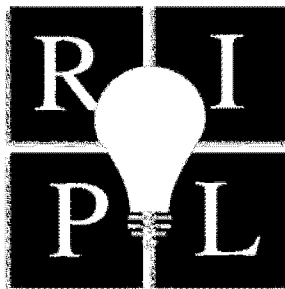


# THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



## GENE PATENTING DEBATE: THE MEANING OF *MYRIAD*

MIRI YOON

### ABSTRACT

The United States District Court for the Southern District of New York recently held in *Association for Molecular Pathology v. United States Patent & Trademark Office* that Myriad's patent claims directed to isolated DNA molecules encoding human breast cancer susceptibility genes BRCA1/2 are not patent-eligible subject matter. Even though the court construed that the patent claims are directed to tangible chemical compounds, the overriding importance of unclaimed DNA sequence information renders claimed molecules as unpatentable products of nature. While the immediate impact of this decision is limited to Myriad's patents-in-suit, this decision reflects the concern about the adverse effects of human gene patents in genetic testing. This comment analyzes the patent-eligibility and constitutionality of human gene patents. As alternatives to a total ban on human gene patents, this comment proposes narrowly tailored legislation to balance the public's interest in access to human gene patents and the biotech industry's incentives to invest capital to translate basic research to commercial products that ultimately benefit the public.

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MARSHALL REV. INTELL. PROP. L. 953 (2010).



## GENE PATENTING DEBATE: THE MEANING OF *MYRIAD*

MIRI YOON\*

*“Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.”*

J. Burger, *Diamond v. Charkarabarty*<sup>1</sup>

### INTRODUCTION

The United States Patent and Trademark Office (“USPTO”) has long granted patents that claim inventions based on human genes.<sup>2</sup> In 2007, Rep. Xavier Becerra introduced the Genomic Research and Accessibility Act to ban human gene patents but this legislation received little support.<sup>3</sup> On May 12, 2009, the Association for Molecular Pathology (“AMP”) filed a lawsuit against the USPTO, Myriad Genetics (“Myriad”), and the University of Utah Research Foundation, challenging the validity of Myriad’s gene patents.<sup>4</sup> Myriad holds, either through assignment or exclusive license, numerous U.S. patents on isolated DNA molecules encoding the human breast cancer susceptibility genes BRCA1 and BRCA2 (collectively “BRCA1/2”) and diagnostic methods using these isolated DNA molecules to determine a predisposition to hereditary breast cancer.<sup>5</sup> In its complaint, AMP challenged patent-eligibility and constitutionality of Myriad’s patents, stating that human genes are products of nature, laws of nature, and abstract ideas.<sup>6</sup>

On March 29, 2010, Judge Robert Sweet of the United States District Court for the Southern District of New York held that Myriad’s patent claims directed to isolated DNA molecules encoding human BRCA1/2 are not patent-eligible and “[t]his

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<sup>1</sup> 447 U.S. 303, 317 (1980).

<sup>2</sup> SECRETARY’S ADVISORY COMMITTEE ON GENETICS, HEALTH AND SOCIETY, REVISED DRAFT REPORT ON GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 57 (Feb. 5, 2010) (“[T]he USPTO begins issuing patents on isolated nucleic acid molecules whose sequences correspond to genes in 1992.”) *available at* <http://oba.od.nih.gov/oba/SACGHS/SACGHS%20Patents%20Report%20Approved%202-5-20010.pdf> (last visited Apr. 20, 2010) [hereinafter SACGHS Report].

<sup>3</sup> Genomic Research and Accessibility Act, H.R. 977, 110th Cong. § 2 (2007).

<sup>4</sup> Complaint at ¶ 32, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09CV04515, 2009 WL 1343027 (S.D.N.Y. May 12, 2009) (challenging the validity of 15 claims in 7 patents) [hereinafter AMP Complaint].

<sup>5</sup> *Id.* at ¶ 31.

<sup>6</sup> *Id.* at ¶¶ 102–03.

conclusion is driven by the overriding importance of DNA's nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated form."<sup>7</sup> The district court's decision was based upon the findings that "DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature" and that "DNA's existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes."<sup>8</sup> However, the district court, invoking the doctrine of constitutional avoidance, dismissed the constitutional claims against the USPTO.<sup>9</sup> On June 16, 2010, Myriad filed a Notice of Appeal to the Court of Appeals for the Federal Circuit ("Federal Circuit").<sup>10</sup> The immediate impact of the district court's decision is limited because "the decision made in a district court does not apply to gene patents other than the ones it considered and its value as a precedent for other courts is limited."<sup>11</sup> However, the district court's decision, if upheld in the Federal Circuit, would have implications reaching far beyond Myriad's patents-in-suit by affecting the validity of numerous other human gene patents.<sup>12</sup>

This comment examines the ongoing legal and policy issues concerning human gene patents in view of *Association for Molecular Pathology v. United States Patent & Trademark Office* ("Myriad").<sup>13</sup> Part I examines the current legal basis for granting human gene patents and policy recommendations for exercising patent rights in the marketplace. Part I also discusses the recent district court's decision in *Myriad*. Part II analyzes the patent-eligibility and constitutionality of Myriad's gene patents-in-suit. Part III advocates narrowly-tailored legislation for compulsory licensing and for exemption from patent infringement remedies for human genetic diagnostic testing.

## I. BACKGROUND

Genetic research was revolutionized by the discovery that deoxyribonucleic acid ("DNA") embodies the genetic information of every living organism.<sup>14</sup> Scientists have identified human genes and their DNA sequences that have diagnostic and therapeutic values.<sup>15</sup> The USPTO has granted patents relating to newly identified

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<sup>7</sup> *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 WL 1233416, \*42 (S.D.N.Y. Mar. 29, 2010) (amended April 5, 2010).

<sup>8</sup> *Id.* at \*1.

<sup>9</sup> *Id.* at \*50–51.

<sup>10</sup> Notice of Appeal to the Federal Circuit, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515 (S.D.N.Y. June 16, 2010).

<sup>11</sup> Andrew Pollack, *After Patent on Genes is Invalidated, Taking Stock*, N.Y. TIMES, March 31, 2010, at B1.

<sup>12</sup> See John Schwartz & Andrew Pollack, *Judge Invalidates Human Gene Patent*, N.Y. TIMES, Mar. 30, 2010, at B1.

<sup>13</sup> 2010 WL 1233416 (S.D.N.Y. Mar. 29, 2010).

