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## COMMENTS

# DNA PATENTABILITY: SHUTTING THE DOOR TO THE UTILITY REQUIREMENT

DONALD L. ZUHN, JR.\*

*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.*<sup>1</sup>

Thomas Jefferson, 1813

### INTRODUCTION

“Achieving the ultimate goal of a patent,” wrote Judge Giles S. Rich,<sup>2</sup> “involves, to use an analogy, having the separate keys to open in succession the three doors of [35 U.S.C.<sup>3</sup>] sections 101, 102, and 103.”<sup>4</sup> Thus, to secure patent protection for an invention, an inventor must first establish, under section 101, that the invention

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1. 13 WRITINGS OF THOMAS JEFFERSON 335 (Andrew A. Lipscomb & Albert Ellery Bergh eds., 1905).

2. Giles Sutherland Rich (1904-1999) was the oldest active federal judge in U.S. history. *Patent and Trademark Office Mourns Death of Judge Giles S. Rich* (last modified July 1, 1999) <http://www.uspto.gov/web/offices/com/speeches/99-14.htm>. Upon his death in 1999, Acting Commissioner of Patents and Trademarks, Q. Todd Dickinson, called Judge Rich “the single most important figure in twentieth century intellectual property law,” and noted that “[h]is life’s work will illuminate the American patent system for decades to come.” *Id.*

3. Title 35 concerns the establishment of the United States Patent and Trademark Office, the requirements for patentability, the grant of patents, and the protection of patent rights. 35 U.S.C. §§ 1-318 (2000).

4. *In re Bergy*, 596 F.2d 952, 960 (C.C.P.A. 1979), *vacated sub nom. Diamond v. Chakrabarty*, 444 U.S. 1028 (1980), *aff’d sub nom. Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

falls within one of the statutory categories<sup>5</sup> and that the invention is “useful.”<sup>6</sup> After the inventor satisfies the requirements of section 101, “he is allowed to pass through to the second door, which is [section] 102.”<sup>7</sup> Here, the inventor must establish that the invention is novel.<sup>8</sup> The third “door” is section 103, where the inventor must establish that the invention is non-obvious.<sup>9</sup> Only after the inventor has satisfied the requirements of all three sections – securing the “key” to each of the “doors of sections 101, 102, and 103” – will the inventor be permitted to secure a patent for an invention.<sup>10</sup>

In describing the significance of the first “door,” Justice Fortas wrote that “[t]he basic *quid pro quo* contemplated by the Constitution and the Congress<sup>11</sup> for granting a patent monopoly [to an inventor] is the benefit derived by the public from an invention with substantial utility.”<sup>12</sup> In the years since Justice Fortas wrote of this “basic *quid pro quo*,” the “door” to section 101 has been, in effect, propped open by the United States Patent and Trademark Office (“USPTO”) and the federal courts, and inventors have been allowed to pass through this “door” with relative ease.<sup>13</sup> The re-

5. 35 U.S.C. § 101 (2000). For an invention to be patentable, it must be directed to a “process, machine, manufacture, or composition of matter, or . . . improvement thereof.” *Id.*

6. *Id.* For an invention to be patentable, it must be “useful.” *Id.*

7. *Bergy*, 596 F.2d at 960.

8. 35 U.S.C. § 102(a) (2000). For an invention to be patentable, it must be novel; for example, the invention must not have been “known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant.” *Id.*

9. 35 U.S.C. § 103 (2000). For an invention to be patentable, it must be non-obvious, that is, “the differences between the subject matter sought to be patented and the prior art [must not be] such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *Id.*

10. *Bergy*, 596 F.2d at 962 (stating that “[i]f the inventor holds the three different keys to the three doors, his invention . . . qualifies for a patent, otherwise not”).

11. The grant of power to Congress to establish the patent system is derived from Article I, Section 8, Clauses 8 and 18 of the U.S. Constitution:

The Congress shall have the Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; . . . And To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers.

U.S. CONST. art. I, § 8, cl. 8.

12. *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966) (holding that an invention possesses “substantial utility” when it has specific benefit in its currently available form).

13. *See, e.g., E. I. du Pont de Nemours & Co. v. Berkley & Co.*, 620 F.2d 1247, 1260 (1980) (holding that an inventor need only establish “[a] small degree of utility.”). *See also* Rebecca S. Eisenberg, *Genes, Patents, and Product Development*, 257 *SCIENCE* 903, 905 (1992) (stating that the USPTO rarely in-

quirement that an inventor demonstrate a “substantial utility” in exchange for the grant of a patent monopoly has become a “low hurdle along the path to a patent.”<sup>14</sup>

This Comment discusses the evolution of the utility requirement and the application of this requirement of patentability to DNA<sup>15</sup> sequences having no known function. Part I of this Comment provides an overview of the recent debate over DNA patentability – specifically the controversy concerning the patentability of expressed sequence tags. Part II analyzes the evolving meaning of the utility requirement as interpreted by the federal courts. Part III analyzes the types of public harm that can result from a weakened utility requirement. Part IV proposes that the USPTO should strictly adhere to the heightened utility requirement set forth by the Supreme Court in *Brenner v. Manson*.<sup>16</sup>

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vokes the utility requirement); Thomas D. Kiley, *Patents on Random Complementary DNA Fragments?* 257 SCIENCE 915, 915 (1992) (arguing that the utility requirement “approaches being a dead letter in current practice”).

14. Reid G. Adler, *Genome Research: Fulfilling the Public’s Expectations for Knowledge and Commercialization*, 257 SCIENCE 908, 911 (1992).

15. The structure, function, and behavior of a cell is determined by its genetic information, and a cell’s genetic information is carried within its deoxyribonucleic acid (“DNA”). BENJAMIN LEWIN, GENES VII 4 (2000). A DNA molecule is a polynucleotide consisting of covalently linked deoxyribonucleotide units, of which there are four types, each type of deoxyribonucleotide possessing a different base. *Id.* at 6. The four types of bases that differentiate each of the deoxyribonucleotides are adenine (A), guanine (G), cytosine (C), and thymine (T). *Id.* In higher organisms, DNA molecules are organized into very long molecules, called chromosomes, which reside within a membrane-bounded organelle known as the nucleus. *Id.* at 3, 955. Chromosomes consist of two complementary DNA molecules; the DNA strands being held together by weak bonds between corresponding bases of the deoxyribonucleotide units. *Id.* at 8, 12. The chromosome can be divided into regions of DNA, or genes, that control discrete hereditary characteristics, often corresponding to a single protein. LEWIN, *supra*, at 63, 959. For example, human chromosomal DNA contains an estimated 26,000 to 38,000 separate genes, the total set of genes comprising the human genome. J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCIENCE 1304 (2001). To translate the genetic information encoded within a cell’s DNA into a polypeptide molecule (or protein), a complementary copy of a gene, known as a messenger ribonucleic acid (mRNA), is first synthesized within the nucleus in a process known as transcription. LEWIN, *supra*, at 119-23, 971. The mRNA is then transported to the cytoplasm – that portion of the cell bounded by the cellular membrane and excluding the nucleus – where the mRNA molecule is translated into a polypeptide molecule in a process known as translation. *Id.* at 125-25, 971. A polypeptide consists of a linear arrangement of covalently linked amino acids, with twenty amino acids being found in naturally occurring polypeptides. GEOFFREY ZUBAY, BIOCHEMISTRY 4-7 (1983). The linear arrangement of amino acids forming a polypeptide is encoded by a series of triplet bases, or codons, in the mRNA molecule (for example, the codon T-C-A encodes the amino acid serine). LEWIN, *supra*, at 25.

16. 383 U.S. at 534-35.

## I. DNA SEQUENCE PATENTABILITY

### A. DNA Sequences Constitute Patentable Subject Matter

For more than ten years, a debate has raged over the patentability of DNA sequences.<sup>17</sup> Although a handful of critics continue to attack the patentability of all DNA sequences (and more specifically, the patentability of human DNA sequences),<sup>18</sup> the federal courts and USPTO<sup>19</sup> now generally recognize that DNA sequences constitute patentable subject matter.<sup>20</sup> However, the efforts of some inventors to secure patent rights to DNA sequences having no known function<sup>21</sup> has intensified the controversy over

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17. Martin Enserink, *Biomedical Patents: Patent Office May Raise the Bar on Gene Claims*, 287 SCIENCE 1196, 1196 (2000).

18. See, e.g., Adler, *supra* note 14, at 909 (discussing the argument that the patenting of DNA sequences is unethical because such patenting limits public access to "our universal heritage"); Bernadine Healy, *On Gene Patenting*, 327 N. ENGL. J. MED. 664, 666 (1992) (discussing the argument that DNA should not be patentable as a matter of social policy); George Poste, *The Case for Genomic Patenting*, 378 NATURE 534, 534 (1995) (discussing the argument that DNA sequences should not be patentable due to the "sanctity" of human DNA sequences).

19. See John J. Doll, *The Patenting of DNA*, 280 SCIENCE 689, 689 (1998) (noting that while naturally occurring products are not patentable, the USPTO recognizes that naturally occurring products – such as DNA sequences – isolated or purified from their natural environment – i.e., cells – are patentable). See also David Dickson, *British MPs 'Likely to Oppose Gene Patents'*, 373 NATURE 550, 550 (1995) (discussing the argument that cDNA molecules are not naturally occurring products since they are generated *in vitro* chemical reactions from spliced mRNA molecules, which in turn are generated from unspliced mRNA molecules following transcription).

