

2007

## In Re Fisher: Denial of Patents for ESTs Signals Deeper Problems in the Utility Prong for Patentability

Lillian Ewing

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### Recommended Citation

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Available at: <https://scholarship.law.umn.edu/mjlst/vol8/iss2/15>

*The Minnesota Journal of Law, Science & Technology* is published by the University of Minnesota Libraries Publishing.

## Notes

### ***In re Fisher*: Denial of Patents for ESTs Signals Deeper Problems in the Utility Prong for Patentability**

Lillian Ewing\*

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## INTRODUCTION

Express sequence tags (ESTs) are “tiny portion[s] of an entire gene that can be used to help identify unknown genes and to map their positions within a genome.”<sup>1</sup> In layman’s terms, an EST is simply a copy of one part of a gene. Since proteins play crucial roles in diseases and genes code for proteins, using ESTs to identify genes is a powerful method of studying diseases. A recent point of controversy surrounding ESTs is whether or not they should be patentable.

*In re Fisher*<sup>2</sup> addresses this very question. In *Fisher*, the court addressed the standard of usefulness required for patentable inventions under 35 U.S.C. § 101 as applied to ESTs. The *Fisher* court considered whether ESTs corresponding to genes of an unknown function are capable of satisfying the utility requirement. The *Fisher* court ultimately found that the claimed ESTs lacked specific and substantial utility because they were “only tools to be used along the way in the search for a practical utility” and, therefore, lacked an “immediate, well-defined, real world benefit” requisite to a finding of “substantial” utility considered mandatory under 35 U.S.C. § 101.<sup>3</sup>

This Note first asks whether ESTs should be patentable and then analyzes the viability of the current utility requirement of the Patent Act<sup>4</sup> as applied to ESTs. The Background section gives an overview of the requirements for patentability, the evolution of judicial interpretations of the utility requirement for patentability, and the U.S. Patent and Trademark Office’s (USPTO) interpretation of the utility requirement as embodied in its revised Guidelines manual.<sup>5</sup> Next, this Note analyzes the reasoning in *Fisher* and addresses whether the *Fisher* decision and current patentability requirements are in line with the goals of the patent system. This Note concludes that the current test for utility of ESTs fails because it is unviable in its application to research tools and inconsistent with the general goals of the

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1. Nat’l Ctr. For Biotech. Info., Just the Facts: A Basic Introduction to the Science Underlying NCBI Resources, *available at* <http://www.ncbi.nlm.nih.gov/About/primer/est.html> (Revised Mar. 29, 2004).

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

3. *Id.* at 1376.

4. The Patent Act, 35 U.S.C. §§ 100-376 (2000).

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

patent system. A new, bright-line test should be adopted in its place, which alters the substantiality prong of the test in its application to research tools. Such a test would promote the goals of the patent system and encourage the “progress of science”<sup>6</sup> by allowing more research tools to qualify for patents.

## I. BACKGROUND

### A. UTILITY REQUIRED BY THE CONSTITUTION

The U.S. Constitution gives Congress the power to “promote the Progress of Science and useful Arts by securing . . . exclusive Right[s] to . . . Discoveries.”<sup>7</sup> This declaration expressly limits the congressional grant of patents to *useful* discoveries and is the basis for the statutory utility requirement for patents.<sup>8</sup> Under 35 U.S.C. § 101, patents may be granted for inventions that involve patentable subject matter<sup>9</sup> and are useful,<sup>10</sup> non-obvious,<sup>11</sup> novel,<sup>12</sup> and adequately disclosed.<sup>13</sup> Section 101 codifies the utility prong of the patentability requirements, stating, “[w]hoever 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 . . . .”<sup>14</sup>

### B. JUDICIAL INTERPRETATION OF UTILITY REQUIREMENT

Courts first interpreted the statutory utility requirement in *Lowell v. Lewis*.<sup>15</sup> In *Lowell*, Justice Story (while riding circuit) adopted a *de minimus* view of utility and a correspondingly low threshold for patentability, allowing patents for compounds with no specific utility as long as they

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6. U.S. CONST. art. I, § 8, cl. 8.

7. *Id.*

8. *See, e.g.*, *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180 (Fed. Cir. 1991).

9. The Patent Act, 35 U.S.C. § 101 (2000).

10. *Id.*

11. *Id.* § 103.

12. *Id.* § 102.

13. *Id.* § 112.

14. *Id.* § 101.

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

were “more or less usefu[.]”<sup>16</sup> The Court of Customs and Patent Appeals (CCPA) later established the requirement of utility for chemical compounds, holding that a patent application must include an “assertion of utility and an indication of the use or uses intended.”<sup>17</sup> This test was softened when the court subsequently held that if actual utility exists, the degree to which it exists is “unimportant.”<sup>18</sup>

The modern utility standard was established in 1966 by the Supreme Court in *Brenner v. Manson*.<sup>19</sup> In *Brenner*, the Court narrowed what it perceived to be an overly broad field for patentability and created a more rigorous test that required an applicant to disclose one specific and substantial utility that qualifies under the USPTO’s Utility Examination Guidelines.<sup>20</sup> The *Brenner* test remains the standard applied by courts today in determining the utility of inventions.<sup>21</sup>

The *Brenner* standard was adapted to its current form in *In re Kirk*<sup>22</sup> and *In re Joly*,<sup>23</sup> which were decided on the same day. *Kirk* extended *Brenner* to apply not only to the process that yielded unpatentable product, but also to intermediates in the production of compounds with no known use. The court additionally found that the specificity requirement is not met if an application vaguely asserts that a compound is useful for its “biological activity” where “one skilled in the art would know how to use the compounds . . . to take advantage of their presently-existing biological activity.”<sup>24</sup> In *Joly*, the majority came to a similar conclusion as the *Kirk* court, holding that a claimed use for a chemical compound as an intermediate to make other compounds without regard for the usefulness of the downstream compounds was inadequate to establish

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

17. *In re Brenner*, 182 F.2d 216, 217 (C.C.P.A. 1950) (emphasis omitted).

18. *In re Nelson*, 280 F.2d 172, 179 (C.C.P.A. 1960).

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

20. *Brenner*, 383 U.S. at 534-35.

21. *See, e.g.*, *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563 (Fed. Cir. 1996) (“[I]t is well established that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered or disclosed.”); *In re Kirk*, 376 F.2d 936 (C.C.P.A. 1967) (finding that intermediate compounds that produce other compounds with no known use do not satisfy the utility requirement).

22. *Kirk* involved an application alleging compounds useful for biological activity that someone skilled in the art could discern. *Kirk*, 376 F.2d at 936-46.

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

24. *Kirk*, 376 F.2d at 941.

utility.<sup>25</sup>

### C. USPTO'S INTERPRETATION OF THE UTILITY REQUIREMENT

The USPTO has published utility guidelines and training materials that outline patentability requirements.<sup>26</sup> These guidelines do not carry precedential weight, but they are regularly relied upon by the courts when analyzing patentability.<sup>27</sup>

In 1995, the USPTO published the Utility Examination Guidelines.<sup>28</sup> These Guidelines made it easier to patent ESTs because they required that an applicant assert only a utility that was "specific" and "credible," eliminating the requirement that the utility also be "substantial." The USPTO clarified its stance on patents for ESTs in 1997, declaring that failure to specify the function of the underlying gene from which that EST was derived was not a bar to patentability because ESTs had utility apart from the full-length genomic DNA sequences from which they were derived.<sup>29</sup>

The USPTO changed its mind in 1999 when it issued its Revised Interim Utility Guidelines, which were intended to restrict the issuance of gene patents in response to substantial criticism from the public and private sectors.<sup>30</sup> The revised directives established a heightened standard for utility under the "credible utility" test, so that "credible utility" was not sufficient without an additional showing of "specific" and "substantial" utility.<sup>31</sup>

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25. *Joly*, 376 F.2d at 908 (emphasis omitted).

26. *See generally* Utility Examination Guidelines, *supra* note 5 at 1092; U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (8th ed. 2004).

27. The MANUAL OF PATENT EXAMINING PROCEDURE, *supra* note 26, and Utility Guidelines, *supra* note 5, are not binding on a court, but they may be given judicial notice to the extent that they do not conflict with patent statutes. *See, e.g.*, *Enzo Biochem v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) (citing *Molins PLC v. Textron*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995)).

28. *See* Utility Examination Guidelines, 60 Fed. Reg. 36,263, 36,264 (July 14, 1995).

