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## Limits on Utility in the Face of 21st Century Invention: The Problem with Limiting Patent Claims on EST Sequences

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# LIMITS ON UTILITY IN THE FACE OF 21<sup>ST</sup> CENTURY INVENTION: THE PROBLEM WITH LIMITING PATENT CLAIMS ON EST SEQUENCES

BY: KYLE STRACHE\*

I.Requirements for Patentability .....	211
II.Molecular Genetics.....	213
III. <i>Chakrabarty</i> and a Composition of Matter .....	214
IV. <i>In re Fisher</i> Narrows the Definition of Utility Regarding EST Sequences. ....	217
A.  Brenner Restricts Utility to Specific and Substantial Utility.....	219
B.  Specific Utility .....	221
C.  Substantial Utility.....	222
D.  The Brenner Court Concerns.....	224
E.  Research Tools .....	225
V.Solutions for EST utility: Non-obviousness.....	227
A.  The <i>Fisher</i> Patent is Obvious:.....	230
1.  The Scope and Content of the Prior Art.....	231
2.  Differences Between the Prior Art and the Claims at Issue .....	231
3.  The Level of Ordinary Skill in the Pertinent Art .....	232
4.  Secondary Considerations.....	232
VI.Effects of the <i>Fisher</i> Limitation.....	233
VII.Conclusion.....	234

Recent court decisions examining the utility of expressed sequence tags, or ESTs, may change the manner in which some companies are able to investigate unknown genes. Limiting patentability of genetic research will only logically slow the innovation and understanding of genetic research. Consider the following hypothetical: SMALL, a biotech company, which during its research regarding a cure for disease XYZ, finds an EST that codes for a gene of no known function. Although its research shows this gene to have some “biological activity” with respect to XYZ, the company otherwise has no other leads. However, SMALL is aware that without knowing the underlying function of the gene for this EST, the claims for its patent must be extremely limited as defined by *In re Fisher*.<sup>1</sup>

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<sup>1</sup> *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

SMALL decides to keep its research secret and continues to research in-house and not file a patent due to its claim to this EST being limited. Years later BIG, another biotech company, finds that XYZ is cured through the same gene which SMALL originally discovered but abandoned for lack of funds.

In 2005, the Federal Court of Appeals held in the case of *In re Fisher*, that ESTs lacked utility and were therefore unpatentable.<sup>2</sup> Yet, these simple adenine (A), thymine (T), guanine (G), and cytosine (C) combinations are the codes for all living organisms and it seems that these should be patentable<sup>3</sup> in the face of the 1980 case *Diamond v. Chakrabarty*,<sup>4</sup> where the court famously held that “anything under the sun that is made by man” is patentable.<sup>5</sup>

The issue addressed by the court in *Fisher* was whether the discovered EST was useful. But, if we look to the dissent, we find that there are significant arguments why the invention should be useful and, furthermore, that it may be useful in multiple ways. Such an invention, short sequences of DNA, is really the discovery of a naturally-occurring structure,<sup>6</sup> and is arguably not patentable on its face; but the patentable contribution of the inventor is in the discovery of such a structure rather than in the creation of such a structure.<sup>7</sup>

Recently, in response to the many thousands of EST applications,<sup>8</sup> courts have made patenting of EST sequences more difficult in order to reduce the number of applications for ESTs with unknown uses.<sup>9</sup> The *Fisher* decision has taken a strong stance against EST claims which are either not directed to a known target or known gene or, alternatively, attempt to claim entire genes or proteins based on the EST only.<sup>10</sup> This intensification of the utility standard will force many inventors to take a new look at their research with ESTs.

Under the SMALL scenario, the 2005 *Fisher* decision is a hurdle which

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<sup>2</sup> *Id.* at 1368-1369.

<sup>3</sup> Philippe Ducor, *Recombinant Products and Nonobviousness: A Typology*, 13 SANTA CLARA COMPUTER & HIGH TECH L.J. 1, 31-32 (1997). Where the author states that “[concerning naturally occurring DNA’s], [i]n such inventions, the contribution of the inventor resides in the discovery of a naturally-occurring structure rather than in the creation of a new structure or of part of it.” *Id.* That the essence of such an invention is not that there is a new structure, but that one has properly identified a structure that either relates to some protein or some other filler in the DNA strand. *Id.*

<sup>4</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>5</sup> *Id.* at 309 (quoting S. REP. NO. 1979 at 5 (1972); H.R. REP. NO.1293 at 6 (1952)).

<sup>6</sup> Ducor, *supra* note 3 at 31-32.

<sup>7</sup> *Id.*

<sup>8</sup> Cynthia D. Lopez-Beverage, *Should Congress Do Something About Upstream Clogging Caused by the Deficient Utility of Expressed Sequence Tag Patents?* 10 J. TECH. L. & POL’Y. 35, 52 (2005). (Commenting that since 2000, the filing for DNA and RNA-based patents has overwhelmed the PTO. Because of the overwhelming number of applications, there is a significant backlog).

<sup>9</sup> See e.g. *Fisher*, 421 F.3d 1365 at 1369, where claims must be specific towards the EST and not generally claiming the entire gene or DNA sequence. See also 884 PLI/Par 247, 261-62, stating that in a first generation EST, that does not itself encode a protein, a claim will likely be rejected for insufficient utility unless a target of the EST is identified, and in this case, only a narrow claim will stand. *Id.* This is the essence of the *Fisher* decision, that such claims must be limited to their exact sequence, “SEQ ID NO:1” for example, and that a new patent could work around such claim simply by inserting a different three base pair code for any one of a number of amino acids. *Fisher*, 421 F.3d at 1369. A work around would also be possible by the introduction of an intron into the sequence.

<sup>10</sup> *Fisher*, 421 F.3d at 1374.

limits the ability of SMALL to protect its interest. Therefore, it decided not to seek a patent on the subject.<sup>11</sup> For a number of reasons, to be discussed in this note, failure to patent is counter to the intentions of the patent system, including the promotion of scientific gains.<sup>12</sup> This note will explore this hypothetical case as well as discover whether or not there is precedent for the patenting of EST sequences and the claims thereupon. Finally it will explore how this precedent has both narrowed and expanded through court decisions over the past fifty years.

This note will further discuss whether the federal courts have narrowed the utility standard too far, and in so doing, actually limit the inventive nature and promotion of science with regard to EST sequences. The first section of this note will outline the requirements for patentability. The second section will briefly introduce molecular genetics. The third section will introduce *Diamond v. Chakrabarty* and its effect of broadening the statutory subject matter requirements to allow plant, animal, and DNA sequences. The fourth section will introduce *In re Fisher* and discuss its impacts on EST utility claims, including a discussion of the *Brenner v. Manson*,<sup>13</sup> *In re Kirk*<sup>14</sup> and *In re Joly*<sup>15</sup> cases regarding the narrowing of the utility scope by requiring specific and substantial utility. This section will also argue that *Fisher* limits patent claims, thereby impeding scientific progress as defined in the Constitution and potentially wasting resources by duplicating research. In the fifth section, I will suggest that obviousness is a more reasonable alternative towards solving the problem of excessive EST patent applications. Finally, I will conclude that the obviousness standard will provide for a more workable standard and will limit the judicial action of deciding what is and is not “useful” per se.

#### I. REQUIREMENTS FOR PATENTABILITY

In 1793, Thomas Jefferson wrote these famous words giving rise to patent law in the United States: “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, subject to the conditions and requirements of this title.”<sup>16</sup> Jefferson, among others, wanted to promote invention and felt that securing rights would give inventors the protection they needed to continue their trade. Congress followed these suggestions and enacted the power to grant patents saying that, “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their

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<sup>11</sup> See generally, 421 F.3d at 1374, see also note 9 supra and accompanying text, for a more detailed analysis on why SMALL would not have proper protection for its invention.

<sup>12</sup> See e.g. U.S. Const. art. I § 8, cl. 8 (stating that the intention of the patent system is to promote the progress of science and useful arts). *Id.* The original Patent Act of 1793 required only utility and novelty. Subsequent Acts have added additional requirements, but all still remain true, that the intention is to promote the progress of science, by conferring a 20 year monopoly on the invention. *Id.*

<sup>13</sup> *Brenner v. Manson*, 383 U.S. 519 (1966).

<sup>14</sup> *In re Kirk*, 376 F.2d 936 (C.C.P.A. 1967).

<sup>15</sup> *In re Joly*, 376 F.2d 906 (C.C.P.A. 1967).

<sup>16</sup> Patent Act (1793).

respective Writings and Discoveries.”<sup>17</sup>

The United States Patent and Trademark Office (USPTO) set up the general requirements necessary to receive a patent. Under the Patent Act, Title 35 U.S.C. an applicant is “entitled to a patent if his invention is new, useful, nonobvious, and his application adequately describes the claimed invention, teaches others how to make and use the claimed invention, and discloses the best mode for practicing the claimed invention.”<sup>18</sup> The patent then allows the inventor to exclude others from making, using, or selling the invention without the inventor’s permission for a period of 20 years from the filing date.<sup>19</sup> The rules, generally speaking, require: (1) a novel invention; (2) that is nonobvious to one skilled in the art; (3) that is properly disclosed to allow one skilled in the art to make and use the invention; and (4) has at least one specific claim.<sup>20</sup>

The requirements set out by the USPTO give specific guidelines for inventors to gain a patent on their inventions.<sup>21</sup> The rules not only help further scientific knowledge, but they also reduce frivolous patents because of the stringency of the requirements. This article will essentially look at the first and third rules above, 35 U.S.C. §§ 101 and 103; separately looking at whether an invention is “useful” and if it is a “process, machine, manufacture or composition of matter;”<sup>22</sup> or whether it is obvious to one skilled in the art.<sup>23</sup>

Courts have held that an invention must be more than “a mere curiosity” or a “frivolous or trifling article or operation not aiding in the progress or increasing the possession of the human race.”<sup>24</sup> Thus to have utility, in the simplest of language, the invention must be capable of some beneficial use. But, in the case of ESTs and biotechnological inventions, it is more difficult to decide what uses are actually

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<sup>17</sup> U.S. Const. art. I, § 8, cl. 8.