<sup>14</sup> J.D. Watson & F.H.C. Crick, *Molecular Structure of Nucleic Acid: A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737, 737–38 (1953); J.D. Watson & F.H.C. Crick, *Genetic Implications of the Structure of Deoxyribonucleic Acid*, 171 NATURE 964, 964–67 (1953).

<sup>15</sup> See NAT'L RESEARCH COUNCIL OF THE NAT'L ACADEMIES, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 32–49 (Stephen A. Merrill & Anne-Marie Mazza, eds., National Academies Press 2006).

genes that encode therapeutic proteins and genes that are linked to a predisposition for rare diseases.<sup>16</sup> The following section examines the current legal basis for human gene patents and policy recommendations for exercising patent rights in the marketplace. This section, then discusses the controversy surrounding Myriad's gene patents.

### *A. Current Legal Basis for Human Gene Patents*

The U.S. Constitution authorizes Congress to enact laws "to promote the Progress of Science and useful Arts."<sup>17</sup> Congress enacted the first Patent Act in 1790<sup>18</sup> and most recently revised the Act in 1952.<sup>19</sup> This section focuses on patent-eligibility under the Patent Act of 1952 and the constitutionality of human gene patents.

#### *1. Patent-Eligibility of Human Gene Patents*

According to the Patent Act of 1952, categories of patent-eligible subject matter include "any . . . process, machine, manufacture, or composition of matter . . ."<sup>20</sup> The Supreme Court has broadly construed statutory subject matter "to include anything under the sun that is made by man."<sup>21</sup> Nonetheless, the Supreme Court held that "laws of nature, physical phenomena, and abstract ideas" are excluded from patent-eligible subject matter.<sup>22</sup> In *Diamond v. Chakrabarty*, the Supreme Court held that a genetically engineered bacterium carrying multiple oil-degrading plasmids was patent-eligible.<sup>23</sup> The Supreme Court concluded that "[p]lasmids are hereditary units physically separate from the chromosomes of the cell" and Chakrabarty produced "a new bacterium with markedly different characteristics from any found in nature" by introducing multiple oil-degrading plasmids into a bacterium, which itself has no capacity for degrading oil.<sup>24</sup>

Although the Supreme Court has not yet addressed patent-eligibility of human genes, courts have implicitly recognized that isolated DNA molecules encoding

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[hereinafter NAT'L RESEARCH COUNCIL'S REPORT]; NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA 5 (2002), available at <http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf> [hereinafter NUFFIELD COUNCIL'S REPORT].

<sup>16</sup> See, e.g., U.S. Patent No. 4,666,828 col. 13 ll. 25–30 (filed Aug. 15, 1984) (claiming the method of genetic testing of Huntington's Disease); U.S. Patent No. 4,703,008 col. 39 ll. 62–68 (filed Nov. 30, 1984) (claiming the isolated DNA molecules encoding human erythropoietin).

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

<sup>18</sup> An Act to promote the progress of useful Arts, ch. 7, 1 Stat. 109 (1790).

<sup>19</sup> Act of 1952, ch. 950, 66 Stat. 792 (1952) (codified as amended under Title 35 of the United States Code).

<sup>20</sup> 66 Stat. at 797 (codified as 35 U.S.C. § 101).

<sup>21</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting *Hearing on H.R. 3760 Before Subcomm. No. 3 of H. Comm. on the Judiciary*, 82d Cong. 37 (1951) (statement of P.J. Frederico, a principal draftsman of Act of 1952)).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 305, 310.

<sup>24</sup> *Id.*

specific genes are patent-eligible.<sup>25</sup> The USPTO has granted human gene patents claiming isolated and purified DNA molecules and any new use of these molecules subject to other statutory requirements for patentability.<sup>26</sup> In *Amgen v. Chugai Pharmaceutical Co.*, the United States District Court for the District of Massachusetts determined “what the invention [was]” before ruling on anticipation of the claim-in-suit.<sup>27</sup> The court rejected Amgen’s contention that the claimed invention was “the DNA sequence encoding human erythropoietin (EPO)” because “the DNA sequence encoding human EPO is a non-patentable natural phenomenon ‘free to all men and reserved exclusively to none.’”<sup>28</sup> The court construed the claimed invention as “‘the purified and isolated’ DNA sequence encoding EPO.”<sup>29</sup> The Federal Circuit affirmed the district court’s ruling on the ground that “[t]he subject matter of claim was the novel *purified and isolated* sequence which codes for EPO” and the Amgen scientists were the first to isolate and characterize the EPO gene.<sup>30</sup>

Such a decision is consistent with upholding patents on new and useful chemical compounds isolated or purified from natural substances.<sup>31</sup> For example, in *Merck & Co. v. Olin Mathieson Chemical Corp.*, the Court of Appeals for the Fourth Circuit held that “there is nothing in the language of the Act which precludes the issuance of patent upon a ‘product of nature’ when it is a ‘new and useful composition of matter,’” subject to other statutory requirements for patentability.<sup>32</sup>

## 2. Constitutionality of Human Gene Patents

The Constitution grants Congress broad power to legislate “to promote the Progress of Science and useful Arts.”<sup>33</sup> The considerable medical benefits of human gene-based inventions are not in dispute, but there are sharply divided views on whether human gene patents promote scientific progress.<sup>34</sup> While some commentators believe that human gene patents stimulate scientific progress by

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<sup>25</sup> See *In re Kubin*, 561 F.3d 1351, 136 (Fed. Cir. 2009) (addressing the obviousness of isolated DNA patents); *Amgen, Inc. v. Chugai Pharma. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) (addressing the novelty of isolated DNA patents).

<sup>26</sup> United States Patent and Trademark Office Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

<sup>27</sup> 13 U.S.P.Q.2d (BNA) 1737, 1759 (D. Mass. 1989).

<sup>28</sup> *Id.* (quoting *Chakrabarty*, 447 U.S. at 309).

<sup>29</sup> *Id.*

<sup>30</sup> *Amgen, Inc. v. Chugai Pharma. Co.*, 927 F.2d at 1206.

<sup>31</sup> See, e.g., *In re Bergstrom*, 427 F.2d 1394, 1402 (C.C.P.A. 1970) (upholding the patent claim on purified prostaglandin as patent-eligible subject matter); *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 162–63 (4th Cir. 1958) (upholding the patent claim on vitamin B12-active composition as patent-eligible subject matter); *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911) (upholding the patent claim on isolated and purified adrenalin as patent-eligible subject matter).

<sup>32</sup> 253 F.2d 156, 161 (4th Cir. 1958).