20. See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (determining that Congress intended statutory subject matter to "include anything under the sun that is made by man"); *In re Bergstrom*, 427 F.2d 1394, 1401 (C.C.P.A. 1970) (holding that prostaglandins purified from a crude cellular extract were not "naturally occurring" since the prostaglandins did not exist in nature in pure form). In addition, DNA patenting has been endorsed by a number of academic, industrial, and governmental groups, including the American Society of Human Genetics ("ASHG"), the Biotechnology Industry Organization ("BIO"), the Danish Council of Ethics, the English Patent Office, the Commission of the European Communities ("EC"), the House of Commons Science and Technology Committee, the Human Genome Organization ("HUGO"), the Industrial Biotechnology Association ("IBA"), the French National Institute of Health and Medical Research ("INSERM"), the United Kingdom Medical Research Council ("MRC"), the National Institutes of Health ("NIH"), the Nuffield Council on Bioethics, the Pharmaceutical Manufacturers Association ("PMA"), and the United States Patent and Trademark Office ("USPTO"). Eisenberg, *supra* note 13, at 907; Adler, *supra* note 14, at 912-13; Poste, *supra* note 18, at 534; *The Human Genome Project and Patents*, 254 SCIENCE 1710, 1710 (1991); David Dixon, *Mixed Reaction Greets New Gene Patent Proposals from Brussels*, 361 NATURE 285, 285 (1993).

21. Where a DNA sequence (for example, a cDNA sequence) has been derived from an mRNA sequence, the function of the DNA sequence is "known"

DNA patentability.<sup>22</sup>

### B. *The Patentability of Expressed Sequence Tags*

In June of 1991, the National Institutes of Health ("NIH") reignited the debate concerning DNA sequence patentability when it announced its intention to secure broad patent rights on a collection of 337 DNA sequences having no known function.<sup>23</sup> The collection of DNA sequences for which the NIH sought patent protection had been identified by a group of NIH investigators led by J. Craig Venter during the course of the group's participation in the Human Genome Project.<sup>24</sup>

A year prior to the filing of the NIH patent application, Venter had developed a technique for partially sequencing the approximately 30,000 expressed DNA sequences in the human brain.<sup>25</sup> Using this technique, Venter's group rapidly determined the DNA sequence for short stretches of several cDNA clones randomly selected from a commercial brain cDNA library.<sup>26</sup> Because the short stretches of cDNA that Venter sequenced corresponded to portions of expressed genes, Venter called the DNA fragments

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(i.e., the DNA sequence encodes a protein), and it is the function of the protein encoded by that DNA sequence that is not actually known. Healy, *supra* note 18, at 664-65.

22. See Christopher Anderson, *Gene Patents: More Questions Than Answers*, 354 NATURE 174, 174 (1991) (calling the controversy over DNA patenting "the most contentious scientific debate of the day").

23. See Leslie Roberts, *Genome Patent Fight Erupts*, 254 SCIENCE 184, 184 (1991) (stating that the NIH "dropped a bombshell whose repercussions . . . reverberat[ed] throughout the genome community" when it filed a patent application directed to a collection of DNA sequence fragments). See also Healy, *supra* note 18, at 665 (stating that the NIH filing "sparked an important debate on the patenting not just of cDNA fragments, but also of complete genes for which knowledge of the *in vivo* biologic function is limited or absent").

24. Christopher Anderson, *US Patent Application Stirs Up Gene Hunters*, 353 NATURE 485, 485 (1991). The Human Genome Project is an international collaborative effort organized to determine the sequence of the entire human genome. Leslie Roberts, *NIH Gene Patents, Round Two*, 255 SCIENCE 912, 912 (1992).

25. See Adams et al., *Complementary DNA Sequencing: Expressed Sequence Tags and Human Genome Project*, 252 SCIENCE 1651 (1991) (describing an automated partial DNA sequencing technique for generating expressed sequence tags). As the vast majority of the human genome consists of noncoding sequence, the cDNA sequencing technique developed by Venter permitted him to more rapidly determine the DNA sequence of that portion of the human genome encoding proteins that are expressed in the human brain. *Id.*

26. A cDNA library is a collection of DNA molecules generated from all of the mRNA molecules present in a particular cell line, tissue, or organism, thus representing all of the protein-encoding sequences in that cell line, tissue, or organism. BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 310 (3rd ed. 1994).

expressed sequence tags, or ESTs.<sup>27</sup>

In its patent application, the NIH sought patent protection not only for the EST sequences themselves, but also for the full-length coding sequences of the genes from which the EST sequences had been derived and for the protein products encoded by these full-length sequences.<sup>28</sup> The NIH sought such broad patent protection despite the fact that Venter had not yet determined the function of the corresponding full-length sequences.<sup>29</sup> Critics asserted that because the NIH could not specify a biological function for the full-length sequences from which its EST sequences were derived, the NIH should not be allowed to secure patent protection for those sequences.<sup>30</sup> In other words, the NIH filing presented the question of whether DNA sequences having no known function satisfied the utility requirement of 35 U.S.C. section 101.<sup>31</sup>

To counter the argument that their EST sequences lacked utility, the NIH set forth several uses for the sequences in their patent application.<sup>32</sup> For example, since the EST sequences were derived from DNA sequences expressed in the human brain, the NIH asserted that their EST sequences could be used as probes to distinguish brain tissue from other types of tissue.<sup>33</sup> Alternatively, the NIH contended that the EST sequences could be used to design oligonucleotides<sup>34</sup> for use in chromosomal analysis,<sup>35</sup> the poly-

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27. Adams et al., *supra* note 25, at 1651.

28. See Roberts, *supra* note 23, at 185 (discussing the first NIH EST patent application which contained claims to more than 300 cDNA sequences).

29. See, e.g., Roberts, *supra* note 23, at 184 (noting that when relying solely on the determined sequence of an EST, Venter could determine the function of the corresponding full-length DNA sequence only when the EST sequence corresponded to a gene whose function was already known).

30. *Gene Patents*, 359 NATURE 348, 348 (1992) ("For what use, in itself, is the nucleotide structure of a gene when nothing is known of its function, in normalcy and disease?").

31. 35 U.S.C. § 101 (2000).

32. See Adler, *supra* note 14, at 911 (supporting first NIH patent application directed to 337 ESTs); Roberts, *supra* note 23, at 185 (discussing first NIH patent application directed to 337 ESTs); Anderson, *supra* note 24, at 485 (discussing first NIH patent application directed to 337 ESTs); Roberts, *supra* note 24, at 913 (discussing second NIH patent application directed to 2375 ESTs); Leslie Roberts, *Gene Patenting: Top HHS Lawyer Seeks to Block NIH*, 258 SCIENCE 209, 210 (1992) (discussing preliminary determination by NIH parent agency to abandon patent applications directed to ESTs).

33. See Anderson, *supra* note 24, at 485 (noting also that since Venter had not yet identified the function of the full-length sequences from which his EST sequences were derived, Venter could not yet establish which of the EST sequences could be used as brain tissue-specific probes). Without additional sequence information concerning the full-length sequences, Venter could not determine which EST sequences would be expressed predominantly or exclusively in the brain. *Id.*

34. Oligonucleotides are short single-stranded DNA or RNA molecules that are often used as probes for detecting complementary DNA or RNA molecules; the interaction between an oligonucleotide and its complementary DNA or

merase chain reaction,<sup>36</sup> recovery of the corresponding full-length gene,<sup>37</sup> as diagnostic markers for disease,<sup>38</sup> or in the design of antisense therapeutics.<sup>39</sup>

Critics of the NIH filing, however, were not persuaded by these recitations of utility.<sup>40</sup> One commentator labeled the NIH effort to secure patent protection on EST sequences having no known function as a modern day land rush.<sup>41</sup> James Watson, who with Francis Crick discovered the structure of DNA,<sup>42</sup> described

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RNA sequence generates a double-stranded molecule. ALBERTS ET AL., *supra* note 26, at G-17.

35. Adler, *supra* note 14, at 911; Roberts, *supra* note 23, at 185; Roberts, *supra* note 24, at 913. An oligonucleotide derived from an EST sequence can be used as a probe to identify a complementary chromosomal DNA sequence containing the EST sequence. ALBERTS ET AL., *supra* note 26, at 312.

36. Adler, *supra* note 14, at 911; Roberts, *supra* note 24, at 913. Two oligonucleotides derived from the ends of an EST sequence can be used as primers for *in vitro* amplification of the EST sequence. ALBERTS ET AL., *supra* note 26, at 316-17.

37. Roberts, *supra* note 23, at 185. An oligonucleotide derived from an EST sequence can be used as a probe to screen a cDNA library that has been enriched for full-length cDNA sequences in order to identify a complementary full-length sequence containing the EST sequence. ALBERTS ET AL., *supra* note 26, at 312.

38. Roberts, *supra* note 32, at 210 (1992).

39. Roberts, *supra* note 23, at 185. An oligonucleotide derived from an EST sequence, and which is complementary to an mRNA transcript generated from a particular gene, can be used as an antisense therapeutic for the purpose of inhibiting translation or promoting premature degradation of the mRNA transcript. LEWIN, *supra* note 15, at 312-15.

