

Spring 2010

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### Recommended Citation

Alex Osterlind, *Staking a Claim on the Building Blocks of Life: Human Genetic Material within the United States Patent System*, 75 Mo. L. REV. (2010)

Available at: <https://scholarship.law.missouri.edu/mlr/vol75/iss2/11>

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# Staking a Claim on the Building Blocks of Life: Human Genetic Material Within the United States Patent System

## I. INTRODUCTION

The discovery of human genetic material introduced an invaluable tool in the advancement of medicine. International efforts under the Human Genome Project have drawn to a close, identifying approximately 20,000-25,000 of the genes in the human body, thereby facilitating diagnoses of disease, predispositions to debilitations, pharmaceutical development, and numerous other fields.<sup>1</sup> Indeed, genetic research enables innumerable beneficial medical applications, and, predictably, such research in the United States has been commodified through patent law. In fact, it is estimated that twenty percent of the human genome is subject to patent protection,<sup>2</sup> prohibiting others from any unauthorized research of the patented genetic material or unauthorized utilization of it in clinical testing procedures.<sup>3</sup> Allowing patent protection for human genetic material has sparked a heated debate, with each side asserting diametrically opposite interpretations of how, or even if, gene patents are contemplated under the Intellectual Property Clause of the Constitution.<sup>4</sup> Competing interests in the field are not easily reconciled. For example, incentivizing genetic research by offering patent protection encourages research and development in the field but simultaneously limits access for illuminating and potentiating additional research on patented genes.

Illustratively, patents held by Myriad Genetics, Inc. (Myriad) for the BRCA1 and BRCA2 genes provide indicators that evince an individual's predisposition to breast and/or ovarian cancer.<sup>5</sup> However, in the United

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1. Human Genome Project Information: How Many Genes Are in the Human Genome?, [http://www.ornl.gov/sci/techresources/Human\\_Genome/faq/genenumber.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/faq/genenumber.shtml) (last visited Oct. 12, 2009) ("Although the completion of the Human Genome Project was celebrated in April 2003 and sequencing of the human chromosomes is essentially 'finished,' the exact number of genes encoded by the genome is still unknown.").

2. Stefan Lovgren, *One-Fifth of Human Genes Have Been Patented, Study Reveals*, NAT'L GEOGRAPHIC NEWS, Oct. 13, 2005, [http://news.nationalgeographic.com/news/2005/10/1013\\_051013\\_gene\\_patent.html](http://news.nationalgeographic.com/news/2005/10/1013_051013_gene_patent.html).

3. See 35 U.S.C. § 271(a) (2006).

4. U.S. CONST. art. I, § 8, cl. 8.

5. See U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,693,473 (filed June 7, 1995); U.S. Patent No. 5,709,999 (filed June 7, 1995); U.S. Patent No. 5,710,001 (filed June 7, 1995); U.S. Patent No. 5,753,441 (filed Jan. 5, 1996); U.S. Patent No. 5,837,492 (filed Apr. 29, 1996); U.S. Patent No. 6,033,857

States, only Myriad may perform testing procedures utilizing the BRCA genes due to patent protection.<sup>6</sup> Yet, in France, a physician not constrained by the United States patents discovered a deficiency in Myriad's testing procedures;<sup>7</sup> such a deficiency could not be discovered by non-Myriad researchers in the United States, who are restricted from unauthorized uses of patented subject matter.<sup>8</sup> However, the value of the BRCA genes as markers for certain cancers was discovered by researchers at Myriad<sup>9</sup> – an advance that was encouraged by the financial benefit of patent protection. The BRCA genes provided a rallying point for salient opponents of gene patents, such as the American Medical Association, the March of Dimes, and the American Society for Human Genetics, who condemn the BRCA gene patents.<sup>10</sup> Thus, while the American judiciary has to date taken a stance that approves the patentability of human genes, intense opposition remains.

This Article examines the place, if any, of genes within the United States patent system by first providing a broad background of the United States patent system, including the foundational cases that have shaped the system. Further, this Article briefly describes human genes to explain how genetic material is viewed within the United States patent system. Subsequently, "gene patents" within the United States are explained. Building upon this milieu, the merits of arguments in opposition to gene patents are examined by focusing on the arguments presented in an ongoing suit filed by the American Civil Liberties Union (on behalf of various parties) against Myriad Genetics, the holder of several gene patents, and the United States

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(filed Mar. 20, 1998). See also U.S. Patent No. 6,162,897 (filed May 2, 1997) (patent held by Myriad Genetics, Inc. covering same subject matter).

6. Brendan L. Smith, *Wrangling Genes*, A.B.A. J., July 2009, at 56, 57.

7. Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 90 (2002).

8. See 35 U.S.C. § 271(a) ("[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." (emphasis added)).

9. Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 131 (2002). Myriad Genetics currently holds the patents on the BRCA1 and BRCA2 genes, though other entities, including researchers at the University of Utah, the U.S. National Institutes of Health, and McGill University, participated in sequencing the BRCA1 gene. *Id.* Myriad Genetics also claims discovery of the BRCA2 gene. *Id.* at 132.

10. See Brief for American Medical Ass'n et al. as Amici Curiae in Support of Plaintiffs' Opposition to Defendants' Motions to Dismiss and in Support of Plaintiffs' Motion for Summary Judgment, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 2009 WL 3614434 (S.D.N.Y. 2009) (No. 1:09CV04515); Brief for March of Dimes Foundation et al. as Amici Curiae in Support of Plaintiffs, *Ass'n for Molecular Pathology*, 2009 WL 3614434 (No. 1:09CV04515).

Patent and Trademark Office.<sup>11</sup> Finally, this Article concludes with a brief forecast of the fate of gene patents in the United States and how concerns about the deleterious effects of gene patents might be addressed.

## II. LEGAL BACKGROUND

Charged with assessing the validity of patents, the United States Patent and Trademark Office (USPTO) will issue a patent to an applicant who “invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”<sup>12</sup> Given only a cursory glance, the requirements to obtain a patent appear precisely defined. However, dramatic intellectual and technological developments in fields such as biotechnology have created substantial difficulties in applying the requirements for a patent in the United States. To adequately convey the intricacies of the patentability of a gene, it is beneficial to outline some basics of DNA.

### A. DNA Background

Traits within a group of organisms are passed from one generation to the next via deoxyribonucleic acid (DNA).<sup>13</sup> Known for its double helix shape, DNA is composed of two chains of nucleotides, with each individual nucleotide containing a sugar, phosphate, and a base consisting of one of adenine, guanine, thymine, or cytosine (referred to as A, G, T, or C, respectively).<sup>14</sup> Thus, the double helix of DNA can be conceptualized as being divisible into a number of shorter sequences of nucleotides.<sup>15</sup> If any shorter sequence of nucleotides codes for a protein, then that shorter sequence is known as a gene.<sup>16</sup> There are a number of stages in the process of making proteins from the shorter sequences within the double helix of DNA (i.e., genes), beginning with gene transcription.<sup>17</sup>

In gene transcription, the double helix of the DNA is unwound, and one of the two chains of nucleotides makes messenger ribonucleic acid (mRNA).<sup>18</sup> A gene is copied onto this mRNA strand, allowing for the production of a protein after a gene translation process whereby a ribosome de-

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11. See Complaint, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 1:09CV04515 (S.D.N.Y. May 12, 2009).

12. 35 U.S.C. § 101 (2006).

13. Lynn C. Tyler, *Genes and 35 U.S.C. § 101: Are DNA Sequences Corresponding to Genes Patentable Subject Matter?*, *INTELL. PROP. & TECH. L.J.*, June 2007, at 16, 16.

14. *Id.*

15. *Id.* at 17.