<sup>18</sup> *Fisher*, 421 F.3d at 1378. Further, Title 35 of the U.S. Code outlines the necessary rules for a patent to be issued. See 35 U.S.C. §§ 101-103, 112. The original Patent Act of 1793 include essentially sections 101 and 102, but numerous revisions have occurred over the past 200 some years. *Id.* The patent laws are often changing, because of new technology and because we now live in a world where information can be rapidly exchanged. Even so, these rules, in general form will likely continue to be present for many years. *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.* The requirements specifically are: (1) the subject matter must be patentable; as a useful process, machine, manufacture, composition of matter or improvement thereof; (2) the invention must be novel; it cannot have been previously described in a published media, used in the public sphere or have been sold for more than a year before patenting; (3) the invention must not have been obvious to one skilled in the art; such that at the time of the filing, the invention would not have been obvious to one having ordinary skill in the art; and (4) that a disclosure of the invention must enable one skilled in the art to make and use the invention; the inventor must disclose the best mode of how to make and use the invention; and the invention must have at least one specific claim so that others in the field will know the metes and bounds of the invention. *Id.*

<sup>21</sup> 35 U.S.C. §§ 101-103, 112.

<sup>22</sup> *Id.* at §101.

<sup>23</sup> *Id.* at § 103.

<sup>24</sup> Donald S. Chisum, *Chisum on Patents* § 4.02., citing W. Robinson, *Treatise on the Law of Patents for Useful Inventions* 463 (1890). The court over the past 200 years has increased or decreased the somewhat subjective requirements for patentability. *Id.* Sometime this comes in the form of an increase in utility standard as in the case of *Brenner v. Manson*, 383 U.S. 519 (1966). Other times the court has suggested that the invention is obvious such as *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976).

beneficial.<sup>25</sup> Today, current law holds that modern scientific inventions must prove that they are useful and not just a “scientific process exciting wonder yet not producing physical results,”<sup>26</sup> and that they must also have a specific and substantial utility.<sup>27</sup>

## II. MOLECULAR GENETICS

The claimed invention in the *Fisher* patent relates to isolated and purified DNA and cDNA, specifically, an EST which is just a short nucleotide fragment of a cDNA clone.<sup>28</sup> To better understand the invention, it is essential to briefly discuss the function and role of such DNA.

Genes are located on chromosomes within the nucleus of any given cell, and these are made up of deoxyribonucleic acid or DNA.<sup>29</sup> Each DNA is two strands of nucleotides, arranged in a double helix form, which was originally discussed by J.D. Watson and F.H.C. Crick in a 1953 publication in *Nature* magazine.<sup>30</sup> Each strand is composed of four bases, adenine, guanine, cytosine and thymine, (collectively, A,T,G,C) and each of these bases arrange themselves in opposing fashion with (A-T) and (G-C) each specifically bonding with one another, through a single hydrogen bond.<sup>31</sup>

When a gene is expressed in a particular cell, the particular strand of DNA that encodes for that gene is transcribed into a single strand by messenger ribonucleic acid (mRNA).<sup>32</sup> This mRNA is released from the nucleus into the cytoplasm of a cell and used by ribosomes to produce proteins for the structure.<sup>33</sup>

Complementary DNA, (cDNA), though, is produced in a synthetic manner by reverse transcribing the mRNA.<sup>34</sup> cDNA is easily created in the laboratory and, over the past twenty years, scientists have compiled libraries of cDNA fragments which help identify which genes are expressing in a cell or cell tissue at any given time.<sup>35</sup>

The expressed sequence tag, (EST), is simply a short strand or fragment of cDNA.<sup>36</sup> Typically, ESTs are created by sequencing a sample cDNA at one end of the strand.<sup>37</sup> ESTs are then often used as a marker in a sample mixture of DNA,

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<sup>25</sup> See e.g. *Fisher*, 421 F.3d at 1370. Discussing *Brenner v. Manson*, and the requirements for usefulness. *Id.* The *Fisher* court went to great detail to discuss that following *Brenner* was the proper standard and that for something to be useful it would need to have specific and substantial utility. *Id.*

<sup>26</sup> Chisum, *supra* note 24, at § 4.02., citing w. Robinson, *Treatise on the Law of Patents for Useful Inventions* 463 (1890).

<sup>27</sup> *Brenner*, 383 U.S at 529.

<sup>28</sup> *Fisher*, 421 F.3d at 1366-67.

<sup>29</sup> See e.g. Benjamin Lewin, *Genes VII* (Oxford University Press, Inc. 2000).

<sup>30</sup> Lopez-Beverage, *supra* note 8 at 41.

<sup>31</sup> *Fisher*, 421 F.3d at 1367.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> See e.g. Benjamin Lewin, *Genes VII* (Oxford University Press, Inc. 2000).

<sup>37</sup> *Id.*

because the EST will bind with its opposing pair sequence, thus identifying that a particular section of DNA was found in the sample.<sup>38</sup> This identifies when particular sequences are expressing within a tissue at a known time, and thus suggests which proteins, if any, are responsible for certain actions within that tissue.<sup>39</sup> Thus, EST sequences are especially valuable and useful when researching a particular gene or a particular action within a body tissue because it is the EST that will identify when a particular sequence is within a mixture.<sup>40</sup>

### III. *CHAKRABARTY* AND A COMPOSITION OF MATTER

Natural products, naturally occurring organisms, and natural phenomena are not patentable under the current patent standards because they do not fit within one of the areas of patentable subject matter.<sup>41</sup> Thus, one cannot patent a natural mineral, a breed of dog, or the theory of gravity because these are naturally occurring matter or phenomena and are thus forbidden.<sup>42</sup> Over time courts have expanded the limits on what qualifies a patentable subject matter. The case for patenting DNA or EST sequences only became a reality when the Supreme Court decided in *Chakrabarty* that manmade, non-naturally occurring organisms were patentable.<sup>43</sup> But because of the nature of genetic science, it is difficult to truly “see” if an EST sequence is more like a natural law and thus forbidden or more like a man-made organism and thus patentable. Yet, courts have decided that EST sequences are patentable subject matter under the current understanding of the law.<sup>44</sup>

Plants and animals can be described in their most simplistic manner as a stunning arrangement of cells working together to create life. Within any living organism there exists a tiny, but essential, set of instructions that tell these cells what to do. It is this DNA, the instructions, which make each organism unique. Thus, the problem of patenting DNA is that one is patenting the instructions of how to make the organism. This makes DNA appear to be more similar to a natural product which does not fall under any of the statutory subject matter

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<sup>38</sup> *Id.*

<sup>39</sup> The Federal Circuit has discussed molecular genetics extensively in cases prior to *Fisher* as identified in note 2 in the *Fisher* case. See e.g. *In re Deuel*, 51 F.3d 1552, 1554-56 (Fed. Cir. 1995); *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1207-08 (Fed. Cir. 1991); *In re O’Farrell*, 853 F.2d 894, 895-99 (Fed. Cir. 1988). Furthermore, there are many significant articles that discuss the intricacies of the molecular issues at hand. Instead, this article will briefly discuss the relevant genetics and focus on the relevant law at issue.

<sup>40</sup> See [http://www.ncbi.nlm.nih.gov/dbEST/how\\_to\\_submit.html](http://www.ncbi.nlm.nih.gov/dbEST/how_to_submit.html) (last visited December 8, 2007) for a short description of EST sequences.

<sup>41</sup> 35 U.S.C. § 103 (2007).

<sup>42</sup> Obviously, there are hundreds of examples of what is and is not patentable under the laws of the United States. But the general point of this article is that something must be non-naturally occurring, as held by the *Diamond v. Chakrabarty*, decision in order to be patentable. *Chakrabarty*, 447 U.S. 303 at 309.

<sup>43</sup> *Chakrabarty*, 447 U.S. at 309, where the Court held that “anything under the sun made by man” was to be patentable subject matter under § 101. *Id.*

<sup>44</sup> *Id.*

requirements.<sup>45</sup> With the expansion of subject matter, the courts have implicitly allowed such DNA to be patented.

Historically, patent law dates to the early English law in 1624; yet, early law did not allow the patenting of live organisms.<sup>46</sup> But Congress has expanded the possible subject matter requirements. This expansion began in 1930 with the Plant Patent Act and continued with the 1970 Plant Variety Protection Act (PVPA) when Congress allowed asexual and sexual plants to have protection.<sup>47</sup> The Acts immediately lifted the ban against issuing patents for plants and opened the door for future patenting of multicellular organisms.

While the Plant Patent Act and the PVPA each give those who patent plant varieties some rights, these rights are severely limited compared to “utility” patents, commonly associated with inventions.<sup>48</sup> The limitations include that a patent holder is required to license their technology upon a reasonable request<sup>49</sup> and research used on a particular variety is always allowed without the owner having any recourse.<sup>50</sup> Clearly, these two exceptions do not allow a PVPA patent holder to “exclude” one from using, making, or selling his invention in the same manner that a patent granted under 35 U.S.C. § 101 *et. seq.*,<sup>51</sup> but it still allows one to protect and profit from his or her work.

Thus, if a plant DNA application were to be filed as a “plant patent,” then the rights to that patent would be limited under the patent rights as discussed *supra*. However, having such limited rights would certainly limit the desirability to research new avenues for drugs or other inventions. These patents work well for such things as plant phenotypes, such as rose varieties, giving some limited rights for the ingenuity. However, the essential limitation towards granting a full patent is that, theoretically, the plants themselves could have created such varieties as are created by the inventors, therefore differentiating them from traditional utility patents.<sup>52</sup> When plants are man-made or when the product is purified and isolated from the natural product, utility patents are permissible.<sup>53</sup> *Diamond v. Chakrabarty* broadened the standard for statutory subject matter allowing

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<sup>45</sup> Ducor, *supra* note 3, discussing the patentability of EST sequences.

