fisher’s alleged uses are so general as to be meaningless”³²² and that “the seven utilities alleged by Fisher are merely starting points for further research, not the end point of any research effort.”³²³ In support of the arguments by the government and by amici, the court compared the facts of the Fisher application to those in *Kirk* and *Joly*.³²⁴ Referring to both the ESTs of the Fisher application and the claimed intermediates at issue in *Kirk* and *Joly* as “research intermediates,”³²⁵ the court invoked the rationale of *Kirk* and *Joly* whereby, as stated by the *Kirk* court, and quoted by the majority in *Fisher II*:

“We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play this sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound *in terms of possible use so general as to be meaningless* and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence

³¹⁹ *Fisher I*, 72 U.S.P.Q. at 1024-25; *Fisher II*, 421 F.3d at 1376-77.

³²⁰ MPEP at § 2107.02(IV) §§ 2100-40 through 2100-41.

³²¹ *Fisher II*, 421 F.3d at 1372.

³²² *Id.* at 1370.

³²³ *Id.*

³²⁴ *Id.* at 1374 (“In addition to approving of the Board’s reliance on *Brenner*, we observe that the facts here are even more analogous to those presented in *Kirk*, 54 C.C.P.A. 1119, 376 F.2d 936, and *In re Joly*, 54 C.C.P.A. 1159, 376 F.2d 906 (C.C.P.A. 1967) . . .”).

³²⁵ *Id.* at 1375 (“Just as the claimed compounds in *Kirk* and *Joly* were useful only as intermediates in the synthesis of other compounds of unknown use, the claimed ESTs can only be used as research intermediates in the identification of underlying protein-encoding genes of unknown function. The rationale of *Kirk* and *Joly* thus applies here.”).

intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.”³²⁶

The court further stated that the rationale had been “drawn from principles set forth by the Supreme Court in *Brenner*”³²⁷ and, “granting a patent to Fisher for its five claimed ESTs would amount to a hunting license because the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes.”³²⁸ The court’s holding acknowledged the “noteworthy contribution” made by Fisher, as did the court in *Ziegler*,³²⁹ but denied patentability for failure to meet the utility requirement premised only on usefulness as a research tool:

The claimed ESTs themselves are not an end of Fisher’s research effort, but only tools to be used along the way in the search for a practical utility. Thus, while Fisher’s claimed ESTs may add a noteworthy contribution to biotechnology research, our precedent dictates that the ‘643 application does not meet the utility requirement of § 101 because Fisher does not identify the function for the underlying protein-encoding genes. Absent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well defined, real world benefit to the public meriting the grant of a patent.³³⁰

Prior to *Brenner*, research was a legitimate basis for practical utility.³³¹ For example, an earlier opinion by Judge Rich discussed

³²⁶ *Fisher II*, 421 F.3d at 1375 (quoting *Kirk*, 376 F.2d at 942).

³²⁷ *Id.*

³²⁸ *Id.* at 1376.

³²⁹ *Ziegler*, 992 F.2d at 1203 (“While we are cognizant of *Ziegler*’s noteworthy contributions to polymer chemistry, we must nevertheless abide by the principle underlying 35 U.S.C. § 101 that a patent ‘is not a reward for a search, but compensation for its successful conclusion.’”).

³³⁰ *Fisher II*, 421 F.3d at 1376.

³³¹ The court in *Fisher II* quoted Judge Rich’s post-*Brenner* opinion in *Nelson v. Bowler* for interchangeability in use of the terms “practical utility” and “real world” utility.

Courts have used the labels “practical utility” and “real world” utility interchangeably in determining whether an invention offers a “substantial” utility. Indeed, the Court of Customs and Patent Appeals stated that “[p]ractical utility’ is a shorthand way of attributing ‘real world’ value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery

above, *In re Nelson*,³³² which preceded *Brenner*, explicitly considered research to be an example of “practical” utility.³³³ Moreover, even though the Supreme Court in *Brenner* stated that *Nelson* began a trend of the C.C.P.A. that “moved sharply away from *Brenner*,”³³⁴ because *Nelson* had reversed a rejection by the Patent Office of claims directed to chemical intermediates that were “‘useful to chemists doing research on steroids,’ despite the absence of evidence that any of the steroids thus ultimately produced were themselves ‘useful,’”³³⁵ the Court did not expressly void usefulness in research as a basis for utility under 35 U.S.C. § 101.