<sup>33</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>34</sup> See, e.g., NAT’L RESEARCH COUNCIL’S REPORT, *supra* note 15, at 2 (“[P]atented inventions . . . rarely impose[] a significant burden for biomedical researchers.”); Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NATURE REVS. GENETICS 803, 804 (2002) (“Gene patents . . . hamper pharmacogenomic research.”).

attracting investment capital to develop commercial products,<sup>35</sup> others think that such patents inhibit translational research and hinder patients' access to the gene-based inventions.<sup>36</sup>

According to a report by the National Research Council ("NRC"), human gene patents rarely impose significant burdens on biomedical research.<sup>37</sup> In contrast, the Nuffield Council on Bioethics reported that several case studies of human gene patents relating to research tools and genetic testing have indicated adverse effects.<sup>38</sup> One survey reported that twenty-five percent of the surveyed scientists stopped performing clinical genetic testing services because of human gene patents, with Myriad's patents among the most frequently mentioned.<sup>39</sup> A more recent survey, however, reported that human gene patents including Myriad's patents have no obvious effects on the price of and patients' access to clinical genetic testing.<sup>40</sup>

### *B. Policy Recommendations for Exercising Gene Patent Rights in the Marketplace*

Although there is no evidence of systematic failure of the licensing practices of gene patents, a few cases of exclusive licensing practices have generated criticism that human gene patents have adverse effects on public health.<sup>41</sup> In 2005, the National Institutes of Health ("NIH") issued the Best Practices for the Licensing of Genomic Inventions.<sup>42</sup> The NIH recommended, whenever possible, non-exclusive licensing should be pursued because non-exclusive licensing facilitates broad access to gene patents.<sup>43</sup> Non-exclusive licensing is proper "[w]hen a genomic invention represents a component part or background to a commercial development."<sup>44</sup> In contrast, exclusive licensing is necessary when commercial development of therapeutics requires investment by a private company.<sup>45</sup> Nevertheless, the same gene patents could be licensed non-exclusively for other fields of use such as diagnostic genetic testing.<sup>46</sup>

In 2006, the NRC issued further recommendations on genomic research.<sup>47</sup> For example, the NRC advocated an experimental use exemption from infringement for

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<sup>35</sup> Allen C. Nunnally et al., *Genetic Patent Protection in the Pharmaceutical and Biotechnology Industries*, 8 COMMUNITY GENETICS 209, 215 (2005); Mike Stott & Jill Valentine, *Gene Patenting and Medical Research: A View from a Pharmaceutical Company*, 3 NATURE REV. DRUG DISCOVERY 364, 364 (2004).

<sup>36</sup> Andrews, *supra* note 34, at 804–05.

<sup>37</sup> NAT'L RESEARCH COUNCIL'S REPORT, *supra* note 15, at 2.

<sup>38</sup> NUFFIELD COUNCIL'S REPORT, *supra* note 15, at 70–73.

<sup>39</sup> Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 5 (2003).

<sup>40</sup> Robert Cook-Deegan et al., *The Dangers of Diagnostic Monopolies*, 458 NATURE 405, 405 (2009).

<sup>41</sup> NAT'L RESEARCH COUNCIL'S REPORT, *supra* note 15, at 146.

<sup>42</sup> Nat'l Institutes of Health, Best Practices for the Licensing of Genomic Inventions, 70 Fed. Reg. 18413 (Apr. 11, 2005).

<sup>43</sup> *Id.* at 18415.

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

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> NAT'L RESEARCH COUNCIL'S REPORT, *supra* note 15, at 133–49.

non-commercial and educational use of gene patents.<sup>48</sup> The NRC also advocated that courts should decline to enjoin patent infringement under “the extraordinary situations in which the restricted availability of genomic inventions threatens the public health.”<sup>49</sup> Further, the NRC recommended that patent owners who control access to gene-based diagnostic tests should establish procedures “for independent verification of test results.”<sup>50</sup>

*C. Recent District Court’s Decision in Association for Molecular Pathology v. United States Patent & Trademark Office*

Myriad’s gene patents and its exclusive licensing practices have attracted significant negative media coverage.<sup>51</sup> Myriad holds, either through assignment or exclusive license, numerous U.S. patents on the human breast cancer susceptibility genes BRCA1/2 that are linked to a predisposition to hereditary breast cancer.<sup>52</sup> Myriad is the sole clinical provider of full-sequence of BRCA1/2 testing in the United States.<sup>53</sup> Although Myriad has not enforced its patents against academic research institutions, Myriad has aggressively enforced its patents against providers of commercial diagnostic testing.<sup>54</sup> For example, Myriad has sent cease and desist letters, stating that clinical diagnostic testing must be done through Myriad’s laboratories or Myriad licensees.<sup>55</sup> Myriad has also engaged in litigation to prevent others from performing clinical diagnostic testing.<sup>56</sup>

On May 12, 2009, AMP requested declaratory judgment that Myriad’s patents on human BRCA1/2 are invalid under 35 U.S.C. § 101 because Myriad’s patents claimed products of nature, manifestations of the laws of nature and abstract ideas.<sup>57</sup> AMP further sought declaratory judgment that Myriad’s patents are unconstitutional because the USPTO’s policy of granting human gene patents violates Article I, section 8, clause 8 and the First Amendment of the Constitution.<sup>58</sup>

Myriad’s patents-in-suit include two groups of claims— composition of matter and method claims.<sup>59</sup> Myriad’s composition of matter claims are directed to isolated DNA molecules encoding normal or mutant forms of human BRCA1/2.<sup>60</sup> A representative of these claims is claim 1 of U.S. Patent 5,747,282:

<sup>48</sup> *Id.* at 144–45.

<sup>49</sup> *Id.* at 147.

<sup>50</sup> *Id.* at 149.

<sup>51</sup> Timothy Caulfield et al., *Myriad and the Mass Media: The Coverage of a Gene Patent Controversy*, 9 GENETICS IN MEDICINE 850, 853 (2007).

<sup>52</sup> AMP Complaint, *supra* note 4, at ¶ 31.

<sup>53</sup> *Id.* at ¶ 28.

<sup>54</sup> Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 669 F.Supp.2d. 365, 378–79 (S.D.N.Y. Nov. 2, 2009).

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

<sup>56</sup> *Id.* at 379.

<sup>57</sup> AMP Complaint, *supra* note 4, at ¶ 102.

<sup>58</sup> *Id.* at ¶ 103.

<sup>59</sup> Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09 Civ. 4515, 2010 WL 1233416, at \*28–\*29 (S.D.N.Y. Mar. 29, 2010) (amended April 5, 2010).