29. Posting of Donald Zuhn, *In re Fisher*: EST Patentability Redux, <http://www.patentlyo.com/patent/2005/05/post.html> (May 2, 2005). *See generally* Donald L. Zuhn, *DNA Patentability: Shutting the Door to the Utility Requirement*, 34 J. MARSHALL L. REV. 973 (2001).

30. *See* Revised Interim Utility Examination Guidelines; Request for Comments, 64 Fed. Reg. 71, 440 (Dec. 21, 1999).

31. Revised Utility Guidelines, 64 Fed. Reg. 71,440 (Dec. 21, 1999). *See*

In 2001, the USPTO issued its current version of the Utility Examination Guidelines. These Guidelines incorporated the same definitions of “specific,” “substantial” and “credible” that were used in the 1999 Guidelines, except that the 2001 Guidelines adopted a “specific, substantial, and credible” test that incorporated a “well-established utility” analysis that was previously a separate test for utility.<sup>32</sup> Therefore, if an invention lacks specific, substantial, and credible utility it fails under both tests. An assertion is credible unless “the logic underlying the assertion is seriously flawed” or “the facts upon which the assertion is based are inconsistent with the logic underlying the assertion.”<sup>33</sup> This is not a significant hurdle to satisfy the utility requirement. The more substantial requirements are those which require that the utility be “specific,” which means that it is specific to the subject matter claimed in the application, and “substantial,” which means that it has a “real world” use.<sup>34</sup>

Court precedent has favored a narrow interpretation of the utility requirement following the Supreme Court’s *Brenner* decision.<sup>35</sup> This has been followed by the USPTO in its most recent Guidelines.<sup>36</sup> Whether this is an appropriate interpretation, specifically with regard to express sequence tags, remains an open question.

#### D. WHAT ARE ESTS?

In order to understand ESTs, it is important to have a basic understanding of genetics and how genetic research is used to study hereditary diseases. The human body is made

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Stephen G. Kunin, *Written Description Guidelines and Utility Guidelines*, 82 J. PAT. & TRADEMARK OFF. SOC’Y 77, 96-97 (2000) (concluding that the Revised Utility Guidelines address more specifically the issues of specific and substantial utility, while keeping the same standard for credible utility from the 1995 Guidelines).

32. *The Fate of Gene Patents Under the New Utility Guidelines*, 2001 DUKE L. & TECH. REV. 8 (2001); see Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

33. *Id.* See also UNITED STATES PATENT AND TRADEMARK OFFICE, REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS 5 (1991) [hereinafter TRAINING MATERIALS].

34. TRAINING MATERIALS at 5-6.

35. See *In re Joly*, 376 F.2d 906, 908 (C.C.P.A. 1967) (denying a patent application for an intermediate compound in the production of a steroid); see also *In re Kirk*, 376 F.2d at 936 (denying a patent application that contained vague claims asserting “biological activity” as the utility).

36. Utility Examination Guidelines 6, 66 Fed. Reg. 1092 (Jan. 5, 2001).



up of many different types of cells, each of which contains deoxyribonucleic acid (DNA), which guides the activities within that cell and determines the unique traits of that cell. DNA is composed of four distinct bases, which are the molecules adenine (A), guanine (G), cytosine (C), and thymine (T). These bases form base pairs (A with T and G with C) that form a two-stranded DNA molecule. Long sequences of double-stranded DNA comprise the total DNA of a cell, called its genome, which includes up to three billion bases in human cells.<sup>37</sup> Genes are sequences of bases within a cell's DNA<sup>38</sup> that give instructions to the cell on how to make proteins.<sup>39</sup> The different proteins encoded by genes are essential for the survival of an organism because they perform most functions necessary for life and make up most of the structures in a cell. Genes, in turn, are significant because they determine the chemistry and behavior of these proteins.

When scientists are able to understand how a gene is expressed<sup>40</sup> under normal circumstances (when a person is healthy), they can then study how it is expressed under abnormal circumstances (when a person has a disease). In the past, this usually required scientists to identify a protein of interest, isolate that protein, determine its function, and then find the specific gene within the genome that coded for that protein.<sup>41</sup> Alternatively, by starting research with the gene instead of the protein, scientists could determine the location of a given gene on the genome and then isolate the protein coded for by that gene.<sup>42</sup> Both of these methods are time-

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37. Office of Biological & Env'tl. Research, U.S. Dep't of Energy Office of Sci., *The Science Behind the Human Genome*, [http://www.ornl.gov/sci/techresources/Human\\_Genome/project/info.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml) (last modified Aug. 29, 2006).

38. *Id.* It is estimated that the human genome contains 20,000 to 25,000 different genes.

39. *Id.* DNA sequences coding for genes comprise only 2% of the human genome. The remainder consists of non-coding regions, which may provide instructions for regulating protein quantities or ensure structural integrity of chromosomes.

40. Wikipedia, *Gene Expression*, available at [http://en.wikipedia.org/wiki/Gene\\_expression](http://en.wikipedia.org/wiki/Gene_expression) (last visited Apr. 12, 2007). Gene expression is the process whereby a gene is "turned on" so that the expressed portions of a gene's DNA sequence are "converted into the structures and functions of a cell." In contrast, the non-protein encoding portions are not translated into protein.

41. Office of Biological & Env'tl. Research, *supra* note 37.

42. *Id.*

consuming<sup>43</sup> and costly, because they require expensive biochemical research methods and focus on only a single gene or protein at a time.<sup>44</sup>

Express sequence tags can decrease the time and cost involved in genetic research. According to the National Institutes of Health (NIH), express sequence tags are “unique segment[s] of cDNA with a base sequence[s] identical to at least part of the coding region of a gene, generally used as landmark for mapping.”<sup>45</sup> In order to get a hold of these gene fragments, scientists must first separate the expressed sequences, which represent just 2% of the genome, from the non-expressed DNA in the genome, which represents the other 98% of the cell’s DNA.<sup>46</sup> This is a process that naturally occurs in the cell when messenger RNA (mRNA) is created along the pathway to protein formation. Messenger RNA is an alternative form of DNA that represents only the expressed portion of DNA and is used by the cell to create proteins in a process called translation.<sup>47</sup> Messenger RNA is not used extensively in genetic research because it is inherently unstable outside of a cell.<sup>48</sup> Instead, scientists use enzymes to create cDNA from the mRNA that represents an exact replica of the cell’s original DNA, minus the unexpressed regions.<sup>49</sup> It

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43. In fact, these methods often take years. *Id.*

44. EST sequences “can be generated rapidly and inexpensively, only one sequencing experiment is needed per each cDNA generated, and they do not have to be checked for sequencing errors because mistakes do not prevent identification of the gene from which the EST was derived.” Nat’l Ctr. for Biotech. Info., *supra* note 1.

45. Nat’l Inst. on Alcohol Abuse and Alcoholism of the Nat’l Insts. of Health, *Concepts and Terms in Genetic Research—A Primer*, <http://pubs.niaaa.nih.gov/publications/arh26-3/165-171.htm> (Prepared June, 2003).

46. Office of Biological & Env’tl. Research, *supra* note 37.

47. Creating proteins from genes in DNA involves transcription, which is the creation of messenger RNA from DNA, followed by translation, which is the creation of a protein from the messenger RNA. “During [transcription], mRNA passes through various phases, including one called splicing, where the non-coding sequences are eliminated. In the next step, translation, the mRNA guides the synthesis of the protein by adding amino acids, one by one, as dictated by the DNA and represented by the mRNA.” Nat’l Ctr. for Biotech. Info., *supra* note 1.

48. *Id.*

49. *Id.* According to the National Center for Biotechnology Information, cDNA is a “form of DNA prepared in the laboratory using an enzyme called reverse transcriptase. cDNA production is the reverse of the usual process of transcription in cells because the procedure uses mRNA as a template rather than DNA. Unlike genomic DNA, cDNA contains only expressed DNA sequences, or exons.” *Id.*

is this cDNA that is used in the creation of ESTs.

