BIOCHEMICAL DISCRIMINATION: A REVIEW OF THE FLAWED UTILITY STANDARD OF PATENTABILITY AS IT RELATES TO CHEMICAL AND BIOLOGICAL INVENTIONS

DYLAN O. ADAMS

I. INTRODUCTION

Flu vaccine in short supply! Production cannot meet demand for avian flu inoculations! Prescription drugs at an all time high![1]

Headlines like these have been pervasive in the last couple of years; however, the root causes of these problems are more elusive and unclear. An increased cost of research, development and production, along with risk created by excessive tort suits are obvious answers, but we should not overlook the fundamental capital structures of the chemical and biological industries that influence how they do business.

Both public and private scientific research entities rely heavily on the patent system and resulting limited monopolies to assure that the huge costs of research and development can eventually be recouped.[2] Accordingly, without the patent system, scientific and medical advances would be severely restricted. Unfortunately, certain

[1] These specific headlines were fabricated for dramatic purpose, but art not far off from extant headlines. See e.g., Hope Yen, Experts: *U.S. unprepared for flu Vaccine shortage for pandemic Doses can't be made fast enough*, Seattle Times, Nov 21, 2005, at A4, 2005 WLNR 18833262; Marsha Mercer, *'Better be Ready' as Flu Vaccine Shortage Again Appears, Fear of Pandemic Rises*, Richmond Times-Dispatch, Nov. 6, 2005, at F4, 2005 WLNR 18020675; John Dorschner, *High Cost of Health Drug Prices Keep Going Up, Increase More Than Twice as Fast as Inflation, A New AARP Survey has Found*, Miami Herald, April 13, 2005, at A1, 2005 WLNR 5726884.

[2] Vernon M. Winters, 2003 Stanford Law & Technology Association Conference: Ideas Without Boundaries: Creating and Protecting Intellectual Property in the International Arena, available at 24 Loy. L.A. Ent. L. Rev. 1, 13 (2003).

aspects of the patent system have become increasingly inhospitable to chemical and biological inventions, which, if left unaddressed, may serve to exacerbate the already high risk business associated with entities that rely on patents as a major source of revenue.

Specifically, the utility standard of patentability has become increasingly stringent over the past fifty years and has become a great difficulty to patent applicants in the chemical and biological arts because these classes of inventions are inherently on the cusp of meeting the utility standard.[3] With the many risks and pressures already associated with sustaining funding for scientific research, problems with the utility standard need to be returned to a less stringent level before they become an overwhelmingly negative contribution to an already critical situation.

Additionally, regarding chemical and biological inventions in particular, the current state of the utility standard creates the possibility that researchers who make a good faith effort to demonstrate the utility of their inventions may lose their patent rights even though they first conceived of and used the invention.[4] Accordingly, because this disparity is simply unfair and creates a disincentive to researchers in the chemical and biological arts, it should be similarly addressed and rectified.

Finally, the current state of the utility standard, as interpreted by the courts, discriminates against molecular and chemical research tools by finding them to lack real-world value. This poorly reasoned rationale for denying patentability to the goods of a large and important industry should also be reviewed and changed.[5]

---

[3] KENNETH BURCHFIEL, BIOTECHNOLOGY & THE FED. CIR., 47 (BNA Books 1995).
[4] See discussion infra at §§ VI(A) and VII(B)
[5] See discussion infra at §§ VI(C) and VII(C)

Following the introduction, Part II of this Comment discusses the basics of patent law in general with an emphasis on the utility standard of patentability. Part III discusses the progression of the utility standard in the courts in Sections A and B. Part III then discusses the current court interpretation of the utility standard, specifically with regard to where utility is asserted and is not asserted, the evidence required to satisfy the utility standard, and the utility standard as it relates to chemical intermediates and research tools.

Part IV then discusses the manner in which the Patent and Trademark Office (PTO) has historically interpreted the utility standard, and then how the standards is dealt with currently. The Sections of Part V then discuss the PTO's interpretation of the specific concepts of credible, specific, substantial, and well established utility.

With the background established in the previous Parts, the Comment then presents the problems created by the current utility standard in Part VI, then the ramification of these problems in Part VII, and finally the solutions to the negative ramifications of the current state of the utility standard. Part IX concludes the Comment.

II. PATENTABILITY GENERALLY

A. Introduction to Patents

The constitution gives Congress the power to "promote the Progress of Science and useful Arts,"[6] which ultimately supports the creation of Patent and Trademark Office (PTO) and the United States patent system.[7] In exchange for public disclosure of inventions, inventors are given a patent, which gives the right to exclude others from

[6] Const. art I § 8 cl 8

[7] EDWARD REISNER, PATENTS, COPYRIGHTS, TRADEMARKS, AND LITERARY PROPERTY COURSE HANDBOOK SERIES 808 (Practicing Law Institute 1995); Stiftung v. Renishaw 945 F.2d 1173, 1180.

making, using, selling, or offering to sell their inventions in the United States or importing them into the United States[8], typically for a period of 20 years[9] from the date of application. To assure that the public is receiving the full benefit of this *quid pro quo*, applicants must demonstrate that their inventions are new[10], useful[11] and non-obvious;[12] additionally, applicants must make an enabling disclosure of the their inventions such that one of reasonable skill in the art could make and successfully use their invention.[13]

B. The Utility Standard

Section 101 of the patent code,[14] the origin of the utility standard, provides that whoever "invents or discovers any new and useful process, machine, manufacture, or composition of matter" may obtain a patent on that invention. [15] When the utility of an invention is questioned, it naturally raises the issue of proper enablement of the invention; consequently, a rejection for lack of utility will naturally implicate both §§ 101 and 112 of the patent code, the latter of which is the section that defines enablement.[16]

The first aspect of utility is that the claimed invention must be operable, which simply means that it is "capable of being used to effect the object proposed."[17] For the majority of inventions, satisfying the operability standard is relatively easy and

---

[8] 35 U.S.C. § 154(a)(1)
[9] 35 U.S.C. § 154(a)(2); note, however, that patents can have adjusted terms for various reasons and that design patents only last for 14 years from the filing date, *See* 35 U.S.C. §§ 155, 155A, 156 and 173.
[10] See 35 U.S.C. § 102
[11] See 35 U.S.C. § 101
[12] See 35 U.S.C. § 103
[13] See 35 U.S.C. § 112
[14] Namely Title 35 of the U.S.C.
[15] 35 U.S.C. § 101
[16] See, e.g., *In Re Zeigler*, 992 F.2d 1197, 2000, 26 U.S.P.Q.2d 1600; Under 35 U.S.C. § 112 an applicant must give a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains" to make and use the invention. This is known as the enablement requirement.
[17] *Mitchell v. Tilghman*, 86 US (19 Wall.) 287, 396, 393; Kenneth Burchfiel, Biotechnology & the Fed. Cir., 48 (BNA Books 1995)

operability will normally only be questioned when the claimed utility is incredible. [18] Chemical and biological inventions are, however, often problematic in regard to operability simply because such inventions typically require more experimentation to prove their efficacy or operability. [19] In such instances, where a *prima facie* case for inoperability can be established by the nature of the invention, the burden shifts to the inventor to rebut the presumption.[20] Classic examples are where inventors claimed to have created a perpetual motion machine or a process of cold fusion.[21] Secondly, an applicant must demonstrate "specific utility," which simply means that the invention has a use that is specific to the invention itself and not just of a class of invention.[22] The final aspect of the utility standard is a requirement of "substantial utility," which, like operability, is again more complicated when applied to chemical or biological inventions because substantial experimentation is typically required. .[23]

III. THE PROGRESSION OF "UTILITY" IN THE COURTS

[18] MPEP § 2107.01(II)
[19] KENNETH BURCHFIEL, BIOTECHNOLOGY & THE FED. CIR., 47 (BNA Books 1995).
[20] *Fregeau v. Mossinghoff* 776 F.2d 1034 (beverage magnet); Note also that while a perpetual motion machine is would be against the laws of physics and is therefore impossible, cold fusion is not. Cold fusion is theoretically possible, but yet undiscovered. These examples are used to demonstrate that both impossible and historically elusive discoveries can establish a prima facie case of an invention being outrageous or inoperable.
[21] *Newman v. Quigg*, 877 F.2d 1575, 1577 (perpetual motion machine); *Ex Parte Dash* 27 U.S.P.Q.2d 1481 (cold fusion); Fregeau v. Mossinghoff 776 F.2d 1034 (using a magnet to improve beverage taste)
[22] MPEP § 2107.01(I)(B); see also discussion infra.
[23] MPEP § 2107.01(I)(B); KENNETH BURCHFIEL, BIOTECHNOLOGY & THE FED. CIR., 48 (BNA Books 1995); also see discussion infra at § V(B).