<sup>60</sup> *Id.* at \*28.



1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.<sup>61</sup>

Myriad's method claims are directed to diagnostic methods for determining a predisposition to breast cancer using isolated DNA molecules encoding human BRCA1/2.<sup>62</sup> A representative of these claims is claim 1 of U.S. Patent 5,709,999:

1. A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.<sup>63</sup>

AMP moved for summary judgment to declare Myriad's patents-in-suit invalid.<sup>64</sup> In response, Myriad moved for summary judgment to dismiss AMP's complaint on the ground that "[t]he difference in the structural and functional properties of *isolated* DNA" rendered Myriad's claim-in-suit patent-eligible.<sup>65</sup> The USPTO also moved for judgment on the pleadings based on the doctrine of constitutional avoidance.<sup>66</sup> Judge Sweet of the United States District Court for the Southern District of New York granted AMP's motion for summary judgment, denied Myriad's cross-motion and granted the USPTO's motion for judgment on the pleadings.<sup>67</sup> The court stated that "DNA represents the physical embodiment of biological information" and that "Myriad's focus on the chemical nature of DNA, however, fails to acknowledge the unique characteristics of DNA that differentiate it from other chemical compounds."<sup>68</sup> Based on this reasoning, the court concluded that "[t]he preservation of this defining characteristic of DNA in its native and isolated forms mandates the conclusion that the challenged composition of matter claims are directed to unpatentable products of nature."<sup>69</sup> Similarly, Myriad's method claims

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<sup>61</sup> U.S. Patent No. 5,747,282 col. 153 ll. 56–58 (filed June 7, 1995) (claiming complementary DNA (cDNA) encoding a 1863 amino acid sequence identified as SEQ ID NO:2).

<sup>62</sup> *Ass'n for Molecular Pathology*, 2010 WL 1233416, at \*28–29.

<sup>63</sup> U.S. Patent No. 5,709,999 col. 161 ll. 17–25 (filed June 7, 1995).

<sup>64</sup> Notice of Plaintiffs' Motion for Summary Judgment at 3, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515 (S.D.N.Y. Aug. 26, 2009).

<sup>65</sup> Myriad Defendants' Memorandum of Law (1) in Support of Their Motion for Summary Judgment and (2) in Opposition to Plaintiffs' Motion for Summary Judgment at 31, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2009 WL 5785008 (S.D.N.Y. Dec. 23, 2009) [hereinafter Myriad Brief].

<sup>66</sup> Memorandum of Law in Support of Defendant United States Patent and Trademark Office's Motion for Judgment on the Pleadings and in Opposition to Plaintiffs Motion for Summary Judgment at 4, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2009 WL 5785024 (S.D.N.Y. Dec. 24, 2009) [hereinafter USPTO Brief].

<sup>67</sup> *Ass'n for Molecular Pathology*, 2010 WL 1233416, at \*1.

<sup>68</sup> *Id.* at \*1, \*41.

<sup>69</sup> *Id.* at \*42.

directed to comparisons of DNA sequences are abstract mental processes that constitute unpatentable subject matter.<sup>70</sup>

## II. ANALYSIS

The following section first examines the Supreme Court's statutory construction of patent-eligibility under the Patent Act of 1952, followed by analysis of Myriad's gene patents under this statutory construction. Then, this section examines the constitutionality of Myriad's gene patents under Article I, section 8, clause 8 and the First Amendment of the Constitution.

### A. Patent-Eligibility under the Patent Act of 1952

#### 1. Statutory Construction of Patent-Eligibility

The statutory language specifying the four categories of patent-eligible subject matter under the Patent Act of 1952 is substantially the same as the language in the Patent Act of 1793.<sup>71</sup> A major change in the Patent Act of 1952 was the codification of conditions for patentability—novelty under section 102 and nonobviousness under section 103.<sup>72</sup> Prior to the Patent Act of 1952, the inquiry for patent-eligible subject matter was intertwined with the inquiry for patentability.<sup>73</sup>

The Supreme Court has construed the Patent Act of 1952 to mean that “no patent is available for a discovery, however useful, novel, and nonobvious, unless it falls within one of the express categories of patentable subject matter of 35 U.S.C. § 101 . . . .”<sup>74</sup> Section 101 provides, “[w]hoever invents or discovers *any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof*, may obtain a patent therefor[e], *subject to the conditions and requirements of this title*.”<sup>75</sup> The Supreme Court has broadly construed section 101 because Congress chose “such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any’ . . . .”<sup>76</sup> This broad construction is supported by the legislative history indicating that Congress intended statutory subject matter “to include anything under the sun that is made by man.”<sup>77</sup> The Court,

<sup>70</sup> *Id.* at \*2.

<sup>71</sup> An Act to promote the progress of useful Arts, ch. 11, 1 Stat. 318, sec. 1 (1793); Act of 1952, ch. 950, 66 Stat. 792, § 101 (1952); see A. Samuel Oddi, *Regeneration in American Patent Law: Statutory Subject Matter*, 46 IDEA 491, 496–97 (2006) (indicating that the only modification was to change the term “art” to “process”).

<sup>72</sup> 35 U.S.C. §§ 102–03 (2006); see P.J. Federico, *Commentary on the New Patent Act*, 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 178, 180 (1993).

<sup>73</sup> Karl B. Lutz, *The New 1952 Patent Statute*, 35 J. PAT. OFF. SOC'Y 155, 157–58 (1953).

<sup>74</sup> *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 486 (1974).

<sup>75</sup> 35 U.S.C. § 101 (emphasis added).