To create an EST, scientists isolate the cDNA that codes for a given protein and determine its sequence (the sequence of A, T, G, and C bases that make up the cDNA).<sup>50</sup> Then they create a short sequence of bases, usually several hundred bases long, that complements either the beginning of the cDNA sequence (a 5' EST tag) or the end of the cDNA sequence (a 3' EST tag).<sup>51</sup> A 5' EST tags the portion of the cDNA that usually codes for a protein, while a 3' EST tags the portion of the cDNA that is often part of an untranslated region.<sup>52</sup> To study a genetic disease, scientists identify ESTs that may correspond to a gene involved in the disease, and then examine the DNA of disease-carrying patients for mutations in the gene to determine if they match.<sup>53</sup> Other uses for ESTs include genome mapping, the process of creating an outline of identified genes in the human genome used by researchers to facilitate further research and understanding of the genome that often uses 3' EST tags.<sup>54</sup>

## II. THE "SUBSTANTIAL" AND "SPECIFIC" UTILITY TEST

### A. THE CURRENT UTILITY TEST UNDER *BRENNER V. MANSON*

The current test for utility was created by the Supreme Court in 1966 in its decision in *Brenner v. Manson*.<sup>55</sup> In *Brenner* the Court addressed whether the utility of a compound produced by a chemical process is an essential element of establishing a prima facie case for patentability of that process.<sup>56</sup> The Court construed 35 U.S.C. § 101 narrowly in its application for method patents and held that utility is required for the product of a process as well as the process itself:

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50. *Id.*

51. *Id.*

52. *Id.*

53. Nat'l Center for Biotech. Info., *Just the Facts: A Basic Introduction to the Science Underlying NCBI Resources, ESTs: Gene Discovery Made Easier*, <http://www.ncbi.nlm.nih.gov/About/primer/est.html> (Revised March 29, 2004). This is the method used to determine the genes involved in Alzheimer's disease and colon cancer, among others.

54. *Id.* 3' EST tags are used for genome mapping because they are usually not conserved between species and thus represent unique identifiers.

55. *Brenner*, 383 U.S. at 519.

56. *Id.* at 520.

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.<sup>57</sup>

The *Brenner* majority reasoned that the patentable field would be too broad with a standard that did not require utility for both the process and product.<sup>58</sup> Consequently, the majority opined that the current *de minimis* utility standard<sup>59</sup> was out of line with the goals of the patent system because “a patent is not a hunting license . . . [or] a reward for the search, but compensation for its successful conclusion.”<sup>60</sup>

The *Brenner* Court created a new test that put at its forefront the requirement that a patentable invention derive some benefit to the public that has “substantial utility” and a “specific benefit [that] exists in currently available form.”<sup>61</sup> Unfortunately the Supreme Court did not delineate what constitutes “specific” and “substantial” in determining whether an invention satisfies the utility requirement. Instead, the task of interpreting this test was left to appellate courts and the Court of Customs and Patent Appeals (CCPA) to determine in subsequent cases.

#### B. “SUBSTANTIAL” UTILITY PRONG

The *Brenner* test’s “substantial” utility requirement has been interpreted by the lower courts to require “practical utility” and “real world” utility.<sup>62</sup> In *Nelson v. Bowler*, the court elucidated the requirement by explaining that, “[p]ractical utility’ is a shorthand way of attributing ‘real-world’ value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner

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57. *Id.* at 535.

58. The *Brenner* Court reasoned: “Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area.” *Id.* at 534.

59. The utility test used before *Brenner v. Manson* was that outlined in *Lowell v. Lewis*, where Justice Story held that 35 U.S.C. § 101 only requires that an invention not be frivolous or injurious to well-being, good policy, or the good morals of society. 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568).

60. *Brenner*, 383 U.S. at 536.

61. *Id.* at 534-35.

62. *See In re Fisher*, 421 F.3d 1365, 1376-77 (Fed.Cir. 2005).

which provides some immediate benefit to the public.”<sup>63</sup> In addition to providing an immediate benefit to the public, the practical or real world utility must be in current form, showing a “significant and presently available benefit to the public.”<sup>64</sup>

To assert utility for a method for making a corresponding product, such as a protein, under *Brenner* one must determine whether or not the corresponding product itself has substantial utility.<sup>65</sup> According to the USPTO’s interpretation of *Brenner* as embodied in the Utility Guidelines, identifying and studying the properties of the corresponding product does not constitute a “real world” context of use.<sup>66</sup> Therefore, the substantial utility test encompasses the requirement for a “real world” context of use that includes an immediate public benefit that is currently available as disclosed in the patent application.

### C. “SPECIFIC” UTILITY PRONG

To satisfy the “specific” utility prong of the utility test, an application must “disclose a use which is not so vague as to be meaningless.”<sup>67</sup> There must be a “well-defined and particular benefit to the public.”<sup>68</sup> Vague assertions of “biological activity”<sup>69</sup> or “biological properties”<sup>70</sup> do not meet the standard. In its non-binding Manual of Patent Examining Procedure (MPEP), the USPTO defined specific utility to require a use particular to the subject matter claimed in the application and not applicable to a broad class of inventions.<sup>71</sup> In contrast, general utility would apply to a broad class of an

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63. *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980).

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

65. See U.S. PAT. & TRADEMARK OFF., REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS 50-53 (1999), available at <http://www.uspto.gov/web/menu/utility.pdf>.

66. *Id.* at 6. According to the USPTO Utility Guidelines, “[u]tilities that require or constitute carrying out further research to identify or reasonably confirm a ‘real world’ context of use are not substantial utilities.” *Id.*

67. *Fisher*, 421 F.2d at 1371.

68. *Id.*

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

70. *Id.*

71. U.S. PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE § 2107.01 (8th ed., 5th rev. 2006), available at [http://www.uspto.gov/web/offices/pac/mpep/mpep\\_e8r5\\_2100.pdf](http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r5_2100.pdf) [hereinafter MPEP].

invention.<sup>72</sup> An example the USPTO gives to clarify this is directly applicable to ESTs: “a claim to a polynucleotide whose use is disclosed simply as a ‘gene probe’ or ‘chromosome marker’ would not be considered to be *specific* in the absence of a disclosure of a specific DNA target.”<sup>73</sup> Further, the Utility Guidelines addresses the utility of hypothetical cDNA fragments used as probes for finding full-length genes and concludes that the utility lacks specificity because,

[t]he use of the claimed nucleic acid is not particular to the sequence being claimed because it would be applicable to the general class of cDNAs. Any partial nucleic acid prepared from any cDNA may be used as a probe in the preparation and or identification of a full-length cDNA.<sup>74</sup>

Therefore, to satisfy the specificity prong of the utility test an application must contain an asserted use that is specific enough that it cannot apply generally to an entire class of invention.

### III. THE *FISHER* DECISIONS

#### A. *EX PARTE FISHER* DECISION

In *Ex parte Fisher*<sup>75</sup> the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences (BPAI) heard an appeal from an examiner’s rejection for lack of utility<sup>76</sup> of a patent application claiming “[a] substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence” selected from a group of five claimed ESTs.<sup>77</sup> The patent application asserted the following seven uses<sup>78</sup> for the claimed ESTs:

1. Serving as a molecular marker for mapping the entire

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72. U.S. PAT. & TRADEMARK OFF., *supra* note 65, at 5.

73. *Id.*

74. *Id.* at 51.

75. 72 U.S.P.Q.2d 1020 (B.P.A.I. 2004).

76. Whether a patent application discloses the requisite utility for a claimed invention is a question of fact. 35 U.S.C. § 101 n.333. A patent application that lacks utility also fails, as matter of law, for lack of enablement. 35 U.S.C. §§ 101 n.12, 112 n.4. See also *In re Brana*, 51 F.3d 1560, 1564 (Fed. Cir. 1995) (“Obviously, if a claimed invention does not have utility, the specification cannot enable one to use it.”).

77. The original application claimed 32,236 ESTs, but this was reduced to five claimed ESTs at the direction of the USPTO examiner, who upon examination for the merits entered a Restriction to reduce the claimed ESTs to five or fewer. 72 U.S.P.Q.2d at 1022.

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

- maize genome, which consists of ten chromosomes that collectively encompass about 50,000 genes;
2. Measuring the level of mRNA in a tissue sample via microarray technology to provide information about gene expression;<sup>79</sup>
  3. Providing source for primers for use in the polymerase chain reaction [PCR] process to enable rapid and inexpensive duplication of specific genes;<sup>80</sup>
  4. Identifying the presence or absence of a polymorphism;<sup>81</sup>
  5. Isolating promoters<sup>82</sup> via chromosome walking;<sup>83</sup>
  6. Controlling protein expression; and
  7. Locating genetic molecules of other plants and organisms.

Although the Appellants asserted seven potential uses for ESTs, the application needed to disclose only a single specific and substantial utility in order to satisfy the utility requirement.<sup>84</sup>

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79. Nat'l Center for Biotech. Info. *supra* note 1. Microarrays, also known as DNA on a chip, are, "a tool for analyzing gene expression that consists of a small membrane or glass slide containing samples of many genes arranged in a regular pattern." Specifically, it works by using an mRNA molecule to hybridize with the DNA template from which it originated. This allows researchers to determine the expression levels of many genes at once by measuring the amount of mRNA bound to each site on the array.