The initial concept of utility was a relatively simple one, which focused on the safety and morality of the invention.[24] In 1966, however, the landmark decision of *Brenner v. Manson* permanently changed the concept of invention utility and paved the way for a slow yet consistent constriction of the utility standard of patentability.[25]

A. Utility before Brenner: A Simple Standard

Initially, the utility standard could be met by simply demonstrating operability and safety of an invention.[26] Thomas Jefferson, who has been noted as the originator of the patent system, was wary of granting monopolies and sought to limit patents to inventions that were worth the "embarrassment" of an exclusive right.[27] The courts, however, adopted a standard that required that an invention not be "mischievous or immoral," which made it relatively easy to patent chemical inventions.[28] For example, in *Potter v. Tone*, a new compound was found to have utility simply because it had educational value, was non-conductive, and was a reducing agent.[29]

Although the standard for utility was low, the applicant was required to state *some* utility so as to satisfy the enablement requirements of §112.[30] For example, in *In Re Bremner*, the court affirmed a rejection for lack of utility where the applicants disclosed resins and melting points, but did not disclose what these compounds could be used for.[31] While some commentators argue that *Bremner* illustrates a tightening of the utility standard, the case only supports the fact that *some* utility must be stated and is simply the

[24] See discussion infra
[25] See discussion infra
[26] Walker on Patents 52; *Lowell v. Lewis* 15 F.Cas 1018
[27] *Grahm v. John Deere Co*., 383 US 1; Margreth Barrett, Intellectual Property 2d 112 (West Group 2001).
[28] Lowell v. Lewis 15 F.Cas 1018 (1817).
[29] Potter v. Tone 36 App. D.C. 181 (1911).
[30] 35 U.S.C. § 112; see also note X supra.
[31] In Re Bremner 182 F.2d 216, 37 C.C.P.A. 1032 (1950).

origin of the "specific utility" requirement. In fact, subsequent cases support this view and uphold the standard that inventions may not be "mischievous or immoral."[32] For example, in *In Re Nelson*, the court found that claimed androstene compounds were useful in research as intermediates to known therapeutic steroids; consequently, the court reversed a rejection for lack of utility.[33] It was not until 1966 that the utility standard began to tighten, which was catalyzed by the decision in *Brenner v. Manson*.

B. The Origins of the Substantial Utility Standard

In its 1966 *Brenner v. Mason* decision, the Supreme Court rejected the previously pervasive "mischievous or immoral" standard of utility and instead adopted a standard of "substantial utility."[34] Manson invented a process of synthesizing steroids which were homologous to steroids that had been shown to have tumor-inhibiting effects in mice, yet his patent application was rejected by the PTO on grounds that it lacked utility.[35] Although there was active research involving this class of steroids, the PTO found that the compound did not have utility simply because it happened "to be closely related to another compound" that was known to be useful. [36]

Ultimately, the Supreme Court upheld the PTO rejection and found that the compound had not been demonstrated to have "substantial utility." The Supreme Court first found that the broad requirement that an invention simply not be "mischievous or immoral" was too broad and there was not evidence that Congress intended such "special meaning" to the word 'useful.' Finally, the Court found that a "potential role as an

[32] In Re Nelson, 47 C.C.P.A. 1031, 1047, 280 F.2d 172 (1960).
[33] In Re Nelson, 47 C.C.P.A. 1031, 1047, 280 F.2d 172 (1960).
[34] See Brenner v. Manson, 383 U.S. 519, 86 S.Ct. 1033 (1966).
[35] Id. at 521-522. (Brenner)
[36] Id. at 522. (Brenner)

object of use-testing" did not give the compound in question "substantial utility" and therefore affirmed the PTO's rejection for lack of utility. The majority opinion based this finding on the assertion that allowing patents on such inventions would result in the stifling of scientific development, which would go against the most basic purpose of the patent system.[37] The Court further noted that a scientific process needs to be "refined and developed," such that "specific benefit" exists, in order to have "specific utility" and thus be potentially patentable.[38]

Brenner has proven to be a seminal case for the utility standard of patentability; however, many questions remained to be fleshed-out once the substantial utility standard has been established.

C. After Brenner: The Utility Requirement Becomes More Defined

After *Brenner,* many issues remained open. Specifically, it was unclear what would be a sufficient assertion of "substantial utility" and what evidence would be required to establish "substantial utility."[39] In the years following the watershed decision of *Brenner*, the utility requirement has remained a contentious issue; consequently, many of the questions that remained unanswered have been addressed and additional caveats have been added to the utility requirement. Currently, to satisfy the § 101 requirement of having utility, an applicant must (1) demonstrate a "specific utility"; and (2) demonstrate

[37] Id. at 534. (Brenner)
[38] Id. at 534-535. (Brenner)
[39] Timothy Balts, Note, *Substantial Utility, Technology Transfer, & Research Utility: It's Time For a Change*, 52 Syracuse L. Rev. 105, 113 (2002).

that the invention has "substantial utility."[40] This standard has been in development ever since *Brenner.*[41]

1. Assertion of a "specific utility"

Although *Brenner* made it clear that it is insufficient to assess that a compound has utility as a research tool, the threshold for what constitutes a sufficient assertion of utility remained unclear. The Court of Customs and Patent Appeals[42] (the "CCPA") addressed this issue a year later in *In Re Kirk*, where an applicant asserted that his compounds[43] had "therapeutic" and "biological activity."[44] The court found these assertions to be "nebulous expressions" that did not give an indication of usefulness and that one skilled in the art would not be able to immediately recognize utility from these assertions.[45] Additionally, the court analogized these claims to an assertion of use for "technical and pharmaceutical purposes," which was cited by the court as being similarly rejected in a previous case.[46]

Similarly, in *Kawai v. Metlesics*, the CCPA found that an assertion of "excellent pharmacological affects on the central nervous system" did not satisfy the disclosure and

[40] *In Re Fisher,* 421 F.3d 1365, U.S.P.Q.2d 1125 (2005).
[41] See discussion infra
[42] The Court of Appeals for the Federal Circuit was established October 1, 1982 and took jurisdiction over hearing patent appeals from Court of Customs and Patent Appeals; hoever, the CCPA decisions are still relied on for authority. *Arshal v. United States*, 621 F.2d 421, 425 n.8 (Ct. Cl. 1980); KENNETH BURCHFIEL, BIOTECHNOLOGY & THE FED. CIR., 5 (BNA Books 1995)
[43] Here, Kirk synthesized compounds that were similar to steroid hormones and were alleged to have biological activity of their own, see In Re Kirk, 54 C.C.P.A. 1119, 376 F.2d 936 (1967).
[44] Kirk at1119-1123, 938-940
[45] Kirk at 1124-1126
[46] Kirk at 1124 (citing *In re Diedrich*, 318 F.2d 946, 50 CCPA 1355).

utility requirements because one skilled in the art would not be able recognize utility so as to use the invention.[47]

In 1993, the Court of Appeals for the Federal Circuit (hereinafter "Federal Circuit") affirmed the holdings of its predecessor court[48] and further delineated what constitutes a sufficient assertion of "specific utility." In *In Re Zeigler*, an applicant attempted to demonstrate utility by disclosing that his polypropylene polymer could "form a film" and was "plastic like."[49] The court found the assertions in his application insufficient to establish "specific utility" and held that Zeigler did not disclose a practical utility for polypropylene and therefore could not claim benefit of the filing date of this application.[50]

More recently, however, the Federal Circuit has extended the "specific utility" requirement by rejecting asserted utility that is of a different character than the cases noted supra.[51] Specifically, in *In re Fisher*, the court applied the "nebulous expressions" language of *Kirk* to several asserted uses of claimed "expressed sequence tags" (EST's), which the court rejected because the uses could apply generally to any EST. Here, Fisher claimed five EST's, which are short fragments of DNA that, as Fisher noted, can be used in mapping a genome, measuring mRNA levels, identifying polymorphisms, isolating promoters, controlling gene expression, locating genetic molecules in general, and for designing primers in PCR[52] In addition to finding these assertions unsupported, the court found them to be "nebulous" and therefore lacking "specific utility." [53] *Fisher,*

[47] Yasuko Kawai v. Metlesics, 480 F.2d 880, 890-91, 174 U.S.P.Q. 158 (1973).
[48] See note (40) supra.
[49] *In Re Zeigler*, 992 F2d. 1197, 1201-03, 26 U.S.P.Q.2d 1600 (1993).
[50] *In Re Zeigler* at 1203
[51] *In Re Fisher,* 421 F.3d 1365, U.S.P.Q.2d 1125 (2005).
[52] *In re Fisher* at 1368
[53] *In re Fisher* at 1375

therefore, extends the doctrine of "specific utility" to exclude asserted utilities that are representative of the class of invention in general and not to the claimed invention specifically.

