

Requirements for Patent Protection: Utility



Utility, like patentable subject matter, is a component of patent eligibility that has recently received considerably more attention because of a series of technological changes. Patentable subject matter was once a sleepy area of patent doctrine, lightly touched on before beginning the real work of the requirements for prosecuting a patent. As we saw in the last chapter, then came the networked computer—which challenged the dividing line between patentable process and unpatentable idea or algorithm. At almost the same time we saw the arrival of the technology of genetic engineering, which disrupted the line between nature and invention.

Utility, beyond a few old cases dealing with immoral or pointless technologies, seemed to have little bite on real patent practice. It was also not clear why we would care about utility. Say we give a person a patent over something that is *not* useful. Who cares? It is not useful—so why would we want it, or care if its price or availability are affected by an incorrectly granted patent? The answer to all of these questions lies in the importance of multi-stage research efforts. A scientist discovers something that raises a question or a technological potential. Then she investigates it further, learning more and more about it. At what stage do her investigations merit a patent? At what stage have they become “useful” to the larger society? Of course, in some senses *all* knowledge is useful. But is that what we mean when we talk about satisfying the utility requirement for patentability?

1.) ‘Research Intermediaries’ and Hunting Licenses

Brenner v. Manson

383 U.S. 519 (1966)



Mr. Justice FORTAS delivered the opinion of the Court.

This case presents [a] question[] of importance to the administration of the patent laws: . . . 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. . . .

In December 1957, Howard Ringold and George Rosenkranz applied for a patent on an allegedly novel process for making certain known steroids. . . . In January 1960, respondent Manson, a chemist engaged in steroid research, filed an application to patent precisely the same process described by Ringold and Rosenkranz. He asserted that it was he who had discovered the process, and that he had done so before December 17, 1956. Accordingly, he requested that an “interference” be declared in order to try out the issue of priority between his claim and that of Ringold and Rosenkranz.

A Patent Office examiner denied Manson’s application, and the denial was affirmed by the Board of Appeals within the Patent Office. The ground for rejection was the failure “to disclose any utility for” the chemical compound produced by the process. This omission was not cured, in the opinion of the Patent Office, by Manson’s reference to an article in the November 1956 issue of the *Journal of Organic Chemistry* which revealed that steroids of

a class which included the compound in question were undergoing screening for possible tumor-inhibiting effects in mice, and that a homologue adjacent to Manson's steroid had proven effective in that role. Said the Board of Appeals, "It is our view that the statutory requirement of usefulness of a product cannot be presumed merely because it happens to be closely related to another compound which is known to be useful."

The Court of Customs and Patent Appeals (hereinafter CCPA) reversed, Chief Judge Worley dissenting. The court held that Manson was entitled to a declaration of interference since "where a claimed process produces a known product it is not necessary to show utility for the product," so long as the product "is not alleged to be detrimental to the public interest." *Certiorari* was granted, to resolve this running dispute over what constitutes "utility" in chemical process claims. . . .

II.

Our starting point is the proposition, neither disputed nor disputable, that one may patent only that which is "useful." In *Graham v. John Deere Co.*, we have reviewed the history of the requisites of patentability, and it need not be repeated here. Suffice it to say that the concept of utility has maintained a central place in all of our patent legislation, beginning with the first patent law in 1790 and culminating in the present law's provision that

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

As is so often the case, however, a simple, everyday word can be pregnant with ambiguity when applied to the facts of life. That this is so is demonstrated by the present conflict between the Patent Office and the CCPA over how the test is to be applied to a chemical process which yields an already known product whose utility—other than as a possible object of scientific inquiry—has not yet been evidenced. It was not long ago that agency and court seemed of one mind on the question. In *Application of Bremner*, the court affirmed rejection by the Patent Office of both process and product claims. It noted that "no use for the products claimed to be developed by the processes had been shown in the specification." It held that "It was never intended that a patent be granted upon a product, or a process producing a product, unless such product be useful." Nor was this new doctrine in the court.

The Patent Office has remained steadfast in this view. The CCPA, however, has moved sharply away from *Bremner*. The trend began in *Application of Nelson*. There, 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." The trend has 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."

It is not remarkable that differences arise as to how the test of usefulness is to be applied to chemical processes. Even if we knew precisely what Congress meant in 1790 when it devised the "new and useful" phraseology and in subsequent re-enactments of the test, we should have difficulty in applying it in the context of contemporary chemistry where research is as comprehensive as man's grasp and where little or nothing is wholly beyond the pale of "utility"—if that word is given its broadest reach.

