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# The New Conquistadors: Patent Law and Expressed Sequence Tags

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# The New Conquistadors: Patent Law and Expressed Sequence Tags

MATTHEW RIMMER\*

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## ***Abstract***

*This article analyses recent litigation over patent law and expressed sequence tags (ESTs). In the case of In re Fisher, the United States Court of Appeals for the Federal Circuit engaged in judicial consideration of the revised utility guidelines of the United States Patent and Trademark Office (USPTO). In this matter, the agricultural biotechnology company Monsanto sought to patent ESTs in maize plants. A patent examiner and the Board of Patent Appeals and Interferences had doubted whether the patent application was useful. Monsanto appealed against the rulings of the USPTO. A number of amicus curiae intervened in the matter in support of the USPTO - including Genentech, Affymetrix, Dow AgroSciences, Eli Lilly, the National Academy of Sciences, and the Association of American Medical Colleges. The majority of the Court of Appeals for the Federal Circuit supported the position of the USPTO, and rejected the patent application on the grounds of utility. The split decision highlighted institutional tensions over the appropriate thresholds for patent criteria - such as novelty, non-obviousness, and utility. The litigation raised larger questions about the definition of research tools, the incremental nature of scientific progress, and the role of patent law in innovation policy. The decision of In re Fisher will have significant ramifications for gene patents, in the wake of the human genome project. Arguably, the USPTO utility guidelines need to be reinforced by a tougher application of the standards of novelty and non-obviousness in respect of gene patents.*

It's akin to the old Spanish, English and Portuguese explorers. They would take their boats until they found some edge of land, then they would go up and plant the flag of their king or queen. They didn't know what they'd discovered; how big it is, where it goes to - but they would claim it anyway.

David Korn of the Association of American Medical  
Colleges<sup>1</sup>

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<sup>1</sup> Stacy Lawrence, 'US Court Case to Define EST Patentability' (2005), *Nature Biotechnology*, <<http://www.nature.com/news/2005/050502/full/nbtO505->

## 1. Introduction

There has been much animated policy debate about whether gene fragments called expressed sequence tags - known by the acronym 'ESTs' - deserve protection under patent law.<sup>2</sup>

The Human Genome Organisation (HUGO) raised concerns that, although it was not difficult to generate ESTs, it was much more difficult to isolate genes and to determine their function. In 1997, HUGO expressed regret over 'the decision of some patent offices, such as the USPTO to grant patents on ESTs based on their utility' as probes to identify specific DNA sequences, urging these offices to rescind these decisions and, pending this, to strictly limit their claims to specified uses, since it would be untenable to make all subsequent innovation in which EST sequences would be involved in one way or other dependent on such patents.<sup>3</sup> In 2000, HUGO emphasized in its statement on patenting DNA sequences its 'previous call to patent offices not to issue patents on ESTs without having found balanced solutions for the obvious problem of arising dependencies.'<sup>4</sup> HUGO expressed 'serious concerns about the negative impact on further progress of genomic research and successful exploitation of its results should broad claims of the so-called "having" and "comprising" type be issued for ESTs.'<sup>5</sup>

Similarly, the Nuffield Council on Bioethics, led by Sandy Thomas, recommended that 'when rights are asserted in terms intended to cover all sequences that contain an EST that is the subject of the original patent, no

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[513.html](#)> at 1 May 2007.

<sup>2</sup> 'An EST is a short nucleotide sequence that represents a fragment of a cDNA clone. It is typically generated by isolating a cDNA clone and sequencing a small number of nucleotides located at the end of one of the two cDNA strands. When an EST is introduced into a sample containing a mixture of DNA, the EST may hybridize with a portion of DNA. Such binding shows that the gene corresponding to the EST was being expressed at the time of mRNA extraction.' Michel CJ, *In re Fisher* 421 F.3d 1365 at 1367 (C.A.Fed.,2005).

<sup>3</sup> Human Genome Organisation Intellectual Property Committee, *Statement on Patenting Issues Related to the Early Release of Sequence Data* (1997), <<http://www.hugointernational.org/PDFs/Statement%20on%20Patenting%20Issues%20Relating%20to%20Raw%20Sequence%20Dat.pdf>> at 1 May 2007.

<sup>4</sup> Human Genome Organisation Intellectual Property Committee, *Statement on Patenting DNA Sequences In Particular Response to the European Biotechnology Directive* (2000): <<http://www.hugointernational.org/PDFs/Statement%20on%20Patenting%20of%20DNA%20Sequences%202000.pdf>> at 1 May 2007.

<sup>5</sup> Ibid.

patent should be granted'.<sup>6</sup> The Australian Law Reform Commission acknowledged that attempts to patent ESTs raised questions of utility for the purposes of patent law: 'ESTs and SNPs may be used to identify previously unknown genetic sequences or as templates for expressing and characterising proteins for the purposes of further research'.<sup>7</sup>

By contrast, some commentators have sought to downplay the policy concerns that patents over ESTs would impede further research, allow 'reach-through' claims, and provide disproportionate rewards for routine steps. In a study of the United States, European, and Japanese patent offices, Melanie Howlett and Andrew Christie commented that patent examiners would reject patent applications, in hypothetical scenarios, in respect of ESTs on the grounds that there was a lack of utility:

This analysis of the Trilateral Office's comparative study has shown that the widespread concern relating to the utility of EST patents seems to be unfounded. A claim to a DNA sequence used as a probe to locate and identify genes of unknown function will not satisfy the utility requirement. Where a DNA sequence is used as a probe to obtain the full length DNA, the requirement of utility or industrial applicability will only be satisfied when the corresponding protein's function or biological activity is known and has specific utility.<sup>8</sup>

Howlett and Christie concluded: 'Accordingly, it seems that the fear of numerous EST patents inhibiting later research is also unfounded'.<sup>9</sup> However, such a statement fails to account for the conflicts that have broken out between ambitious biotechnology companies making patent applications in respect of ESTs, and commercial and public research institutions who are concerned about such over-reaching claims.

The question of the patent protection of ESTs has re-emerged in the case of *In re Fisher* before the Court of Appeals for the Federal Circuit.<sup>10</sup> The

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<sup>6</sup> Nuffield Council on Bioethics, *The Ethics of Patenting DNA*, A Discussion Paper: (2002), <[http://www.nuffieldbioethics.org/go/ourwork/patentingdna/publication\\_310.html](http://www.nuffieldbioethics.org/go/ourwork/patentingdna/publication_310.html)> at 1 May 2007 at 58.

<sup>7</sup> Australian Law Reform Commission, *Gene Patenting and Human Health*, Issue Paper 27. (2003): (2003), <<http://www.austlii.edu.au/au/other/alrc/publications/issues/27/>> at 1 May 2007 at 136.

<sup>8</sup> Howlett, Melanie and Andrew Christie, 'An Analysis of the Approach of the European, Japanese and United States Patent Offices to Patenting Partial DNA Sequences (ESTs)' (2003) 34 *International Review of Industrial Property and Copyright* 581-602.

<sup>9</sup> Ibid.

<sup>10</sup> *In re Fisher* 421 F.3d 1365 (CA.Fed., 2005).

agricultural biotechnology firm, Monsanto, applied for a patent in respect of ESTs for identifying nucleic acid sequences in maize genes.

The United States Patent and Trademark Office (USPTO) considered whether the application met the statutory requirements of the *Patent Act* 1952 (US). 35 U.S.C. § 101 provides: '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.' The provision lays down the requirements for eligible patentable subject matter; it also requires that an invention be useful. Furthermore, 35 U.S.C. § 102 and 35 U.S.C. § 103 of the legislation require that an invention be novel and non-obvious to a person skilled in the art when compared to the prior art. 35 U.S.C. § 112 demands:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In respect of the patent application of Monsanto, the examiner rejected the patent application on the grounds that the patent claim lacked utility under 35 U.S.C. § 101; was anticipated by two prior art references under 35 U.S.C. § 102; and failed to satisfy the enablement and written description requirements of 35 U.S.C. § 112. The Board of Patent Appeals and Interferences ruled that the claim was unpatentable because of a lack of utility and enablement.<sup>11</sup> The Court of Appeals for the Federal Circuit ruled by a majority of two to one that patent application by the Monsanto scientists was invalid because of a lack of utility.<sup>12</sup> The decision highlighted tensions within the institution over the appropriate thresholds for statutory criteria in respect of gene patent applications.

This article explores the recurring legal debates over the patentability of ESTs. It is argued that heightened utility guidelines alone will fail to properly regulate gene patent applications; there is a need to raise the thresholds of novelty and inventive step. Section 1 investigates the patent applications filed by J. Craig Venter and the National Institutes of Health (NIH) in respect of ESTs. Section 2 explores the development of administrative guidelines by the USPTO in respect of utility and biotechnological inventions. Section 3 examines the arguments of the applicants, respondents and friends of the court in the Court of Appeals for the Federal Circuit *In re Fisher*. Section 4 analyses the divisions amongst the judges, Michel CJ and Rader J, in the Court of Appeals for the Federal Circuit

<sup>11</sup> *Ex parte Fisher* 72 U.S.P.Q.2d 1020, 2004 WL 2185929 (United States Patent and Trademark Office Board of Patent Appeals and Interferences), <[http://patentlaw.typepad.com/patent/Ex\\_20Parte\\_20Fisher.pdf](http://patentlaw.typepad.com/patent/Ex_20Parte_20Fisher.pdf)>

<sup>12</sup> *In re Fisher* 421 F.3d 1365 (CA.Fed., 2005).

*In re Fisher*. In particular, it focuses upon the debate as to whether ESTs could be best conceived of as research tools, and the proper threshold for determinations of utility. The conclusion considers the implications of the decision of the Court of Appeals for the Federal Circuit of *In re Fisher* for the patent applications in respect of genes and gene sequences, in the wake of the human genome project. It examines the interpretation and application of the decision of *In re Fisher* by the Board of Patent Appeals and Interferences in a number of recent rulings.<sup>13</sup> It is questioned whether the administrative guidelines in respect of utility will be sufficient to address the policy problems associated with gene patents. The decision of the Supreme Court of the United States in *KSR International Co. v. Teleflex, Inc* underlines the need for a tough application of the standards of novelty and non-obviousness in respect of gene patent applications.<sup>14</sup>

## 2. *Darth Venter*

In 1991, the NIH sought to obtain patent protection in relation to thousands of DNA sequences corresponding to portions of expressed genes. The leader of this project, J. Craig Venter, called these gene fragments 'expressed sequence tags', or ESTs. He recalled the impetus for this scientific work:

When I was at NIH, I was a Section Chief at the National Institute for Neurological Disease and Stroke (NINDS). My lab was involved in a large scale chromosome sequencing effort to discover genes associated with neurological functioning and disease. During this research, my colleagues and I developed a new strategy for identifying genes more rapidly and at much less expense than previously had been possible... With the new strategy we greatly exceeded the work of many previous years of effort in just a few months. This new strategy known as Expressed Sequence Tags (ESTs) was published in the journal *Science* in June 1991.<sup>15</sup>

The NIH sought to protect not only the ESTs themselves, but also the full-length sequences from which the ESTs were derived and the protein

<sup>13</sup> *Ex Parte Raymond H. Boutin* 2006 WL 2822238, \*4+ (Bd.Pat.App & Interf. Sep 28, 2006) (NO. APL 2006-1879, APP 10/010,114); *Ex Parte Preeti Lal, Neil Corley et. al* 2006 WL 2710996, \*3+ (Bd.Pat.App & Interf. Sep 18, 2006) (NO. APL 2006-1035, APP 09/925,140); *Ex Parte d. Wade Walke* 2006 WL 2711006, \*2+ (Bd.Pat.App & Inter. Sep 18, 2006) (NO. APL 2006-2131, APP 10/309,422); *Ex Parte Preeti Lal, Jennifer Hillman, et al.*, 2006 WL 1665364, \*3+ (Bd.Pat.App & Interf. Jan 01, 2006) (NO. APL 2005-0102, APP 09/840,787); *Ex Parte Gary C. Starling*, 2006 WL 1665405, \*2+ (Bd.Pat.App & Interf. Jan 01, 2006) (NO. APL 2005-2121, APP 09/745,605).

<sup>14</sup> *KSR International Co. v Teleflex, Inc.* 2007 WL 1237837, 82 U.S.P.Q.2d 1385 (2007).

<sup>15</sup> J. Craig Venter, 'The Human Genome Project', Congressional Testimony Before the Subcommittee on Energy and Environment, United States House of Representatives Committee on Science', (1998), 17 June.

products encoded by the full-length sequences, without first determining the biological function of the encoded protein products. The funding agencies asserted a number of utilities, including the design of oligonucleotides for use in chromosomal analysis, PCR amplification, and recovering the corresponding full-length gene.