16. *Id.*

17. *Id.*

18. *Id.*

codes the mRNA to create the particular protein.<sup>19</sup> However, while each gene has “exons” that code for proteins and regions that mark the beginning and the end of the gene, additional areas that do not code for proteins, called “introns,” are also present in each gene.<sup>20</sup> Consequently, the introns must be spliced out of the gene when the mRNA is made, and only the exons and the regions marking the beginning and the end of the gene form the final mature mRNA.<sup>21</sup> This mature mRNA contains a number of sequences of three nucleotides, identified as codons, which individually code for a specific amino acid.<sup>22</sup> On a ribosome, adjacent amino acids are joined to form a protein.<sup>23</sup> The entire process from transcription to translation is known as gene expression, and the expression of the gene is realized in certain cells – e.g., heart cells, lung cells, and so forth.<sup>24</sup>

The entire process of gene transcription and translation occurs within a chromosome and is therefore intrinsically unobservable by any individual attempting to extrapolate data.<sup>25</sup> However, it is possible to identify particular genes using technologies such as Expressed Sequence Tags (ESTs).<sup>26</sup> In a laboratory, an EST can be created by introducing special enzymes to the mRNA, causing synthesis from an mRNA strand to a complementary DNA (cDNA) strand.<sup>27</sup> The ESTs are subsequently created from fragments of the cDNA.<sup>28</sup> A cDNA strand will bind to a synthesized DNA complement and accordingly will facilitate in locating a specific gene on a chromosome.<sup>29</sup> Once a gene has been identified through the use of cDNA, it is possible to establish the function of that individual gene.<sup>30</sup> The implications of identifying the functions of individual genes are both extraordinary and extensive. Particularly, certain genes act as indicators of an individual’s genetic susceptibility to a specific ailment.<sup>31</sup>

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19. *Id.*

20. *Id.* at 18.

21. *Id.*

22. John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part I)*, 85 J. PAT. & TRADEMARK OFF. SOC’Y 301, 312 (2003).

23. *Id.* at 313.

24. *Id.* at 311.

25. Tyler, *supra* note 13, at 18-19.

26. *Id.* at 19.

27. *Id.*

28. Conley & Makowski, *supra* note 22, at 315.

29. *Id.* at 314.

30. Erin Bryan, Note, *Gene Protection: How Much Is Too Much? Comparing the Scope of Patent Protection for Gene Sequences Between the United States and Germany*, 9 J. HIGH TECH. L. 52, 54 (2009).

31. Debra Greenfield, *Intangible or Embodied Information: The Non-Statutory Nature of Human Genetic Material*, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 467, 484 (2009).

### B. Patent Law and Patentable Subject Matter

In the United States, a patent bestows upon the patentee the exclusive right to prohibit others from making, using, or selling his invention for twenty years from the date the patent application is filed.<sup>32</sup> In this way, the rights of an inventor in his invention are reconciled with the benefit the public receives from the invention. Correspondingly, laws of nature, physical phenomena, and scientific formulas are inherently unpatentable because there would be no benefit to the public to reconcile with the patentee.<sup>33</sup>

The federal government derives its power to grant patents from Article I, section 8, clause 8 of the Constitution, which provides, “Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Rights to their respective Writings and Discoveries.”<sup>34</sup> To facilitate this constitutional authority, the USPTO was established to administer and manage patents within the United States.<sup>35</sup> Coupled with this office, Congress enacted the Patent Act of 1952 (1952 Act),<sup>36</sup> which demarcated the requirements for acquiring a patent as novelty, utility, and nonobviousness.<sup>37</sup> Consequently, the Supreme Court has had a number of occasions in which to interpret Congress’s meaning and intent behind the 1952 Act.

In a precedential decision regarding the 1952 Act, the Supreme Court of the United States endeavored to define patentable subject matter with respect to processes in *Gottschalk v. Benson*.<sup>38</sup> In *Gottschalk*, the Court denied a patent for a process to “convert[] binary-coded decimal . . . numerals into pure binary numerals,” asserting that the “[t]ransformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.”<sup>39</sup> Moreover, the Court determined that such a patent would be tantamount to patenting an idea because “[t]he mathematical formula . . . has no substantial practical application except in connection with a digital computer[;] . . . the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.”<sup>40</sup> Similar to *Gottschalk*, *Parker v. Flook* presented to the Supreme Court a potential patent for a method identical to pre-

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32. 35 U.S.C. § 154(a)(1)-(2) (2006).

33. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (“Such discoveries are ‘manifestations of . . . nature, free to all men and reserved exclusively to none.’” (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (alteration to original in quoted text))).

34. U.S. CONST. art. I, § 8, cl. 8.

35. 35 U.S.C. § 1(a) (2006).

36. Pub. L. No. 593, §§ 1-3, 66 Stat. 792 (codified at 35 U.S.C.).

37. 35 U.S.C. §§ 101-103 (2006).

38. 409 U.S. 63 (1972).

39. *Id.* at 64, 70, 73 (quoting *Cochrane v. Deener*, 94 U.S. 780, 788 (1876)).

40. *Id.* at 71-72.

vious systems already in use except for the mathematical algorithm used by the system to perform its end function.<sup>41</sup> Accordingly, the Court found the system unpatentable because the introduction of an alternative mathematical formula to a prior art system was, in effect, an attempt to patent a scientific formula that always has existed.<sup>42</sup> However, the Court prudently noted that “[w]hile a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”<sup>43</sup>

Thus, the Supreme Court has extrapolated some boundaries of patentable subject matter under the Patent Act of 1952. However, burgeoning fields such as biotechnology continuously necessitate the Supreme Court’s application and interpretation of the 1952 Act.

### *C. Patentability of Biological Subject Matter*

The current legal climate of patentable biological subject matter has its roots in the landmark Supreme Court decision of *Diamond v. Chakrabarty*.<sup>44</sup> In *Chakrabarty*, a genetic engineer developed a non-naturally occurring, living bacterium, derived from the genus *Pseudomonas*, capable of breaking down crude oil.<sup>45</sup> Initially, the genetic engineer was denied a patent by the USPTO on the ground that living things are not patentable subject matter as contemplated by Section 101 of the 1952 Act.<sup>46</sup> However, the Supreme Court determined that the genetically engineered bacterium was patentable subject matter under the 1952 Act.<sup>47</sup> In finding the bacterium patentable, the Court explained that the patent claim was for a non-naturally occurring composition of matter, created through the ingenuity of the genetic engineer.<sup>48</sup> Thus, the fact that the bacterium was a living micro-organism did not preclude it from patent protection.<sup>49</sup> Famously, the Court stated that “Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”<sup>50</sup> However, the Court tempered this assertion by excluding from patentability “laws of nature, natural phenomena, and abstract ideas.”<sup>51</sup> Reflect-

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41. 437 U.S. 584, 585-86 (1978).

42. *Id.* at 593 n.15.

43. *Id.* at 591 (quoting *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939)).

44. 447 U.S. 303 (1980).

45. *Id.* at 305.

46. *Id.* at 306.

47. *Id.* at 310.

48. *Id.* at 309-10.

49. *Id.* at 318.

50. *Id.* at 309 (quoting S. Rep. No. 82-1979, at 5 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2399; H.R. Rep. No. 1923, at 6 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2399).

51. *Id.*

ing the gravity of this constraint, the Supreme Court reiterated the same limitation in *Diamond v. Diehr*.<sup>52</sup>

The *Chakrabarty* decision is fundamental to the instant patent landscape. The broad interpretation of Section 101 of the 1952 Act espoused by the *Chakrabarty* Court<sup>53</sup> has led to patents being issued for more complex living organisms, such as genetically engineered corn.<sup>54</sup> Manifestly, the crux of current patentability lies not in whether a thing is living but in whether the thing is a product of nature or a product of human ingenuity, as even unforeseen technologies are intrinsically patentable so long as such technologies are manmade.<sup>55</sup>

#### D. Gene Patents

Even with the patentability of living things resolved in the affirmative, uncertainties emerge when the subject of a potential patent is derived from a more complex organism, like a person. However, the USPTO provides only vague guidelines regarding such peripheral cases of living things, such as genes, hence offering no substantial explanation as to why genes are considered patentable subject matter.<sup>56</sup> Despite their controversial patentability status, genes have been held patentable by the USPTO.<sup>57</sup> Appropriately, patents on these DNA sequences have been dubbed “gene patents.”<sup>58</sup> However, the term “gene patent” has no legal or otherwise significant meaning, but is

52. 450 U.S. 175, 185 (1981) (“[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that  $E = mc^2$ ; nor could Newton have patented the law of gravity. Such discoveries are manifestations of . . . nature, free to all men and reserved exclusively to none.” (quoting *Chakrabarty*, 447 U.S. at 309) (internal quotation marks omitted)).