40. In December 1991, the American Society of Human Genetics ("ASHG"), an organization consisting of 4,500 physicians, scientists, and genetic counselors, argued that "[t]he anticipated utility of an EST is simply that one could be used as a research tool to identify the remainder of the coding region of the gene. . . . The EST is, at best, a starting point for further research and should not be patentable." *The Human Genome Project and Patents*, *supra* note 20, at 1711-12. In January 1992, the NIH Department of Energy Subcommittee for Intraagency Coordination of Human Genome Research wrote: "We are unanimous in deploring the decision [of the NIH] to seek such patents. The subcommittee is particularly concerned that the claims widely reported in the press extend far beyond the partial cDNAs themselves to include genes from which they derive and the proteins they specify." Roberts, *supra* note 24, at 913. Maynard Olsen, a member of the Human Genome Project advisory panel, stated that "[i]f the law is interpreted to give intellectual property rights for naked DNA sequences [*i.e.*, sequences having no known function], then the law should be changed." Anderson, *supra* note 24, at 485.

41. *See Free Trade in Human Sequence Data?* 354 NATURE 171, 171 (1991) (stating that the effort by the NIH to secure broad patent protection on its EST sequences "is the equivalent in molecular biology of the nineteenth century practice in the United States of letting gold miners stake claims to the mineral resources beneath arbitrarily chosen plots of land").

42. In 1962, James Watson and Francis Crick received a Nobel Prize for Physiology and Medicine for their discovery of the structure of the DNA molecule. *Medicine 1962*, at <http://www.nobel.se/chemistry/laureates/1980/> (last visited Oct. 15, 2000).



the sequencing of cDNA molecules using modern automated sequence analyzers as something “virtually any monkey” could do.<sup>43</sup> Nobel laureate Paul Berg<sup>44</sup> stated that in filing a patent application directed to EST sequences having no known function, the NIH had “opened Pandora’s box.”<sup>45</sup>

Other critics of the NIH filing argued that if the USPTO granted the NIH a patent for its EST sequences, the purpose of the patent system – to secure for the public’s benefit inventions having substantial utility<sup>46</sup> – would be betrayed.<sup>47</sup> C. Thomas Caskey, the president of the Human Genome Organization (“HUGO”),<sup>48</sup> noted that since “[t]he task of identifying the biological function of a gene is by far the most important step in terms of both its difficulty and its social benefit,” one of the primary objectives of the United States patent system should be to ensure that this step “merits the most incentive and protection.”<sup>49</sup> Caskey also warned that the patenting of DNA sequences having no known function could lead to increased health-care costs and restricted access to DNA-based therapies and diagnostics.<sup>50</sup>

Several commentators predicted that EST patenting would result in a curtailment in the commercial development of DNA-based therapies and diagnostics.<sup>51</sup> For example, if two patentees held broad patent rights to different EST sequences derived from the same gene, both patentees would hold dominant rights to that gene.<sup>52</sup> As a result, a researcher wishing to develop therapies or

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43. Roberts, *supra* note 23, at 184. In April of 1992, Watson resigned as head of the NIH genome project, in part because of his disagreement with the NIH concerning the patenting of EST sequences. Leslie Roberts, *Genome Data: Two Strikes Against cDNA Patents*, 257 *SCIENCE* 1620, 1620 (1992).

44. In 1980, Paul Berg received a Nobel Prize for Chemistry for his pioneering work in genetic engineering. *Chemistry 1980*, at <http://www.nobel.se/medicine/laureates/1962/> (last visited Oct. 15, 2000).

45. Roberts, *supra* note 24, at 912.

46. *Brenner v. Manson*, 383 U.S. 519, 534 (1966).

47. See, e.g., Kiley, *supra* note 13, at 917 (calling for the USPTO to reject the NIH EST application and thus, “restore teeth” to the requirement that inventions have substantial utility).

48. HUGO, a collaboration between England, France, Japan, and the United States, was formed in 1990 for the purpose of sequencing the entire human genome by the year 2005. *HUGO Warning over Broad Patents on Gene Sequences*, 387 *NATURE* 326, 326 (1997).

49. David Dickson, *HUGO and HGS Clash over ‘Utility’ of Gene Sequences in US Patent Law*, 374 *NATURE* 751, 751 (1995).

50. Declan Butler, *Patent System Gets Vote of Support from Gene Workers*, 373 *NATURE* 376, 376 (1995).

51. Leslie Roberts, *Gene Patents: Scientists Voice Their Opposition*, 256 *SCIENCE* 1273, 1273 (1992) (quoting patent attorney Michael Roth as saying that EST sequence patenting “does not build a road to further advances, it just builds a toll booth along the way”).

52. Doll, *supra* note 19, at 690; Rebecca S. Eisenberg, *Do EST Patents Matter?* 14 *TRENDS GENET.* 379, 379 (1998). Alternatively, broad patent rights to

diagnostics related to a particular gene would be forced to secure multiple licenses on that gene or forgo the development of such therapies or diagnostics.<sup>53</sup> The Industrial Biotechnology Association ("IBA")<sup>54</sup> predicted that the patenting of EST sequences would encourage pharmaceutical companies to abandon research efforts aimed at developing pharmaceutical products – such efforts having significant social benefits – in order to engage in "routine genetic sequencing for the purpose of staking claims to as much of the genome as possible" – such efforts having far less social benefit.<sup>55</sup>

In September of 1992, a little more than one year after the NIH had announced the EST patent application filing,<sup>56</sup> NIH Director Bernadine Healy informed the Senate judiciary subcommittee on patents that the USPTO had rejected the application.<sup>57</sup> The application had been rejected on the grounds that the EST sequences recited by the NIH lacked utility and novelty and were obvious.<sup>58</sup> The USPTO found that the EST sequences lacked novelty because they had been derived from cDNA clones present in a publicly available cDNA library.<sup>59</sup> The EST sequences were found to be obvious because portions of the EST sequences had already been published.<sup>60</sup> Finally, the USPTO found that the EST se-

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a single EST sequence may encompass all of the members from a group of related genes, *i.e.*, a gene family. *The Human Genome Project and Patents*, *supra* note 20, at 1712.

53. Eisenberg, *supra* note 52, at 379. See also *The Human Genome Project and Patents*, *supra* note 20, at 1712 (noting that "[i]n the commercial sector there may be a reluctance to invest in research on EST-identified genes when a small but unknown fraction of them will turn out to have commercial utility, and when the useful ones may be contested by patents on other ESTs from the same gene").

54. The IBA consists of 125 companies representing eighty percent of the U.S. investment in biotechnology. Adler, *supra* note 14, at 912.

55. Eisenberg, *supra* note 13, at 907.

56. The NIH had announced the filing of a second patent application covering 2,375 additional EST sequences – or approximately five percent of estimated number of human genes – in February of 1992. Roberts, *supra* note 24, at 912. This announcement had coincided with the publication of the additional EST sequences. Adams et al., *Sequence Identification of 2,375 Human Brain Genes*, 355 NATURE 632 (1992). In a "retreat" from its original position, the NIH sought claims to only the EST sequences and the full-length sequences of the corresponding genes in the second application. Roberts, *supra* note 24, at 913.

57. See Leslie Roberts, *Gene Patents: Rumors Fly over Rejection of NIH Claim*, 257 SCIENCE 1855, 1855 (1992) (noting that the initial NIH EST application had been rejected by the USPTO in an office action dated August 20, 1992).

58. Roberts, *supra* note 32, at 210; Roberts, *supra* note 57, at 1855.

59. Roberts, *supra* note 57, at 1855. Venter had determined the DNA sequence for cDNA clones selected from a commercially available brain cDNA library. Adams et al., *supra* note 25, at 1651.

60. Christopher Anderson, *NIH cDNA Patent Rejected; Backers Want to Amend Law*, 359 NATURE 263, 263 (1992). In its EST sequence applications,

quences lacked utility because the functions of their corresponding full-length genes were unknown, and in the absence of such knowledge the value of the EST sequences as probes was unclear.<sup>61</sup>

Despite external opposition and intra-agency debate,<sup>62</sup> the NIH continued to prosecute its EST sequence applications.<sup>63</sup> However, upon receiving a second rejection on its initial filing,<sup>64</sup> the NIH abruptly abandoned its efforts to secure patent protection for the sequences.<sup>65</sup> The withdrawal by the NIH of its EST sequence applications from further consideration,<sup>66</sup> and the two prior USPTO rejections, did not, as many opponents of the NIH filings

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the NIH had claimed both the EST sequence as well as any 15-nucleotide fragment derived from the EST sequence. *Id.* Claims to the 15-nucleotide fragments were rejected as obvious because a number of the claimed 15-nucleotide fragments could be found in publicly accessible DNA sequence databases. *Id.*

61. Roberts, *supra* note 57, at 1855. In rejecting the claims for lack of utility, the USPTO stated that:

Given what is disclosed in the instant application, it would be necessary for one to do further work in order to establish a utility for any of the nucleotides embraced by the claims. . . . Although the oligonucleotides embraced by the claims may be hybridized to a variety of different preparations of other nucleic acids, one of skill in the art has no clue as to the significance of any result of such hybridization because the instant application fails to provide any basis for the interpretation of any putative results.