Respondent does not—at least in the first instance—rest upon the extreme proposition, advanced by the court below, that a novel chemical process is patentable so long

as it yields the intended product and so long as the product is not itself “detrimental.” Nor does he commit the outcome of his claim to the slightly more conventional proposition that any process is “useful” within the meaning of § 101 if it produces a compound whose potential usefulness is under investigation by serious scientific researchers, although he urges this position, too, as an alternative basis for affirming the decision of the CCPA. Rather, he 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. We do not accept any of these theories as an adequate basis for overriding the determination of the Patent Office that the “utility” requirement has not been met.

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 his 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.” In these circumstances and in this technical area, we would not overturn the finding of the Primary Examiner, affirmed by the Board of Appeals and not challenged by the CCPA.

The second and third points of respondent’s argument present issues of much importance. 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? These contentions present the basic problem for our adjudication. Since we find no specific assistance in the 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.

In support of his plea that we attenuate the requirement of “utility,” respondent relies upon Justice Story’s well-known statement that a “useful” invention is one “which may be applied to a beneficial use in society, in contradistinction to an invention injurious to the morals, health, or good order of society, or frivolous and insignificant”—and upon the assertion that to do so would encourage inventors of new processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge. Justice Story’s language sheds little light on our subject. Narrowly read, it does no more than compel us to decide whether the invention in question is “frivolous and insignificant”—a query no easier of application than the one built into the statute. Read more broadly, so as to allow the patenting of any invention not positively harmful to society, it places such a special meaning on the word “useful” that we cannot accept it in the absence of evidence that Congress so intended. There are, after all, many things in this world which may not be considered “useful” but which, nevertheless, are totally without a capacity for harm.

It is true, of course, that one of the purposes of the patent system is to encourage dissemination of information concerning discoveries and inventions. And it may be that inability to patent a process to some extent discourages disclosure and leads to greater secrecy than would otherwise be the case. The inventor of the process, or the corporate

organization by which he is employed, has some incentive to keep the invention secret while uses for the product are searched out. However, in light of the highly developed art of drafting patent claims so that they disclose as little useful information as possible—while broadening the scope of the claim as widely as possible—the argument based upon the virtue of disclosure must be warily evaluated. Moreover, the pressure for secrecy is easily exaggerated, for if the inventor of a process cannot himself ascertain a “use” for that which his process yields, he has every incentive to make his invention known to those able to do so. Finally, how likely is disclosure of a patented process to spur research by others into the uses to which the product may be put? To the extent that the patentee has power to enforce his patent, there is little incentive for others to undertake a search for uses.

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. 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.

These arguments for and against the patentability of a process which either has no known use or is useful only in the sense that it may be an object of scientific research would apply equally to the patenting of the product produced by the process. Respondent appears to concede that with respect to a product, as opposed to a process, Congress has struck the balance on the side of non-patentability unless “utility” is shown. Indeed, the decisions of the CCPA 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. 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. That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.

This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something “useful,” or that we are blind to the prospect that what now seems without “use” may tomorrow command the grateful attention of the public. 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 realm of philosophy. * * *”

The judgment of the CCPA is
Reversed.

Mr. Justice DOUGLAS, while acquiescing in Part I of the Court’s opinion, dissents on the merits of the controversy for substantially the reasons stated by Mr. Justice HARLAN.

Mr. Justice HARLAN, concurring in part and dissenting in part.

While I join the Court’s opinion on the issue of *certiorari* jurisdiction, I cannot

agree with its resolution of the important question of patentability.

Respondent has contended that a workable chemical process, which is both new and sufficiently nonobvious to satisfy the patent statute, is by its existence alone a contribution to chemistry and "useful" as the statute employs that term. Certainly this reading of "useful" in the statute is within the scope of the constitutional grant, which states only that "[t]o promote the Progress of Science and useful Arts," the exclusive right to "Writings and Discoveries" may be secured for limited times to those who produce them. Art. I, § 8.[cl. 8] Yet the patent statute is somewhat differently worded and is on its face open both to respondent's construction and to the contrary reading given it by the Court. In the absence of legislative history on this issue, we are thrown back on policy and practice. Because I believe that the Court's policy arguments are not convincing and that past practice favors the respondent, I would reject the narrow definition of "useful" and uphold the judgment of the Court of Customs and Patent Appeals (hereafter CCPA).

The Court's opinion sets out about half a dozen reasons in support of its interpretation. Several of these arguments seem to me to have almost no force. For instance, it is suggested that "[u]ntil 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" and "[i]t may engross a vast, unknown, and perhaps unknowable area." I fail to see the relevance of these assertions; process claims are not disallowed because the products they produce may be of "vast" importance nor, in any event, does advance knowledge of a specific product use provide much safeguard on this score or fix "metes and bounds" precisely since a hundred more uses may be found after a patent is granted and greatly enhance its value.