53. 447 U.S. at 308 (“In choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.”).

54. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc., 534 U.S. 124, 127-29 (2001).

55. *Chakrabarty*, 447 U.S. at 313. “A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability. . . . Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable.” *Id.* at 316.

56. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2105 (8th ed., 2001, rev. 2008), available at [http://www.uspto.gov/web/offices/pac/mppe/mppe\\_e8r6\\_2100.pdf](http://www.uspto.gov/web/offices/pac/mppe/mppe_e8r6_2100.pdf) (With regard to living organisms, the USPTO “will decide the questions as to patentable subject matter under 35 U.S.C. [§] 101 on a case-by-case basis following the tests set forth in *Chakrabarty*.”).

57. Gregory C. Ellis, *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents*, 15 RICH. J.L. & TECH. 1, 23 (2008).

58. *Id.* at 10-11.



simply a colloquialism.<sup>59</sup> Without explicitly defining “gene patent,” the USPTO identifies a gene as patentable when “isolated from [both] its natural state” and “from [any] other molecules naturally associated with it.”<sup>60</sup> In support of issuing patents on genes, the USPTO reasons that an isolated gene does not occur naturally and, additionally, that a gene either isolated and purified or synthetic is different from its naturally occurring counterpart.<sup>61</sup> Further expounding upon this reasoning, the USPTO states that patenting isolated compounds is rooted in established practice.<sup>62</sup> Gene patents, however, extend to encompass more than an ordinary gene. The USPTO has held patentable genetic material beyond the traditional scientific definition of a gene, including “a gene fragment, a regulatory region, or a genomic region of unknown function, i.e., so-called ‘junk DNA.’”<sup>63</sup>

Despite the uncertainty in this field, the practice of the USPTO in allowing patents for genes has been met with almost no judicial scrutiny. Indeed, most cases involving gene patents have implicitly accepted the patentability of a gene.<sup>64</sup> To explain how a gene should be treated in the patent system, both the United States Court of Appeals for the Federal Circuit and the USPTO have drawn a comparison between a gene and a complex chemical compound.<sup>65</sup> In analogizing a gene to a complex chemical compound, a rational basis is established for viewing an isolated gene as new and patentable material as opposed to a naturally occurring DNA sequence.

In support of gene patents, the judicial affirmation of the patentability of an isolated and purified compound enjoys a considerable history. As early as

59. *Id.* at 11.

60. Utility Examination Guidelines, 66 Fed. Reg. 1092-02, 1093 (Jan. 5, 2001).

61. *Id.*

62. *Id.* (“For example, Louis Pasteur received U.S. Patent 141,072 in 1873, claiming ‘[y]east, free from organic germs of disease, as an article of manufacture.’ Another example is an early patent for adrenaline.” (citing *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911) (opinion written by Judge Learned Hand))).

63. Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 312 (2007) (footnotes omitted). A “gene fragment” is only a portion of a DNA sequence, but it is representative of an expressed gene. A gene fragment is also known as an Expressed Sequence Tag (EST). An EST must have substantial “‘real world’ utility” to be eligible for patent protection. Ellis, *supra* note 57, at 17, 20.

64. See, e.g., *In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993) (addressing only whether an amino acid sequence of a protein was obvious, not whether the amino acid sequence was itself patentable); *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995) (ignoring the general patentability of a gene and instead reaffirming the holding in *In re Bell* that the “existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious”).

65. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991); Utility Examination Guidelines, 66 Fed. Reg. at 1093.

1911, the judiciary recognized that even “an extracted product without change” is eligible for a patent.<sup>66</sup> Not occurring in nature, an extracted product, in a pure and isolated form, is construed as new and patentable.<sup>67</sup> Further, with respect to the 1952 Act, the courts found that a product of nature is not prohibited from patentability “when it is a new and useful composition of matter.”<sup>68</sup> To evince the isolation and purification of a particular gene, “a precise definition, such as by structure, formula, chemical name, or physical properties” is required for patentability.<sup>69</sup> In clarification, patents are not granted on genetic material as it appears within the host organism; rather, gene patents are available exclusively for “a gene or protein that has been isolated from the body and is useful in that form as a pharmaceutical drug, screening assay, or other application.”<sup>70</sup> Furthermore, the controversy over patented genes should not be interpreted to extend to new genes invented through recombinant methods, as such genes do not naturally exist within a human.<sup>71</sup>

Courts have addressed the specific requirements for the patentability (e.g., nonobviousness) of genes to a lesser degree. In *In re Bell*, a patent application was denied by the USPTO for obviousness because the protein sequence already was known.<sup>72</sup> The United States Court of Appeals for the Federal Circuit, however, overturned the USPTO’s ruling, holding that the nearly infinite number of nucleotide sequences potentially coding for a particular protein rendered the identification and isolation of the instant DNA sequence nonobvious.<sup>73</sup>

Similarly, in *In re Deuel*, the USPTO rejected a patent application for a process to isolate and purify DNA and cDNA molecules encoding heparin-binding growth factors on the ground that the process for isolating the sequences already was known, rendering the subject of the patent claim obvious.<sup>74</sup> Reaffirming *In re Bell* and reversing the USPTO’s claim rejection,

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66. *Parke-Davis & Co.*, 189 F. at 103.

67. *In re Bergstrom*, 427 F.2d 1394, 1401 (C.C.P.A. 1970).

68. *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 161 (4th Cir. 1958) (internal quotation marks omitted).

69. *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

70. James Bradshaw, Comment, *Gene Patent Policy: Does Issuing Gene Patents Accord with the Purposes of the U.S. Patent System?*, 37 WILLAMETTE L. REV. 637, 649 (2001) (quoting Biotechnology Indus. Org., Primer: What Can Be Patented?, <http://www.bio.org/ip/primer/whatcanbepatented.asp> (last visited Feb. 15, 2010)).

71. See Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 786 (2000). “Recombinant DNA research involve[s] splicing together DNA from different sources to create a new sequence . . . .” Susan M. Wolf, Rishi Gupta & Peter Kohlhepp, *Gene Therapy Oversight: Lessons for Nanobiotechnology*, 37 J.L. MED. & ETHICS 659, 662 (2009).

72. 991 F.2d 781, 782 (Fed. Cir. 1993).

73. *Id.* at 784.

74. 51 F.3d 1552, 1553-54 (Fed. Cir. 1995).

the Court of Appeals for the Federal Circuit found that the method of isolating cDNA or DNA molecules has no bearing on the obviousness of the identification and isolation of specific cDNA or DNA molecules.<sup>75</sup>

Arguably the most controversial gene patents are those currently held by Myriad covering the methods and materials used to isolate and detect the human breast and ovarian cancer predisposing gene (BRCA1), to isolate and detect the human breast cancer predisposing gene (BRCA2), and to screen the BRCA1 and/or BRCA2 (together, BRCA1/2) genes for mutations, which facilitate diagnosing the predisposition to breast (both BRCA1 and BRCA2) and ovarian (BRCA1) cancer.<sup>76</sup> Myriad has at least eight patents covering the BRCA1/2 genes, mutations, and methods for comparing an individual's BRCA1 or BRCA2 gene to a wild-type (i.e., normal) BRCA1 or BRCA2 gene, respectively, to determine if a mutation exists.<sup>77</sup> Many of these patents include twenty or more individual claims, designed to exclude others not just from the use of one specific isolated DNA sequence coding for the expressed BRCA1 protein, but even from the use of isolated DNA that is only identified in that patent as having some small overlap with a specific isolated DNA sequence while still coding for the BRCA1 protein.<sup>78</sup> Another patent issued to Myriad relating to the BRCA1 gene contains a method claim that is, in substance, only a comparison of a BRCA1 gene from an individual to a typical BRCA1 gene to determine if there is an alteration in the individual's BRCA1 gene.<sup>79</sup> Similarly, Myriad holds a patent for the BRCA2 gene that is only a comparison of an individual's BRCA2 gene to a normal BRCA2 gene, thereby adducing a predisposition for breast cancer if an alteration exists.<sup>80</sup>

Myriad's patents for the BRCA1/2 genes afford Myriad the luxury of being the sole entity entitled to offer genetic testing for the diseases based on

75. *Id.* at 1559.

