THE PROBLEMS OF THE UTILITY ANALYSIS IN *FISHER* AND ITS ASSOCIATED POLICY IMPLICATIONS AND FLAWS

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INTRODUCTION

Expressed sequence tags (ESTs) are short DNA sequences containing the information to code usually a portion of a protein, and many debate whether they should be patented.[1] In *In re Fisher*,[2] the Court of Appeals for the Federal Circuit[3] found that, despite having several potential uses as research tools, ESTs lacked utility, which is required for patentability.[4] The court's analysis of utility was flawed, however, because it did not apply the traditional evidentiary standard, misapplied its own evidentiary standard, failed to recognize there was sufficient substantial utility as a research tool under *Brenner v. Manson*,[5] and altered the specific utility requirement in detrimental ways without distinguishing or reconciling prior precedent.

The Federal Circuit not only misconstrued the case, but its failure to adequately address the policy implications of the decision reveals general problems with the treatment of policy considerations in the patent system. First, as Professor Arti K. Rai articulates, the Federal Circuit appears unwilling to address policy concerns at all,[6]

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1. Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735, 738–39 (2000).

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

3. The Federal Circuit hears all appeals in patent cases. Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1037 (2003).

4. *Id.* at 1368, 1379.

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

6. *See id.* at 1123 ("[T]he Federal Circuit appears to be quite resistant to economic policy analysis.").

which supports the argument that there is no institution in the current patent system both willing and able to address policy.[7] Second, the distinction the Federal Circuit draws between ESTs of genes with known and unknown functions is not meaningful, and illustrates that utility makes a poor doctrinal mechanism with which to draw the distinctions the court may be interested in, such as preventing an anticommons.[8] Third, *Fisher* illustrates the recurring problem of using technology-specific rules when the court either does not understand the science or is making unreviewable policy determinations.[9] *Fisher* falls at the center of many pressing policy considerations, and provides a useful lens to analyze and support prior theories about the consideration of policy and technology specific rules.

This Note begins in Part I by providing the necessary general background on the utility requirement, ESTs, and DNA patents. Part II then provides a summary of the *Fisher* court's analysis of the utility of the ESTs. The evidentiary, substantial utility, and specific utility problems with the analysis are laid out in Part III. Finally, Part IV analyzes the policy problems and theoretical implications of the decision.

I. THE BACKGROUND: UTILITY AND EST HISTORY

A. The Utility Requirement Generally

Of the requirements for a patent,[10] utility is the most important in *Fisher*.[11] Utility generally requires that the invention be "useful."[12]

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7. *See id.* at 1040–41 ("[N]o institution has taken responsibility for elaborating patent law in the fact-specific, policy-oriented manner that the language of the statute encourages.").

8. The anticommons concept was first articulated in Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998). Matthew D. Satchwell, Note, *The Tao of Open Source: Minimum Action for Maximum Gain*, 20 BERKELEY TECH. L.J. 1757, 1763–64 (2005).

9. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1157 (2002).

10. Patentability has five major requirements: the invention must be within a patentable category, have utility, be nonobvious to a practitioner in the field, be novel, and be adequately disclosed. Byron V. Olsen, *The Biotechnology Balancing Act: Patents for Gene Fragments, and Licensing the "Useful Arts,"* 7 ALB. L.J. SCI. & TECH. 295, 312–13 (1997).

11. *See In re* Fisher, 421 F.3d 1365, 1379 (Fed. Cir. 2005) (affirming the rejection of the claims based on lack of utility).

12. *See* 35 U.S.C. § 101 (2000) ("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 . . . ." (emphasis added)). Utility is also a constitutional

The threshold for utility is typically quite low.[13] An inventor must proffer at least one reasonable use for the invention, and, so long as the invention can perform the function asserted for it, even if it does so poorly, it may be patentable.[14] Only those inventions "totally incapable of achieving a useful result" or those that are inoperable are barred from patentability by the utility standard.[15]

In *Brenner*, however, the Supreme Court articulated an elevated utility standard for research intermediates. In that case, a chemical process produced a product whose only known utility was as an object of scientific inquiry.[16] The Court found that a "use" as an "object of scientific research" (an "object of use-testing") was insufficient to meet the utility requirement, whether the claims were to the product or to the processes that produced it.[17] A patent is not intended to be a "hunting license"; it must relate to "commerce" rather than "philosophy."[18] A plausible reading of *Brenner* characterizes this distinction as one between basic research that must be left in the public domain and patentable applied technology with tangible benefits.[19] *In re Joly*[20] clarified that the utility of an intermediate could

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requirement based on the mandate to promote the "*useful* arts." U.S. CONST. art. I, § 8, cl. 8 (emphasis added); U.S. PATENT AND TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2107.01 (8th ed., 2d rev. 2004) [hereinafter MPEP].

13. Holman & Munzer, *supra* note 1, at 757. For example, one court said, "The threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366 (Fed. Cir. 1999).

14. Holman & Munzer, *supra* note 1, at 757.

15. Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571 (Fed. Cir. 1992).

16. Brenner v. Manson, 383 U.S. 519, 529 (1966).

17. *See id.* at 535 ("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.").

18. *Id.* at 536 (quoting *In re* Ruschig, 343 F.2d 965, 970 (C.C.P.A. 1968)).

19. *See* Andrew T. Kight, Note, *Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines in Light of* Brenner, 73 IND. L.J. 997, 1012 (1998) ("[T]he utility requirement operates to distinguish between basic research and applied technology. In this sense, it serves a timing function, 'leaving basic research discoveries in the public domain until they have yielded tangible benefits and have thereby left "the realm of philosophy" and entered "the world of commerce."'" (quoting Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 6 (1995) (quoting *Ruschig*, 343 F.2d at 970)). A full analysis of the *Brenner* decision is beyond the scope of this piece.

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

be shown through the utility of the final product, but simple use as an intermediate was not sufficient to show utility.[21]

Thus, the Supreme Court in *Brenner* rejected a "de minimis" view of utility,[22] and instead offered a new test requiring both specific and substantial utility:[23]

> 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.[24]

Although the Supreme Court has not specifically defined "specific" and "substantial," the Federal Circuit and its predecessor court have developed definitions.[25] Substantial utility, synonymous with "practical utility," is "a shorthand way of attributing 'real-world' value to claimed subject matter."[26] It requires that an invention, in its current form, can be used in "a manner which provides some *immediate benefit to the public*."[27] A "real world" use will not exist if there must be further research to identify or confirm the use.[28]

In order to possess specific utility, "an application must disclose a use which is not so vague as to be meaningless."[29] There must be a "well-defined and particular benefit to the public."[30] Examples of asserted utilities that fail on the specific utility requirement include

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21. *Id.* at 908; Timothy A. Worrall, *The 2001 PTO Utility Examination Guidelines and DNA Patents*, 16 BERKELEY TECH. L.J. 123, 130 (2001).

22. *In re* Fisher, 421 F.3d 1365, 1370 (Fed. Cir. 2005). The *Fisher* court's summary of the utility requirement is a generally good overview of the law. Justice Story's "de minimis" view of 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.'" Brenner v. Manson, 383 U.S. 519, 532–33 (1966) (quoting Note on the Patent Laws, 3 Wheat. App. 13, 24 (1818)).

23. *Fisher*, 421 F.3d at 1371.

24. *Brenner*, 383 U.S. at 534–35.

25. *Fisher*, 421 F.3d at 1371.

26. *Id.* (quoting Nelson v. Bowler, 626 F.2d 853, 856 (C.C.P.A. 1980)) (internal quotations omitted).

27. *Id.* (quoting *Nelson*, 626 F.2d at 856). Utility does not require that the product or process be superior to existing products or processes. Olsen, *supra* note 10, at 314.

28. *Fisher*, 421 F.3d at 1372; MPEP, *supra* note 12, § 2107.01(I).

29. *Fisher*, 421 F.3d at 1371.

30. *Id.*

"biological activity," "biological properties," and "technical and pharmaceutical purposes."[31] These are so "nebulous" that they fail to communicate an explicit indication of use for the compounds in the application.[32] The Patent and Trademark Office (PTO), meanwhile, takes the view that specific utility must be "*specific* to the subject matter claimed," as opposed to the "*general* utility . . . applicable to the broad class of the invention."[33] This diverges, however, from court precedent and is less preferable than the approach taken by previous courts.[34]

Although an invention must have specific utility and substantial utility that does not require further research to confirm, it is irrelevant to determining specific and substantial utility that an invention is used as a research tool.[35] As with any other invention, the critical question under *Brenner* for research tools is whether they are unpatentable objects of use-testing or patentable items in the "world of commerce."[36] Despite controversy surrounding the patentability of research tools under *Brenner*,[37] many research tools have implicitly been recognized to fall into the latter category because they were found to be patentable.[38] That research tools meet the *Brenner*

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31. *Id.* (quoting *In re* Kirk, 376 F.2d 936, 941 (C.C.P.A. 1967)).

32. *Id.* (quoting *Kirk*, 376 F.2d at 941).

33. MPEP, *supra* note 12, § 2107.01(I). The *Fisher* court says this is consistent with its interpretation of utility. *Fisher*, 421 F.3d at 1372.

34. Generally, the application of this standard to other technologies would be problematic because patents on distinct but related products with similar uses would be excluded from patentability. *See infra* Part III.C.