<sup>46</sup> Ryan M.T. Iwasaka, *Chakrabarty to Chimeras: The Growing Need for Evolutionary Biology in Patent Law*, 109 YALE L.J. 1505, 1511 (2000).

<sup>47</sup> *Id.* at 1513.

<sup>48</sup> 35 U.S.C. §§ 161, 163 (2007).

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* at §§ 161, 271.

<sup>52</sup> PVPA opponents would suggest that a plant patent should never be allowed because, the inventor or “breeder” as it may be, is simply crossing plants, in a sexual or asexual manner, a la Gregor Mendel and that such an inventor is doing the work that nature could theoretically do itself. But proponents would suggest that any plants or varieties created, are done through work that nature itself has either not created because the plants would be selected against in a Darwinian struggle, or that we are simply giving plants a chance to cross with plants that would not likely meet, such as plants from the USA and from Siberia. See <http://www.plantpatent.com/irget.html>, (last visited March 31, 2007). While both are essentially correct on their points, the United States has, through policy reasons, chosen to reward new types of plants with limited protection, especially for new colors or greater vigor. *Id.*

<sup>53</sup> 35 U.S.C. § 101 (2007).



traditional utility patents to claim plants and animals.<sup>54</sup>

In 1980, the United States Supreme Court reviewed the issue of whether a man-made non-naturally occurring multicellular organism would qualify as patentable subject matter.<sup>55</sup> In the original utility application, the inventors, realizing that animals had not been allowed to be patented, stated that the claimed bacteria was not an “animal” and that the rights to the organism were similar to those of a plant breeder.<sup>56</sup> The Court rejected the claims for the bacterium as a plant because clearly it was not a plant.<sup>57</sup> Yet, the Court realized that, although the bacterium were not in-fact plants, the invention was still novel and useful.<sup>58</sup> Although it was an animal, the bacteria met all other facets of patentability and the Court granted the patent.<sup>59</sup>

The *Chakrabarty* court, finding that the bacterium was patentable, held that man-made, non-naturally occurring multicellular organisms fit within the § 101 definition of “composition of matter.”<sup>60</sup> The Court held that in regards to what is or is not patentable, “anything under the sun that is made by man” should fall within the language of the 1952 Act.<sup>61</sup> Here, in a historic decision, the Court broadened the language of the Act to include any organism that was produced by the hands of man, including, but not-limited to, plants or animals that were not previously naturally occurring.<sup>62</sup> By extension, this case extended subject matter to DNA and EST sequences alike, as they were produced by man and the purification and isolation of the DNA made these non-naturally occurring.<sup>63</sup>

In the case of *Animal Legal Defense Fund v. Quigg*,<sup>64</sup> the Court stood by its decision in *Chakrabarty*, citing *Ex parte Allen*,<sup>65</sup> where a polyploidy non-naturally occurring oyster was held to be patentable.<sup>66</sup> The Court stood by and affirmed the language of 35 U.S.C. § 101 providing that “[t]he Patent and Trademark Office now considers non-naturally occurring nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of [§ 101].”<sup>67</sup>

While plants and animals each specifically received status as a “composition of matter,” other matter seemingly invented or discovered by man was still considered as non-patentable.<sup>68</sup> Prohibitions still remained on such discoveries as

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<sup>54</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 313-14 (2004).

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> *See generally id.*

<sup>59</sup> *Id.*

<sup>60</sup> *See Chakrabarty*, 447 U.S. 303.

<sup>61</sup> *Id.* at 309.

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920 (1991).

<sup>65</sup> *Ex parte Allen*, 2 U.S.P.Q.2d 1425 (1987).

<sup>66</sup> *Quigg*, 932 F.2d at 923.

<sup>67</sup> *Id.* at 922.

<sup>68</sup> *Chakrabarty*, 447 U.S. at 310.

mathematical formulae and liberal arts.<sup>69</sup> *Chakrabarty* and its progeny represent a liberalization of the patent standards towards an ever-increasing subject matter.<sup>70</sup> Yet, simply by isolating and purifying a DNA sequence, inventors blur the line between invention on the one hand and a natural product on the other hand, which has generally been held to be unpatentable.<sup>71</sup> The courts, however, have held for the past twenty years that such sequences in a “purified and isolated” form are the handiwork of man and are patentable as a “composition of matter” under § 101.<sup>72</sup> Thus, DNA sequences of all types have been held to be patentable subject matter under the *Chakrabarty* line of cases.

Over the past fifty years, a number of patent cases have attempted to redefine and broaden the scope of utility.<sup>73</sup> Today, while scientists want to promote invention, sometimes the inventions have gone too far and they seek to claim rights to things with little or no value.<sup>74</sup> Simply because *Chakrabarty* declared that man-made inventions were patentable does not equate that a man-made invention (whether a machine, plant, animal, chemical compound, or DNA sequences) has the right to be patented if it is useless.<sup>75</sup> This line has been blurred as inventors have attempted to apply for patents on every invention possible, regardless of the utility of the invention, in the name of science, or, in the more likely scenario, in search of the almighty dollar.

#### IV. *IN RE FISHER* NARROWS THE DEFINITION OF UTILITY REGARDING EST SEQUENCES.

In 2005, when the Federal Court of Appeals decided the case of *In re Fisher*, the court defined the “utility” of EST sequences and, in the process, limited the scope of the claimed subject matter.<sup>76</sup> The case arose when Fisher appealed the USPTO’s final decision of patent No. 09/619,643 (‘643), which held that patent ‘643 was non-patentable for lack of utility under 35 U.S.C. § 101 and 35 U.S.C. § 112 for lack of enablement.<sup>77</sup> The *Fisher* application involved the claims for “five purified nucleic acid sequences that encode proteins and protein fragments in maize plants.”<sup>78</sup> The *Fisher* patent included seven specific claims: (1) serving as a

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<sup>69</sup> Andrew Chin, *Research in the Shadow of DNA Patents*, 87 J. PAT. & TRADEMARK OFF. SOC’Y 846, 867-68 (2005). Stating that, “products of nature and discoveries in non technological fields, such as pure mathematics and the liberal arts, are specifically excluded from patentability.” *Id.*

<sup>70</sup> *Id.* at 868, quoting *Chakrabarty*, on how the scope of “composition of matter” has been expanded, “all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.” *Id.*

<sup>71</sup> *Id.* at 870.

<sup>72</sup> *Id.* at 873.

<sup>73</sup> See Chisum *Supra* note 24, which describes the historical lineage of the Utility requirement for patents.

<sup>74</sup> Ted Van Cleave, *Totally Absurd Inventions America’s Goofiest Patents* (Andrews McMeel Publishing) (2001).

<sup>75</sup> *Chakrabarty*, 447 U.S. at 308-10.

<sup>76</sup> *Fisher*, 421 F.3d at 1367.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

molecular marker; (2) measuring mRNA in a sample; (3) providing a primer source for PCR; (4) identifying or denying the presence of sequences; (5) isolating promoters; (6) controlling protein expression; and (7) locating genetic molecules of other plants and organisms.<sup>79</sup>

Fisher appealed the final decision of the USPTO, which held that patent application '643 was unpatentable for lack of utility under 35 U.S.C. § 101 and 35 U.S.C. § 112 for lack of enablement.<sup>80</sup> In the final rejection, the examiner found that the claimed uses were "not specific to the claimed ESTs but instead were generally applicable to any EST,"<sup>81</sup> therefore, they were "lack[ing] a specific and substantial utility."<sup>82</sup> Although these ESTs do serve some laboratory purposes, they are not so specific as to warrant a patent.<sup>83</sup> The "ESTs lacked a substantial utility because there was no known use for the underlying proteins produced as final products resulting from processes involving the claimed ESTs."<sup>84</sup> Finally, the USPTO noted that "[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."<sup>85</sup>

Fisher then appealed to the Board of Patent Appeals and Interferences for a new review of the rejection of the '643 patent.<sup>86</sup> The board held that the application "failed to explain why any of the claimed ESTs would be useful in detecting polymorphisms in maize plants;"<sup>87</sup> that, "without knowing any further information in regard to the gene represented by an EST . . . [t]he presence or absence of a polymorphism provides the barest information in regard to genetic heritage."<sup>88</sup> The board also concluded that isolating a nucleic acid sequence without a "known utility, is not a substantial utility."<sup>89</sup> Thus, the board firmly established that the application did not provide a specific utility or benefit and could not be patentable. Fisher challenged this decision by appealing to the Federal Court of Appeals.

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<sup>79</sup> *Id.* at 1368.

<sup>80</sup> *Id.* at 1367.

<sup>81</sup> *Id.* at 1368. Specifically, the court was discouraged by Fisher's lack of work in proving that the EST had actual value. *Id.* There was considerable time spent in the discussion by the majority discussing that any in-vitro, in-vivo or other tests to show the use of the EST would have given the Fisher patent a fighting chance. *Id.* Finally, it was evident that the five claimed ESTs were really no different than any others created by Fisher, and the parent company Monsanto. *Fisher*, 421 F.3d at 1368. The court felt that conferring a monopoly on a small sequence, for such little laboratory work, was improper, Fisher, et. al. needed to bring more to the table. *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> *Fisher*, 421 F.3d at 1368.

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* The fact is that an EST gives one skilled in the art the ability to identify a nucleotide sequence. *Id.* An EST is essentially a guide marker for a gene and in this case the five markers (*ESTs*) only marked unknown genes of unknown function of a section of DNA. *Id.* It is entirely possible that such areas of the gene are just introns, or areas of repeated DNA, and that the region holds little to no value. *Id.* But the essential point of this article is that we do not know, and it is improper to pass judgment on that which is unknown.