76. *See* U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,693,473 (filed June 7, 1995); U.S. Patent No. 5,709,999 (filed June 7, 1995); U.S. Patent No. 5,710,001 (filed June 7, 1995); U.S. Patent No. 5,753,441 (filed Jan. 5, 1996); U.S. Patent No. 5,837,492 (filed Apr. 29, 1996); U.S. Patent No. 6,033,857 (filed Mar. 20, 1998). *See also* U.S. Patent No. 6,162,897 (filed May 2, 1997) (patent held by Myriad Genetics, Inc. covering same subject matter).

77. *See* sources cited *supra* note 76. *See also* U.S. Patent No. 5,753,441 (filed Jan. 5, 1996); U.S. Patent No. 6,033,857 (filed Mar. 20, 1998).

78. *See* U.S. Patent No. 5,747,282 (filed June 7, 1995). This Patent has twenty claims. *Id.* Claim 1 of the patent is for a specific isolated DNA (called SEQ ID NO: 2) coding for the BRCA1 protein, while Claim 5 of the patent is for an isolated DNA with at least fifteen nucleotides of SEQ ID NO: 2. *Id.* SEQ ID NO: 2 codes for an amino acid sequence with 1863 amino acids, and, because there must be at least three nucleotides to code for an amino acid, SEQ ID NO:2 must have at least 5,589 nucleotides. *Id.* Therefore, Claim 5 covers any isolated DNA that codes for the BRCA1 protein and has at least  $\approx$ .03% of the nucleotides from the DNA sequence fully identified.

79. U.S. Patent No. 5,753,441 (filed Jan. 5, 1996).

80. U.S. Patent No. 6,033,857 (filed Mar. 20, 1998).

the BRCA1/2 genes.<sup>81</sup> Due to Myriad's monopoly, the BRCA1/2 tests have proved prohibitively expensive for some women at risk, costing as much as \$3,200 for a comprehensive test.<sup>82</sup> Furthermore, Myriad's BRCA1/2 patents exclude any external physicians or researchers from critiquing or improving testing – an almost indispensable safeguard in the field of medicine.<sup>83</sup> Consequently, Myriad's BRCA1/2 patents prevent any scrutiny or validation of the results of Myriad's genetic testing from any external doctors or laboratories.<sup>84</sup>

### III. RECENT DEVELOPMENTS

As observed earlier, the issue of the validity of a patent on a gene has largely avoided any substantive judicial inquiry. However, the escalating profile of the benefits obtained through gene patents recently has invited a confrontation. In May 2009, a complaint was filed in the United States District Court for the Southern District of New York against the USPTO and Myriad (the Myriad suit) declaring many claims of Myriad's gene patents invalid for three reasons: (1) gene patents are "products of nature" and are thus prohibited by United States patent law,<sup>85</sup> (2) gene patents are unconstitutional under the First and Fourteenth Amendments,<sup>86</sup> and (3) gene patents are violative of the Intellectual Property Clause of the Constitution.<sup>87</sup> The complaint was filed by the American Civil Liberties Union (ACLU) on behalf of numerous diverse parties, including breast cancer survivors, women's health groups, and four scientific organizations purportedly representing over 150,000 researchers.<sup>88</sup>

The lawsuit does not paint with such broad strokes as to explicitly ask the court to hold all gene patents invalid, but instead focuses on Myriad's patents for the BRCA1 and BRCA2 gene mutations.<sup>89</sup> Though each person's genome has both the BRCA1 and BRCA2 genes, the sequence of the genes can vary across individuals.<sup>90</sup> As a result, when these genes express a mutative sequence, researchers can deduce a correlative increase in an individual's potential development of breast and/or ovarian cancer.<sup>91</sup> Mutative or not, because each person intrinsically possesses both the BRCA1 and BRCA2

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81. Smith, *supra* note 6, at 57.

82. *Id.* See also Breastcancer.org, Genetic Testing Facilities and Cost, [http://www.breastcancer.org/symptoms/testing/genetic/facility\\_cost.jsp](http://www.breastcancer.org/symptoms/testing/genetic/facility_cost.jsp) (last visited Jan. 23, 2010).

83. Complaint, *supra* note 11, at 2.

84. *Id.*

85. *Id.* at 29 (citing 35 U.S.C. § 101 (2006)).

86. *Id.* (citing U.S. CONST. amend. I, XIV).

87. *Id.* (citing U.S. CONST. art. I, § 8, cl. 8).

88. Smith, *supra* note 6, at 57.

89. Complaint, *supra* note 11, at 14-15.

90. *Id.* at 16.

91. *Id.* at 16-17.

genes, the ACLU claims that the gene sequences are products of nature and therefore unpatentable.<sup>92</sup> In a May 2009 statement issued by Myriad, the company contended that the Supreme Court's decision in *Diamond v. Chakrabarty* implicitly allows for gene patents, as evidenced by the subsequent perpetual grant of gene patents by the USPTO.<sup>93</sup>

More recently, the ACLU filed a motion for summary judgment in the Myriad suit.<sup>94</sup> Somewhat surprisingly, the district court recently granted this motion for summary judgment.<sup>95</sup> In the memorandum of law in support of its motion for summary judgment, the ACLU suggests that *Chakrabarty* has been incorrectly applied by the USPTO in that the *Chakrabarty* decision disallows "patenting laws of nature, physical phenomena, and abstract ideas."<sup>96</sup> The ACLU contends that Myriad's patented genes are identical to those occurring naturally in the human body and, as such, are inherently unpatentable.<sup>97</sup> Additionally, the motion for summary judgment argues that gene patents violate the First Amendment.<sup>98</sup> In a bifurcated constitutional argument, the ACLU first asserts that the patents on the BRCA1/2 genes are essentially patents on abstract mental processes<sup>99</sup> and thus cannot be limited by the government.<sup>100</sup> Second, because the BRCA1/2 "gene patents . . . directly limit thought and knowledge," the gene patents are an unconstitutional violation of the First Amendment's prohibition on the government from limiting

92. *Id.* at 29. See 35 U.S.C. § 101 (2006).

93. *ACLU Files Suit Against Myriad over BRCA Patents*, GENOMEWEB DAILY NEWS, May 13, 2009, <http://www.genomeweb.com/dxpgx/aclu-files-suit-against-myriad-over-brca-patents> ("Since a landmark US Supreme Court decision in 1980 relating to gene patenting, the USPTO has granted tens of thousands of genetic and genetic related patents which cover a large number of life-saving pharmaceutical and diagnostic products," the firm said.) (referring to 447 U.S. 303 (1980)).

94. Plaintiffs' Motion for Summary Judgment, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 1:09CV04515 (S.D.N.Y. Aug. 26, 2009).

95. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 1:09CV04515 (S.D.N.Y. Mar. 29, 2010). It is highly unlikely that this decision will stand. An appeal to the United States Court of Appeals for the Federal Circuit is nearly guaranteed, and the Federal Circuit will almost certainly overturn this decision. See Posting of Dennis Crouch to Patently-O Blog, <http://www.patentlyo.com/patent/2010/03/court-essentially-all-gene-patents-are-invalid.html> (Mar 30, 2010, 7:17 AM).

96. Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgment at 19, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 1:09CV04515 (S.D.N.Y. Aug. 26, 2009).

97. *Id.* at 20.

98. *Id.* at 32.

99. *Id.* at 29 ("What is patented is the mere thought process of looking at a *BRCA1* sequence and noting whether or not the specified naturally-occurring alterations appear.").