The further argument that an established product use is 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. The same infirmity seems to inhere in the Court's argument that chemical products lacking immediate utility cannot be distinguished for present purposes from the processes which create them, that respondent appears to concede and the CCPA holds that the products are nonpatentable, and that therefore the processes are nonpatentable. Assuming that the two classes cannot be distinguished, a point not adequately considered in the briefs, and assuming further that the CCPA has firmly held such products nonpatentable, this permits us to conclude only that the CCPA is wrong either as to the products or as to the processes and affords no basis for deciding whether both or neither should be patentable absent a specific product use.

More to the point, I think, are the Court's remaining, prudential arguments against patentability: namely, that disclosure induced by allowing a patent is partly undercut by patent-application drafting techniques, that disclosure may occur without granting a patent, and that a patent will discourage others from inventing uses for the product. How far opaque drafting may lessen the public benefits resulting from the issuance of a patent is not shown by any evidence in this case but, more important, the argument operates against all patents and gives no reason for singling out the class involved here. The thought that these inventions may be more likely than most to be disclosed even if patents are not allowed may have more force; but while empirical study of the industry might reveal that chemical researchers would behave in this fashion, the abstractly logical choice for them seems to me to maintain secrecy until a product use can be discovered. As to discouraging the search by others for product uses, there is no doubt this risk exists but the price paid for any patent is that research on other uses or improvements may be hampered because the original patentee will reap much of the reward. From the standpoint of the public interest the Constitution seems to have resolved that choice in favor of patentability.

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 respondent’s position in this case. . . .

Fully recognizing that there is ample room for disagreement on this problem when, as here, it is reviewed in the abstract, I believe the decision below should be affirmed.

Questions:

1.) “[A] patent is not a hunting license.” This is one of the most quoted lines in patent law. What does it *mean*? Is this the patent version of *Pierson v. Post*—you do not own the fox until you have completed the chase and the capture?

2.) The Court acknowledges that this development of a method of synthesizing a new class of steroids may turn out to be useful. And it acknowledges that if patents cannot be obtained for “research intermediaries”—promising targets for future clinical research—there may be some danger of greater secrecy. Why does the Court nevertheless rule against patents on research intermediaries?

3.) Test tubes, reagents, agar jelly and many other objects are mainly used to perform other experiments—that is, they are a means to an experimental end, not the end itself. Does that mean that one could not get a patent over any of those? What is the distinguishing principle from this case?

4.) Justice Harlan says

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Why is the majority unpersuaded by this, apparently powerful, point? Is there any limiting principle on the idea? Does it imply abolishing the utility requirement altogether?

5.) Justice Harlan is unconvinced by the majority’s claim that a more limited utility requirement will help us in defining the limits of the patent’s reach. The majority had argued that “[u]ntil 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.” With whom do you agree?

6.) Harlan goes on to say “nor . . . does advance knowledge of a specific product use provide much safeguard on this score or fix ‘metes and bounds’ precisely since a hundred more uses may be found after a patent is granted and greatly enhance its value.” In saying

this, he is restating hornbook law. The utility requirement requires the patent applicant to state *one* credible utility. After that, he or she has the right to exclude others from making, using, offering for sale or importing the patented item *for any purpose or function* whatsoever. The person to invent the laser probably did not foresee its use to detect speeders or scan barcodes. Nevertheless, if it were still in force, a laser patent would preclude the use of the laser for all of those purposes (at least without a license from the patentee). On the other hand, the person who later comes up with a novel and non-obvious way to *use* the patented invention—for example, to remove unwanted body hair come swimsuit season—would be able to patent *those* methods or processes. (All subject to the consent—and probably the requirement to pay—the initial patent holder.) Is this good policy? Why should we not confine the monopoly profits of the patent holder to the precise utility that he or she has identified? To foreseeable or proximate utility?

2.) Genetic Engineering & Utility

Brenner proved to be a prescient case. The genetic revolution produced some remarkable situations involving similar facts. In 1991 and 1992, Dr. Craig Venter, a prominent biotechnology researcher then working with NIH, filed patent applications on behalf of NIH on approximately 2700 partial cDNA sequences. As you may remember from our discussion of patentable subject matter, cDNA, or complementary DNA is—effectively—a purified (“exon only”) form of DNA with all of the portions (“introns”) that do not code for proteins spliced out. So what did Venter know? At the time the patent applications were filed, Venter and NIH knew that this was the cDNA—it coded for proteins. It *did something*. That is a significant finding—about 97–98% of human DNA does not code for proteins. (This DNA is sometimes dismissively described as “junk DNA.” Of course, it turns out that it may well have many important functions.) But what did the cDNA do? What was the function of these proteins? Did this affect eye color, fast twitch muscle proportion, or propensity to get early onset Alzheimer’s disease? That, the researchers did not know. They had—quite brilliantly—found 2700 keys scattered in an immense field, but they did not know which locks they opened. The PTO rejected the claims for lack of utility. (A correct application of *Brenner*?)