Judge Rich in his dissent in *Kirk* points out an apparent contradiction in *Brenner* whereby the Court states that “Congress intended that no patent be granted on the chemical compound whose sole ‘utility’ consists of its potential role as an object of use testing,”³³⁶ but then expressly states, in footnote 17, that “we express no view as to the patentability of a process whose sole demonstrated utility is to yield a product shown to inhibit the growth of tumors in laboratory animals.”³³⁷ Upon inspection, however, there is no discrepancy between the two statements made by the Supreme Court. In particular, in the sentence immediately preceding the Court’s statement with regard to compounds “whose sole ‘utility’ consists of its potential role as an object of use testing,”³³⁸ the Court cited three cases as being “in accord with the view that a product may not be patented absent a showing of utility greater than any adduced in the present case.”³³⁹ Those three cases were *Bergel*, *Nelson* and *Folkers*.³⁴⁰ As discussed above, both *Nelson* and *Folkers* were cases where utility was held to be met precisely because the claimed compounds were useful in research. Further, the third case, *Bergel*, was also cited in footnote 17 of the

in a manner which provides *some immediate benefit to the public.*”

Fisher II, 421 F.3d at 1365 quoting *Nelson v. Bowler*, 626 F.2d 853, 856. (emphasis added).

³³² *Nelson*, 280 F.2d 172 (C.C.P.A. 1960).

³³³ *Id.* at 180 (“Surely a new group of steroid intermediates is *useful to chemists doing research* on steroids [*sic*], and in a ‘practical’ sense too. Such intermediates are ‘useful’ under § 101.”).

³³⁴ *Brenner*, 383 U.S. at 530.

³³⁵ *Id.*

³³⁶ *Kirk*, 376 F.2d at 949 (Rich, J., dissenting) (quoting *Brenner*, at 383 U.S. at 535).

³³⁷ *Brenner*, 383 U.S. at 531, n.17.

³³⁸ *Id.* at 535.

³³⁹ *Id.*

³⁴⁰ *Id.* at n.23.

opinion by the Supreme Court as an example of a situation where the Court expressed “no view as to the patentability of a process whose sole demonstrated utility is to yield a product shown to inhibit the growth of tumors in laboratory animals.”³⁴¹ The point, as stated by Judge Rich in his dissent in *Kirk*, is that the Court in *Brenner* was not precluding usefulness in research as a basis for utility under 35 U.S.C. § 101, but instead was mandating only that there be “a showing of utility greater than any adduced in the present case”³⁴² of *Brenner*. In contrast to the cases identified by the Supreme Court, all three of which based utility on experimental models or usefulness in research, the Manson patent application included “no disclosure of a use for the compound, reliance being placed on a mere assertion that utility was obvious.”³⁴³ In other words, the distinction between previous cases cited with approval by the Court and the Manson patent application at issue in *Brenner* was, as stated by Judge Rich, the difference “between *some* disclosure of utility and *none*.”³⁴⁴

The majority in both *Kirk* and *Joly*, however, interpreted *Brenner* as denying utility to materials, the sole utility of which is described as being “useful in research”³⁴⁵ or the “subject of research.”³⁴⁶ These cases and their progeny presumed that, regardless of the contribution being made to the field, usefulness as an object of research was inadequate under 35 U.S.C. § 101 and, consequently, not enabled under 35 U.S.C. § 112, first paragraph. The basis for these holdings is not properly founded on *Brenner* and, in fact, is unsupported by any earlier legal precedent.

The correct basis for analyzing patentability of claimed subject matter in a patent or application specification having a statement of intended use and for which an enabling description has been provided, albeit as a research tool, can be found, not in 35 U.S.C. § 101 or even under 35 U.S.C. § 112, but in the statutory requirement for nonobviousness under 35 U.S.C. § 103. As indicated above, very

³⁴¹ *Id.* at 531, n.17.

³⁴² *Id.* at 535.

³⁴³ *Kirk*, 376 F.2d at 949 (Rich, J., dissenting).

³⁴⁴ *Id.* at 948 (Rich, J., dissenting).

³⁴⁵ *Kirk*, 376 F.2d at 945 (“There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of ‘useful to research’ or ‘useful as building blocks of value to the research’ was recognized, and clearly rejected, by the Supreme Court....”).