2. Where no "specific utility" is asserted

As mentioned supra, "specific utility" can be established where no "specific utility" is actually asserted. For example, in both *Kirk* and *Kawai*, the court recognized that unless a person reasonably skilled in the art would be able to infer "specific utility" from the disclosure, the given disclosures of "specific utility" were insufficient.[54] Accordingly, it follows that even where *no* specific utility is asserted, the requirement may be satisfied if a person reasonably skilled in the art would recognize utility in the disclosure.

This proposition was recognized by the CCPA, in *Rey-Bellet v. Engelhardt*, where an applicant failed to assert a specific utility, yet was found to have satisfied the utility requirement.[55] The court found that although Engelhardt failed to add a limitation that related to utility, he could still satisfy the utility requirement of § 101 if there was "evidence which would establish a substantial utility for any purpose."[56] This standard was subsequently upheld in *Fujikawa v. Wattanasin*, where the court noted that the "evidence of *any* pharmacological activity" would suffice where the applicant "does not recite a particular utility."[57]

---

[54] See *In Re Kirk*; see also *Yasuko Kawai v. Metlesics*
[55] See *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 181 U.S.P.Q. 453 (1974).
[56] *Rey-Ballet v. Engelhardt* at 1383 (citing Campbell v. Wettstein, 476 F.2d 642 (CCPA 1973)).
[57] *Fujikawa v. Wattanasin*, 93 F.3d 1559, n. 4, 39 U.S.P.Q.2d 1895 (1996).

A separate and distinct "specific utility" requirement, however, was not officially recognized until 2005 in *In Re Fisher*.[58] Here, the court articulated that a patent disclosure must "establish a specific and substantial utility for the claimed invention,"[59] while further noting that to satisfy the "specific utility" requirement, an applicant must "disclose a use which is not vague as to be meaningless."[60]

3. Evidence Required to Satisfy the "Substantial Utility" Requirement

While *Brenner* found there was not "substantial utility" in steroids that were analogous to steroids that inhibited tumors in mice, the court did not establish what evidence would actually be sufficient to satisfy the "substantial utility" requirement.[61] In fact, the court specifically refused to rule or express a view on cases decided by the CCPA involving compounds that had been shown to inhibit tumors in research animals.[62] For example, in *In re Krimmel*, the applicant demonstrated that his compound had efficacy as an anti-inflammatory in the eyes of rabbits, yet the PTO rejected the application for lack of utility.[63] The CCPA reversed, finding that a demonstration of efficacy in a standard animal model was sufficient to establish utility and that proven

[58] *In Re Fisher,* 421 F.3d 1365, U.S.P.Q.2d 1125 (2005).
[59] This standard is a bit odd in light of previous decisions (discussed supra) suggesting that "specific utility" can be satisfied by evidence of "substantial utility" where no "specific utility" is expressly asserted. Logically this seems to make the rule pointless because it can be interpreted to say: if you do not assert specific utility then you have to prove both substantial utility and substantial utility. (which is clearly redundant)

[60] *In Re Fischer* at 1371
[61] See *Brenner v. Manson*
[62] Brenner v, Manson, n. 17
[63] *In Re Krimmel*, 48 C.C.P.A. 1116, 1117-18, 292 F.2d 948 (1961).

safety in humans was not requisite.[64] After *Brenner,* this rationale was used and upheld in subsequent decisions.[65]

In 1970, the Second Circuit was presented with the same issue in *Carter-Wallace, Inc, v. Riverton Laboratories, Inc.,* where Riverton clamed that Carter-Wallace failed to meet the utility requirement.[66] Here, Carter-Wallace submitted data from tests performed on mice that supported its assertion that the claimed meprobamate compound had anticonvulsant properties that were superior compared to other known compounds.[67] Although, Riverton argued that this evidence was insufficient to demonstrate utility, the Court followed the rationale in *Krimmel* and held that there was sufficient evidence of utility because mice, in this context specifically, were standard experimental animals.[68]

Ten years later, while addressing a similar issue, the CCPA further defined the elusive concept of "substantial utility."[69] In *Nelson v. Bowler*, the applicant sought to prove utility by relying on tests involving the blood pressure of rats and stimulation of gerbil colon, which the PTO Board of Appeals (the "Board") found to be insufficient.[70] Judge Rich, who had been a frequent supporter of a broader interpretation of the "substantial utility" requirement,[71] wrote the opinion for the CCPA, which ultimately reversed the Board's decision.[72] Rich wrote that the "practical utility" requirement,

---

[64] *Krimmel* at 1124-25
[65] See *Carter-Wallace, Inc. v. Riverton Labs. Inc.*, 443 F.2d 1034, 167 U.S.P.Q 656 (1970).
[66] See *Carter-Wallace, Inc. v. Riverton Labs. Inc.*
[67] *Carter-Wallace, Inc. v. Riverton Labs. Inc.* at 1036
[68] *Carter-Wallace, Inc. v. Riverton Labs. Inc.* at 1040
[69] See *Nelson v. Bowler,* 626 F.2d 853, 206 U.S.P.Q 881 (1980).
[70] *Nelson v. Bowler* at 855-56
[71] Judge Rich had often been dissenter in previous utility cases, writing long dissents in favor of a broad interpretation of the utility standard in both in both *In Re Kirk* and *In Re Jolly*.
[72] *Nelson v. Bowler* at 856

which is recognized as being equivalent to "substantial utility,"[73] is essentially another way of saying that the claimed invention has "real world" value and "immediate benefit" to the public; moreover, he noted that evidence of any pharmacological activity is sufficient to establish "substantial utility".[74] Regarding Nelson's evidence, the court found that pharmacological activity had been established by the tests on rats and gerbil colon and consequently reversed the Board's finding of lack of utility.[75]

Although several courts had already found that *in vivo* tests can establish "substantial utility,"[76] it had not yet been decided whether a test such as the *in vitro* gerbil colon tests could be sufficient.[77] The Federal Circuit faced this issue in *Cross v. Iizuka*, where it affirmed a Board finding that *in vitro* testing, which demonstrated pharmacological activity, was sufficient to establish "substantial utility."[78] The Court found that although *in vitro* testing was a "first link" in the chain of screening for useful pharmaceutical compounds, positive results would subsequently lead to *in vivo* testing, which could give *in vitro* testing immediate public benefit and therefore "substantial utility."[79] Additionally, regarding the standard of evidence, the court noted that there must be a "reasonable correlation" between the *in vitro* test results and the *in vivo* test results for the *in vitro* evidence to establish "substantial utility."[80]

---

[73] *In Re Fischer* at 1371 (noting that "Courts have used the labels 'practical utility' and 'real world' utility interchangeably in determining whether an invention offers a 'substantial' utility").
[74] *Nelson v. Bowler* at 856
[75] *Nelson v. Bowler* at 857-58
[76] See, e.g., *Carter-Wallace v. Riverton Labs*, 433 F.2d 1034, 167 U.S.P.Q. 656 (1970); *In Re Krimmell*, 48 C.C.P.A. 1116, 292 F.2d 948 (1961); *Nelson v. Bowler*, 626 F.2d 853, 206 U.S.P.Q 881 (1980)
[77] Note that *in vivo* means a test performed on a living organism, whereas *in vitro* (literally meaning in glass) indicates a test performed in an artificial environment such as a test tube. (maybe define separately and at the word)
[78] See *Cross v. Iizuka*, 753 F.2d 1040, 224 U.S.P.Q. 739 (1985).
[79] *Cross v. Iizuka* at 1051
[80] *Cross v. Iizuka* at 1050

