IN RE FISHER: RAISING THE UTILITY HURDLE FOR EXPRESS SEQUENCE TAGS

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The Federal Circuit's *In re Fisher* decision signaled a return to a more stringent statutory interpretation of utility[1] and provided the first judicial recognition of the United States Patent and Trademark Office's (PTO) 2001 Utility Guidelines.[2] In *Fisher*, the Federal Circuit affirmed the decision of the Board of Patent Appeals and Interferences (BPAI), denying a patent application claiming five express sequence tags (ESTs)[3] of the maize plant.[4] The court dismissed Fisher's contention that the BPAI applied a heightened standard in evaluating the utility of the claimed ESTs,[5] thus reiterating the utility test outlined in *Brenner v. Manson*.[6] Furthermore, the court found Fisher provided no evidence that the claimed ESTs correlated to a gene with a known function.[7]

Fisher presented the Federal Circuit with its first opportunity to rule on the circumstances under which ESTs satisfy the utility requirement of 35 U.S.C. § 101. Unfortunately, the Federal Circuit declined to provide the biotechnology community with much substantive guidance on this issue.[8] Instead, the court simply held that Fisher's seven proposed uses for ESTs did not satisfy the statutory utility requirement.[9] Presenting no bright-line rules, the *Fisher* decision provided little more than a rough framework for analyzing whether a proposed use for an EST satisfies the statutory utility requirement.

This Note explores the EST utility standard and suggests that the invention's patentability under the utility analysis can be best conceptualized as a timeline tracking the invention's "ripeness." Part I outlines the

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1. 421 F.3d 1365, 1372 (Fed. Cir. 2005) (2-1 decision).
2. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 2, 2001) [hereinafter 2001 Utility Guidelines].
3. ESTs are short sequences of DNA that encode structurally and functionally undefined proteins or fragments thereof. *See* National Center for Biotechnology Information, ESTs: Gene Discovery Made Easier, http://www.ncbi.nlm.nih.gov/About/primer/est.html (last visited Feb. 17, 2006).
4. *Fisher*, 421 F.3d at 1379.
5. *Id.* at 1372.
6. 383 U.S. 519 (1966).
7. *Fisher*, 421 F.3d at 1373.
8. *See id.*
9. *Id.* at 1374.

evolution of the modern utility standard in both the courts and the PTO. Part II provides a scientific primer and Part III summarizes the *In re Fisher* decision. Finally, Part IV argues that by serving as a "timing device," the utility requirement assesses not only the "ripeness" of an invention but also the height of the utility barrier as well.

I. EVOLUTION OF THE MODERN UTILITY STANDARD

A. Judicial and Statutory Development

The U.S. Constitution charges Congress "to promote the Progress of Science and useful Arts . . . ."[10] The constitutional limits imposed by the Patent and Copyright Clause are reflected in several statutory hurdles to patentability. Thus, the PTO grants limited patent monopolies for inventions that are within the ambit of patentable subject matter,[11] useful,[12] nonobvious,[13] novel,[14] and adequately disclosed.[15] Section 101 codifies the utility prong of these patentability requirements: "Whoever invents or discovers any new or *useful* process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor . . . ."[16]

Generally, a finding of usefulness requires that an invention be more than "a mere curiosity, a scientific process exciting wonder yet not producing physical results . . .";[17] the invention must be capable of providing some benefit to society. More specifically, an invention must have both a "specific" and "substantial" utility[18]—it has to be capable of some practical purpose.[19]

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10. U.S. CONST. art. I, § 8, cl. 8.
11. 35 U.S.C. § 101 (2000).
12. *Id.*
13. *Id.* § 103.
14. *Id.* § 102.
15. *Id.* § 112; *see also* Byron V. Olsen, *The Biotechnology Balancing Act: Patents for Gene Fragments, and Licensing "Useful Arts"*, 7 ALB. L.J. SCI. & TECH. 295, 312-13 (1997).
16. 35 U.S.C. § 101 (emphasis added).
17. *See* 1 DONALD CHISUM, CHISUM ON PATENTS § 4.02 (2005) (citation omitted).
18. *See* Brenner v. Manson, 383 U.S. 519, 534-35 (1966).
19. *See id.*; *see also* Nelson v. Bowler, 626 F.2d 853, 856 (C.C.P.A. 1980) ("'Practical utility' is a shorthand way of attributing 'real-world' value to claimed subject matter . . . . [O]ne skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.").

1. *Early Judicial Interpretation of Utility*

Justice Story provided the first judicial interpretation of the statutory utility standard in *Lowell v. Lewis*.[20] In *Lowell*, the plaintiff alleged infringement of his patent that claimed an improvement of construction pumps.[21] In countering the defendant's contention that the plaintiff's pump should have a general utility that exceeds the common one, Justice Story declared:

> [I]f the invention steers wide of . . . objections, whether it be more or less usefu[l] is a circumstance very material to the interests of the patentee, but of no importance to the public. If it be not extensively useful, it will silently sink into contempt and disregard.[22]

Justice Story continued to elucidate his definition of "useful" in *Bedford v. Hunt*, which involved a method patent for making boots and shoes.[23] In finding for the defendants, Justice Story stated that the use had to be beneficial, but cautioned that the law did not require a specific degree of utility.[24] Thus, according to Justice Story, at the time of patent application, an invention need not perform better than similar available means or demonstrate commercial viability.[25]

In sum, early interpretation of the statutory utility requirement provided quite a low threshold. As long as the invention was not "frivolous or injurious to the well-being, good policy, or sound morals of society,"[26] it complied with the statute.

2. *Utility in the Chemical Arts*

Prior to 1950, following Justice Story's interpretation, patents issued for chemical compounds with no specific utility.[27] The Court of Customs

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20. 15 F. Cas. 1018 (C.C. Mass. 1817).

21. *Id.* at 1019.

22. *Id.*

23. 3 F. Cas. 37 (C.C. Mass. 1817); *see* CHISUM, *supra* note 17, § 4.02[1].

24. *Bedford*, 3 F. Cas. at 37.

25. CHISUM, *supra* note 17, § 4.02[1] ("[U]tility . . . refers rather to *utility of purpose* than a utility of means.") (citation omitted) (internal quotations omitted); *cf.* Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 960 n.12 (Fed. Cir. 1986) ("Finding that an invention is an 'improvement' is not a prerequisite to patentability. It is possible for an invention to be less effective than existing devices but nevertheless meet the statutory criteria for patentability.").

26. *Lowell*, 15 F. Cas. at 1019.