Realizing that utility would become a common ground of battle in early-stage biotech patents, the PTO issued revised Utility Examination Guidelines in 2001. It has since amended them to take account of the America Invents Act. Remember, “these Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable.” Having said that, the Guidelines are extremely important in at least two ways. First, these are the internal rules that the examiners will be trying to follow. Second, they represent a snapshot of the PTO’s own cultural understanding of its role in interpreting the concept of “utility.”

USPTO Utility Examination Guidelines¹



The following Guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the utility requirements of 35 U.S.C. 101 and 35 U.S.C. 112(a), or pre-AIA 35 U.S.C. 112, first paragraph. These Guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The Guidelines do not alter the substantive requirements of 35 U.S.C. 101 and 35 U.S.C. 112, nor are they designed to obviate the examiner's review of applications for compliance with all other statutory requirements for patentability. The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable. . . .

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

(A) Read the claims and the supporting written description.

- (1) Determine what the applicant has claimed, noting any specific embodiments of the invention.
- (2) Ensure that the claims define statutory subject matter (i.e., a process, machine, manufacture, composition of matter, or improvement thereof).
- (3) If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.

(B) Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible:

- (1) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.
 - (i) A claimed invention must have a specific and substantial utility. This requirement excludes "throw-away," "insubstantial," or "nonspecific" utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. 101.
 - (ii) Credibility is assessed from the perspective of one of

¹ Available at <http://www.uspto.gov/web/offices/pac/mpep/s2107.html>.

ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

(2) If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a readily apparent well-established utility, reject the claim(s) under 35 U.S.C. 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, rejection imposed in conjunction with a 35 U.S.C. 101 rejection should incorporate by reference the grounds of the corresponding 35 U.S.C. 101 rejection.

(3) If the applicant has not asserted any specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility, impose a rejection under 35 U.S.C. 101, emphasizing that the applicant has not disclosed a specific and substantial utility for the invention. Also impose a separate rejection under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, on the basis that the applicant has not disclosed how to use the invention due to the lack of a specific and substantial utility. The 35 U.S.C. 101 and 35 U.S.C. 112 rejections shift the burden of coming forward with evidence to the applicant to:

(i) Explicitly identify a specific and substantial utility for the claimed invention; and

(ii) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established at the time of filing. The examiner should review any subsequently submitted evidence of utility using the criteria outlined above. The examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.

(C) Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

(1) Where the asserted utility is not specific or substantial, a *prima*

facie showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. . . .

(2) Where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. . . .

(3) Where no specific and substantial utility is disclosed or is well-established, a *prima facie* showing of no specific and substantial utility need only establish that applicant has not asserted a utility and that, on the record before the examiner, there is no known well-established utility.

. . . Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. . . .

Questions:

- 1.) On whom does the burden of proof on utility lie in a patent application? What is that burden of proof, precisely? If I assert that basketball shoes made out of “flubber” will allow anyone to dunk, should the examiner accept that? What if I say they will allow the average athlete to jump between .75 and 1.3 inches higher during a standing leap?
- 2.) Your client believes he has finally developed cold fusion—i.e. fusion at room temperatures and pressures. His device looks like a beaker of water with two different electrodes in it. You explain that the PTO might be skeptical. He suggests that the patent instead specify “making decorative bubbles in a beaker of liquid” as the utility. Patentable? If it were to be patentable, and the device was later shown to produce unlimited fusion power, would your client’s patent cover that use?
- 3.) Justice Harlan and the Guidelines both reiterated the point that, once any specific and substantial utility is shown, the patent is valid for *all* uses. Are there particular dangers to this doctrine in the genetic realm? Benefits?

3.) Utility in the Court of Appeals for the Federal Circuit

In re Fisher
421 F.3d 1365 (Fed. Cir. 2005)



MICHEL, Chief Judge.

Dane K. Fisher and Raghunath Lalgudi appeal from the decision of the U.S. Patent and Trademark Office (“PTO”) Board of Patent Appeals and Interferences (“Board”) affirming the examiner’s final rejection of . . . application Serial No. 09/619,643 (the “643 application”), entitled “Nucleic Acid Molecules and Other Molecules Associated

with Plants,” as unpatentable for lack of utility under 35 U.S.C. § 101. . . . Because we conclude that substantial evidence supports the Board’s findings that the claimed invention lacks a specific and substantial utility and that the ’643 application does not enable one of ordinary skill in the art to use the invention, we affirm.