Roberts, *supra* note 32, at 210.

62. Michael Astrue, the general counsel for the Department of Health and Human Services (the parent agency of the NIH) – following an unsuccessful attempt to convince the USPTO to suspend consideration of the first NIH application on policy grounds – initiated an intraagency “civil war” by instructing the NIH not to file a response to the August, 1992 rejection. Christopher Anderson, *Gene Wars Escalate as US Official Battles NIH over Pursuit of Patent*, 359 NATURE 467, 467 (1992). The NIH, however, prevailed when Astrue departed from the Department of Health and Human Services in November of 1992. Christopher Anderson, *NIH to Appeal Patent Decision*, 259 SCIENCE 302, 302 (1993).

63. See Anderson, *NIH to Appeal Patent Decision*, *supra* note 62, at 302 (noting that the NIH filed a response to the USPTO rejection in January of 1993).

64. See Diane Gershon, *US and British Researchers Agree Not to Seek Gene Fragment Patents*, 367 NATURE 583, 583 (1994) (noting that in August of 1993, the USPTO rejected NIH claims to 2,421 EST sequences – which included the original 337 EST sequences and an additional 2,084 EST sequences filed in a subsequent continuation-in-part of the original application).

65. Following the second rejection of its initial filing, NIH Director Harold Varmus announced that any effort to secure patent rights on DNA sequences having no known function was “not in the best interests of the public or science.” Christopher Anderson, *NIH Drops Bid for Gene Patents*, 263 SCIENCE 909, 909 (1994).

66. See Gershon, *supra* note 64, at 583 (noting that the NIH decided not to appeal the second rejection of its initial application and to withdraw a pending application directed to 4,448 additional cDNA sequences). In total, the NIH had filed on 6,869 EST sequences. Anderson, *supra* note 65, at 909.

had hoped, resolve the issue of whether DNA sequences having no known function were patentable.<sup>67</sup>

Instead, the controversy surrounding the NIH applications merely initiated a race on the part of both public research organizations<sup>68</sup> and private companies<sup>69</sup> to secure patent protection on DNA sequences having no known function.<sup>70</sup> In July of 1995, these secondary combatants were rewarded for their efforts when the USPTO published new Utility Examination Guidelines that seemingly removed some obstacles from the patenting of EST sequences.<sup>71</sup> The USPTO further clarified its position regarding this issue in February of 1997 when, in what some commentators saw as a reversal from its previous position,<sup>72</sup> the USPTO declared that EST sequences were indeed patentable.<sup>73</sup> The USPTO declared that since EST sequences were acknowledged to have utilities apart from the full-length genes from which they were derived, the failure to specify the function of a full-length gene would no longer prevent an inventor from securing broad patent rights to an EST sequence.<sup>74</sup> However, the publication of the Utility Examination Guidelines and USPTO declarations did not completely resolve the uncertainty concerning the issue of EST patentability.<sup>75</sup>

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67. Anderson, *supra* note 65, at 909.

68. In July of 1992, the MRC had filed a patent application directed to approximately 1,200 EST sequences. Anderson, *supra* note 65, at 910; Alan Howarth, *Patenting Complementary DNA*, 256 *SCIENCE* 11, 11 (1992). In announcing its filing, the MRC stated that it would waive its patent rights to the sequences if an international agreement prohibiting the patenting of DNA sequences having no known function was reached. Howarth, *supra*, at 11; David Dixon, *MRC to Limit Patents on cDNA Sequences*, 366 *NATURE* 6, 6 (1993). The MRC subsequently joined with the NIH in withdrawing its application. Gershon, *supra* note 64, at 583.

69. Human Genome Sciences, Inc. (Rockville, Maryland), the commercial arm of The Institute of Genomic Research ("TIGR") (Gaithersburg, Maryland), a non-profit research institute formed by Venter following his departure from the NIH in July of 1992, began to seek patent protection for the numerous EST sequences it identified. Anderson, *supra* note 65, at 910. Incyte Pharmaceuticals Inc. (Palo Alto, California) also began to file patent applications directed to uncharacterized cDNA sequences. Anderson, *NIH to Appeal Patent Decision*, *supra* note 62, at 302 (1993).

70. See Anderson, *supra* note 65, at 910 (discussing the decision by the NIH to abandon their EST patent applications).

71. *Utility Examination Guidelines*, 60 Fed. Reg. 36263, 36264 (1995).

72. See Dorothy R. Auth, *Are ESTs Patentable?* 15 *NAT. BIOTECHNOL.* 911, 911 (1997) (stating that the issue of EST patentability has not yet been resolved).

73. Claire O'Brien, *US Decision 'Will Not Limit Gene Patents'*, 385 *NATURE* 755, 755 (1997).

74. See Doll, *supra* note 19, at 689-90 (stating that ESTs have patentable utility).

75. See Meredith Wadman, *Patent Office Replies to Fears over ESTs*, 386 *NATURE* 747, 747 (1997) (noting that USPTO commissioner Bruce Lehman, in responding to a letter from the NIH arguing that EST sequences lack utility,

## II. THE EVOLUTION OF THE UTILITY REQUIREMENT

### A. *The Basis of the Modern Utility Requirement*

The modern utility requirement derives from three sources: the Constitution,<sup>76</sup> Congressional legislation implementing the Constitutional mandate,<sup>77</sup> and federal court decisions interpreting the meaning of the word "useful" in the Constitution and in the implementing legislation.<sup>78</sup> Of all the requirements for patentability,<sup>79</sup> only the utility requirement finds explicit mandate in the constitutional text,<sup>80</sup> and since the passage of the first Patent Act in 1790, an inventor has been required to demonstrate that his invention is "useful" in order to secure a patent on the invention.<sup>81</sup> However, while the concept of utility holds a central place in patent legislation,<sup>82</sup> the Patent Act fails to provide a definition for the term "useful."<sup>83</sup> Inventors have had to rely instead on the interpretations of the term "useful" as provided by the federal courts – primarily by the Court of Appeals for the Federal Circuit ("CAFC"), its predecessor, the Court of Customs and Patent Appeals ("CCPA"), and the Supreme Court.

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stated that the "[m]ere allegation of the utility of an EST as a probe without further disclosure is not sufficient to meet the utility and enablement criteria"). This statement seemed to conflict with an earlier declaration that the assertion of a utility of an EST sequence as a probe would be sufficient. O'Brien, *supra* note 73, at 755. In a subsequent clarification, Lehman suggested that sufficient utilities included the use of an EST sequence as a probe for forensic identification, tissue type identification, chromosome mapping, and identification of the full-length gene from which the EST sequence was derived. Auth, *supra* note 72, at 911.

76. U.S. CONST. art. I, § 8, cl. 8.

77. 35 U.S.C. § 101 (2000) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.").

78. Andrew T. Kight, Note, *Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines in Light of Brenner*, 73 IND. L.J. 997, 1017 (1998); Nathan Machin, Comment, *Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act*, 87 CALIF. L. REV. 421, 437 (1999).

79. *In re Kirk*, 376 F.2d 936, 963 (C.C.P.A. 1967) (stating that for an invention to be patentable it must be novel, useful, nonobvious, and directed to statutory subject matter, as required by 35 U.S.C. sections 101, 102, and 103, and disclosed so as to make the invention available to the public, as required by 35 U.S.C. sections 112 and 113).

80. U.S. CONST. art. I, § 8, cl. 8.

81. *Graham v. John Deere Co.*, 383 U.S. 1, 15 (1966).

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

83. 35 U.S.C. § 101 (2000).

### B. Judicial Interpretation of the Utility Requirement

The first interpretation of the term “useful” was provided by Justice Story in *Lowell v. Davis*<sup>84</sup>: “[a]ll that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word ‘useful,’ therefore, is incorporated into the act in contradistinction to mischievous or immoral.”<sup>85</sup> Justice Story’s concept of utility – in which utility was intertwined with morality – relegated the utility requirement to *de minimis* status.<sup>86</sup> By applying a moral utility standard, an inventor could not be denied a patent on the grounds that his invention lacked utility if the invention was neither harmful nor immoral.<sup>87</sup>

By lowering the utility requirement to merely a *de minimis* standard, however, a patentee might secure patent rights to an invention that – while neither harmful nor immoral – was not truly “useful.” Justice Story noted that while it was material to the interests of a patentee that an invention be useful, the utility of the invention was ultimately of no importance to the public.<sup>88</sup> An invention that was “not extensively useful” would “silently sink into contempt and disregard.”<sup>89</sup> Because the market ultimately determined the value of any invention, an invention lacking utility would be of little value to a patentee and a limited monopoly extended to the patentee for such an invention would be of little cost to the public.<sup>90</sup>

The sufficiency of the *de minimis* utility standard rests, there-

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84. 15 F. Cas. 1018 (D. Mass. 1817). In a patent infringement suit in which the alleged infringer challenged the utility of the patentee’s invention, the court found that the invention satisfied the utility requirement as it was neither “mischievous” nor “injurious.” *Id.* at 1019.