35. *See* MPEP, *supra* note 12, § 2107.01(I) ("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."). The *Fisher* court favorably cited and accepted this analysis. *Fisher*, 421 F.3d at 1372. A determination that an invention is a research tool does not help determine whether the invention meets these utility standards. *See id.* ("An 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.").

36. Brenner v. Manson, 383 U.S. 519, 535–36 (1966) (quoting *In re* Ruschig, 343 F.2d 965, 970 (C.C.P.A. 1968)).

37. *Compare* Justine Pila, *Bound Futures: Patent Law and Modern Biotechnology*, 9 B.U. J. SCI. & TECH. L. 326, 354 n.79 (2003) (expressing the view that the PTO guidelines were contrary to *Brenner* in making a designation as a research tool irrelevant), *with* Natasha N. Aljalian, *The Role of Patent Scope in Biopharmaceutical Patents*, 11 B.U. J. SCI. & TECH. L. 1, 58 n.220 (2005) (expressing the view that a particular invention's use as a research tool should meet the *Brenner* utility requirements).

38. For example, the PTO has recognized chromatographs, screening assays, and nucleotide sequencers are all patentable despite being research tools because they have clear, specific, and unquestionable utilities. MPEP, *supra* note 12, § 2107.01(I).

standard is evidenced by the increase in patents covering research tools.[39]

To reject an application based on lack of utility, the patent examiner must make a *prima facie* showing 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."[40] An applicant's assertion of utility creates a presumption that the utility is sufficient to meet the utility requirement.[41] Only if a *prima facie* case is made does the applicant have the burden to provide rebuttal evidence to convince one skilled in the art of the invention's utility.[42]

B. The Molecular Biology of ESTs

The patent in *In re Fisher* involved expressed sequence tags (ESTs).[43] Organisms have their genetic information, or "genome," stored in DNA.[44] The information from the DNA is copied into mRNA, and then from mRNA into proteins, which do most of the work in the cell.[45] RNA is chemically distinct from DNA,[46] and the mRNA sequence differs from that of the original DNA because non-coding sequences in the middle of the gene's DNA sequence are removed.[47] Researchers may then copy the mRNA sequence into cDNA, which contains the same chemical components as DNA, but has the same sequence as the mRNA.[48] Because different cells will

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39. *See* David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 997 (2005) (noting the number of patents on biotechnology research tools has increased substantially).

40. MPEP, *supra* note 12, § 2107.02(IV).

41. *Id.* § 2107.02(III).

42. *See In re* Brana, 51 F.3d 1560, 1566 (1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence to convince such a person of the invention's asserted utility."); MPEP, *supra* note 12, § 2107.02(VI) ("If a rejection [is] properly imposed, . . . the burden shifts to the applicant to rebut the *prima facie* showing.").

43. *In re* Fisher, 421 F.3d 1365, 1366–67 (Fed. Cir. 2005).

44. BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL, at G:15 (4th ed. 2002).

45. *Id.* at 302, 335–36.

46. *Id.* at 302.

47. *Id.* at 317–18.

48. *See id.* at 503–04 (describing cDNA production to make a "library" of sequences). cDNA is made because it is more stable and more manipulable by scientists. *See* Margaret Sampson, Comment, *The Evolution of the Enablement and Written Description Requirements Under* 35 U.S.C. § 112 *in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1237 (2000) ("Scientists can generate stable copies of mRNA using the original DNA nucleotides (A, G, C,

express different proteins at different times, the collection of cDNAs from those cells will differ.[49]

ESTs are lengths of cDNA that typically do not contain the entire gene sequence.[50] Among other uses,[51] the ESTs can help isolate the full gene sequence and can identify where the gene is expressed.[52] These uses are based on an important property of ESTs, and all DNA sequences, in binding and recognizing complementary sequences.[53]

C. DNA Patents Prior to Fisher

Because DNA has "specific chemical structures that impart specific properties,"[54] courts treat it as a chemical for the purposes of patentability,[55] despite problems associated with the treatment of DNA *only* as a chemical.[56] Historically, the PTO granted patents on

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and T). These condensed copies of genes, called complementary DNA ('cDNA'), have been crucial in the development of recombinant DNA technology.").

49. *See* ALBERTS ET AL., *supra* note 44, at 503 ("Because the cells of different tissues produce distinct sets of mRNA molecules, a distinct cDNA library is obtained for each type of cell used to prepare the library.").

50. Holman & Munzer, *supra* note 1, at 748. The length of the EST is limited by the length of DNA that can be sequenced at any one time, which is shorter than the length of the full gene. *Id.* at 749. It is possible a short gene could be encoded by an EST, but that situation is likely to be rare. *Id.*

51. *See infra* Part III.A.

52. Holman & Munzer, *supra* note 1, at 749.

53. *See* ALBERTS ET AL., *supra* note 44, at G:9 ("Two nucleic acid sequences are said to be complementary if they can form a perfect base-paired double helix with each other."); *id.* at 534 (describing a microarray that can be used to detect the presence sequences based on their ability to bind their complementary sequences). In the DNA code, each base pairs with one other base: A with T and C with G. *Id.* at 194. The complementary sequence has the paired base for the one in the sequence of interest, and is in the opposite orientation. *See id.* at 195 ("[M]embers of each base pair can fit together within the double helix only if . . . the polarity of one strand is oriented opposite to that of the other strand . . . . [E]ach strand of a DNA molecule contains a sequence of nucleotides that is exactly complementary to the nucleodite sequence of its partner strand."). For example, the sequence "ACTGGA" would have the complement "TCCAGT."

54. Worrall, *supra* note 21, at 136.

55. *See In re* Wallach, 378 F.3d 1330, 1335 (Fed. Cir. 2004) (treating a gene as a chemical compound for the purposes of the written description requirement); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991) (finding that "[a] gene is a chemical compound, albeit a complex one," and treating the gene as a chemical compound for purposes of conception).

56. Courts have been slow to recognize the "informational link" between DNA and protein. *See* Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 836 (1999) ("[The Federal Circuit failed] to recognize DNA-based technologies as involving information first and foremost . . . . [T]o the extent that it has acknowledged this link, the CAFC appears to be well behind the technology.") This is particularly clear in the nonobviousness standard, where knowing a method of

ESTs. For example, a patent issued on ESTs from genes coding members of a protein family with a generally known function.[57] The functions of the specific genes associated with the ESTs, however, were not always precisely known. For example, the PTO granted a patent for proteins secreted from cells, even though it was not known what specifically the proteins did.[58] Many EST applications were notable because of their broad claims to an EST, the full associated gene, and its future uses.[59]

In response to pressure from the scientific research community,[60] the PTO revised its utility examination guidelines[61] in 2001[62] to require further characterization of the cDNAs, including ESTs.[63] Under the PTO's new standards, an identification of a gene and a function are sufficient to show utility.[64] However, uses such as mapping genes, probing for genes, and identifying chromosomes do not meet the specific utility test, unless the associated sequence correlates with a disease.[65] Because the PTO lacks rulemaking authority, courts do not

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identifying a gene and a partial protein sequence does not make the DNA sequence obvious for purposes of patentability because the court focuses on DNA as a chemical. *Id.* at 833–34 (describing *In re* Bell, 991 F.2d 781 (Fed. Cir. 1993)). This is problematic because a DNA sequence may be deemed nonobvious merely because no structurally similar chemical exists, even if the sequence was "easy or routine" to isolate based on a technical use of the informational connection. *Id.* at 833–36.

57. *See* Human Kinase Homologs, U.S. Patent No. 5,817,479 (filed Aug. 7, 1996) (issued Oct. 6, 1998) (patenting ESTs of genes encoding protein kinases); Holman & Munzer, *supra* note 1, at 771 (noting proteins in the kinase family were known to be involved in signaling).

58. *See* Secreted Proteins and Polynucleotides Encoding Them, U.S. Patent No. 5,654,173 (filed Aug. 23, 1996) (issued Aug. 5, 1997) (patenting sequences from genes that produce secreted proteins); Holman & Munzer, *supra* note 1, at 773 ("[W]hen the patent application was filed, Genetics Institute apparently did not know what the secreted proteins might be.").

59. Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 104 (1999).

60. Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 840 n.111 (2001). The research community "continues to resist broad patenting of the most upstream research." *Id.*

61. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

62. The interim guidelines were issued in 1999, and the final guidelines issued in 2001. Rai, *supra* note 60, at 840.

63. *See* Holman & Munzer, *supra* note 1, at 759 (describing a prominent PTO official's belief that the revision of the utility guidelines was intended to heighten the utility requirement by requiring a characterization of the cDNA).

64. *See* Holman & Munzer, *supra* note 1, at 759 ("For example, the PTO will apparently consider the identification of the open reading frame of a nucleic acid sequence to be sufficient, at least in combination with the identification of a functional domain.").

65. *Id.* at 760; MPEP, *supra* note 12, § 2107.01(I). *See infra* Part III (discussing why this standard is inappropriate).

defer to these guidelines.[66] They are nevertheless significant because they establish the posture of cases that come to the courts.[67] Also, the Federal Circuit in *Fisher* demonstrated great willingness to accept these particular guidelines.[68]

II. THE *FISHER* COURT'S ANALYSIS OF UTILITY

The patent application in *Fisher* was for five ESTs generated from corn leaf tissue at a particular period in development.[69] The structure and function of the underlying genes and proteins were not known,[70] but the proposed utilities of the ESTs included:

> (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.[71]

The patent applicants also suggested the ESTs could be used to screen for, identify, and characterize the underlying genes.[72]

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66. Rai, *supra* note 3, at 1132.