100. *Id.* at 33 (citing *Palko v. Connecticut*, 302 U.S. 319 (1937)).

knowledge.<sup>101</sup> Finally, the ACLU posits that many of Myriad's gene patents violate the Intellectual Property Clause of the Constitution.<sup>102</sup> In support of this allegation, the ACLU avers that the BRCA1/2 gene patents inhibit scientific progress as a matter of law<sup>103</sup> and therefore violate the Intellectual Property Clause's purpose "[t]o promote the Progress of Science and useful Arts."<sup>104</sup>

While the outcome of the ambitious action by the ACLU against Myriad will likely prove precedential in the field of gene patents, the patent law system as a whole has itself proved somewhat malleable in the preceding years. Indicatively, the decision of the Court of Appeals for the Federal Circuit in *In re Bilski* has caused a dramatic change to the patent system.<sup>105</sup> In *In re Bilski*, the patent applicants sought to patent a method for hedging risk in commodities trading.<sup>106</sup> The court defined the principal underlying issue as "whether a claim to a process is patentable under § 101 or, conversely, is drawn to unpatentable subject matter because it claims only a fundamental principle."<sup>107</sup> Ultimately, the court found the method at issue to be ineligible for patent protection.<sup>108</sup> In so finding, the court deemed "the machine-or-transformation" test to be the appropriate barometer "for determining [the] patent eligibility of a process."<sup>109</sup> Citing the precedent in *Gottschalk v. Benson*, the court explained the machine-or-transformation test as a two-part inquiry wherein an applicant must demonstrate that the at-issue process is either tied to a specific machine or transforms a specific article.<sup>110</sup> In doing so, the court found "the 'useful, concrete and tangible result' inquiry" insufficient to satisfy a patent claim.<sup>111</sup> While seemingly unrelated to gene patents, the decision in *In re Bilski* potentially will have tangential implications in the area, as many gene patents claim patentability as a process.<sup>112</sup> However, *In re Bilski*

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101. *Id.* at 33-34.

102. *Id.* at 37-38. See U.S. CONST. art. I, § 8, cl. 8.

103. Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgment, *supra* note 96, at 38.

104. U.S. CONST. art. I, § 8, cl. 8.

105. 545 F.3d 943 (Fed. Cir. 2008) (en banc), *cert. granted*, *Bilski v. Doll*, 129 S. Ct. 2735 (June 1, 2009).

106. *Id.* at 949.

107. *Id.* at 952.

108. *Id.* at 966.

109. *Id.* at 956.

110. *Id.* at 961 (citing 409 U.S. 63, 70 (1972)).

111. *Id.* at 959-60. In finding the "'useful, concrete and tangible result' inquiry" insufficient for patent eligibility, the court noted that the opinion in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir.1998), could no longer be relied upon. *Id.* at 960 n.19.

112. Holman, *supra* note 63, at 312 ("Another complication in defining human gene patents is that patent claims reciting human genetic sequences vary widely in scope, and can claim either products or processes.").

recently has been granted certiorari and thus will face additional scrutiny in the near future.<sup>113</sup>

#### IV. DISCUSSION

Shortly after the Supreme Court adjudged biological subject matter patentable in the 1980 case of *Diamond v. Chakrabarty*,<sup>114</sup> the first gene patent was issued to the Regents of the University of California for recombinant DNA transfer vectors containing codons for human somatomammotropin and for human growth hormone.<sup>115</sup> Following this patent, a dramatic increase in the issuance of gene patents led to patents on approximately twenty percent of the human genome.<sup>116</sup> With such an extraordinary amount of genetic material patented,<sup>117</sup> the USPTO faced unremitting criticism of its liberal issuance of gene patents.<sup>118</sup> In response to the criticism, the USPTO promulgated the Utility Examination Guidelines (the Guidelines) in 2001.<sup>119</sup> The Guidelines were an effort to address the perpetual concerns by some that gene patents failed to substantially satisfy the utility requirement of patentability.<sup>120</sup> Also addressed by the Guidelines, and even more fundamental to the validity of gene patents, is the issue of whether genetic material is patentable subject matter contemplated by the Intellectual Property Clause, as effected by 35 U.S.C. § 101.<sup>121</sup> The Guidelines adduce that genes are patentable because Congress is expressly permitted to grant a monopoly to any inventor who “invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”<sup>122</sup>

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113. *Bilski v. Doll*, 129 S. Ct. 2735 (2009).

114. 447 U.S. 303 (1980).

115. U.S. Patent No. 4,363,877 (filed Apr. 19, 1978) (issued Dec. 14, 1982) (claiming a recombinant DNA transfer vector comprising codons for human chorionic somatomammotropin comprising a specific nucleotide sequence and a recombinant DNA transfer vector comprising codons for human growth hormone).

116. Lovgren, *supra* note 2.

117. Please note that the study finding approximately twenty percent of the human genome patented was published in 2005, *see id.*, while the USPTO Guidelines were issued in 2001. *See* 66 Fed. Reg. 1092-02 (Jan. 5, 2001). Nonetheless, it was concerns about the abundant and perpetual grant of gene patents that led to the promulgation of the USPTO's Utility Examination Guidelines. *See supra* note 103.

118. Jonathan Kahn, *What's the Use? Law and Authority in Patenting Human Genetic Material*, 14 STAN. L. & POL'Y REV. 417, 421 (2003).

119. *See* 66 Fed. Reg. 1092-02.

120. *See id.* at 1092 (citing 35 U.S.C. § 101 (2006)).

121. *Id.* at 1093-94 (citing U.S. CONST. art. I, § 8, cl. 8).

122. *Id.* at 1093 (quoting 35 U.S.C. § 101 (emphasis added)).

While the Guidelines are intended to assist USPTO patent examiners, they are clearly not intended to be law.<sup>123</sup> Thus, because the Guidelines do not necessarily foreclose the issue of gene patentability, the ACLU's suit against Myriad and the USPTO, diametrically opposed to the USPTO's interpretation of patentable subject matter as proffered in the Guidelines,<sup>124</sup> is not inescapably futile from the outset. As previously noted, the acceptability of a gene as a patentable invention has yet to be directly adjudicated.<sup>125</sup> Thus, while the Myriad suit only calls into question fifteen claims across seven patents,<sup>126</sup> the tangential effect of a ruling in favor of the plaintiffs could be devastating to a substantial percentage of gene patent holders.

Theoretically, in evaluating whether a claim is patentable, the USPTO should act with strict deference to the United States patent statutes;<sup>127</sup> however, the USPTO has a pecuniary interest in granting patents.<sup>128</sup> Unlike most federal agencies, the USPTO derives the majority of the funding for its operations from the fees associated with filing and issuing patents.<sup>129</sup> While this fiscal practice has been feasible in the past, the USPTO has been faced with declining patent applications and, accordingly, will be struggling with its budget in 2009 and going forward.<sup>130</sup> Thus, it is economically advantageous for the USPTO to effect a very broad interpretation of patentable subject matter in an effort to issue additional patents and, in the future, collect additional maintenance fees.

While the USPTO has sometimes favored constricting patentable subject matter – even recently in the notable *In re Bilski*<sup>131</sup> – a nascent field such as gene patents can provide a substantial quantity of new patents and, as a result, new fees. Illustratively, during the 1990s the number of DNA-related patents

123. *Id.* at 1097-98 (Jan. 5, 2001) (“The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law.”).

124. Complaint, *supra* note 11, at 1.

125. Andrews, *supra* note 7, at 70.

126. Complaint, *supra* note 11, at 15.

127. See 35 U.S.C. §§ 101-105, 112 (2006).

128. See 35 U.S.C. § 42 (2006).

129. *Id.* For patent application fees, see 37 C.F.R. § 1.16 (2009). For patent maintenance fees, see 37 C.F.R. § 1.20 (2009). For a complete patent fee schedule, see United States Patent & Trademark Office, Current Fee Schedule, <http://www.uspto.gov/web/offices/ac/qs/ope/fee2009september15.htm> (last visited Jan. 22, 2010).

130. Posting of Gene Quinn to IPWatchdog.com Blog, <http://www.ipwatchdog.com/2009/03/02/pto-hiring-freeze-and-budget-problems/id=2099/> (Mar. 2, 2009, 12:31 EST).