³⁴⁶ *Joly*, 376 F.2d at 908. (“Nor is it enough that the product disclosed to be obtained from the intermediate belongs to some class of compounds which is now, or in the future might be, the subject of research to determine some specific use.”) (quoting *Kirk*, 376 F.2d at 945).

early interpretations of usefulness contrasted inventions that were “slight and trivial as being so obvious and apparent that it cannot be considered a discovery,” with those that were “trivial or frivolous in respect to its effect upon industry and production.”³⁴⁷ The former was considered to render the patent “void as being for a subject that is not an invention,” while the latter was a question of degree that was considered “immaterial” to the question of patentability.³⁴⁸ Out of this distinction grew a dichotomy between “new” and “useful,” whereby novelty was based on being “substantially different from anything that has been known or used before,” and “useful” was synonymous with being “capable of use,” while not being “injurious to the well-being, good policy or sound morals of society.”³⁴⁹ As described by Curtis, and as discussed above, although both interpretations were applied to the phrase “new and useful” in the early Patent Acts, the phrase “new and useful invention” became limited to the “class of inventions which can be the subjects of valid patents,” as opposed to being “one of the tests of novelty, or of substantial difference of structure or mode of operation.”³⁵⁰

Obviousness became codified as a statutory requirement distinct from novelty under the Patent Act of 1952.³⁵¹ Despite Curtis’ caution, and evolution of distinct doctrines of novelty and obviousness, courts have, at times, confused “positive utility” with “comparative or relative utility,” such as was the case in *In re Holmes*,³⁵² where a pipe with a seam was construed to have no utility because it had “no special utility” nor was it “particularly adapted for any use other than that to do which any pipe would be commonly put.”³⁵³ The distinction between “positive utility” and “comparative or relative utility” also was the basis for Judge Rich’s warning in his dissent in *Kirk*, where the majority opinion held that statements of “biological activity” and “biological properties” were inadequate under 35 U.S.C. §§ 101 and 112.³⁵⁴ Specifically, Judge Rich analogized the distinction

³⁴⁷ WILLARD PHILLIPS, *THE LAW OF PATENTS FOR INVENTIONS: INCLUDING THE REMEDIES IN LEGAL PROCEEDINGS IN RELATION TO PATENT RIGHTS* (1873) at 142.

³⁴⁸ *Id.*

³⁴⁹ See *Curtis I*, *supra* note 34, at 15.

³⁵⁰ See *Curtis II*, *supra* note 53, at 110.

³⁵¹ Kenneth J. Burchfiel, *Revising the “Original” Patent Clause: Pseudohistory in Constitutional Construction*, 2 HARV. J.L. & TECH. 155 (1989)(discussing early developments of non-obviousness requirement).

³⁵² *In re Holmes*, 63 F.2d 642 (C.C.P.A. 1933).

³⁵³ *Id.* at 644.

³⁵⁴ *Kirk*, 376 F.2d at 941 (Rich, J., dissenting).

between “*utility per se*” and “*unobviousness*... in terms of *degree* of utility as an *indication* thereof,” to a “mental elephant pit.”³⁵⁵ Further, this “mental elephant pit” was what Judge Rader was referring to in his dissent, where he stated “[t]he Patent Office has seized upon this utility requirement to reject these research tools as contributing ‘insubstantially’ to the advance of the useful arts.”³⁵⁶ As further stated by Judge Rader, “[t]he utility requirement is ill suited to that task, however, because it lacks any standard for assessing the state of the prior art and the contributions of the claimed advance.”³⁵⁷

As did Curtis 150 years ago, and Judge Rich 40 years ago, Judge Rader linked sufficiency of contribution to the useful arts, not with utility *per se*, but with a requirement for non-obviousness (i.e., “comparative or relative utility,” as compared to “positive utility,” in terms employed by Curtis). Evidence in support of Judge Rader’s assessment, that the court in *Fisher II* based its holding on sufficiency of contribution rather than the fact of utility, can be found in its summary of the government’s analogy with other patentable research tools, such as the microscope. Specifically, the court in *Fisher II*, like the government, contrasted the “specific benefit of optically magnifying an object to immediately reveal its structure”³⁵⁸ afforded by a microscope, with Fisher’s claimed ESTs, which “can only be used to detect the presence of genetic material having the same structure as the EST itself.”³⁵⁹ Both the government and the court overlooked the fact that the ability of an EST “to detect the presence of genetic material having the same structure as the EST itself” is a specific use; whether it is a sufficiently beneficial contribution to the art is a question of inventiveness properly considered under 35 U.S.C. § 103. Moreover, the majority opinion clearly based its holding with