67. *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 250 (3d ed. 2002) ("To the extent that the 2001 Guidelines indicate a tightening of agency policy, the PTO will be denying more applications than it previously would have and, as those disappointed applicants appeal to the Federal Circuit, the agency will find itself defending its new approach in court.").

68. *See In re* Fisher, 421 F.3d 1365, 1372 (Fed. Cir. 2005) ("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.").

69. *Id.* at 1367–68.

70. *Id.* at 1368, 1373.

71. *Id.* at 1368.

72. *See* Corrected Brief for Appellants at 13, *In re* Fisher, 421 F.3d 1365 (Fed. Cir. 2005) (No. 04-1465), *available at* Posting of Dennis Crouch to Patently-O blog, http://patentlaw.typepad.com/patent/2005/03/monsanto_asks_t.html (Mar. 23, 2005) ("[T]he claimed ESTs could be used as research probes to screen a cDNA library for the specific gene sequence to which the EST uniquely corresponds. The successful hybridization . . . [to the] corresponding gene sequence would confirm that the gene was being expressed in certain tissues, at certain times, by certain organisms." (citation omitted)).

Despite these assertions, the court rejected the patent, finding that the ESTs lacked utility.[73] The court wanted a showing by the applicant that the ESTs were actually or could be used in the asserted ways.[74] The court found the application fell short under this evidentiary standard because the asserted uses were merely "hypothetical possibilities" any EST could achieve, but which the particular ESTs in the application had not achieved.[75]

Turning to substantial utility, the Federal Circuit analogized the case to *Brenner*, in which the applicant was not allowed to claim a process for preparing compounds of unknown use.[76] The court viewed the ESTs as only being useful as research intermediates to identify, isolate, and experiment on the underlying genes of unknown functions.[77] Because the ESTs were employed to search for a use of the underlying gene, there was no "immediate, well-defined, real world benefit to the public."[78] Thus, the ESTs were seen as unpatentable "mere 'objects of use-testing,'" which the court defined as an "object[] upon which scientific research could be performed with no assurance that anything useful will be discovered in the end."[79]

The court rejected the analogy between the ESTs and the microscope, a quintessentially patentable research tool.[80] The analogy was based on the fact that both the microscope and the ESTs can generate data about a sample with unknown properties.[81] The court, however, found it significant that the microscope immediately reveals the structure of a sample through magnification, while the ESTs can only detect the presence of the genetic material with the same

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73. *Fisher*, 421 F.3d at 1379.

74. *See id.* at 1373–74 ("Fisher has not presented any evidence . . . showing that the claimed ESTs have been used in either way. . . . There also is no disclosure establishing that any of the claimed ESTs were used or, for that matter, could be used to control or provide information about gene expression.").

75. *Id.* at 1373. For example, while ESTs could be used to identify promoters, the applicant did not provide any evidence the ESTs actually identified a promoter. *Id.*

76. *See id.* at 1374 ("We agree . . . that the facts here are similar to those in *Brenner* . . . . The *Brenner* court held that the claimed process lacked a utility because it could be used only to produce a compound of unknown use.").

77. *Id.* at 1373–74.

78. *Id.* at 1376.

79. *Id.* at 1373. It should be noted that the "assurance" of a useful discovery appears to be an addition to the *Brenner* standard described in Part III.B.

80. *Id.* at 1373.

81. *Id.*

structure, and provide no information on the structure or function of the underlying gene.[82]

Furthermore, the Federal Circuit emphasized that the use of an EST as an intermediate is not sufficient for utility.[83] The court also suggested that a similarity to other ESTs was insufficient to demonstrate utility.[84] Although this appears consistent with *Brenner*, which held that an applicant could not show the utility of a steroid by relying on the uses of structurally similar steroids, *Brenner* rested on the recognized unpredictability of steroid compounds, a property not inherent in ESTs.[85]

Next considering specific utility, the court held that the uses were not specific because any EST from any gene has the potential to perform any of the proposed uses.[86] Under the traditional view of specific utility, the court analogized the uses to the "nebulous" and nonspecific assertion of "biological activity" as a use.[87] The court also accepted the PTO's alternative formulation that required the use be specific to the claimed invention,[88] and found the ESTs did not meet that standard since any EST would have the same uses.[89]

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82. *Id.*

83. *Id.* at 1375.

84. First, the court noted that the steroids in *Joly* did not have utility even though they were structurally similar to steroids known to be useful. *Id.* at 1375. Second, the court rejected the applicants' reliance on *In re Jolles*, 628 F.2d 1322, 1327–28 (C.C.P.A. 1980), in which the court found untested compounds had utility based on their structural similarity to tested compounds that were also claimed. *Fisher*, 421 F.3d at 1376. The ability to rely on other ESTs to show utility appeared to be limited to cases were the EST relied on was also claimed in the patent, analogous to the *Jolles* situation as described by the *Fisher* court. *See id.* at 1377 ("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.").

85. *See* Brenner v. Manson, 383 U.S. 519, 532 (1966) ("[D]espite the reference to the adjacent homologue, respondent's papers did not disclose a sufficient likelihood that the steroid . . . would have similar tumor-inhibiting characteristics. . . . [T]he presumption that adjacent homologues have the same utility has been challenged in the steroid field because of 'a greater known unpredictability of compounds . . . .'" (footnotes omitted)).

86. *Fisher*, 421 F.3d at 1374.

87. *Id.* at 1374–75.

88. *Id.* at 1372. The court thought the PTO's standard was consistent with the previous standard. *See id.* ("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 . . . .").

89. *Id.* at 1374.

Lastly, while the court was generally uninterested in policy,[90] it did consider policy issues specifically mentioned in *Brenner*.[91] *Brenner* discouraged granting monopolies without utility.[92] Such monopolies had boundaries that could not be precisely delineated, and thus the monopoly would block areas of scientific development without benefiting the public.[93] The *Fisher* court viewed granting a patent on ESTs as giving an impermissible "hunting license" because the only use would be to gain more information about the underlying genes.[94]

III. WHY THE *FISHER* COURT'S ANALYSIS OF UTILITY WAS INCORRECT

A. The Proposed Uses Are Sufficient Under the Traditional Evidentiary Standard for Utility

The *Fisher* court did not apply the traditional evidentiary standard and failed to scientifically analyze the asserted utilities.[95] A technical evaluation of the asserted utilities shows the assertions were sufficient under both a traditional and an elevated evidentiary

90. *See id.* at 1378 ("Congress did not intend for these practical implications to affect the determination of whether an invention satisfies the [patentability] requirements . . . . [P]ublic policy considerations . . . are more appropriately directed to Congress as the legislative branch . . . rather than this court as a judicial body responsible simply for interpreting and applying statutory law."). The court decided the utility issue without considering the policy concerns. *See id.* ("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.").

91. *See id.* at 1375–76 (quoting *Brenner* and describing the Supreme Court's concern with "creating an unwarranted monopoly to the detriment of the public"). Although the *Brenner* considerations appear to be policy issues, the court never described them as such.

92. *See* Brenner v. Manson, 383 U.S. 519, 534 (1966) ("[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."). This portion of *Brenner* was quoted in *Fisher*. *Fisher*, 421 F.3d at 1375–76.

93. *Brenner*, 383 U.S. at 534.

94. *Fisher*, 421 F.3d at 1376. While the court quoted the language on the relationship to "commerce" and "philosophy" from *Brenner*, 383 U.S. at 536, the court failed to apply this language specifically to the EST situation. One possible application would be that the ESTs were not the ends of research related to commerce, but were tools to be used in searching for practical utility in "the realm of philosophy." *Id.*

95. *See Fisher*, 421 F.3d at 1380 (Rader, J., dissenting) ("[T]his court . . . discounts these ESTs because it concludes (without scientific evidence) that they do not supply enough information."). A technical analysis appears to be necessary to accurately determine if the uses asserted are substantial and specific. This Part provides the technical analysis of the uses, and Parts III.B and III.C address whether these uses are substantial and specific as technically described.

standard for utility, contrary to the assertion that the uses were only "hypothetical."[96]

Traditionally, the initial burden is on the PTO to establish a *prima facie* case that it is more likely than not that a person of ordinary skill in the art would not consider the utility specific and substantial.[97] There is no requirement the applicant prove the utility with statistical certainty.[98]

The *Fisher* court, however, did not follow this standard. Rather than find that the PTO failed to established a *prima facie* case because there was no showing that the ESTs were incapable of performing the asserted functions,[99] the *Fisher* court shifted the burden to the patent applicant to prove the uses[100] and show they were actual, not "hypothetical."[101] The court could not require that every invention actually be used prior to patenting and maintain consistency with other patent law principles.[102] Thus, under the new standard the Federal Circuit adopts here, there should be a similar exception to that found in the "on sale" doctrine for "devices [that] are so simple and their purpose and efficacy so obvious that their

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96. *Id.* at 1373 (majority opinion).