<sup>89</sup> *Id.*

Fisher argued that § 101 requires only that an invention not be “frivolous, injurious to the well-being, good policy, or good morals of society.”<sup>90</sup> The court agreed with Fisher that the “utility threshold is not high,” but that a patent still needed to “disclose only a single and specific utility pursuant to *Brenner*,”<sup>91</sup> suggesting that § 101 requires more than just an invention that is not frivolous. The court rejected Fisher’s arguments and announced a more rigorous test echoing its predecessor *Brenner*:

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.<sup>92</sup>

*Brenner* significantly asserts that unless the invention has a specific and substantial use, then it has no utility.<sup>93</sup> Yet, this very premonition essentially allows the court to find any invention as unpatentable; because, it is extremely difficult to say what is or is not useful when the patented product is new or is so unique that its value cannot be readily determined.

#### A. *Brenner Restricts Utility to Specific and Substantial Utility*

Following the 1966 *Brenner* decision, the utility standard required that an invention have a “specific and substantial utility to satisfy § 101.”<sup>94</sup> The case arose when the Court of Customs and Patent Appeals (CCPA) held that the invention “produce[d] a known product, [making] it [un]necessary to show utility for the product.”<sup>95</sup> The patent discussed the manufacture of chemical compounds, which were similar to compounds with possible tumor-inhibiting effects in mice.<sup>96</sup> The Appeals board found that “usefulness of a product cannot be presumed merely because it happens to be closely related to another compound which is known to be useful.”<sup>97</sup> The CCPA reversed, holding that “where a claimed process produces a known product, it is not necessary to show utility for the product.”<sup>98</sup> The USPTO sought *certiorari*, which the Supreme Court granted, to resolve the dispute over what constituted utility.<sup>99</sup>

The Supreme Court granted *certiorari* to determine the meaning of utility in

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<sup>90</sup> *Fisher*, 421 F.3d at 1369. This argument was also brought in *Application of Nelson*, 47 C.C.P.A., 1031, 1040, (1960).

<sup>91</sup> *Id.* at 1370.

<sup>92</sup> *Brenner*, 383 U.S. at 534-35 (emphasis added).

<sup>93</sup> *Id.*

<sup>94</sup> *Fisher*, 421 F.3d at 1371. See also *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563 (1996).

<sup>95</sup> *Brenner*, 383 U.S. at 522.

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

reference to a chemical patent.<sup>100</sup> The Court held that “a simple, everyday word can be pregnant with ambiguity when applied to the facts of life,”<sup>101</sup> suggesting that the definition from the Patent Act of 1793 may not always appropriately determine utility.<sup>102</sup> The Court noted that “[i]t was never intended that a patent be granted upon a product, or a process producing a product, unless such product be useful.”<sup>103</sup> Essentially, the Court held that an invention lacks utility “[u]nless and until a process is refined and developed to this point – where specific [and substantial] benefits exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.”<sup>104</sup>

In the case of *Brenner*, the patent application identified a compound of unknown use, while *Fisher*'s application claimed five ESTs hybridizing to genes of unknown use.<sup>105</sup> Seemingly, in each case, more research was needed to identify the scope and extent of the invention would have made each application stronger; but the application as filed did not explain the whole picture.<sup>106</sup> Thus, the *Fisher* decision affirmed *Brenner*, holding that there must be a specific and substantial utility for the EST sequences to achieve utility under § 101.<sup>107</sup> As a result, under the original claims in the *Fisher* application, there must have been a claimed specific and substantial utility before the *Fisher* application would meet the § 101 utility requirements.

Following the *Brenner* decision, the courts were again faced with a utility question surrounding chemical compounds.<sup>108</sup> *In re Joly* and *In re Kirk* both involved applications for patents involving chemical intermediates, each of which produced chemical compounds of no known use. In both cases, the court rejected the argument that “disclosure of a steroid as useful as an intermediate to make other steroids by specified reactions [was] an adequate disclosure of utility.”<sup>109</sup> The *Joly* court held that simply because a chemical compound was “closely related” in structure to compounds of known usefulness does not confer utility.<sup>110</sup> In *Kirk*, the court rejected the argument that compounds showing valuable “biological properties” were useful; instead, the court reasoned that the compounds were ambiguous and lacking in utility.<sup>111</sup> Both cases confirmed that chemical intermediates producing a compound of no known utility renders the chemical

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<sup>100</sup> *Id.*

<sup>101</sup> *Brenner*, 383 U.S. at 529.

<sup>102</sup> The Court in *Brenner* suggested that the 1793 Act did not provide enough guidance and nuance as is needed and appropriate for the inventions of the time; that what was once useful, or could be dreamed to be useful today, is far different from what was envisioned just some 200 years ago. *Brenner*, 383 U.S. at 529.

<sup>103</sup> *Id.*

<sup>104</sup> *Id.* at 534-35.

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*; see also *Fisher*, 421 F.3d at 1375.

<sup>107</sup> *Brenner*, 383 U.S. at 534-35.

<sup>108</sup> See generally *Brenner*, 383 U.S. 519.

<sup>109</sup> *Joly*, 376 F.2d 906.

<sup>110</sup> *Id.* at 907-08.

<sup>111</sup> *Fisher*, 421 F.3d at 1375.

intermediate itself unpatentable for lack of utility.<sup>112</sup>

The facts of *Fisher* are even more similar to *Kirk* and *Joly* than to *Brenner*.<sup>113</sup> Where the *Kirk* and *Joly* applications each claimed utility of certain chemical intermediates producing unknown compounds, *Fisher* claimed utility for an EST which marked an unknown gene. Furthermore, each application asserted value to a compound or gene which itself was useless at the time of filing. In each case, the patent was rejected for lack of utility because the compounds “were useful only as intermediates in the synthesis of other compounds of unknown use.”<sup>114</sup> The Court of Appeals in *Fisher* held that ESTs were analogous to the chemical intermediaries of *Joly* and *Kirk* and thus confirmed the lack of utility for similar reasons. *Fisher* did not, in the court’s view, have a total understanding of the gene or underlying protein such that it was reasonable to grant an exclusive patent thereupon.<sup>115</sup> *Fisher*, like *Joly* and *Kirk*, did not claim a specific and substantial utility; thus the patent did not meet § 101 utility standard as defined under *Brenner*.<sup>116</sup>

Absent any specific and substantial utility, *Brenner* holds that a patent is not useful and thus does not meet the requirements as set forth under the USPTO requirements.<sup>117</sup> Thus, while almost any idea can be patentable, even completely ridiculous inventions, it must have a specific and substantial utility to pass the requirements under the *Brenner* decision.<sup>118</sup>

### B. Specific Utility

According to the Utility Guidelines of the USPTO, specific utility is “particular to the subject matter claimed and would not be applicable to a broad class of invention.”<sup>119</sup> The “specific” utility requirement of an application must “disclose a use which is not so vague as to be meaningless”<sup>120</sup> and an application must describe the invention in terms that are not merely “nebulous expressions [of] biological activity.”<sup>121</sup> Finally, the properties that are defined in a specification must assert a value that is well-defined and provides a “particular benefit to the public.”<sup>122</sup> Specific utility must not just be a broad general statement of what the class of the invention can do but the specification must also disclose what this invention in particular actually does.<sup>123</sup> *Fisher*’s seven claims were too broad; it was this breadth within the claims that was disproportionate to the contributions of

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<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> *Fisher*, 421 F.3d at 1375; *see also* 35 U.S.C. § 101.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.* at 1372.

<sup>120</sup> *Id.* at 1371.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

the inventors.<sup>124</sup>

The court did not find that Fisher's arguments were significantly persuasive to overcome the burden of proving utility.<sup>125</sup> Fisher's alleged uses were found to be "so general as to be meaningless,"<sup>126</sup> in other words, the same uses could be applied to not just these five ESTs but to any EST or sequence for that matter derived from any different plant or animal organism.<sup>127</sup> Fisher's invention serves no utility because the invention serves as "merely starting points for further research, not the end point of any research effort."<sup>128</sup> Further, that any uses suggested by Fisher are not specific claims but are only a "laundry list"<sup>129</sup> of research plans, tools or methods, and none with a substantial benefit in its currently available form.<sup>130</sup> Therefore, the court in *Fisher* limits utility to only those ESTs that give an immediate benefit to the public in its current form.<sup>131</sup>

### C. Substantial Utility

The USPTO Utility Guidelines have exclaimed that a substantial utility defines a "real world" use.<sup>132</sup> "If a utility requires further research, then it does not constitute a substantial utility under these Guidelines."<sup>133</sup> The CCPA has stated that "practical (substantial) utility is a shorthand way of attributing 'real-world' value to claimed subject matter."<sup>134</sup> There must be some "immediate benefit to the public" for an invention to have substantial utility.<sup>135</sup> The benefit Fisher's ESTs provided was to identify the specific underlying genes of the EST sequences.<sup>136</sup> The court held that the benefit conferred was simply too small compared to the breadth of the asserted claims to confer utility over the entire gene in which the EST probed.<sup>137</sup>

What, then, does *Fisher* actually teach us about the state of chemical and sequence based patent applications? According to the Federal Court of Appeals and in reference to *In re Jolles*,<sup>138</sup> *Nelson v. Bowler*<sup>139</sup> and *Cross v. Iizuka*,<sup>140</sup> utility may be found in a variety of manners. Utility exists when the applicant proved that the compound gave a specific use which had generally been fully

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<sup>124</sup> *Fisher*, 421 F.3d at 1371.

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

<sup>130</sup> *Fisher*, 421 F.3d at 1371.

<sup>131</sup> *Id.*

<sup>132</sup> *Id.* at 1372.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* at 1371.

<sup>135</sup> *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980).

<sup>136</sup> *Fisher*, 421 F.3d at 1371.

<sup>137</sup> *Id.*

<sup>138</sup> *In re Jolles*, 628 F.2d 1322 (C.C.P.A. 1980).

<sup>139</sup> *Nelson v. Bowler*, 626 F.2d 853 (C.C.P.A. 1980).