³⁵⁵ *Id.* at 955 (Rich, J., dissenting). Judge Rich stated that:

In considering this case-law history one must be alert, in order to escape mental elephant pits, to avoid being confused by opinions which are dealing not with *utility per se* but with the *unobviousness* issue (or its predecessors, the presence of “invention,” or “inventive level” as Stringham calls it) in terms of *degree of utility* as an *indication* thereof. The same precaution is called for in deciding the patentability issue in current cases so as not to confound the requirement of section 101 with that of section 103.” *Id.*

³⁵⁶ *Fisher*, 421 F.3d at 1382 (Rader J., dissenting).

³⁵⁷ *Id.* (Rader, J., dissenting).

³⁵⁸ *Id.* at 1373.

³⁵⁹ *Id.*

respect to utility on “real world benefit,” and blurred Curtis’ distinction between “positive utility” and “comparative or relative utility”:

[One of the claimed ESTs]...is unable to provide any information about the overall structure let alone the function of the underlying gene. Accordingly, while a microscope can offer an immediate, real world benefit in a variety of applications, the same cannot be said for the claimed ESTs. Fisher’s proposed analogy is thus inapt. Hence, we conclude that Fisher’s asserted uses are insufficient to meet the standard for a “substantial” utility under § 101.³⁶⁰

Therefore, Curtis, Judge Rich and Judge Rader all respectively identified obviousness or its predecessor “comparative or relative utility” as the test properly suited: to “distinguish one invention from another,” as stated by Curtis³⁶¹; to determine patentability in terms of “degree of utility as an *indication* thereof,” as stated by Judge Rich³⁶²; or, as stated by Judge Rader, “to reject inventions that may advance the ‘useful arts’ but not sufficiently to warrant the valuable exclusive right of a patent.”³⁶³

Contrary to the conclusion made by Judge Rader, the court in *Deuel* did not preclude obviousness as a basis for assessing the advance to the “useful arts” of expressed sequence tags, at least as applied to the facts of *Fisher I* and *II*. More specifically, the court in *Deuel* stated that a *prima facie* case of obviousness of a sequence cannot be predicated on well known methods of isolation of nucleic acid sequences in combination with a partial amino acid sequence of a protein.³⁶⁴ Judge Rader’s parallel, presumably, is that, despite the obviousness of applying a known technique for generating a cDNA library to any given tissue, the holding in *Deuel* dictates that Fisher’s specific nucleic acid sequences would not be obvious in view of the broad range of compounds made possible by the obvious technique,

³⁶⁰ *Id.*

³⁶¹ See *Curtis II*, *supra* note 53, at 110.

³⁶² *Kirk*, 376 F.2d at 955 (Rich, J., dissenting).

³⁶³ *Fisher*, 421 F.3d at 1382 (Rader, J., dissenting).

³⁶⁴ *Deuel*, 51 F.3d at 1557, 1560. The court stated, in particular, that:

“Thus, the appeal raises the important question whether the combination of a prior art reference teaching a method of gene cloning, together with a reference disclosing a partial amino acid sequence of a protein, may render DNA and cDNA molecules encoding the protein *prima facie* obvious under § 103 The board’s decision affirming the final rejection of claims 4-7 is reversed.”

since conception requires the sequence and, as stated by the court in *Deuel*, “what cannot be contemplated or conceived cannot be obvious.”³⁶⁵

However, the facts of *Fisher I* and *II* are different than those in *Deuel*, because the relation of the nucleic acid sequence to a portion of the encoded protein in *Deuel* was known, as was the function of the protein.³⁶⁶ In *Fisher*, although the claimed ESTs were derived from a particular source (i.e., pooled leaf tissues from maize (RX601) Asgrow Seed Company, Des Moines, Iowa USA),³⁶⁷ there was no established link with any specific proteins.³⁶⁸ Therefore, absent establishment of some relation to their respective encoded native protein, the ESTs claimed by *Fisher* were, in essence, random combinations of nucleic acids. Random sequences of nucleic acids may be novel, but should be considered obvious.