27. CHISUM, *supra* note 17, § 4.02[2]. One court allowed satisfaction of the utility requirement by allowing the inventor to simply describe the characteristics of the inven-

and Patent Appeals (CCPA) eventually raised the utility standard in *In re Bremner*, which involved a claim for a product, polydihydropyran, and the process for making it.[28] The patent application did not disclose the chemical's utility.[29] The court affirmed the decision of the patent examiner in denying the patent, stating that "the law requires that there be in the application an assertion of utility and an indication of the use or uses intended."[30]

A decade later, the CCPA relaxed the *Bremner* standard in *In re Nelson*.[31] In *Nelson*, the applicant claimed new steroid compounds, alleging that they could be used as intermediates to produce new therapeutic compounds.[32] The applicant failed to disclose, however, a method to convert his intermediate compounds.[33] The court held that the use disclosed was adequate because "[w]hen actual utility exists, its degree is unimportant."[34] In fact, the *Nelson* court pointed out that other steroid researchers could use the applicant's compounds.[35]

In *Brenner v. Manson*, the Supreme Court established the utility standard that continues to serve as the controlling interpretation of the utility requirement.[36] Manson filed a patent application for a process of making a

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tion. Potter v. Tone, No. 666, 1911 U.S. App. LEXIS 5561 (D.C. Cir. 1911) (involving a silicon monoxide compound that was able to reduce other compounds in other chemical reactions) (unpublished). Another court allowed satisfaction of the utility requirement when the inventor simply listed chemical compounds, but did not specify any uses for them. *Ex parte* Watt, 63 U.S.P.Q. (BNA) 163 (Pat. Off. Bd. App. 1942).

28. 182 F.2d 216 (C.C.P.A. 1950).
29. *Id.*
30. *Id.*
31. 280 F.2d 172 (C.C.P.A. 1960).
32. *Id.* at 175.
33. *Id.* at 176.
34. *Id.* at 179 (quoting ROBINSON ON PATENTS § 341 (1890)). The court stated that:

> [t]he Patent Office position seems to have been that there must be a presently existing "practical" usefulness to some undefined class of persons. We have never received a clear answer to the question. "Useful to whom and for what?" Surely a new group of steroid intermediates is useful to chemists doing research on steroids, and in a "practical" sense too. Such intermediates are "useful" under section 101. . . . Refusal to protect them at this stage would inhibit their wide dissemination, together with the knowledge of them which a patent disclosure conveys, which disclosure the potential protection encourages. This would tend to retard rather than promote progress.

Id. at 180-81.

35. *See id.* at 180.
36. 383 U.S. 519 (1966).

particular steroid.[37] He requested an interference when he learned of the existence of a previously issued patent on the process.[38] Subsequently, his application was denied because he failed to disclose a utility for the compound.[39] Manson argued that the compound possessed utility because, at the time of his application, a recent scientific paper suggested that the steroid class, to which the contested compound belonged, had possible tumor-inhibiting effects in mice.[40] Additionally, a structural homologue of Manson's compound had given rise to such an effect.[41] The CCPA reversed, reasoning that it was unnecessary for Manson to show utility because the claimed process produced a known product and that product was not "detrimental to the public interest."[42]

The Supreme Court reversed the CCPA's decision, noting that the idea that "adjacent homologues [possessed] the same utility [had] been challenged in the steroid field because of a greater known unpredictability of [the] compounds . . . ."[43] The Court narrowed Justice Story's definition of utility stating that "[t]here are . . . many things in this world which may not be considered 'useful' but which, nevertheless, are totally without a capacity for harm."[44] After dismissing this broad notion of utility, the Court relied on constitutional principles to establish a heightened utility standard:

> 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.[45]

While recognizing the importance of scientific research and thus implicitly acknowledging Manson's chemical contribution, the Court declared, nonetheless, that a "patent is not a hunting license" but instead serves as "compensation for [the] successful conclusion [of research]."[46] An invention,

37. *Manson*, 383 U.S. at 520-21.
38. *Id.* at 521.
39. *Id.*
40. *Id.* at 522.
41. *Id.*
42. *Id.*
43. *Id.* at 532 (internal quotation omitted).
44. *Id.* at 533.
45. *Id.* at 534-35 (emphasis added).
46. *Id.* at 536.

therefore, must go beyond the realm of mere scientific interest; it must possess specific and substantial utility to constitute a patentable entity.

After *Manson*, the CCPA applied this heightened standard of utility.[47] For example, *In re Kirk* involved the patentability of several steroid compounds.[48] The applicants argued that one skilled in the art could delineate actual uses for the compounds.[49] They asserted that the disputed compounds were structurally similar to compounds that possessed "biological activity"[50] and alleged that the compounds were useful as intermediaries in the synthesis of other biologically active compounds.[51] The CCPA declared that the production of intermediates that give rise to a class of compounds with no known use fails to satisfy the utility standard under § 101.[52]

In its most recent utility interpretation in *In re Brana*, the Federal Circuit applied *Manson* more liberally.[53] In *Brana*, the Federal Circuit, reversing a decision of the BPAI, held that a rejected patent application proffered sufficient utility for the anti-tumor compounds claimed therein.[54] Although *Brana* concerned compliance with § 112, an evaluation of the invention's practical utility was at the core of the decision.[55]

The BPAI affirmed the patent examiner's rejection of the application on two grounds: (1) the lack of disclosure of a specific disease to target the claimed compounds and (2) the failure to show that the compounds were useful.[56] Distinguishing *Kirk* on the first ground of rejection, the Federal Circuit held that the applicants' specification targeted a specific disease because the derived cell lines were from mice afflicted with a particular type of leukemia.[57] Furthermore, the applicants' explicit reference to prior art in comparing their compounds implied that the claimed compounds

47. *See, e.g.*, *In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967); *see also In re* Joly, 376 F.2d 906 (C.C.P.A. 1967). *But see In re* Brana, 51 F.3d 1560 (Fed. Cir. 1995).

48. *Kirk*, 376 F.2d at 937.

49. *Id.* at 939.

50. *Id.*

51. *Id.*

52. *Id.* at 945 ("It is not enough that the specification disclose that the intermediate exists and that it works, reacts, or can be used to produce some intended product of no known use.") (internal citation omitted); *see also Joly*, 376 F.2d at 906 (holding that a claimed compound with a disclosed utility of serving as an intermediate to produce other compounds with unknown utility did not satisfy § 101).

53. 51 F.3d 1560 (Fed. Cir. 1995).

54. *Id.* at 1562.

55. *See id.* at 1564 & n.12 (stating that a rejection of lack of utility can be sustained under both § 101 and § 112).

56. *Id.* at 1565-66.