131. 545 F.3d 943, 949, 964 (Fed. Cir. 2008). In *In re Bilski*, the USPTO argued that a method of hedging risk in the field of commodities trading was unpatentable because the method was a purely mental process and, therefore, a fundamental principle. *Id.* at 949, 952. For additional cases where the USPTO favored constricting patentable subject matter, see *Gottschalk v. Benson*, 409 U.S. 63, 64 (1972); *Parker v. Flook*, 437 U.S. 584, 587 (1978); *Diamond v. Chakrabarty*, 447 U.S. 303, 305-06 (1980); *Diamond v. Diehr*, 450 U.S. 175, 179-80 (1981).



increased at a sizeable rate of approximately fifty percent each year.<sup>132</sup> In 2005, the number of human genes subject to patent protection was approximated at 4,382 of the 23,688 contained in the National Center for Biotechnology Information's database.<sup>133</sup> However, even the 4,382 figure does not adequately reveal the vast number of gene patents because "some genes have up to 20 patents asserting rights to various gene uses and manifestations including diagnostic uses, single nucleotide polymorphisms (SNPs), cell lines, and constructs containing the gene."<sup>134</sup> The sheer volume of gene patents, both currently issued and potentially issued, provides the USPTO with a source of revenue – one in which it is in the USPTO's best interest to protect. Consequently, a decision on gene patents by the United States District Court for the Southern District of New York in the Myriad suit would justly resolve the conflict, at least until further appeal.

### *A. Patented Genes as a Product of Nature*

Central to the opposition of gene patents is the claim that an isolated and purified gene sequence is outside the scope of patentability because the same gene appears naturally within a chromosome, though with introns.<sup>135</sup> Further, though the synthesized and patented final product (e.g., cDNA) is a man-made creation, the value of the gene is generally not in the gene itself but in the ability to make the natural protein for which the gene codes.<sup>136</sup> Thus, the isolated and purified product serves precisely the same function as a naturally occurring gene.<sup>137</sup> If the value of a gene often resides in the natural, corresponding protein, an isolated and purified gene could be construed as outside the gamut of patentable inventions due to the absence of the requisite "new" attribute.<sup>138</sup> Conversely, proponents of gene patents circumvent the question of patentability by focusing on the utility provided by gene patents, as evidenced by the Guidelines.<sup>139</sup> Emphasis on whether an isolated and purified

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132. Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1091 (2006).

133. Kyle Jensen & Fiona Murray, *The Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239, 239 (2005). The National Center for Biotechnology Information (NCBI) is a U.S. government-funded national resource for molecular biology information. Information regarding the NCBI is available at Nat'l Ctr. for Biotechnology Info., Welcome to NCBI, <http://www.ncbi.nlm.nih.gov/> (last visited Feb. 17, 2010).

134. Jensen & Murray, *supra* note 133, at 239.

135. Andrews, *supra* note 7, at 72.

136. Martin Bobrow & Sandy Thomas, *Patents in a Genetic Age*, NATURE, Feb. 15, 2001, at 763, 764.

137. *Id.*

138. See 35 U.S.C. § 101 (2006).

139. See Utility Examination Guidelines, 66 Fed. Reg. 1092-02, 1093 (Jan. 5, 2001).

gene satisfies the patentability standards of utility eschews the supposition that the inherent value of a gene (i.e., coding for a specific protein) is natural and therefore not new. However, the metric of patentability is inextricably intertwined with the utility of the invention, and the Guidelines have fixed the boundaries of utility at “specific, substantial, and credible” – a standard that embraces isolated and purified genes, according to the USPTO.<sup>140</sup>

The Supreme Court’s opinion in *Diamond v. Chakrabarty* is essential to the support of gene patents, as both the proponents and the Guidelines reference the famous standard of “‘anything under the sun that is made by man’” for patentability.<sup>141</sup> Elaborating upon this statement, the Court found “a non-naturally occurring manufacture or composition of matter – a product of human ingenuity ‘having a distinctive name, character [and] use’” within patentable subject matter.<sup>142</sup> However, by its own admission, the Court in *Chakrabarty* did not intend for the opinion to extend to all discoveries. For example, the Court emphasized that simply discovering natural phenomena does not bring the discovery within patentable subject matter because “[s]uch discoveries are ‘manifestations of . . . nature, free to all men and reserved exclusively to none.’”<sup>143</sup> While the *Chakrabarty* opinion undeniably compelled a broad interpretation of patentability, the Court distinguished the instant invention from others held ineligible for patent protection because the instant invention was a “new bacterium with *markedly different characteristics* from any found in nature.”<sup>144</sup> An isolated and purified gene with only the non-coding introns absent and, therefore, still coding for the same protein as the natural gene probably does not cross the threshold of “markedly different” from the gene found in nature. Relatedly, an isolated and purified gene would probably not have a “‘distinctive name[ and] character’” because such a gene is identical in primary function to the natural gene.<sup>145</sup>

Referencing a case predating the *Chakrabarty* decision, the Guidelines cite the opinion of Judge Learned Hand in *Parke-Davis & Co. v. H.K. Mulford Co.*<sup>146</sup> Particularly detrimental to opponents of gene patents, Judge Hand’s opinion expressly finds isolated adrenaline patentable because the inventor made it “available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to

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140. *Id.*

141. 447 U.S. 303, 309 (1980) (quoting S. Rep. No. 82-1979, at 5 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2399; H.R. Rep. No. 1923, at 6 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2399).

142. *Id.* at 309-10 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887) (alteration to original in quoted text)).

143. *Id.* at 309 (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (alteration to original in quoted text)).

144. *Id.* at 310 (emphasis added).

145. *Id.* at 309-10 (quoting *Hartranft*, 121 U.S. at 615).

146. Utility Examination Guidelines, 66 Fed. Reg. 1092-02, 1093 (Jan. 5, 2001) (citing 189 F. 95 (S.D.N.Y. 1911)).

call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically.”<sup>147</sup> Conversely, opponents posit that the *Parke-Davis & Co.* opinion is both incorrect and inapposite because, first, the court erroneously followed two prior decisions in arriving at its opinion and, second, the isolated adrenaline is scientifically distinguishable from isolated and purified genes.<sup>148</sup> In reference to the former, Judge Hand’s specific detrimental statement in the *Parke-Davis & Co.* opinion, mentioned above, is immediately followed by a citation to two cases.<sup>149</sup> The first, *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, dealt with the patentability of aspirin,<sup>150</sup> and the second, *Union Carbide Co. v. American Carbide Co.*, addressed the patentability of a new form of crystalline calcium carbide.<sup>151</sup> In both cases cited by Judge Hand to support the patentability of isolated adrenaline, the respective courts were addressing man-made compounds, as opposed to an isolated and purified natural substance; thus, the *Parke-Davis & Co.* decision draws an incongruous analogy that should not substantiate a basis for gene patents. Furthermore, the *Parke-Davis & Co.* decision apparently conflicts with earlier Supreme Court precedent disallowing patent protection for an extracted and purified product of nature.<sup>152</sup> Turning to the former, applying the *Parke-Davis & Co.* opinion of extracted and purified adrenaline to gene patents is arguably scientifically suspect because the analogy disregards a fundamental difference between the two in the patent spectrum. To attain the requisite utility, adrenaline must be purified, which the human body lacks the capacity to do; conversely, the isolating and splicing of genes occurs naturally with the body.<sup>153</sup> Thus, adrenaline’s utility is a product of human ingenuity, whereas often patented genes “have the same function and information and that function and information was dictated by nature, not by scientists.”<sup>154</sup>

A final case spearheading the Guidelines’ support of gene patents is *In re Bergstrom*.<sup>155</sup> In *Bergstrom*, the United States Court of Customs and Pat-

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147. *Parke-Davis & Co.*, 189 F. at 103.

148. See Plaintiffs’ Memorandum of Law in Support of Motion for Summary Judgment, *supra* note 96, at 25.

149. *Parke-Davis & Co.*, 189 F. at 103.

150. 179 F. 701, 702-03 (7th Cir. 1910).

151. 181 F. 104, 104 (2d Cir. 1910).

152. See *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. 566, 593-94 (1874) (finding unpatentable cellulose obtained from straw, wood, and vegetables); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 311 (1884) (“Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially for the first time . . .”).