80. PCR is a molecular biology technique used to replicate DNA exponentially. PCR typically amplifies short pieces of DNA, up to ten kilo base pairs in length. Wikipedia, *Polymerase Chain Reaction*, [http://en.wikipedia.org/wiki/Polymerase\\_chain\\_reaction](http://en.wikipedia.org/wiki/Polymerase_chain_reaction) (last visited Apr. 18, 2007).

81. In the field of biology, a polymorphism refers to having multiple alleles of a gene within a population, usually expressing different phenotypes. Wikipedia, *Polymorphism*, <http://en.wikipedia.org/wiki/Polymorphism> (last visited Apr. 18, 2007).

82. "In genetics, a promoter is a DNA sequence that enables a gene to be transcribed. The promoter is recognized by RNA polymerase, which then initiates transcription. In RNA synthesis, promoters are a means to demarcate which genes should be used for messenger RNA creation - and, by extension, control which proteins the cell manufactures." Wikipedia, *Promoter*, <http://en.wikipedia.org/wiki/Promoter> (last visited Apr. 18, 2007).

83. Chromosome walking is a method in genetics for identifying and sequencing long parts of a DNA strand, e.g., a chromosome. As the traditional chain termination method does not allow long DNA strands to be sequenced, this method works by dividing the long sequence into several consecutive short ones . . . That way, the short part of the long DNA that is sequenced keeps 'walking' along the sequence. The method can be used to sequence entire chromosomes (thus, chromosome walking). Wikipedia, *Chromosome Walking*, [http://en.wikipedia.org/wiki/Chromosome\\_walking](http://en.wikipedia.org/wiki/Chromosome_walking) (last visited Apr. 18, 2007).

84. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (2001). The

In analyzing the utility of the claimed ESTs, the BPAI focused primarily on three of the asserted uses: identifying a polymorphism, the use as a probe to isolate promoters, and the use as a source for primers.<sup>85</sup> The court held that identifying a polymorphism, which claimants asserted was useful in identifying a common genetic heritage among populations, was indeed a use for the ESTs, but that the use failed to be substantial enough<sup>86</sup> because it provided only the “barest information” about genetic heritage.<sup>87</sup> With regards to the claimed use of ESTs as probes or primers, the court found that the ESTs were not “tissue specific, cell-specific, cell-type, developmental or environmentally regulated”<sup>88</sup> because the cDNA library used to isolate the ESTs was not a subtractive cDNA library<sup>89</sup> specific to portions of the genome actually expressed in leaf tissue during anthesis.<sup>90</sup> In other words, the court found the claimed ESTs to be “randomly selected”<sup>91</sup> so that there was no reasonable expectation that they could fulfill the claimed specific use in their currently available form

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Guidelines state that the patentee is “required to disclose only one utility, that is, teach others how to use the invention in at least one way. The patentee is not required to disclose all possible uses, but promoting the subsequent discovery of other uses is one of the benefits of the patent system.”

85. *Ex parte Fisher*, 72 U.S.P.Q.2d 1020, 1026 (2004). The BPAI combined the latter two uses, those of ESTs as probes and primers, under a single analysis. In reviewing the court’s analysis, this Note also combines the two uses into a single analysis for the sake of clarity.

86. *Id.* The *Ex parte Fisher* court concluded that polymorphisms are natural variations that do not have an independent meaningful use and, therefore, a correct analysis would require first determining if there was a polymorphism and then determining “how to use this information in a patentably meaningful way.”

87. *Id.*

88. *Id.* at 1027.

89. A subtractive cDNA library is one which has effectively eliminated (“subtracted”) the cDNA from parts of the genome not of interest. In the case of Fisher’s claimed ESTs, a subtractive cDNA library could subtract nucleic acid molecules from other, non-leaf maize tissue or from other developmental stages to leave only cDNA from maize leaf tissue from the anthesis developmental stage. *Id.*

90. *Id.* Appellants argued that the claimed ESTs, which were isolated from maize leaves during anthesis, provided a useful starting point for isolating a promoter active in leaves during anthesis and that this constituted a substantial use because isolation of the promoter would allow research into protein expression during a developmental stage in the leaf life cycle, including proteins that provide disease resistance.

91. *Id.*



without being further “refined and developed.”<sup>92</sup> Therefore, each use analyzed by the BPAI was rejected for failing the “substantial” use prong of the *Brenner* utility test.

#### B. THE *IN RE FISHER* MAJORITY’S ANALYSIS: ESTS AS RESEARCH INTERMEDIATES

In *In re Fisher*, the Federal Circuit heard the appeal of the BPAI decision finding that the claimed uses for ESTs failed for lack of utility under the *Brenner* standard.<sup>93</sup> The majority of the Federal Circuit found that the ESTs are “no more than research intermediates” that can be used to identify the underlying genes and conduct further research on those genes.<sup>94</sup> The Federal Circuit held that ESTs, as research intermediates, fail the utility standard because there is “no assurance that anything useful will be discovered in the end.”<sup>95</sup>

##### 1. “Substantial” Use

The court agreed with the Appellants that the seven asserted uses in the application were valid experimentation goals for ESTs, but found that there was no satisfactory evidence that the claimed ESTs could actually be used in the seven ways outlined in the patent application.<sup>96</sup> The ESTs failed to satisfy the *Brenner* utility standard because they remained “object[s] of use-testing”<sup>97</sup> without any current real-world utility.

Most of the claimed uses for ESTs involved studying other molecules.<sup>98</sup> The majority advanced the BPAI’s utility inquiry by exploring not only whether the claimed uses satisfied the utility standard, but whether the products associated with the ESTs (i.e., the underlying gene corresponding to the EST, the protein expressed by the underlying gene, or the promoter that an EST could locate) satisfied the utility standard

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92. *Id.*

93. *In re Fisher*, 421 F.3d 1365, 1369 (Fed. Cir. 2005).

94. *Id.* at 1373.

95. *Id.*

96. *Id.* at 1373–74. The Court of Appeals found that there was no evidence showing that any polymorphisms, any promoters, or any genetic molecules in other plants or organisms had been identified, or that the ESTs had been used as molecular markers in maize genome mapping.

97. *Id.* at 1374; *Brenner*, 383 U.S. at 535.

98. *See Fisher*, 421 F.3d at 1376.

independently.<sup>99</sup> Under *Brenner*, a useful process must yield a product that independently satisfies the utility test.<sup>100</sup> Therefore, if an EST is useful because it can identify an underlying gene, then that underlying gene must have a specific and substantial use itself. Similarly, if an EST is useful because it can identify a promoter or polymorphism, then that promoter or polymorphism must also have a specific and substantial use. The majority applied *Brenner* and found that products of processes or experiments identified as uses for ESTs must themselves have a use that satisfies the utility standard.<sup>101</sup> For Fisher's claimed ESTs, the court determined that the underlying genes, the corresponding promoters, and the associated polymorphisms failed to satisfy the utility standard.<sup>102</sup> Therefore, the ESTs failed the utility test for lack of substantial use.

## 2. "Specific" Use

The *Fisher* majority found that the claimed ESTs also failed the "specific" use prong of the *Brenner* utility test.<sup>103</sup> The court determined that the asserted uses were general in nature rather than specific to the ESTs in the application (i.e., the exact nucleotide sequence of each EST identified) and therefore failed for lack of specificity.<sup>104</sup> The court reasoned that:

[A]ny EST transcribed from any gene in the maize genome may be a molecular marker or a source for primers. Likewise, any EST transcribed from any gene in the maize genome may be used to measure the level of mRNA in a tissue sample, identify the presence or absence of a polymorphism, isolate promoters, control protein expression, or locate genetic molecules of other plants and organisms.<sup>105</sup>

The court determined that nothing about the asserted uses for the five claimed ESTs made them distinct "from the more than 32,000 ESTs disclosed in the . . . application or

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99. *See id.* at 1374.

100. *See Brenner*, 383 U.S. at 534.

101. *See Fisher*, 421 F.3d at 1373-76. As an example, the court illustrated that an EST may be used to detect a complementary genetic sequence of DNA, but it is unable by itself "to provide any information about the overall structure let alone the function of the underlying gene." *Id.* at 1373.

102. *Id.* at 1373.

103. *Id.* at 1374.

