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# THE EVOLUTION OF U.S. GENE PATENT LAW: FINDING THE BALANCE BETWEEN BLATANTLY OBVIOUS AND OVERLY-BROAD GENE PATENTS

*by Jad Allen Mills<sup>1</sup>*

## I. INTRODUCTION

Most anyone who has paid attention to stocks or medical journals knows that biotechnology is big business. The most exciting biotechnology developments often include the use of patented gene sequences. Genes encode protein structures and together they regulate how the body works. Gene patents are valuable because they allow the owner to control gene sequences used in gene therapies and in the testing and development of new treatments for debilitating diseases. Many people have argued against gene patents. Some individuals are opposed to all gene patents, while others argue only against the way that gene patent law has evolved in the United States. However, I maintain that the evolution of U.S. gene patent law has developed to prevent patents that close off entire industries, while providing a clear framework for determining whether a gene patent is obvious or not. The non-obviousness requirement for patents is designed to balance the interests of society and inventors by avoiding both overly-broad and blatantly obvious patents. The evolution of gene patent law preserves this balance and allows the discoverers of gene sequences to obtain funding and protect expected returns on their investments of time and money, resulting in the rapid evolu-

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tion of genetic technology. This paper first describes the controversy that surrounded early gene patents and common objections that were made against them. Then the development of the U.S. patent system is discussed to provide a framework to evaluate the evolution of U.S. patent law. Finally, this evolution is evaluated in terms of finding balance between the interests of society and intellectual property investors.

## II. BACKGROUND

In 1991 the U.S. Supreme Court affirmed the 1987 patent of the erythropoietin gene, which codes for a hormone used to treat patients with kidney disease. The decision was of great financial importance to the parties involved because the owner of the patent was making over one billion dollars a year from the patent.<sup>2</sup> If the patent had not been affirmed, other companies would be allowed to compete for this business. This major case represented the kind of returns available from biomedical research and the importance of properly protecting intellectual property. Companies and inventors began testing the bounds of patent law by claiming increasingly broad patents with as little information as possible. As companies made and sometimes received broad claims of patent protection, the applications, lawsuits, and controversy intensified.

One such case occurred in October 1992 when the U.S. Patent and Trademark Office (PTO) granted patent rights to Agracetus Inc. for rights to all forms of genetically engineered cotton, regardless of the genes affected or the techniques used.<sup>3</sup> Agracetus had used one procedure to genetically alter cotton in one way and received a patent on any kind of genetically altered cotton, no matter the process involved. In 1994 the European Patent Office (EPO) granted Agracetus a patent on all genetically engineered soybeans plants.<sup>4</sup>

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2 Eliot Marshall, *Companies Rush to Patent DNA*, 275 SCI., NEW SERIES, 780-81 (1997).

3 Richard Stone, *Sweeping Patents Put Biotech Companies on the Warpath*, 268 SCI., NEW SERIES, 656 (1995).

4 *Id.* at 657.

The controversy and legal challenges erupted as people asked how one can patent all genetically altered forms of a natural product. They may have felt like the magician's guild had made a lucky rabbit's foot and was attempting to patent the whole rabbit. These broad patent claims intensified the race by biomedical companies to submit broader claims. The controversy reached an international furor in 1992 when a U.S. government body, the National Institutes of Health (NIH), submitted a patent application on cDNA pieces of approximately 5 percent of all human genes.<sup>5</sup> The broad claims would have forced corporations to pay license fees for a patent that many argued was unpatentable as a natural product. While the NIH controversy was delayed and the broad claims were tied up in court, for many genetic researchers the question of the patentability of genetic material seemed unanswered. The law, on the other hand, had been prepared for this eventuality for some time.<sup>6</sup>

In 1980 the US Supreme Court reversed a PTO ruling denying a patent to Ananda Chakrabarty for the first genetically engineered organism.<sup>7</sup> In essence Mr. Chakrabarty had created a bacterium that could clean up oil spills. The PTO had ruled that life could not be patented. The Supreme Court, however, ruled that, though living, this was an artificial substance. Further judicial decisions have made clear that even unchanged DNA sequences, once obtained from living beings, are artificial products, because these compounds do not exist in nature in an isolated, purified state.<sup>8</sup> As John Doll, then PTO Biotech Section Chief explained, "Nobody owns the gene in your body, [but] inventors can own the right to exploit it commercially; you can't turn over a rock and find a gene."<sup>9</sup> Between 1980 and 1997, over fifteen hundred of five thousand whole gene patent applications

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5 Anna Maria Gillis, *The Patent Question of the Year*, 42 *BioSci.*, 336 (1992).