<sup>140</sup> *Cross v. Iizuka*, 753 F.2d 1040 (Fed. Cir. 1985).

researched as to its effects.<sup>141</sup> Applicants have used: (1) in vivo data; (2) in vitro data; (3) pharmacological tests on animals; and (4) shown an actual DNA or protein target.<sup>142</sup> In each case, the applicant knew that the protein, chemical compound, or sequence had value because it was effective or useful in one or more of the listed applications.<sup>143</sup> Fisher did not attempt to prove his claims by any of the above listed applications; instead, he provided a simple list of what the claimed ESTs could in theory do.<sup>144</sup> The *Fisher* court held that without a firm indication of what the ESTs could actually do, it was not reasonable to grant a patent on the matter as claimed.<sup>145</sup>

But the *Fisher* court failed to recognize that, while specific and substantial utility is required for chemical compounds and intermediates, in the case of EST sequences such utility is immaterial.<sup>146</sup> On the surface, it appears that chemical compounds and ESTs are remarkably similar; but this is not always true.<sup>147</sup> While both chemical compounds and EST sequences may have homologous known materials, small changes in each can have huge effects on its use.<sup>148</sup> The difference lies in the fact that, in the present form, the chemical intermediaries in *Joly* and *Kirk* were useless while the ESTs in *Fisher* did have a use.<sup>149</sup> ESTs, regardless if they are targeted to a known protein, actually mark and identify such a gene or protein on which they sit.<sup>150</sup> This use, while seemingly trivial, allows one to test for the gene in a number of applications.<sup>151</sup> For example, ESTs can be used to test for activation of the gene within an experiment.<sup>152</sup> Thus the need to have a known use, as in chemical compounds, is unfounded in EST sequences

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<sup>141</sup> See e.g. *Jolles*, 628 F.2d 1322; *Bowler*, 626 F.2d 853; *Iizukia*, 753 F.2d 1040.

<sup>142</sup> Applicants in the *Jolles*, *Nelson* and *Cross* patents all made statements of utility, but based their claims on scientific data from their research. *Jolles*, 628 F.2d 1322, *Nelson*, 626 F.2d 853, *Cross*, 753 F.2d 1040. The difference between these cases and the *Fisher* patent is that *Fisher* did not properly qualify his research through some accepted research practice to show that the ESTs in the patent were directed to some actual protein target. *Fisher*, 421 F.3d at 1376.

<sup>143</sup> See e.g. *Nelson*, 626 F.2d 853, *In re Jolles*, 628 F.2d 1322, *Cross*, 753 F.2d 1040. Where in vivo data, or in vitro data was used to test the applicability and value of the compounds at issue. See e.g. *Nelson*, 626 F.2d 853, *In re Jolles*, 628 F.2d 1322, *Cross*, 753 F.2d 1040. The applicants here supported the asserted claims with data showing that the compounds specifically provided the claimed function. See e.g. *Nelson*, 626 F.2d 853, *In re Jolles*, 628 F.2d 1322, *Cross*, 753 F.2d 1040.

<sup>144</sup> *Fisher*, 421 F.3d at 1376.

<sup>145</sup> *Id.* Of course, this is the strength of this decision, that the Federal Circuit is requiring inventors to bring patents before the USPTO only when they in fact have value and not when they are merely early stages of an invention. *Id.* Inventors must fully analyze and research their inventions before they bring them before the USPTO before a patent will be granted. *Id.* When inventions are truly novel and actually confer value, few issues such as faced by *Fisher* in this case arise. *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> *Fisher*, 421 F.3d at 1376.

<sup>148</sup> See *id.* Where the small changes in chemical structure can lead to large changes in function. Chemical compounds along with proteins are known to exert great changes in their physical properties and chemical efficacy from small changes resulting in different shape or binding ability.

<sup>149</sup> *Id.* The use in the *Fisher* case is that the ESTs may be used in any of the asserted manners as suggested by the applicant in *Fisher*. *Id.* But convincing the court that an EST has value, while a novel chemical compound has no value, has proved to be too difficult a task. *Id.*

<sup>150</sup> *Id.*

<sup>151</sup> *Fisher*, 421 F.3d at 1376.

<sup>152</sup> *Id.*



since they have a use without regard to the identity of the underlying gene.

*D. The Brenner Court Concerns*

The *Brenner* court was primarily concerned with creating an unwarranted monopoly to the detriment of the public:

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 which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. 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 . . . But a patent is not a hunting license. It is not a reward to the search, but compensation for its successful conclusion.<sup>153</sup>

The *Brenner* concern is valid and is still of concern, but for different reasons than the *Fisher* case.<sup>154</sup> The concern should not be that we are creating such a monopoly; rather, that we are limiting disclosure and encouraging secrecy due to a narrow utility standard.<sup>155</sup> While it is extremely important in chemical cases to identify the actual underlying compound of interest when making a chemical intermediate, this is unnecessary in the patenting of an EST.<sup>156</sup> Useless chemicals have no function or value in contrast to ESTs or DNA sequences which can (and do) code for proteins and maintain significant commercial value.<sup>157</sup> Although these underlying proteins, or the underlying gene as in *Fisher*, did not have any known use it is precisely in these areas that future research will be directed towards seeking to unlock the mystery of diseases, functions of genes, or other breakthroughs.<sup>158</sup>

In light of this, the *Fisher* court, while echoing that a patent is not a “hunting license,” should also acknowledge that without a patent it is not feasible to undertake the immense financial burden of unlocking the potential of gene or a

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<sup>153</sup> *Brenner*, 383 U.S. at 534-36.

<sup>154</sup> *Id.*; see also *Fisher*, 421 F.3d at 1365.

<sup>155</sup> U.S. Const. art I, § 8, cl. 8. If, for example an EST was found, but not disclosed this would be contrary to the intent of the patent laws. *Id.* The point of a patent is of dual nature, you disclose the invention, including how to make and use it, for a limited period of exclusive use. *Id.* Secrecy seems to be contrary to the goals of the founders, although they may not have been able to imagine the current state of patents as it currently exists in the 21<sup>st</sup> century. *Id.*

<sup>156</sup> See *Brenner*, 383 U.S. 519. If a chemical exists but has not effect in-vivo or in-vitro, or in any biological system then by its inherent inability to react becomes less valuable to cause effects in a body. The EST on the other hand can and will be used in the laboratory to identify genes, thus it will have some use, even if it is identifying a gene or section of cDNA of no known use. *Fisher*, 421 F.3d 1365.

<sup>157</sup> *Fisher*, 421 F.3d at 1370.

<sup>158</sup> This may not always be true, as many areas of the genome include a redundancy, or introns, that do not translate any protein. Nonetheless, one can assume that the future breakthroughs will come from unexpected places as we learn more about the systems which we are studying.

particular protein.<sup>159</sup> ESTs provide a research tool to identify a specific sequence and in this manner, even though they do not code for a known useful gene or protein, they themselves should be patentable. The question becomes, which of these ESTs are useful and which are merely lists of potential EST sequences identified by a computer program? Ostensibly, both may have value, but which sequences will prove valuable is the million dollar question. Therefore, it is inappropriate to reject sequences simply because they may target an unknown region of the genome.<sup>160</sup>

It is fruitful to look at Example 9 of the USPTO's "revised Interim Utility Guidelines Training Materials" to see that a "cDNA fragment disclosed as being useful as a probe to obtain the full length gene corresponding to a cDNA fragment was deemed to lack a specific and substantial utility."<sup>161</sup> Furthermore, claims for "utility" as "gene probe[s]" or "chromosome marker[s]" fail to satisfy the utility requirement unless the invention points to a specific DNA target, which is also disclosed and which also possesses some utility itself.<sup>162</sup> Essentially, the claims of Fisher's ESTs are nothing more than "research intermediates that may help scientists to isolate the particular . . . genes."<sup>163</sup> According to *Brenner*, such claims and invention would merely be "object[s] of use-testing" which provides no assurance that the invention has any useful value.<sup>164</sup>

Example 9 of the USPTO materials reaches to the root of the problem that a small cDNA fragment, or in the case of *Fisher*, an EST, should not give rise to a claim for the entire full length gene that corresponds to that marker. However, the need to point to a specific gene is too narrow for the field and will limit research on new and inherently unknown areas.<sup>165</sup> Furthermore, as these genes become known, the USPTO may be forced to grant patents on these known genes intensifying the need for a different standard. The essence of the *Fisher* decision is that a claim for the entire sequence marked by the EST is not proper; while a full length DNA sequence is inherently patentable and proper.<sup>166</sup> The court goes too far in saying that an EST does not have any utility or that it lacks utility as a research tool; a closer analysis reveals that an EST does in-fact serve as a proper research tool.<sup>167</sup>

#### E. Research Tools

*Fisher's* final argument was that ESTs were similar to a microscope, in that each is a "research tool."<sup>168</sup> Instead, the court held that whether an invention is

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<sup>159</sup> *Fisher*, 421 F.3d at 1376.

<sup>160</sup> See *supra* note 35.

<sup>161</sup> *Fisher*, 421 F.3d at 1372-73.

<sup>162</sup> *Id.* at 1373.

<sup>163</sup> *Id.*

<sup>164</sup> *Brenner*, 383 U.S. at 535.

<sup>165</sup> *Fisher*, 421 F.3d at 1380 (J. Radar, dissenting).