In 1995, the Federal Circuit had the opportunity to solidify some key elements of the "substantial utility" doctrine, specifically relating evidentiary standards.[81] In *In re Brana*, the Federal Circuit evaluated the Board's rejection of an application on the grounds that *in vivo* tests, which demonstrated anti-tumor properties of claimed compounds, were insufficient to establish utility.[82] First, the court found that the PTO failed to rebut the initial presumption that the applicant has satisfied the enablement requirement of utility; in other words, that the PTO did not provide "evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility" so as to shift the burden to the applicant to prove asserted utility.[83] Alternatively, the court found that even if the burden had shifted to the applicant to prove asserted utility, Brana's *in vivo* tests would have been sufficient to convince one skilled in the art of the asserted utility.[84] Moreover, the court noted that FDA approval was not prerequisite for demonstrating utility, as the Board implied by its ruling.[85] In addition to strengthening the established standards for evidence required to establish "substantial utility," *Brana* also solidified the well established standard associated with the burden shifting doctrine of utility rejections.[86] This standard, however, would only survive for ten years until it was toppled by a subsequent Federal Circuit decision.[87]

In *Rasmusson v. Smithkline Beecham Corp.*, the Federal Circuit was once again asked to evaluate the Board's rejection of a patent application for lack of enablement of

[81] See *In Re Brana*, 51 F.3d 1560, 63 USLW 2656, 34 U.S.P.Q.2d 1436 (1995).
[82] *In Re Brana* at 1564-65
[83] *In Re Brana* at 1566
[84] *In Re Brana* at 1567
[85] *In Re Brana* at 1568
[86] See *In Re Brana*
[87] See *Rasmusson v. Smithkline Beecham Corp*., 413 F.3d 1318, 75 U.S.P.Q.2d 1297 (2005); see also discussion infra.

utility.[88] Here, the issue was whether Rasmusson's assertion that his alpha-R-inhibitors were effective in treating cancer would be believed by someone reasonably skilled in the art.[89] The court ultimately found that one of reasonable skill in the art would not have believed Rasmusson's assertion of anti-cancer properties at the time the application was filed; [90] however, the most notable aspect of this decision was the standard by which the court evaluated Rasmusson's asserted utility.[91] Although the court cited *Brana* when recognizing that the PTO must shift the burden to the applicant, it impliedly rejected the *Brana* standard for burden shifting.[92] Instead of requiring that one of ordinary skill in the art "reasonably doubt the asserted utility," the court stated that where no evidence has been averred to support the claimed utility and a person skilled in the art would not accept the asserted utility "without question," the applicant would fail to establish sufficient utility.

4. "Substantial Utility" as it Relates to Intermediates and Research Tools

In the wake of *Brenner*, there has been a subsequent line of cases that have rejected utility for chemical intermediates and molecular research tools.[93] In *Brenner*, the Court effectively overruled several previous cases[94] when it held that a process for making steroids that was only homologous to known anti-tumor steroids, which thereby made the process a mere object of "use-testing," should not be patentable, while further

[88] See *Rasmusson v. Smithkline Beecham Corp*.
[89] *Rasmusson v. Smithkline Beecham Corp*. at 1323
[90] *Rasmusson v. Smithkline Beecham Corp*. at 1334
[91] See, e.g., 2 Rasmusson v. Smithkline Beecham Corp.: Enablement Under 35 U.S.C. § 112, First Paragraph, available at http://www.pattm.com/Rasmusson.pdf
[92] *Rasmusson v. Smithkline Beecham Corp*. at 1323
[93] See discussion infra.
[94] The CCPA officially overruled *In re Nelson* and other cases as a result of *Brenner* in *In Re Kirk,* 54 C.C.P.A. 1119, 1130, 376 F.2d 936 (1967).

noting that a "patent is not a hunting license," and is "not a reward for the search, but compensation for its successful conclusion."[95] This rationale was used in *In Re Kirk* and *In Re Joly,* a pair of cases which were decided by the CCPA shortly after *Brenner.*[96]

In *Kirk* and *Joly* the court relied on *Brenner* to reject "use as intermediates" as sufficient utility.[97] As discussed, supra, Kirk asserted that his compounds had "use as intermediates in the production of aromatic steroidal hormones and other biologically useful compounds." In evaluating utility as an intermediate, the court noted that it is insufficient to simply show that a chemical process works; moreover, it found that if a chemical intermediate was to have utility, the resulting final compound would be required to have a substantial utility itself.[98] Ultimately, the court found that the intermediate in question had not been shown to be useful in making any compounds that had a known use or utility; accordingly, the court affirmed the PTO's rejection of Kirk's application due to lack of utility.[99]

Similarly, in *In Re Joly*, applicants asserted that their claimed compounds were "useful as intermediates" in the preparation of steroids, which as in *Kirk*, did not themselves have a "specific utility".[100] Again, the court applied the rationale of *Brenner,* and additionally *Kirk*, when affirming the Board's rejection of Joly's application for lack of utility.[101]

---

[95] *Brenner v Manson* at 1042
[96] See discussion infra
[97] *In Re Kirk* at 1128-1129; *In Re Joly,* 54 C.C.P.A. 1159, 1161-62, 376 F.2d 906 (1967).
[98] *In Re Kirk* at 1129
[99] *In Re Kirk* at 1126 and 1130
[100] *In Re Joly* at 1161
[101] *In Re Joly* at 1161-1162

In regard to research tools specifically, the Federal Circuit addressed their patentability specifically in *In re Fisher.*[102] In *Fisher,* as discussed supra, the applicants sought to patent EST's that would be useful in genetic research of corn and its genome.[103] Although Fisher asserted a long list of uses for the EST's,[104] the Court found no evidence that supported *actual* use and therefore affirmed the Board's rejection because the EST's were only "object[s] of use-testing", i.e., mere research tools.[105] Additionally, the Federal Circuit found support for their findings in several PTO sources, including the "Utility Examination Guidelines," "Revised Interim Utility Guidelines Training Materials" and the Manual for Patent Examining Procedure" or MPEP.[106]

IV. UTILITY EXAMINATION STANDARDS AS DEFINED BY THE PTO

Aside from the standards espoused by court system, the PTO promulgates its own standards that patent examiners are directed to follow when evaluating the utility of patent applications. While courts have occasionally given deference to these regulations, they do not have the force of law and thus the courts are not obligated to follow them.[107] Nevertheless, it is important to review the PTO's examination standards because they are were influenced by seminal patent cases and are often referenced and incorporated into judicial opinions.[108]

---

[102] See *In Re Fisher*
[103] *In Re Fisher* at 1373
[104] See discussion supra
[105] *In Re Fisher* at 1372-3
[106] See *In Re Fisher*; see also discussion infra
[107] *In Re Fisher* at 1372
[108] See e.g. *In Fisher* at 1372 (citing both the MPEP and Revised Interim Utility Guidelines); see also MPEP § 2107.01 (citing and quoting numerous utility cases).

The landmark decision of *Diamond v. Chakrabarty* and a healthy American economy helped precipitate the biotech boom of the late 1980's and early 1990's, which created the need for the PTO to solidify its evaluation of the utility requirement.[109] *Chakrabarty* opened patent protection to inventions involving living subject matter and the PTO thereafter experienced a great increase in biotech applications.[110] In 1995, after receiving scathing criticism for inconsistent treatment of utility issues, the PTO responded by creating formal guidelines for evaluating utility.[111]

A. The 1995 Utility Examination Guidelines

Essentially following the Federal Circuit's decision in *Brana*, the 1995 Guidelines served to codify much of the recent case law on utility.[112] First, the guidelines established that the PTO has the initial burden of making a prima facie showing that an invention lacks utility by demonstrating (A) that an asserted "specific utility" would not be "considered credible by a person of ordinary skill in the art," or (B) where the inventor has not asserted a "specific utility," there is therefore not a "well-established utility" for the claimed invention.[113] Once a prima facie showing has been made, the burden then shifts to the applicant to rebut it or amend the application.[114] The guidelines additionally required that a rejection for lack of utility under § 101 must also be accompanied by a

[109] *Diamond v. Chakrabarty*, 447 U.S. 303, 100 S.Ct. 2204 (1980); Peter L. Giunta , QUID PRO WHOA!: AN EXPONENTIAL FEE STRUCTURE FOR PATENT APPLICATIONS, 25 Cardozo L. Rev. 2317, 2363-4 (2004).
[110] During the twelve year period of 1977-1989 the PTO had only 111 biotechnology patents issue; however, during the two year period of 1990-2000 the PTO recoded the issuance of 2,645 biotechnology patents. U.S. Patent & Trademark Office, Patent Counts by Class by Year, at ftp://ftp.uspto.gov/pub/taf/cbcby.pdf (last visited Feb. 2, 2006).
[111] See, e.g., Salim Hasan, A Call for Reconsideration of the Strict Utility Stanadard in Chemical Patent Practice, 9 High Tech. L.J. 254 (1994).
[112] See e.g., *In Re Brana; Brenner v. Manson*
[113] Utility Examination Guidelines, 60 Fed. Reg. 36263, 36264 (July 14, 1995).
[114] Utility Examination Guidelines, 60 Fed. Reg. 36263, 36264 (July 14, 1995).

rejection under § 112 for lack of enablement. Only a few years later, however, these guidelines proved inadequate and the PTO promulgated a new set of Examination Guidelines.