I. BACKGROUND

A. Molecular Genetics and ESTs

The claimed invention relates to five purified nucleic acid sequences that encode proteins and protein fragments in maize plants. The claimed sequences are commonly referred to as “expressed sequence tags” or “ESTs.” Before delving into the specifics of this case, it is important to understand more about the basic principles of molecular genetics and the role of ESTs.

Genes are located on chromosomes in the nucleus of a cell and are made of deoxyribonucleic acid (“DNA”). DNA is composed of two strands of nucleotides in double helix formation. The nucleotides contain one of four bases, adenine (“A”), guanine (“G”), cytosine (“C”), and thymine (“T”), that are linked by hydrogen bonds to form complementary base pairs (i.e., A–T and G–C).

When a gene is expressed in a cell, the relevant double-stranded DNA sequence is transcribed into a single strand of messenger ribonucleic acid (“mRNA”). Messenger RNA contains three of the same bases as DNA (A, G, and C), but contains uracil (“U”) instead of thymine. mRNA is released from the nucleus of a cell and used by ribosomes found in the cytoplasm to produce proteins.

Complementary DNA (“cDNA”) is produced synthetically by reverse transcribing mRNA. cDNA, like naturally occurring DNA, is composed of nucleotides containing the four nitrogenous bases, A, T, G, and C. Scientists routinely compile cDNA into libraries to study the kinds of genes expressed in a certain tissue at a particular point in time. One of the goals of this research is to learn what genes and downstream proteins are expressed in a cell so as to regulate gene expression and control protein synthesis.

An EST is a short nucleotide sequence that represents a fragment of a cDNA clone. It is typically generated by isolating a cDNA clone and sequencing a small number of nucleotides located at the end of one of the two cDNA strands. When an EST is introduced into a sample containing a mixture of DNA, the EST may hybridize with a portion of DNA. Such binding shows that the gene corresponding to the EST was being expressed at the time of mRNA extraction. . . .

The ’643 application generally discloses that the five claimed ESTs may be used in a variety of ways, including: (1) serving as a molecular marker for mapping the entire maize genome, which consists of ten chromosomes that collectively encompass roughly 50,000 genes; (2) measuring the level of mRNA in a tissue sample via microarray technology to provide information about gene expression; (3) providing a source for primers for use in the polymerase chain reaction (“PCR”) process to enable rapid and inexpensive duplication of specific genes; (4) identifying the presence or absence of a polymorphism; (5) isolating promoters via chromosome walking; (6) controlling protein expression; and (7) locating genetic molecules of other plants and organisms.

B. Final Rejection

In a final rejection, dated September 6, 2001, the examiner rejected claim 1 for lack of utility under § 101. The examiner found that the claimed ESTs were not supported by a specific and substantial utility. She concluded that the disclosed uses were not

specific to the claimed ESTs, but instead were generally applicable to any EST. For example, the examiner noted that any EST may serve as a molecular tag to isolate genetic regions. She also concluded that the claimed ESTs lacked a substantial utility because there was no known use for the proteins produced as final products resulting from processes involving the claimed ESTs. The examiner stated: “Utilities that require or constitute carrying out further research to identify or reasonably confirm a ‘real world’ context of use are not substantial utilities.”

C. Board Proceedings

The Board . . . concluded that using the claimed ESTs to isolate nucleic acid molecules of other plants and organisms, which themselves had no known utility, is not a substantial utility. . . .

. . . The Board analogized the facts to those in *Brenner v. Manson* (1966), in which an applicant claimed a process of making a compound having no known use. In that case, the Supreme Court affirmed the rejection of the application on § 101 grounds. Here, the Board reasoned: “Just as the process 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 . . . specific gene expression data.” . . .

II. DISCUSSION

Whether an application discloses a utility for a claimed invention is a question of fact. . . .

A. Utility

1.

Fisher asserts that the Board unilaterally applied a heightened standard for utility in the case of ESTs, conditioning patentability upon “some undefined ‘spectrum’ of knowledge concerning the corresponding gene function.” Fisher contends that the standard is not so high and that Congress intended the language of § 101 to be given broad construction. In particular, Fisher contends that § 101 requires only that the claimed invention “not be frivolous, or injurious to the well-being, good policy, or good morals of society,” essentially adopting Justice Story’s view of a useful invention from *Lowell v. Lewis* (C.C.D. Mass. 1817). Under the correct application of the law, Fisher argues, the record shows that the claimed ESTs provide seven specific and substantial uses, regardless whether the functions of the genes corresponding to the claimed ESTs are known. Fisher claims that the Board’s attempt to equate the claimed ESTs with the chemical compositions in *Brenner* was misplaced. . . . Fisher likewise argues that the general commercial success of ESTs in the marketplace confirms the utility of the claimed ESTs. Hence, Fisher avers that the Board’s decision was not supported by substantial evidence and should be reversed.