<sup>166</sup> See generally *id.*

<sup>167</sup> *Id.*

<sup>168</sup> *Id.* at 1380.

useful as a research tool does not then confer that the invention is “useful” in a patent sense.<sup>169</sup> While many previous research tools such as the microscope, telescope, NMR,<sup>170</sup> GC-MC,<sup>171</sup> LC-MS,<sup>172</sup> etc. have been held to be patentable the court quickly points out that this analogy is flawed.<sup>173</sup> The court held that the difference is that a microscope has the benefit of immediately revealing the structure of its target.<sup>174</sup> Instead of being useful, the court held that the ESTs, while they enable one to generate data, cannot immediately reveal the structure or “the functions of the underlying gene.”<sup>175</sup> *Fisher’s* claims assert “hypothetical possibilities” which the ESTs could achieve but none that would have real world applicability.<sup>176</sup> Specifically, if any of the claims were to actually isolate promoters or useful proteins Fisher has failed to provide the evidence of such value.<sup>177</sup> Nor has Fisher disclosed or established any uses as a molecular marker or that any of the ESTs corresponds to any maize protein of any value.<sup>178</sup>

The court’s holding in regard to ESTs lacking any utility is flawed. As detailed in the dissent, it is apparent that there is utility and that the commercial success notwithstanding is further proof of the success of such a research tool.<sup>179</sup> Justice Rader commented in the dissent that “if the claimed ESTs qualify as research tools, then they have a ‘specific’ and ‘substantial’ utility sufficient for § 101.”<sup>180</sup> Thus, the test for utility in this case should not have focused on whether there was *specific and substantial utility*, for this exists if ESTs are research tools;

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<sup>169</sup> *Id.*

<sup>170</sup> *E.g.*, US Patent 4,998,976; US patent 5,063,934.

<sup>171</sup> *E.g.*, EP 0,708,475: *Mass spectra deconvolution method*; Gray, Zachary A.; Abel, Roger H. Hewlett-Packard Company; 1995, US 4,807,148; *Deconvolving chromatographic peaks*; Lacey; Richard F. , Palo Alto, CA; Hewlett-Packard Company, Palo Alto, CA; 1989.

<sup>172</sup> *E.g.*, US Patent 5,495,108.

<sup>173</sup> *Fisher*, 421 F.3d at 1373. The majority in *Fisher* suggests that such examples, such as the microscope confer a real world benefit. *Id.* The problem with this analysis is that we are allowing the Court to determine what is and is not useful. What may be useful to one may be junk to another, clearly the old saying “one man’s trash is another man’s treasure,” could not be more appropriate in this instance. *Id.* A microscope in many cases does no more than reveal a physical structure; where as an EST sequence may do no more than signal the presence of a DNA or cDNA sequence. *Id.* Each may be instrumental to some and utterly useless to others, simply depending on the experiment or the detail required. *Id.*

<sup>174</sup> *Id.*

<sup>175</sup> *Fisher*, 421 F.3d at 1373.

<sup>176</sup> *Id.* The dissent states, in direct opposition to the majority, that the EST may in fact be useful in the laboratory and therefore has a specific and substantial utility. Surprisingly, the majority does not attempt to assert any utility on the product, but instead suggests that it is the fault of the petitioner for his lack of detail regarding the usefulness of the inventions. *Id.*

<sup>177</sup> *Id.* While it is interesting to note that both promoters and proteins would prove to be extremely valuable. A promoter is simply a region of the gene that allows the gene to be transcribed. Each sequence must have a promoter to enable the sequences to be transcribed and created by the ribosome within the cell body. Absent the promoter, there will be not action. Proteins are the result of a transcribed region of the gene. Proteins are some of the most essential chemicals with the body, allowing use to function.

<sup>178</sup> *Id.* at 1374. Both promoters and proteins, as discussed *supra* note 177, are valuable, but so would be a sequence, or EST that enabled one to identify when such a sequence, corresponding to the protein or promoter was active or present in a particular mixture. *Id.*

<sup>179</sup> *Fisher*, 421 F.3d at 1370.

<sup>180</sup> *Id.* at 1379. (J. Rader, dissenting).

rather the test should be whether these particular ESTs do or do not enhance research.<sup>181</sup> If the latter, then *Brenner* will control and the ESTs may fail for lack of utility.<sup>182</sup> Furthermore, where *Joly's* and *Kirk's* applications failed because their intermediates produced compounds of no known use, the ESTs in *Fisher* have a clear known use within the laboratory setting. Thus, we should differentiate *Fisher* from *In re Joly* and *In re Kirk*, on the basis that the EST is useful because it in fact has known and actual use.

#### V. SOLUTIONS FOR EST UTILITY: NON-OBVIOUSNESS

The dissent suggests that the court should have addressed the patent under the obviousness standard, instead of resurrecting the heightened utility standard of *Brenner*.<sup>183</sup> Obviousness allows the court to see if the patent as presented would be obvious to one skilled in the art.<sup>184</sup> Such a standard properly allows the court to judge whether the invention provides any new leap in the field, or whether it is merely an adaptation or small change on the existing published material.<sup>185</sup> Obviousness prevents the court from determining whether the invention will be useful or not, simply based on their impressions of the invention and not on its real world value and applicability.<sup>186</sup>

The court's holding in *Fisher* will clearly limit the breadth of EST claims in future applications.<sup>187</sup> But, its unintentional consequences in this holding will do more harm than good. As Justice Rader suggested in the dissent, the patent office does not know which steps will contribute to a substantial breakthrough in genomic study.<sup>188</sup> Because of the nature of genomic research and that of ESTs, to hold that a genetic sequences of any length may not be useful because it does not claim to a specific useful gene, or hold out some other substantial use, is simply ignoring the complex nature of the science and its potential value within the laboratory.<sup>189</sup>

To be patentable, an invention must not only be useful, but also novel and non-obvious.<sup>190</sup> Interestingly, among these requirements, it is non-obviousness

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<sup>181</sup> *Id.*

<sup>182</sup> *Id.*, if the EST does in-fact enhance research it will have substantial value, absent any research functionality, it will serve as a placeholder in the vast array of known sequences.

<sup>183</sup> *Id.*

<sup>184</sup> *Id.*

<sup>185</sup> See e.g. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007); *Graham v. John Deere*, 383 U.S. 1 (1966).

<sup>186</sup> *Id.*

<sup>187</sup> See e.g. 884 PLI/PAT 247, 261 (2007), stating that in an instance such as the *Fisher* decision, the patent applicant will have to prove that the EST corresponds to a particular protein or gene, and that even when the practitioner can show that the EST has a target, that only a very narrow claim will be allowed.

<sup>188</sup> *Fisher*, 421 F.3d at 1379 (J. Rader, dissenting). Again the dissent correctly states that utility is not proper. When faced with the unknown, suggesting that it inherently has no value appears to be the wrong analysis.

<sup>189</sup> See generally, Chisum *supra* note 24.

<sup>190</sup> See 35 U.S.C. §§ 101-103, which states that an invention must be useful, novel and nonobvious. Furthermore the invention must enable one skilled in the art to use the invention and it must also give

that provides for the greatest legal uncertainty as to patentability.<sup>191</sup> Under the original 1793 Patent Act, utility and novelty existed as the only requirements for patentability.<sup>192</sup> It was not until 1851 in *Hotchkiss v. Greenwood* that the Supreme Court decided that patentability required something more than just utility and novelty.<sup>193</sup> *Hotchkiss* recited:

Unless more ingenuity and skill were required. . . than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention. In other words, the improvement is the work of the skillful mechanic, not that of the inventor.<sup>194</sup>

But it was not until the Patent Act of 1952, when Congress codified the essential holding of *Hotchkiss* that the law became firmly grounded in statute.<sup>195</sup> However, as with many laws, the original version as created by Congress was not without flaws and in 1966 the Supreme Court in *Graham v. John Deere Co.*, clarified the test for obviousness.<sup>196</sup> It requires that: (1) the scope and content of the prior art are to be determined; (2) differences between the prior art and the claims at issue are to be ascertained; and (3) the level of ordinary skill in the pertinent art resolved.<sup>197</sup> Finally, the Court suggested that secondary considerations “may have relevancy.”<sup>198</sup>

If the “prior art provides the motivation of suggestion for making an invention, the invention may be non-obvious – hence patentable – [only] if no enabling method is available at the time the invention is made.”<sup>199</sup> As applied to *Fisher*, such enabling method would have been available. Most likely, EST sequences are created by a mechanized or computerized program or process. The fact that the maize genome may not have been fully completed at the time does not inherently suggest that the five EST sequences in the patent were not available someplace, or were not suggested through teachings of any number of prior

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the best mode contemplated by the inventor and the specification must end with at least one claim as to give the proper scope as to the claimed invention.

<sup>191</sup> Ducor, *supra* note 3 at 11, discussing that the nonobvious condition is the most difficult concept in patent law. *Id.* There have been a number of standards over the course of lifetime of the nonobvious standard, and really there existed no proper standard until the *Hotchkiss* standard was codified in § 103 of the Patent Act of 1952. *Id.* Even after the 1952 Act, the nonobvious standard has undergone changes, most specifically the discussion in *Graham v. John Deere*, and most recently the Supreme Court case, under review of *KSR International v. Teleflex, Inc.* *Id.*

<sup>192</sup> Ducor, *supra* note 3 at 11

<sup>193</sup> *Id.*

<sup>194</sup> *Hotchkiss v. Greenwood*, 52 U.S. 248, 266 (1850).

<sup>195</sup> Ducor, *supra* note 3 at 12.

<sup>196</sup> *Graham v. John Deere*, 383 U.S. 1 (1966).

<sup>197</sup> *Id.* at 37-39.