153. Declaration of Myles W. Jackson at 9-10, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 1:09CV04515 (S.D.N.Y. Aug. 26, 2009).

154. *Id.* at 10.

155. 427 F.2d 1394 (C.C.P.A. 1970).

ent Appeals found two prostaglandins<sup>156</sup> extracted from human and animal prostate glands to be eligible for patent, reasoning that the two compounds in a pure form are “not ‘naturally occurring’” and therefore have not “previously existed in fact in nature’s storehouse, albeit unknown, or what has previously been known to exist.”<sup>157</sup> The dispute in *Bergstrom*, however, did not address patentable subject matter but focused on the specific statutory patent requirements of novelty and nonobviousness.<sup>158</sup> Thus, the *Bergstrom* court evidently implicitly accepted that the extracted and purified prostaglandins were patent eligible.<sup>159</sup> Indeed, the court displayed this preconception by rebuffing arguments against patentability under 35 U.S.C. § 101 without citing to any apposite case law.<sup>160</sup>

### B. First Amendment Challenges to Gene Patents

An especially novel argument against gene patents is the theory that extending patent eligibility to genes is violative of the First Amendment and therefore unconstitutional.<sup>161</sup> The ACLU advances this proposition in its suit against Myriad over the BRCA1/2 patents.<sup>162</sup> The contention finds its keystone in perhaps the most eminent of United States rights, the First Amendment, and because the First Amendment protects one of the most fundamental rights, it surely defines the boundaries of the patent system as instituted under the Intellectual Property Clause.<sup>163</sup> Indeed, like any other government institution, the patent system is constrained by the First Amendment,<sup>164</sup> but a First Amendment contestation of patentable subject matter has yet to be adjudicated. Thus, the ACLU’s First Amendment challenge of Myriad’s BRCA1/2 patents is one of first impression with respect to gene patents. In light of this, a First Amendment challenge to gene patents suggests at first glance that the ACLU is grasping at straws should its argument that the BRCA1/2 genes are unpatentable products of nature fail. Nonetheless, some innovative reasoning

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156. A “prostaglandin” is “any of various oxygenated unsaturated cyclic fatty acids of animals that are formed chiefly by the action of cyclooxygenase on arachidonic acid and perform a variety of hormonelike actions (as in controlling blood pressure or smooth muscle contraction).” Merriam-webster.com, Prostaglandin, <http://www.merriam-webster.com/dictionary/Prostaglandin> (last visited Jan. 22, 2010).

157. *In re Bergstrom*, 427 F.2d at 1401.

158. *See id.* at 1401-02.

159. *See id.*

160. *Id.* *See* Plaintiffs’ Memorandum of Law in Support of Motion for Judgment, *supra* note 96, at 24.

161. *See* U.S. CONST. amend. I.

162. Complaint, *supra* note 11, at 29.

163. *See* U.S. CONST. art. I, § 8, cl. 8.

164. Plaintiffs’ Memorandum of Law in Support of Motion for Summary Judgment, *supra* note 96, at 32-33.

and analogies buttress the allegation of unconstitutionality against gene patents.

Primarily, patent law is analogized to copyright law in an effort to establish apposite case law. The two ostensibly parallel one another because the power to enact each is derived from the Intellectual Property Clause.<sup>165</sup> The Copyright Act of 1976<sup>166</sup> (Copyright Act) distinguishes between ideas and the expression of ideas, with the latter subject to copyright whereas the former is not.<sup>167</sup> While the Copyright Act defines the limits of copyright law, the Supreme Court held in *Harper & Row Publishers, Inc. v. Nation Enterprises* that it is the First Amendment that compels the idea/expression dichotomy of the Copyright Act.<sup>168</sup> Citing an earlier decision, the Court noted that “[c]opyright laws are not restrictions on freedom of speech as copyright protects only form of expression and not the ideas expressed.”<sup>169</sup> In relation to genes, the idea/expression dichotomy differentiates between genes and other patentable inventions because gene patents are not the expression of any idea; rather, “[a] genetic sequence is *biological information itself*.”<sup>170</sup> Because the function of both natural genes and isolated and purified genes is to code for a specific protein, a patent for an isolated and purified gene cannot be the expression of an idea.<sup>171</sup> More succinctly, a patent over an isolated and purified gene coding for a specific protein is tantamount to a patent for natural genetic information.<sup>172</sup> Accepting this logic, affording patent protection to genes would impermissibly prevent the flow of information about genes because “the State may not, consistently with the spirit of the First Amendment, contract the spectrum of available knowledge.”<sup>173</sup> However, analogizing patent

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165. See U.S. CONST. art. I, § 8, cl. 8.

166. Copyright Act of 1976, Pub. L. No. 94-553, 90 Stat. 2541 (codified at 17 U.S.C. §§ 101-810 (2006)).

167. 17 U.S.C. § 102(b) (2006) (“In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work.”).

168. 471 U.S. 539, 556 (1985) (“The Second Circuit noted, correctly, that copyright’s idea/expression dichotomy ‘strike[s] a definitional balance between the First Amendment and the Copyright Act by permitting free communication of facts while still protecting an author’s expression.’” (quoting *Harper & Row Publishers, Inc. v. Nation Enters.*, 723 F.2d 195, 203 (2d Cir. 1983), *rev’d*, 471 U.S. 539 (1985))).

169. *Id.* (citing *N.Y. Times Co. v. United States*, 403 U.S. 713, 726, n.\* (1971) (Brennan, J., concurring)).

170. Plaintiffs’ Memorandum of Law in Support of Motion for Summary Judgment, *supra* note 96, at 35.

171. *Id.* at 34-35.

172. *Id.* at 36.

173. *Griswold v. Connecticut*, 381 U.S. 479, 482 (1965). In *Griswold*, the Executive Director of the Planned Parenthood League of Connecticut, and the Medical Director of the League, gave information and instruction to married persons concerning contraception. *Id.* at 480. Connecticut prosecuted them for violations of statutes

law to copyright law may prove specious, particularly when centuries-old Supreme Court precedent affords patent protection to an idea if that idea meets the requirements of patentability.<sup>174</sup>

Additionally, the reasoning behind the ACLU's First Amendment challenge has been called weak, as no court has ever invalidated a patent on constitutional grounds.<sup>175</sup> But in the patent field, the ACLU, with no patents of its own to protect, can make bold and imaginative arguments and "can . . . play the [public relations] game with abandon."<sup>176</sup> Furthermore, invalidating gene patents as violative of the First Amendment would have the deleterious potential to drastically transform the architecture of patent law. A precedential decision based in the First Amendment invites a broad interpretation of the fundamental freedom that could incorrectly or adversely be applied to other categories of patents, especially in nascent fields. An extreme, though unlikely, example is the prospect of a purified chemical compound, such as adrenaline in the *Parke-Davis & Co.* decision,<sup>177</sup> being found unpatentable because the function of the compound is inherent, and thus a patent over the intrinsic information of the compound would be an unconstitutional restraint on the free flow of information.

A final consequence of gene patents that approaches a violation of the Supreme Court's First Amendment prohibition of "contract[ing] the spectrum of available knowledge"<sup>178</sup> is the delay of information disclosure inherent in patent filing. Generally, patent law facilitates the disclosure of information because patents are made available to the public, thus allowing future inventors to improve upon the inventions released in earlier patents.<sup>179</sup> In support, the Supreme Court opined that the intention of a patent monopoly is to reward an inventor for the public disclosure of his invention.<sup>180</sup> Contradictorily, patent law encourages researchers to conceal discoveries of genetic infor-

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that prohibited the dissemination of information about contraception. *Id.* The Supreme Court held that the Connecticut statutes were an unconstitutional invasion of protected freedoms. *Id.* at 485.

174. *Pennock v. Dialogue*, 27 U.S. 1, 7-8 (1829). See also MARTIN J. ADELMAN, RANDALL R. RADER & JOHN R. THOMAS, CASES AND MATERIALS ON PATENT LAW 5 (3d ed. 2009) (discussing the *Pennock v. Dialogue* opinion).