B. The 2001 Utility Examination Guidelines

The new 2001 guidelines retained much of the same language as the 1995 guidelines, yet the newly added sections served to strengthen the utility requirement. The first major change was the addition of a requirement that the invention have specific, substantial, and credible utility.[115] Additionally, the new guidelines explicitly reject "throw-away," "insubstantial," and "nonspecific" utilities as unsatisfactory of the "specific and substantial" requirement; for example, a complex invention being used as landfill.[116] These current guidelines were subsequently incorporated into the MPEP.[117]

Neither set of guidelines define the terms 'specific, substantial, or credible'; however, these terms have been defined by other PTO materials in addition to case law.[118]

V. Summary of Current PTO Guidelines and Case Law

To satisfy both the utility requirement of §101[119] and the enablement requirement of §112,[120] a patent application must demonstrate to a person reasonably skilled in the art

[115] Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001).
[116] Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001).
[117] *In Re Fisher* at 1372
[118] See 1995 guidelines and 2001 guidelines and discussion infra
[119] 35 U.S.C. § 101
[120] 35 U.S.C. § 112

that the claimed invention has (1) credible utility, (2) specific utility, and (3) substantial utility.[121] The definitions and scope of these requirements are discussed below.

A. Credible Utility

Although the PTO considers credible utility along with both substantial and specific utility requirements, credible utility issues tend to arise in cases separate from those where substantial and specific utility are questioned.[122] This practical case dichotomy can most likely be attributed to the fact that the credible utility standard is easy to satisfy unless an applicant claims outlandish utility that goes against known scientific principles.[123] The PTO has defined a claimed assertion as credible unless it is based on flawed logic or is inconsistent with given facts, which is itself generally consistent with court interpretations of the "credible utility" requirement;[124] for example, where applicants claim to have invented a perpetual motion machine, or a method of cold fusion.

B. Specific Utility

The "specific utility" requirement, as defined by the PTO, relates to utility that is "specific to the subject matter claimed" as compared to "general utility that would be applicable to the broad class of invention."[125] Additionally, the PTO has followed the holding of cases addressing "specific utility," stating that broad assertions such as

[121] MPEP § 2107.01
[122] See, e.g., Newman v. Quigg, 877 F.2d 1575, 1577 (perpetual motion machine); Ex Parte Dash 27 USPQ2d 1481 (cold fusion); Fregeau v. Mossinghoff 776 F.2d 1034 (using a magnet to improve beverage taste); compare to *Rasmusson v. Smithkline-Beecham Corp.*
[123] KENNETH BURCHFIEL, BIOTECHNOLOGY & THE FED. CIR., 47-48 (BNA Books 1995).
[124] Revised Interim Utility Guidelines Training Materials, Available at http://www.uspto.gov/web/offices/pac/dapp/mpep_examguide.html; see also MPEP § 2107.01(II).
[125] MPEP § 2107.01

"therapeutic" application or "biological activity," are insufficient.[126] On the other hand, it was the PTO who first excluded utilities that were applicable to a broad class of invention and the courts have recently followed this rule.[127] Nevertheless, current cases are generally in line with the PTO's definition of "specific utility," and it seems that both the PTO and the courts have relied on each other to develop this standard.[128]

This standard becomes a less clear in situations where an applicant makes no assertion of specific utility. The PTO suggests that an applicant must assert specific utility unless the invention's usefulness would be "immediately apparent to those familiar with the technological field of the invention. The courts have historically agreed with this standard.

C. Substantial Utility

Both the courts and PTO agree that "substantial utility" defines a "real world" use that must have "immediate benefit to the public"[129] Additionally, the PTO agrees with court holdings when citing exemplary situations where further research is required to attain "substantial utility," the PTO incorporates many of the facts and holdings of relevant case law while adding their own supplementary examples.[130] For example, PTO Training Materials give thirteen detailed examples of molecular and therapeutic inventions that may raise questions of utility, one of which was specifically cited in *Fisher.*[131]

---

[126] See, e.g., *In Re Kirk*; see also MPEP § 2107.01
[127] See, e.g, *In Re Fisher*.
[128] See e.g. *In Fisher* at 1372 (citing both the MPEP and Revised Interim Utility Guidelines); see also MPEP § 2107.01 (citing and quoting numerous utility cases).
[129] MPEP 2107.01(I)(B); *In Re Fisher* at 1371,
[130] MPEP 2107.01; Revised Interim Utility Guidelines Training Materials
[131] MPEP 2107.01(I)(B); *In Re Fisher* at 1371.

VI. PROBLEMS WITH THE CURRENT UTILITY STANDARD

The current state of the utility standard creates some serious problems for molecular and pharmacological inventions. First, because it is inherently more difficult to establish the utility of this class of inventions, [132] there exists a great disparity between the level of effort required to preempt patent rights and the level of effort required to demonstrate utility. Second, along with the inherent difficulty in establishing the utility of chemical and pharmacological inventions, there also exists a *de facto* heightened utility standard for this class of invention. Finally, the current standard, as espoused by the courts unfairly discriminates against an important area of scientific patents, namely molecular research tools.

A. Disparity Between Enabled Prior Art and Enabled Inventions

Under §§ 102 and 103 of the patent code, a patent application will be rejected if prior art references anticipate or render the claimed invention obvious.[133] As discussed above, patent applicants must satisfy the utility requirement by demonstrating both "substantial" and "specific" utility.[134] Moreover, where an applicant does not provide evidence to support utility, the application will be rejected unless one skilled in the art would accept the assertions of utility "without question."[135] On the other hand, for a prior art reference to anticipate the claims of an application, it need not demonstrate

[132] KENNETH BURCHFIEL, BIOTECHNOLOGY & THE FED. CIR., 47 (BNA Books 1995).
[133] 35 U.S.C. § 102; 35 U.S.C. § 103
[134] See discussion supra at Section V
[135] *Rasmussion v. Smithkline Beecham Corp.* at 1323; see also discussion supra

utility.[136] Accordingly, there exists a great disparity in the evidence required to create a patent rejection and the evidence required to satisfy the utility standard, especially in the art of chemical and biological inventions.

For example, consider a situation where a research scientist discovers a new process for a new compound that is analogous to compounds that are known to have anti-tumor properties and wishes to obtain patent protection for his method.[137] Because the researcher cannot yet provide proof that his compound will have anti-tumor properties, he must at least conduct *in vitro* tests to determine if it will have the assumed efficacy so as to satisfy the requirements of "substantial utility."[138] Moreover, even if he were to file a patent application and assert that his compound was highly likely to have anti-tumor properties, and even if one reasonably skilled in the art would reasonably accept this assertion, he would have his application rejected unless one reasonably skilled in the art would accept his assertion "without question."[139] Then assume that while the researcher is conducting *in vitro* tests, which are ultimately successful, another scientist discovers the same method and publishes a paper on the method before the first scientist can conclusively establish efficacy of the drug with his *in vitro* testing. In this case, although the first scientist clearly invented the method first, he would not be entitled to a patent under the rationale of *Rasmusson.*[140]

Because these types of utility issues normally only arise in the chemical or biological arts, this example illustrates how patents in this field are intrinsically harder to

---

[136] *Rasmussion v. Smithkline Beecham Corp.* at 1326; 35 U.S.C. § 102
[137] This "anti-tumor" fact pattern is indeed similar to *In Re Joly* and *Brenner v. Manson*
[138] *Cross v. Iizuka* at 1050-51.
[139] *Rasmusson v. Smithkline Beecham Corp.* at 1323
[140] Namely that a person of reasonable skill in the art would accept the asserted utility without question. See *Rasmusson v. Smithkline Beecham Corp.* at 1323; 35 U.S.C. § 102.

obtain because of the high level of proof required to meet the utility standard and the low standard required for invalidating prior art. Accordingly, research and development of inventions in the chemical or biological arts is inherently more difficult and risky than in other fields.