6 Marshall, *supra* note 2, at 780.

7 *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

8 Marshall, *supra* note 2, at 781.

9 *Id.* at 781.

were granted.<sup>10</sup> From 1980 to 1992 the PTO awarded over 112 patents on approaches to recombinant plant DNA and on genetically engineered plants alone.<sup>11</sup> Despite the intense opposition of the scientific community against patenting genes, the law was quite clear by 1990. As one U.S. Patent Office administrator, Charles Van Horn, put it, the furor was all about arguing over “what patent law should be, and not what it is.”<sup>12</sup>

### III. THREE OBJECTIONS TO GENE PATENTS

Objections to the gene patents generally come in three varieties. The first objection is that patenting a human gene is immoral. For instance, objections to the EPO patent granted to Agracetus on genetically altered soybeans were based on an obscure statute regarding public morality.<sup>13</sup> The suit claimed that a patent that broad created a monopoly on a vital food supply, and that such a threat to the world food supply was immoral. Interestingly enough, the European Parliament now claims that they prohibit gene patents because they offend morality<sup>14</sup> and are an immoral inhibition to genetic research.<sup>15</sup> Some may argue that gene patents are immoral because they say that any developments derived from our genes should be shared freely with all, and gene patents prevent this from happening. Others argue genetic research leads to increases in pollution and disease and decreases in genetic diversity and the value of human life.<sup>16</sup> Egypt, India, Brazil, and the Andean Community all restrict gene patents to some degree or another.<sup>17</sup> Although there may be a moral basis for

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10 *Id.* at 781.

11 Stone, *supra* note 3, at 656.

12 Gillis, *supra* note 5, at 339.

13 Stone, *supra* note 3, at 657.

14 Nuno Pires De Carvalho, *The Problem of Gene Patents*, 3 WASH. U. GLOBAL STUD. L. REV. 701, 709 (2004) n21

15 *Id.* at 706.

16 Diamond, 447 U.S. 303, 316 (1980).

17 De Carvalho, *supra* note 14, at 707–708.

rejecting gene patents, this paper focuses instead on the legal basis for the validity of gene patents.

The second objection to gene patents is that genes should not be patentable because they are natural substances that exist in each of us, and natural substances should not be patented. Hubert Curien, then French Minister for Research and Technology, said:

A description of a short sequence of DNA or of cDNA is not an invention. It is knowledge about a part of the natural world that exists independently of the scientist, like the discovery of a new star or a new physical law. If the main argument for patenting cDNA sequences is that they are obtained thanks to innovative procedures, then let the procedures themselves be patented, but not the sequences established as a result of those procedures.<sup>18</sup>

Although Curien's argument makes a lot of sense to many people, his sentiments simply do not match up with the intent of the U.S. Patent system.

According to the United States Code, the PTO has power to grant patents to inventors for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."<sup>19</sup> Though the naturally occurring gene as such is not patentable, the purified and isolated form is not considered a natural substance. The European Directive on Biotechnological Inventions captures the basic legal rationale for genes not being classified as natural substances. The directive states that "biological material which is isolated from its natural environment or produced by means of a technical process may be [the] subject of an invention even if it previously occurred in nature," and even if the isolated structure is identical to the natural one.<sup>20</sup> This distinction is justified by the claim that the isolated version of the gene is "the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body," techniques that nature alone has not and never

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18 Gillis *supra* note 5, at 336; (quotes Sci. 254:1711).

19 35 U.S.C. § 101 (2007)

20 De Carvalho, *supra* note 14, at 718 (See De Carvalho's notes 68 and 70).

will produce without human intervention. The difference between a natural substance and a manmade substance is that the manmade substance would not exist in its useful form without the intervention of a human; human authorship makes the substance artificial.

Some may question whether this definition makes anything a possible object of invention. For example, although patenting a method of isolating a diamond from a rock formation may be patentable, the diamond itself cannot be patentable because it exists naturally in isolated form. Because nature isolates diamonds from rock formations by the natural processes of erosion, both the isolated diamond and using natural erosion to isolate the diamond are not patentable. However, methods for isolating the diamond may be patentable if they isolate the diamond in some other way. Nature never isolates genes or purifies them into forms amenable to genetic research. For this reason genes and methods of obtaining gene are patentable subject matter. The difference comes in whether the invention would have “spontaneously come into existence without the applicants’ exertions.”<sup>21</sup> Natural objects and phenomena occur without the aid of man, manipulatable genes do not.

Although this line of reasoning may not convince everyone that genes are potentially patentable material, precedence has already established this point of law in the United States. As I have mentioned before, the Supreme Court has already affirmed the validity of gene patents, some worth billions of dollars. Because U.S. law and the rule of law rely on binding legal precedence, it is not necessary to provide a comprehensive defense of the potential patentability of genes and genetic material.