85. *Id.*

86. Justice Story offered several examples of inventions unpatentable for want of utility: “a new invention to poison people, or to promote debauchery, or to facilitate private assassination.” *Id.*

87. *Id.*

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

89. *Id.*

90. See Machin, *supra* note 78, at 436 (noting that “misinterpretation of Judge Story’s insightful articulation of the utility requirement as shrill moralizing obscures his real message which is that the marketplace is the ultimate arbiter of an invention’s utility”). See also Kight, *supra* note 78, at 1010 (noting that the public does not desire inventions lacking intrinsic utility); Eric P. Mirabel, “Practical Utility” is a Useless Concept, 36 AM. U.L. REV. 811, 823 (1987) (stating that when a patent is granted on an invention having limited or uncertain use, the patentee takes nothing from the public since the public does not desire “to make, use, or sell a useless invention”); Rebecca S. Eisenberg and Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q. J. 1, 5 (1995) (stating that the market functions to limit the value of patents on inventions having only minimal utility).

fore, on the proposition that few individuals will go to the trouble and expense of securing patents on inventions that lack utility.<sup>91</sup> However, while the *de minimis* standard may be adequate for assessing the patentability of inventions in the mechanical arts, some have argued that this standard is far from adequate for assessing the patentability of inventions in the chemical and biological arts.<sup>92</sup> For example, DNA sequences having no known function would appear to satisfy the *de minimis* utility standard, as such sequences are neither harmful nor immoral. However, because the function of these sequences can be eventually determined, such sequences are not truly useless, and therefore, limited monopolies extended on such sequences may ultimately be of great cost to the public.<sup>93</sup>

For nearly 150 years following *Lowell*, the federal courts applied Justice Story's *de minimis* utility standard.<sup>94</sup> This changed when the Supreme Court, in *Brenner v. Manson*,<sup>95</sup> determined that

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91. Eisenberg, *supra* note 13, at 905.

92. *See id.* (contending that although the sequences that the NIH seeks patent protection for are not useless, the NIH – in the absence of ascribing a function to these sequences – should not be able to secure patent protection ahead of subsequent researchers who discover the function); Karen F. Lech, Note, *Human Genes Without Functions: Biotechnology Tests the Patent Utility Standard*, 27 SUFFOLK U. L. REV. 1631, 1654-55 (1993) (stating that in the area of recombinant DNA technology, the application of a less rigorous utility standard will permit patentees to secure patent rights for inventions lacking the degree of utility contemplated by Congress). *But see* Mirabel, *supra* note 90, at 823 (stating that there are “negative consequences” when patent protection is denied for an invention having “limited or uncertain” use, but that there are no negative consequences when patent protection is granted for a “useless” invention since the patentee takes nothing from the public).

93. *See* Eisenberg, *supra* note 13, at 907 (discussing the possible effects of EST patenting on commercial scientific research); Lech, *supra* note 92, at 1657 (noting that DNA sequences having no known function may, at the time of patenting, have no diagnostic or therapeutic utility and that such utilities may be determined following an elucidation of the function).

94. *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966) (holding that for an invention to be patentable, it must possess “substantial utility”).

95. *Id.* The Commissioner of Patents (Brenner) sought review of the judgment by the CCPA that Manson was entitled to a declaration of interference. *Id.* at 522. Manson contended that he had discovered a process for making certain known steroids prior to the earliest priority date of a patent disclosing the same process. *Id.* at 521. Manson's request for an interference was denied by the examiner on the ground that Manson failed to disclose any utility for the steroids produced by the claimed process. *Id.* In affirming the examiner's determination, the Board stated that “[i]t is our view that the statutory requirement of usefulness of a product cannot be presumed merely because [the product] happens to be closely related to another compound which is known to be useful.” *Id.* at 522. The CCPA reversed the decision of the Board, stating that “‘where a claimed process produces a known product it is not necessary to show utility for the product,’ so long as the product ‘is not alleged to be detrimental to the public interest.’” *Id.* The Supreme Court reversed the decision of the CCPA. *Id.* at 536.

Justice Story's interpretation of the utility requirement gave the term "useful" a "special meaning" that the Court could not accept "in the absence of evidence that Congress so intended."<sup>96</sup> While recognizing that "a simple, everyday word can be pregnant with ambiguity when applied to the facts of life,"<sup>97</sup> the Court found Justice Story's *de minimis* standard to be particularly insufficient in assessing the patentability of inventions in the chemical arts.<sup>98</sup>

While any invention that is not "frivolous or injurious to the well-being, good policy, or sound morals of society"<sup>99</sup> will satisfy the moral utility standard, only an invention exhibiting "specific" and "substantial" utility will satisfy the *Brenner* utility standard.<sup>100</sup> The Supreme Court's interpretation of the utility requirement was grounded in its understanding that 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."<sup>101</sup> When a patent is granted for an invention "which has not been developed and pointed to the de-

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96. *Id.* at 533.

Justice Story's language sheds little light on our subject. Narrowly read, it does no more than compel us to decide whether the invention in question is "frivolous and insignificant"—a query no easier of application than the one built into the statute. Read more broadly, so as to allow the patenting of any invention not positively harmful to society, it places such a special meaning on the word "useful" that we cannot accept it in the absence of evidence that Congress so intended. There are, after all, many things in this world that may not be considered "useful" but which, nevertheless, are totally without a capacity for harm.

*Id.*

97. *Id.* at 529.

98. *Id.* at 530 (stating that the utility requirement is difficult to apply to inventions in the chemical arts, "where little or nothing is wholly beyond the pale of 'utility' - if the word is given its broadest reach").

99. *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (D. Mass. 1817).

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

Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge that should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

*Id.* at 534-35.

101. *Id.* at 534.



gree of specific utility,"<sup>102</sup> such a patent can "confer power to block off whole areas of scientific development, without compensating benefit to the public."<sup>103</sup>

In a foreshadowing of the controversy surrounding the patentability of DNA fragments, the Court recognized that "what now seems without 'use' may tomorrow command the grateful attention of the public."<sup>104</sup> Still, the Court declared that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."<sup>105</sup> In determining that Manson's claimed process for the production of compounds having no known function failed to satisfy the utility requirement, the Court confined the operation of the patent system "to the world of commerce rather than to the realm of philosophy."<sup>106</sup> It has been suggested that the *Brenner* utility standard functions to distinguish basic research (that which is in the "realm of philosophy" and therefore unpatentable) from applied technology (that which is in the "world of commerce" and therefore patentable).<sup>107</sup> Thus, it would appear that until an inventor can ascribe a function to a DNA sequence, the sequence belongs not to the "world of commerce," but rather to the "realm of philosophy."

As the Supreme Court was providing the utility requirement with teeth in *Brenner*,<sup>108</sup> the CCPA was hearing oral arguments in a case involving very similar circumstances.<sup>109</sup> In *In re Kirk*,<sup>110</sup> the CCPA determined that the applicants' assertion that their claimed compounds possessed "biological activity" was too vague to satisfy the *Brenner* utility standard.<sup>111</sup> *Kirk*, however, is remembered

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102. *Id.*

103. *Id.*

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

105. *Id.* at 536.

106. *Id.*

107. Eisenberg, *supra* note 13, at 905.

108. 383 U.S. at 519; Kiley, *supra* note 13, at 917.

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

110. *Id.* Appellants (Kirk and Pertrow) sought review of the judgment by the Board affirming the examiner's rejection of claims to certain steroid compounds. *Id.* at 937. Appellants contended that their specification complied with 35 U.S.C. sections 101 and 112 because the claimed steroids "have present and useful biological activity of the nature known for analogous steroidal compounds," and "one skilled in the art would know how to use the compounds of the claims to take advantage of their presently-existing biological activity." *Id.* at 939. In rejecting appellants' claims, the examiner concluded that: "[w]hat appellants are really saying to those in the art is take these steroids, experiment, and find what use they do have as medicines." *Id.* at 940. The Board affirmed the examiner's rejection of appellants' claims and the CCPA affirmed the Board's decision. *Id.* at 946.

111. *Id.* at 942.

We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of

more for Judge Rich's critical dissent against the higher utility standard prescribed by the Supreme Court in *Brenner* than for the CCPA majority's application of this standard.<sup>112</sup>

Judge Rich believed that the majority, in applying the *Brenner* utility standard in *Kirk*, was reading the *Brenner* decision too broadly,<sup>113</sup> thereby "changing the course of the law as it has been established for over a century and a half."<sup>114</sup> According to Judge Rich, Justice Story's *de minimis* standard more closely paralleled the intention of Congress<sup>115</sup> that "any degree of utility, however slight" complies with the requirement that an invention be "useful."<sup>116</sup> The modifiers used by the majority to describe the degree of utility required for patentability<sup>117</sup> were, due to their "great vagueness,"<sup>118</sup> "nothing but trouble-makers, as time will amply demonstrate."<sup>119</sup> Judge Rich also believed that the application of a higher utility standard would lead inventors to concoct "legal utilities"<sup>120</sup> or conceal, rather than disclose, information.<sup>121</sup>

Judge Rich further argued that the "*quid pro quo*" philosophy – used by the Court in *Brenner* to justify a higher utility standard – had no statutory basis<sup>122</sup> and could not be "squared with legal

the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless.