<sup>198</sup> *Graham*, 383 U.S. 1; *see also* Ducor, *supra* note 3 at 40. Because later court decision have said that secondary consideration must always be taken into account in determining whether a patent is nonobvious. Ducor, *supra* note 3 at 40. Furthermore, there is significant evidence of nonobviousness that includes not just commercial success, but also considers the failure of others, unexpected results, evidence of copying, skepticism in the profession, and licensing, among others. *Id.*

<sup>199</sup> *Id.* at 33. Enablement as used here requires only that the inventor has a reasonable expectation of success to make the invention.

publications.<sup>200</sup>

In *Amgen v. Chugai*,<sup>201</sup> the Federal Circuit held that even if the prior art suggested that it was “obvious to try” to find a particular sequence, if there was no reasonable expectation of success, then such process was non-obvious.<sup>202</sup> This standard would certainly doom the *Fisher* patent, as by today’s standards creation of any EST sequences is a routine process automatically created by computers.<sup>203</sup> But these cases were overruled by *In re Deuel*,<sup>204</sup> which held that the reasonable expectation of success was improper.<sup>205</sup> But this is certainly an improper analysis for DNA-like sequences, as they are not created in a mechanical manner such as chemical compounds.<sup>206</sup>

The *In re Deuel* standard suggests that structural similarities in chemical compounds will make one obvious as to another.<sup>207</sup> But, in regards to DNA based structures such as the ESTs at issue here, they clearly have a similar structure based on the double helix.<sup>208</sup> Anyone skilled in the art or one that has taken basic genetics<sup>209</sup> knows that there are numerous ways to code for many of the amino acids, and that a different section of code can actually code for the same protein.<sup>210</sup> Instead, the standard for ESTs must focus on a system where any EST created that corresponds to an already created sequence, within some similarity, such as 90-

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<sup>200</sup> *Fisher*, 421 F.3d at 1367.

<sup>201</sup> *Amgen v. Chugai*, 927 F.2d 1200 (Fed. Cir. 1991).

<sup>202</sup> *Id.* at 1208.

<sup>203</sup> *Ducor*, *supra* note 3 at 35. EST sequences, like any other sequence is readily and effortlessly created on sequencing machines, essentially automated processes that determine the sequence of a particular nucleotide sample.

<sup>204</sup> *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995).

<sup>205</sup> *Id.*

<sup>206</sup> *Id.* at 43-45. Chemical compounds may be “created” or envisioned on a computer program or in times past, may have been written on the chalkboard. Each compound has certain “active sites” and it is these areas of the compound that give its functionality. Thus, chemical engineers look at the active site of the chemical and add or subtract features from it to create chemicals with new functionality. Such simple examples such as adding a single hydrogen instead of a double bond, or adding an oxygen group or a phenol ring would all add to a structure. But also, these additions may make small changes to an area but create a different chirality for the compound or left and right enantiomers. Such changes can make amazing changes or no change at all. For example, the class of opiate compounds, such as morphine, heroin, and codeine are all amazingly similar in structure but have significantly different effects in the body. See <http://www.a1b2c3.com/drugs/opi005.htm> (last visited January 1, 2007).

<sup>207</sup> See generally *In re Deuel*, 51 F.3d 1552.

<sup>208</sup> As identified briefly in the “genetics” section of this paper, the structure of the DNA is a double-helix shape, with pairs of amino acids bonding through a single hydrogen that create the structure. It is clear that all structures will have essentially the same shape, although there will be differences in the actual structure because of the slight differences in the amino acids, making even a single base pair change, resulting in a very small difference.

<sup>209</sup> A basic element of genetics is that there are many ways in which to code for any of the naturally occurring amino acids.

<sup>210</sup> This happens because each set of three bases codes for a single amino acid. For example Leucine (L), Serine (S), and Arginine (R) are all coded for six different ways: (L): CTT, CTC, CTA, CTG, TTA, TTG; (S): TCT, TCC, TCA, TCG, AGT, AGC; (R): CGT, CGC, CGA, CCG, AGA, AGG. While there are also two amino acids that are only coded for by single code patterns, Methionine (M), ATG; and Tryptophan (W), TGG. This shows the significant difference between the amino acids and shows how a single change in base pairs can make a significant difference or none at all. See <http://www.cbs.dtu.dk/courses/27619/codon.html>, for a full chart of the twenty amino acids and their potential coding pairs (last visited January 31, 2007).

95% similar, must not be considered novel.<sup>211</sup> This system is not perfect, but nonetheless when one creates sequences from a “library,” it seems that it is inherently obvious to anyone skilled in the art of how to make and use such sequences.<sup>212</sup> Thus, either only truly novel sequences should receive protection or all sequences should get protection.<sup>213</sup> Finally, sequences in which the character of the underlying gene or protein is identified should qualify for protection, because such functional sequences inherently confer more value than those to which the underlying gene is unknown.<sup>214</sup>

#### A. *The Fisher Patent is Obvious*

The court in *Fisher* is in error in holding that EST sequences are not useful, as they certainly hold value. But the patent may still fail under an obviousness test, which would provide a more concrete foothold for future patents instead of resurrecting the heightened utility standard from *Brenner*.<sup>215</sup> The purpose of a patent is to provide a platform for, and to reward ingenuity. It is not for the Court to determine if an invention is useful or not.<sup>216</sup> The essence of the *Brenner* decision is that it allows the court to determine the usefulness of a patent without first letting the market determine if it is in-fact useful.<sup>217</sup>

Most recently, the supreme court reaffirmed the strength of the *Graham* analysis, holding that the method developed by the Federal Circuit requiring a “teaching, suggestion or motivation,” did not conform with long held standards.<sup>218</sup> Non-obviousness analysis under the *Graham v. John Deere* standard will serve as the framework for determining whether an EST is patentable.<sup>219</sup> Under this analysis we analyze the following four (4) factors:

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<sup>211</sup> Wesley Elsberry, *Sequences and Common Descent How We Can race Ancestry Through Genetics*, <http://www.antievolution.org/people/wre/evc/argresp/sequence.html> (last visited 3/31/07). To further analyze, if a sequence of 500 base pairs is identical to another 500 base pair sequence, they are obviously the same. *Id.* Yet if a sequence of 500 base pairs is not identical, but still codes for the identical protein, these too must be considered to be related. Thus, if one sequence is 95% similar and codes for the identical protein as to a second sequence, then the second created sequences must not be considered novel, based upon the first sequence. *Id.*

<sup>212</sup> *See e.g. Graham*, 383 U.S. 1.

<sup>213</sup> *See e.g. Fisher*, 421 F.3d 1365.

<sup>214</sup> *Id.*

<sup>215</sup> *Brenner*, 383 U.S. 519, created the standard that a patent must have specific and substantial utility. *Id.* This Judicially created standard is different from the original intent of the Patent Act of 1793 standard that required only “useful.” *Id.* While the original standard is vague, the intent was to force inventors to create something that could be used. *Id.* Courts, inventors and the public have found that many things happen to be useful that on first appearance seem trivial. *Id.* It is not for the court to decide what is “substantially” useful and this is the inherent flaw and the increased standard found in the *Brenner* decision. *Id.*

<sup>216</sup> *Id.*

<sup>217</sup> *Id.*

<sup>218</sup> *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

<sup>219</sup> *Graham*, 383 U.S. 1.

### 1. *The Scope and Content of the Prior Art*

The ESTs in Fisher's application were for *Zea mays*, or better known to the layman as maize or corn.<sup>220</sup> At the time of the application the Maize genome was beginning to be described.<sup>221</sup> Certainly many important genes had already been discovered in a number of similar plants, among them *Arabidopsis Thaliana* (*A. Thaliana*), *Glycine Max* (soybean), and *Oryza Sativa* (rice).<sup>222</sup> The fact of the matter is that the prior art did show and suggested that one in the art should combine the knowledge of genetic sequencing with any and all valuable crop species.<sup>223</sup> Specifically here, Fisher was working with maize, a monocot plant, and one would imagine that such differences between previously identified monocot and dicot plants would not be so different that the results would be unusual.<sup>224</sup> Thus, the scope and content of the prior art suggests that the sequences, while novel, may have been obvious to one skilled in the art.<sup>225</sup>

### 2. *Differences Between the Prior Art and the Claims at Issue*

The differences between the prior art and the claims at issue are relatively small.<sup>226</sup> All gene sequence patents essentially hold out the same or similar claims as the *Fisher* patent.<sup>227</sup> The prior art would likely suggest using the ESTs in the manner suggested by the *Fisher* patent.<sup>228</sup> Thus the difference between the art and the claims is small and would suggest that the patent may be obvious to one skilled in the art.<sup>229</sup> But we need to be wary of gathering the "prior art with the invention in mind," as hindsight is a dangerous weapon against any patent.<sup>230</sup>

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<sup>220</sup> *Fisher*, 421 F.3d 1365.

<sup>221</sup> <http://www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi?id=381124> (last visited January 29, 2007).

<sup>222</sup> *Id.* While not relevant to the prior art, it is interesting to note that the current database found at <http://www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi?id=381124> (last visited January 29, 2007), includes some 486,480 nucleotides for the maize genome. It is relevant to point out how easily such sequences are produced, and in 2003 or earlier, when Fisher was creating the sequences at issue, such mechanized or computerized systems were available and in use. *Id.*

<sup>223</sup> *See Fisher*, 421 F.3d 1365.

<sup>224</sup> *See* <http://www.ucmp.berkeley.edu/glossary/gloss8/monocotdicot.html> which discusses the differences between monocot and dicot plants. The essential issue being that as long as there was a single monocot plant that was in the prior art, it would have been obvious to one in the art, and would have been reasonably likely to succeed, creating ESTs for the maize genome.

<sup>225</sup> *See Fisher*, 421 F.3d 1365.

<sup>226</sup> *Id.*

<sup>227</sup> *Id.*

<sup>228</sup> *Id.*

<sup>229</sup> *Id.*

<sup>230</sup> *See Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309 (1985), where the court held "prior art may not be gathered with the claimed invention in mind."