The third common objection to gene patents is that the claims on these patents are too broad. Thomas Kiley, former vice president and general counsel at Genentech in California described the broad patents as an attempt to seek control of “not discoveries, but of the means of making discoveries.”<sup>22</sup> With broad patents obtained on genes before the function or purpose of the gene was even known, companies may be able to profit from or control a field of unknown

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21 Gillis, *supra* note 5, at 338.

22 *Id.* at 339.

potential. Such broad control would limit research to the handful of large corporations that hold control of these few broad patents. Although patents do not exclude research for academic purposes,<sup>23</sup> funding for ventures with no hope of financial gain would be extremely limited. In addition, the broad patent rights might increase cross-licensing cooperation among the large firms and drive smaller companies out of the business.<sup>24</sup> This argument seemed so compelling that a British Science Minister sought an agreement with its researchers to not seek patents on genes of unknown utility from research conducted using public funds.<sup>25</sup> In 1996, Francis Collin, director of the National Center for Human Genome Research, asked recipients of grants from his organization to release genetic data daily and not to seek patents on “raw genomic sequence” data because of the effect this would have on future research investment.<sup>26</sup>

Whereas some countries have outright rejected gene patents on moral and legal grounds, the U.S. patent system has attempted only to regulate gene patents in order to prevent overly broad or unsupported patents from being issued. In 1993 the PTO rejected the NIH application citing a lack of proven commercial utility. As Bruce Lehman, then PTO commissioner explained, “a lot of this stuff is just data,” and data alone is not patentable.<sup>27</sup> Because of the volume of sequences per application and the percentage of sequences lacking sufficient description to prove commercial utility, the PTO limited each application to no more than ten sequences in order to force applicants to focus on real innovations. As recently as November 2007, PTO has once again attempted to alter patent examination rules to further regulate the issuance of patents.<sup>28</sup> The new rules would limit

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23 *Id.* at 337.

24 Stone, *supra* note 3, at 658.

25 Gillis, *supra* note 5, at 336.

26 Eliot Marshal, *Is Data-hoarding Slowing the Assault on Pathogens*, 275 *SCI.*, NEW SERIES, 780 (1997).

27 *Id.* at 781.

28 Rules and Regulations, 72 Fed. Reg. 46,716 ( August 21, 2007) (to be codified at 37 C.F.R pt. 1).

the number of automatic claims and continuations allowed per application. While the new rules will affect only 18 percent of all patent applications, they will affect 85 percent of biotech patents.<sup>29</sup>

Over the years, biotechnology case law has developed to create a balance in the types of gene patents that are considered valid. The system seeks to prevent the issuance of overly-broad patents, without allowing patents to be issued for obvious inventions. Our current system resulted in part from those first broad and controversial gene patents just discussed in this background. In order to better illustrate the balance that has developed, I now review the basis and evolution of the U.S. patent system as it has adapted itself to properly apply the uniformity of the U.S. patent system to the development of genetic technology. I then review and evaluate some criticisms of this development. In this discussion I attempt to show that the current system is a natural outgrowth of the broad purposes of the patent system—to promote technological development by balancing the dichotomy between overly-broad and obvious patents.

#### IV. THE BASIS AND PURPOSE OF THE PATENT SYSTEM

Whereas some earlier patent systems served as arbitrary reward systems for favorites of the reigning king, the U.S. patent system was set up deliberately as a means for promoting technological progress. In sixteenth and seventeenth century England, patents were frequently abused by the sovereigns who would grant monopolies to their friends for practices that had long been common knowledge.<sup>30</sup> In contrast, Article I of the Constitution grants Congress the power to grant exclusive ownership rights in order to “promote the Progress [sic] of Science and useful Arts.”<sup>31</sup> The constitution allows the federal government to grant monopolies for limited terms, but only

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29 Letter from A. Scott Whitaker, Chief Operating Office, Biotechnology Industry Org., to Robert W. Bahr, Assistant Commissioner for Patents (May 2, 2006) <http://www.bio.org/ip/letters/20060502.pdf>.

30 *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 5 (1966).