<sup>76</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

<sup>77</sup> *Id.* at 309 (quoting *Hearing on H.R. 3760 Before Subcomm. No. 3 of H. Comm. on the Judiciary*, 82d Cong. 37 (1951) (statement of P.J. Federico, a principal draftsman of Act of 1952)).

however, held that section 101 does not embrace every discovery and “the laws of nature, physical phenomena, and abstract ideas” are not patent-eligible.<sup>78</sup>

In *Diamond v. Chakrabarty*, the Supreme Court determined whether the claimed microorganism carrying oil-degrading plasmids constitutes a ‘manufacture’ or ‘composition of matter’ within the meaning of section 101 without considering “the other ‘conditions and requirements’ of the patent laws, such as novelty and nonobviousness.”<sup>79</sup> The Supreme Court defined the term “manufacture” as “the production of articles for use for raw or prepared materials by giving these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.”<sup>80</sup> The Supreme Court construed “composition of matter” to include “all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.”<sup>81</sup> Then, the Court held that the claimed microorganism was patent-eligible because it was not directed to “a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter— a product of human ingenuity ‘having distinctive name, character [and] use.’”<sup>82</sup>

## 2. *Are Myriad’s Composition of Matter Claims on Isolated DNA Molecules Encoding Normal or Mutant Forms of Human BRCA1/2 Patent-Eligible?*

AMP contended that Myriad’s composition of matter claims are drawn to unpatentable products of nature because Myriad only discovered the pre-existing human BRCA1/2 gene sequences.<sup>83</sup> AMP also contended that these claims are unpatentable manifestations of the laws of nature because the claimed gene sequences embody naturally-occurring genetic code that acts as a law of nature.<sup>84</sup> In response, Myriad contended that isolated DNA molecules encoding BRCA1/2 are structurally and functionally different from naturally occurring BRCA1/2 DNA.<sup>85</sup>

In its recent opinion, the United States District Court for the Southern District of New York first concluded that “products of nature” are well-established, judicially created exceptions to patentable subject-matter.<sup>86</sup> Then, the court framed the issue as “whether the claimed invention constitutes statutory subject matter . . . or whether the claimed invention instead falls within the judicially created ‘products of nature’ exception to patentable subject matter, i.e., ‘laws of nature, natural phenomenon, and abstract idea.’”<sup>87</sup> Relying on a number of cases predating *Diamond*

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

<sup>79</sup> *Id.* at 307, 307 n.5.

<sup>80</sup> *Id.* at 308 (quoting *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931)).

<sup>81</sup> *Id.* (quoting *Shell Dev. Co. v. Waston*, 149 F. Supp. 279, 280 (D.D.C. 1957)).

<sup>82</sup> *Id.* at 309–10 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

<sup>83</sup> Plaintiffs’ Memorandum of Law in Support of Motion for Summary Judgment at 19–26, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2009 WL 3269113 (S.D.N.Y. Aug. 26, 2009) [hereinafter AMP Brief].

<sup>84</sup> *Id.* at 26–29.

<sup>85</sup> Myriad Brief, *supra* note 65, at 20–34.

<sup>86</sup> *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 WL 1233416 at \*33 n.40 (S.D.N.Y. Mar. 29, 2010) (amended April, 5, 2010).

<sup>87</sup> *Id.* at \*35.

*v. Chakrabarty*, the court concluded that “the Supreme Court precedent has established that products of nature do not constitute patentable subject matter absent a change that results in the creation of a fundamentally new product.”<sup>88</sup> The court further concluded that Myriad’s composition of matter claims-in-suit are unpatentable products of nature because “[i]n light of DNA’s unique qualities as a physical embodiment of information,” isolated DNA molecules encoding human BRCA1/2 are not markedly different from naturally-occurring BRCA1/2 DNA.<sup>89</sup>

Despite the district court’s opinion, it is not clear that products of nature are well-established as judicially created exceptions to patent-eligibility because the Supreme Court has never made a general statement that products of nature are not patent-eligible.<sup>90</sup> For example, in *American Fruit Growers, Inc. v. Brodgex Co.*, the Supreme Court held that a citrus fruit impregnated with borax to retard blue mold was not a manufacture because “addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property.”<sup>91</sup> Likewise, in *American Wood-Paper Co. v. Fibre Disintegrating Co.*, the Supreme Court held that “a pulp suitable for the manufacture of paper, made from wood and other vegetable substances” was not a new manufacture on the ground that the patent-in-suit was “void for want of novelty in the manufacture patented” because “paper pulp obtained from various vegetable substances was in common use before the original patent was granted.”<sup>92</sup> Similarly, in *Cochrane v. Badische Anilin & Soda Fabrik*, the Supreme Court held that an artificial version of natural dye called alizarine was not a new composition of matter because natural and artificial versions of alizarine were well-known.<sup>93</sup> In *Merck & Co. v. Olin Mathieson Chemical Corp.*, the Court of Appeals for the Fourth Circuit (“Fourth Circuit”) concluded that the Supreme Court precedent has established that a product derived from a new source or process is not patentable if the product is substantially the same as a known product.<sup>94</sup> The Fourth Circuit further concluded that “[t]here is nothing in the language of the Act which precludes the issuance of a patent upon a ‘product of nature’ when it is a ‘new and useful composition of matter’” and reversed the district court’s decision that vitamin B12-active composition was not patentable on the ground that it was a product of nature.<sup>95</sup>

On the other hand, in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,<sup>96</sup> the Supreme Court invalidated the patent claiming a mixture of mutually non-inhibitive strains of bacteria because the patentee “[did] not create [a] state of inhibition or of non-inhibition in the bacteria” and those qualities are “the manifestations of laws of nature, free to all men and reserved exclusively to none.”<sup>97</sup> Further, Justice

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<sup>88</sup> *Id.* at \*36.

<sup>89</sup> *Id.* at \*42.

<sup>90</sup> See, e.g., *Am. Fruit Growers, Inc. v. Brodgex Co.*, 283 U.S. 1, 11 (1931); *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. 566, 577-596 (1874); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 311 (1884).

<sup>91</sup> 283 U.S. 1, 11 (1931).

<sup>92</sup> 90 U.S. 566, 577, 596 (1874).

<sup>93</sup> 111 U.S. 293, 311 (1884).

<sup>94</sup> 253 F.2d 156, 162-64 (4th Cir. 1958) (distinguishing the case at issue from *American Wood-Paper* and *Cochrane*).

<sup>95</sup> *Id.* at 161-63.

<sup>96</sup> 333 U.S. 127 (1948).

<sup>97</sup> *Id.* at 130.