104. *Id.*

105. *Id.*

indeed from any EST derived from any organism.”<sup>106</sup> Fisher’s ESTs failed the specificity test because they were general, rather than specific, in nature and they could apply to “any EST transcribed from any gene in the maize genome.”<sup>107</sup>

The court again extended the analysis to address the utility of the products associated with the claimed ESTs. In analyzing the specific utility of the products correlated with the ESTs, the court relied heavily on *In re Kirk*.<sup>108</sup> *Kirk* extended *Brenner* to apply not only to processes that yielded unpatentable product, but to intermediates in the production of compounds with no known use.<sup>109</sup> Under *Kirk*, a compound that is useful as an intermediate step in the preparation of compounds of unknown use fails to have specific utility.<sup>110</sup> “It is not enough that the specification discloses that the intermediate exists and that it ‘works,’ reacts, or can be used to produce some intended product of no known use.”<sup>111</sup> Therefore, under this expanded test the ESTs would remain subject to the *Brenner* test even if they did not constitute a “process” because they qualify as intermediates in the production of compounds with no known use. Applying the test to the claimed ESTs as intermediate compounds, the court held that they lacked specificity because they disclosed products of unknown use (i.e., there was no known specific use for the underlying gene or protein it encoded).<sup>112</sup>

### C. THE *IN RE FISHER* DISSENT’S ANALYSIS: ESTS AS RESEARCH TOOLS

Judge Rader dissented from the *Fisher* majority, disagreeing with the identification of ESTs as research intermediates.<sup>113</sup> Instead, he argued that ESTs constitute

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106. *Id.*

107. *Id.*

108. 376 F.2d 936 (C.C.P.A. 1967). *See also In re Joly*, 376 F.2d 906 (C.C.P.A. 1967) (adopting the reasoning of the *In re Kirk* court to nearly identical facts); *In re Fisher*, 421 F.3d 1365, 1374–77 (Fed. Cir. 2005).

109. *Kirk*, 376 F.2d at 945–46.

110. *Id.*

111. *Id.* at 945. The court went on to comment that it is not enough that “the product disclosed [is] obtained from [an] intermediate [that] belongs to some class of compounds which now is, or in the future might be, the subject of research to determine some specific use.” *Id.* at 945 (footnote omitted).

112. *Fisher*, 421 F.3d at 1375–77.

113. *See id.* at 1379 (Rader, J., dissenting).

research tools, which have utility that is “generally . . . beyond question”<sup>114</sup> in a utility analysis by the USPTO. Judge Rader agreed with the majority that if the *Brenner* test applied to ESTs (i.e., if ESTs are methods rather than research tools) that the ESTs would fail to be patentable for lack of utility.<sup>115</sup>

There is currently no bright line test to determine what constitutes a research tool. The USPTO has not explicitly defined what constitutes a research tool, although it restricts what constitutes a research tool by preventing patents for tools that do not provide “substantial” advances.<sup>116</sup> Janice Mueller, in an article about patent infringement for biomedical research tools, defined research tools as “the many varied resources used by scientists to conduct research and development of new drugs, therapies, diagnostic methods, and other therapeutic products.”<sup>117</sup> Research tools may include biochemicals, such as reagents, plasmids, antibodies, and enzymes used to develop subsequent pharmaceutical end products or they may include a device that can be used and reused during the course of research, such as PCR.<sup>118</sup> The NIH defines research tools as “the full range of tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.”<sup>119</sup>

The dissent in *Fisher* adopted this same broad definition of research tools. Opining that ESTs constitute research tools, Judge Rader argued that although the ESTs in the application corresponded to genes of unknown function, the ESTs nonetheless remain research tools because they “enhance research” into “isolating and studying other molecules”<sup>120</sup> by taking a researcher “one step closer to identifying and

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114. *Id.*

115. *Id.*

116. See MPEP, *supra* note 71, § 2107.01.

117. Janice M. Mueller, *No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 4 (2001).

118. Natalie M. Derzko, *In Search of a Compromised Solution to the Problem Arising from Patenting Biomedical Research Tools*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 347, 348 (2004).

119. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,092 n.1 (Dec. 23, 1999).

120. *Fisher*, 421 F.3d at 1379 (Rader, J., dissenting).

understanding a previously unknown and invisible structure.”<sup>121</sup> Rader’s dissent concluded that ESTs qualify as research tools which have established utility in a laboratory research setting, and that the strict *Brenner* utility test was therefore inapplicable.<sup>122</sup>

#### IV. IMPLICATIONS OF *IN RE FISHER*: A BETTER UTILITY TEST IS NEEDED

##### A. THE *BRENNER* TEST IS ILL-SUITED FOR DETERMINING UTILITY

The *Brenner* utility test fails to meet the needs of modern scientific research. There are practical problems with the application of a rule that lacks bright-line standards<sup>123</sup> for satisfying its individual prongs and policy problems associated with a rule that was created during a time before the advent of modern molecular genomics. The greatest problem with the test is not the specificity prong, which rightly requires an invention to have a specific, rather than general, application; it is the vague and poorly applied substantial utility prong, which lacks relevance in contemporary scientific research.

In the wake of *Brenner*, courts have interpreted “substantial” as requiring “one skilled in the art” to be able to use the discovery, in its currently available form, in a manner providing an “immediate benefit to the public.”<sup>124</sup> If the *Fisher* court’s interpretation of this rule is correct, in that an invention has utility only if the studied object is understandable using the claimed invention, then “only the final step of a lengthy incremental research inquiry gets protection.”<sup>125</sup> This standard is unrealistic for research-related inventions, which by their very nature encompass

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121. *Id.* at 1380 (Rader, J., dissenting).

122. *See id.* at 1379–82 (Rader, J., dissenting).

123. The practical problems associated with the *Brenner* rule were predicted by Judge Rich, dissenting in *Kirk*:

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

376 F.2d 936, 960 (C.C.P.A. 1967) (Rich, J., dissenting).

124. *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980).

125. *Fisher*, 421 F.3d at 1380 (Rader, J. dissenting).

research into the unknown. For research-related inventions, the public benefits from the research as it is conducted because each incremental step brings a scientist closer to an ultimately large discovery. This does not mean that the incremental step is insignificant or lacking a benefit to society. To the contrary, “[e]ach step, even if small in isolation, is nonetheless a benefit to society sufficient to give a viable research tool ‘utility’ under § 101 . . . [because even] experiments that fail still serve to eliminate some possibilities and provide information to the research process.”<sup>126</sup> Under the current reasoning, the requirement of an immediate public benefit would have precluded many important past inventions simply because the public benefit was not in currently available form.<sup>127</sup>

The current substantial utility prong requires an inquiry into whether or not a product corresponding to the claimed invention itself has substantial utility.<sup>128</sup> In creating this requirement, the *Brenner* Court reasoned that without this virtual fence in place, the monopoly created by a patent would have no identifiable boundaries, that it could be “vast” and unknowable.<sup>129</sup> This argument lacks validity because process claims are not denied based on whether or not what they produce may ultimately cause a monopoly that is greater than expected, since “a hundred more uses may be found after a

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

127. This was noted by Justice Rich, who dissented to the majority’s denial of a patent for lack of utility in *In re Joly*:

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

376 F.2d 906, 917 (C.C.P.A. 1967).

128. U.S. PAT. & TRADEMARK OFF., *supra* note 65, at 50–53 (1999), available at [www.uspto.gov/web/menu/utility.pdf](http://www.uspto.gov/web/menu/utility.pdf).

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

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

*Id.* at 534 (footnote omitted).

patent is granted and greatly enhance its value.”<sup>130</sup> The *Brenner* court also justified this requirement by describing a useful product as the “basic *quid pro quo*”<sup>131</sup> for a patent, a reward for the “successful conclusion” of the search for an invention.<sup>132</sup> This argument; however, “beg[s] the very question whether the process is ‘useful’ simply because it facilitates further research into possible product uses.”<sup>133</sup>

The current utility prong qualifies what constitutes substantial utility as only that which has a “real world” context, which does not include identifying and studying the properties of a product corresponding to an invention.<sup>134</sup> The reasoning behind this requirement, created by *Brenner* and reinforced by *Kirk*, is that “a method of producing a compound with no known use has no more benefit to society than the useless compound itself.”<sup>135</sup> This is not always true in contemporary scientific research. A research method that involves identifying and studying properties of products corresponding to an invention, such as studying the underlying gene and encoded protein associated with an EST, has a “real world” context: increasing the overall understanding of that product (i.e., increasing the overall understanding of the maize genome via research into the underlying gene and its unknown gene products). Although this may not have been foreseeable at the time of *Brenner*, in contemporary science a “real world” context is present even with a conceivably small increase in understanding because of the fast-paced and interdisciplinary nature of research.