## 2.1 Bernadine Healy and The National Institutes of Health

The new head of the NIH, Bernadine Healy, sought to pursue a new technology transfer strategy for the funding agency, seeking patent rights in respect of research that it had underwritten.<sup>16</sup> She declared that obtaining patents was a social good: 'I think the patent system is the underpinning of commercializing new products'<sup>17</sup> Healy sought to explain the controversial decision of the public funding agency to seek patents in respect of ESTs:

NIH has taken the interim steps of publishing, and simultaneously applying for a patent to protect, the series of more than 2,000 partial gene sequences discovered in its laboratory. The rationale is not to make money, but rather to promote and encourage the development and commercialization of products to benefit the public and to do so in a socially responsible way<sup>18</sup>.

Healy acknowledged that the decision to seek patent applications was controversial and had attracted much criticism. However, she defended her actions, observing that if the NIH had simply published its genetic research without legally protecting them, the full genes might not be patentable by anyone. Healy observed that, if the patent applications were granted, the funding agency would license the rights to private developers. She commented: 'In the face of these many uncertainties, the NIH and the Department of Health and Human Services have adopted a pragmatic interim policy that protects our options and the interests of taxpayers'.<sup>19</sup>

Healy wrote that 'the NIH is amenable to an international agreement that patent protection not be sought for partial gene sequences the function of which is unknown if it is clear that publishing the sequences, however extensive, as "incomplete discoveries" will not impede the ability to obtain adequate patent protection subsequently for the full gene.'<sup>20</sup> She reflected that sui generic legislation might be needed to address genetic inventions:

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<sup>16</sup> Edmund Andrews, 'Making a Difference; Dr. Healy's Big Push on Patents', *The New York Times* (New York), 16 February 1992 at 12.

<sup>17</sup> Ibid.

<sup>18</sup> Bernadine Healy, 'On Patenting Genes' (1992) 327 (9) *New England Journal of Medicine* 664-668 at 665.

<sup>19</sup> Ibid at 667.

<sup>20</sup> Ibid at 667.

'Alternatively, new legislation may be needed, as was the case for varieties of plants developed by breeding in the agricultural sector or for the protection of semiconductor-chip masks in the computer industry'.<sup>21</sup> Healy concluded that biotechnology raised questions unforeseen by the inventors of the patent regime: 'Surely, Thomas Jefferson could never have predicted what a quandary his highly successful patent system would face over Mother Nature's secrets.'<sup>22</sup>

James Watson - the co-discoverer of the Double Helix, Nobel laureate, the head of the United States Human Genome Project - doubted the wisdom of lodging patent applications in respect of ESTs where there was no knowledge of the function of particular genes. He questioned the 'non-obviousness' of Venter's sequencing work, calling it 'sheer lunacy' and 'brainless work... this is a perfect case of a brainless robot'.<sup>23</sup> Cuttingly, he suggested that the EST program 'could be run by monkeys'.<sup>24</sup> Watson was concerned that the plan to patent the random DNA sequences would undermine the national and international collaboration behind the Human Genome Project.<sup>25</sup> He pointed out: 'If Craig can do it, so can the UK.'<sup>26</sup> Watson later reflected:

The very notion of blindly patenting sequences without knowledge of what they do was outrageous.... This conduct could only be seen as a preemptive financial claim on a truly meaningful discovery someone else might yet make.<sup>27</sup>

Watson was shocked that the NIH had applied for patents in respect of ESTs, without consulting him. For her part, Healy was 'enraged when Watson began denouncing the plan as idiotic and destructive to the project, the biotech industry, and international relations'.<sup>28</sup> In 1991, Watson resigned as the director of the United States Human Genome Project, because of his antagonistic conflict with Healy and his anger at the decision to patent

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<sup>21</sup> Ibid at 667.

<sup>22</sup> Ibid at 668.

<sup>23</sup> Kevin Davies, *The Sequence: Inside the Race For The Human Genome* (2001) at 62.

<sup>24</sup> Ibid.

<sup>25</sup> Leslie Roberts, 'Genome Patent Fight Erupts: An NIH Plan to Patent Thousands of Random DNA Sequences Will Discourage Industrial Investment and Undercut the Genome Project Itself, the Plan's Critics Charge' (1991) 254 (5029) *Science* 184.

<sup>26</sup> Ibid.

<sup>27</sup> Watson, James with Andrew Barry (2004), *DNA: The Secret of Life*, 180.

<sup>28</sup> Leslie Roberts, 'Why Watson Quit As Project Head' (1992) 256 *Science* 301-302.



ESTs.<sup>29</sup>

The academic, Rebecca Eisenberg, observed that the dispute over the patent applications in respect of ESTs involved a curious reversal of positions from the debate in *Diamond v. Chakrabarty*.<sup>30</sup> She noted that the government agency enthusiasm for patenting express sequence tags stood at odds with the ambivalence of industry groups: A telling distinction between the present controversy and that which erupted around the time of the *Diamond v. Chakrabarty* decision is that today it is the federal government that is pushing forward in pursuit of patent protection, while industry representatives are hesitating on the sidelines. And although some scientists are raising their voices in a now familiar refrain about the detrimental effects of patenting on scientific communications, the present controversy seems to be as much about the role of patents in promoting product development as it is about the role of patents in basic research.<sup>31</sup>

Eisenberg questioned whether the claims of the NIH were well-founded: 'At the very least, it seems fair to say that the first premise of NIH's argument - that it is entitled to patent rights that will offer effective commercial protection to licensees seeking to develop related products - is subject to considerable doubt under current law.'<sup>32</sup> She also doubted whether the funding agency needed patent protection to garner industry support: 'It is worth noting that views expressed to date by industry trade groups generally contradict NIH's hypothesis that patent protection for the sequences may be necessary in order to protect the interests of firms that might develop related products in the future.'<sup>33</sup>

## 2.2 The United States Patent and Trade Mark Office

On the 20 August 1992, the USPTO rejected the patent applications over the ESTs. It ruled that the claims failed to meet the patent criteria - novelty, non-obviousness, and utility - because they were 'vague, indefinite, misdescriptive, incomplete, inaccurate, and incomprehensible'.<sup>34</sup> The NIH case was apparently damaged by the identification of 15-letter segments in

<sup>29</sup> Robert Cook-Deegan, *The Gene Wars: Science, Politics And The Human Genome* (1994) at 333-340; Kevin Davies, *The Sequence: Inside The Race For The Human Genome* (2001) at 30-31; Glyn Moody, *Digital Code of Life: How Bioinformatics is Revolutionizing Science, Medicine, and Business* (2004) at 50-51; and James Shreeve, *The Genome War: How Craig Venter Tried to Capture the Code of Life and Save the World* (2004) at 80-85.

<sup>30</sup> *Diamond v Chakrabarty* 447 US 303 (1980)

<sup>31</sup> Rebecca Eisenberg, 'Genes, Patents, and Product Development' (1992) 257 (5072) *Science* 903.

<sup>32</sup> Ibid.

<sup>33</sup> Ibid.

<sup>34</sup> Kevin Davies, above n 29 at 63.

some of the ESTs in other genes in the database. Bernadine Healy told the Senate Judiciary Committee's Subcommittee on Patents, Copyrights and Trademarks about the adverse decision:

The PTO, in its initial finding, rejected the pending claims, questioning whether the inventions were novel, useful, and nonobvious. It should be noted, however, that these issues are raised by the PTO in well over 90 percent of all patent applications - and that the preliminary finding is typically part of a confidential dialogue with the PTO. The PTO contended that the claimed sequences lacked novelty because of the existence of publicly available cDNA libraries, from which the claimed sequences were derived. Taken to its logical extension, however, the PTO's reasoning would deny novelty to virtually all products isolated from expected sources of biomolecules, such as blood, saliva, or tissues. And it would also bring into broad question any gene lying within any available cDNA library.<sup>35</sup>

Healy was troubled by the USPTO's denial of claims to full coding portions of some genes because partial sequences previously had been discovered and published: 'Indeed, this was a major concern that led NIH to file for patents - namely, dumping sequence information on thousands of genes into the public domain might jeopardize later obtaining patents on the full gene or a gene fragment with apparent function,' 36<sup>36</sup>

With the arrival of the Clinton Administration, Bernadine Healy ended her term as the leader of the NIH.<sup>37</sup>Harold Varmus, the new head of the NIH, decided not to appeal a further rejection of the original application and withdrew the application in 1994. He explained the rationale for his decision:

We decided not to appeal the rejection of NIH's application by the Patent and Trademark Office for several reasons: my concern about the lack of demonstrated utility of these sequences; the possible complications of having what is referred to as 'patent clutter,' that is, multiple patents that would ultimately prove to be held on the same gene; and the problem of speculative claims, or so-called 'gotcha' patents, in which someone would do a lot of work on a gene and find that a patent had already been established on the gene. All in all, such patent activity might well restrict progress. Although NIH withdrew from this argument under those circumstances, the issue is

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<sup>35</sup> Scott Veggeberg, 'HHS Secretary Sullivan to Determine if NIH Gene Patent Quest is Over', (1992) 6 (21) *The Scientist* at 3.

<sup>36</sup> Ibid.

<sup>37</sup> Healy was later to become the director of the Red Cross. She resigned amidst controversy over the handling of donations in the wake of the September 11 attack on the World Trade Centre.

not completely resolved.<sup>38</sup>

Articulating his personal opinion, Varmus observed: 'My view is that widespread patenting of ESTs will pose some fairly serious problems.'<sup>39</sup> He was of the belief that the decisions of the NIH about intellectual property should foster scientific discovery, promote human health, and protect the rights of NIH employees.

Venter became the focus of much personal criticism for his patent applications in respect of ESTs -he was dubbed 'Darth Venter' by his detractors.<sup>40</sup> Incensed by such invective, Venter resigned from the NIH, explaining:

I was eager to scale up our research program at NIH in order to implement a successful, large-scale genome sequencing and gene discovery program. However, the extramural genome community did not want genome funding being used on intramural programs. I was frustrated that I would be unable to participate in the revolution in biology that we had helped start. I did not want to leave NIH, but after much soul-searching I felt it was the most appropriate option.<sup>41</sup>

In 1995, Venter set up a non-profit research centre called The Institute for Genomic Research (TIGR). It was funded by the biotechnology firm Human Genomics Sciences, which had ownership rights over all the discoveries of the organisation. In 1998, Craig Venter established Celera Genomics with the help of the Parker Elmer Corporation. The company sought patent applications in relation to hundreds of medically significant genes which it identified in its shotgun sequencing of the human genome. Likewise, competitors, such as Incyte Genomics and Human Genome Sciences, filed numerous patent applications in respect of genes and gene sequences. Such developments led to the USPTO tightening the thresholds of patent criteria to curb gene patent applications.

### **3. Raising the Bar: The United States Patent and Trademark Office Utility Guidelines**

In the United States, the courts have sought to define the requirement of

<sup>38</sup> Harold Varmus, Chapter 6 of *Intellectual Property Rights and Research Tools in Molecular Biology*, in National Research Council, *Summary of a Workshop Held at the National Academy of Sciences* (1996), <<http://www.nap.edu/readingroom/books/property/6.html>> at 1 May 2007.

<sup>39</sup> Ibid.

<sup>40</sup> Robin McKie, 'I'm the Human Genome, Says 'Darth Venter' of Genetics', *The Guardian* (London), 28 April 2002 at 28.

<sup>41</sup> Glyn, Moody, *Digital Code of Life: How Bioinformatics is Revolutionizing Science, Medicine, and Business* (2004) at 58.

utility under patent law. In *Brenner v. Manson*, the Supreme Court of the United States took a restrictive view of utility.<sup>42</sup> It held that a chemical product with no known use, or useful for merely further research, was not a patentable invention. Fortas J emphasised the importance of the requirement of utility in patent law:

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>43</sup>

The judge observed: '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.'<sup>44</sup> Fortas J warned: 'Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public.'<sup>45</sup> Emphasizing that 'a patent is not a hunting license', his Honour observed: 'It is not a reward for the search, but compensation for its successful conclusion'.<sup>46</sup> The judge concluded: '[A] patent system must be related to the world of commerce rather than to the realm of philosophy'.<sup>47</sup>

### 3.1 Revised Utility Examination Guidelines

In 2001, the USPTO issued revised examination guidelines explaining how the utility requirement should be applied by patent examiners.<sup>48</sup> The guidelines required patent applicants to explicitly identify, unless already well established, a specific, substantial and credible utility for all inventions. In effect, it raised the bar to ensure that patent applicants demonstrate a 'real world' utility. The Director of the USPTO, Todd Dickinson, explained the

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<sup>42</sup> *Brenner v Manson*, 383 US 519 (1966).