The government agrees with Fisher that the utility threshold is not high, but disagrees with Fisher’s allegation that the Board applied a heightened utility standard. The government contends that a patent applicant need disclose only a single specific and substantial utility pursuant to *Brenner*, the very standard articulated in the PTO’s “Utility Examination Guidelines” (“Utility Guidelines”) and followed here when examining the ’643 application. It argues that Fisher failed to meet that standard because Fisher’s alleged uses are so general as to be meaningless. What is more, the government asserts that the same generic uses could apply not only to the five claimed ESTs but also to any EST derived from

any organism. It thus argues that the seven utilities alleged by Fisher are merely starting points for further research, not the end point of any research effort. It further disputes the importance of the commercial success of ESTs in the marketplace, pointing out that Fisher's evidence involved only databases, clone sets, and microarrays, not the five claimed ESTs. Therefore, the government contends that we should affirm the Board's decision.

Several academic institutions and biotechnology and pharmaceutical companies write as *amici curiae* in support of the government. Like the government, they assert that Fisher's claimed uses are nothing more than a "laundry list" of research plans, each general and speculative, none providing a specific and substantial benefit in currently available form. The *amici* also advocate that the claimed ESTs are the objects of further research aimed at identifying what genes of unknown function are expressed during anthesis and what proteins of unknown function are encoded for by those genes. Until the corresponding genes and proteins have a known function, the *amici* argue, the claimed ESTs lack utility under § 101 and are not patentable.

We agree with both the government and the *amici* that none of Fisher's seven asserted uses meets the utility requirement of § 101. Section 101 provides: "Whoever invents . . . any new and *useful* . . . composition of matter . . . may obtain a patent therefor. . . ." (Emphasis added). In *Brenner*, the Supreme Court explained what is required to establish the usefulness of a new invention, noting at the outset that "a simple, everyday word ["useful," as found in § 101] can be pregnant with ambiguity when applied to the facts of life." Contrary to Fisher's argument that § 101 only requires an invention that is not "frivolous, injurious to the well-being, good policy, or good morals of society," the Supreme Court appeared to reject Justice Story's *de minimis* view of utility. 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 place, the Supreme Court announced a more rigorous test, stating:

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. . . .

The Supreme Court has not defined what the terms "specific" and "substantial" mean *per se*. Nevertheless, together with the Court of Customs and Patent Appeals, we have offered guidance as to the uses which would meet the utility standard of § 101. From this, we can discern the kind of disclosure an application must contain to establish a specific and substantial utility for the claimed invention.

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 in a manner which provides some immediate benefit to the public." *Nelson*. It thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the "substantial" utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.

Turning to the “specific” utility requirement, an application must disclose a use which is not so vague as to be meaningless. Indeed, one of our predecessor courts has observed “that the nebulous expressions ‘biological activity’ or ‘biological properties’ appearing in the specification convey no more explicit indication of the usefulness of the compounds and how to use them than did the equally obscure expression ‘useful for technical and pharmaceutical purposes’ unsuccessfully relied upon by the appellant in *In re Diedrich* [(1963)].” Thus, in addition to providing a “substantial” utility, an asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public.

In 2001, partially in response to questions about the patentability of ESTs, the PTO issued Utility Guidelines governing its internal practice for determining whether a claimed invention satisfies § 101. See Utility Examination Guidelines, 66 Fed.Reg. 1092 (Jan. 5, 2001). The PTO incorporated these guidelines into the Manual of Patent Examining Procedure (“MPEP”). The MPEP and Guidelines “are not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute.” *Enzo Biochem v. Gen-Probe* (Fed. Cir. 2002) (citing *Molins PLC v. Textron, Inc.* (Fed. Cir. 1995)). According to the Utility Guidelines, a specific utility is particular to the subject matter claimed and would not be applicable to a broad class of invention. Manual of Patent Examining Procedure § 2107.01. The Utility Guidelines also explain that a substantial utility defines a “real world” use. In particular, “[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.” Further, the Utility Guidelines discuss “research tools,” a term often given to inventions used to conduct research. The PTO particularly cautions that

[a]n assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact “useful” in a patent sense. [The PTO] must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm.