97. MPEP, *supra* note 12, § 2107(II).

98. MPEP, *supra* note 12, § 2107.02(VII).

99. *See Fisher*, 421 F.3d at 1381 (Rader, J., dissenting) ("[T]he Board did not reject Fisher's utilities on the basis that the ESTs were *unable to perform* the purported utilities. Thus, the Board did not establish a prima facie challenge to the ESTs' ability to perform these two utilities.").

100. *See id.* at 1374 (majority opinion) ("Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed.").

101. *See supra* notes 74–75 and accompanying text. This standard is different even from *In re Kirk*, 376 F.2d 936 (C.C.P.A. 1967), that found "conjectural" uses were not sufficient for utility because the examples of "conjectural" uses primarily included cases where there was no known use. *See id.* at 945 ("[I]f a process for producing a product of only conjectural use is not itself 'useful' . . . the starting materials . . . are [not] 'useful.' It is not enough that the specification disclose that the intermediate exists and . . . can be used to produce some intended product of no known use.").

102. For example, this would bar patents on impractical, but operable inventions, such as producing water and oxygen from moon rocks, which traditionally have been considered patentable. *See* MERGES & DUFFY, *supra* note 67, at 216 (describing *Ex parte McKay*, 200 U.S.P.Q. (BNA) 324 (P.T.O. Bd. App. 1975)) (describing that even though making water and oxygen from moon rock is not practical on earth, utility is not typically measured by what is practical). It could be problematic for the PTO to bar inventions that are prohibitively expensive to practice at the time of invention, rather than letting the market determine what is practical, because the market may be a better judge of feasibility. *See id.* ("[T]he claimed inventions might have been prohibitively expensive to implement, but no one expressed doubt as to whether the claimed methods would work . . . . [T]he PTO issues the patent and lets the market decide the practicality of the inventions.").

complete construction is sufficient to demonstrate their workability."[103] This is supported by language in *Fisher* suggesting that a use one of ordinary skill would consider certain could meet the elevated evidentiary standard.[104]

Regardless of the standard adopted, at least some uses of the ESTs should meet the evidentiary standard. Under the traditional standard of convincing a person of ordinary skill in the art, one skilled in the art would be convinced the ESTs could be used in the asserted ways because "many in the research community" view ESTs as useful research tools.[105] Even if a higher standard requiring certainty is used, at least some of the uses would not be considered hypothetical by one skilled in the art.[106] To illustrate this, it is necessary to scientifically analyze what researchers in the field view as the uses of ESTs.[107]

Uses based on known complement binding properties of ESTs[108] would be recognized as certain uses. Such uses would include

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103. E. Rotorcraft Corp. v. United States, 384 F.2d 429, 431 (Ct. Cl. 1967).

104. First, the court lists whether the ESTs "could be used to control or provide information about gene expression" as an alternative to whether they were actually used. *Fisher*, 421 F.3d at 1374. Second, the court found there was no proof that the ESTs "can be *successfully* used in the seven ways disclosed," *id.* at 1374 (emphasis added), rather than continuing to insist on the absence of actual use. Third, the court required more than "merely hypothetical possibilities," which would be met either by a certain ability to use the invention or an actual use. *See id.* at 1373 ("[A]ll of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, *could* possibly achieve, but none for which they have been used in the real world."). There is, however, a great deal of language emphasizing actual uses are necessary. *See supra* notes 74–75 and accompanying text. Nevertheless, the combination of the actual use and potential to use language suggests that a certain ability to use an invention could be sufficient to show utility.

105. Stacy Lawrence, *US Court Case to Define EST Patentability*, 23 NATURE BIOTECHNOLOGY 513, 513 (2005). Many researchers, however, believe that because ESTs are research tools, they should be left in the public domain unless they are related to a specific process. *Id.* Even amici in *Fisher* opposed to patentability recognized the asserted uses were nothing other "than already well-known potential uses." Brief of Genetech, Inc. as Amicus Curiae Supporting Affirmance and Supporting the U.S. Patent and Trademark Office at 13, *In re* Fisher, 421 F.3d 1365 (Fed. Cir. 2005) (No. 04-1465), *available at* Posting of Dennis Crouch to Patently-O blog, http://patentlaw.typepad.com/patent/files/genentech_amicus_brief_for_in_re_fisher.pdf (Mar. 23, 2005).

106. On the other hand, if actual use without any exceptions for certain ability to use were required, despite the language in *Fisher* and inconsistency with other patent law principles and precedent, the ESTs would likely fail on that standard if they were not actually used. *See supra* notes 97–98, 102, 104 and accompanying text.

107. Although the following discussion is aimed at examining the uses under the elevated standard, any use accepted under the elevated standard would also be accepted under the lower traditional standard. Thus, acceptance of particular uses as research tools is not discussed under the traditional standard unless the analysis diverges from that of the elevated standard.

108. *See supra* note 53 and accompanying text.

"measuring the level of mRNA in a tissue sample via microarray technology to provide information about gene expression," "providing a source for primers for use in the polymerase chain reaction ('"PCR'") process to enable rapid and inexpensive duplication of specific genes,"[109] and screening for or identifying the underlying genes.[110] A microarray consists of several known cDNAs that can bind cDNA made from a sample to determine which genes are expressed.[111] Because ESTs can bind their matching complementary sequence, one skilled in the art would know with certainty they can be used in a microarray based on this property alone. The ability of the EST to bind its complement also makes its ability to identify the underlying gene or create PCR primers that bind and allow amplification of the target sequence certain.[112] Similarly, the mapping uses of "isolating promoters via chromosome walking" and "serving as a molecular marker for mapping the entire maize genome"[113] are certain based on the same complement sequence binding properties because ESTs are in fact used in mapping.[114]

Despite these uses, not all uses in "controlling protein expression"[115] are certain. Decreasing protein expression is a more certain use similar to designing PCR primers because complementary sequences can be used to prevent the conversion of mRNA

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109. *Fisher*, 421 F.3d at 1368.

110. *See supra* note 72 and accompanying text.

111. ALBERTS ET AL., *supra* note 44, at 534.

112. PCR generates many copies of a genetic sequence in a short time by heating the sample to separate DNA strands, hybridizing primers that are sequence specific, synthesizing a complementary strand, and repeating this process. *Id.* at 508–09. The primers are short DNA sequences complementary to the ends of the sequence of which amplification is desired (the target sequence). *Id.* Identification or characterization of the underlying gene could involve PCR or microarray techniques.

113. *Fisher*, 421 F.3d at 1368.

114. *See, e.g.*, H.-M. Ma et al., *An EST Survey of the Sugarcane Transcriptome*, 108 THEORETICAL & APPLIED GENETICS 851, 851 (2004) (sequencing ESTs to better understand the sugarcane genome); Jianzhong Wu et al., *A Comprehensive Rice Transcript Map Containing 6591 Expressed Sequence Tag Sites*, 14 PLANT CELL 525, 525 (2002) (describing an EST map, which can be used for further mapping efforts, of the rice genome by creating ESTs, designing primers to the ESTs, and locating the sequences in a library). Chromosome walking uses the complementary binding properties to determine the next portion of the genomic sequence beyond what is known. ANTHONY J.F. GRIFFITHS ET AL., AN INTRODUCTION TO GENETIC ANALYSIS 810 (7th ed. 2000) ("[Chromosome walking is] [a] method for the dissection of large segments of DNA, in which a cloned segment of DNA . . . is used to screen recombinant DNA clones from the same genome bank for other clones containing neighboring sequences.").

115. *Fisher*, 421 F.3d at 1368.

information into protein.[116] On the other hand, increasing protein expression would likely require adding back the complete protein sequence, which is not a certain use if the EST does not contain the complete sequence.[117]

It is almost certain that ESTs can be used in "locating genetic molecules of other plants and organisms" or "identifying the presence or absence of a polymorphism."[118] While it is extremely likely there are similar genes in other organisms and polymorphisms, it is also possible there are not.[119] Thus, if the standard were that one of ordinary skill must think the use likely, these uses would suffice. If the standard required absolute certainty, these would fail.

The *Brenner* prohibition on analogies to similar chemicals to show utility[120] should not bar the considerations of the general properties of ESTs to show the utility of the particular ESTs. In *Brenner*, analogies were prohibited for steroids, in which minor variations could result in large changes in function.[121] The Court in *Brenner* acknowledged that this rule might be limited to certain technologies.[122] Although the effect of a change on a steroid may be unknown, the effect of a change in EST sequence alters only the

116. Small double-stranded RNAs can be used to prevent the production of the associated proteins based on its ability to bind the mRNA. Craig C. Mello & Darryl Conte, Jr., *Revealing the World of RNA Interference*, 431 NATURE 338, 339–40 (2004).

117. A gene can "be rather easily integrated into random positions of many animal genomes," including an egg cell to produce an animal carrying the gene. ALBERTS ET AL., *supra* note 44, at 540–41.

118. *Fisher*, 421 F.3d at 1368.