Another problem with the substantial use prong of the utility test is that it is vague and open to subjective bias. This was elucidated in *Ex parte Fisher*, where the court noted that,

[s]omewhere between having no knowledge (the presence circumstances) and having complete knowledge of the gene and its role in the plant’s development and/or phenotype lies the line between “utility” and “substantial utility.” We need not draw the line

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

131. *Id.* at 534.

132. *Id.* at 536.

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

134. U.S. PAT. & TRADEMARK OFF., *supra* note 65, at 50–53. According to the USPTO Utility Guidelines, “[u]tilities [that] require or constitute carrying out further research to identify or reasonably confirm a ‘real world’ context of use” are not substantial utilities. *Id.* at 52–53.

135. *In re Fisher*, 421 F.3d 1365, 1380 (Fed. Cir. 2005) (Rader, J., dissenting).

or further define it in this case because the facts in this case represent the lowest end of the spectrum, i.e., an insubstantial use.<sup>136</sup>

There is no bright-line test for courts to use in interpreting exactly where on the spectrum a given invention may lie. A test needs to be created because there is the temptation for courts to not elucidate their reasoning in determining where on the spectrum a given invention may reside. For example, in *Ex parte Fisher* the court concluded that Fisher's invention was on the lowest end of the spectrum, but failed to clarify why this was so. A clarified substantiality test would preclude the temptation for courts to make conclusions without illuminating their reasoning while also promoting consistency in judicial decision-making.

#### B. AN APPROPRIATE UTILITY TEST COINCIDES WITH CONSTITUTIONAL REQUIREMENTS, CONGRESSIONAL INTENT, AND GOALS OF THE PATENT SYSTEM

The Constitution grants Congress the power to "promote the Progress of Science and useful Arts by securing . . . exclusive Right[s] to . . . Discoveries."<sup>137</sup> Any law, judicial decision, or USPTO guideline must satisfy this constitutional requirement. With the advent of modern science, just what constitutes progress has been difficult to determine and controversial. As the dissenting Judge noted in *Brenner*,

[t]o encourage one chemist or research facility to invent and disseminate new processes and products may be vital to progress, although the product or process be without "utility" . . . because that discovery permits someone else to take a further but perhaps less difficult step leading to a commercially useful item.<sup>138</sup>

Determining what constitutes "Progress of Science" was difficult when the founding fathers created the Intellectual Property Clause<sup>139</sup> and remains open to interpretation today,<sup>140</sup> so that it is of little help in formulating a valid utility

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136. *Ex parte Fisher*, 72 U.S.P.Q. 2d 1020, 1026 (Bd. Pat. App. Int. 2004).

137. U.S. CONST. art. I, § 8, cl. 8.

138. *Brenner v. Manson*, 383 U.S. 519, 539 (1966) (Harlan, J., concurring in part and dissenting in part).

139. U.S. CONST. art. I, § 8, cl. 8.

140. Thomas Jefferson wrote: "Considering the exclusive right to invention as given not of natural right, but for the benefit of society, I know well the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not." Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in 13 THE WRITINGS OF THOMAS JEFFERSON 333-35 (Andrew A. Lipscomb & Albert Ellery Bergh eds., 1905), available at



test.

Statutory language and congressional intent provide more guidance in creating an appropriate utility test for patentability. The utility standard for patentability originated with the Patent Act of 1790, which used the term “useful.”<sup>141</sup> The *Brenner* court noted the problem with the vagueness of this term:

Even if we knew precisely what Congress meant in 1790 when it devised the “new and useful” phraseology and in subsequent re-enactments of the test, we should have difficulty in applying it in the context of contemporary chemistry where research is as comprehensive as man’s grasp and where little or nothing is wholly beyond the pale of “utility”—if that word is given its broadest reach.<sup>142</sup>

The congressional intent behind the current statute<sup>143</sup> is clearer because it was based in part on the Supreme Court decision in *Diamond v. Chakrabarty*,<sup>144</sup> which codified the Court decision so that patentable subject matter includes “anything under the sun that is made by man.”<sup>145</sup> Clearly this tends towards a view of the patent system favoring the granting of patents to inventors for a broad range of inventions.

A proper utility test must adhere to constitutional and statutory requirements, but it should also promote the general goals of the patent system. These goals are to reward an inventor for his contribution to society and to increase the public good with inventions. U.S. Supreme Court Justice Stephen Breyer correctly concluded that patent law should

encourage useful discovery and disclosure without unduly restricting the dissemination of those discoveries, hindering the circulation of important scientific ideas, or scattering ownership to the point where it inhibits the use of the underlying genetic advance.<sup>146</sup>

The difficulty arises in balancing the interests of the public against those of the inventor. The theory behind patents for inventions is that inventions promote the public

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[http://press-pubs.uchicago.edu/founders/documents/a1\\_8\\_8s12.html](http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html).

141. Patent Act of 1790, ch. 7, 1 Stat. 109–12 (Apr. 10, 1790).

142. *Brenner*, 383 U.S. at 530.

143. 35 U.S.C. § 101 (2000).

144. 447 U.S. 303 (1980).

145. S. Rep. No. 82-1979 (1952); U.S. Code Cong. & Admin. News at 2394, 2399.

146. Stephen G. Breyer, *Genetic Advances and Legal Institutions*, 28 J.L. MED. & ETHICS 23, 27 (2000).

good by enhancing the quality of life (e.g., with medicines to combat disease, machines to perform labor) and that inventors, because of their contribution to the public good, deserve to be rewarded for their contribution to society with a patent that confers a monopoly on that invention for a limited time.<sup>147</sup> The patent encourages innovation (and therefore increases the public good) by rewarding the inventor for his toil. When the monopoly conferred to the inventor is too broad, it limits the public good (e.g., by increasing the cost to the public of using the invention or preventing other inventors from using the invention as a means to create newer, better inventions). The fear is that “[s]uch a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public.”<sup>148</sup> Correspondingly, if a patent is too narrow or not allowed at all, a researcher may be discouraged from conducting research.

## V. A REVISED UTILITY TEST

### A. THE PROPOSED REVISION TO THE UTILITY TEST: AN ALTERED “SUBSTANTIAL” USE PRONG FOR RESEARCH TOOLS

#### 1. Is it a Research Tool?

The current utility test for patentability should be revised in its application to research tools. In a revised utility test for research tools, the first consideration should be whether a given invention qualifies as a research tool. As mentioned previously, there are presently no guidelines to determine whether or not a given invention qualifies as a research tool. This is because such a distinction is irrelevant with the current utility test. The *Fisher* dissent loosely defines research tools as inventions that “enhance research,” but this is too broad and would provide little guidance.<sup>149</sup> A better definition would use factors similar to those outlined by the

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147. Patents “encourage dissemination of information concerning discoveries and inventions.” *Brenner*, 383 U.S. at 533 (citing *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (“As a reward for inventions and to encourage their disclosure, the United States offers a seventeen-year monopoly to an inventor who refrains from keeping his invention a trade secret.”)).

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

149. *Fisher*, 421 F.3d at 1379 (Rader, J., dissenting).

NIH in considering whether a resource fits the definition of a research tool:

1. The primary usefulness of the resource has as a tool for discovery rather than an FDA-approved product or integral component of such a product;
2. Whether the resource is a broad, enabling invention that will be useful to many scientists . . . rather than a project or product-specific resource; and
3. Whether the resource is readily useable or distributable as a tool rather than the situation where private sector involvement is necessary or the most expedient means for developing or distributing the resource.<sup>150</sup>

These factors provide a good starting point for determining whether an invention is a research tool, but they need not be exhaustive. It is, however, important that any definition adopted for research tools be able to readily distinguish between inventions, and aid in consistent judicial determinations.

Determining whether or not an invention is a research tool does not conclude the revised utility test. The property of being a research tool is not a utility in and of itself. The USPTO warns that “[a]n assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact ‘useful’ in a patent sense.”<sup>151</sup> The invention must still have specific and substantial use, but what constitutes substantial use should be different for an invention that is a research tool.

## 2. Is the Use Substantial?

The substantiality prong should be altered for inquiries regarding research tools. A research tool should satisfy the substantiality prong even if it does not provide a traditionally recognized “immediate benefit to the public”<sup>152</sup> in its currently available form. This relaxed standard would recognize that “[s]cience always advances in small incremental steps”<sup>153</sup> and that the public may benefit from each incremental step. Further, it should be irrelevant for research tools whether the product corresponding to the research tool itself has

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150. NIH Principles and Guidelines, 64 Fed. Reg. 72,090, 72,094 (Dec. 23, 1999).

151. MPEP, *supra* note 71, § 2107.01.

152. *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980).