The PTO’s 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.

Here, 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. 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.

2.

Fisher’s reliance on *Jolles*, *Nelson*, and *Cross*, cases which found utility in certain claimed pharmaceutical compounds, is misplaced. In *Jolles*, the applicant filed an application claiming naphthacene compounds useful in treating acute myeloblastic leukemia. To support the asserted utility, the applicant presented *in vivo* data showing eight of the claimed compounds effectively treated tumors in a mouse model. Our

predecessor court reversed the Board's affirmation of the final rejection for lack of utility, finding that the structural similarity between the compounds tested *in vivo* and the remaining claimed compounds was sufficient to establish utility for the remaining claimed compounds. *Jolles*.

In *Nelson*, decided by the Court of Customs and Patent Appeals in the same year as *Jolles*, *Nelson* claimed prostaglandin compounds. . . . The issue before the Board was whether *Nelson* had established utility for the claimed prostaglandins as smooth muscle stimulants and blood pressure modulators via *in vivo* [tests on living organisms] and *in vitro* [laboratory tests literally "in glass,"] data, specifically, an *in vivo* rat blood pressure test and an *in vitro* gerbil colon smooth muscle stimulation test. The Board declined to award priority to *Nelson*, characterizing *Nelson*'s tests as "rough screens, uncorrelated with actual utility [in humans]." Our predecessor court reversed, concluding that "tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use." *Nelson*.

In *Cross*, decided by the Federal Circuit five years after *Jolles* and *Nelson*, *lizuka* filed an application claiming thromboxane synthetase inhibitors, alleged to be useful in treating inflammation, asthma, hypertension, and other ailments. The Board concluded that it offered a sufficient disclosure based upon *in vitro* data showing strong inhibitory action for thromboxane synthetase for structurally-similar compounds in human or bovine platelet microsomes. We affirmed, reasoning:

Opinions of our predecessor court have recognized the fact that pharmacological testing of animals is a screening procedure for testing new drugs for practical utility. This *in vivo* testing is but an intermediate link in a screening chain which may eventually lead to the use of the drug as a therapeutic agent in humans. We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question. Successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an *in vivo* utility.

The facts in these three cases are readily distinguishable from the facts here. In *Jolles*, *Nelson*, and *Cross*, the applicants disclosed specific pharmaceutical uses in humans for the claimed compounds and supported those uses with specific animal test data, *in vitro*, *in vivo*, or both. In contrast, *Fisher* disclosed a variety of asserted uses for the claimed ESTs, but failed to present any evidence—test data, declaration, deposition testimony, or otherwise—to support those uses as presently beneficial and hence practical. *Fisher* did not show that even one of the claimed ESTs had been tested and successfully aided in identifying a polymorphism in the maize genome or in isolating a single promoter that could give clues about protein expression. Adopting the language of the *Cross* court, the alleged uses in *Jolles*, *Nelson*, and *Cross* were not "nebulous expressions, such as 'biological activity' or 'biological properties' [alleged in the application in *Kirk*]," that "convey little explicit indication regarding the utility of a compound." *Cross*. Instead, the alleged uses in those cases gave a firm indication of the precise uses to which the claimed compounds could be put. For example, in *Nelson*, the claimed prostaglandins could be used to stimulate smooth muscle or modulate blood pressure in humans as shown by both *in vivo* and *in vitro* animal data. Hence, the *Jolles*, *Nelson*, and *Cross* courts concluded that the claimed pharmaceutical compounds satisfied the specific and substantial utility requirements of § 101. We cannot reach that same conclusion here. *Fisher*'s laundry list

of uses, like the terms “biological activity” or “biological properties” alleged in Kirk, are nebulous, especially in the absence of any data demonstrating that the claimed ESTs were actually put to the alleged uses.

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. See *Raytheon Co. v. Roper Corp.* (Fed. Cir. 1983) (stating that proof of a utility may be supported when a claimed invention meets with commercial success).

3.

As a final matter, we observe that the government and its *amici* express concern that allowing EST patents without proof of utility would discourage research, delay scientific discovery, and thwart progress in the “useful Arts” and “Science.” See U.S. Const. art. I, § 8, cl. 8. The government and its *amici* point out that allowing EST claims like Fisher’s would give rise to multiple patents, likely owned by several different companies, relating to the same underlying gene and expressed protein. Such a situation, the government and *amici* predict, would result in an unnecessarily convoluted licensing environment for those interested in researching that gene and/or protein.