*Id.*

112. Michelle L. Johnson, Comment, *In re Brana and the Utility Examination Guidelines: A Light at the End of the Tunnel?* 49 RUTGERS L. REV. 285, 310-11 (1996) (stating that the patent bar and public interest may have been better served by a recognition of the *per se* utility requirement supported by Judge Rich in *Kirk*); Machin, *supra* note 78, at 430 (suggesting that the USPTO and the CAFIC, by moving away the "extreme and unequivocal holding" of *Brenner*, were responding to Judge Rich's dissent in *Kirk*).

113. *Kirk*, 376 F.2d at 948.

114. *Id.* at 964.

115. *Id.* at 954. "Though I am sure the majority think they are being most reasonable, adhering to principles embodied in the Constitution, and following what Congress 'must have intended,' in point of fact they are legislating and ignoring the law as Congress enacted it." *Id.* "It has been pointed out time and again since the days of Justice Story. . . that degree of utility is of no public concern whatsoever." *Id.* at 955.

116. *Id.*

117. Terms such as "practical," "substantial," "specific," and "currently available." *Id.* at 960.

118. *Kirk*, 376 F.2d at 960.

119. *Id.*

120. *Id.* at 961 (stating that the public interest would not be benefited if an inventor was forced to waste "scarce scientific and inventive brainpower. . . concocting 'legal utilities'" that ultimately would not be pursued, merely to satisfy a higher utility standard).

121. *Id.* (stating that the utility standard advocated by the majority would encourage an inventor to conceal, rather than disclose, the important uses the inventor contemplates for fear of having to actually prove that such uses exist).

122. *Id.* at 964.

history.<sup>123</sup> Such a philosophy was also unnecessary, in Judge Rich's opinion, since a patent granted on an invention having very little use would be of correspondingly little value to the patentee.<sup>124</sup> In fact, in determining the patentability of chemical compounds, Judge Rich contended that a *per se* utility standard (in which chemical compounds were presumed to be useful) would be more practical from an administrative standpoint than either the *de minimis* or *Brenner* standards.<sup>125</sup>

In view of Judge Rich's discussion of patentability in *In re Bergy*,<sup>126</sup> wherein an inventor must obtain "the separate keys to . . . the three doors of sections 101, 102, and 103"<sup>127</sup> in order to secure a patent, it is somewhat surprising that Judge Rich advocated merely a *per se* utility requirement in *Kirk*. The application of a *per se* utility requirement would prop open one of the "doors" to patentability, and thus, compromise an important goal of the patent system – to acquire meaningful disclosure for the public's benefit.<sup>128</sup> Furthermore, it is difficult to square Judge Rich's belief that the majority in *Kirk* was "legislating"<sup>129</sup> by applying the higher utility standard of *Brenner*, with the role played by the Court in developing the requirement of nonobviousness.<sup>130</sup> While the requirement of nonobviousness was codified in the Patent Act of 1952 – largely through the efforts of Judge Rich<sup>131</sup> – the concept was first injected into the patent law by the Supreme Court, and not Congress, nearly 100 years earlier.<sup>132</sup>

Notwithstanding arguments favoring the utility standard articulated in *Brenner*, many opponents of the "substantial" utility requirement viewed the CAFC's next significant utility-related decision in *In re Brana*<sup>133</sup> as a move away from *Brenner*'s "extreme

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123. *Kirk*, 376 F.2d at 955.

124. *Id.* "[I]f the inventor has given nothing, the government has given nothing. The right to exclude others from the use of something no one wishes to use is worthless - economically." *Id.* at 964.

125. *Id.* at 957.

126. 596 F.2d 952 (C.C.P.A. 1979), *vacated sub nom.* *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980), *aff'd sub nom.* *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

127. *Bergy*, 596 F.2d at 960.

128. *Brenner v. Manson*, 383 U.S. 519, 533 (1966).

129. *In re Kirk*, 376 F.2d 936, 954 (C.C.P.A. 1967).

130. *Id.* at 965. "The only point in the statute at which Congress injected any concept in the nature of degree is the nonobviousness requirement of section 103, a requirement injected into the law by the Supreme Court in 1850." *Id.*

131. *Patent and Trademark Office Mourns Death of Judge Giles S. Rich*, *supra* note 2.

132. *Hotchkiss v. Greenwood*, 52 U.S. 248, 267 (1850) (holding a patent on a porcelain door knob invalid because the substitution of porcelain for wood required no more ingenuity and skill than that possessed by "an ordinary mechanic").

133. 51 F.3d 1560 (Fed. Cir. 1995). Appellants (*Brana et al.*) sought review

and unequivocal holding"<sup>134</sup> and towards the view put forth by Judge Rich in *Kirk*.<sup>135</sup> However, the CAFC did not go quite that far, since the court was able to distinguish the utilities asserted by the appellants in *Brana* from those asserted by the appellants in *Kirk*.<sup>136</sup> Furthermore, in *Brana*, the CAFC addressed the question of whether the appellants produced sufficient proof of an asserted utility, rather than whether the degree of utility asserted by the appellants complied with the utility requirement.<sup>137</sup> Finally, in *Brenner*, the Supreme Court refused to express a view on the question addressed by the CAFC in *Brana*,<sup>138</sup> specifically whether proof of an asserted utility can be demonstrated using accepted animal or cellular models. Yet, to many practitioners, the decision in *Brana*, when coupled with the USPTO's contemporaneous publication of new Utility Examination Guidelines,<sup>139</sup> suggested that the CAFC and USPTO were lowering the utility requirement<sup>140</sup> and perhaps even returning to the *de minimis* standard.<sup>141</sup>

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of the judgment by the Board affirming the examiner's rejection of claims to 5-nitrobenzodeisoquinoline-1,3-dione compounds for use as antitumor substances. *Id.* at 1562. Appellants contended that their specification complied with 35 U.S.C. section 112 because it stated that the claimed compounds had "a better action and a better action spectrum as antitumor substances" than the related compounds of K.D. Paull et al., which had been screened for antitumor activity in mouse tumor models. *Id.* In rejecting appellants' claims, the examiner concluded that the prior art tests of K.D. Paull et al. were insufficient to establish a reasonable expectation that the claimed compounds had a practical utility. *Id.* at 1563-64. The Board affirmed the examiner's rejection of appellants' claims. *Id.* at 1564. In reversing the Board's decision, the CAFC stated that "proof of an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utility." *Id.* at 1567.

134. Machin, *supra* note 78, at 430.

135. *Id.*

136. *Brana*, 51 F.3d at 1565-66.

137. *Id.* at 1564. "The question is, with regard to pharmaceutical inventions, what must the applicant prove regarding the practical utility or usefulness of the invention for which patent protection is sought." *Id.* See Kight, *supra* note 78, at 1014 (noting that *Brana* specifically deals with what patent applicants must prove regarding utility); Eisenberg & Merges, *supra* note 90, at 10 (noting that in *Brana* the issue was what an applicant must prove to establish utility).

138. *Brenner v. Manson*, 383 U.S. 519, 532 (1966) (stating in note 17 that "[i]n light of our disposition of the case, we express no view as to the patentability of a process whose sole demonstrated utility is to yield a product shown to inhibit the growth of tumors in laboratory animals").

139. *Utility Examination Guidelines*, *supra* note 71.

140. See Eisenberg & Merges, *supra* note 90, at 12 (stating that as a result of *Brana* and the Utility Examination Guidelines, the utility standard "may be receding from its recent high-water mark"); Johnson, *supra* note 112, at 305-06 (stating that *Brana* restores the traditional *de minimis* utility standard).

141. Johnson, *supra* note 112, at 305-06.

### C. Utility Examination Guidelines

Under the 1995 Utility Examination Guidelines,<sup>142</sup> an inventor complied with section 101 by asserting a single utility that was both "specific" and "credible."<sup>143</sup> In omitting the requirement from *Brenner* that an asserted utility be "substantial,"<sup>144</sup> the Utility Examination Guidelines were seen by many as propping open the "door" to section 101.<sup>145</sup> By weakening the utility requirement, the USPTO allowed a number of inventors to secure broad patent rights on inventions related to DNA sequences having no known function.<sup>146</sup>

## III. PUBLIC HARM RESULTING FROM A WEAKENED UTILITY REQUIREMENT AND THE REVISED UTILITY EXAMINATION GUIDELINES

### A. Patent Protection for Unknown Uses

When a patent protection is granted for a DNA sequence having no known function, several aspects of patent law conspire to damage the public interest. For example, to secure a patent, an inventor need only specify a single utility,<sup>147</sup> and once a patent has been granted, the inventor is entitled to "every use of which his invention is susceptible, whether such use be known or unknown to him."<sup>148</sup> Thus, under the Utility Examination Guidelines, an inventor who asserted that an EST sequence could be used as a probe would have the right, after securing a patent on that sequence, to exclude others from using the EST sequence for any other use.<sup>149</sup> Critics of the Utility Examination Guidelines sug-

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142. *Utility Examination Guidelines*, *supra* note 71.

143. *Id.* at 36264. "If the applicant has asserted that the claimed invention is useful for any particular purpose (*i.e.*, a 'specific utility') and that assertion would be considered credible by a person of ordinary skill in the art, [an examiner shall] not impose a rejection based on lack of utility." *Id.* at 36264.

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

145. See Kenneth G. Chahine, *Patent Office Resurrects EST Debate*, 16 NAT. BIOTECHNOL. 711, 711 (1998) (stating that "[u]nless the guidelines are amended. . . they will represent a major victory for those seeking broad EST patent protection"); Kight, *supra* note 78, at 999-1000 (stating that the "guidelines. . . make utility-based rejections mere artifacts").