57. *Id.* at 1565.

targeted the same tumor models.[58] As to the second ground for rejection, the Federal Circuit found that persons of ordinary skill in the art would not doubt the utility asserted by the applicants and noted that the compounds were structurally similar to potent chemotherapeutic compounds cited in the references proffered by the BPAI.[59]

Although the CCPA required a showing of "specific" and "substantial" utility in *Kirk*, and thus adhered to the more stringent standard of utility outlined in *Manson* in the context of chemical inventions, the contemporary Federal Circuit appeared to back away from the strict *Manson* utility standard in *Brana*. In reconciling its determination with the current judicial standard of § 101 utility, the Federal Circuit relied on acceptable general principles in the scientific community regarding the behavior of particular classes of chemical compounds. In *Kirk*, there was a general consensus regarding the variable potency of structurally similar steroid compounds.[60] Conversely, in *Brana*, the applicants enjoyed greater leeway because the prior art contained compounds structurally similar to those claimed in the disputed application and the effectiveness of the prior art compounds were comparable against a *variety* of tumor models.[61] Thus, the Federal Circuit's interpretation of the utility requirement appeared to lie somewhere on a spectrum bookmarked by the strict *Manson* standard and the less exacting *Brana* standard.

B. PTO Utility Guidelines

The *Manson* Court failed to clearly define "specific" and "substantial" utility.[62] The CCPA and, later, the Federal Circuit attempted to fill this legal vacuum by shaping the contours of "substantial" and "specific" utilities,[63] but the standard remained in need of further clarification. To ameliorate this situation, the PTO attempted to provide guidance for its examiners by publishing utility guidelines and training materials.[64] While the guidelines do not carry the weight of judicial authority, they do aid patent

58. *Id.*

59. *Id.* at 1566; *see also In re* Jolles, 628 F.2d 1322 (C.C.P.A. 1980) (reversing the BPAI's utility rejection of claimed but untested compounds that were structurally similar to other claimed but tested compounds *in vivo*).

60. *Cf.* Brenner v. Manson, 383 U.S. 519, 532 (1966).

61. *See Brana*, 51 F.3d at 1566.

62. *See Manson*, 383 U.S. at 534-35.

63. *See Fisher*, 421 F.3d at 1371.

64. Guidelines for Examination of Applications for Compliance with the Utility Requirement, 60 Fed. Reg. 36263, 36264 (July 14, 1995) [hereinafter Compliance with the Utility Requirement 1995]; 2001 Utility Examination Guidelines, 66 Fed. Reg. 1092, 1092 (Jan. 2, 2001).

examiners in addressing the patentability of ESTs and other DNA compositions.[65] They also represent the PTO's attempt to ensure compliance with precedent.[66]

After issuing its first set of guidelines in 1995,[67] the PTO eventually replaced them with the 2001 Utility Examination Guidelines.[68] These guidelines require that a patent applicant present either a "well-established" utility[69] or a "practical" utility (i.e., a "specific" and "substantial" utility) that would be credible to a person skilled in the art.[70] While it appears that the Guidelines set out two alternative tests, if an invention lacks specific, substantial, and credible utility, it fails under both the practical utility and the well-established utility tests.[71] These tests, while not formulated by the courts, govern the PTO's initial determination of utility.[72]

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65. Joshua C. Benson, Note, *Resuscitating the Patent Utility Requirement, Again: A Return to* Brenner v. Manson, 36 U.C. DAVIS L. REV. 267, 284 (2002).

66. *Id.*

67. The 1995 Guidelines stated that § 101 required an inventor to provide a single utility that was both "specific" and "credible," omitting the *Manson* standard of "substantial" utility. *See* Compliance with the Utility Requirement 1995, 60 Fed. Reg. at 36264; Donald L. Zuhn, Jr., Comment, *DNA Patentability: Shutting the Door to the Utility Requirement*, 34 J. MARSHALL L. REV. 973, 992 (2001). This omission led to the filing of numerous patent applications to bare genetic information (i.e., DNA sequence information). Mary Breen Smith, Comment, *An End to Gene Patents? The Human Genome Project versus the United States Patent and Trademark Office's 1999 Utility Guidelines*, 73 U. COLO. L. REV. 747, 768 (2002). This weakened standard provoked an outcry that prompted the PTO to release a revision of the guidelines in 1999. Benson, *supra* note 65, at 286. The revised guidelines restored the "substantial" utility standard adopted by the *Manson* Court. *Id.*

68. 2001 Utility Guidelines, 66 Fed. Reg. at 1092.

69. The Guidelines define a "well-established" utility as the following:

> (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention . . . *and* (2) the utility is specific, substantial and credible.

Id. at 1098 (emphasis added). "Credible utility" is whether "a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use." U.S. PATENT & TRADEMARK OFFICE, REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS 5 (1999), *available at* http://www.uspto.gov/web/menu/utility.pdf [hereinafter TRAINING MATERIALS]. "Specific utility" is specific to the subject matter claimed. *Id.* at 5. "Substantial utility" requires "real world" use. *Id.* at 6.

70. 2001 Utility Guidelines, 66 Fed. Reg. at 1098.

71. *See id.*

72. *See* TRAINING MATERIALS, *supra* note 69; *see also* Timothy A. Worrall, Note, *The 2001 PTO Utility Examination Guidelines and DNA Patents*, 16 BERKELEY TECH. L.J. 123, 141-42 (2001). Example nine of the materials provides an example of an application for numerous DNA sequences for use as probes to procure an unknown, full-length

II. SCIENTIFIC BACKGROUND

To garner a full appreciation of the legal complexities that surround the issue of gene patenting, it is necessary to elucidate basic principles of molecular biology. The human body consists of cells with differential functions that communicate by way of a complex system of interactions.[73] The gene is the functional hereditary unit and is composed of deoxyribonucleic acid (DNA). DNA is a linear polymer that contains two complementary strands and is comprised of four bases or "nucleotides": adenine ("A"), guanine ("G"), cytosine ("C"), and thymine ("T").[74] The complementary strand of the molecule is linked (i.e., "hybridized") to the other by hydrogen bonds, thus forming the familiar double helix.[75] An arrangement of these bases in a specific sequence serves as a "biological message" that delineates a particular gene.[76] The biochemical and genetic make-up of most cells is fundamentally similar: the nucleus houses chromosomes that contain most of the cell's genetic material.[77]

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gene. TRAINING MATERIALS, *supra* note 69, at 50-53. The PTO states that there is no "specific utility" in this application for the claimed sequences because the "utility" of the probes exists for the class of molecules and is not unique to any particular claimed probe. *Id.* at 51. It goes further to note that no "substantial" utility exists because the function of the targeted gene remains unknown. *Id.* On the other hand, Example ten of the materials provides a situation where the patent application was for a DNA fragment that encoded an open-reading frame, which had significant homology (i.e., a common DNA sequence) to a known class of protein and as such the application provided a "specific" and "substantial" utility for the claimed DNA fragment. *Id.* at 53-54. An open-reading frame is a sequence that encodes a protein. WILLIAM S. KLUG & MICHAEL R. CUMMINGS, GENETICS: A MOLECULAR PERSPECTIVE 182 (2003).

73. BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 3, 36 (3d ed. 1994).

74. *Id.* at 98. Adenine pairs with thymine and guanine pairs with cytosine. *Id.*

75. *Id.*

76. *See id.* at 102. Chemically related, ribonucleic acid (RNA) is similar to DNA in that it has three bases, A, C, and G that are the same; however, it contains uracil ("U") as opposed to T as its fourth subunit; this unit still pairs with adenine. *Id.* RNA is usually present as a single strand in contrast to the double helix of DNA. KLUG & CUMMINGS, *supra* note 72, at 8.