<sup>43</sup> Ibid at 534.

<sup>44</sup> Ibid.

<sup>45</sup> Ibid.

<sup>46</sup> Ibid at 536.

<sup>47</sup> Ibid.

<sup>48</sup> United States Patent and Trademark Office, 'Utility Examination Guidelines', (2001) 66 *Federal Register* 1092: <<http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>> at 1 May 2007.

administrative reforms to Congress:

The issue of the utility of an invention is one that the USPTO takes very seriously. That is why we continue to take steps to ensure that genomic patent applications are meticulously scrutinized for an adequate written description, sufficiency of the disclosure, and enabled utilities, in accordance with the standards set forth by our reviewing courts. In order to meet the utility requirement of 35 U.S.C. § 101, our new utility guidelines require patent applicants to explicitly identify, unless already well-established, a specific, substantial and credible utility for all inventions. In effect, we have raised the bar to ensure that patent applicants demonstrate a 'real world' utility. One simply cannot patent a gene itself without also clearly disclosing a use to which that gene can be put. As a result, we believe that hundreds of genomic patent applications may be rejected by the USPTO, particularly those that only disclose theoretical utilities.<sup>49</sup>

He observed: 'An asserted utility is credible unless the logic underlying the assertion is seriously flawed, or the facts upon which the assertion is based are inconsistent with the logic underlying the assertion'.<sup>50</sup> Dickinson noted: 'A utility is specific when it is particular to the subject matter claimed'.<sup>51</sup> Finally, he observed: 'A substantial utility is one that defines a 'real world' use'.<sup>52</sup> Dickinson noted: 'Utilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use are not substantial utilities'.<sup>53</sup>

### 3.2 Public Comment

The utility guidelines attracted 51 public comments from a range of private companies, research institutions, and individuals.<sup>54</sup> The USPTO vigorously responded to various criticisms of the guidelines in its public consultation

<sup>49</sup> Todd Dickinson, 'Statement of Todd Dickinson Before the Subcommittee on Courts and Intellectual Property of the House Committee on the Judiciary', 13 July 2000, <<http://www.house.gov/judiciary/dick0713.htm>> at 1 May 2007.

<sup>50</sup> Ibid.

<sup>51</sup> Ibid.

<sup>52</sup> Ibid.

<sup>53</sup> Ibid.

<sup>54</sup> United States Patent and Trademark Office, 'Public Comments on the United States Patent and Trademark Office Revised Interim Utility Examination Guidelines' (2000) 65 Federal Register 3425, <<http://www.uspto.gov/web/offices/com/sol/comments/utilguide/index.html>> at 1 May 2007.

process.<sup>55</sup> It dismissed a host of objections to the patenting of genes and gene sequences.

First, a number of critics argued that genes should not be considered to be patentable subject matter because they were scientific discoveries, not inventions. The USPTO responded that 'an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it'.<sup>56</sup> Second, several comments stated that a gene was not a new composition of matter because it was a 'product of nature'. In response, the USPTO responded: 'Patenting compositions or compounds isolated from nature follows well-established principles, and is not a new practice'.<sup>57</sup> Several comments suggested that the USPTO should seek guidance from Congress as to whether naturally occurring genetic sequences were patentable subject matter. The Patent Office declined such an invitation:

[T]he intent of Congress with regard to patent eligibility for chemical compounds has already been determined: DNA compounds having naturally occurring sequences are eligible for patenting when isolated from their natural state and purified, and when the application meets the statutory criteria for patentability.<sup>58</sup>

Third, several comments stated that patents should not issue for genes because the human genome was part of the common heritage of humankind, and should not be open to private ownership. Other comments stated that patents should be for marketable inventions and not for discoveries in nature. The USPTO rejected this argument that life forms should not be able to be commercialised:

The patent system promotes progress by securing a complete disclosure of an invention to the public, in exchange for the inventor's legal right to exclude other people from making, using, offering for sale, selling, or importing the composition for a limited time.<sup>59</sup>

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<sup>55</sup> United States Patent and Trademark Office, 'Revised Interim Utility Examination Guidelines' (1999) 64 (244) *Federal Register*, <<http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>> at 1 May 2007.

<sup>56</sup> Ibid.

<sup>57</sup> Ibid.

<sup>58</sup> Ibid.

<sup>59</sup> Ibid.

### 3.3 Stakeholder Perspectives

There has been much policy discussion about the new USPTO examination guidelines for the requirement of utility.<sup>60</sup> The leader of the United States component of the human genome project, Francis Collins, provided qualified praise for the utility guidelines:

The Patent Office is seeing fewer of what they call 'generation one' patents, where there's just a sequence and no clue as to what it does. PTO intends to reject those. They are seeing a reasonable number of 'generation two' applications, where there's a sequence, and homology suggests a function. NIH views such applications as problematic, since homology often provides only a sketchy view of function. Increasingly, PTO is seeing more in the 'generation three' category, which I think most people would agree is more appropriate for patent protection. These are gene sequences for which you have biochemical, or cell biological, or genetic data describing function.<sup>61</sup>

Collins concluded: 'I think the Patent Office deserves credit for moving toward a stronger requirement for utility.'<sup>62</sup>

Harold Varmus, the President of Memorial Sloan-Kettering Cancer Center in New York City, and the Director of the NIH from 1993 to 1999, testified about the utility guidelines to the House of Representatives Subcommittee on Courts and Intellectual Property:

Recently, to the relief of many of us, the PTO has considered raising the bar to gene patenting, especially for the utility standard. Although the new proposal is an improvement and the final position of the PTO has not yet been announced, I believe that the bar may still not be

<sup>60</sup> Julie Grisham, 'New Rules for Gene Patents' (2000) 18 *Nature Biotechnology* 921; Joshua Benson, 'Resuscitating the Patent Utility Requirement, Again: A Return to *Brenner v Manson*', (2002) 36 *University of California Davis Law Review* 267-295; Mary Breen Smith, 'An End to Gene Patents? The Human Genome Project Versus the United States Patent and Trademark Office's 1999 Utility Guidelines' (2002) 73 *University of Colorado Law Review* 747-785; Tanya Wei, 'Patenting Genomic Technology -2001 Utility Examination Guidelines: An Incomplete Remedy in Need of Prompt Reform' (2003) 44 *Santa Clara Law Review* 307-333; Cynthia Lopez-Beverage, 'Should Congress Do Something About Upstream Clogging Caused By The Deficient Utility of Expressed Sequence Tag Patents?' (2005) 10 *Journal of Technology Law and Policy* 35-92; and Sean Pippen, 'Dollars and Lives: Finding Balance in the Patent 'Gene Utility' Doctrine' (2006) 12 *Boston Journal of Science and Technology Law* 193-226.

<sup>61</sup> Eliot Marshal, Elizabeth Pennisi, and Leslie Roberts (2000), 'In the Crossfire: Collins on Genomes, Patents, and 'Rivalry'' (2000) 287 (5462) *Science* 2396-2398.

<sup>62</sup> Ibid.

raised high enough. Under the new proposal, a patent could be issued for a gene or a portion of a gene based on still quite superficial and potentially misleading information about the properties of the gene or about how it might be used to diagnose, prevent, or treat disease. Such information may be dependent only on the similarity between the new gene and others previously described. Establishing the legitimacy of such claims, even if the predictions were confirmed experimentally, would doubtless require legal proceedings, such as those that follow accusations of infringement.<sup>63</sup>

He commented that 'overly enthusiastic protection of intellectual property, too early in the process of product development, can impede the delivery of public health benefits from discoveries in many important fields, including genomics.'<sup>64</sup>

The Nuffield Council on Bioethics has argued that the USPTO has set the requirement of utility too low:

While we welcome the new USPTO guidelines, we take the view that where 'credibility' means no more than 'theoretical possibility' (ie where something is credible simply where it is not incredible) the threshold for utility is still set too low. The current state of genetics and biochemistry does not make it difficult to suggest functions for DNA sequences that are 'theoretically possible', in the sense that they are not ruled out by what is already known; but this should not suffice for the award of a patent. Instead, what is required is some evidence that the DNA sequence actually has the claimed 'specific' utility and that the claimed utility is truly 'substantial'.<sup>65</sup>

The Council recommended that the USPTO should monitor the impact of the Guidelines on the examination of patents to ensure that the criterion for utility was rigorously applied so that the grant of a patent more properly reflects the inventor's contribution. If this proves not to be the case, the Guidelines should be reviewed and strengthened to achieve this purpose as soon as is practicable.<sup>66</sup>

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<sup>63</sup> Harold Varmus, (2000), 'Testimony for Hearing on Gene Patents and Other Genomic Inventions', House of Representatives Subcommittee on Courts and Intellectual Property, 13 July/2000, <<http://judiciary.house.gov/Legacy/varm0713.htm>> at 1 May 2007.

<sup>64</sup> Ibid.

<sup>65</sup> Nuffield Council on Bioethics, *The Ethics of Patenting DNA, A Discussion Paper* (2002): <[http://www.nuffieldbioethics.org/go/ourwork/patentingdna?publication\\_310.html](http://www.nuffieldbioethics.org/go/ourwork/patentingdna?publication_310.html)> at 1 May 2007 at 45.

<sup>66</sup> Ibid at 60.



Andrea Ryan, president-elect of the American Intellectual Property Law Association, observed: 'The patent issues surrounding biotechnology and specifically genes and gene-related technology are less than 20 years old and it will take time to sort out the application of the patent laws to this technology.'<sup>67</sup> She submitted: We believe the Revised Written Description Guidelines and the Utility Guidelines as published by the Office have taken great steps forward in the complex area of the written description requirements for a biotechnology patent.<sup>68</sup>

Charles Ludlam, vice president for government relations at the Biotechnology Industry Organization, was broadly supportive of the utility guidelines. He observed that there was a lack of consensus amongst the members of BIO as to the threshold required for utility:

There is a difference of opinion among BIO members as to whether different types of inventions will or will not satisfy the utility requirement. For example, some BIO members believe that utility of most proteins cannot be conclusively demonstrated until the protein has been expressed and biologically characterized. Other BIO members believe that utility can be based on a prediction of biological activity made on the basis of homology to existing classes of polypeptides and proteins.<sup>69</sup>

Ludlam commented: 'Rather than attempting to dictate one standard or the other, BIO encourages the PTO to carefully evaluate the rationale presented in support of an asserted utility, particularly with respect to the specificity of the recited utility, and the scientific credibility of the basis for that specifically recited utility.'<sup>70</sup>

Randal Scott of the biotechnology firm, Incyte Genomics, argued that patent law should be applied to genetic inventions, much the same as it had been applied to other technologies: 'Incyte believes that the application of existing patent law principles to genomic inventions will support the continued acceleration of genomic research, resulting in an increase in the pipeline of new drugs that are safer and less expensive than has previously been

<sup>67</sup> Andrea Ryan, 'Testimony for Hearing on Gene Patents and Other Genomic Inventions', House of Representatives Subcommittee on Courts and Intellectual Property, 7 July 2000, <[http://www.aipla.org/Content/ContentGroups/Legislative\\_Action/106th\\_Congress/Testimony4/Statement\\_at\\_Oversight\\_Hearing\\_on\\_Gene\\_Patents\\_and\\_other\\_Genomic\\_Inventions,by\\_M\\_Andrea\\_Ryan\\_July\\_.htm](http://www.aipla.org/Content/ContentGroups/Legislative_Action/106th_Congress/Testimony4/Statement_at_Oversight_Hearing_on_Gene_Patents_and_other_Genomic_Inventions,by_M_Andrea_Ryan_July_.htm)> at 1 May 2007.

<sup>68</sup> Ibid.

<sup>69</sup> Charles Ludlam, 'Biotechnology Industry Organization Comment on Interim Utility and Written Description Guidelines', 22 March 2000, <<http://www.uspto.gov/web/offices/com/sol/comments/utilitywd/bio.pdf>> at 1 May 2007.