146. Janice Au-Young et al., *Human Kinase Homologs*, U.S. Patent No. 5,817,479 (1998) is generally considered to be the first EST patent granted by the USPTO. Tony Reichhardt, *Patent on Gene Fragment Sends Researchers a Mixed Message. . . as Germany Hesitates over Brussels Directive*, 396 NATURE 499, 499 (1998).

147. 35 U.S.C. § 101 (2000).

148. *In re Thuau*, 135 F.2d 344 (C.C.P.A. 1943).

149. See *Kiley*, *supra* note 13, at 915 (noting that an inventor may exclude others from making, using, or selling his patented invention for any use, even though the inventor recognizes only one use for that invention); Chahine, *supra* note 145, at 711 (noting that a researcher who determines the function of a gene that contains a patented EST sequence could be found to infringe that

gested that by applying a lower utility standard, the USPTO encouraged inventors to concoct utilities,<sup>150</sup> the very harm of which Judge Rich warned.<sup>151</sup>

### B. "Open" Claim Language

When patent protection is granted for DNA sequences having no known function, the longstanding practice of granting very broad claim coverage to an inventor who uses "open" claim language (*i.e.*, the claim transition term "comprising"<sup>152</sup>) can also result in damage to the public interest. Thus, when an inventor uses "open" claim language in a claim to an EST sequence (*e.g.*, "[a]n isolated nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1."), covers both the recited EST sequence and any larger sequence containing the EST sequence.<sup>153</sup> Under the Utility Examination Guidelines, "open" language claims to EST sequences would encompass the corresponding full-length gene even if the full-length gene was characterized at a later date.<sup>154</sup> However, the prior grant of an EST patent to the corresponding full-length gene.<sup>155</sup> The USPTO, in addressing the scope of protection for claims to EST sequences, contended that since a patent for a television picture tube would not preclude another from securing a patent for a television set, an EST patent would not preclude another from securing a patent would not preclude another from securing a patent for the corresponding full-length sequence.<sup>156</sup> This analogy, however, fails to acknowledge the critical distinction between the two inventions. Specifically, while an inventor can readily choose to "invent around" the television picture tube patent,<sup>157</sup> an inventor will most certainly be unable to "invent around"

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EST patent by using the gene).

150. See Kiley, *supra* note 13, at 916 (stating that the utilities asserted by the NIH in their initial EST filing "are utilities concocted to carry the patents until someone finds out what the DNA is really good for").

151. *In re Kirk*, 376 F.2d 936, 961 (C.C.P.A. 1967).

152. ROBERT PATRICK MERGES, PATENT LAW AND POLICY 15 (1997).

153. Auth, *supra* note 72, at 911.

154. *Id.*

155. See Doll, *supra* note 19, at 690 (stating that the patenting of a DNA fragment is analogous to having a patent on a picture tube). The USPTO contended that as the granting of a patent for the picture tube would not have precluded another from securing a patent for the television set, the granting of an EST patent would not preclude another from securing a patent for the corresponding full-length sequence. *Id.* However, the USPTO also contended that as the holder of a picture tube patent could have sued the holder of a television set patent for infringing the picture tube patent, the holder of an EST patent could sue the holder of a patent for the corresponding full-length sequence for infringing the EST patent. *Id.*

156. *Id.*

157. The inventor who secures a subsequent patent on a television could, for example, use an active matrix screen.

the EST sequence patent.<sup>158</sup>

### C. Overlapping Patent Rights

The use of "open" claim language in claims to EST sequences also raises the possibility that by claiming different EST sequences within a single gene, multiple parties will secure patent rights blocking the use of that gene.<sup>159</sup> This could lead to increased costs for biomedical research as investigators who are interested in developing therapies or diagnostics related to that gene will be forced to secure multiple licenses.<sup>160</sup> The overlapping patent rights arising from the patenting of EST sequences could also lead to increased costs for producing commercial genetic diagnostic devices (such as gene chips<sup>161</sup>), which require the use of multiple DNA fragments from thousands of different genes.<sup>162</sup>

### D. Revised Utility Examination Guidelines

The USPTO attempted to address the concerns of those who criticized the Utility Examination Guidelines by publishing Revised Utility Examination Guidelines in December of 1999.<sup>163</sup> Many opponents of EST patentability view the revision to the Utility Examination Guidelines as yet another dramatic change in USPTO policy.<sup>164</sup> Under the Revised Utility Examination Guidelines, an inventor must assert a utility that is "specific," "credible," and "substantial" in order to comply with the requirements of section 101.<sup>165</sup> Thus, the Revised Utility Examination Guidelines

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158. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 700 (1998).

159. *Id.* at 699; Rebecca S. Eisenberg, *Genetics and the Law: The Ethical, Legal, and Social Implications of Genetic Technology and Biomedical Ethics: Intellectual Property at the Public-Private Divide: The Case of Large-Scale cDNA Sequencing*, 3 *U. CHI. L. SCH. ROUNDTABLE* 557 (1996).

160. *In re Kirk*, 376 F.2d 936, 964 (C.C.P.A. 1967).

161. See Stephen P. A. Fodor et al., *Light-Directed, Spatially Addressable Parallel Chemical Synthesis*, 251 *SCIENCE* 767 (1991) (describing a process for fabricating gene chips); Michael C. Pirrung et al., *Large Scale Photolithographic Solid Phase Synthesis of Polypeptides and Receptor Binding Screening Thereof*, U.S. Patent No. 5,143,854 (1992) (describing a process for fabricating gene chips).

162. Heller & Eisenberg, *supra* note 158, at 699.

163. *Revised Utility Examination Guidelines; Request for Comments*, 64 Fed. Reg. 71,440 (1999) (noting that many comments received in response to the request for public comment on the Interim Written Description Guidelines and Utility Examination Guidelines argued that sufficient patentable utility is not shown when the sole disclosed use of an EST sequence is to identify the function of its corresponding gene, suggesting that the final Utility Examination Guidelines should be revised and clarified).

164. Enserink, *supra* note 17, at 1196; Tom Hollon, *Gene Patent Revisions to Remove Some Controversies*, 6 *NAT. MED.* 362, 362 (2000).

165. *Revised Utility Examination Guidelines*, *supra* note 163, at 71441.

seemingly restore the requirement from *Brenner* that an asserted utility be "substantial."<sup>166</sup> The USPTO has suggested that under the Revised Utility Examination Guidelines, DNA sequences having no known function will be unlikely to satisfy the utility requirement.<sup>167</sup> However, it remains to be seen whether the new standard will, in practice, "raise the bar" as to the utility requirement.<sup>168</sup>

#### IV. RESOLVING THE ISSUE OF EST PATENTABILITY

The Revised Utility Examination Guidelines were drafted in large part to address the issue of the patentability of biotechnological inventions.<sup>169</sup> The Revised Guidelines attempt to resolve this issue by restoring a "substantial" utility query to the examination process.<sup>170</sup> Only a strict adherence to the "substantial" utility requirement will confer upon the public the benefit of valuable invention disclosures. However, it is not surprising that, in view of the debate that has surrounded the patentability of DNA sequences having no known function, critics of the heightened *Brenner* standard have proposed other means for resolving the issue of patentability for inventions related to recent developments in the field of biotechnology.

In an effort to restore a lower utility standard, several opponents of the heightened *Brenner* standard have sought Congressional intervention.<sup>171</sup> In *Kirk*, for example, Judge Rich saw the majority's improper extension of *Brenner* as demonstrating the need for Congressional action to remove the uncertainty and confusion surrounding the utility requirement.<sup>172</sup> Judge Rich strongly

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166. *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966).

167. *Revised Interim Utility Guidelines Training Materials 5* (2000), available at <http://www.uspto.gov/web/menu/utility.pdf>. "[T]he credibility of . . . an assertion [that nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers] would not be questioned, although such a use might fail the specific and substantial tests." *Id.* "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." *Id.* See Enserink, *supra* note 17, at 1197 (discussing the possible effects on DNA patentability of the Revised Utility Examination Guidelines).

168. Enserink, *supra* note 17, at 1196.

169. See *Revised Utility Examination Guidelines*, *supra* note 163, at 71441 (stating that the changes to the Revised Utility Examination Guidelines were made as a result of comments submitted in response to the *Utility Examination Guidelines*, *supra* note 71, and directed to the issue of EST patentability).

170. *Id.* at 71441.

171. *In re Kirk*, 376 F.2d 936, 948, 957-58 (C.C.P.A. 1967); Adler, *supra* note 14, at 912, 913; Healy, *supra* note 18, at 667; Machin, *supra* note 78, at 440-41; Byron v. Olsen, *The Biotechnology Balancing Act: Patents for Gene Fragments, and Licensing the "Useful Arts"*, 7 ALB. L.J. SCI. & TECH. 295, 312, 321-22, 333 (1997).