77. KLUG & CUMMINGS, *supra* note 72, at 6. In its capacity as an informational unit, DNA serves as a template for the eventual assembly of a particular protein. *Id.* at 8. Through an interplay involving various molecules, the information of DNA is transcribed to single-stranded messenger RNA ("mRNA"). *Id.* Upon the release of the mRNA from the cell nucleus, the mRNA associates with ribosomes located in the cytoplasm of the cell and the information stored in the mRNA is translated into proteins. *Id.* The diversity in function of proteins is what influences the "biochemical identity of cells." *Id.* at 7. A protein is a linear polymer that consists of chemical subunits called amino acids; there are 20 different types of amino acids. *Id.* at 8. It is the translation of the specific triplet nucleotides present in mRNA that determines the sequence of amino acids. *Id.*

During the life of a cell, only a few genes are expressed at any given time.[78] The transcripts (i.e., mRNA) can be extracted, converted to cDNA, and sequenced.[79] ESTs are simply short sequences of cDNA that represent the small fraction of genes expressed at the time of collection.[80] ESTs can be utilized as intermediaries to isolate the full gene, as markers to locate a particular gene on a chromosomal map, or to explore gene expression and regulation and therefore constitute important research tools.[81]

III. CASE SUMMARY

Dane Fisher and Raghunath Lalgudi (collectively "Fisher") appealed a decision from the BPAI on the only claim of their patent application for five ESTs from the maize plant, which was rejected due to lack of utility and enablement.[82] The Federal Circuit affirmed the decision of the BPAI.[83]

A. Facts and Procedural History

Fisher[84] applied for a patent on five ESTs from an unknown gene in the maize plant, disclosing seven uses for the molecules.[85] The examiner

78. *See* KLUG & CUMMINGS, *supra* note 72, at 432; CAS Registry, Sequence Tags, http://www.cas.org/express/help/601/blast/topics/seq_tags.htm. (last visited Oct. 27, 2005).

79. cDNA is "complementary DNA." ALBERTS ET AL., *supra* note 73, at 310. It can be produced by reverse transcribing mRNA transcripts. *Id.*

80. CAS Registry, Sequence Tags, http://www.cas.org/express/help/601/blast/topics/seq_tags.htm. (last visited Oct. 27, 2005).

81. National Center for Biotechnology Information, ESTs Factsheet, http://www.ncbi.nlm.nih.gov/About/primer/est.html (last visited Nov. 23, 2005).

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

83. *Id.*

84. The actual party in interest was Monsanto Co., a downstream user of research tools. *Fisher*, 421 F.3d. at 1366 n.1; *see also* Harold C. Wegner, Patent Developments, Address Before the Connecticut Intellectual Property Law Association (Nov. 9, 2004) (paper on file with the author), http://www.cipla.net/calendar/november_presentation.pdf.

85. The seven disclosed uses were the following:

> (1) serving as a molecular marker for mapping the entire maize genome, . . . (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.

Fisher, 421 F.3d at 1368.

rejected Fisher's claim on § 101 grounds because it failed to disclose a "specific and substantial utility" for the claimed molecules.[86] The examiner determined that the invention lacked a specific utility because Fisher's delineated uses were not specific to any claimed EST but were generally applicable to any EST molecule.[87] Additionally, the claimed ESTs lacked substantial utility because the resulting protein products did not have a known use.[88]

Fisher appealed to the BPAI.[89] Although the Board considered all seven uses, the appeal focused on only two: (1) the use of the ESTs for the identification of polymorphisms[90] (genetic variations in a DNA sequence) and (2) the use of the molecules as probes or as a primer source.[91] The BPAI declared that the scant disclosure of the patent application failed to show how the ESTs would be useful in the detection of polymorphisms.[92] Moreover, the BPAI declared that "without knowing any further information in regard to the gene represented by an EST . . . detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage."[93] The BPAI went further, dismissing Fisher's substantial utility offerings for using the ESTs as probes, concluding that using the claimed ESTs to probe functionally nebulous genes of other organisms also did not constitute a "substantial utility."[94] The Board considered the remaining uses, focusing on the use of the molecules to monitor gene expression and as molecular markers. Because the gene data obtained would not provide any clear teachings to a learned artisan, the Board

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86. *Id.*

87. *Id.*

88. *Id.* The examiner also rejected the application under the first paragraph of § 112 because she believed that a skilled artisan would not possess the requisite knowledge to utilize the claimed ESTs *because* of the lack of a specific and substantial utility of the molecules. *Id.*

89. *Id.*

90. *Id.* A polymorphism is defined as "a variation in the DNA that is too common to be due merely to new mutation. A polymorphism must have a frequency of at least 1% in the population." Polymorphism, MEDICINENET.COM, http://www.medterms.com/script/main/art.asp?articlekey=4992 (last visited Jan. 26, 2006).

91. Primers are "short preexisting [DNA] chain[s] to which new [nucleotides] can be added by DNA polymerase." Primer, HUMAN GENOME PROJECT INFORMATION: GENOME GLOSSARY, http://www.ornl.gov/sci/techresources/Human_Genome/glossary/glossary_p.shtml (last visited Feb. 19, 2006).

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

93. *Id.* (quoting *Ex parte* Fisher, 72 U.S.P.Q.2d 1020 (Bd. Pat. App. & Int'fs. 2004)).

94. *Id.*

stated that using ESTs to monitor gene expression and as molecular markers were insufficient to establish substantial utility.[95]

B. The Federal Circuit's Analysis

On appeal, Fisher argued that § 101 requires simply that an invention be not "frivolous, injurious to the well-being, good policy, or good morals of society"—a contention the Federal Circuit firmly rejected in affirming the BPAI determination.[96] The court stated that for an invention to have a "substantial utility," it must evince a presently significant benefit to the public.[97] Moreover, in addition to possessing a "substantial utility," the court stated that an invention had to have a "specific utility"—a well-defined use with a particular benefit to the public.[98] Hence, the court declared that an invention had to be useful, not in the future or after additional research, but at the time of the patent application.[99] Furthermore, the court found that merely appending the terms "biological activity or biological properties" or "useful for technical and pharmaceutical purposes" does not provide the specific details necessary to establish sufficient utility.[100] While indicating that it was not bound by the Utility Guidelines provided by the PTO, the court did agree that the guidelines "comport[ed] with [the] court's interpretation of the utility requirement of § 101."[101] In light of the judicial acknowledgement of the PTO's guidelines, the court quickly dismantled Fisher's legal argument that the BPAI applied a heightened standard in evaluating the utility of the invention.[102]