Frankfurter, in his concurring opinion, concluded that the claim-in-suit was invalid because it encompassed *all* combinations of compatible strains of bacteria.<sup>98</sup> Nonetheless, he stated that a specific combination of compatible strains identified through experimental research is patentable.<sup>99</sup>

Accordingly, whether Myriad's composition of matter claims-in-suit are patent-eligible under 35 U.S.C. § 101 should depend on (1) whether they are within the meaning of the four statutory categories of subject matter and (2) whether they do not fall within judicially created exceptions to patent-eligible subject matter— "the laws of nature, natural phenomenon and abstract ideas."<sup>100</sup> For the first issue, Myriad's claims-in-suit are directed to "compositions of matter" in light of the district court's claim construction.<sup>101</sup> Myriad's claims are directed neither to the naturally occurring human BRCA1/2 genes nor to the naturally occurring human BRCA1/2 proteins but to the isolated DNA molecules encoding normal or mutant forms of human BRCA1/2.<sup>102</sup> The court rejected AMP's construction of "DNA" as a "sequence of nucleic acids, also referred to as nucleotides" and construed as "an acid— a tangible chemical compound."<sup>103</sup> The court further construed "isolated DNA" as "a segment of DNA nucleotides existing separate from other cellular components normally associated with native DNA, including proteins and other DNA sequences comprising the remainder of the genome, and includes both DNA originating from a cell as well as DNA synthesized through chemical or heterologous biological means."<sup>104</sup> Thus, Myriad's claims-in-suit are directed to tangible chemical compounds, which fall within the Supreme Court's definition of "compositions of matter."<sup>105</sup>

Additionally, Myriad's claims-in-suit may qualify as "manufacture" because isolated DNA molecules encoding human BRCA1/2 are significantly different in structure and function from the naturally-occurring human BRCA1/2 DNA.<sup>106</sup> Myriad's claims on isolated DNA encoding human BRCA1/2 are structurally different from the native DNA because the claimed DNA molecules are separated from "other cellular components normally associated with native DNA, including proteins and other DNA sequences comprising the remainder of the genome" in a cell or are synthesized DNA "through chemical or heterologous biological means."<sup>107</sup> Further, it is undisputed that Myriad's claims-in-suit possess utility<sup>108</sup> because "unlike native DNA in cells, the claimed isolated BRCA1/2 DNA molecules can be used as diagnostic

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<sup>98</sup> *Id.* at 133–34 (Frankfurter, J., concurring) (indicating that the claim-in-suit was directed to all mixtures of compatible strains without adequately indentifying the particular combinations of the strains that the patentee had discovered).

<sup>99</sup> *Id.* at 133 ("[T]he packaging of a particular mixture of compatible strains is . . . patentable . . . provided . . . that the particular strains are identifiable and adequately identified.").

<sup>100</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

<sup>101</sup> *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 WL 1233416, at \*31–\*32 (S.D.N.Y. Mar. 29, 2010) (amended April 5, 2010).

<sup>102</sup> See U.S. Patent No. 5,747,282 col. 153 ll. 57–59 (filed June 7, 1995).

<sup>103</sup> *Ass'n for Molecular Pathology*, 2010 WL 1233416, at \*31.

<sup>104</sup> *Id.* at \*32.

<sup>105</sup> See *Chakrabarty*, 447 U.S. at 308.

<sup>106</sup> See Myriad Brief, *supra* note 65, at 20–34.

<sup>107</sup> *Ass'n for Molecular Pathology*, 2010 WL 1233416, at \*32.

<sup>108</sup> *Id.* at \*35.

probes and primers” in determining a predisposition to breast cancer.<sup>109</sup> Thus, Myriad’s claims-in-suit are directed to man-made manufacture, consistent with the Supreme Court’s definition to mean “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.”<sup>110</sup>

For the second issue, AMP contended that Myriad’s claims-in-suit are judicially excluded from patent-eligible subject matter because the claimed gene sequences embody a law of nature similar to genes, which “embody a naturally-occurring genetic code and acts as a law of nature.”<sup>111</sup> As mentioned above, the district court rejected AMP’s claim construction to equate DNA with DNA sequence and concluded that Myriad’s composition of matter claims-in-suit are directed to “tangible chemical compound[s].”<sup>112</sup> In light of this claim construction, Myriad’s claims-in-suit are not directed to DNA sequence and thus do not encompass the law of nature, but rather tangible chemical compounds that fall within the statutory subject matter.<sup>113</sup>

However, the district court equated “products of nature” with the judicially recognized exceptions— laws of nature, natural phenomenon, and abstract ideas.<sup>114</sup> It concluded that “[i]n light of DNA’s unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad between native BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed in the patents-in-suit render the claimed DNA ‘markedly different.’”<sup>115</sup> Further, the district court stated that “[t]his conclusion is driven by the overriding importance of DNA’s nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated form.”<sup>116</sup> Based on this reasoning, the district court held that Myriad’s composition of matter claims-in-suit are “unpatentable products of nature.”<sup>117</sup>

### 3. Are Myriad’s Method Claims for Diagnostic Genetic Testing Patent-Eligible?

AMP, citing Justice Breyer’s dissenting opinion in *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*,<sup>118</sup> contended that Myriad’s method claims are not patent-eligible because the correlation between mutations in the human BRCA1/2 genes and predispositions to breast cancer is a law of nature.<sup>119</sup> Alternatively, AMP contended that Myriad’s method claims are not patent-eligible in view of *In re Bilski*<sup>120</sup> because these claims did not satisfy the machine-or-transformation test.<sup>121</sup> Myriad, relying

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<sup>109</sup> Myriad Brief, *supra* note 65, at 33.

<sup>110</sup> *Chakrabarty*, 447 U.S. at 308.

<sup>111</sup> AMP Brief, *supra* note 83, at 26–27.

<sup>112</sup> *Ass’n for Molecular Pathology*, 2010 WL 1233416, at \*31.

<sup>113</sup> *See id.* at \*31–\*32.

<sup>114</sup> *Id.* at \*35.

<sup>115</sup> *Id.* at \*42.

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

<sup>117</sup> *Id.*

<sup>118</sup> 548 U.S. 124 (2006) (dismissing writ of certiorari as improvidently granted).

<sup>119</sup> AMP Brief, *supra* note 83, at 30–31.

<sup>120</sup> 545 F.3d 943 (Fed. Cir. 2008), *cert. granted*, 129 S. Ct. 2735 (2009).