B. Heightened Standard for Molecular and Pharmacological Inventions

The courts and the PTO deny the existence of a heightened utility standard for chemical and biological inventions,[141] but a different standard for molecular and pharmacological inventions exists nonetheless. Although the PTO does not have an explicitly separate standard for evaluating the utility of these classes of inventions, evidence of a *de facto* disparity can be seen in the PTO's training materials.[142] As noted above, the PTO's patent examiner Training Materials include thirteen examples of situations where an examiner might be required to reject an application for lack of utility. These examples include inventions relating to proteins, DNA and chemical compounds with either pharmacological or experimental uses, which suggests that the standard of utility is most applicable to, or should only be applied to molecular or pharmacological subject matter.[143] The PTO has nonetheless maintained that the rules governing the evaluation of utility apply to all patent examiners and the Board, regardless of subject matter.[144]

---

[141] *In Re Fisher* at 1370
[142] Notice that essentially all of the examples of given in the Revised Interim Utility Guidelines Training Materials are directed towards molecular and pharmacological inventions. This creates and impression that inventions that are not in this class are treated differently or at least considered *prima facie* useful.
[143] Revised Interim Utility Guidelines Training Materials; Id.
[144] 60 FR 36263, 36264 (July 14, 1995).

Naturally, molecular or pharmacological inventions tend to reside closer to the cusp of utility than other classes of invention;[145] however, glairing examples of useless patents on other classes of inventions suggest that the utility standard is all but ignored in most cases. One of the most prominent illustrations is the patent on a "method of swinging on a swing," which discloses a novel way of swinging on "a standard swing suspended by two chains from a substantially horizontal tree" whereby the user "induces side to side motion by pulling alternately on one chain and then the other."[146] While one could argue that this patented method has "substantial utility" because it gives "real world" and "immediate benefit" to the public through amusement, this argument seems comical when it is compared to cases like *Joly,* where an application was rejected because the claimed chemical intermediates could only produce steroids that were analogous to known anti-tumor steroids.[147]

Although it might be argued that allowing alternative standards of utility would have a negligible or even positive effect on the patent system, this argument ignores the basic purpose of the patent system.[148] Most simply, the use of different standards for patentability runs contrary to the basic sources of the utility requirement, namely the U.S. Constitution and the Patent Act.[149] Both documents provide for the protection of "useful" inventions without consideration of the field of art and indeed they do not suggest that the utility standard should not be applied uniformly to all inventions.[150] Accordingly, allowing separate standards, even *de facto* separate standards, would be outside the

[145] KENNETH BURCHFIEL, BIOTECHNOLOGY & THE FED. CIR., 47-48 (BNA Books 1995).
[146] US Pat. 6368227 (filed Nov. 7, 2002).
[147] See discussion of "substantial utility supra at §(V)(B); See also *In Re Joly*.
[148] To "promote the Progress of Science and useful Arts." Const. art I § 8 cl 8.
[149] Const. art I § 8 cl 8; 35 U.S.C § 101; 35 U.S.C. § 101
[150] Const. art I § 8 cl 8; 35 U.S.C § 101; 35 U.S.C. § 101

current scope of PTO or court power. Because the current treatment of the utility standard de-emphasizes classes of inventions outside the molecular and pharmacological arts,[151] it creates an impression that other classes of inventions are *prima facie* useful.

C. Unfair Treatment of Research Tools

After *Brenner,* compounds that were potentially objects of "use-testing" were no longer patentable for lack of utility.[152] Indeed, subsequent cases affirmed rejections of intermediates that could be used to synthesize compounds that were not yet know to have a specific use.[153] Additionally, in *Fisher,* the Federal Circuit held that claimed EST's were not patentable because they were simply research tools. While these cases seek to maintain the integrity of the patent system, they ultimately serve to discriminate against a specific type of invention.[154]

When most people think about scientific research, they probably imagine a person with large glasses, messed up hair and a white lab-coat mixing and combining chemicals while heating them over a Bunsen burner.[155] This comical impression of science goes to show that there is wide-spread lack of appreciation for the increasing complexity of research tools required to support even the most basic of scientific research and the huge

[151] Revised Interim Utility Guidelines Training Materials
[152] *Brenner v. Manson* at 1042
[153] See In Re Kirk; see also In Re Joly
[154] By integrity of the patent system, I mean the balance between promoting the useful arts and protecting useless inventions.
[155] Jrène Rahm & Paul Charbonneau, *Probing stereotypes through students' drawings of scientists*, American Journal of Physics, Vol. 65, No. 8 (Aug. 1997).

industry that has arisen to fill this demand[156], which like other commercial fields, relies heavily on patents to protect its proprietary products.[157]

The major gap in reasoning, when it comes to the patentability of research tools, is the lack of appreciation for the research and development that goes into developing products that are subsequently used in the research and development of drugs and technologies that directly benefit the public.[158] Accordingly, where courts use a rationale that potential research tools lack utility because they do not bring real-world value, it directly trivializes the indirect benefit that scientific supply industry has on the public and denies it the patent protection that other industries readily enjoy.

Although the PTO seems to recognize that research tools and chemical intermediates are not per se unpatentable,[159] the courts have not been not been clear on this issue. Although both the PTO and the courts require that inventions have "real world" use that is "available to the public,"[160] each seems to have a different definition for these terms. The PTO leaves open the possibility for research tools to be of "real world" value;[161] however, the courts seem to find that "real world" value means an invention that could be appreciated and used by the public at large, i.e. non-scientists.[162] "Available to the public" is also seems to be restricted to non-scientists when interpreted

---

[156] For example, see http://www.coleparmer.com or http://www.sigmaaldrich.com. These websites will give one an idea of the vast range and number of research tools that are available to the scientific industry.
[157] Vernon M. Winters, 2003 Stanford Law & Technology Association Conference: Ideas Without Boundaries: Creating and Protecting Intellectual Property in the International Arena, available at 24 Loy. L.A. Ent. L. Rev. 1, 12-13 (2003).
[158] McKercher PL, *Pharmaceutical research and development*, Clinical Theraputics Vol 14, Issue 5, p760 (Sep-Oct 1992).
[159] See MPEP § 2107.01(I)(C): "… Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as 'research tool,' 'intermediate' or 'for research purposes' are not helpful in determining if an applicant has identified a specific and substantial utility for the invention."
[160] *Brenner v Manson*; MPEP § 2107.01(I)(B).
[161] MPEP § 2107.01(I)(B).
[162] See *Brenner v Manson*

by the courts, whereas the PTO embraces the potential for broader interpretation.[163] Consequently, the court interpretation discriminates against research tools and thereby unfairly discriminates against the scientific supply industry.

VII. RAMIFICATIONS

While all inventors are potentially effected by the negative ramifications of the current utility standards, larger entities such as universities and private industry are most affected because they are the source of the majority of chemical and biological patent applications.[164] Put simply, the cost of research and development of new scientific technology is an expensive and risky proposition and these larger entities are some of the few inventive groups that can absorb the high cost and risk.[165]

Over the years, the line between a public university and a private research and development corporation has become increasingly blurry.[166] Accordingly, these entities now share many of the same issues when it comes to development of new technologies, financing, and protection of intellectual property.[167] More specifically, the university system has become increasingly similar to the private corporation.[168]

---

[163] See *Brenner v Manson*; *In Re Kirk*; *In Re Joly*, *In Re Fisher*, and MPEP § 2107.01

[164] For example, note the number of patents issued to by the following organizations in 2004: University of California (422); Pfizer, Inc. (164); Bristol-Myers Squibb Co. (96); Johns Hopkins Univ. (94); Smithkline Beecham Co. (78); University of Michigan (66); Abbott Labs (65); Genentech, Inc. (62); Merch & Co., Inc. (58). Available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/topo_04.htm#PartA1_1 (last visited Feb. 3, 2006).

[165] Vernon M. Winters, 2003 Stanford Law & Technology Association Conference: Ideas Without Boundaries: Creating and Protecting Intellectual Property in the International Arena, available at 24 Loy. L.A. Ent. L. Rev. 1, 12-13 (2003).

[166] Jennifer Washburn, *University, Inc.* 137-41 (Basic Books 2005).

[167] Jennifer Washburn, *University, Inc.* 137-41 (Basic Books 2005).

[168] Jennifer Washburn, *University, Inc.* 137-41 (Basic Books 2005).