119. Typically, genes in diverse organisms will be similar. *See* ALBERTS ET AL., *supra* note 44, at 453 ("[G]enes with similar functions can be found in a diverse range of living things. . . . [T]he actual nucleotide sequences of many genes are sufficiently well conserved that homologous genes . . . can often be recognized across vast phylogenetic distances."). A polymorphism is a difference between copies of a gene in different individuals, which may or may not be present. *See id.* at G:28 ("Polymorphic: Describes a gene with many different alleles."). If there are no polymorphisms, there could be no use of them by plant breeders to determine heritage, which was another asserted use. Corrected Brief for Appellants, *supra* note 72, at 18. Similarly, whether the ESTs could be used to determine the source of a tissue or provide an understanding of the response of a tissue to various treatments, Corrected Brief for Appellants, *supra* note 72, at 15, would depend on whether there are differences in expression between tissues or treatments.

120. *See supra* notes 84–85 and accompanying text.

121. Brenner v. Manson, 383 U.S. 519, 532 (1966).

122. *Id.* ("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.").

sequence to which it will bind, a predictable change.[123] Thus, there should be no prohibition against relying on what is known about general EST properties.

Because some of these uses are certain to be recognized by those skilled in the art merely based on the properties of the "constructed" EST, they should not be considered hypothetical.

B. The Proposed Uses Do Meet the Substantial Utility Standard

The *Fisher* court claimed, based on *Joly* and *Brenner*, the ESTs lacked utility because they were mere objects of use-testing and were just intermediates that produced a product with no known use because the underlying genes had no known function.[124] The court failed to recognize, however, that the ESTs had uses sufficient for substantial utility, and that their status as research tools or intermediates should not bar their patentability.

Brenner held that a use as an "object of use-testing" was not sufficient to show utility.[125] An "object of use-testing" appears to be an "object of scientific research," as was the case in *Brenner* because the steroid had no known use and was merely the object of "scientific inquiry."[126] The *Joly* court indicated that a function as an intermediate was similarly insufficient to show utility.[127] Rather than suggesting that intermediates were unpatentable, however, the *Joly* court allowed the utility of an intermediate to be shown by its product.[128]

The ESTs do not fail under *Brenner* and *Joly* for two reasons. First, the ESTs are not objects of use-testing lacking substantial utility because the EST itself is not an object of use-testing. Rather, the object of study is the underlying gene or the genome. ESTs are chemically and legally distinct from the mRNA and genomic DNA

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123. The Federal Circuit held in regards to the description requirement that a protein sequence would put one of ordinary skill in the art in possession of the entire genus of DNA sequences that can encode the protein. *In re* Wallach, 378 F.3d 1330, 1333 (Fed. Cir. 2004). The court reached this conclusion even though the protein sequence does not precisely predict a particular DNA or RNA sequence because more than one codon codes for each amino acid in the protein. ALBERTS ET AL., *supra* note 44, at 336. Thus, if the nucleic acid genus is predicable from the protein sequence, the binding sequence of an EST certainly is as well because it is perfectly predictable.

124. *In re* Fisher, 421 F.3d 1365, 1373–75 (Fed. Cir. 2005).

125. *Brenner*, 383 U.S. at 535.

126. *Id.* at 529, 535.

127. *In re* Joly, 376 F.2d 906, 908 (C.C.P.A. 1967).

128. *Id.*

that they are used to study. ESTs differ from mRNA because they are chemically DNA, and are distinct from the genomic DNA because noncoding segments within genes and surrounding chromosomal sequences are removed.[129] This difference is significant for patentability because the unpurified gene is unpatentable, but the purified EST is patentable subject matter.[130] Because this distinction from the underlying gene qualifies the EST as patentable subject matter, it would be illogical to collapse the distinction by considering the EST itself as an object of use-testing simply because it enables research on the unpurified gene.[131]

Second, the *Fisher* court's characterization of ESTs as research intermediates without analyzing the products[132] fails to disprove utility because, under *Joly*, utility may be shown by evaluating the products of the intermediates.[133] To the extent that ESTs qualify as intermediates,[134] their products have real world uses other than as objects of use-testing.[135] Genome maps produced in part from ESTs

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129. *See supra* note 47 and accompanying text; *see also* ALBERTS ET AL., *supra* note 44, at G:6 (cDNA is a "DNA molecule made as a copy of messenger RNA and therefore lacking the introns that are present in genomic DNA").

130. *See* Tanya Wei, Comment, *Patenting Genomic Technology – 2001 Utility Examination Guidelines: An Incomplete Remedy in Need of Prompt Reform*, 44 SANTA CLARA L. REV. 307, 321–322 (2003) ("Since the sequenced gene fragments, like ESTs, do not exist in their natural state and are therefore 'not nature's handiwork,' they are 'patentable subject matter under § 101.'" (quoting Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980))). Under the *Parke-Davis & Co. v. H.K. Mulford & Co.*, 189 F. 95 (S.D.N.Y. 1911), analysis of purification, a purified substance is considered a "new 'composition of matter.'" *Id.* at 103.

131. Even if the chemical analysis were abandoned and ESTs were viewed as identical to the DNA or mRNA based on the same informational content, the EST is still not identical to the entire genome it is used to map. Thus, even if the EST were an object of use-testing, its use as an intermediate could be demonstrated under *Joly* by showing the map it created was useful.

132. *See In re* Fisher, 421 F.3d 1365, 1375 (Fed. Cir. 2005) ("Just as the claimed compounds in *Kirk* and *Joly* were useful only as intermediates in the synthesis of other compounds of unknown use, the claimed ESTs can only be used as research intermediates in the identification of underlying protein-encoding genes of unknown function. The rationale of *Kirk* and *Joly* thus applies here.").

133. *In re* Joly, 376 F.2d 906, 908 (C.C.P.A. 1967).

134. The use of the ESTs in a microarray can be a direct use not dependent on intermediaries. ESTs are generally 400 to 500 bases in length. Holman & Munzer, *supra* note 1, at 749. One study compared microarray probes between 25 and 1000 bases long, and recognized there are microarrays with cDNA probes. Cheng-Chung Chou et al., *Optimization of Probe Length and the Number of Probes per Gene for Optimal Microarray Analysis of Gene Expression*, 32 NUCLEIC ACIDS RES., 1, 7 (2004).

135. *See supra* Part III.A.

are widely recognized as useful to scientists who study genes.[136] The PCR primers created from ESTs are useful to detect or isolate a sequence,[137] and scientists recognize the creation of constructs decreasing protein levels as a useful tool for studying protein function.[138] Unlike the process in *Brenner* or the intermediate in *Joly*, the EST is not used to make the underlying gene being studied because that gene already exists.[139] Thus, the ESTs should have substantial utility because researchers use their products to study the distinct underlying gene.

The ESTs and their products are used as research tools,[140] but status as a research tool does not alone determine the usefulness of an invention or automatically preclude patentability.[141] Instead, patentability depends on the existence of substantial utility, or if further research is required to confirm the utility.[142] The identified uses of ESTs as research tools require no further research to confirm.[143] A good analogy for ESTs is nucleotide sequencers, which have a clear and accepted utility in analyzing compounds.[144] Even though the nucleotide sequencer produces a chemical with the same sequence as a portion of the gene or genome under study,[145] the nucleotide sequencer still has utility. The same should be true for the ESTs.

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136. *See* ALBERTS ET AL., *supra* note 44, at 507–08 (noting that having a genomic map allows evolutionary relationships to be traced between genes and organisms, to discover new genes, and to predict the function of genes).

137. *Id.* at 508–09.

138. *See, e.g.*, Shenliang Wang et al., *Tools For Target Identification and Validation*, 8 CURRENT OPINION IN CHEMICAL BIOLOGY 371, 373–74 (2004) (describing the importance of inhibiting a gene's function in identifying drug targets, and the ability to "knockdown" a gene with the introduction of RNA sequences matching those of the target gene).

139. *See* Brenner v. Manson, 383 U.S. 519, 520 n.1, 532 (1966) (describing the steroid-producing process that that the Court found to lack utility); *In re* Joly, 376 F.2d 906, 908 (C.C.P.A. 1967) (describing the argument that the claimed compounds were intermediates that created compounds with a known use).

140. *See supra* Part III.A.

141. *See supra* notes 35–39 and accompanying text.

142. *See supra* note 35 and accompanying text.

143. The dissent in *Fisher* considered the use of ESTs as a research tool sufficient to show utility. *See In re* Fisher, 421 F.3d 1365, 1379 (Fed. Cir. 2005) (Rader, J. dissenting) ("While I agree that an invention must demonstrate utility to satisfy § 101, these claimed ESTs have such a utility, at least as research tools in isolating and studying other molecules.").

144. MPEP, *supra* note 12, § 2107.01(I).

145. *See* ALBERTS ET AL., *supra* note 44, at 505 fig. 8–36 (illustrating the process of sequences that produces molecules with the nucleotides in the same order as the molecule being sequenced).

A less apt, but still relevant, analogous technology is the microscope. While a microscope reveals the physical structure of an unknown substance or object, the ESTs can help reveal the structure of the corn genome or a gene's function.[146] To understand the function of the structure seen through a microscope, further research is typically required.[147] Thus, ESTs should not be disqualified merely because they do not immediately reveal the ultimate function of the underlying gene.