In assessing Fisher's proffered utilities, the Federal Circuit noted that the claimed ESTs served as research tools that could enable scientists to isolate particular genes and perform further research on those genes.[103] The Federal Circuit stated, however, that the "overall goal of such experimentation is presumably to understand the maize genome [, hence determining] the functions of the underlying genes . . ." and thus there is no invention per se.[104]

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95. *Id.* at 1369. The Board also affirmed the examiner's enablement rejection. *Id.*
96. *Id.* at 1366, 1371 (citation omitted).
97. *Id.* at 1371.
98. *Id.*
99. *Id.*
100. *Id.*
101. *Id.* at 1372.
102. *Id.*
103. *Cf. id.* at 1373. Fisher admitted that, as of the patent application, the gene target to which the ESTs were directed had no known function. *Id.*
104. *Id.*

Fisher also argued that ESTs could be analogized to other molecular research tools like the microscope.[105] Rejecting this argument, the court explained that while a microscope—by magnifying an object to reveal its structure—provided a "specific benefit," the ESTs performed no such function and simply detected a similarly structured molecule without providing additional information.[106] The court also noted that Fisher advanced no concrete examples of polymorphic or promoter uses.[107] Because Fisher provided no examples of the seven proposed uses, the court concluded that there existed no "substantial utility."[108] Additionally, the seven means failed to offer "specific utility" because any transcribed EST could perform the disclosed uses and none were unique to the claimed molecules.[109] Analogizing to *Manson*, the court firmly stated that since the claimed ESTs did not correlate to a gene with a known function, they did not satisfy the statutory utility requirement.[110]

The Federal Circuit stated that to allow the patenting of the contentious ESTs would have been to grant Fisher "a hunting license [because] the claimed ESTs [were] only tools to be used along the way in search for a practical utility . . . ."[111] The court thus concluded that the claimed ESTs

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105. *Id.*

106. *Id.*

107. *Id.* 1373-74. The court also noted that Fisher disclosed no evidence to substantiate the remaining asserted uses. *Id.* at 1374.

108. *Id.* at 1374. The court dismissed Fisher's attempt to analogize the claimed ESTs to the pharmaceutical inventions in *In re Jolles*, 628 F.2d 1322 (C.C.P.A. 1980), *Nelson v. Bowler*, 626 F.2d 853 (C.C.P.A. 1980), and *Cross v. Iizuka*, 753 F.2d 1040 (Fed. Cir. 1985). In those cases, the court noted that the proposed uses for the pharmaceutical compounds were substantiated by experimental evidence. *Fisher*, 421 F.3d at 1377. Fisher also attempted to provide evidence of utility by pointing to the commercial success of general EST databases. *Id.* While acknowledging that commercial success could support an invention's utility, the court stated that *Fisher* provided no evidence that there was any commercial interest in Fisher's claimed ESTs. *Id.* (citation omitted).

109. *Id.*; *see In re* Kirk, 376 F.2d 936, 936 (C.C.P.A. 1967) (affirming the BPAI's decision to reject an application on utility grounds because the steroid compounds were useful for simply their "biological activity" and that the compounds could be used only as intermediates in the preparation of unknown steroid compounds); *see also In re* Joly, 376 F.2d 906, 906 (C.C.P.A. 1967) (affirming the BPAI's rejection on utility grounds for an application for intermediary steroidal compounds that were structurally similar to known pharmacologically active compounds). The *Fisher* court also noted that although the analogized cases involved chemical as opposed to biological molecules, the same line of reasoning was applicable. *Fisher*, 421 F.3d at 1375.

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

111. *Id.* at 1376. The court also affirmed the BPAI's enablement decision because of the utility requirement in § 112. *Id.* at 1378. Therefore, the court stated that since the five claimed ESTs were found to lack utility, they were non-enabled as well. *Id.* at 1379.

failed to meet the § 101 utility requirement because they did not delineate the function of the underlying gene.[112]

In his dissent, Judge Rader argued that the claimed ESTs did possess statutory utility as research tools.[113] He stated that research tools generally were valuable and possessed utility, conceding that their use was limited to a laboratory setting.[114] Judge Rader stated that the ESTs were analogous to the microscope and hence beneficial to society because "both take a researcher one step closer to identifying and understanding a previously unknown and invisible structure."[115] Furthermore, the utility standard, Judge Rader argued, is not the proper standard to survey the prior art and assess what constitutes a substantive scientific advance.[116]

IV. DISCUSSION

"No recompense can properly be made to one from whom the community receives no consideration . . . ."[117] The *quid pro quo* of the patent system requires, in exchange for the grant of exclusive rights to the patentee, disclosure to the public of an invention that possesses "substantial" utility in its current form. To be patentable, the invention must be appropriately "ripe" on its developmental timeline.[118] By denying the application for the disputed ESTs in *Fisher*, the Federal Circuit provided the biotechnology community with a clearer picture regarding the time at which ESTs are appropriately "ripe" for patent purposes.

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112. *Id.* at 1376 ("Absent [the] identification [of the underlying gene] . . . the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.").

113. *Id.* at 1379.

114. *Id.* ("Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds).") (quoting U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) § 2107.01, at 2100-33 (8th ed. 2001, rev. Feb. 2003)).

115. *Id.* at 1380-81 ("Each step, even if small in isolation, is nonetheless a benefit to society sufficient to give a viable research tool 'utility' under § 101. In fact, experiments that fail still serve to eliminate some possibilities and provide information to the research process.").

116. *See id.* at 1382. Judge Rader stated that § 103 is the proper standard to use in assessing how much an invention contributes to a particular art. *Id.* Utilizing the "obvious" standard, however, was unavailable because of the precedent of the Federal Circuit. *Id.* (citing *In re* Deuel, 51 F.3d 1552 (Fed. Cir. 1995)).

117. CHISUM, *supra* note 17, § 4.01 n.2 (quoting 1 W. ROBINSON, TREATISE ON THE LAW FOR USEFUL INVENTIONS 462-63 (1890)).

118. *See* CHISUM, *supra* note 17, § 4.02; *cf. Fisher*, 421 F.3d at 1371 & n.4 (citing Nelson v. Bowler, 626 F.2d 853, 856 (C.C.P.A. 1980)).