31 U.S. Const. art. I, § 8, cl. 8 (See also *Diamond*, *supra* note 7, at 315 and *Graham*, *supra* note 30, at 5).

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for “innovation, advancement, and things which add to the sum of useful knowledge.”<sup>32</sup> This power was applied broadly from the very beginning. The Patent Act of 1793 described what could be patented as “any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof].”<sup>33</sup> Thomas Jefferson, the author of the 1793 patent legislation and one of the first patent commissioners stated that “certainly an inventor ought to be allowed a right to the benefit of his invention for some certain time. . . . Nobody wishes more than I do that ingenuity should receive a liberal encouragement.”<sup>34</sup>

Patents exist to help address the economic problems of free-riders. People who create advances in technology are unlikely to share information with others because they will then lose their effective advantage gained by discovering the invention. However, if society will enforce their ownership of that information, the chances of disclosure increase. With increased disclosure, technological advances can take place more quickly as others can build upon the original advance. Thus the U.S. patent system is designed to encourage capital and intellectual investment in innovation by rewarding those who successfully invest by giving them a temporary monopoly. This encouragement comes at a price, as the monopolist will raise prices in the absence of competition. In order to reduce the cost of patents to the free market, patent systems seek to balance patent breadth by allowing neither “sweeping” patents nor patents of obvious innovations.

Inventors seek to construe the claimed invention to be as wide in applicability as possible in order to increase the market value of their patent. However, a sweeping patent may “foreclose entire portions of developing technologies in exchange for either insufficient or already available information,” thereby accomplishing an inefficient transfer

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32 Graham, *supra* note 30 at 6.

33 Patent Act of Feb. 21, 1793, § 1, 1 Stat. 319 (See Diamond, *supra* note 7, at 314).

34 Letter to Oliver Evans (May 1807), V Writings of Thomas Jefferson, at 75–76 (Washington ed.); quoted in Graham, *supra* note 30, at 8.

of wealth.<sup>35</sup> If, however, patent scope is limited to avoid granting only a few, sweeping patents, a large number of limited patents may be granted, some of which may be obvious considering prior inventions. Thus, patent granting is a balancing act between allowing the overly broad, and allowing the blatantly obvious.

## V. PATENT ELIGIBILITY CRITERIA

### *A. Novelty and Utility*

Statutory subject matter, as described in the response to objection two, must also be novel, non-obvious, and useful in order to be patentable.<sup>36</sup> If any one of these three conditions is not met a patent cannot be granted.

To be novel an invention must not have been published or used anywhere in the world more than a year prior to the application for the patent. To have utility the invention must have at least one known credible and specific application. Utility also requires that the invention be enabled. Enablement includes providing a description of the preferred embodiment of the invention that contains sufficient description that an individual skilled in the technology (called an art) would be able to make and use the invention as intended without excessive experimentation.<sup>37</sup> If the description does not adequately explain the use of the claimed invention, then the standards of enablement and utility are not met and that invention cannot be patented. Meeting standards of utility and novelty have been requirements for receiving a patent since the U.S. patent statute of 1793.<sup>38</sup> More

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35 Anita Varma and David Abraham, *Dna is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 Harv. J. Law & Tec. 53, 55 (1996).

36 35 U.S.C. § 101, 102, 103 (2007).

37 John J. Doll, *The Patenting of DNA*, 280 SCI., NEW SERIES, 690 (1998).

38 Patent Act of Feb. 21, 1793, § 1, 1 Stat. 319 (See Diamond, *supra* note 7, at 314).

recent cases have helped to elucidate the meaning of these requirements for gene patents.

In 1966, the US Supreme Court ruled in *Brenner v. Manson* that chemical inventions must be coupled with a likely and useful application in order to be patentable.<sup>39</sup> The court stated that “unless and until . . . 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>40</sup> However, the requirement of having utility does not mean that a patent must describe a completely optimized embodiment of the invention. In the 1980 8<sup>th</sup> Circuit case of *E. I. DuPont de Nemours & Co. v. Berkley & Co.*,<sup>41</sup> the court found that “an invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely. . . . A commercially successful product is not required.”<sup>42</sup> In addition, not all possible uses must be known. The requirement is fulfilled if sufficient evidence is provided that the invention is potentially useful. The U.S. standard requires only a small threshold for proving utility. For example, U.S. patent law allows patents to be granted on protein or cDNA sequences even if the protein function is not yet known because the sequence has possible uses by itself, such as acting as a probe for karyotyping.<sup>43</sup> In contrast, in Great Britain, patent protection cannot be obtained unless the invention comprises an immediate industrial application.

### B. Obviousness

In the first sixty years of U.S. patent law, commissioners and judges evaluated patent applications with the two defined parameters of novelty and utility, but also with a very vague requirement that it must describe an invention. In 1851 the Supreme Court formulated

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39 Gillis, *supra* note 5, at 338–339.

40 *Brenner v. Manson* 383 U.S., 519, 535 (1966).

41 *E.I. du Pont de Nemours & Co. v. Berkley & Co., Inc.*, 620 F.2d 1247, 1257 (8<sup>th</sup> Cir. 1980).