The court in *Fisher*, however, draws a distinction between research tools used to study one or a few compositions and those tools used to study a potentially large number of compositions.[148] For the *Fisher* court, the ESTs differ significantly from the microscope because they only detect material with the same sequence, which the court claims does not provide information about the function of the gene.[149] This ignores that genetically-based research tools are useful precisely because they detect and can be used to manipulate only the genetic material similar to them, which is actually how researchers gather information on the function of the genes.[150] There is no difference in the presence or absence of utility in cases of research tools that can be used to study a single material or multiple materials; there is only a difference in the scope of utility, which is not relevant to patentability since only one assertion of utility is required.[151]

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146. *See Fisher*, 421 F.3d at 1380 (Rader, J., dissenting) ("Both [the microscope and ESTs] advance research and bring scientists closer to unlocking the secrets of the corn genome to provide better food production for the hungry world.").

147. *Id.* For example, cancerous cells can be identified under a microscope, but further research is required to grasp why the cancer spreads and understand the compounds that interact with the cancer. *Id.* at 1380–81. The use of ESTs is clear because they "have already been used to advance cancer research well beyond what is achievable using microscopes alone." *Id.* at 1381 n.1.

148. *Fisher*, 421 F.3d at 1373 ("[A] microscope has the specific benefit of optically magnifying an object to immediately reveal its structure. One of the claimed ESTs, by contrast, can only be used to detect the presence of genetic material having the same structure as the EST itself.").

149. *Id*. The MPEP also states there is no utility in "assaying for or identifying a material that has no specific and/or substantial utility." MPEP, *supra* note 12, § 2107.01(I).

150. For example, analyzing gene expression can provide some indication of a gene's function. ALBERTS ET AL., *supra* note 44, at 536. Decreasing, increasing, or altering either the time or location of protein expression further aid in identifying the function of the gene. *Id.* Some of the uses of ESTs, such as in microarrays or PCR, do allow for the study of a gene's function in these ways. *See supra* Part III.A.

151. Also, there is no indication that the *Fisher* court's distinction tracks the division between inventions with an identified utility and those that require further research to confirm. *See supra* Part III.A.

The *Fisher* court's treatment of objects of use testing and research tools is inconsistent with *Brenner* because the *Fisher* court inappropriately attempted to alter the definition of object of use-testing provided by the Supreme Court. In *Brenner*, the Court defined an "object of use-testing" as something that was *itself* an "object of scientific research."[152] The Federal Circuit impermissibly redefined the Supreme Court's standard for an "object of use-testing" as an "object[] upon which scientific research could be performed with no assurance that anything useful will be discovered in the end."[153] If patents were not allowed on inventions that lack an "assurance that anything useful will be discovered at the end," patents would be unavailable for many important research tools because of the uncertainty inherent in most research.[154] Thus, although it is not certain what ESTs and nucleotide sequencers will discover, neither is itself an object of study and both are used to study an underlying gene or genome.[155] Thus, the ESTs in *Fisher* should not have failed for lack of substantial utility.

C. The Proposed Uses Meet the Specific Utility Standard

Just as the ESTs have substantial utility, they also have specific utility. Specific utility appears to have multiple meanings, one defined previously by the courts and the other adopted by the PTO and accepted in *Fisher*. The standard previously adopted by the courts

152. Brenner v. Manson, 383 U.S. 519, 535 (1966). For example, in *Brenner*, the steroid was an object of use-testing because its only use was as an object of research. *See supra* note 126 and accompanying text.

153. *Fisher*, 421 F.3d at 1373. This is consistent with other cases where the Federal Circuit has disregarded the Supreme Court's determinations. *See, e.g.*, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 739 (2002) ("The Court of Appeals ignored the guidance of *Warner-Jenkinson* [a Supreme Court decision], which instructed that courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." (describing Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 28 (1997))); J. Jason Lang, Comment, *The German Resolution: A Proposed Doctrine of Equivalents Analysis and a Flexible Rule of Prosecution History Estoppel for Biotechnology*, 52 EMORY L.J. 427, 486 (2003) ("[T]he Federal Circuit dogmatically invokes the triple-identity test, ignoring Supreme Court's counsel and the test's obvious unsuitability for biotechnology.").

154. *See Fisher*, 421 F.3d at 1380 (Rader, J., dissenting) ("These criticisms would foreclose much scientific research and many vital research tools. Often scientists embark on research with no assurance of success and knowing that even success will demand 'significant additional research.'").

155. *See supra* note 145 and accompanying text; *see also* MPEP, *supra* note 12, § 2107.01(I) (recognizing that nucleotide sequencers are patentable, despite being research tools, because they have clear, specific, and substantial utilities).

should be used because of the problems in applying the *Fisher* standard to other technological fields.

Courts initially defined specific utility as requiring that "an application must disclose a use which is not so vague as to be meaningless."[156] The primary example of a use "so general as to be meaningless" was "biological properties."[157] It was a "nebulous" expression that did not convey a "more explicit indication of the usefulness of the compounds and how to use them . . . ."[158] This standard requires distinguishing between situations where a use is disclosed and those where the application fails to specify "why [the invention] *is* considered useful"[159] or only "vaguely intimate[s]" the use.[160]

The application in *Fisher* meets this definition of specific utility because the proffered uses were sufficiently precise that one skilled in the art would know how the invention could be used.[161] The application expressly identified the particular biological properties and their applications, which sufficiently demonstrates specific utility.[162]

The PTO asserted a different standard, however, which the *Fisher* court adopted with no extended analysis,[163] despite deviating significantly from previous case law.[164] Under this standard, specific utility must be "*specific* to the subject matter claimed," as opposed to

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156. *Fisher*, 421 F.3d at 1371.

157. *In re* Kirk, 376 F.2d 936, 940 (C.C.P.A. 1967).

158. *Id.*

159. MPEP, *supra* note 12, § 2107.01(I).

160. *In re* Brana, 51 F.3d 1560, 1565 (Fed. Cir. 1995).

161. *See supra* notes 71–72 and accompanying text; *see also supra* Part III.A.

162. The uses are not too general because while all chemicals have some biological property, not all chemicals have the uses asserted in *Fisher*. For example, a use as a chromosome marker or gene probe appear to be clear assertions of utility.

163. *See In re* Fisher, 421 F.3d 1365, 1372 (Fed. Cir. 2005) (accepting the PTO's standard merely by saying it is consistent with the Federal Circuit's interpretation of utility).

164. The MPEP fails to cite any support for the PTO's interpretation of specific utility. MPEP, *supra* note 12, § 2107.01(I). The only case cited in the relevant section, *Knapp v. Anderson*, 477 F.2d 588 (C.C.P.A 1973), supports the proposition that "[a] general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed," especially if a useful invention could arise from the claimed invention. MPEP, *supra* note 12, § 2107.01(I); *see Knapp*, 477 F.2d at 590–91 (finding no reduction to practice because laboratory testing was insufficient to show the invention could be used in the asserted ways). This is consistent with the Federal Circuit ignoring policy issues and instead accepting the decisions of the PTO on significant patentability matters. *See infra* Part IV.A.

the general utility applicable to the broad class of inventions.[165] This differs from the prior standard that did not suggest the use must be exclusive to the invention, only that it must be clear.[166] The PTO particularly asserts that a use as a "gene probe" or a "chromosome marker" is not sufficient, but is instead analogous to claiming "biological properties."[167]

Because patent law is typically technology neutral,[168] this standard would presumably apply generally, which would be problematic. For example, multiple patents protect steroids appearing to have a common general structural formula and that are all claimed to act as anti-inflammatories.[169] If only specific properties not applicable to the class were considered for utility, perhaps these patents on steroids would be barred by the PTO's standard as well. While this presents problems for technological fields, the PTO's specific utility standard also appears inconsistent with the suggestion in *Brenner* that if the steroids could have been shown to have the same properties as the homologue, they would be patentable.[170]

Thus, because the PTO's standard is problematic when applied to other technologies and is inconsistent with previous case law, the original standard developed by courts should have been used to find the ESTs have specific utility.

IV. THE POLICY IMPLICATIONS AND PROBLEMS OF *FISHER*

A. Policy, Institutional Roles and Competence, and Fisher

The actions of the *Fisher* court support the assertions of Professor Rai that no institution in the patent system adequately

165. MPEP, *supra* note 12, § 2107.01(I).

166. *See supra* notes 156–60 and accompanying text.

167. MPEP, *supra* note 12, § 2107.01(I).

168. Burk & Lemley, *supra* note 9, at 1156.

169. *See, e.g.*, Steroid Compounds, U.S. Patent No. 5,116,829 (filed April 10, 1991) (issued May 26, 1992); Soft Steroids Having Anti-Inflammatory Activity, U.S. Patent No. 4,710,495 (filed April 8, 1985) (issued Dec. 1, 1987).

170. *See* Brenner v. Manson, 383 U.S. 519, 522, 532 (1966) (noting that the steroids in the class with the claimed compound under investigation had potential tumor-inhibiting effects, and accepting the PTO's determination that there was insufficient evidence of such effect from the claimed compound).

deals with policy issues.[171] Congress has delegated the power to develop the patent statute through policy elaboration to the courts,[172] but the Federal Circuit in *Fisher* refused to consider public policy because it believed the task fell to Congress.[173] This refusal to consider policy is consistent with the broader observation that the Federal Circuit's opinions display a general disinterest in both economics and policy.[174]

Because neither the Congress nor the Federal Circuit appear willing to consider policy, this leaves the PTO to make policy by issuing guidelines interpreting the patent statute,[175] as was the case in *Fisher*.[176] Because the Federal Circuit in *Fisher* followed these guidelines without extended analysis,[177] even though the guidelines do not receive formal deference from courts,[178] the PTO became the *de facto* policy maker. This is problematic, however, because the PTO may not be competent to make economic and policy decisions.[179] Thus, *Fisher* illustrates the patent system's institutional difficulties in dealing with policy issues.