A. *Fisher* Heightens the Utility Hurdle for ESTs by Delaying Patentability

The nature of the art dictates the point on the developmental timeline at which an invention complies with the utility requirement and thus becomes "ripe" for patenting.[119] Inventions in fields such as the mechanical arts, where inventors usually have a specific purpose in mind before commencing work, tend to satisfy the utility requirement early on the developmental timeline.[120] On the other hand, inventions in the chemical and biological arts often satisfy the utility requirement much later on the timeline because the creation of novel chemical compounds or processes frequently occurs long before the discovery of any specific utility.[121]

At what point on an invention's developmental timeline should patent rights vest to ensure that the public receives a benefit? If the rights vest too early, a significant impediment in the progress and development of a field could result. Conversely, if the granting of rights is delayed significantly, patent-sensitive industries, like biotechnology, would lack incentive to engage in costly research because of the potentially poor return on the investment.[122] The PTO and, ultimately, the courts will have to determine the appropriate point on the timeline for each industry to avoid these extremes.[123]

Rejecting the CCPA's utility standard in *Manson*, the Supreme Court avoided a bottleneck in the inventive stream for a utility-deficient product.[124] Because Manson provided no proof of *any* utility for the product that resulted from his claimed process, the Court's analysis implicitly focused on the early stage in the invention's development, finding that Manson's invention was not sufficiently "ripe" to merit patenting.[125]

Application of the *Manson* utility standard to ESTs requires that the molecules have a nexus to a *known* gene or protein—even those physiologically detrimental.[126] In *Fisher*, the applicants put forth seven *possible*

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119. *Cf.* Julian David Forman, Comment, *A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications*, 12 ALB. L.J. SCI. & TECH. 647, 662 (2002) (stating that the utility requirement serves as a "timing device" that assesses the "ripeness" of a particular invention).

120. *See* Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2085-86 (2000).

121. *Id.* at 2085.

122. *See* Forman, *supra* note 119, at 649.

123. *See* Forman, *supra* note 119, at 649.

124. *See* Brenner v. Manson, 383 U.S. 519, 532-33 (1966).

125. *Cf. id.* at 532.

126. *See In re* Fisher, 421 F.3d 1365, 1373 (Fed. Cir. 2005).

uses for the claimed ESTs but did not provide any supplementary experimental evidence that supported any of the uses proposed.[127] The rapid advances in molecular biology allow scientists to obtain or isolate genetic material more readily, and thus it is the nature of the DNA art that delays the patenting of ESTs at Fisher's stage of development. By demanding evidence demonstrating a nexus between an EST and its target gene, the court propelled the inventive process forward. Scientists will not expend time and energy attempting to uncover, sequence, and patent as many ESTs as possible, regardless of their utility. Instead, they will probe deeper into the complexities of understanding the various systems that spring from a particular genetic base in order to identify ESTs with specific and substantial utility.

Some Federal Circuit judges appear to champion the position that in unpredictable arts, such as chemistry, the compounds created have inherent utility, rendering showing of additional utility unnecessary.[128] Judge Rich, in his vigorous dissent in *Kirk*, insisted that:

> [c]learly it is against public policy to so establish the dynamics of the patent system that they operate to cause scarce scientific and inventive brainpower to waste its time concocting "legal utilities" merely for the purpose of satisfying the Patent Office, . . . instead of promoting honest disclosures which simply state that compounds are useful as "intermediates" and are intended merely to be supplied to another research group as the raw materials for further research. Such fantastic "law" is never indulged in with respect to other scientific "tools" of a mechanical or optical or electronic sort, such as a new laboratory balance, electron microscope, oscilloscope, or spectrophotometer, for example, yet they have no use whatever except to provide information and make research possible.[129]

Judge Rader articulated a similar position in his dissent in *Fisher*.[130] He argued that the ESTs possessed inherent utility as research tools, aiding in the study of other molecules.[131]

The overly broad conception of utility adopted by Judge Rich and Judge Rader creates considerable potential for abuse. This possibility explains precisely why the *Fisher* court properly disallowed the premature

127. *Id.*

128. *See In re* Kirk, 376 F.2d 936, 961 (C.C.P.A. 1967) (Rich, J., dissenting); *see also Fisher*, 421 F.3d at 1379 (Rader, J., dissenting).

129. *See Kirk*, 376 F.2d at 961.

130. *See Fisher*, 421 F.3d at 1380.

131. *Id.* at 1379.

vesting of patent rights for ESTs on the research timeline with nominal disclosures of utility. If permitted, early patenting of ESTs would cause a scientific "upstream clogging" and provide the public—even if limited to the scientific public—with little benefit of the EST "inventions" in their current form.[132] Thus, it is the inherent nature of ESTs that dictates the requirement of further development of the "invention" and not some burdensome requirement of "concocting" additional utilities.

B. The *Fisher* Decision and Anticommons Concerns

Exclusive rights in a scarce resource can give rise to a "tragedy of the anticommons."[133] An anticommons problem may arise when multiple owners of a scarce resource possess the right to exclude others.[134] In the biotechnology sector, an anticommons problem can arise if a high number of exclusive "upstream" rights preclude "downstream" uses.[135] This imbalance would lead to increased transaction costs for the "downstream" users desiring to improve upon earlier discoveries.[136]

While *Fisher* provided no examples of utility for the five ESTs and no information regarding the function of the underlying gene, *Fisher* did present the Federal Circuit with an opportunity to identify the proper point at which patent rights should vest for EST "research tools"—an opportunity for judicial clarification conspicuously avoided by the court.[137] Although the court declined to address the issue of patenting EST research tools, it appeared implicitly sensitive to the possibility that a tragedy of the anticommons could result, and thus the court required a higher degree of utility for ESTs.[138]

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132. *Cf.* Karen F. Lech, Note, *Human Genes Without Functions: Biotechnology Tests the Patent Utility Standard*, 27 SUFFOLK U. L. REV. 1631 (1993).

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

134. *Id.* at 698.

135. *Id.*

136. *Id.* at 700.

137. *See* Wegner, *supra* note 84, at 48; *see also In re* Fisher, 421 F.3d 1365, 1368 (Fed. Cir. 2005).

138. *Cf. Fisher*, 421 F.3d at 1375-76. The court stated:

> [u]ntil the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public.

Id. (citing Brenner v. Manson, 383 U.S. 519, 535-36 (1966).).

While the general debate regarding the patenting of research tools continues,[139] the Federal Circuit can turn to the successful patenting of other research tools for guidance in its future contemplation of the patentability of EST research tools. This history reveals that patenting research tools need not spur the development of an anticommons problem when rights vest only when technologies are sufficiently "ripe." Two examples of such technologies are the recombinant DNA technology and the polymerase chain reaction (PCR) technology.

In 1973, Stanley Cohen and Herbert Boyer pioneered a remarkable technology using a restriction enzyme to cut DNA from both a virus and bacteria, eventually creating an antibiotic-resistant plasmid.[140] This plasmid was then "spliced" into the genome of bacteria, thus creating the first recombinant organism. In 1980, Dr. Cohen and Dr. Boyer first patented this technology,[141] which subsequently generated millions of dollars in licensing revenue.[142] Here, patenting rights of the research tool vested at the appropriate time. This technological innovation not only dramatically facilitated the study of gene organization and expression, Cohen and Boyer's technology propelled an entire industry.[143] Moreover, at the time

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139. *See, e.g.*, Heather Hamme Ramirez, Comment, *Defending the Privatization of Research Tools: An Examination of the "Tragedy of the Anticommons" in Biotechnology Research and Development*, 53 EMORY L.J. 359 (2004).