42 Gillis, *supra* note 5, at 338.

43 *Id.*

a guideline for determining whether a claim truly constituted an invention. In *Hotchkiss v. Greenwood*, the Court invalidated a patent by introducing the requirement of non-obviousness. The Court held that an invention requires a contribution to the specific field of the innovation that would not be obvious to a practitioner of common skill in that particular field.<sup>44</sup> “Unless more ingenuity and skill . . . were required . . . than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention. In other words, the improvement is the work of a skillful mechanic, not that of the inventor.”<sup>45</sup> In *Hotchkiss*, the court tried to clarify a more specific parameter for determining whether some development is really an invention by introducing the requirement of non-obviousness. In so doing, the court also tied the non-obviousness threshold to the level of common skill in each particular art (field of invention).<sup>46</sup> In addition to making patent law industry specific, the requirement of non-obviousness also placed the patent system in a delicate balancing act. If obviousness depends on the level of expertise of the art’s common practitioner, fields with a low perceived threshold of skill in the art might be tempted to allow overly broad patents. On the other hand, in an attempt to avoid allowing patents of an overly sweeping scope, the patent office might allow a multitude of seemingly obvious patents.

In 1952, Congress incorporated and codified the requirement of non-obviousness into the 1952 Patent Act.<sup>47</sup> In *Graham v. John Deere*, the Supreme Court set out to determine whether the Patent Act of 1952 changed the statutory and judicial tests of patentability.<sup>48</sup> They concluded that the act merely included the judicial test described in the *Hotchkiss v. Greenwood* decision of 1851, and that “the general level of innovation necessary to sustain patentability

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44 Graham, 383 U.S. 1, 11 (1966).

45 *Id.* (quotes *Hotchkiss v. Greenwood*, 11 How. 248, 268 (1851)).

46 Graham, *supra* note 44, at 14.

47 *Id.* at 3–5.

48 *Id.*

remains the same” as before the 1952 Patent Act.<sup>49</sup> In *Graham*, the court identified four parts to an obviousness inquiry.<sup>50</sup> The inquiry includes first determining the scope and content of the prior art, and second determining the difference between the claimed invention and the prior art. Thirdly, the level of ordinary skill in the pertinent art must be identified, after which the fourth step of considering any secondary indications of non-obviousness may be undertaken. Secondary indications may include commercial success or a long-felt need in the art.<sup>51</sup> After completing these four steps, an innovation is determined to be obvious “[i]f the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”<sup>52</sup> It is this standard that has been applied over the past fifty years to balance the intellectual property rights of the inventor with the needs of the market, all the while tailoring the inquiry to the current state of the particular art by tying obviousness to the level of skill of an average practitioner in that particular art.

### C. *Prima Facie Obviousness*

Although this four-step plan seems simple enough, it becomes much more complex when one considers the incredible amount of prior art that has been accumulating over the last two centuries. In order to deal with this difficulty, procedures for determining prima facie obviousness have been developed. Patent applications are presumed patentable when filed with the PTO.<sup>53</sup> If the examiner can build a case of prima facie obviousness, the applicant must then pres-

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49 *Id.*

50 *Id.*

51 Varma, *supra* note 35, at 66 (See also Varma’s notes 61 and 62, and *Graham*, *supra* note 30 at 17–18).

52 *Id.* at 65 (See Varma’s note 59).

53 See *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) and *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

ent evidence to overcome the prima facie rejection.<sup>54</sup> One proposed method for establishing a prima facie case of obviousness includes using the “suggestion test.” The suggestion test asks whether teachings in the prior art “would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.”<sup>55</sup>

Gene patents frequently claim methods of obtaining and using genes as well as actual structures (nucleotide sequences) of genes. When a gene structure (sequence) is claimed, the doctrine of structural similarity is generally applied to determine obviousness. The doctrine of structural similarity existed before the 1952 Patent Act and was reaffirmed in the Federal Circuit case of *In re Dillon*.<sup>56</sup> Since chemical function corresponds with structure, compounds with the same chemical structure are assumed to have similar functions. DNA and RNA are merely large, complex chemical compounds. As such, they have traditionally been evaluated by means of the structural similarity test.

*In re Bell* teaches that when a specific gene is claimed as a composition by detailing the sequence, only prior disclosure of that sequence or other sequences with an intrinsic motivation to convert it to the claimed sequence can be used to determine obviousness. The PTO initially rejected Bell’s patent because the primary sequence of the protein was known, as were methods of obtaining the DNA sequence.<sup>57</sup> The court ruled that “the PTO’s focus on Bell’s method is misplaced. Bell does not claim a method. Bell claims compositions, and the issue is the obviousness of the claimed compositions, not of the method by which they are made.”<sup>58</sup> This position was reaffirmed in *Deuel*.<sup>59</sup>

Although a method of obtaining the correct gene sequence may be obvious, this does not make the gene sequence itself obvious, and

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54 Varma, *supra* note 35, at 66–67.