After the passage of the Bayh-Dole Act[169] and Federal Technology Transfer Act,[170] universities were able to retain title of inventions developed using federal funds. Consequently, universities began establishing technology transfer offices and began filing patent applications in record numbers.[171] At the same time, public funding for universities began to decline and these institutes began to rely increasingly on revenue generated from patents and related products, thereby putting their interests in concert with those of corporations who similarly rely on patents as a major source of revenue.[172]

Regarding, the utility standard, both universities and scientific technology companies experience a chilling effect as a result of the currently stringent standards required to establish utility. First, in light of *Rasmusson,* there is now a higher risk associated with the research and development process. Requiring that a person skilled in the art accept asserted utility "without question," absent other proof, essentially places an added burden of testing on these institutions. This burden requires that more time and resources be placed into these inventions, when there is not a reciprocal guarantee that an invention will be protected once utility is substantially proven. While time and money is being expended to prove utility, the inventor runs the risk of being preempted by others who invent and publish on the same subject matter, but who are not required to prove

---

[169] Bayh-Dole Act was passed in 1980 and allowed small businesses and universities to own the rights to their own inventions instead of the previously mandatory assignment to other agencies. The rationale for this was to increase the development of these inventions by giving the patent rights to people who had most incentive to develop them. See John H. Raubitschek, *Reasonable Pricing – A New Twist for March-in Rights Under the Bayh-Dole Act*, 22 Santa Clara Computer & High Tech. L.J. 149 (2005).

[170] Among other things, the Technology Transfer Act requires a percentage of the governments research and development budget to be applied to transferring technology rights to states, localities and industry. See Robert H. Swennes II, *Commercializing Government Inventions: Utilizing the Federal Technology Transfer Act of 1986*, 20 Pub. Cont. L.J. 365 (1991).

[171] Jennifer Washburn, *University, Inc.* 42 (Basic Books 2005).

[172] Vernon M. Winters, 2003 Stanford Law & Technology Association Conference: Ideas Without Boundaries: Creating and Protecting Intellectual Property in the International Arena, available at 24 Loy. L.A. Ent. L. Rev. 1, 12-13 (2003); Jennifer Washburn, *University, Inc.* 184 (Basic Books 2005).

utility to act as prior art. In addition to the already extant risk inherent in research and development, the disparity in standards enabling prior art compared to enabling a patent application creates more risk, and therefore a chilling effect on research in general.

If there is more risk in obtaining patent protection for chemical and biological inventions, two consequences will inevitably follow: first, biotechnology and pharmaceutical companies will be exposed to greater risk of losing money in research and development and will consequently be restricted in their research or will be forced out of business if they are unable to successfully to manage the risk; second, these institutions will be more likely to retain these technologies as trade secrets, which would result in a determent to the public through the inefficiency caused by lack of disclosure through the patent process.

Similarly, universities and its researchers may lose incentive to pursue research that will not easily yield patentable technology. As institutions, the universities will likely give more preference and funding to the faculty who add patents to the university's intellectual property portfolio. Accordingly, researches will tend to focus on research that can easily demonstrate utility along with enabling the technology. Unfortunately, this will not necessarily give researchers the incentive to develop inventions that are most beneficial to the public and instead only to develop inventions that will likely be patentable.

Overall, the most negative ramifications of a heightened utility standard are a severe restriction in viable research because of an increased risk of research and development, along with reduced public disclosure through the patent system.

VIII. Restricted Research and Risk to Funding

Corporations and that rely on revenue from patents to fund their research programs must naturally pursue projects that are likely to create a return on capital invested in research and development. Accordingly, when the risk of losing invested capital increases, the pool of viable research projects will decrease because some projects will no longer be worth the investment risk. Unfortunately, where researchers are restricted to only a few projects that will have a likelihood of producing revenue, scientific development will be stymied because important advances may never be attempted in the first place due to the inherent financial risk. Additionally, increased risk in research and development will likely lead to some businesses and universities being unable to sustain their research due to lack of revenue from patents.

The detrimental effects of increased risk in research and development can be seen in the current situation with large pharmaceutical companies. It's hard not to notice recent news headlines about shortages of flu vaccines and slow production of avian flu vaccine.[173] Although many factors contribute to this problem, one major issue is lack of production capacity due to a limited number of pharmaceutical companies. Demand for drugs increased exponentially, but the capacity to fill that demand has not been able to keep up. Especially in the United States, there is little incentive to enter the risky drug market.[174]

---

[173] See e.g. Hope Yen, Experts: *U.S. unprepared for flu Vaccine shortage for pandemic Doses can't be made fast enough*, Seattle Times, Nov 21, 2005, at A4, 2005 WLNR 18833262; Marsha Mercer, *'Better be Ready' as Flu Vaccine Shortage Again Appears, Fear of Pandemic Rises*, Richmond Times-Dispatch, Nov. 6, 2005, at F4, 2005 WLNR 18020675.

[174] Clare Kittredge, *A Shrinking Target*, The Scientist, April 11, 2005, at 46, 2005 WLNR 6228424.

It costs drug companies roughly one 800 million dollars and ten to fifteen years to develop one successful drug.[175] Moreover, it has been estimated that one out of ever thousand experimental drugs makes it to clinical trials.[176] Because the cost associated with development and promotion of each of its drugs is so high, pharmaceutical companies rely heavily on patent protection to recoup these capital investments.[177] The stringent utility standards of patentability only add to the risk that existing pharmaceutical companies must absorb. Unfortunately, this high risk limits companies from expanding production capacity and prevents competitors from entering the market as well.[178] In the end, the public loses because of exorbitant drug costs and lack of production capacity in times of crisis.

B. Reduced Disclosure of New Technology

Along with a chilling effect on research and development, the stringent utility standard also creates incentive for inventors to retain their inventions as trade secrets instead of seeking patent protection; consequently, the public will lose the benefit of the disclosure of new technology through patents. The incentive to keep new inventions as trade secrets comes from several sources. First, inventors who wish to secure patent protection outside the United States will have their patent applications published after

[175] Vernon M. Winters, 2003 Stanford Law & Technology Association Conference: Ideas Without Boundaries: Creating and Protecting Intellectual Property in the International Arena, available at 24 Loy. L.A. Ent. L. Rev. 1, 13 (2003).
[176] Vernon M. Winters, 2003 Stanford Law & Technology Association Conference: Ideas Without Boundaries: Creating and Protecting Intellectual Property in the International Arena, available at 24 Loy. L.A. Ent. L. Rev. 1, 13 (2003).
[177] Dennis Fernandez & Mary Chow, *Symposium Review: Intellectual Property Stategy in Bioinformatics and Biochips*, 19 Santa Clara Computer & High Tech. L.J. 491, 492 (2003).
[178] Clare Kittredge, *A Shrinking Target*, The Scientist, April 11, 2005, at 46, 2005 WLNR 6228424.

eighteen months[179] and thereby publicly disclosed, even if the application does not end in an issued patent. Second, even if the patent is issued, the strict utility standard, and ease by which prior art will preempt a patent, creates a greater risk that a patent will be invalidated in subsequent litigation.

By keeping new technology secret, the research and development community in the art will not have access to information that would otherwise be disclosed during the patent process; consequently, this will inevitably lead to inefficient and redundant technology development. A basic purpose of the patent system is to allow the art to progress in a cooperative atmosphere, which is defeated if inventions are kept secret.[180]

On the other hand, one of the major arguments against allowing liberal patent protection in the chemical and biological arts is that research will be inhibited by patentees who refuse to license their technology or through increased cost to research from licensing costs and maintenance.[181] Although there are examples of this happening,[182] the benefits gained by open disclosure through patents greatly outweigh some of the negative consequences that result from a limited patent monopoly. In fact, the basic *quid pro quo* of the patent system anticipates and accepts the negative aspects of the patent monopoly.

It is clear that research can be stifled by those who refuse or make it difficult to license technology; however, the technology itself may have never been known at all had

---

[179] Actually, all applications will be published 18 months after their filing date unless a non-publication request is filed. Applicants seeking foreign patent protection, however, are not eligible for non-publication.
[180] Joseph Mohr, Unshackle Academia and Allow it to Exemplify the Purpose of Patent Law: "To Promote the Progress of Science and the Usefyl Arts," 88 Marq. L. Rev. 671, 681-83 (2004).
[181] *See, e.g., Brenner v. Manson*, 383 U.S. 519, 534, 86 S.Ct. 1033 (1966).
[182] For example, an unfortunate case where researchers at the University of Utah discovered a breast cancer gene, patented it, and sold an exclusive license to the start-up company of a University of Utah professor, who subsequently hoarded the gene and prevented other researchers from using it. Jennifer Washburn, *University, Inc.*, page xi (Basic Books 2005).

it not been brought to the public by the inventor in the first place. Where technology is not publicly disclosed, many researchers might waste valuable time and money developing a technique or compound that had already been discovered. On the other hand, where new developments are known, but maybe not useable, the researchers will at least save time and money that would otherwise be spent developing the same technology, and may actually be able to improve on patented technology or design around it, which would actually promote development.