140. *See* About Biotech, Expanding the Boundaries of DNA Research, http://www.accessexcellence.org/RC/AB/BC/1953-1976.html (last visited Jan. 25, 2006). A plasmid is a circular piece of double-stranded DNA. ALBERTS ET AL., *supra* note 73, at 308. Restriction enzymes are "biochemical scissors" that recognize a specific sequence of DNA and cut the DNA at that site. *See* MedicineNet.com, Definition of a Restriction Enzyme, http://www.medterms.com/script/main/art.asp?articlekey=5337 (last visited Jan. 26, 2006). Bacteria that contain the "antibiotic resistant" plasmid will survive exposure to antibiotics, while those that do not contain the plasmid will die. *See* An Introduction to Recombinant DNA, http://www.rpi.edu/dept/chem-eng/Biotech-Environ/Projects00/rdna/rdna.html (last visited Nov. 22, 2005). Thus the selection technique allows a researcher to recover specific bacteria containing the "foreign" circular DNA. *Id.*

141. *See* Rebecca Eisenberg, *Case Studies*, *in* 5 INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY 40-56 (1997), *available at* http://www.nap.edu/readingroom/books/property/2.html. Three patents on this technology issued. Ronald I. Eisenstein & David S. Resnick, *Going for the Big One: Blockbuster Patents Enrich University Coffers, but Can Also Affect Future Patenting and Research Decisions*, 19 NATURE BIOTECHNOLOGY 881 (2001), *available at* http://biotech.nature.com (subscription required).

142. Eisenberg, *supra* note 141, at 41.

143. *Id.*; *see also* KLUG & CUMMINGS, *supra* note 72, at 493 (discussing how recombinant DNA technology techniques supplied the "foundation" for the biotechnology industry).

of patenting the invention, alternative technologies were nonexistent.[144] Thus, steady progression of the art would occur notwithstanding the allowance of patenting the recombinant technology.

Another example of a research tool that was "ripe" for patenting was the Polymerase Chain Reaction technology. PCR allows for specific and rapid amplification of targeted DNA sequences using *Taq* polymerase, a heat-stable DNA polymerase enzyme.[145] This technology had a remarkable effect on basic research because it enabled the study of DNA extracted from varied sources (e.g., amplifying small quantities of DNA for forensic analysis or in medical diagnostics). Moreover, the elegant simplicity of the system provided an alternative to the sometimes labor-intensive use of recombinant technology.[146] Devised at the Cetus Corporation by Dr. Kary Mullis in 1984, PCR technology revolutionized biotechnology and now serves as a standard technique utilized in most molecular biology laboratories.[147] Its use was directed specifically and substantially to the amplification of nucleic acid sequences, hence acquiring patent protection at the appropriate point in the developmental timeline. In part because alternative technologies existed, the patenting of this research tool did not hinder, but rather aided scientific progression.[148]

Summarily, the patenting of the recombinant DNA and the PCR research tools were successful for two reasons. First, both technologies were disseminated widely and thus were publicly accessible. Second, at the time, the art could withstand patenting of these research tools because other tools were available to researchers. The availability of these other tools allowed progression of the art.

In stark contrast to the research tools discussed in this section, if the *Fisher* court allowed the patenting of bare ESTs, the genetic "gold rush" would create a complex structure of overlapping patent rights.[149] Because there are no gene "alternatives," the patenting of an EST would temporar-

144. Eisenberg, *supra* note 141, at 41.

145. An enzyme is a protein molecule that catalyzes—speeds up—chemical reactions. LUBERT STRYER, BIOCHEMISTRY 181 (4th ed. 1995). Polymerase is a type of enzyme that aids in the molecular "construction" of a DNA molecule. *Id.* at 89.

146. *See* KLUG & CUMMINGS, *supra* note 72, at 429.

147. Eisenberg, *supra* note 141, at 43.

148. *See* KLUG & CUMMINGS, *supra* note 72, at 429.

149. *See* Andrew T. Kight, Note, *Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines in Light of Brenner*, 73 IND. L.J. 997, 997 (1998); *cf.* Shanshan Zhang, *Proposing Resolutions to the Insufficient Gene Patent System*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1139, 1156 (2004) (arguing that because of the complex genetic interplay of various diseases, allowing DNA patenting would result in a complicated licensing picture).

ily remove it from the public domain. In addition, allowing patents on ESTs would focus inventive efforts in sequencing ESTs rather than in delineating the function of the target genes, and thus would impede scientific development in the field as a whole.

Although *Fisher* was a poor test case for establishing the proper utility standard for ESTs, the Federal Circuit demonstrated that it was not necessarily adverse to patenting these molecules.[150] Nevertheless, the court is sensitive to the possibility of "upstream clogging" because it implicitly demands a *higher* degree of utility for ESTs (i.e., allowing compliance with the statutory utility requirement later on the timeline).[151] Unlike the research tools previously discussed, none of the ESTs in *Fisher* could provide additional information either about the identity of the gene or its secondary structure or function, hence providing only a nominal degree of utility. Furthermore, the techniques utilized in the generation of the ESTs themselves did not involve novel techniques.[152]

It is difficult to predict whether the Federal Circuit, in future contemplations of the patentability of ESTs, will adhere to the utility stricture of *Manson* or settle into the more relaxed *Brana* standard. Additionally, it remains unclear whether the implicit degree requirement of *Fisher* will be applied narrowly to genetically-based inventions or to research tools generally.

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150. *In re* Fisher, 421 F.3d 1365, 1378 (Fed. Cir. 2005). After outlining the government and the amici's concerns regarding patenting ESTs without proof of utility, the court stated:

> The concerns of the government and the amici, which may or may not be valid, are not ones that should be considered in deciding whether the application for the claimed ESTs meets the utility requirement of § 101 . . . . They are public policy considerations which are more appropriately directed to Congress as the legislative branch of government . . . . [W]hen Congress enacted § 101, it indicated that 'anything under the sun that is made by man' constitutes potential subject matter for a patent.

Id. (citation omitted).

151. *But see* Bedford v. Hunt, 3 F. Cas. 37, 37 (C.C. Mass. 1817) ("The law, however, does not look to the degree of utility; it simply requires, that [the invention] shall be capable of use . . . ."); *see also In re* Kirk, 376 F.2d 936, 954 (C.C.P.A. 1967) ("[T]he case law [has shown] that any degree of utility to anybody [is] legal utility.") (Rich, J., dissenting) (internal quotation omitted).

152. *See* Leslie G. Restaino, Stephen E. Halpern & Dr. Eric L. Tang, *Patenting DNA-Related Inventions in the European Union, United States, and Japan: A Trilateral Approach or a Study in Contrast?*, 2002 UCLA J.L. & TECH. 2 (2003).

C. Implications of *Fisher* for Other Technologies

While the *Fisher* court decided that appropriate "ripeness" of patenting EST research tools will occur later in the invention's developmental timeline, the case is not broadly illustrative of the utility evaluation that will occur in delineating the patentability of other research tools.