<sup>121</sup> AMP Brief, *supra* note 83, at 29 n.9.

on *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*,<sup>122</sup> contended that its method claims are patent-eligible in view of *In re Bilski*.<sup>123</sup> The United States District Court for the Southern District of New York concluded that Myriad's claims-in-suit are not patent-eligible in view of *In re Bilski*.<sup>124</sup> In *In re Bilski*, the Federal Circuit held that a process is patent-eligible under section 101 if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."<sup>125</sup>

Justice Breyer's dissenting opinion, in *Lab. Corp.*, stated that diagnostic method claims using the correlation between blood homocysteine levels and deficiencies in vitamin B12 were unpatentable laws of nature.<sup>126</sup> However, in *Prometheus*, the Federal Circuit stated that the dissenting opinion is not controlling law and whether a diagnostic method claim is a patent-eligible process depends on the machine-or-transformation test in view of *In re Bilski*.<sup>127</sup> Then, the Federal Circuit held that Prometheus' diagnostic method claims are patent-eligible because they are directed to the "transformation . . . of the human body following administration of a drug and the various chemical and physical changes of the drug's metabolites that enable their concentrations to be determined."<sup>128</sup>

Thus, the ultimate issue is whether Myriad's method claims-in-suit are directed to patent-eligible processes in view of *In re Bilski*.<sup>129</sup> Myriad's method claims using the correlation between mutations in the human BRCA1/2 genes and predispositions to breast cancer may satisfy the machine-or-transformation test.<sup>130</sup> As Myriad indicated, the initial transformation occurs when the patient's DNA or RNA is isolated from his body.<sup>131</sup> Further transformation occurs when a primer or probe binds to the patient's isolated DNA or RNA before analyzing the correlation of the patient's DNA sequence encoding human BRCA1/2 and a predisposition to breast cancer.<sup>132</sup> Myriad indicated that these transformations were crucial to its method claims.<sup>133</sup>

However, the district court recently concluded that Myriad's claims-in-suit were distinguishable from Prometheus' claims and failed the machine-or-transformation test.<sup>134</sup> The district court stated that Myriad's method claims-in-suit "are directed only to abstract mental process of 'comparing' or 'analyzing' gene sequences" and "the transformative steps associated with isolating and sequencing DNA described in the unchallenged dependent claims" cannot be incorporated into the claims-in-suit.<sup>135</sup>

<sup>122</sup> 581 F.3d 1336 (Fed. Cir. 2009).

<sup>123</sup> Myriad Brief, *supra* note 65, at 35.

<sup>124</sup> *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 WL 1233416, at \*49 (S.D.N.Y. Mar. 29, 2010) (amended April 5, 2010).

<sup>125</sup> *In re Bilski*, 581 F.3d at 954.

<sup>126</sup> *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006) at 137–38 (Breyer, J., dissenting).

<sup>127</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d at 1342, 1346 n.3.

<sup>128</sup> *Id.* at 1346.

<sup>129</sup> See *Ass'n for Molecular Pathology*, 2010 WL 1233416, at \*46.

<sup>130</sup> See Myriad Brief, *supra* note 65, at 35.

<sup>131</sup> *Id.* at 37.

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

<sup>133</sup> *Id.* at 35.

<sup>134</sup> *Ass'n for Molecular Pathology*, 2010 WL 1233416, at \*48–49.

<sup>135</sup> *Id.* at \*48.

The court further held that even if Myriad's method claims were construed to include these physical transformations, "these transformations would constitute no more than 'data-gathering step[s]' that are not 'central to the purpose of the claimed process.'"<sup>136</sup>

### *B. Constitutionality of Myriad's Human Gene Patents*

This section examines the constitutionality of Myriad's gene patents under Article I, section 8, clause 8 and under the First Amendment.

#### *1. Are Myriad's Gene Patents Unconstitutional under Article I, Section 8, Clause 8?*

AMP moved for summary judgment on the ground that the USPTO's policy of granting human gene patents is unconstitutional under Article I, section 8, clause 8 because human gene patents in general and Myriad's patents in particular impede rather than promote the progress of science.<sup>137</sup> The USPTO, relying on *Ashwander v. Tenn. Valley Authority*<sup>138</sup> and *Spector Motor Serv., Inc. v. McLaughlin*,<sup>139</sup> moved for judgment on the pleadings based on the doctrine of constitutional avoidance, which states that courts should not reach unnecessary constitutional issues if a case can be decided on statutory grounds or general law.<sup>140</sup> The United States District Court for the Southern District of New York granted the USPTO's motion for judgment on the pleadings and dismissed AMP's claim for constitutional violations without prejudice.<sup>141</sup>

Even though the district court did not address AMP's constitutional challenges, AMP's contention has several flaws. First, Article I, section 8, clause 8 is irrelevant to the USPTO's authority to grant human gene patents because this clause delegates Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . . ."<sup>142</sup> The Constitution further delegates Congress the power "[t]o make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers . . . ."<sup>143</sup> Under these powers, Congress enacted the Patent Act of 1952 in general and specifically section 101.<sup>144</sup> Congress has delegated the USPTO power to grant patents under section 2.<sup>145</sup>

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<sup>136</sup> *Id.* at \*49.

<sup>137</sup> AMP Brief, *supra* note 83, at 38.

<sup>138</sup> 297 U.S. 288 (1936) (Brandeis, J., concurring).

<sup>139</sup> 323 U.S. 101 (1944).

<sup>140</sup> USPTO Brief, *supra* note 66, at 4.

<sup>141</sup> *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 WL 1233416, at \*51 (S.D.N.Y. Mar. 29, 2010) (amended April 5, 2010).

<sup>142</sup> U.S. CONST. art I, § 8, cl. 8.

<sup>143</sup> *Id.* cl. 18.

<sup>144</sup> Act of 1952, ch. 950, 66 Stat. 792, § 101 (1952).

<sup>145</sup> 35 U.S.C. § 2(a)(1) (2006).



Further, the proper focus of constitutional challenges should be on the Patent Act itself, rather than individual patents granted under the Act.<sup>146</sup> The USPTO argued that the issue should be “whether there is a ‘rational relationship’ between permitting patents on ‘composition[s] of matter’ and ‘process[es]’ . . . which cover the gene-related patents and methods in the present case and Congress’s legitimate objective under the . . . Clause.”<sup>147</sup> Congress has a rational basis to employ broad language in drafting section 101 to countenance human gene patents because “[a] rule that unanticipated inventions are without protection would conflict with the core concept of the patent law”<sup>148</sup> Congress may freely amend section 101 to exclude human genes from patent-eligible subject matter.<sup>149</sup> In fact, Congress recently considered but did not enact legislation that would have banned human gene patents.<sup>150</sup>

Even if it is appropriate to focus on individual patents, there is no consensus that human gene patents including Myriad’s patents impede “the Progress of Sciences and useful Arts.”<sup>151</sup> First, the Patent Act of 1952 promotes this progress by offering an inventor the right to exclude others for a limited period, in exchange for a complete disclosure of his invention.<sup>152</sup> Myriad contends that there are more than 8,600 research papers on BRCA1/2, including Myriad’s 48 research papers, since Myriad’s discovery of the human BRCA1/2 genes.<sup>153</sup> Further, diagnostic methods for determining a predisposition to breast cancer using human BRCA1/2 have been improved.<sup>154</sup> For example, Myriad’s initial diagnostic method was based on the sequencing of the human BRCA1/2 genes but other scientists developed an improved method based on the analysis of the rearrangement of these genes.<sup>155</sup> Recently, a novel diagnostic method was developed by assaying the ability of human BRCA1/2 DNA molecules to produce functional human BRCA1/2 proteins, instead of assaying the structure and sequences of human BRCA1/2 genes.<sup>156</sup>

The Patent Act of 1952 also promotes the progress of science and useful arts by encouraging investments to translate the inventions into commercial products.<sup>157</sup>

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<sup>146</sup> See USPTO Brief, *supra* note 66, at 8.