VIII. SOLUTIONS

As discussed above, the heightened utility standard will restrict viable research because of an increased risk of research and development, in addition to reduced public disclosure through the patent system. To remedy these negative ramifications, three courses of action should be taken. First, *Rasmusson* should be overturned and the utility should be returned to it former level. Second, the disparity that allows prior art with non-enabled utility to preempt inventors who are yet to prove utility should be reformed. Finally, the courts should adopt the PTO's view of research tools, which theoretically allows molecular research tools to be patentable.

A. Rasmusson Should be Overturned and the Utility Standard Reverted

The decision in *Rasmusson* has tightened the requirements of an already stringent utility standard and deviates from well established patent precedent and accepted scientific principles; accordingly, the decision should be reconsidered and reversed in part. First, the requirement that applicants must substantially prove utility unless one

reasonably skilled in the art would accept their assertions of utility "without question" is too stringent. In effect, this standard requires that inventors of chemical and biological inventions conduct at least *in vitro* tests to prove their invention has utility, and it is no longer enough that a person reasonably skilled in the art would reasonably believe the asserted utility.

Moreover, this standard is too high, especially given the nature of the scientific method.[183] Rarely, if ever, are there scientific principles that are accepted "without question," especially in emerging fields of study where theories are yet to receive strong scrutiny.[184] In fact, even well designed and statistically significant scientific research can never actually be "without question."[185] Hypothesies and scientific theories that survive the scrutiny of experimentation are only considered to be not disproved and can only be falsified instead of actually proven.[186] Accordingly, because the "without question" standard does not comport with basic scientific principals, it should be lowered to the level it was before *Rasmusson*, namely it should be sufficient that one skilled the art would reasonably believe the asserted utility.

B. The Disparity Between Prior Art and Invention Enablement Should Be Closed

As discussed supra, prior art that can preempt a patent does not need to demonstrate utility, which creates more risk for subject matter that does not immediately satisfy the otherwise strict utility standard. Chemical and biological subject matter,

[183] Sir Karl Popper agrees with David Hume's assertion that inductive logic is a failure with respect to the scientific method and that theories and laws are simply yet to be disproved. For example while it is considered common knowledge that unicorns do not exist, however, it is logically impossible to conclusively prove this proposition because it is theoretically possible that we are simply yet to see a unicorn. Hugh G. Gauch, Jr., Scientific Method in Practice 81-82 (Cambridge University Press 2003).
[184] Hugh G. Gauch, Jr., Scientific Method in Practice 81-82 (Cambridge University Press 2003).
[185] Hugh G. Gauch, Jr., Scientific Method in Practice 81-82 (Cambridge University Press 2003).
[186] Hugh G. Gauch, Jr., Scientific Method in Practice 81-82 (Cambridge University Press 2003).

unlike other classes of inventions, typically requires complex and expensive testing to demonstrate actual utility,[187] thereby creating an unfair disadvantage to inventors in the chemical and biological arts. Accordingly, this disparity should be removed.

Because this disparate standard is only inequitable in situations where the first inventor reduces to practice, but is unable to substantially prove utility before another creates prior art without having to satisfy utility, there should be an exception in this specific situation. Therefore, where inventors can show they have a fully enabled invention, aside from demonstrating utility, they should not be barred by prior art that comes into existence while they are diligently attempting to prove utility. In other words, first inventors seeking priority over prior art would have to demonstrate (1) that their invention was fully enabled, aside from utility, prior to the effective date of the art in question; (2) that they have sufficiently demonstrated utility since then, and (3) that they worked diligently from time of conception until proof of utility was demonstrated.

It is not uncommon for the PTO to carve out exceptions for certain types of art[188] and this standard would not be very similar to the current standards used to determine priority of invention in cases where two independent inventors invent at almost the same time.[189] By carving out an exception for an inequitable situation, *de facto* discrimination against the biological and chemical arts would be removed and the existing equitable remainder of the system would remain intact.

---

[187] See, e.g., *In Re Kirk; In Re Joly*.

[188] For example, the Drug Price Competition and Patent Term Restoration Act of 1984 allowed for an extension of the patent term for certain products that require FDA approval. This statute was primarily aimed at benefiting the pharmaceutical and biotechnology industries. See MPEP § 2750

[189] 35. U.S.C. § 102(g)(2) provides that in determining priority of invention, the PTO will award priority to the party who invented first and also diligently reduced the invention to practice. For example, if I1 invents but is not diligent in reducing to practice and I2 invents after I1 invents, but before I1 reduces to practice, and is diligent in reducing to practice, I2 will be awarded priority instead of I1.

C. The PTO's Evaluation of Research Tools Should be Adopted by Courts

The narrow interpretation of "real-world" value and "available to the public" adopted by the courts negate the value that molecular and biological inventions may have as commercial research products.[190] The PTO, on the other hand, adopts a broader and more realistic definition of these terms that does not restrict or reject utility where an invention is only useful to research scientists and should be adopted by the courts.[191]

As the PTO notes, the evaluation of research tools should focus on whether the asserted utility is substantial and whether it requires further research to be proven instead of focusing on who the invention will be useful to.[192] Researchers and scientists should not have a special standing as "non-public" for purposes of determining utility. In fact, in other areas of patent law, these types of people are considered members of the public for purposes of evaluating patentability, and it is inconsistent that the standard should be different regarding utility.[193] The current court interpretation demonstrates a lack of appreciation for the scale and scope of scientific research and development along with a lack of consideration for the pervasive standards of patent law as a whole and should therefore be changed.

IX. CONCLUSION

Several current interpretations of the utility requirement of patentability create inequitable discrimination in the chemical and biological arts. This creates great

[190] See discussion supra
[191] See MPEP § 2107.01(I)(C)
[192] See MPEP § 2107.01(I)(C)
[193] Rejections under 102(a), (b) consider "public" to be just about anyone, even disclosing to a single person is considered a "public" disclosure. *Egbert v. Lippmann*, 104 U.S. 333, 336, 14 Otto 333 (1881)(noting that if an inventor "gives or sells it to another, to be used by the donee or vendee, without limitation or restriction, or injunction of secrecy, and it is so used, such use is public, even though the use and knowledge of the use may be confined to one person.").

disincentives to efficient progression of the art and discourages a much needed expansion of the pharmaceutical and biotechnology industries.

More specifically, the decision in *Rasmusson* creates a requirement that utility be conclusively proven, even where one skilled in the art would reasonably believe an asserted utility; moreover, along with a higher standard to demonstrate utility, *Rasmusson* also affirms a disparate standard of enablement of prior art compared to a patent. Because prior art need not demonstrate utility to preempt a patent application, this creates a situation where applicants can lose their patent rights even though they invented a technology before others who did not need to meet the high requirements of utility. Additionally, current court precedent regarding research tools is too stringent and does not seem to appreciate the nature of modern scientific research and industry.

Accordingly, these erroneous standards should be reformed. First, the requirement that one skilled in the art accept asserted utility "without question," unless the applicant gives sufficient proof, should revert to a standard where the applicant need only prove substantial utility where one skilled in the art would not reasonably accept the asserted utility. Second, an exception should be carved out for cases where an applicant has an invention reduced to practice, save proof of utility, and they are faced with a rejection because prior art came into existence while they were diligently proving utility; in such cases, the prior art should be required to demonstrate utility to be enabling. Finally, the courts should adopt the same evaluation of research tools that is used by the PTO. Instead of focusing on the class of person who will find the invention useful, the analysis should simply focus on whether the use is substantial, even where that use is for research purposes.

Adopting these changes would rectify the de facto patent discrimination of the chemical and biological arts and would help reduce one of the many risky aspects of an industry that relies on these types of patents as a major, if not exclusive source of revenue. The universities and corporate entities that make a business in this art are already burdened with the high risks associated with development and sale of their products, and the patent system is increasingly becoming another substantial risk, which stifles the progression of science and medicine. Accordingly, the aforementioned reforms to the utility standard of patentability are much needed to ensure that the patent system does indeed promote the useful arts and science as the Constitution allows.