Support for randomness as a basis for statutory obviousness can be found, for example, in arguments presented in a *Petition for a Writ of Certiorari* by KSR International Co. (KSR) (*Petition*) and in a *Motion of Leave to Amicus Curiae Brief and Brief of Twenty-Four Intellectual Property Law Professors as Amici Curiae in Support of Petitioner* in an unpublished decision of the Federal Circuit, *Teleflex, Incorporated v. KSR International*, 04-1152 (Fed. Cir. 2005) (*Brief*). The *Petition* argues that a split has developed between the Supreme Court and the Federal Circuit over the threshold of statutory obviousness. As stated in the *Petition*, under Supreme Court precedent, an “‘invention,’... does not meet the ‘condition for patentability’ specified in § 103(a), if each element in the claimed combination does nothing more than what it was previously known or designed to do,”³⁶⁹ whereas “the Federal Circuit holds that a combination of pre-existing elements will always constitute an ‘invention,’ and *will always* meet the ‘condition for patentability’ specified in § 103, unless there is proven some ‘suggestion, teaching or motivation’ that would have led a person of ordinary skill in the art to combine the relevant

³⁶⁵ *Id.* at 1558.

³⁶⁶ *Id.* at 1555 (“As disclosed in *Deuel*’s patent application, *Deuel* isolated and purified HBGF from bovine uterine tissue, found that it exhibited mitogenic activity, and determined the first 25 amino acids of the protein’s N-terminal sequence. *Deuel* then isolated a cDNA molecule encoding bovine uterine HBGF...”).

³⁶⁷ *Fisher*, 421 F.3d at 1368.

³⁶⁸ *Id.* at 1373 (“Significantly, despite the fact that maize leaves produce over two thousand different proteins during anthesis, *Fisher* failed to show that one of the claimed ESTs translates into a portion of one of those proteins.”).

³⁶⁹ *Petition* at page 4.

prior art teaching in the manner claimed.”³⁷⁰ The *Petition* further stated that the Federal Circuit’s test under 35 U.S.C. § 103 has no textual basis and is inconsistent with Court precedent.³⁷¹ Amici, in the *Brief*, argue that the current Federal Circuit legal standard for obviousness “blurs the distinction between novelty and unobviousness” because, contrary to the statute, it “relegates the ‘person having ordinary skill in the art’ to the sidelines and looks almost entirely to the contents of the prior art references to demonstrate obviousness....”³⁷²

Random nucleic acid sequences, by definition, lack a suggestion in the prior art to combine the component nucleic acids in any given sequence. Following the logic of the *Petition* and the *Brief*, failure of the prior art to provide any suggestion of the particular sequence would, under the Federal Circuit’s current standard for obviousness under the “teaching-suggestion-motivation” test, render all random sequences, if novel, also non-obvious, thereby collapsing non-obviousness into novelty. The *Petition* and the *Brief* advocate that, to be consistent with Supreme Court decisions, such as *Graham v. John Deere*, 383 U.S. 1 (1966), non-obviousness means more than bare novelty, and requires consideration of “one having ordinary skill in the art.”³⁷³ A random sequence involves no such consideration because random selection is not, and cannot be, a function of skill. Therefore, under the position advocated by both the *Petition* and the *Brief* as being consistent with Supreme Court precedent, a random sequence of nucleic acids and, for that matter, any random combination, should be considered obvious as a matter of law.

Fisher’s claimed ESTs, though not truly random because they are derived from a selected source, are random in the sense that, unlike the nucleic acid sequences in *Deuel*, their relation to functional native proteins is unknown. Therefore, although the claimed ESTs should properly meet the utility requirement because the specification made “an assertion of utility and an indication of the use or uses intended,” as required by *Bremner*,³⁷⁴ even if that utility is as a tool in research to achieve specific objectives, such as those set forth in the application by Fisher, such ESTs should also be considered obvious under 35 U.S.C. § 103 absent some link to a protein, whether or not previ-

³⁷⁰ *Id.* (quoting *Teleflex*).