175. Posting of Gene Quinn to IPWatchdog.com Blog, <http://www.ipwatchdog.com/2009/05/14/aclu-files-frivolous-lawsuit-challenging-patents/id=3417/> (May 14, 2009, 11:46 EST).

176. Turna Ray, *Can ACLU Expect to Win Its BRCA Gene Patenting Case Before it Even Gets to Trial?*, PHARMACOGENOMICS REP., Sept. 16, 2009, <http://www.genomeweb.com/dxpgx/can-aclu-expect-win-its-brca-gene-patenting-case-it-even-gets-trial?page=3>.

177. See *supra* notes 146-47.

178. *Griswold*, 381 U.S. at 483.

179. JOHN W. SCHLICHER, PATENT LAW, LEGAL AND ECONOMIC PRINCIPLES § 1:1 (2d ed. 2008).

180. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989).

mation because an invention is rendered unpatentable if, prior to applying for patent protection, the invention is described in a printed publication.<sup>181</sup> Indeed, it has been adduced that twenty percent of medical scientists suspend the public dissemination of their research for at least six months for fiscal gain.<sup>182</sup> While not entirely defeating the purpose of information disclosure because the material is eventually published by the USPTO, it is counterintuitive that the patent system operates to hinder the dissemination of genetic research when one purpose is to publicize such research. Conversely, proponents contend that gene patents do not hinder genetic research; thus, they contend that statistics evidencing research delays in the field are misleading. Instead, proponents suggest that to accurately determine whether gene patents impede genetic studies, the focus should be placed on “whether biomedical researchers without commercial interests are prevented from acquiring materials.”<sup>183</sup> Applying this standard, there is little evidence that gene patents interfere with biomedical research.<sup>184</sup> Thus, the encumbrance of genetic research is inaccurately imputed to patents in the field, when in fact the debilitation is attributable to separate, independent factors.

Furthermore, the common-law doctrine of experimental use acts as a defense to patent infringement for the use of a patented invention when done “solely for research, academic or experimental purposes.”<sup>185</sup> However, the experimental use privilege may still expose researchers to infringement liability when using patent-protected genes because the privilege is characterized as “‘crabbed,’ ‘narrowly construed,’ and ‘rarely sustained.’”<sup>186</sup> Regardless of whether genetic researchers are afforded access to patented genetic information, the patent system here produces an interruption in the public distribution of research in a field where the delay of even a few weeks is considerable. Contrary to other patentable inventions, the public dissemination of genetic information is vital because of the innate difference between genes and other inventions – a gene cannot be “invented around,” so its function is unattainable through alternate or creative means.

### *C. Gene Patents Under the Intellectual Property Clause*

As opposed to analogizing patent law with copyright law, a challenge to gene patents may be more successful by focusing on how gene patents do not “promote the Progress of Science and useful Arts” as required by the Intellec-

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181. 35 U.S.C. § 102(a) (2006).

182. Andrews, *supra* note 7, at 80.

183. Ellis, *supra* note 57, at 27.

184. John P. Walsh, Charlene Cho & Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002 (2005).

185. *Madey v. Duke Univ.*, 307 F.3d 1351, 1355 (Fed. Cir. 2002) (internal quotation marks omitted).

186. ADELMAN, RADER & THOMAS, *supra* note 174, at 791.

tual Property Clause.<sup>187</sup> The goal of promoting the progress of science is realized by patents because “patent law encourages competitors to design or invent around existing patents.”<sup>188</sup> Indeed, “[o]ne of the benefits of a patent system is its so-called ‘negative incentive’ to ‘design around’ a competitor’s products, even when they are patented, thus bringing a steady flow of innovations to the marketplace.”<sup>189</sup> Gene patents, however, inhibit the objective of the Intellectual Property Clause, and therein lies the fallacy of equating a gene to a complex chemical compound. A patented chemical compound can be invented around by manufacturing a different chemical compound that achieves a functionally comparable result. By contrast, a different gene that includes the same genetic sequence that occurs in nature cannot be invented. Thus, a gene patent effects a monopoly over the natural information contained in a genetic sequence. Viewed in this light, a gene patent is evidently violative of both the objective of the Intellectual Property Clause and the Supreme Court’s interpretation of the First Amendment that “the State may not . . . contract the spectrum of available knowledge.”<sup>190</sup> Conversely, gene patents provide incentive to conduct research in a field fraught with financial peril, and, thus, investments into genetic research necessitate patent protection.<sup>191</sup> This is especially true for smaller research firms with minimal or no other sources from which to derive funding.<sup>192</sup> Therefore, by incentivizing genetic research and thereby encouraging research and development in the field, gene patents do, in fact, promote the progress of science in accordance with the goal of the Intellectual Property Clause.

## V. CONCLUSION

The opposition to gene patents, manifested immediately by the ACLU, confronts a near insuperable challenge in seeking to invalidate patents on genetic material. Though not mandatory standing alone, the Guidelines have buttressed the expansive support of gene patents. Furthermore, the Guidelines were substantially indoctrinated into law by the United States Court of Appeals for the Federal Circuit in *In re Fisher*.<sup>193</sup> Coupled with the judiciary’s implicit acceptance, the dispute over the patentability of genes essentially has been affirmatively resolved. The ACLU’s suit against Myriad will very likely provide final closure of the issue. Due to the incorporation of the Guidelines into common law, it is highly likely that Myriad will appeal the

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187. U.S. CONST. art. I, § 8, cl. 8.

188. *WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999).

189. *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985).

190. *Griswold v. Connecticut*, 381 U.S. 479, 482 (1965).

191. Bradshaw, *supra* note 70, at 653.

192. *Id.*

193. 421 F.3d 1365, 1372 (Fed. Cir. 2005).



decision of the District Court for the Southern District of New York in favor of the plaintiffs. Accordingly, it seems likely that any higher courts will sustain the decision of the district court. This hypothesis is reinforced in light of the dramatic effect the invalidation of gene patents would have on current holders of gene patents, biotechnology research and development firms, and funding for the USPTO. While interpretations of the purpose of the Intellectual Property Clause vary dramatically across factions, the existing interpretation is likely to prevail, as gene patents do not indisputably hinder the promotion of science. To the contrary, gene patents provide incentives to conduct research into a field that might otherwise be a pecuniary wasteland. Thus, the dispute over gene patents is likely to culminate with the uneventful preservation of the status quo. Still, opponents of certain claims under gene patents, especially those claims over the “process” of comparing an individual’s gene to a wild-type gene to discover an existing mutation, will inevitably remain.

As opposed to an expansive invalidation of gene patents, a beneficial compromise in the field of genetic research should be sought. Research advancement and economic gain are not mutually exclusive; a plausible scheme could be developed to facilitate genetic research while still maintaining the financial allure. One possibility is a patent pool providing non-exclusive licenses to those desiring access to the genes, possibly at a staggered fee for researchers. A similar plan enabled the creation of DVD players because of the numerous patented components necessary to realize the final product.<sup>194</sup> A second option is the compulsory licensing of patented genes. With a compulsory license, the holder of a gene patent would be compelled by government intervention to license patented genes for predetermined fees.<sup>195</sup> Finally, a Department of Health and Human Services committee has recently advised exempting gene patents from infringement.<sup>196</sup> The proposal would exempt researchers and clinics from infringement liability when using patented genes for research or in medical tests.<sup>197</sup>

Isolated and purified human genes incontrovertibly are an invaluable tool in the advancement of health sciences. Incentivizing genetic research through the patent system has undoubtedly facilitated tremendous advancements in the field. Unfortunately, this structure simultaneously has deleteriously affected many individuals. In the near future, the federal courts will adjudicate the merits of arguments both in favor and in opposition of gene patents. Still, more equitable solutions to the gene patent problem are feasible apart from the mutual exclusivity exhibited in the *Myriad* suit.

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194. Andrews, *supra* note 7, at 102.

195. *Id.* at 103.

196. Matt Jones, *Task Force Advises Making Gene Patents Exempt from Infringement*, GENOMEWEB DAILY NEWS, Oct. 8, 2009, <http://www.genomeweb.com/dxpgx/task-force-advises-making-gene-patents-exempt-infringement>.

197. *Id.*