172. *Kirk*, 376 F.2d at 957-58 (asking that Congress enact a "statute which



advocated a move towards a *per se* utility standard – especially for chemical compounds that satisfy the remaining requirements for patentability.<sup>173</sup> In the event that Congress refused to further delineate the boundaries of the utility requirement, Judge Rich thought it critical that the Supreme Court provide further illumination regarding the meaning of the term “useful,” specifically with respect to inventions in the chemical arts.<sup>174</sup>

Although several commentators followed Judge Rich’s lead in calling for Congress to reformulate the utility requirement,<sup>175</sup> others sought a complete overhaul of the patent laws as they are applied to biotechnology.<sup>176</sup> Several commentators contend that as Congress created separate intellectual property systems for plant varieties and semiconductor chip masks, so too should Congress create a biotechnology-specific system.<sup>177</sup> The USPTO, however, has argued against the enactment of a new patent system for biotechnology, noting that the statutory requirement of novelty would be rendered meaningless if Congress were to create a specialized intellectual property system to address each new area of technology.<sup>178</sup> Other commentators have suggested that issues related to

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would restore the law to what it was for a century and a half”).

173. *See id.* at 957-58 (arguing that an effective statute would specify that “new and nonobvious chemical compounds” were *per se* useful within the meaning of 35 U.S.C. section 101 and that chemists would be presumed to know how to use such compounds within the meaning of 35 U.S.C. section 112).

174. *See id.* at 948 (asking the Supreme Court to find patentable utility in chemical compounds having any commercial value). *But see Brenner*, 383 U.S. at 533 (determining that a *de minimis* utility standard “places such a special meaning on the word ‘useful’ that we cannot accept it in the absence of evidence that Congress so intended”).

175. *See, e.g.,* Adler, *supra* note 14, at 912 (arguing that Congress should set a lower utility hurdle); Machin, *supra* note 78, at 440-41 (arguing that the *Brenner* utility standard “inefficiently promotes the progress of the useful arts by insisting that each patented invention be useful in its current form,” and that Congress should therefore either eliminate the utility requirement altogether, enact a *per se* utility requirement, or restore “Judge Story’s elegant definition of utility”); Olsen, *supra* note 171, at 321 (contending that if the current patent laws do not support the patentability of DNA fragments having possible use in the treatment of human disease, then the patent laws should be changed to reflect the special nature of biotechnology).

176. Adler, *supra* note 14, at 913; Healy, *supra* note 18, at 667; Olsen, *supra* note 171, at 333.

177. *See, e.g.,* Adler, *supra* note 14, at 913 (arguing that a new intellectual property system may be needed to encourage development of DNA sequence inventions); Healy, *supra* note 18, at 667 (arguing that a new intellectual property system may be needed for DNA sequences); Olsen, *supra* note 171, at 333 (arguing that Congress should amend the Patent Act to create a new biotechnology-specific provision).

178. *See* Doll, *supra* note 19, at 689 (noting that “in the USPTO’s view, new areas of technology do not create the need for a whole new specialized patent law”).

DNA sequence patentability would be better resolved by requiring researchers to seek copyright, rather than patent, protection for newly identified DNA sequences.<sup>179</sup>

While many critics of the *Brenner* utility standard have sought major revisions to the Patent Act (ranging from the elimination of the utility standard to the creation of an entirely new patent system for biotechnology), less drastic statutory changes have been suggested by those having no *Brenner* axe to grind.<sup>180</sup> One proposed change would alter the categories of statutory subject matter<sup>181</sup> to change the way in which claims to "old" compositions of matter are examined.<sup>182</sup> While, under current patent law, a claim to a new method of using an "old" composition may be patentable, a claim to an "old" composition for a new use is not.<sup>183</sup> However, because claims to methods of use are more difficult to enforce, such claims are not as desirable as those to compositions of matter.<sup>184</sup> Thus, it has been suggested that the Patent Act be

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179. See, e.g., Adler, *supra* note 14, at 913 (arguing that a registration system for DNA sequences would be simpler and more affordable). But see S. M. Thomas et al., *Ownership of the Human Genome*, 380 NATURE 387, 388 (1996) (arguing that the enactment of a copyright system for DNA sequences would be unrealistic and impractical, and that efforts should be made to restrict the scope of DNA sequence patents so that one company cannot gain proprietary rights over an entire gene and its mutations for all diagnostic and therapeutic purposes).

180. See, e.g., Kiley, *supra* note 13, at 915-16 (arguing that an "old" DNA fragment for which a function had not yet been assigned could be found to be new by the discovery of its utility); Poste, *supra* note 18, at 535 (arguing for compulsory licensing of patents directed to DNA sequences having significant therapeutic or diagnostic utility).

181. 35 U.S.C. § 101 (2000).

182. See, e.g., Kiley, *supra* note 13, at 915-16 (arguing for the allowance of claims to "old" compositions of matter for new methods of use).

183. 35 U.S.C. § 101 (2000) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore. . ."). See *In re Thuau*, 135 F.2d 344 (C.C.P.A. 1943) (stating that "it is clearly contrary to the spirit [and] letter of the patent laws that patents should be granted for old compositions of matter based upon new uses of such compositions where such uses consist merely in the employment of such compositions"). The CCPA affirmed the Board's rejection of claims to metacresolsulfonic acid-aldehyde condensation products for use in treating cervicitis, cervical erosions, and related ailments, since a person skilled in the art would know that that applicant's products would have therapeutic properties. *Id.*

184. See Kiley, *supra* note 13, at 916 (stating that although method of treatment claims are believed to be less desirable than composition of matter claims, "the cure – a grant to NIH of patents on thin grounds – may be worse than the disease"). See also Adler, *supra* note 14, at 912-13 (noting that in many countries, DNA sequence claims are allowable, but method of use claims for human therapeutic and diagnostic methods involving DNA sequences are not, and arguing for a strengthening of method of use claims internationally); Healy, *supra* note 18, at 668 (arguing for a strengthening of method of use claims internationally).

modified to permit those who identify a new and non-obvious use for an "old" DNA sequence (*i.e.*, a use for which a patent has been previously granted) to claim that DNA sequence for the new use.<sup>185</sup> However, such a change to the Patent Act would, in all likelihood, affect the value of claims to compositions of matter and lead to increased litigation between patentees holding patents to the same composition (albeit for different uses).

As an alternative to Congressional modification of the Patent Act, it has been suggested by one commentator that the issue of EST patentability could be resolved by the application of a "prospective" utility requirement.<sup>186</sup> Under this proposal, the *Brenner* utility standard would be extended to encompass inventions "having a reasonable chance of being reasonably useful in the foreseeable future."<sup>187</sup> However, since it would be difficult to refute an applicant's assertion that an EST sequence would have a "reasonable chance of being reasonably useful in the foreseeable future," the "prospective" utility standard would have the same effect, in practice, as a *per se* or *de minimis* utility standard.

In returning to the utility standard established in *Brenner*, the Revised Utility Examination Guidelines constitute a step forward in the examination of inventions directed to DNA sequences having no known function. Yet, it remains to be seen whether the USPTO will raise the utility requirement bar with respect to claims to DNA sequences having no known function as it begins to examine patent applications directed to such subject matter.

Following an examination of the many proposals for addressing the perceived deficiencies in the utility requirement, however, it becomes clear that only a strict adherence to the heightened utility standard as set forth by the Supreme Court in *Brenner* will confer upon the public the benefit of *valuable* invention disclosures. This is particularly true for inventions directed to DNA sequences having no known function, where a weakened utility requirement will result in patentees gaining limited monopolies for disclosures lacking "substantial" utility. Furthermore, for patents directed to ESTs, the public will be additionally harmed when the function of a gene from which multiple ESTs were derived becomes known and multiple patentees are permitted to extract licensing fees from researchers who desire to use that gene. As the issue of the patentability of DNA sequences having no function illustrates, it is the heightened utility standard of *Brenner* that allows the patent system to fulfill its ultimate purpose.

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185. Kiley, *supra* note 13, at 915-16.

186. See Machin, *supra* note 78, at 451 (stating that the "prospective" utility requirement will prevent "unfortunate holdings" like that in *Brenner*).

187. Machin, *supra* note 78, at 441.

## CONCLUSION

An inventor is entitled to patent protection only after the inventor has secured the "keys" to each of the "doors of sections 101, 102, and 103."<sup>188</sup> No inventor should be allowed to pass freely through any of these "doors." When any one of the statutory requirements for patentability is weakened, the likelihood increases that certain inventors (especially those seeking patent protection for DNA sequences having no known function) will be able to secure overly broad patent rights. Thus, the patent system satisfies its purpose of benefiting the public by securing valuable invention disclosures only when each of the statutory requirements for patentability is given appropriate consideration.<sup>189</sup> To fulfill the "*quid pro quo*" contemplated by the Constitution and the Congress,<sup>190</sup> the USPTO should strictly adhere to the utility requirement as set forth in *Brenner*. In proposing the Revised Utility Examination Guidelines, the USPTO appears to be returning to the higher *Brenner* standard and, thus, restoring the lock to the door of section 101. Inventors presenting claims to DNA sequences having no known function should once again prepare to secure the key before being allowed to pass through this door.

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188. *In re Bergy*, 596 F.2d 952, 960 (C.C.P.A. 1979), *vacated sub nom.* *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980), *aff'd sub nom.* *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

189. See *Machin*, *supra* note 78, at 453 (noting that the requirements for patentability are interrelated and that the utility requirement "does not operate in a vacuum").

190. *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966).