153. *Fisher*, 421 F.3d at 1380.

substantial utility. Only the research tool itself should have required utility. This recognizes that while the research process typically involves many unfruitful products before a fruitful product, this nonetheless does not negate the value of the process itself because “experiments that fail still serve to eliminate some possibilities and provide information to the research process.”<sup>154</sup> A “real world” context of use that excludes “[b]asic research such as studying the properties of the claimed product itself or the mechanism in which the material is involved”<sup>155</sup> should not be expressly excluded from potential patentability. Instead, basic research using research tools that are themselves the subject of the research should be patentable if they have a “real world” use in a research or laboratory setting.

### 3. Is the Use Specific?

The revised utility test for research tools should remain the same with regards to the test for specificity and would require a specific, as opposed to general, assertion of utility. This specific utility can be hypothetical, but it cannot be so hypothetical so as to be general. A specific use does not necessarily negate a hypothetical use, especially with regards to research tools where a use may be known to exist (and therefore not general in nature) but may not actually have been carried out fully (and thus still technically hypothetical).

## B. APPLICATION OF REVISED UTILITY TEST TO ESTS

Under the revised utility test, Fisher’s claimed ESTs qualify as research tools. Applying the NIH factors, Fisher’s ESTs are “tool[s] for discovery” that are useful in gaining understanding about the maize genome and the proteins encoded by the genes within that genome. The specific ESTs claimed are product-specific resources because they apply to specific underlying genes within the maize genome. ESTs, as a group, constitute a “broad, enabling invention that will be useful to many scientists” because ESTs can be used in many research contexts to better understand the genome of any species of interest. Further, ESTs are “readily usable” as a tool because they can be created and used in any research setting or, alternatively, distributed to (or created by) any

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154. *Id.* at 1381.

155. U.S. PAT. & TRADEMARK OFF., *supra* note 65, at 6.

laboratory that wishes to make use of them.

Because ESTs would qualify as research tools, they would be subject to the revised substantiality prong for utility. This means that the products associated with ESTs, such as the proteins encoded by the underlying gene or the underlying gene itself, need not independently exhibit substantial use. Only the ESTs themselves must exhibit “real world” use. As a research tool usable in a laboratory setting for basic research studying the genes and encoded proteins of the maize genome, ESTs satisfy this standard.

The claimed ESTs satisfy the relaxed substantial use prong for utility, but they must still exhibit specificity of use in order to have patentable utility. Under the revised substantiality prong, “merely hypothetical”<sup>156</sup> assertions of utility that represent what researchers may be able to do, rather than what they have already proven, are sufficient as long as they have a research context and correspond to a specific use. Fisher’s ESTs have claimed uses that are applicable to all ESTs as a group and are therefore general in nature, rather than specific. The claimed uses, including as a molecular marker or source for primers, apply to all ESTs associated with the maize genome. Because of the extent of generality of the claimed uses, they could actually apply to any EST on any genome, not just the maize genome. The generality of the claimed utilities results in Fisher’s ESTs failing the specificity prong of the revised utility test. For this reason, the claimed ESTs fail to exhibit the requisite utility for patentability.

Fisher’s claimed ESTs fail the revised utility test, but not all ESTs would necessarily fail the test. ESTs could potentially pass a revised utility test if the claimed utility was specific to particular cDNA sequences being claimed, rather than applicable to a general class of cDNAs.<sup>157</sup> An example of a specific use would be using an EST to control the protein expression of a specific protein *A*, rather than a general assertion of controlling protein expression of an unknown protein. Another example of a sufficiently specific use would be using an EST corresponding to an underlying gene *X* to locate the *Y* gene in either plant *A* or organism *B*, as opposed to a general assertion of locating genetic molecules of other

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156. *Fisher*, 421 F.3d at 1373.

157. U.S. PAT. & TRADEMARK OFF., *supra* note 65, at 51.

plants and organisms.

### C. APPLICATION OF REVISED UTILITY TEST TO OTHER POTENTIAL RESEARCH TOOLS

#### 1. Partially Characterized Proteins

Under the USPTO's current Guidelines, which are based on the *Brenner* utility test, partially characterized proteins are generally unpatentable.<sup>158</sup> The revised Guidelines give an example of a protein with a disclosed amino acid sequence and a non-explicitly disclosed utility demonstrating that the protein can "specifically bind with another protein X such that X can be isolated and quantified."<sup>159</sup> The asserted utility qualifies as specific because it indicates that the claimed protein will specifically bind to protein X.<sup>160</sup> However, under the current utility test, the asserted utility lacks substantial utility because there is no disclosed "real world" use since further experimentation is needed to elucidate a use for the claimed protein.<sup>161</sup>

Under the revised utility test, such a partially characterized protein would qualify as a research tool because it is a "tool for discovery" that could be used, for example, to learn the role of the claimed protein and protein X in the context of a cell and to investigate their potential downstream therapeutic uses. Knowledge of such protein-protein interactions would constitute a "broad, enabling invention . . . useful to many scientists" and would be readily usable and distributable.<sup>162</sup> As a research tool, the claimed protein would be subject to the relaxed substantial utility prong, which would not require an immediate benefit to the public in currently available form.<sup>163</sup> Using the partially characterized protein in a research setting to better understand biological processes would constitute a sufficient real world use to satisfy utility. Therefore, unlike the current *Brenner* standard, the proposed revised utility test would render partially characterized proteins patentable as research tools.

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

159. *Id.* at 34.

160. *Id.* at 35.

161. *Id.*

162. NIH Principles and Guidelines, 64 Fed. Reg. at 72,094.

163. *Nelson*, 626 F.2d at 856.

## 2. Receptor Molecules

Similarly, under the current utility test, receptor molecules are typically unpatentable for lack of utility. One example illustrating this, given by the USPTO in its revised Guidelines, is that of a claimed protein receptor *A*, which binds to protein *X* of unknown identity, but has not been characterized with regards to its biological function or role in any disease or condition.<sup>164</sup> The asserted utility is for “identifying materials that bind the receptor and the potential use of such materials as therapeutics” and for producing a monoclonal antibody that binds receptor *A*.<sup>165</sup>

The hypothetical receptor *A* has sufficient specificity under the *Brenner* utility test because the claimed uses, identifying materials that bind only receptor *A* and making antibodies that bind only receptor *A*, are not applicable to a general class of receptor molecules.<sup>166</sup>

In determining whether the substantial utility prong is satisfied, the current utility test requires not only that receptor *A* have substantial utility, but additionally that the materials that bind receptor *A* and the antibody that binds receptor *A* have substantial utility apart from that of receptor *A* itself.<sup>167</sup> The method of identifying materials that bind receptor *A* has an asserted therapeutic use to “effect control over receptor *A*” that fails for lack of substantial utility since “a method of treating an unspecified, undisclosed disease or condition, does not define a ‘real world’ context of use.”<sup>168</sup> The disclosed method of making an antibody for receptor *A* also fails for lack of substantial utility for the same reason.<sup>169</sup> Since both the material that binds receptor *A* and the antibody for receptor *A* lack substantial utility, receptor *A* fails the *Brenner* utility test.

Under the proposed revised utility test, receptor *A* would likely qualify as a research tool because it is a “tool for discovery” to be used in researching diseases or conditions related to the activity of the receptor, because it is a “broad, enabling invention” useful to any scientist researching the role

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164. U.S. PAT. & TRADEMARK OFF., *supra* note 65, at 63.

165. *Id.*

166. *Id.* at 65.

167. *Id.*; see *Brenner*, 383 U.S. at 535-36.

168. U.S. PAT. & TRADEMARK OFF., *supra* note 65, at 65.

169. *Id.*

of receptors generally or the specific role of receptor *A* in various cellular processes, and because it is “readily useable or distributable as a tool” by any researcher who could isolate the protein in her laboratory from cellular extracts. As a research tool, the receptor would be subject to the relaxed substantial utility prong.

Under the revised utility test, receptor *A* would be considered useful because it aids in the incremental discovery process of understanding a disease mechanism, which would constitute a substantial utility in that it serves to “eliminate some possibilities and provide information to the research process.”<sup>170</sup> Importantly, under the revised utility test it would be unnecessary to separately determine the utility of either the material that binds receptor *A* or the antibody for receptor *A* since “studying the properties of the claimed product itself or the mechanism in which the material is involved”<sup>171</sup> would not be expressly excluded as a substantial utility. Therefore, under a revised utility test, a receptor molecule such as receptor *A* would not be denied patentability as it would under the *Brenner* standard for lack of substantial utility.