<sup>70</sup> Ibid.

possible.<sup>71</sup> The company generally supported the efforts of the USPTPO in clarify the existing law in the utility guidelines, particularly as they applied to ESTs: 'We favor this clarification of the proper application of current law to a new category of genomic inventions.'<sup>72</sup> Nonetheless, the company was somewhat concerned that examiners from the USPTO could apply such guidelines in an over-zealous fashion: 'Incyte has concerns, however, about unattributed quotes that purport to announce a Patent Office 'decision' to limit the issuance of gene patents... [and] suggest that the Patent Office will issue patents on genes only if the specific biological activity of the genes is disclosed in the patent application.'<sup>73</sup>

The patent litigator, Gerald Dodson, observed that his university clients wanted a wide perimeter in which to protect inventions whose potential for use was uncertain.<sup>74</sup> He believed that the utility guidelines of the USPTO were too restrictive and could hit universities with a devastating economic blow. Dodson would rather the court system make these decisions instead of patent examiners:

Bring a lawsuit and let the court decide if something has utility. The court could give a small damage award if they thought the utility was small. To the extent that people have received patents on inventions or devices perceived as having insignificant or de minimus utility, the system will remedy that.<sup>75</sup>

Dodson maintains that the characterisation of the utility directives as guidelines, rather than rules, is ultimately a meaningless distinction. He observes, 'They will spill over into court challenges.'<sup>76</sup> Dodson observes: 'The patent system should be allowed to work, and it makes more sense to give people patents for inventions that have utility, even if the utility may not seem significant at the time of application.'<sup>77</sup>

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<sup>71</sup> Randal Scott, 'Testimony for Hearing on Gene Patents and Other Genomic Inventions', House of Representatives Subcommittee on Courts and Intellectual Property, 7 July 2000, <<http://judiciary.house.gov/Legacy/scot0713.htm>> At 1 May 2007.

<sup>72</sup> Ibid.

<sup>73</sup> Ibid.

<sup>74</sup> Victoria Slind Flor, 'Both Sides Now: MoFo IP Partners Kate Murashige and Gerald Dodson Diverge on the PTO's New Guidelines for Biotech Patents', (2001) *IP Worldwide*, 14 June.

<sup>75</sup> Ibid

<sup>76</sup> Ibid

<sup>77</sup> Ibid

#### 4. *The Fisher King*

In the case of *In re Fisher*, Dane K. Fisher and Raghunath V. Lalgudi of the agricultural biotechnology firm, Monsanto, filed a patent application in 2001 claiming compounds and compositions related to molecules derived from maize, corn, plant tissue.<sup>78</sup> The application included a 'Sequence Listing' disclosing partial sequences for 32,236 nucleic acid molecules extracted from corn plants. Claim 1 of the application recited: 'A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 5.'<sup>79</sup> Claim 2 was directed to proteins, and Claims 3-7 related to transformed plants'.

In January 2001, the Patent Examiner issued a restriction requirement ordering the Applicants to elect certain claims and to limit their invention to 'no more than five of the individual sequences for examination.'<sup>80</sup> In response, Monsanto withdrew claims 2-7 and limited claim 1 to five nucleic acid sequences.

Monsanto claimed that the patent application disclosed that the five claimed ESTs may be used in a variety of ways, including:

- (1) serving as a molecular marker for mapping the entire maize genome, which consists of ten chromosomes that collectively encompass roughly 50,000 genes;
- (2) measuring the level of mRNA in a tissue sample via microarray technology to provide information about gene expression;
- (3) providing a source for primers for use in the polymerase chain reaction ('PCR') process to enable rapid and inexpensive duplication of specific genes;
- (4) identifying the presence or absence of a polymorphism;
- (5) isolating promoters via chromosome walking;
- (6) controlling protein expression; and

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<sup>78</sup> Dane Fisher, and Raghunath Lalgudi, 'Nucleic Acid Molecules and Other Molecules Associated with Plants' (2001), US Patent Application Serial No.: 09/619,643.

<sup>79</sup> Ibid.

<sup>80</sup> As cited in *In re Fisher* 421 F.3d 1365 at 1374 (CA.Fed., 2005).

(7) locating genetic molecules of other plants and organisms.<sup>81</sup>

The biotechnology company maintained that these were specific, credible, and substantial uses, to use the language of the utility guidelines promulgated by the USPTO.

In September 2001, the Patent Examiner issued a final rejection of claim 1 of the 643 application, finding that the claim lacked utility under 35 U.S.C. § 101; failed to satisfy the enablement and written description requirements of 35 U.S.C. § 112; and was anticipated by two prior art references under 35 U.S.C. § 102. In the examiner's opinion, the alleged uses of the ESTs are 'non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acids being claimed.'<sup>82</sup> Monsanto appealed against the ruling to the Board of Patent Appeals and Interferences.

In its March 2004 decision, the Board of Patent Appeals and Interferences affirmed the Examiner's final rejection of claim 1 for failure to satisfy the utility requirement of Section 101 and the enablement requirement of Section 112.<sup>83</sup> However, it reversed the Examiner's written description rejection. The Board was unconvinced by the analogies drawn between ESTs and microscopes:

This argument has been reviewed but is not convincing because the microscope provides information to the scientist which is automatically useful. For example, the microscope may be used for identification and differentiation between gram-positive and gram-negative bacteria. The differentiation of bacteria facilitates in the administration of proper antibiotics. For example, if the microscope is used to determine whether Staph is present or whether Strep is present provides valuable information to the scientist and/or doctor for treating patients. The instant invention, however, provides no information to this extent. If the scientist determines that SEQ ID NO: 1 is present, the scientist does not know how to use this information. Thus, the identification of SEQ ID NO: 1 is not a substantial utility.<sup>84</sup>

Accordingly, Monsanto appealed to the Court of Appeals for the Federal Circuit. First, it asked whether 'the Board erred by concluding that an EST is subject to a heightened standard of utility under 35 US 101 that hinges upon

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<sup>81</sup> Monsanto elaborates upon such uses in its briefs. Monsanto Inc., 'Corrected Brief for Appellants Dane K. Fisher and Raghunath V. Lalgudi', 2004 WL 4996614, 27 September 2004, 12-20.

<sup>82</sup> As reported in *Ex parte Fisher* above n 11.

<sup>83</sup> Ibid.

<sup>84</sup> Ibid.

some undefined 'spectrum' of knowledge about the function of the gene that corresponds to the EST'.<sup>85</sup> Second, it questioned 'whether the Board erred by concluding that ESTs corresponding to genes of unknown function are incapable of satisfying the utility requirement of 35 USC 101, even though all ESTs, including each of the claimed ESTs, can be used as research tools to provide one or more specific, substantial, and commercially valuable benefits to the scientific community'.<sup>86</sup> It is worth noting that the company had six other appeals pending on the same legal issue.<sup>87</sup>

David Korn of the Association of American Medical Colleges speculated: 'I wouldn't be amazed if somebody from Monsanto said that they were doing this to test the guidelines'.<sup>88</sup> The USPTO defended the decision of the Board of Patent Appeals and Interferences, with the support of a number of amicus curiae, including Genentech Inc., Affymetrix, Eli Lilly, and various research organisations.

#### 4.1 Monsanto

Summarising their argument on appeal,<sup>89</sup> Monsanto protested that the patent application had amply satisfied the requirements of utility under the *Patent Act* 1952 (US):

As the U.S. Supreme Court announced nearly four decades ago in *Brenner v. Manson*, the 'basic quid pro quo contemplated by the Constitution and the Congress for granting a monopoly is the benefit derived by the public from an invention with substantial utility' - that is, 'where specific benefit exists in currently available form.' The Applicants have satisfied their end of the bargain here. The record contains more than ample evidence demonstrating that, as a matter of scientific truth, *all* ESTs - including each of the claimed ESTs - can be used as research tools to provide the public with a host of specific, substantial, and commercially valuable benefits - *regardless* of the level of knowledge of the corresponding gene function.<sup>90</sup>

The agricultural biotechnology firm held that the examiner and the Board of Patent Appeals and Interferences had failed to apply the proper standard of utility to the facts of the case: 'The Board fashioned new law by applying a

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<sup>85</sup> Above n 81.

<sup>86</sup> Ibid.

<sup>87</sup> *In re Kovalic*, No. 05-1007; *In re Lalgudi*, No. 05-1010; *In re Byrum*, No. 1011; *In re Anderson*, No. 1012; *In re Adab*, No. 05-1013; and *In re Boukharov*, No. 05-1014.

<sup>88</sup> *In re Kovalic*, No. 05-1007; *In re Lalgudi*, No. 05-1010; *In re Byrum*, No. 1011; *In re Anderson*, No. 1012; *In re Adab*, No. 05-1013; and *In re Boukharov*, No. 05-1014.

<sup>89</sup> Above n 81.

<sup>90</sup> Ibid at 24-25.

heightened 'spectrum' of knowledge utility test under Section 101 to reject the patentability of claim 1.<sup>91</sup> Monsanto argued that this was an error of law: 'In so doing, the Board inappropriately expanded the holding of *Brenner* and its progeny by effectively declaring that *no* EST can satisfy the utility requirement of Section 101 in the absence of some undefined level of knowledge concerning the function of the corresponding gene.'<sup>92</sup>

Monsanto argued that the Board had improperly applied a heightened and ill-defined standard of utility to reject the patentability of the claimed ESTs.<sup>93</sup> The biotechnology firm contended:

Rather than apply the minimal standard of utility established by Section 101 and repeatedly applied by the courts, the Board instead applied a new heightened utility standard of its own creation that conditions the patentability of ESTs upon some undefined 'spectrum' of knowledge concerning the corresponding gene function. The Board's unilateral establishment of a utility requirement for ESTs that is far more demanding than the utility standard applicable to other chemical compounds and inventions was error. It is well established that Congress alone has been entrusted with the power to define the level of utility necessary to effectuate the constitutional requirement that patentable inventions be 'useful'; a power that Congress has exercised through its enactment of 35 U.S.C. § 101.<sup>94</sup>

The suggestion here is that the USPTO had usurped the role of Congress by implementing a higher threshold of utility, without legislative authority or backing.

Monsanto maintained that the ESTs could be considered analogous and equivalent to research tools,<sup>95</sup> such as microscopes, telescopes, and screening assays:

As a practical matter, a decision to the contrary would mean that other inventions of unquestionable and critical value to the scientific community similarly lack substantial utility. For example, in a number of key respects, the claimed ESTs are directly analogous to research tools such as microscopes, telescopes, and screening assays - all of which can be utilized to study, locate, and generate scientific data about samples with currently unknown properties. It would make

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<sup>91</sup> Ibid at 25.

<sup>92</sup> Ibid.

<sup>93</sup> Ibid at 33.

<sup>94</sup> Ibid.

<sup>95</sup> For a history of the microscope in the golden age of scientific discovery, see Lisa Jardine, *Ingenious Pursuits: Building the Scientific Revolution* (1999).

little sense to hold - as the Board effectively did below - that research tools such as these have substantial utility when used to analyze a sample of known function, but no substantial utility when used to analyze a sample of unknown function. In fact, research tools arguably have even greater value when used to probe, examine, and understand the properties of a sample with an unknown function.<sup>96</sup>

Monsanto questioned the finding of the Board that the claimed ESTs differ from a microscope 'because the microscope provides information to the scientist which is automatically useful'.<sup>97</sup> The company commented: 'Tellingly, nor did the Board provide any evidence to support its incorrect factual conclusion that information gained from an EST is not automatically useful.'<sup>98</sup>

Monsanto also emphasized that the patentability of the ESTs was further confirmed by considerations of commercial value. The agricultural biotechnology firm commented:

Here, the utility of the claimed ESTs is not merely an abstract exercise in 'the world of philosophy.' Rather, a vast industry has developed in the commercial marketplace for ESTs -including for ESTs that, like those at issue here, code for genes of unknown function. Indeed, numerous companies have dedicated substantial funds to research and discover ESTs that correspond to genes of *both* known and unknown function, and large sophisticated companies collectively have paid hundreds of millions of dollars to obtain access to databases of ESTs.<sup>99</sup>

Monsanto argued that it was axiomatic that such commercially valuable work should be patentable: 'It runs contrary to common sense to think that sophisticated corporations and knowledgeable scientists would dedicate hundreds of millions of dollars to an industry based upon useless items of commerce'.<sup>100</sup> The company asserted that the Board had erred by dismissing this evidence: 'The undeniable existence of such an industry here further confirms that the claimed ESTs meet the minimal utility requirement of 35 U.S.C. § 101.'<sup>101</sup> Monsanto adds, waspishly: 'Indeed, the PTO itself has recognized as much in other cases by allowing patents to issue for inventions directed to a single component that plainly must be used with

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<sup>96</sup> Above n 81.

<sup>97</sup> Ibid at 40.

<sup>98</sup> Ibid.

<sup>99</sup> Ibid at 41.

<sup>100</sup> Ibid.