B. The Absence of a Meaningful Distinction Between ESTs of Genes With and Without Known Functions, and the Problems with the Use of Utility in Trying to Create One

The poor policy choices made in *Fisher* illustrate the inability of institutions in the patent system to adequately address policy issues. For example, the court's distinction between ESTs for genes of known and unknown functions[180] is not a principled distinction. This

171. *See* Rai, *supra* note 3, at 1040–41 ("[N]o institution has taken responsibility for elaborating patent law in the fact-specific, policy-oriented manner that the language of the statute encourages.").

172. *Id.* at 1102.

173. *In re* Fisher, 421 F.3d 1365, 1378 (Fed. Cir. 2005).

174. Rai, *supra* note 3, at 1073 ("After all, the court's opinions as a whole appear to betray little interest in economic or policy analysis.").

175. *Id.* at 1131.

176. *See, e.g.*, *supra* notes 60–68 and accompanying text.

177. *Fisher*, 421 F.3d at 1372.

178. Rai, *supra* note 3, at 1132. The PTO does not have substantive rulemaking authority, which means its guidelines interpreting the patent statute do not receive judicial deference. *Id.*

179. *Id.* For example, the PTO does not employ economists and has an institutional culture that treats potential patentees as clients to be served rather than claimants needing to prove they deserve a patent. *Id.* at 1133. See *infra* Parts IV.B and IV.C for a discussion of the problems with the analysis ultimately adopted by the court consistent with the PTO's policy.

180. *Fisher*, 421 F.3d at 1375.

attempted division also illustrates the problems with using utility to draw the desired policy distinctions.

Fisher does not make a principled distinction because ESTs of genes with and without known functions are used in much the same way.[181] The primary uses of the ESTs are as research tools,[182] and they are used to study what is unknown about the underlying genes, regardless of whether or not the gene's central function is known. Given this, there may be more utility in ESTs for genes without known functions and properties.[183] ESTs of genes without known functions will provide researchers with even more information about the underlying gene because even the general function will be learnable. The dissent notes the majority may have made a value judgment that ESTs do not produce "enough valuable information."[184] The majority's approach is problematic because science proceeds in incremental steps and the majority lacks a sufficient "scientific foundation" to make its determination.[185]

Similarly, no policy distinctions exist between ESTs of genes with known or unknown functions based on *Brenner*'s reasoning. The *Brenner* Court wanted to avoid granting a monopoly if the bounds of the monopoly were not precisely delineated.[186] It is not clear, however, why the bounds of a patent would be significantly less defined if the genes underlying the ESTs lacked a known function, particularly because the bounds of a patent are not defined by

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181. *See, e.g.*, EGVIII Endoglucanase and Nucleic Acids Encoding the Same, U.S. Patent No. 7,049,125 (filed Dec. 18, 2001) (issued May 23, 2006) (describing the use of a gene to identify and study similar genes in other organisms); Salicylic Acid Biosynthetic Genes and Uses Thereof, U.S. Patent No. 7,070,772 (filed July 18, 2001) (issued July 4, 2006) (providing uses for the gene including creating PCR primers and controlling protein expression).

182. *See supra* note 105 and accompanying text.

183. Corrected Brief for Appellants, *supra* note 72, at 39–40.

184. *Fisher*, 421 F.3d at 1380 (Rader, J., dissenting). If this were the majority's basis for the decision, the criticism would apply equally well to ESTs with and without known functions because the uses for ESTs with and without known functions are essentially the same.

185. *Id.*

186. *See* Brenner v. Manson, 383 U.S. 519, 534 (1966) ("[W]e 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. Unless and until a process is refined and developed to this point . . . there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.").

utility.[187] Moreover, *Brenner* only requires that courts avoid granting a monopoly over inventions with no utility,[188] which is irrelevant to determining whether ESTs have utility in the first place.

Also, ESTs are unlike a "hunting license"[189] in the way likely intended by the *Brenner* Court. Because ESTs are tools to be used rather than mere discoveries, they are "commerce" rather than "philosophy."[190] There is no continuing search for a use for the ESTs because the uses are already known. "Search" cannot refer to a search using the patented product as a tool, as the *Fisher* court interprets it,[191] because this would bar the patentability of all research tools, at least some of which have clearly been patentable.[192]

Even though the *Fisher* court did not address the impact of EST patents on the anticommons, these concerns also fail to provide a basis upon which to distinguish between patents on ESTs of genes with known and those with unknown functions. A "tragedy of the anticommons" occurs when a resource is underused because multiple owners "have a right to exclude others from a scarce resource and no one has an effective privilege of use."[193] In the EST context, this leads to concerns that multiple overlapping patents on the same underlying gene or protein will issue, and all of them would need to be cleared

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187. *See* Melissa E. Horn, Note, *DNA Patenting and Access to Healthcare: Achieving the Balance Among Competing Interests*, 50 CLEV. ST. L. REV. 253, 279 (2003) ("[O]ne utility description is enough to get a patent that covers all of a gene's functions . . . ."). It was also recognized in another opinion in *Brenner* that "advance knowledge of a specific product use [does not] 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." *Brenner*, 383 U.S. at 537 (Harlan, J., concurring in part and dissenting in part).

188. *Brenner*, 383 U.S. at 534–35 (majority opinion).

189. *Id.* at 536.

190. *See id.* at 536 ("'[A] patent system must be related to the world of commerce rather than to the realm of philosophy . . . .'" (quoting *In re* Ruschig, 343 F.2d 965, 970 (C.C.P.A. 1965))). Although there is some question as to the literal commercial success of the ESTs, this should be largely irrelevant to *Brenner*'s distinction. *See Fisher*, 421 F.3d at 1370, 1377 (describing the patentee's claim to the commercial success of the ESTs and the courts' determination that commercial success was irrelevant since evidence was not presented).

191. Despite the application's asserted uses for ESTs as research tools, *see supra* Part III.A & III.B, the *Fisher* court nonetheless found that "[t]he 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." *Fisher*, 421 F.3d at 1376.

192. *See supra* notes 35–39 and accompanying text.

193. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998).

prior to performing research.[194] Even without multiple patents on a single gene, uses, such as microarrays, that require large numbers of genes to be effective would still encounter anticommons problems. Because there would be many patents on upstream research, the patents could completely "strangle downstream product development in a morass of required licenses"[195] and block groups of researchers from the patented ESTs,[196] or at least drive up research costs.[197] Rather than fulfilling the Constitutional goal of patents in promoting progress,[198] such patents could "discourage research, delay scientific discovery, and thwart progress in the 'useful Arts' and 'Science.'"[199] Because "progress" depends on using research tools, patents on ESTs could stifle future innovation by preventing the creation of another patentable invention.[200]

If the Federal Circuit's goal was to avoid some of these problems the distinction between ESTs with and without known functions does not significantly aid in that effort. Regardless of whether a function must be shown, different companies will still own patents on ESTs, which could create an anticommons. Even if a function requirement could ensure there would be only one patent per gene, researchers developing technologies requiring multiple genes would still have difficulties coordinating licenses. While a requirement to show a function could possibly delay patenting and allow for the creation of more prior art, this would not necessarily dissuade individuals from

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194. Debora Robertson, *EST Patent Granted for Human Kinase Homologs*, 17 NATURE BIOTECHNOLOGY 125, 125 (1999) ("Jack Tribble, head of Merck's (Wilmington, DE) biotechnology patent group, points out another problem. 'If there are multiple patents on ESTs within a well-known gene, one may require license for [all] those ESTs so you can use the full-length gene,' he says.").

195. Burk & Lemley, *supra* note 9, at 1195–96.

196. Debora Robertson, *EST Patent Granted for Human Kinase Homologs*, 17 NATURE BIOTECHNOLOGY 125, 125 (1999).

197. Olsen, *supra* note 10, at 323.

198. U.S. CONST. art. I, § 8, cl. 8.

199. *See In re* Fisher, 421 F.3d 1365, 1378 (Fed. Cir. 2005) (presenting the government's argument that ESTs without utility would discourage research and discovery) (quoting U.S. CONST. art. I, § 8, cl. 8).

200. *See* Katherine J. Strandburg, *What Does the Public Get?: Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 123 (2004) ("[W]hen research tools are patented . . . [progress] usually depends upon using an embodiment of the invention—the research tool itself—to make a further, and often patentable, innovation. . . . The concern with patented research tools arises from the fear that a research tool may give the tool inventor the ability to block technological progress by controlling the research that may be performed using the tool . . . .").

seeking patents. To avoid anticipating disclosures, greater secrecy could be employed until a sufficient function was discovered.[201] This could result in both a less cooperative scientific community[202] and wasteful duplication of efforts.[203] Thus, distinguishing between ESTs of genes with known and unknown functions does not avoid an anticommons, and it produces other problems.