55 *Id.* at 67 and 79.

56 *Id.* at 67.

57 *In re Bell* 991 F.2d 781, 785 (Fed. Cir. 1993).

58 *Id.* at 785.

59 *In re Deuel* 51 F.3d 1552, 1559 (Fed. Cir. 1995).

thus allows the gene sequence to be patented.<sup>60</sup> Given that Deuel claimed a new chemical entity in structural terms, prima facie obviousness would require that the prior art suggest the claimed structure, not simply how to obtain the structure.<sup>61</sup> The court defined the issue in *Bell* and *Deuel* not as a matter of the uncertainty in obtaining a particular sequence, but in the uncertainty of predicting or visualizing from the prior art what sequence would be found.<sup>62</sup>

The courts also dismissed the idea that the translational relationship between proteins and DNA makes the DNA sequence obvious based on the known protein sequence, “because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein. No particular DNA sequence can be obvious unless there is something in the prior art to lead to that particular DNA sequence and indicate that it should be prepared.<sup>63</sup> The actual structure of the sought gene sequence is almost never obvious in light of the protein sequence because the degeneracy of the genetic code allows multiple gene sequences to code for the same amino acid.

#### *D. Actual Sequences Required to Define and Describe Genes*

In addition to defining the nonobviousness threshold for genetic inventions, the structural similarity test also impacts the standard required to define the invention. The courts have long held that an actual gene sequence is required as part of a composition claim for a gene. In *Fiers v. Revel*, the court held that disclosing a method for isolating DNA that would enable an ordinary practitioner to have a reasonable chance of success in obtaining the DNA does not establish conception of the DNA sequence, and therefore cannot consti-

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60 *Id.* at 1557–1558. See also *Bell*, *supra* note 56 at 784–785, and *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985).

61 *Id.* at 1557–1558.

62 Dan L. Burk and Mark A. Lemley, *Is Patent Law Technology-Specific*, 17 *Berkeley Tech. L. J.* 1155, 1179 (2002).

63 *Deuel*, *supra* note 59, 1558–1559.

tute a claim on the DNA itself.<sup>64</sup> Furthermore, the court held that it is “not sufficient to define it [the gene] solely by its principal biological property, e.g., encoding human erythropoietin [protein], because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.”<sup>65</sup> The court further explained that “when an inventor is unable to envision the detailed chemical structure of the gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.”<sup>66</sup> “Irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility.”<sup>67</sup> A definition by function only defines what the gene does and not what it is.<sup>68</sup> “Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties.”<sup>69</sup>

The actual sequence is required not only as proof of conception of the invention, but also to provide an adequate description of the invention.<sup>70</sup> “A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that [the inventor is] in possession of the DNA.”<sup>71</sup> This idea was confirmed in another case, the *Regents of the University of California v. Eli Lilly*.<sup>72</sup> The court found that the specifics required for a competent description of DNA requires describing the “structure,

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64 Fiers v. Revel 984 F.2d 1164, 1167 (Fed. Cir. 1993).

65 *Id.* at 1169.

66 *Id.*

67 *Id.*

68 Burk, *supra* note 62, at 1176.

69 Fiers, *supra* note 64, at 1169.

70 Burk, *supra* note 62, at 1175.

71 *Id.* at 1175 (See Burk’s note 81).

72 *Id.* (See Burk’s note 84).

formula, chemical name, or physical properties.”<sup>73</sup> A description requires more than just saying that the gene is part of the invention because one has part of the gene and a potential method for isolating the entire gene.<sup>74</sup>

Each of these cases has refined biotechnology patent law to a position in which genes are not obvious based on the proteins they code for, and in which the sequence of that gene is required both to define and to describe the invention itself. According to one commentator:

The conceptual linkage of obviousness and enablement to the depiction of macromolecular sequences in, respectively, the prior art or the patent disclosure, dictates a particular and predictable result for the availability and scope of such biotechnology patents. The expected outcome is that DNA patents will be numerous but extremely narrow. Under the Federal Circuit’s precedent, a researcher will be able to claim only sequences disclosed under the stringent written description rules—the actual sequence in hand, so to speak. . . . At the same time, the inventor is shielded from obviousness by the lack of such explicit and detailed disclosure in the prior art. This lack of effective prior art seems to dictate that anyone who has isolated and characterized a novel DNA molecule is certain to receive a patent on it. But the inventor is certain to receive a patent only on that molecule, as the Federal Circuit appears to regard other related molecules as inadequately described until the sequence is disclosed.<sup>75</sup>

## VI. ATTACKING THE EVOLUTION OF GENE PATENT LAW

According to Varma and Abraham, this state of affairs in biotechnology patent law has upset the balance between protecting the

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73 *Id.* at 1174 (See Burk’s note 78).