<sup>101</sup> Ibid at 42.

other components to have any meaningful commercial value - for example, a patent on a single LEGO block.<sup>102</sup>

#### 4.2. The United States Patent and Trademark Office

The USPTO maintained that Monsanto's patent application in respect of ESTs lacked specific and substantial utility:

Monsanto is claiming molecules containing five ESTs derived from corn, but discloses no specific and substantial utility for any of them. Some of the proposed utilities involve using the claimed ESTs to find their binding partners, mates, or complements, but no specific and substantial uses for those objects are disclosed. Some of the proposed utilities would use the claimed ESTs to find other molecules that might be more or less close to the EST on a chromosome, but there are no specific and substantial utilities for those other molecules disclosed. In short, all of the proposed utilities are simply methods of investigating what to do with the claimed molecules or the others that could be found.<sup>103</sup>

The USPTO submitted: 'Fisher's compounds can be used in research procedures which may or may not lead to later discoveries of practical uses, and may lead to the discovery of other compounds of unknown utility.'<sup>104</sup>

The USPTO argued that the metaphor of microscopes raised by Monsanto was an old canard, and should be dismissed by the Court of Appeals for the Federal Circuit:

Reviving an argument rejected by the majority in *Kirk*, Fisher argues that the claimed molecules are research tools like microscopes and other instruments. However, the claimed molecules do not have a function analogous to a microscope. A microscope has the specific benefit of magnifying other objects clearly. ESTs for anonymous genes do not have an analogous specific use, and therefore don't meet the requirement for a currently available specific benefit<sup>105</sup>

The USPTO preferred a different metaphor: 'A more apt analogy is that Fisher's ESTs are akin to a manufactured copy of a portion of one's fingerprint.'<sup>106</sup> It noted: 'While machines for reading fingerprints, and

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<sup>102</sup> Ibid.

<sup>103</sup> United States Patent and Trademark Office, 'Brief and Addendum for Appellee, Director of the United States Patent and Trademark Office *In re Fisher*', 7 December 2004 at 13.

<sup>104</sup> Ibid at 46.

<sup>105</sup> Ibid at 26-27.

<sup>106</sup> Ibid at 26-27.



methods for fingerprinting, and computer programs for matching fingerprints may all be patentable, a copy of a portion of one's fingerprint is not because there is no specific benefit to the individual fingerprint.<sup>107</sup> By extension, the USPTO reasoned: 'Similarly, whereas methods for making cDNAs, methods for random sequencing, robots for implementing the methods, and computers for comparing the ESTs may be patentable, until a specific benefit is identified for an EST, an individual EST is not useful under § 101.'<sup>108</sup>

The USPTO also expressed broader public policy concerns that allowing patents on ESTs would result in a monopolisation of knowledge and research. It noted: 'As asserted in the specification, the utilities alleged are the same for any one of the thousands of corn ESTs Monsanto discloses.'<sup>109</sup> The USPTO observed: 'Moreover, these same utilities could similarly be asserted for any EST from any other plant or animal'.<sup>110</sup> The Patent Office commented:

Apart from its lack of legal support, Monsanto's position in this case would be poor patent policy with unfortunate consequences for the genetics field in general and the future of corn production in particular. If Monsanto were to obtain patent protection for the thousands of corn sequences that its automated tools have identified, it would obtain the very sort of 'monopoly of knowledge' that the Supreme Court has warned 'should be granted only if clearly commanded by the statute.'<sup>111</sup>

The USPTO alleged: 'In the field of plant genetics, it is reasonable to expect that issuing a patent on Fisher's compounds now would hurt, rather than help, progress in the field.'<sup>112</sup> The submission feared that 'thousands or tens of thousands of patents on ESTs would issue for every plant or animal.'<sup>113</sup> The USPTO also alluded to the problem of patent thickets, noting: 'For each of the genes, or fragments thereof, that is the subject of a patent claim held by someone else, a license would have to be negotiated.'<sup>114</sup> The USPTO noted that, in such a situation, patent trolls could flourish: 'Each overlapping

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<sup>107</sup> Ibid.

<sup>108</sup> Ibid.

<sup>109</sup> Ibid at 14.

<sup>110</sup> Ibid.

<sup>111</sup> Ibid.

<sup>112</sup> Ibid at 44.

<sup>113</sup> Ibid at 45.

<sup>114</sup> Ibid.

patent claim would be an extra "tollbooth" for the same cDNA.<sup>115</sup>

### 4.3 Genentech

The biotechnology firm, Genentech, has a longstanding interest in the patentability of ESTs. The company's officers expressed mixed views about the topic in the initial dispute over the NIH's patent applications. A senior patent counsel at Genentech, Max Hensley, encouraged Reid Adler of the NIH to apply for a patent in respect of Craig Venter's ESTs.<sup>116</sup> Interestingly, corporate counsel for Genentech, Thomas Kiley, was critical of the NIH proposal to patent ESTs: 'The NIH proposal for patents is only an extreme example of a widespread practice in biotechnology that seeks to control not discoveries themselves but the means of making discoveries.'<sup>117</sup> The episode demonstrates what an important role Genentech played in pushing the boundaries of patent law. In this case, the company was not only the instigator of patent reform, but also at the same time its critic.

Subsequently, the chief executive officer of Genentech, Arthur Levinson, supported the guidelines on utility that were issued by the USPTO: 'We support the PTO's guideline on utility, which creates an appropriately higher bar for biotechnology companies in requiring demonstration of biological function and use'.<sup>118</sup> Dennis Henner, the Senior Vice President of Research, approved of the position of the USPTO to stringently review ESTs in light of the new utility guidelines:

The PTO has indicated that certain 'first generation' EST filings are the most likely to receive the hardest review. The PTO has also indicated that a 'second generation' of filings that disclose full sequences of genes will receive a more rigorous evaluation for compliance with utility, written description and enablement. We believe this is the proper course for the PTO to follow.<sup>119</sup>

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<sup>115</sup> Ibid.

<sup>116</sup> Robert Cook-Deegan, above n 29, at 316-317; and see also Kevin Davies, above n 29.

<sup>117</sup> Robert Cook-Deegan, above n 29 at 321.

<sup>118</sup> Arthur Levinson, 'Genentech CEO Says Amgen/TKT Trial Outcome Not A Bellwether For Biotech -Broader Issue of Gene Patents Addressed at Congressional Hearings This Week', Genentech Press Release, San Francisco And South San Francisco, California, (Press Release, 13 July 2000), <<http://www.gene.com/gene/news/detail.jsp?detail=4624&pNo=9>> at 1 May 2007.

<sup>119</sup> Dennis Henner, 'Statement of the Genentech Senior Vice President of Research', United States Judiciary Subcommittee on Courts And Intellectual Property, 13 July 2000, <<http://www.bio.org/laws/commentsO71200.html>> at 1 May 2007.

Henner also affirmed the administrative guidelines on utility, praising the PTO for its impressive job in promulgating guidelines that accurately reflected the current state of the law governing specific utility and written description.<sup>120</sup> However, he also expressed some concerns about the application of these guidelines as part of the PTO's notice and comment process - in particular about the scientific assumptions used by the USPTO in their training materials.<sup>121</sup> However, the company was confident that the guidelines and the training examples ultimately would be consistent with the law and reflect a proper perspective on scientific assumptions. It did not support legislative action to alter the standards of utility, enablement or written description in the name of genome research. However, there have been some reservations about administrative guidelines by the USPTO amongst the biotechnology industry.<sup>122</sup>

In the case of *In re Fisher*, Genentech made an amicus curiae submission, reflecting its long interest in the topic:

Genentech Inc., the world's first biotechnology company, uses human genetic information to identify and develop new pharmaceutical products to address significant unmet medical needs. The more than 900 United States patents granted to Genentech cover not only its products, but also technologies relevant to the commercial-scale production, isolation, purification and formulation of the therapeutic proteins that are often the central component of these products... As both a patent holder and a consumer of information produced by others, Genentech presents a balanced industry perspective regarding the implications of this singularly important issue.<sup>123</sup>

Genentech emphasized that it relied upon patent protection to recoup its significant investments in research and development; and it also licensed patent rights and other intellectual property rights from other companies.

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<sup>120</sup> Ibid.

<sup>121</sup> Genentech Inc, 'Submission on the Revised Interim Guidelines Concerning the Revised Written Description Requirement and the Revised Utility Examination Guidelines', 22 March 2000, <<http://www.uspto.gov/web/offices/com/sol/comments/utilitywd/genentech.pdf>> at 1 May 2007.

<sup>122</sup> Lawrence Kass, and Michael Nitabach, 'A Roadmap For Biotechnology Patents? Federal Circuit Precedent And The PTO's New Examination uidelines' (2002) 30 (2) *AIPLA Quarterly Journal* 233; and Mary Breen Smith, 'An End to Gene Patents? The Human Genome Project Versus the United States Patent and Trademark Office's 1999 Utility Guidelines' (2002) 73 *University of Colorado Law Review* 747-785.

<sup>123</sup> Genentech Inc., 'Brief of Genentech Inc. as Amicus Curiae Supporting Affirmance and Supporting the United States Patent and Trademark Office *In re Fisher*', 15 December 2004 at 1.

Genentech endorsed the USPTO's utility guidelines and their application to reject Fisher's claims.<sup>124</sup> The company maintained that the USPTO's guidelines appropriately focused on the sufficiency of a 'prospective' utility.<sup>125</sup> Genentech opined:

Genentech believes that a substantial and credible utility that is specific to a particular claimed gene sequence must be disclosed to meet the requirements of 35 U.S.C. § 101. It will be the rare case that utility for such a sequence can be credibly demonstrated in the absence of at least some experimental demonstration of the biological functions or the biological role of the claimed gene or its expression product.<sup>126</sup>

The company advised: 'Genentech accordingly believes that the PTO's Utility Guidelines appropriately require a showing of a substantial and specific credible utility in a patent application claiming a genomic-related invention.'<sup>127</sup> The firm concluded: 'Genentech respectfully submits that this Court's endorsement of the standards reflected in the PTO Guidelines is vital to the continued advancement of the biotech industry.'<sup>128</sup>

#### 4.4 Affymetrix

The company, Affymetrix, put in an amicus curiae submission, because it was concerned about the ramifications of the dispute for its DNA micro array and genechip business:

Affymetrix and its customers and collaborators develop clinical applications of GeneChip technologies for diagnosing and treating disease. Because of the ability the GeneChip technology provides for studying complex biological systems, over 1,000 peer-reviewed publications in 2003 alone cited GeneChip technology. Thus, Affymetrix is in a unique position to address Appellants' arguments relating to the utility of the claimed expressed sequence tags in a micro array.<sup>129</sup>

The company was concerned that the grant of patent rights in ESTs could lead to allegations of patent infringement against its customers, and perhaps by extension itself, as the developer of microarrays and GeneChip

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<sup>124</sup> Ibid at 7.

<sup>125</sup> Ibid at 15.

<sup>126</sup> Ibid at 21.

<sup>127</sup> Ibid at 22.

<sup>128</sup> Ibid.

<sup>129</sup> Affymetrix Inc., 'Brief for Amicus Curiae Affymetrix, Inc. in Support of Appellee *In re Fisher*', 2004 WL 4996615, 14 December 2004.

technologies.

First, the company submitted that the *Fisher* patent application did not satisfy the legal requirements for utility, especially in light of past precedents in respect of chemicals:

The claimed expressed sequence tags (ESTs) lack the specific and substantial utility required by controlling precedent to be patentable. Appellants do not describe a function for the claimed ESTs: Rather, they only indicate some ways the ESTs could be *used* without demonstrating their *usefulness*. The claimed ESTs are analogous to a chemical intermediate of a final product with no known function - a composition of matter that does not have patentable utility under the controlling precedent. Any nucleic acid sequence that does not have a known function, whether it is an EST or full-length RNA molecule, does not have patentable utility. To allow patenting of ESTs will only inhibit further research into the function, if any, of the ESTs.<sup>130</sup>

The company emphasized that the asserted uses for the claimed ESTs were not substantial or specific. Affymetrix argued that the claimed ESTs were fragments of full-length nucleic acids of unknown function: 'Like the claimed chemical intermediates in *Joly* and *Kirk*, the claimed EST is an intermediate to an RNA of unknown function, and thus does not possess patentable utility.'<sup>131</sup>

Second, Affymetrix argued that the use of ESTs without a known function in microarrays does not provide a patentable utility: 'Using the claimed ESTs as probes on a DNA microarray does not represent a specific utility because any nucleic acid sequence could be used as a probe.'<sup>132</sup> The company explained:

Scientists have used Affymetrix microarrays to study the genetic basis for a number of diseases and other conditions. Typically, researchers compile a genetic profile or signature for a given condition based on a statistically significant set of microarray experiments. In other words, the experiments do not determine whether an increase or decrease in a particular well-characterized gene or EST is associated with a disease. But, instead, a pattern of thousands of genes and ESTs across the entire genome, expressed at different levels, correlates with a disease.