### 3. Large Chemical Groups

Large chemical groups are generally unpatentable for lack of substantial use under the current utility test. An example given by the USPTO in its revised Guidelines is that of a claimed group of chemical compounds sharing a chemical formula.<sup>172</sup> The hypothetical chemical compounds have no asserted physical, chemical, or biological properties, and an asserted use as biomedical research tools after the physical, chemical, and biological properties are determined.<sup>173</sup> Under the current utility test, there is no specific utility because all chemical compounds can potentially be used for biomedical research, so that the utility is general in nature.<sup>174</sup> The hypothetical chemical group also lacks substantial utility because biomedical research to determine the properties of the compounds does not constitute a “real world” context of use, since further research would be required to find a downstream

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170. *Fisher*, 421 F.3d at 1381 (Rader, J., dissenting).

171. U.S. PAT. & TRADEMARK OFF., *supra* note 65, at 6.

172. *Id.* at 71–74.

173. *Id.*

174. *Id.*



application for the compounds once their properties were discovered.<sup>175</sup>

Under the proposed revised utility standard, the chemical group would constitute a research tool because the primary use would be as a “tool for discovery” in biomedical research, which would be broad and enabling since it is a large chemical group with many potential avenues for biomedical research, and readily useable by a scientific laboratory in any way they saw fit for their given avenues of research using the claimed compounds.<sup>176</sup> As a research tool, the chemical group would be subject to the revised substantial utility prong. It would satisfy the substantial utility requirement since a “real world” context would include utility as a tool in biomedical research.

However, the hypothetical chemical group would still fail to be patentable under the revised test for lack of specificity. Like Fisher’s claimed ESTs, the chemical group in this example asserts a claimed utility (use in “biomedical research”) that is broadly applicable to any chemical compound. In order to have specific utility, the claimed biomedical research use would need to pertain to a particular chemical, physical, or biological property of the compound group in order to distinguish it from any other chemical group. Thus, under the revised utility test, large chemical groups with no claimed biological, physical, or chemical properties corresponding to their utility would fail the utility test as they would under the current *Brenner* standard. Yet, in contrast to their failed patentability under the *Brenner* standard, large chemical groups with utility corresponding to specific biological, physical, or chemical properties unique to the claimed chemical group would be potentially patentable.

#### D. THE REVISED UTILITY TEST SATISFIES THE GOALS OF THE PATENT SYSTEM

##### 1. Potential Problems with the Revised Test

The proposed revised utility test would confer more patents for research tools than are granted under the current test. This raises concerns about lack of access causing a biomedical anticommmons, where upstream “clogging” of

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175. *Brenner*, 383 U.S. at 535-36.

176. See NIH Principles and Guidelines, 64 Fed. Reg. at 72,094.

patents for research tools could lead to a decrease in downstream innovation.<sup>177</sup> When access to important research tools is impeded, there is a fear that research will be delayed, stopped completely, or conducted without proper authorization, thereby threatening to stifle valuable research or beget future litigation over patent infringement.<sup>178</sup> Another concern is that a policy promoting more research tool patents would unfavorably alter the balance between rewarding the inventor and enhancing the public good by giving too great a reward to inventors who have put little effort into the discovery process<sup>179</sup> and “tip[ping] the economic balance against drug development.”<sup>180</sup>

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177. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, in FOUND. OF INTELL. PROP. 177, 178-79 (Robert P. Merges & Jane C. Ginsburg eds., 2004). If too many patents are granted for biomedical research tools, the fear is that a biomedical anticommons will come into existence. Rebecca Eisenberg and Michael Heller assert that a “tragedy of the anticommons” comes into being when multiple owners of patents each have the right to exclude others from a scarce resource, leaving no one with effective access to the resource. An anticommons is essentially a problem of access to research tools, but it is more complex than the problem of under-use inherent in the patent system in that each upstream patent “allows its owner to set up another tollbooth on the road to product development, adding to cost and slowing the pace of downstream biomedical innovation.” *Id.*

178. See Brief for Eli Lilly and Co. as Amicus Curiae Supporting Appellee at 4, *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005) (No. 04-1465) (“[S]uch claims [for EST patents], if granted, could be used to prevent, threaten to prevent, or extract value from everything that might later be discovered about genes and proteins associated with genetic sequences.”); Brief for Genentech as Amicus Curiae Supporting Appellee at 12, *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005) (No. 04-1465) (“Patents issued on inventions that are yet to be made are harmful to the biotechnology industry and the public, because they effectively extinguish commercial interest in developing new drugs or diagnostic products based on genomic information.”).

179. For example, patents for relatively easily-discovered research tools such as ESTs might unjustly reward an inventor who expends little time or energy in discovering the EST by conferring a monopoly that extends to downstream product development that, in contrast, takes a great expenditure of time, money, and effort.

180. JAMES D. WATSON, *DNA: THE SECRET OF LIFE* (2003) (“The large royalties demanded by gene-finding monopolies tip the economic balance against drug development; cloning a drug target is at most 1 percent of the way to an approved drug.”).

## 2. Solutions to Potential Problems with the Revised Test: Narrow Patent Scope and User-Friendly Licensing Agreements

Narrow patents for research tools and user-friendly licensing agreements could limit potential problems associated with a proliferation of upstream research tool patents causing “clogging” that limits downstream innovation. Patents for research tools should be narrow in scope so that they are commensurate with what the invention actually is: a research tool. The patent should not grant rights to downstream inventions, such as therapeutic products that treat a disease, which will potentially be discovered later.<sup>181</sup> A strictly enforced specificity prong could provide a means of enforcing narrow patents for research tools so that inventors would not have broad claims outweighing the amount of work they put into the discovery. For example, inventors who claim ESTs with only a general use would not be entitled to a patent, while inventors who expend greater effort to identify an underlying gene or corresponding protein to distinguish it from other ESTs would satisfy the specificity requirement and deserve a patent (although it would still be narrow and apply only to the EST in its capacity as a research tool).

Problems of access to patented research tools could also be resolved with favorable licensing agreements or research exemptions.<sup>182</sup> The biomedical research community is a collaborative network including public research institutions, small private biotechnology companies and large pharmaceutical companies, where a strong business reputation is vital for the success of its members. Favorable licensing agreements promote strong long-term business

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181. Using ESTs as an example, a potential patent would not entitle the patent holder to claim the entire full-length cDNA or the whole underlying gene associated with the EST, but instead only the EST itself in its applications as a research tool.

182. Several proposals to enable access to patented research tools include exclusive licensing arrangements, nonexclusive licensing arrangements, and research exemptions. It is beyond the scope of this Note to discuss these options in depth.

partnerships and have proved effective in the past for research tools, such as PCR. Upstream patent holders in the biomedical research community would have a strong incentive to encourage further development of their products because, with narrow research tool patents, the ultimate pay-out would come from separate patents for the therapeutically useful pharmaceutical products that are created downstream. Inventors unable to fully develop the downstream products associated with their patented research tool would be likely to license out use of the research tool (even *without* a broad patent that confers rights to the downstream inventions) because they gain a greater economic reward from fees associated with licensing than from blocking access to a tool they have no intent to develop. An inventor able and willing to develop downstream products could block access to the tool without detriment to the public because the downstream innovation would still be taking place.

The tension between rewarding an inventor for her contribution to society and contributing to the public good with a beneficial invention is a dynamic tension that will never be completely resolved, but licensing agreements and narrow patent scope may provide a viable means of approximating a balance between these two competing interests.

### CONCLUSION

Current controversy exists over the extent to which upstream research tools, including ESTs, should be patentable. The fear is that overbroad biomedical research patents will cause upstream “clogging” that deters downstream invention of vital therapeutic products. In *In re Fisher*, the court addressed this issue by applying the standard of usefulness required for patentable inventions under 35 U.S.C. § 101 to ESTs, finding that they were unpatentable because they lacked the requisite specific and substantial utility and were “only tools to be used along the way in the search for a practical utility.”<sup>183</sup>

The *Fisher* analysis reveals that the current test for utility fails to address the importance of research tools in modern biomedical research and poorly addresses the goals of the patent system, thereby necessitating its revision. A new

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183. *Fisher*, 421 F.3d at 1376.

test should be adopted, which alters the substantiality prong of the utility test in its application to research tools by allowing a research use in a laboratory setting to constitute a “real world” utility that is substantial. Such an altered utility test, when combined with a narrow patent scope for research tools and reasonable licensing schemes, would recognize the significance of research tools in modern biomedical research by adequately rewarding inventors while promoting the “Progress of Science.”<sup>184</sup>

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184. U.S. CONST. art. I, § 8, cl. 8.