The central problem is that the utility doctrine is not well adapted to draw the relevant policy distinctions desired.[204] It may be advantageous to exclude inexpensive and easy to develop research tools, such as ESTs, from patentability because patents would create high transactions costs and costs to creativity.[205] On the other hand, it could be detrimental to exclude research tools that are expensive and time-consuming to create, such as certain types of genetically engineered mice,[206] which require incentives to develop and the transaction and creativity costs are low. Thus, a desirable doctrine should be able to exclude ESTs, but allow some genetically engineered mice. The utility standard, however, is incapable of accomplishing this because it applies generally to all inventions without consideration of the difficulty in creating the invention,

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201. *See* Joshua A. Newberg & Richard L. Dunn, *Keeping Secrets in the Campus Lab: Law, Values and Rules of Engagement for Industry-University R&D Partnerships*, 39 AM. BUS. L.J. 187, 227, 238–39 (2002) (explaining policies of a university laboratory collaborating with industry to delay disclosure, particularly through publication, until a patent application can be filed and an expectation by the university of contractual restrictions on disclosure).

202. The ideal conditions for facilitating science are "[p]erfect interconnectivity and open access," which greater secrecy due to patents or the desire for credit can hinder. Jim Chen, *Biodiversity and Biotechnology: A Misunderstood Relation*, 2005 MICH. ST. L. REV. 51, 66 (2005). Patents under a low utility requirement system at least allow for safe disclosure by scientists after filing the patent application, even if researchers are still excluded from their use. *See* Newberg & Dunn, *supra* note 201, at 227, 238–39 (describing delay of disclosure, not failing to disclose, to the scientific community in the current system).

203. Patents allow firms "to signal each other, thus reducing the amount of duplicative investment in innovation." Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 278 (1977). If secrecy increases, a competing firm would wastefully expend efforts researching the invention when it had already been discovered. *Id.*

204. Although Professor Rai notes that the utility analysis could be used as a proxy for a complicated economic analysis, Rai, *supra* note 59, at 141, the *Fisher* court claims to be uninterested in this type of policy analysis, *Fisher*, 421 F.3d at 1378. Regardless, it is difficult to understand why the Federal Circuit would contradict precedent without some policy motivation. Thus, the Federal Circuit may be performing a complicated economic analysis, unaided and unchecked, in the guise of adhering to precedent.

205. Rai, *supra* note 59, at 140–41.

206. *Id.* at 141.

transaction costs, or creativity costs.[207] Therefore, other limits on patentability, such as nonobviousness, may better draw the distinction because they can address these issues and preclude, rather than merely delay, the patent.[208]

C. Problems with and Explanations of the Technology-Specific Rules

Without any overt consideration of technology-specific policy, the *Fisher* court appears to have applied *sub silentio* a different standard for utility that may apply only to this specific technology and that is not well suited to address the relevant policy considerations.[209] In this way, *Fisher* illustrates the problems in unguided technology-specific rules and potential explanations for these problems.

Theoretically, the patent system "provides technology-neutral protection to all kinds of technologies" with flexible standards designed to apply to a wide assortment of technologies.[210] Professors Burk and Lemley note, however, that technology-specific standards do exist through different applications of the same rule.[211] In biotechnology generally, they found a low nonobviousness standard, but a stricter enablement and written description requirement than in other disciplines.[212] They explain that the "person having ordinary skill in the art" (PHOSITA) in biotechnology is assumed by the courts to know little about his or her field.[213]

Thus, the *Fisher* case is not novel in applying divergent technology-specific rules, and at least the court's altered evidentiary standard[214] can be explained under the PHOSITA theory. If the Federal Circuit assumed that biotechnology practitioners know little about their field,[215] the Federal Circuit would require more proof than would actually be necessary to convince today's biotechnology

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207. *Id.*

208. *See infra* note 231.

209. *See supra* Part IV.B.

210. Burk & Lemley, *supra* note 9, at 1156.

211. *Id.*

212. *Id.*

213. *See id.* at 1157, 1192–93 ("The court seems to believe that biotechnology is as much a black art as a science, where the result of experimentation is largely out of the skilled artisan's hands."). The more skill those in the art have, the less information an applicant has to disclose in order to meet the enablement requirement, but the harder it is to meet the nonobviousness requirement. *Id.* at 1156.

214. *See supra* Part III.A.

215. Burk & Lemley, *supra* note 9, at 1156.

practitioner of the uses of ESTs. Although the PHOSITA standard may provide the necessary flexibility for patent law to apply to different technologies,[216] the level of skill in biotechnology appears to have been set at an earlier time and has not changed with the field.[217] This is a problem because the decisions do not accurately reflect the realities of the industry, making the rules adopted inappropriate for the industry in which they are specifically applied.[218]

Nevertheless, the PHOSITA standard does not explain the larger change in specific and substantial utility for biotechnology because PHOSITAs are not a part of the remainder of the utility analysis.[219] There are two probable, coexisting explanations for the biotechnology-specific utility standard. First, the Federal Circuit may not understand the technology. This is a likely explanation because the technical knowledge of the Federal Circuit is limited to the training of the individuals within it, who could not possibly be technically trained in all the necessary areas in which cases arise.[220] The court's failure to engage in a technical analysis of utility illustrates this point.[221] This possibility is troublesome because it suggests that the Federal Circuit bases its judgments on its own beliefs about the field rather than an analysis of the actual case, and thus making an incorrect result likely.

Second, despite claiming a lack of interest in policy,[222] the Federal Circuit could be attempting to create a separate standard for biotechnology to meet its special needs by deliberately manipulating the doctrine.[223] If the court is motivated by policy yet does not articulate its policy rationales, it precludes the development of

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216. *Id.* at 1157.

217. *Id.*

218. *See id.* ("[W]e believe the courts must take more care than they currently do to ensure that their assessments of patent validity are rooted in understandings of the technology that were accurate at the time the invention was made.").

219. Moreover, the utility standard has no explicit technology-specific aspect like the PHOSITA. Thus, the utility standard is particularly ill-suited to become a technology-specific standard because it is expected to apply generally. *See supra* notes 204–07 and accompanying text. The *Fisher* court's utility standard is described as technology-specific because the court may never apply the standard outside DNA sequence patents or biotechnology, particularly because the application of this standard in other areas would result in problems. *See supra* notes 168–70 and accompanying text.

220. Rai, *supra* note 3, at 1068–69.

221. *See supra* note 95 and accompanying text.

222. *In re* Fisher, 421 F.3d 1365, 1378 (Fed. Cir. 2005) (majority opinion).

223. Burk & Lemley, *supra* note 9, at 1194–95.

coherent patent policy in the case law[224] and stymies the evaluation of patent policy by other institutions.[225] This is of particular concern when the courts can be mistaken about the policy needs of the industry, as Professors Burk and Lemley have observed in the biotechnology context.[226] It would be further disconcerting to have a court disavow interest in policy matters,[227] and then make policy-based decisions.

To make appropriate technology-specific standards suited to the needs of the field, there must be an accurate analysis both of the field and of the relevant policy, neither of which was present in *Fisher*. To explain the absence of technical analysis[228] and the departure from precedent for no explicit reason,[229] it appears most likely the court attempted to draw a technology-specific standard without articulating the policy basis and misunderstood the technology.

CONCLUSION

The use of the utility standard is unnecessary because there are several alternatives to limit the patentability of ESTs. For example, Congress could decide to alter patent laws or create a separate system of rights from patent to address the special needs of biotechnology.[230] Alternatively, the courts could alter the nonobviousness standard to better reflect the current needs of biotechnology.[231]

Nevertheless, the *Fisher* court chose to use the utility standard to try to exclude certain EST patents. The application of the utility

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224. Rai, *supra* note 3, at 1073.

225. *Cf. id.* at 1125 (suggesting that review by other courts would cause the Federal Circuit to address persuasive policy arguments in its opinions).

226. *See* Burk & Lemley, *supra* note 9, at 1195 (noting the Federal Circuit's approach to biotechnology was likely to cause an anticommons).

227. *In re* Fisher, 421 F.3d 1365, 1378 (Fed. Cir. 2005).

228. *See supra* note 95 and accompanying text.

229. *See supra* notes 163–64 and accompanying text.

230. Olsen, *supra* note 10, at 331–33.

231. The nonobviousness requirement appears better suited to exclude ESTs, but not other valuable inventions, because it considers whether "a patentable invention represent[s] an advance over the prior art that would not have been obvious to someone of 'ordinary skill in the art.'" Rai, *supra* note 59, at 107; *In re* Fisher, 421 F.3d 1365, 1382 (Fed. Cir. 2005) (Rader, J., dissenting). However, *In re Deuel*, 51 F.3d 1552, 1158–59 (Fed. Cir. 1995), which found a protein sequence and a method of cloning a gene were not sufficient to make the sequence obvious, would need to be overturned. *See Fisher*, 421 F.3d at 1382 (Rader, J., dissenting) ("Unfortunately this court has deprived the Patent Office of the obviousness requirement for genomic inventions.").

standard to draw a distinction between ESTs of genes with known and unknown functions had no basis in policy. Further, the analysis of the utility standard was flawed in its use of the evidentiary standard, substantial utility, and specific utility. Finally, the flawed analysis in the *Fisher* case supports the theory that the patent system has no adequate institution to deal with policy, and provides insight into the nature of technology-specific rules. Thus, regardless of whether the court reached the right result in denying the patent in this particular case, the reasoning behind this decision was problematic and may prove detrimental.