<sup>133</sup>

Affymetrix advised: 'Knowing the relative amount of that EST that a cell

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<sup>130</sup> Ibid at 2.

<sup>131</sup> Ibid at 8-9.

<sup>132</sup> Ibid at 9.

<sup>133</sup> Ibid at 13.

expresses is meaningless without some idea of the function of the gene from which the EST is derived and how that function correlates with the phenotype of the cell.<sup>134</sup> Consequently, the company was of the view: 'Thus, the use of an EST without a known function does not provide a specific utility under *Brenner*.'<sup>135</sup>

Third, Affymetrix also went further, and argued that the ESTs were not patentable subject matter because they were 'products of nature':

In addition, as products of nature, the claimed ESTs are not patentable subject matter. The claimed nucleic acid sequences have not been subject to sufficient human action to acquire 'markedly different characteristics' from their naturally-occurring counterparts. The only difference is that the claimed EST is removed from its natural environment. That trivial difference is insufficient to render the claimed ESTs patentable subject matter.<sup>136</sup>

Such arguments were reminiscent of the legal debate in the Supreme Court of the United States about the limits of patentable subject matter in the 'Metabolite' case.<sup>137</sup>

#### 4.5 ELi Lilly

Finally, there was an amicus brief filed by the pharmaceutical company, Eli Lilly, the Association of American Medical Colleges, The Baxter Healthcare Corporation, The National Academy of Sciences, Dow Agrosciences, and the American College of Medical Genetics.<sup>138</sup> The submission noted that this grand coalition of private companies, public research groups, and professional organisations had a common interest in ensuring that fundamental scientific research was not adversely affected by patents on ESTs:

[The amicus curiae] are entities having common interest that fundamental research, which is essential for their constituents, customers, and/ or the public to realize benefits derived from the study of plant, animal, and human genomes, not be deterred or

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<sup>134</sup> Ibid at 12-13.

<sup>135</sup> Ibid.

<sup>136</sup> Ibid at 2.

<sup>137</sup> *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.* 126 S.Ct. 2921 (2006).

<sup>138</sup> Eli Lilly et al., 'Brief for Amici Curiae Eli Lilly and Company, Association of American Medical Colleges, Baxter Healthcare Corporation, National Academy of Sciences Dow AgroSciences LLC, and American College of Medical Genetics in Support of the United States Patent and Trademark Office in Support of Affirmance *In re Fisher*' 2004 WL 4996616, 14 December 2004.

delayed by improperly granted EST patents. If patents merely disclose ESTs, but make no actual contribution toward understanding the biological significance of any proteins associated with the ESTs, then scientists may not feel free to undertake the arduous research required to determine the proteins' biological significances. Without knowing the biological significance, the additional research necessary to translate such knowledge into improved plants, agricultural chemicals, medical treatments, diagnostics, and drugs useful to the public will be delayed or not undertaken.<sup>139</sup>

The amici sought to persuade the Federal Circuit not to allow patents that are incommensurate with the patentee's contribution to the art because the 'patents that will inhibit research and development'.<sup>140</sup> The group submitted that granting the patent claims at stake in *In re Fisher* would be inconsistent with prior Federal Circuit and Supreme Court decisions.

First, Eli Lilly contended that patenting ESTs would discourage and impair basic research: 'It is critical that research scientists and clinicians both have and believe they have freedom to use nucleic acids whose function and biological relevance remain unknown.'<sup>141</sup> The amici warned: 'Constraints on research that would result from the issuance of patents like Fisher's would inhibit vast opportunities in "downstream" research.'<sup>142</sup> Eli Lilly commented:

Fisher seeks a patent covering an "invention" not yet complete or sufficiently definite to be adequately described, nor explored enough to provide specific benefit in currently available form. Fisher seeks a patent that would deter every other scientist from investigating *any* use of a large number of genetic sequences - none of which Fisher has discovered or adequately described, and which provide only a partial sequence, at best, for unidentified proteins having unspecified uses. Fisher fails to identify any use for these sequences, other than speculative research. In short, Fisher seeks to preempt other scientists from entire fields of research.

Those who, like Fisher, would seek to patent nucleic acids comprising ESTs without real knowledge of the claimed invention's utility are staking claims based upon no real knowledge of their discovery. But such claims, if granted, could be used to prevent, threaten to prevent, or extract value from everything that might later be discovered about genes and proteins associated with genetic

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<sup>139</sup> Ibid at 1.

<sup>140</sup> Ibid at 2.

<sup>141</sup> Ibid at 7.

<sup>142</sup> Ibid.

sequences. They are, in effect, laying claim to a function or use that does not yet exist in currently available form, and posing a threat to those who would, but for the patent, discover the function or use.<sup>143</sup>

Eli Lilly cited the opinion of Breyer J of the Supreme Court of the United States that '[the] job [of the patent law] is developing financial incentives that, as they operate in the marketplace, will encourage useful discovery and disclosure without unduly restricting the dissemination of those discoveries, hindering the circulation of important scientific ideas, or scattering ownership to the point where it inhibits the use of the underlying genetic advance.'<sup>144</sup> Drawing upon such sentiments, the amicus brief argued: 'Because no useful discovery, disclosure, or social benefit has yet occurred, issuing a claim like Fisher's would unduly hinder circulation of important scientific ideas and would likely scatter ownership, inhibiting the use of any potential underlying genetic advance.'<sup>145</sup>

Second, the amicus brief submitted that the Board of Patent Appeals and Interferences correctly found that the claimed invention lacked utility. Eli Lilly argued that Fisher's asserted research uses were insubstantial, and thus did not meet the utility guidelines: 'Fisher merely provides a "laundry list" of research plans, each general and speculative, and none providing a substantial, specific benefit in currently available form'.<sup>146</sup> The amicus brief submitted that the claimed invention was nothing like a microscope:

Rather than being a research tool used to study other objects, the claimed invention itself is the object of Fisher's asserted research plans. Such 'uses,' which are solely directed to discovering further information about the claimed invention including its utility, cannot be considered substantial utilities in currently available form, as section 101 requires. The posited research proposals for the claimed invention are thus not akin to a microscope, as Fisher asserts. Although a novel and unobvious microscope would be patentable subject matter under section 101, Fisher's analogy is simply misplaced. A microscope is not the object of the research; it is not being studied. The properties and real-world utility of the microscope are established. New scientific information derived from the use of the microscope relates solely to objects under examination, rather than relating to the microscope itself.<sup>147</sup>

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<sup>143</sup> Ibid at 4-5.

<sup>144</sup> Stephen Breyer (2000) 'Genetic Advances and Legal Institutions' (2000) 28 *Journal of Law, Medicine, and Ethics* 23-28.

<sup>145</sup> Eli Lilly et al., above n 138 at 6.

<sup>146</sup> Ibid at 9-10.

<sup>147</sup> Ibid at 18-19.



In the absence of real agronomic significance, the amicus brief maintained that the claimed invention lacked substantial utility: 'Not everything used to generate scientific information is patentable, nor should it be'.<sup>148</sup> Eli Lilly submitted: 'The claimed invention lacks utility because each potential research purpose asserted by Fisher is merely' a hunting license'.<sup>149</sup>

Third, Eli Lilly argued that Fisher's specification failed to provide an adequate written description of the invention:

Fisher completely fails to provide any relevant, identifying characteristics, such as structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics. Therefore, Fisher fails to provide the description required by this Court's precedent and the Guidelines.<sup>150</sup>

Eli Lilly also maintained that 'enablement is lacking, not only because the claim lacks utility, but also because determining which, if any, of the species are operable and useful would require undue experimentation'.<sup>151</sup>

## 5. *Ingenious Pursuits*

The Court of Appeals for the Federal Circuit was established by the United States Congress in 1982 to hear all patent appeal cases. There has been much concern that the institution has displaced, as a practical matter, the Supreme Court of the United States jurisdiction in patent cases.<sup>152</sup> Scholars Peter Drahos and John Braithwaite have suggested that the institution has a bias in favour of patent holders.<sup>153</sup> The Court of Appeals for the Federal Circuit has expanded the boundaries of patentable subject matter in relation to products of nature, plants, agriculture, medical treatments, mathematical algorithms, and business methods.<sup>154</sup> The institution has also applied the standards of novelty, non-obviousness, and utility in a formalistic way. Professor Janice Mueller of the University of Pittsburgh has lamented of the patent jurisprudence at work in the Court of Appeals for the Federal

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<sup>148</sup> Ibid at 20-21.

<sup>149</sup> Ibid at 3.

<sup>150</sup> Ibid at 29.

<sup>151</sup> Ibid at 3.

<sup>152</sup> Kenneth Dam, 'The Economic Underpinnings of Patent Law' (1994) 23 *Journal of Legal Studies* 247 at 270.

<sup>153</sup> Peter Drahos and John Braithwaite, *Information Feudalism* (2002) at 162.

<sup>154</sup> Rebecca Eisenberg, 'Biotech Patents: Looking Backward While Moving Forward', (2006) 24 (3) *Nature Biotechnology* at 317-319.

Circuit: 'Patent law scholars have noted a rise of formalism in recent Federal Circuit decisions, evidenced by a preference for bright-line rules over more nuanced, multi-factored, "totality of the circumstances" standards'.<sup>155</sup> The Court of Appeals for the Federal Circuit has interpreted both the defence of experimental use, and the safe harbour for research in respect of pharmaceutical drugs in a narrow, pernickety way.<sup>156</sup> The Supreme Court of the United States has expressed some unease at the judicial creativity and adventurism of the Court of Appeals for the Federal Circuit.<sup>157</sup>

In the course of oral argument, the Court of Appeals for the Federal Circuit relied upon various metaphors to make sense of ESTs.<sup>158</sup> Equating genetics with literature, Rader J sought to compare ESTs to a page of a book within a vast library:

Isn't this the equivalent of claiming a single page of a book in the middle of a library? The library as a whole will be very valuable once it's complete, but one page out of the library would not seem to be enough for a patentable invention.<sup>159</sup>

Monsanto's eminent counsel, Seth Waxman, replied that ESTs could be used in ways having nothing to do with the library: 'The mapping is desired to establish a statistical correlation between identified sequences and plant traits identified by cross breeding,' he explained.<sup>160</sup> There was also much debate in argument as to whether ESTs could be likened to microscopes - a well-accepted research tool.

The Court of Appeals for the Federal Circuit was deeply divided over the patent application by Monsanto in respect of ESTs in maize.<sup>161</sup> For the majority, Michel CJ held that the invention lacked specific and substantial

<sup>155</sup> Janice Mueller (2004), 'The Evanescent Experimental Use Exemption from US. Patent Infringement Liability: Implications for University/Nonprofit Research and Development,' (2004) 56 *Baylor Law Review* 918-980 at 963.

<sup>156</sup> *Madey v Duke University*, 307 F.3d 1351 (2002); and *Integra Lifesciences Ltd v Merck KGaA*, 331 F. 3d 860 (2003).

<sup>157</sup> For instance, Scalia J in *Merck KGaA v Integra Lifesciences I, Ltd.* 545 U.S. 193 (2005); and Breyer J in *Laboratory Corp. of America Holdings v Metabolite Laboratories, Inc.* 126 5.Ct. 2921 (2006).

<sup>158</sup> For a theoretical discussion of the use of metaphor in the biological sciences, see Evelyn Fox Keller, *Refiguring Life: Metaphors of Twentieth-Century Biology* (1995); Evelyn Fox Keller, *The Century of the Gene* (2000); and Evelyn Fox Keller, *Making Sense of Life: Explaining Biological Development with Models, Metaphors, and Machines* (2002).

<sup>159</sup> *In re Fisher*, Fed. Cir., No. 04-1465, 5/3/05 oral argument.

<sup>160</sup> *Ibid.*

<sup>161</sup> *In re Fisher* 421 F.3d 1365 at 1374 (C.A.Fed., 2005).

utility, and, in any case, the application failed because there was a lack of enablement. Bryson J supported this opinion. Dissenting, Rader J argued that the patent application satisfied the requirements of utility under United States patent law. In addition, he held that the ruling on enablement should be reversed because it was consequential upon the other findings in respect of utility. In addition to divisions as to the application of patent doctrine, the judges of the Court of Appeals for the Federal Circuit expressed larger philosophical differences of opinion as to the nature of research tools, the level of scientific progress, and the role of patent policy.

### 5.1 Michel CJ

In his opinion for the majority, Michel CJ provides support for the USPTO utility guidelines. His Honour has several main arguments.