³⁷¹ *Id.* (“The Federal Circuit’s so-called ‘teaching-suggestion-motivation test’ has no basis in the text of § 103 or in any decision of this Court. Indeed, it is -- as numerous commentators have noted -- quite inconsistent with this Court’s interpretation of § 103.”).

³⁷² *Brief*, at pages 5-6.

³⁷³ *Petition* at page 2; *Brief* at page 6.

³⁷⁴ *Bremner*, 182 F.2d at 217.

ously known or isolated. Even when such a link is established, non-obviousness will be determined by prevailing legal precedent as applied to novel nucleic acid sequences, such as *Deuel*.

By including the person having ordinary skill in the art in an assessment of obviousness of claimed ESTs, utility of ESTs can be considered and established without the claimed sequences necessarily meeting the statutory requirement of non-obviousness for lack of suggestion of the combination of nucleic acids constituting each sequence. This would permit employment of a standard for utility consistent with the narrow holding of *Brenner*, as understood by Judges Rich and Smith, whereby a statement of utility must be made in a specification for a product formed by a claimed process, and would prevent automatic findings of non-obviousness of ESTs in view of *Deuel*, as Judge Rader suggested in his dissent in *Fisher II* would be the case. Moreover, it would be consistent with the standard of non-obviousness set forth by the Supreme Court, albeit contrary to the current standard applied by the Federal Circuit.

IV. Conclusion

At least as applied to individual sequences, as opposed to libraries of such sequences, patentability of ESTs has been denied by the Federal Circuit in *Fisher II*. The basis for the holding in *Fisher II* was under 35 U.S.C. § 101, as lacking statutory utility because the claimed sequences, in and of themselves, did not “provide any information about the overall structure let alone the function of the underlying gene” from which the claimed sequences were derived. Instead, the claimed sequences were considered as “only tools to be used along the way in the search for a practical utility” and, therefore, lacked “an immediate real world benefit” sufficient to meet the standard for a “substantial” utility under Section 101.

Utility has existed as a statutory requirement since the first Patent Act of 1790. Judicial interpretation of the requirement derives from common law notions of usefulness and from the constitutional threshold that inventors be granted an exclusive right for a limited time to discoveries that “promote the Progress of Science and useful Arts.” During the nineteenth century, a distinction was eventually drawn between “positive utility” to distinguish subject matter as a class, and “comparative or relative utility” which looked to whether an invention was a contribution sufficient to award grant of the exclusive right of a patent. “Comparative or relative utility” became associated with the idea of “substantial novelty” that was the collective predecessor to the modern ideas of novelty and non-obviousness. “Positive utility,” while conceptually distinct from considerations of degree of contribution, during the twentieth century became refined,

particularly with advances in chemical inventions, whereby novel and nonobvious methods of forming compounds produced products that, although belonging to a class of compounds known to be useful, themselves had no known use. Eventually, the criteria of "specific," "substantial" and "credible" uses became the threshold requirements for establishing utility under 35 U.S.C. § 101 of the 1952 Patent Act.

The ESTs claimed in *Fisher* have no known relation to any protein nor to the function of any protein. The decision by the court is based on a misunderstanding of *Brenner*, which, as interpreted by Judge Rich in his dissent from the holding in *Kirk*, decided shortly after *Brenner*, was limited to the narrow decision that a statement of utility for products of claimed processes must be included in a specification. The fact that an invention has its sole use as a tool in research was never mandated by the Court in *Brenner* as a basis for finding a lack of utility under 35 U.S.C. § 101.

Denial of patent protection by the court in *Fisher II* for this reason threatens patentability of a wide variety of inventions, "the immediate real world benefit" of which may not be appreciated until well after the tool becomes commercially available and well known. Instead, in patent applications where there is an assertion of utility and an indication of the use or uses intended for claimed subject matter, which is no less than what was required by the decisions of *Bremner* and *Brenner*, the statutory utility of claimed ESTs and of other so-called "research tools" should be granted. The *benefit* of such subject matter, however, should be evaluated, not as a function of utility, but under the standard suggested by Judge Rich in his dissent in *Kirk* and by Judge Rader in his dissent in *Fisher II*, of obviousness under 35 U.S.C. § 103. Moreover, as specifically applied to ESTs, non-obviousness should be predicated on demonstrable distinctions of claimed molecular sequences from random sequences which, by definition, have no known relation to functional proteins or fragments thereof.