For example, DNA microarrays ("chips") often are designed to serve as research tools.[153] These chips generally allow for the efficient gathering of genomic information.[154] These DNA chips can hold thousands of isolated, synthetic or reversed transcribed DNA molecules in discreet locations.[155] Under conditions favorable to hybridization, application of an unknown DNA sample to a chip and subsequent analysis can reveal the expression level of numerous genes contained in the sample.[156] DNA microarrays are thus powerful research tools in monitoring disease progression, as a clinical diagnostic, or in drug development.[157]

Under a literal reading of *Fisher*, if the sequences contained on the chip lack utility, then the entire chip may not be useful.[158] However, finding a "specific" and "substantial" utility for a particular chip probably would be more facile than attempting to find a utility for a bare EST. A

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153. Andrew Wang, Supervisory Patent Examiner, United States Patent and Trademark Office, Tech. Center 1600 Symposium (Oct. 2005), http://www.sdipla.org/files/MicroarrayIssue.pdf.

154. A microarray is "[a] tool used to sift through and analyze the information contained within a genome. A microarray consists of different nucleic acid probes that are chemically attached to a substrate, which can be a microchip, a glass slide or a microsphere-sized bead." National Center for Toxicogenomics, Glossary of Terms, http://www.niehs.nih.gov/nct/glossary.htm (last visited Nov. 23, 2005).

155. Andrew Chin, Artful Prior Art and the Quality of DNA Patents 47 (Oct. 2005) (unpublished manuscript, on file with author), http://www.unclaw.com/chin/scholarship/priorart.pdf. Affymetrix, who filed an amicus brief in the *Fisher* case, is said to own chips that can hold up to 400,000 genes as nucleotide probes! *See* Randall Osborne, *Affymetrix Venture Raises $100M to Exploit Wafers for Genomics*, BIOWORLD TODAY, Apr. 4, 2001.

156. Chin, *supra* note 155, at 48.

157. *See* National Center for Biotechnology Information, Microarrays Factsheet, http://www.ncbi.nlm.nih.gov/About/primer/microarrays.html (last visited Nov. 23, 2005); *see also* J.P. Jakupciak et al., *Mitochondrial DNA as a Cancer Biomarker*, 7 J. MOLECULAR DIAGNOSTICS 258 (2005).

158. *See, e.g.*, Brief for Affymetrix, Inc. as Amicus Curiae in Support of the Appellee at 12-13, *In re* Fisher, 421 F.3d 1365 (Fed. Cir. 2005); *see also* Wang, *supra* note 153. The current litigation surrounding the patenting of DNA microarrays seems to involve infringement of process patents (i.e., in the creation of the chip) as opposed to infringement of the claimed genetic material contained on the chip. *See, e.g.*, Richard Rouse & Gary Hardiman, *Microarray Technology—An Intellectual Property Retrospective*, 4 PHARMACOGENOMICS 3 (2003).

patent applicant could overcome a utility objection by patenting a method by which the microarray could constitute the invention, even if the particular subunits of the invention fail to satisfy the utility standard.[159]

Fisher may prove to be more directly applicable to nanotechnology. Nanotechnology comprises technology at the nanometer scale—one billionth of a meter.[160] Nanotechnology is remarkably interdisciplinary, cutting across a variety of disciplines, including chemistry, physics, biology, pharmaceuticals, and computer science.[161] The primary areas of interest in the field are in the creation of "nanomachines" and "molecular manufacturing."[162]

The *Fisher* court, in dicta, declared that regardless of its comparisons to *Manson*, "the Supreme Court . . . [decision] applies with equal force in the fields of chemistry and biology as well as in *any* scientific discipline."[163] Given that it encompasses a variety of disciplines and industries, nanotechnology is likely to place significant strain on this reasoning. Little prior art exists for nanotechnology, and determining a person of ordinary skill in the art may prove difficult.[164] Furthermore, one commentator noted that unlike early patents in biotechnology and other sectors, some of the existing nanotechnology patents are for the "basic building blocks" of the field.[165] Thus, in nanotechnology the tragedy of the anticommons presents a significant danger because the patents issued for these "building blocks" may be construed broadly, impeding the development of the field.[166] Additionally, properly determining when a particular nanotechnology invention is "ripe" for patenting may be a complex task. At present, there are a number of patents issued in the nanotechnology field but few products to show for them.[167]

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159. Wang, *supra* note 153.

160. David S. Almeling, Note, *Patenting Nanotechnology: Problems with the Utility Requirement*, 2004 STAN. TECH. L. REV. N1, ¶ 1 (2004), http://stlr.stanford.edu/STLR/Articles/04_STLR_N1.

161. *Id.* ¶ 7.

162. Qin Shi, *Patent System Meets New Sciences: Is the Law Responsive to Changing Technologies and Industries?*, 61 N.Y.U. ANN. SURV. AM. L. 317, 343 (2005). The commentator states that "molecular manufacturing" utilizes nanomachines to make products that exist on the atomic scale. *Id.*

163. *Fisher*, 421 F.3d at 1375 (emphasis added).

164. *See* Almeling, *supra* note 160, ¶ 21.

165. *See* Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 613-14 (2005).

166. *See id.* at 618-21.

167. *See id.* at 604.

While it appeared the PTO would traverse the same road for patenting nanotechnology that it tread when ESTs first came before the office, issuing numerous patents in a poorly understood technological sector,[168] the recent actions of the PTO are promising. The Office is taking proactive measures to educate itself on this emerging field.[169] In conjunction with the PTO's effort to prevent immature patenting, the Federal Circuit should use the implicit utility standard established in *Fisher* to limit patenting of nanotechnology products until further down the developmental timeline.[170]

V. CONCLUSION

The *Fisher* decision provided the first judicial acknowledgment of the 2001 PTO Utility Guidelines and also provided some initial guidance regarding the substance of the utility requirement for ESTs. While *Fisher* did not provide a precise standard for the minimum necessary utility, the decision effectively eliminates generic uses not unique to the claimed EST molecules. The case reflected perfectly the utility standard serving as a "timing device,"[171] allowing clearance of the utility hurdle only when the invention is "ripe." The impact of this standard on the patentability of ESTs as well as its applicability to other nascent industries remains an open question.

168. *See id.* at 613.

169. *See id.* at 603. The PTO has created a novel "cross-reference" system to track the new art in the nanotechnology sector. *See id.* at 603 n.8. It also holds annual meetings to become better educated in the field by other nanotechnologists. *See* M. Veronica Mullally & David R. Winn, *Patenting Nanotechnology: A Unique Challenge to IP Bar*, N.Y. L.J., July 6, 2004, http://www.orrick.com/fileupload/324.pdf.

170. *See* Lemley, *supra* note 165, at 628.

171. *See* Forman, *supra* note 119, at 648.