First, Michel CJ agreed with the submission of the United States Government and the amici that none of Fisher's seven asserted uses meets the utility requirement of § 101. The judge applied the ruling of the Supreme Court of the United States in *Brenner v. Manson*,<sup>162</sup> and held that Fisher's application lacked utility

We agree with the Board that the facts here are similar to those in *Brenner*. There, as noted above, the applicant claimed a process for preparing compounds of unknown use. Similarly, Fisher filed an application claiming five particular ESTs which are capable of hybridizing with underlying genes of unknown function found in the maize genome. The *Brenner* court held that the claimed process lacked a utility because it could be used only to produce a compound of unknown use. The *Brenner* court stated: 'We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product.' Applying that same logic here, we conclude that the claimed ESTs, which do not correlate to an underlying gene of known function, fail to meet the standard for utility intended by Congress.<sup>163</sup>

The judge held that Fisher had failed to provide any evidence to prove that his claimed ESTs could be successfully used in the seven ways disclosed in the patent application: 'All of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, *could* possibly achieve, but none for which they have been used in the real world.'<sup>164</sup> Michel CJ concluded that Fisher had only disclosed

<sup>162</sup> *Brenner v Manson*, 383 US 519 (1966).

<sup>163</sup> *In re Fisher* 421 F.3d 1365 at 1374 (C.A.Fed.,2005).

<sup>164</sup> *Ibid* at 1373.

general uses for its claimed ESTs, not specific ones that satisfy § 101: 'Any EST transcribed from any gene in the maize genome has the potential to perform anyone of the alleged uses.'<sup>165</sup>

Second, Michel CJ denied that there were strong analogies between ESTs and other patentable research tools, such as microscopes:

Fisher compares the claimed ESTs to certain other patentable research tools, such as a microscope. Although this comparison may, on first blush, be appealing in that both a microscope and one of the claimed ESTs can be used to generate scientific data about a sample having unknown properties, Fisher's analogy is flawed. As the government points out, a microscope has the specific benefit of optically magnifying an object to immediately reveal its structure. One of the claimed ESTs, by contrast, can only be used to detect the presence of genetic material having the same structure as the EST itself. It is unable to provide any information about the overall structure let alone the function of the underlying gene. Accordingly, while a microscope can offer an immediate, real world benefit in a variety of applications, the same cannot be said for the claimed ESTs. Fisher's proposed analogy is thus inapt.<sup>166</sup>

His Honour concluded that Fisher's asserted uses were insufficient to meet the standard for a 'substantial' utility under § 101.

Third, Michel CJ noted that proof of a utility may be supported when a claimed invention meets with commercial success. However, his Honour rejected the arguments of Monsanto that the database of ESTs had a significant commercial value:

Fisher's reliance on the commercial success of general EST databases is also misplaced because such general reliance does not relate to the ESTs at issue in this case. Fisher did not present any evidence showing that agricultural companies have purchased or even expressed any interest in the claimed ESTs. And, it is entirely unclear from the record whether such business entities ever will.<sup>167</sup>

Again, the judge was concerned that Monsanto had failed to provide factual evidence to support its arguments that there was a commercial market for the ESTs at issue in the case.

Finally, Michel CJ held that the policy concerns raised by the *amicus curiae* were beyond the purview of the Court of the Appeals for the Federal Circuit:

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<sup>165</sup> Ibid at 1374.

<sup>166</sup> Ibid at 1373.

<sup>167</sup> Ibid at 1377-1378.

The concerns of the government and amici, which may or may not be valid, are not ones that should be considered in deciding whether the application for the claimed ESTs meets the utility requirement of § 101. The same may be said for the resource and managerial problems that the PTO potentially would face if applicants present the PTO with an onslaught of patent applications directed to particular ESTs. Congress did not intend for these practical implications to affect the determination of whether an invention satisfies the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and 112. They are public policy considerations which are more appropriately directed to Congress as the legislative branch of government, rather than this court as a judicial body responsible simply for interpreting and applying statutory law.<sup>168</sup>

This judicial disavowal of policy considerations is disappointing. The concerns of the government and the amici about the development of unwarranted monopolies in respect of genes and gene fragments are pertinent to the issues at hand in the litigation. The court is unwise and short-sighted to discount the resource and managerial problems of the USPTO. An administrative failure to properly deal with the flood of gene patent applications will have flow-on impact for the judiciary. A better approach would be to adjust the settings of patent criteria, in light of the policy directions of the Congress.

It is doubtful that the USPTO utility guidelines will be an effective means of addressing some of the problems with gene patents, if the courts remain blind to the public policy considerations that are being targeted.

## 5.2 Rader J

In his forceful dissent, Rader J maintained that the ESTs satisfied the requirements of the utility guidelines, because they constituted research tools: 'While I agree that an invention must demonstrate utility to satisfy § 101, these claimed ESTs have such a utility, at least as research tools in isolating and studying other molecules.'<sup>169</sup>

First, Rader J submitted that the ESTs satisfied the demands of the Supreme Court of the United States in *Brenner v. Manson*:

Several, if not all, of Fisher's asserted utilities claim that ESTs function to study other molecules. In simple terms, ESTs are research tools. Admittedly ESTs have use only in a research setting. However, the value and utility of research tools generally is beyond question, even though limited to a laboratory setting. (Many research tools such as gas chromatographs, screening assays, and nucleotide

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<sup>168</sup> Ibid at 1378.

<sup>169</sup> Ibid at 1379.

sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). Thus, if the claimed ESTs qualify as research tools, then they have a 'specific' and 'substantial' utility sufficient for § 101. If these ESTs do not enhance research, then *Brenner v. Manson* controls and erects a § 101. bar for lack of utility. For the following reasons, these claimed ESTs are more akin to patentable research tools than to the unpatentable methods in *Brenner*.<sup>170</sup>

Rader J observed that the cases of *Brenner v. Manson* and *In re Kirk*<sup>171</sup> 'share a common underpinning - a method of producing a compound with no known use has no more benefit to society than the useless compound itself.'<sup>172</sup> His Honour contended that the factual matrix contained in *re Fisher* was very different: 'Unlike the methods and compounds in *Brenner* and *Kirk*, Fisher's claimed EST's are beneficial to society.'<sup>173</sup> Approvingly, the judge observed that the ESTs would help scientists obtain a better understanding of the maize genome.

Second, Rader J argued that the analogies between microscopes and ESTs were persuasive, because both were research tools, which led to incremental improvements in scientific knowledge:

These research tools are similar to a microscope; both take a researcher one step closer to identifying and understanding a previously unknown and invisible structure. Both supply information about a molecular structure. Both advance research and bring scientists closer to unlocking the secrets of the corn genome to provide better food production for the hungry world. If a microscope has § 101 utility, so too do these ESTs...

Even with a microscope, significant additional research is often required to ascertain the particular function of a 'revealed' structure. To illustrate, a cancerous growth, magnified with a patented microscope, can be identified and distinguished from other healthy cells by a properly trained doctor or researcher. But even today, the scientific community still does not fully grasp the reasons that cancerous growths increase in mass and spread throughout the body, or the nature of compounds that interact with them, or the interactions of environmental or genetic conditions that contribute to developing cancer.

Significant additional research is required to answer these questions.

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<sup>170</sup> Ibid at 1379.

<sup>171</sup> *In re Kirk* 54 C.C.P.A. 1119, 376 F.2d 936 (1967).

<sup>172</sup> *In re Fisher* 421 F.3d 1365 at 1380 (C.A.Fed.,2005).

<sup>173</sup> 173 Ibid at 1380.

Even with answers to these questions, the cure for cancer will remain in the distance. Yet the microscope still has 'utility' under §101. Why? Because it takes the researcher one step closer to answering these questions. Each step, even if small in isolation, is nonetheless a benefit to society sufficient to give a viable research tool 'utility' under § 101. In fact, experiments that fail still serve to eliminate some possibilities and provide information to the research process.<sup>174</sup>

Such comparisons are deft and cunning (if not wholly convincing). By drawing affinities with microscopes, Rader J seeks to legitimize ESTs, and make them seem worthy of protection under patent law.

Scathingly, Rader J remarks: 'Nonetheless, this court, oblivious to the challenges of complex research, discounts these ESTs because it concludes (without scientific evidence) that they do not supply enough information.'<sup>175</sup> His Honour doubts the conclusions of his fellow judges: 'This court reasons that a research tool has a "specific" and "substantial" utility *only* if the studied object is readily understandable using the claimed tool - that no further research is required.'<sup>176</sup> Rader J reasons: 'Otherwise, only the final step of a lengthy incremental research inquiry gets protection.'<sup>177</sup>

Third, Rader J is critical that the USPTO does not, in his view, recognise the gradual and incremental nature of scientific development:

Science always advances in small incremental steps. While acknowledging the patentability of research tools generally (and microscopes as one example thereof), this court concludes with little scientific foundation that these ESTs do not qualify as research tools because they do not 'offer an immediate, real world benefit' because further research is required to understand the underlying gene. This court further faults the EST research for lacking any 'assurance that anything useful will be discovered in the end.' These criticisms would foreclose much scientific research and many vital research tools. Often scientists embark on research with no assurance of success and knowing that even success will demand 'significant additional research.'<sup>178</sup>

Rader J contended: 'The United States Patent Office, above all, should recognize the incremental nature of scientific endeavor'.<sup>179</sup> He questioned the

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<sup>174</sup> Ibid at 1380-81.

<sup>175</sup> Ibid at 1380.

<sup>176</sup> Ibid.

<sup>177</sup> Ibid.

<sup>178</sup> Ibid.

<sup>179</sup> Ibid at 1381.

distinction drawn between research tools, which provided 'substantial' and 'insubstantial' advances: 'How does the Patent Office know which 'insubstantial' research step will contribute to a substantial breakthrough in genomic study?'<sup>180</sup> Answering this rhetorical question for himself, Rader J concludes: 'Quite simply, it does not.'<sup>181</sup>

Finally, Rader J was willing to address the some of the administrative concerns of the USPTO about the exponential increase in the volume of patent applications in the field of biotechnology. He comments insightfully that the patent doctrine of utility is a poor instrument to discriminate between such applications:

In truth, I have some sympathy with the Patent Office's dilemma. The Office needs some tool to reject inventions that may advance the 'useful arts' but not sufficiently to warrant the valuable exclusive right of a patent. The Patent Office has seized upon this utility requirement to reject these research tools as contributing 'insubstantially' to the advance of the useful arts. The utility requirement is ill suited to that task, however, because it lacks any standard for assessing the state of the prior art and the contributions of the claimed advance. The proper tool for assessing sufficient contribution to the useful arts is the obviousness requirement of 35 U.S.C. § 103.<sup>182</sup>

Rader's J comments are particularly interesting given that the Court of Appeals for the Federal Circuit has contributed to the reading down of the obviousness requirement. Although his advocacy for patent protection for ESTs is questionable, Rader J's concerns about the utility standard should be taken seriously. A more rigorous application of the requirements of novelty and non-obviousness - through according greater creative problem-solving capacities to the person skilled in the art - would ultimately be a better means of regulating patent law in the field of biotechnology.<sup>183</sup>

## 6. *Conclusion*

After the long-standing controversy over ESTs, the decision of the Court of Appeals for the Federal Circuit in *In re Fisher* has received an enthusiastic reaction. Montreal academic, Yann Joly, commented that the decision represents an important shift in United States jurisprudence on patent law and biotechnology. 'It seems that with the *Fisher* case, the American judiciary has made another important step toward ending the early abuse of some

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<sup>180</sup> Ibid.

<sup>181</sup> Ibid.

<sup>182</sup> Ibid.

<sup>183</sup> Richard Gold, and Karen Durell, 'Innovating the Skilled Reader: Tailoring Patents to New Technologies' (2005) 19 (1) *Intellectual Property Journal* 189-226.



biotechnology companies and relieving the concerns of a majority of actors in this dynamic research field.<sup>184</sup> Dianne Nicol from the University of Tasmania was similarly enthused: 'This decision lends support to the view that, as a general rule, it will be extremely difficult to overcome the utility hurdle for EST claims in the US.'<sup>185</sup> Paula Davis, James Kelley, and Steven Caltrider from Eli Lilly and Stephen Heinig from the Association of American Medical Colleges were delighted by the majority decision:

The majority in the *Fisher* case would require patent applicants seeking to protect their ESTs to first identify the function of the underlying protein-encoding sequences... What is very clear from *Fisher* is that filing as soon as the EST is sequenced, as was the norm previously, is not sufficient. It is thus evident that many of the EST applications currently filed with the PTO will not meet the threshold for utility and will likely be abandoned. The ESTs disclosed within these applications (many of which have been published) will be available freely for use in research.<sup>186</sup>

Jim Brogan from Cooley Goddard LLP cautioned that the decision of *In re Fisher* was not necessarily a definitive one on ESTs, as there remained scope for patent attorneys to develop a stronger factual record to support the utility of their patent claims.<sup>187</sup> Nonetheless, Brogan was of the view that the ruling by the Court of Appeals for the Federal Circuit would allay the concerns of the biotechnology industry about patents being granted on ESTs, where there was no knowledge of function.