### 3. *The Level of Ordinary Skill in the Pertinent Art*

Here, we find that the ordinary skill in the relevant art is actually very low.<sup>231</sup> Many entry level biologists, chemists, chemical engineers, and geneticists work in the numerous small and large companies throughout the world on sequencing plants and animals.<sup>232</sup> Such analysis is almost always done on a computerized or mechanized program and can be taught even to those not skilled in the relevant art.<sup>233</sup> While higher level understanding may be more advanced, I would suggest that there are many thousands of persons who would understand the issues at hand. But one needs to be cautious that they are not looking at such a patent in hindsight.<sup>234</sup> Clearly today, just some five years later, the patent may seem obvious, but at the time it may have been more nuanced than we would expect.<sup>235</sup>

### 4. *Secondary Considerations*

If we conclude that simply because a patented invention has financial benefits for its inventor, or that it has a clearly defined market, then we would have to conclude that ESTs are non-obvious.<sup>236</sup> But the success of an invention in the market is considered in the secondary considerations aspect of the non-obviousness analysis.<sup>237</sup> Here, the value of Fisher's EST sequences is significant and Fisher may even be able to make significant profit from the invention; yet that does not mean that it should be patentable.<sup>238</sup> Instead, other means of protection (such as trade secret) might serve as an appropriate vehicle for Fisher to profit from the invention for a limited time.<sup>239</sup>

*Graham v. John Deere* provides a set of factors in which to analyze the patent against prior art.<sup>240</sup> The four factor test suggests that the *Fisher* patent is

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<sup>231</sup> See *Fisher*, 421 F.3d 1365.

<sup>232</sup> See *supra* note 202.

<sup>233</sup> *Id.*

<sup>234</sup> *Graham*, 383 U.S. 1.

<sup>235</sup> *Webster Loom Co. v. Higgins*, 105 U.S. 580, 591 (1881), where the court first warned of the dangers of hindsight stating: "[I]t is plain, from the evidence and from the very fact that it was not sooner adopted and used, that it did not, for years, occur . . . to even the most skillful persons. It may have been under their very eyes, they may almost be said to have stumbled over it; but they certainly failed to see it, to estimate its value and to bring it into notice. . . . Now that it has succeeded, it may seem very plain to anyone, that he could have done it as well. This is often the case with inventions of the greatest merit. It may be laid down as a general rule, though perhaps not an invariable one, that if a new combination and arrangement of known elements produce a new and beneficial result, never attained before, it is evidence of invention."

<sup>236</sup> Through the mid 1990's at least six larger firms had spent at least \$100 million on licensing fees for EST sequences. <http://www.nap.edu/readingroom/books/property/5.html> (last visited January 31, 2007).

<sup>237</sup> See *Graham*, 383 U.S. 1.

<sup>238</sup> See *Fisher*, 421 F.3d 1365.

<sup>239</sup> Trade secret protection is available as a form of intellectual property "protection." While there is no actual hard and fast protection in trade secret, one is protected if the information is stolen or misappropriated from the company. *Id.* Trade secret is a commonly used form of protection, with the most famous trade secret, being the formula for Coca Cola®.

<sup>240</sup> See *Graham*, 383 U.S. 1.

likely taught by the relevant art, but nonetheless it may still produce novel sequences.<sup>241</sup> Thus we create a problem where novel and valuable information is created, but it is created through a process that may have been obvious to anyone in the art, and it may have only been created later because of cost.<sup>242</sup> Thus, the nonobvious standard would be a superior method to analyzing the *Fisher* patent.

## VI. EFFECTS OF THE *FISHER* LIMITATION

What *Fisher* actually accomplishes is limiting the scope of the claims of EST applications.<sup>243</sup> Due to this limitation there will be some unwanted consequences.<sup>244</sup> The *Fisher* court claimed that there is no utility unless there can be conferred “real world benefit.”<sup>245</sup> The problems that exist associated with attributing this so called “real world benefit” are that the true benefits can only be seen through hindsight.<sup>246</sup> Many patents are given for products that turn out later to have absolutely no value, but since they are judged at the time of filing it is impossible to say whether or not they have utility.<sup>247</sup> The same logic should follow here with the EST sequences; we will not know what is useful until some years later.<sup>248</sup> It is not the job of the USPTO to recognize on first glance those inventions that will provide incremental gains into scientific knowledge; rather, it is the job of the USPTO to give rights to those who want to patent inventions which may lead to these incremental gains.<sup>249</sup>

Returning to the hypothetical at the beginning, SMALL did not file a patent application because of the inherent limitations on its proposed claims. Instead, consider the situation where multiple companies might each independently be working on the same gene or idea due to the lack of patents on that issue. Each group might then be working on the same issues and, as a result, each might end up reinventing the wheel. Thus, without the public disclosure there would be a duplication of resources which is excessive.<sup>250</sup> This does not benefit society at

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<sup>241</sup> See *Fisher*, 421 F.3d 1365.

<sup>242</sup> It is expensive to not only purchase the necessary computers and machines to properly sequence, but it is extremely labor intensive to ensure that the work is done properly under laboratory conditions and that it is replicable for future experiments. The Maize genome was a secondary project to Arabidopsis, because it is much longer than the Arabidopsis genome. Arabidopsis was completed in 2000, with five chromosomes and between 120 and 130 million base pairs. [http://www.arabidopsis.org/portals/genAnnotation/gene\\_structural\\_annotation/agicomplete.jsp](http://www.arabidopsis.org/portals/genAnnotation/gene_structural_annotation/agicomplete.jsp) (last visited January 31, 2007). While the maize genome boasts ten chromosomes and some 2.5 billion nucleotides, see <http://www.maizegenome.org> (last visited January 31, 2007).

<sup>243</sup> *Fisher*, 421 F.3d 1365.

<sup>244</sup> See *id.* One of many cases where a patent was not conferred due to the restrictions placed upon inventors by the USPTO. In the case of *Fisher*, time has not yet told whether the invention was truly novel and useful.

<sup>245</sup> *Id.* at 1371.

<sup>246</sup> By this I mean that it is difficult to envision which products will eventually be a success. For example, if everyone knew that the “George Foreman Grill” would be so successful, someone would have made it earlier.

<sup>247</sup> Van Cleave, *supra* note 74.

<sup>248</sup> *Fisher*, 421 F.3d at 1381.

<sup>249</sup> *Id.*

<sup>250</sup> U.S. Const. art I § 8 cl. 8.

large; in fact, it contradicts the purpose of patents as promotions of inventions and stifles the inventive process.<sup>251</sup>

A second negative impact from the *Fisher* decision is that because of the limitation and restriction on claims, companies such as SMALL might be hesitant to research into “dead end” pathways or proteins due to their patent claims being limited without a known target.<sup>252</sup> This, also, seems contrary to the purpose of patents. Society should encourage the type of research that will lead to revolutionary discoveries such as curing debilitating diseases and eradicating harmful viruses and bacteria. Without companies such as SMALL researching into highly unpredictable areas we will limit the future of American research and allow such inventions to be born outside of the United States.

To fix the issue at hand, ESTs need to be recognized as “research tools” and given their due as such. This means that while one cannot file infinite patents of every known 350bp combination,<sup>253</sup> the standards for utility of an EST should return to the pre-*Fisher* standard.<sup>254</sup> ESTs as “research tools” are useful and to find them unpatentable, one needs to seek another hurdle. This hurdle should instead be one of obviousness, as suggested in Justice Rader’s dissent.<sup>255</sup>

This issue demands a solution. One suggestion would be that an inventor would have to prove that there were no other known markers on the same gene before a patent could be awarded on that EST. Another possible answer is to create a separate class of patents for such sequences in general, possibly giving a seven year exclusive period instead of twenty years, or some other shorter duration. Finally, ESTs could be limited to one per gene, and would be required to be of a set length. Regardless if these suggestions affect current law, these suggestions would hold that for many species no more EST patents would be available. For many species, the underlying sequences have been publicly accessible within the past few years, thereby relegating them to being obvious. These solutions will meet the goals of the USPTO in limiting EST applications; yet, more importantly, they will still award novel EST applications their proper patent protection.

## VII. CONCLUSION

While we can understand the Court of Appeals wanting to help the USPTO limit the EST sequence applications, we should also recognize that more benefit has come from EST sequences in areas such as cancer research than many other research tools before them.<sup>256</sup> Rejecting ESTs for obviousness would simplify the USPTO’s problem, while ESTs identified in novel areas or areas of interest would still find utility and would therefore protect the investment of the company. This

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<sup>251</sup> *Id.*

<sup>252</sup> *Fisher*, 421 F.3d 1365.

<sup>253</sup> As a reference, the five EST sequences in the *Fisher* patent were 429, 423, 365, 411, and 311 base pairs long. *Id.*

<sup>254</sup> *See e.g. Brenner*, 383 U.S. 519.

<sup>255</sup> *Fisher*, 421 F.3d at 1382.

<sup>256</sup> *Id.* at 1380.

would then again help promote the discovery of novel sequences.

In our hypothetical, under an obviousness claim, SMALL would have known that its EST was useful under the patent laws. But it would have had to face the task of proving that the invention and the sequence was not obvious in light of the prior art.<sup>257</sup> But, by pursuing the patent the public would have been aware of the gene and its potential implications on disease XYZ and other companies might have either licensed the patent or found a way to work around it while still focusing on the gene. This would then promote the furtherance of scientific inquiry on the topic and, in time, would save resources and lead to faster developments regarding the treatment of XYZ.

Allowing judges to decide what is and is not useful is not only foolish, but it is a waste of such judicial resources. Judges are not usually skilled in the relevant art – nor can we say today what may or may not be useful tomorrow. It is the role of patent law to allow for new inventions without creating undue hurdles. Furthermore, we want to promote discovery, not limit the creation of new and useful works of art.

Patent application for EST sequences should face the burden of obviousness, not that of utility. There is strong evidence to prove that an EST sequence has at least some laboratory utility and that alone should be sufficient to overcome the minimal burden of the utility standard.<sup>258</sup> Obviousness is a stronger standard and faces a more demanding proof, but with more factual analysis. In this manner, obviousness can reduce judicial interpretations of what is and is not useful.

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<sup>257</sup> *KSR Int'l Co. v Teleflex Inc.*, 127 S. Ct. 1727 (2007). Here, the analysis of the *Graham* factors would clear up the issue of what makes a particular sequence obvious over another. *Id.* Similarly, it would be interesting to see how the Court would treat secondary considerations and the relevant skill of the art for such inventions. *Id.*

<sup>258</sup> *Fisher*, 421 F.3d at 1381.