74 Fiers, *supra* note 64 at 1170. See also Regents of the University of California v. Eli Lilly and Co., 199 F.3 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

75 Burk, *supra* note 62, at 1181.

interests of patent applicants and the interests of society.<sup>76</sup> Varma and Abraham argue that this occurred because court decisions have improperly applied the structural relationship test of obviousness to DNA,<sup>77</sup> improperly rejected general process disclosures from questions of obviousness of compositions,<sup>78</sup> and improperly applied the doctrine of selection inventions.<sup>79</sup> They argue that the structural relationship test does not work appropriately with DNA because the value of DNA is in its correlative relationship to protein structures, and not in its own structure.<sup>80</sup> Because seemingly minute changes in a DNA structure can cause enormous and unanticipated changes in protein structure, they claim that the structural relationship test is insufficient to determine obviousness of DNA sequences. This has led to an imbalance in favor of applicants seeking to patent gene sequences, as almost any gene sequence turns out to be patentable. Varma and Abraham cite the case of *DeForest Radio v. General Electric*<sup>81</sup> to show that general processes have been used as prior art to invalidate compositions. Regarding the doctrine of selection inventions, they argue that it was inappropriately used in *Bell* and *Deuel* because the breadth of choices should be considered relative to the practitioner of average skill in the art, and not in absolute numbers.<sup>82</sup> They urge use of the suggestion test instead of the structural similarity test and show that doing so will make most, if not all new gene patents, obvious in the current state of the art.

## VII. DEFENDING THE EVOLUTION OF GENE PATENT LAW

In response to Varma and Abraham, I argue that their use of the suggestion test enforces a much higher standard of invention than

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76 Varma, *supra* note 35, 55–56.

77 *Id.* at 69.

78 *Id.* at 76.

79 *Id.* at 73.

80 *Id.* at 68–69.

81 *DeForest Radio Co. v. General Elec. Co.*, 283 U.S. 664, (1931).

82 Varma, *supra* note 35, at 79.

was envisioned by the statute or constitution, and I contend that their use of *Deforest* is ill founded. In *Deforest*, the prior art disclosed the exact same structure for the exact same use.<sup>83</sup> A vacuum tube was described and claimed and it was suggested that a higher vacuum in the tube would be beneficial. A method for creating a higher vacuum was also described. The later patent that was invalidated merely disclosed the same vacuum tube from the prior art with the greater vacuum that had been suggested and enabled in the prior art patent.<sup>84</sup>

Although anyone with a Ph.D. in a relevant field, given the proper time and funding can reasonably expect to isolate a gene sequence given the protein sequence, this still constitutes a real and important advance in available technology. Because a substantial investment is still required to obtain the invention and because the prior art cannot predict the exact nature of the invention, newly sequenced genes are not obvious. The reason gene sequences are so unpredictable from protein sequences lies not in the field of genetic technology, but in thermodynamics. Science's current understanding of the laws of thermodynamics has proven insufficient to accurately predict the effects of pinpoint gene mutations in final protein structures.<sup>85</sup> Because of this lack of comprehension, practitioners are almost entirely at a loss to accurately predict gene structure from protein structure. Making a completely unknown structure obvious simply because it is known to exist and methods of finding it can be postulated significantly increases the inventive standard envisioned by the drafters of both the original and subsequent patent acts. Doing so may be akin to ruling all inventions of any kind obvious because someone can envision a method of creating an invention.

To illustrate this point, I describe a generic method of creating an invention with four steps. Step 1: Determine an area of production or industry facing some sort of problem or inefficiency. Step 2: Design a novel way to address that problem or inefficiency. Step 3: Enable the method. Step 4: Apply for a patent on the method. Although

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83 *Deforest*, *supra* note 81, at 675.

84 *Id.* at 676.

85 Interview with Mathew C. Asplund, Assistant Professor of Chemistry and Biochemistry at Brigham Young University in Provo, Utah (Dec. 4, 2007).

it may seem absurd that this method could make any invention obvious because the method is so generic, if followed by a practitioner of average skill in an art, that practitioner has a reasonable chance of arriving at a solution. The reason this method does not make that solution obvious is the same reason that DNA probing techniques do not make DNA sequence obvious: the methods give little or no information about the product being sought. My method cannot define nor describe the invention being sought, but if followed with diligence it will almost certainly yield a productive result.