The decision in *In re Fisher* is already proving to be influential in the administrative practice of the USPTO in reviewing patent applications in respect of biological inventions.

The Board of Patent Appeals and Interferences distinguished the facts of the decision laid down by *In re Fisher* in the matter of *Ex Parte Raymond H. Boutin*.<sup>188</sup> The Board considered an appeal against a decision of a patent

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<sup>184</sup> Yann Joly, 'Wind of Change: In re Fisher and the Evolution of American Biotechnology Patent Law', in Matthew Rimmer (ed). *Patent Law and Biological Inventions* (2006) 24 (1) *Law in Context* 67-84 at 80.

<sup>185</sup> Dianne Nicol, 'On the Legality of Gene Patents' (2005) 29 (3) *The University of Melbourne Law Review* 809-841 at 835.

<sup>186</sup> Paula Davis, James Kelly, Steven Caltrider, and Stephen Heinig, 'ESTs Stumble at the Utility Threshold' (2005) 23 *Nature Biotechnology* 1227-1229.

<sup>187</sup> Jim Brogan, 'Federal Court Rules Gene Fragments Not Patentable' (2005) Cooley Alert, <[http://www.cooley.com/files/tbl\\_s24News%5CPDFUpload152%5C1646%5CALERT\\_GeneFragPatents.pdf](http://www.cooley.com/files/tbl_s24News%5CPDFUpload152%5C1646%5CALERT_GeneFragPatents.pdf)> at 1 May 2007.

<sup>188</sup> *Ex Parte Raymond H. Boutin* 2006 WL 2822238, \*4+ (Bd.Pat.App & Interf. Sep 28, 2006) (NO. APL 2006-1879, APP 10/010,114)

examiner to reject claims to a method of transferring nucleic acids into cells as non-enabled. The Board commented:

The ESTs at issue in *Fisher* lacked substantial utility because they were useful only for conducting experiments on the genes of which the ESTs were part; they were not useful for conducting research generally but only for conducting research to learn more about the ESTs themselves and the genes from which they were derived. Here, by contrast, the claimed method is broadly useful for transferring nucleic acids into cells. The instant claims are directed to a completed invention, not a 'research intermediate' as in *Fisher*, that can be used to carry out research using a variety of nucleic acids, cells, and subjects. Thus, the instantly claimed method is a valid research tool that can be used to carry out research in general rather than research limited to discovering information about the claimed invention itself.<sup>189</sup>

The board did not agree with the examiner that enabling the claims required enabling therapeutically effective gene therapy. In its view, the specification provided adequate guidance to enable those skilled in the art to use the claimed method to transfer nucleic acids to cells. The board reversed the rejection for lack of enablement.

In *Ex Parte Preeti Lal, Neil Corley et. al*, the Board of Patent Appeals and Interferences considered patent claims to a polynucleotide encoding, among other things, a 'naturally occurring amino acid sequence at least 90% identical' to SEQ ID NO:1.<sup>190</sup> The examiner rejected the claims as non-enabled and lacking adequate written description. The Board applied the decision in *In re Fisher* and upheld the decision of the patent examiner:

In this case, Appellants argue that those skilled in the art could have used polynucleotides encoding inactive SDHH variants in hybridization assays to detect and quantitate gene expression, to detect related sequences or polymorphisms, or to carry out expression profiling in connection with toxicology testing. We do not agree that using the claimed polynucleotides to detect related sequences or to monitor expression of the corresponding gene constitutes a specific and substantial utility, as defined by the *Fisher* court. Like the generic utilities asserted in *Fisher*, Appellants' asserted uses are neither substantial nor specific. Appellants have not disclosed how the results of the asserted hybridization assays would provide a real-world benefit.<sup>191</sup>

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<sup>189</sup> Ibid at 6.

<sup>190</sup> *Ex Parte Preeti Lal, Neil Corley et. al* 2006 WL 2710996,\*3+(Bd.Pat.App & Interf. Sep18, 2006) (NO.APL 2006-1035, APP 09 /925,140).

<sup>191</sup> Ibid at 4.

The Board, furthermore, observed that nothing about the asserted utilities set the claimed polynucleotides apart from any other human cDNA: 'Nor are they specific utilities, because they could be asserted for any cDNA transcribed from any gene in the human genome.'<sup>192</sup>

In *Ex Parte d. Wade Walke*, the Board of Patent Appeals and Interferences considered patent claims to polynucleotides encoding human peptides referred to by the applicant as 'novel human proteins'.<sup>193</sup> Patent claim number 3 related to 'An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:16 or SEQ ID NO: 28.' The patent examiner had rejected the claims on the grounds that they lacked sufficient utility. The Board upheld this finding

Appellants also argue that the claimed polynucleotides are useful for 'tracking the expression of the gene encoding the described protein, for example using high-throughput DNA chips'; that they are useful in mapping human chromosomes; and that they are 'useful for functionally defining exon splice-junctions'. We find that none of these uses meet the requirements of § 101. In this case, as in *Fisher*, the generic uses asserted by Appellants - assessing gene expression, mapping human chromosomes, and defining exon splice-junctions - are neither substantial nor specific.<sup>194</sup>

The Board concluded: 'In addition to lacking support in the specification, the polymorphism-based utility is neither substantial nor specific.'<sup>195</sup> The Board observed: 'It is not substantial because it is merely a hypothetical possibility, an objective which the disclosed polymorphisms, or any polymorphism for that matter, could achieve, but not one for which the claimed nucleic acids have been used in the real world'.<sup>196</sup> The Board averred: 'It is not specific because nothing about the asserted utility sets apart the polymorphism in the claimed nucleic acids from any other polymorphism found in the human genome.'<sup>197</sup>

In *Ex Parte Preeti Lal, Jennifer Hillman, et al.*, the Board of Patent Appeals and Interferences considered a patent application, which disclosed forty-nine proteins, generically referred to as 'human regulatory molecules' or

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<sup>192</sup> Ibid at 5.

<sup>193</sup> *Ex Parte d. Wade Walke* 2006 WL 2711006, \*2+ (Bd.Pat.App & Interf. Sep 18, 2006) (NO. APL 2006-2131, APP 10/309,422).

<sup>194</sup> Ibid at 5.

<sup>195</sup> Ibid at 6.

<sup>196</sup> Ibid.

<sup>197</sup> Ibid.

HRMs.<sup>198</sup> Defending the decision of the patent examiner, the Board held:

Appellants argue that the claimed polynucleotides are useful because they can be used in expression profiling methods in connection with 'toxicology testing, drug discovery, and disease diagnosis.' According to Appellants, 'all expressed genes have a utility for toxicological screening,' and therefore so does SEQ ID NO:19... As the examiner has pointed out, the specification provides no guidance on the meaning of a change in HRM-19 expression. A substantial utility is one that makes the invention useful to the public in its current form, not potentially useful in the future after further research. Since the specification does not provide a disclosure that would allow those skilled in the art to use the information that results from an expression profiling experiment in any practical way, expression profiling of HRM-19 is not a substantial utility that would satisfy § 101.<sup>199</sup>

The Board agreed with the examiner that the specification failed to disclose a utility that satisfied the requirements of 35 U.S.C. § 101.

In *Ex Parte Gary C. Starling*, the Board of Patent Appeals and Interferences considered a patent application, which claimed an isolated nucleic acid molecule encoding a protein designated APEX-1, a member of the CD2 subgroup of the immunoglobulin superfamily.<sup>200</sup> The examiner rejected claims 1-5 and 53-65, as lacking patentable utility and enablement. In addition, the examiner rejected certain claims as indefinite, as anticipated, and as lacking adequate written descriptive support. The Board of Appeals and Interferences applied the decision established by *In re Fisher*:

As the examiner has pointed out, the specification provides no guidance on the meaning of an increase or decrease in APEX-1 expression or activity, other than a hypothetical association with inflammation, cancer and/ or immune disorders. Thus, we agree with the examiner that the specification fails to disclose a substantial utility that satisfies the requirements of 35 U.S.C. § 101. To the extent appellants argue that 'credible utility is established at the very least by the use of the claimed compounds as molecular weight markers', we disagree. A utility that could be asserted for any expressed human gene is not a 'specific' utility that will satisfy § 101... Any expressed human gene could be used as a molecular weight marker -

<sup>198</sup> *Ex Parte Preeti Lal, Jennifer Hillman*, et al., 2006 WL 1665364, \*3+ (Bd.Pat.App & Interf. Jan 01, 2006) (NO. APL 2005-0102, APP 09/840,787).

<sup>199</sup> *Ibid.*

<sup>200</sup> David Resnik, 'Comments on the United States Patent and Trademark Office Utility Guidelines', 16 March 2000: <http://www.uspto.gov/web/offices/com/sol/comments/utilguide/dresnick.pdf> at 1 May 2007.

just as any expressed gene 'can be used to map the location of [its] corresponding gene and other related naturally occurring genomic sequences', as well as 'to access and elaborate [its own] functions'.<sup>201</sup>

The Board of Appeals and Interferences concluded that the specifications did not disclose a specific and substantial utility for the claimed polynucleotides.

This small sample of decisions from the Board of Appeals and Interferences suggests that the USPTO will apply the decision *In re Fisher* with vigor and purpose. However, the limitations of the utility doctrine should be recognized. As the academic, David Resnik, has observed: 'While it may be a good idea to 'raise the bar' on gene patents, this new PTO policy is little more than a temporary and limited solution to some of the difficult economic, legal, scientific and medical issues relating to gene patents'.<sup>202</sup> The USPTO utility guidelines are a makeshift and stop-gap measure to address the glut of biotechnology patent applications. Although utility is an important consideration, novelty and non-obviousness will be the critical criteria to discriminate between gene patent applications. This administrative response of the USPTO is no substitute for full-bodied legislative reform in respect of intellectual property and biotechnology.

There is a need for greater care and delicacy in the application of the threshold requirements of novelty and non-obviousness in respect of biotechnology inventions. In the May 2007 case of *KSR International Co. v. Teleflex, Inc.*, the Supreme Court of the United States emphasized the need for the USPTO and lower courts to set a high threshold for the standard of non-obviousness.<sup>203</sup> Kennedy J cautioned:

We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold

<sup>201</sup> Ibid.

<sup>202</sup> David Resnik, 'Comments on the United States Patent and Trademark Office Utility Guidelines', 16 March 2000: <http://www.uspto.gov/web/offices/com/sol/comments/utilguide/dresnick.pdf> at 1 May 2007.

<sup>203</sup> The matter concerns the validity of Steven Englgau, 'Adjustable Pedal Assembly With Electronic Throttle Control' (2000), US Patent No. 6,237,565 B1. At issue is claim 4, which comprises (i) a pre-existing 'adjustable pedal assembly,' combined with (ii) a pre-existing 'electronic control' The Supreme Court of the United States is considering whether the Federal Circuit has erred in holding that a claimed invention cannot be held 'obvious', and thus unpatentable under 35 U.S.C. § 103(a), in the absence of some proven 'teaching, suggestion, or motivation' that would have led a person of ordinary skill in the art to combine the relevant prior art teachings in the manner claimed.' *KSR International Co. v Teleflex, Inc.* 2007 WL 1237837, 82 U.S.P.Q.2d 1385 (2007).

from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts. See U. S. Const., Art. I, §8, cl. 8. These premises led to the bar on patents claiming obvious subject matter established in *Hotchkiss* and codified in §103. Application of the bar must not be confined within a test or formulation too constrained to serve its purpose.<sup>204</sup>

The judge noted that 'inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known'.<sup>205</sup> Kennedy J warned: 'The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents'.<sup>206</sup> The judge counselled: 'The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way'.<sup>207</sup> Kennedy J counselled: 'Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility'.<sup>208</sup> Such advice should certainly be heeded in the context of patent applications in respect of ESTs and genes in the fields of agriculture, medicine, and scientific research.

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<sup>204</sup> *KSR International Co.v Teleflex, Inc.* 2007 WL 1237837, 82 U.S.P.Q.2d 1385 (2007) at 19.

<sup>205</sup> *Ibid* at 14

<sup>206</sup> *Ibid.*

<sup>207</sup> *Ibid.*

<sup>208</sup> *Ibid.*