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. The same may be said for the resource and managerial problems that the PTO potentially would face if applicants present the PTO with an onslaught of patent applications directed to particular ESTs. Congress did not intend for these practical implications to affect the determination of whether an invention satisfies the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and 112. 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. Under Title 35, an applicant is entitled to a patent if his invention is new, useful, nonobvious, and his application adequately describes the claimed invention, teaches others how to make and use the claimed invention, and discloses the best mode for practicing the claimed invention. What is more, when Congress enacted § 101, it indicated that “anything under the sun that is made by man” constitutes potential subject matter for a patent. S.Rep. No. 82-1979, at 7 (1952), U.S. Code Cong. & Admin. News at 2394, 2399. Policy reasons aside, because we conclude that the utility requirement of § 101 is not met, we hold that Fisher is not entitled to a patent for the five claimed ESTs.

Questions:

- 1.) Why is the court inclined to look favorably on *in vitro* and *in vivo* animal studies as evidence of utility, but skeptical of Fisher’s claims? Is this a modification of *Brenner* or simply an application of its tenets in the world of clinical trials on human beings, where there are no easy and safe alternatives?
- 2.) What role does commercial success have in showing utility? Why? What if a patent is being challenged for failing the utility requirement, and the patent holder uses her large licensing fee revenue as proof of utility? Do you see a problem? Have we met it before?

3.) Does *Fisher* implicitly say that the PTO got it right when it reframed the Utility Examination Guidelines?

PROBLEM 19-1

a.) Target, the store, has conducted extensive research over the susceptibility to advertising of its potential customers. It finds that store loyalty is very “sticky.” People are unlikely to change stores except at significant life-change moments, such as the birth of a child. But it also finds that those who have just had children are too busy to pay attention to advertising. The key is to identify women who are about to give birth and advertise to them heavily before the baby is born. Target’s demographers and statisticians conduct an extensive research program and find that pregnant women show distinct purchasing patterns—they tend to shift to cosmetic products with fewer fragrances, they purchase bland crackers and so on. Target develops a predictive statistical formula that identifies these women in its customer base, and produces a software application that employs the formula to “tag” their customer IDs with a particular probability of pregnancy. The application proves to be extremely accurate, sometimes even identifying women as potentially pregnant before they know it themselves. The CEO of Target is excited by the software and believes he can market it to advertisers across the United States.

i.) (A quick review of the last chapter.) Is the software patentable subject matter?

ii.) You are shown the current draft of the patent application. It states as the utility “a program accurately to identify women who may be particularly good advertising targets.” Does this satisfy the utility requirement? Do you have suggested drafting changes?

b.) The Senate Judiciary Committee is disturbed by the number of times the Supreme Court has recently reversed the Court of Appeals for the Federal Circuit. You work for a Senator who wonders if the Senate should be asking better questions about judicial philosophy during the confirmation process. She tells you to take a look at this passage from *In re Fisher* and to give her your assessment of whether the nation’s premier patent court is unduly formalistic.

[W]e observe that the government and its *amici* express concern that allowing EST patents without proof of utility would discourage research, delay scientific discovery, and thwart progress in the “useful Arts” and “Science.” See U.S. Const. art. I, § 8, cl. 8. The government and its *amici* point out that allowing EST claims like Fisher’s would give rise to multiple patents, likely owned by several different companies, relating to the same underlying gene and expressed protein. Such a situation, the government and *amici* predict, would result in an unnecessarily convoluted licensing environment for those interested in researching that gene and/or protein. . . . 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. . . . Congress did not intend for these practical implications to affect the determination of

whether an invention satisfies the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and 112. 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.

Is this a good or bad way for the court to determine what utility *means*? Is attention to the practical effect of a definition of utility on a particular technology, patent law, or the “promote the progress” clause a non-judicial consideration? How does this fit with the attitude towards such “definitions” in the copyright field? (*Lotus, Sega, Computer Associates* and so on.) How does it fit with the Federal Circuit’s own decision in the *Skylink* case interpreting § 1201 of the DMCA? What are its benefits—both in terms of fidelity to judicial role and in terms of practical effect? Does it support or refute the claim by some scholars, as discussed in Chapter 17, that the Federal Circuit is relatively formalistic?

c.) 23 & Me, a genetic research company, provides genetic testing kits. Individuals swab their mouths, send in their kits and receive back in the mail a lengthy printout of the probabilities they have of various negative health outcomes—senility, predisposition towards obesity, diabetes and so on.

i.) How would you state the utility of tests such as these in a patent application?

ii.) One of the most highly touted features of the tests is that they “let you know what to watch for in your health.” Is this a utility that is distinguishable from *Brenner* and if so, how?

iii.) After *Athena v. Mayo* (discussed in the last chapter) are all diagnostic tests suspect on subject matter grounds? Only some of them?