There is a clear corollary in biotechnology that illustrates the absurd consequences of allowing generic methods of discovery to obviate particular inventions. Vaccines have been developed and used for years. Any immunologist can testify that there are tried and true methods of obtaining a vaccine for a normal pathogen. I say normal here, because some diseases, such as HIV, adapt so quickly that normal methods of vaccine development are not effective. The method includes identifying a pathogen-born disease to which one desires to develop a vaccine. One may then isolate weakened or dead samples of the pathogen and inject them into a healthy immune system. The immune system develops antibodies to the pathogen, and the researcher isolates, purifies, and mass produces the antibodies in a vaccine to administer to others. Despite the fact that the average practitioner in the art has a reasonable expectation of success in developing the antibody, the specific antibody, the doses required, and the ideal medium for administration, are unknown. Knowing a generic method of finding the desired product contributes little to our conception of the final product. Individuals must still go through the sometimes tedious process of invention and development, even knowing that they have a method that gives a reasonable probability of success.

The vaccine example also connects well with gene patents for a second reason. Both genes and antibodies are naturally occurring materials that become patentable compositions when they are isolated from their natural state and purified into a form that allows for their manipulation. Whereas two hundred years ago most inventions were merely the adaptation of naturally occurring minerals or fibers

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for the use of mankind, genes and antibody inventions adapt naturally occurring micro-objects for the use of mankind. Traditionally, inventors made machines to transform a natural element into a man-made product; naturally occurring iron ore may be put into a smelter and processed to create steel. Some may find it distasteful to use a living thing, especially a human body, as part of a machine to transform the natural into the manmade. However, all of our machines are merely natural objects combined or adapted for the use we design for them. The fact that we have used a living organism, even a human, to develop a transferable immunity that would not otherwise naturally occur, is probably much more beautiful than it is scary. Along with genes, the antibody that is developed and isolated may be exactly like the one that may exist naturally in each of us. However, such antibodies do not tend to naturally jump from one person to immunize an entire population. Similarly, naturally occurring genes very infrequently pop out of people's bodies naturally in a condition where they can be manipulated by mankind. Even if the isolated antibody can be proven to be exactly like one naturally existing in our bodies, and even if the method used to obtain it could have been predicted to be successful by most immunologists out there, is there not still an inventive spark in developing that new vaccine? The presence of a pathogenic disease and a method of obtaining a vaccine against it certainly does not predict for us the specifics of that vaccine or the antibody within it. Then, certainly the existence of a protein and a method of obtaining a genetic sequence for it does not make the specifics of the gene obvious.

So far as fears that patents will have an adverse effect on research and biomedical progress, such has been the fear from the beginning of intellectual property protection in the 1790s. The same arguments were used forty years ago when polymer chemistry was introduced.<sup>86</sup> Critics claimed that patents granted on synthetic polymer products and processes would devastate the market. The truth was that the first polymer patent in 1965 did not prevent later patents of related inventions. Similarly, polymerase chain reaction (PCR) and HIV Protease patents did not hinder biotechnology research,

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86 Doll, *supra* note 37, at 689.

but rather encouraged innovations based on the original patent.<sup>87</sup> That is the purpose of patents, to encourage investment and the dissemination of technology by ensuring the protection of intellectual property.

### VIII. CONCLUSION

Though some will continue to question the morality of patenting a gene sequence derived from a living organism and especially from a human being, the fact is that as a matter of law, genes are patentable materials in the U.S. I began this paper by discussing the fear and controversy surrounding those first, broad gene patents. I then presented the basics of patent law and the evolution of gene patents that are defined specifically and narrowly by specific gene sequences. Next, I reviewed the argument from Varma and Abraham that this evolution has led us down a mistaken path and damaged the economic balance of the patent system. These objections, though interesting, are unconvincing. The non-obviousness requirement of patents is designed to balance the interests of society and inventors by finding the right path between granting sweeping, overly-broad patents, and allowing patents on the blatantly obvious. The current evolution of gene patents has struck that balance, allaying the fears about patenting entire industries with insufficient information while providing a clear framework for determining whether a gene patent is obvious or not. This framework allows discoverers of gene sequences to obtain funding and protect expected returns on their investments of time and money. Without patent protection, perhaps we would not have all of the gene sequences today that we do. The evolution of gene patent law, in light of the non-obviousness requirement, has preserved the careful balance between granting a few overly broad patents and granting many narrow patents that, if upset, may have inhibited financial investment and new discoveries.

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87 *Id.* at 689.