<sup>147</sup> *Id.*

<sup>148</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 316 (1980).

<sup>149</sup> See *id.* at 318.

<sup>150</sup> Genomic Research and Accessibility Act, H.R. 977, 110th Cong. § 2 (2007).

<sup>151</sup> NAT’L RESEARCH COUNCIL’S REPORT, *supra* note 15, at 2.

<sup>152</sup> Giles S. Rich, *The Relation Between Patent Practices and the Anti-Monopoly Laws*, 24 J. PAT. OFF. SOC’Y 159, 176–77 (1942).

<sup>153</sup> Myriad Brief, *supra* note 65, at 46.

<sup>154</sup> See, e.g., Suhwan Chang et.al., *Expression of Human BRCA1 Variants in Mouse ES Cells Allows Functional Analysis of BRCA1 Mutations*, 119 J. CLINICAL INVESTIGATION 3160, 3160 (2009); Sergey G. Kuznetsov et.al., *Mouse Embryonic Stem Cell-Based Functional Assay to Evaluate Mutations in BRCA2*, 14 NATURE MED. 875, 875 (2008); Sophie Gad et al., *Identification of a Large Rearrangement of the BRCA1 Gene Using Colour Bar Code on Combed DNA in an American Breast/Ovarian Cancer Family Previously Studied by Direct Sequencing*, 38 J. MED. GENETICS 388, 388 (2001); Lori S. Friedman et al., *Confirmation of BRCA1 by Analysis of Germline Mutations Linked to Breast and Ovarian Cancer in Ten Families*, 8 NATURE GENETICS 399, 399 (1994).

<sup>155</sup> Gad, *supra* note 154, at 388.

<sup>156</sup> Chang, *supra* note 154, at 3160; Kuznetsov, *supra* note 154, at 875.

<sup>157</sup> Rich, *supra* note 152, at 177.

Myriad contends that it would not have invested millions of dollars to commercialize diagnostic testing for human BRCA1/2 without patent protection.<sup>158</sup>

## 2. *Are Myriad's Gene Patents Compatible with the First Amendment?*

AMP moved for summary judgment to declare the USPTO's policy of granting human gene patents unconstitutional under the First Amendment because human gene patents "directly limit thought and knowledge."<sup>159</sup> AMP specifically contended that the USPTO gave complete control over knowledge on the human BRCA1/2 genes to Myriad.<sup>160</sup> The USPTO stated that Myriad's gene patents are by no means unique in their impact on the First Amendment issue and that the issue "is not whether any given patent might inhibit more speech than it promotes, but rather whether in establishing a patent system that awarded such a patent, Congress somehow violated the First Amendment."<sup>161</sup> The United States District Court for the Southern District of New York dismissed AMP's constitutional challenges without prejudice based on the doctrine of constitutional avoidance.<sup>162</sup>

Even though the district court did not address AMP's constitutional challenge, AMP's contentions have numerous flaws. First, the Patent Act of 1952 is compatible with the First Amendment because the Patent Act requires the complete disclosure of the claimed inventions in exchange for the right to exclude others.<sup>163</sup> Second, the Patent Act of 1952 gives an inventor only the right to exclude others from making, using, selling, offering for sale or importing the patented invention into the United States.<sup>164</sup>

Even if it is appropriate to focus on individual patents, the USPTO did not grant patents on thought or knowledge protected by the First Amendment.<sup>165</sup> The USPTO has never granted patents claiming human gene sequence information.<sup>166</sup> Because the USPTO had not granted an exclusive right on knowledge of human BRCA1/2 genes to Myriad, many scientists have published research papers describing variants of human BRCA1/2 genes and correlations between the genetic variants and predispositions to breast or ovarian cancer.<sup>167</sup>

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<sup>158</sup> Myriad Brief, *supra* note 65, at 47.

<sup>159</sup> AMP Brief, *supra* note 83, at 34.

<sup>160</sup> *Id.* at 35.

<sup>161</sup> USPTO Brief, *supra* note 66, at 14, 16.

<sup>162</sup> Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09 Civ. 4515, 2010 WL 1233416, at \*51 (S.D.N.Y. Mar. 29, 2010) (amended April 5, 2010).

<sup>163</sup> *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974).

<sup>164</sup> 35 U.S.C. § 154 (2006).

<sup>165</sup> See USPTO Brief, *supra* note 66, at 20.

<sup>166</sup> *Id.* at 22.

<sup>167</sup> See, e.g., Kangjian Wu et al., *Functional Evaluation and Cancer Risk Assessment of BRCA2 Unclassified Variants*, 65 CANCER RESEARCH 417 (2005); Nebojsa Mirkovic et al., *Structure-Based Assessment of Missense Mutations in Human BRCA1: Implications for Breast and Ovarian Cancer Predisposition*, 64 CANCER RESEARCH 3790 (2004); Ashok R. Venkitaraman, *Cancer Susceptibility and the Functions of BRCA1 and BRCA2*, 108 CELL 171 (2002); Ralph Scully & David M. Livingston, *In Search of the Tumor-Suppressor Functions of BRCA1 and BRCA2*, 408 NATURE 429 (2002); S.V. Tavtigian et al., *The Complete BRCA2 Gene and Mutations in Chromosome 13q-linked Kindreds*, 12 NATURE GENETICS 333 (1996); Y. Miki et al., *A Strong Candidate for the Breast and Ovarian Cancer Susceptibility Gene BRCA1*, 266 SCIENCE 66 (1994).

### III. PROPOSAL

While the recent district court's decision invalidating Myriad's gene patents has a limited immediate legal effect, it will have far-reaching consequences of invalidating thousands of human gene patents if the Federal Circuit upholds the decision.<sup>168</sup> The district court acknowledged that its decision is "driven by the overriding importance of DNA's nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated form."<sup>169</sup> However, the Supreme Court previously rejected the contention that the "Court should weigh potential hazards in considering whether . . . [the] invention is patentable subject matter under § 101" because "[t]he choice we are urged to make is a matter of high policy for resolution within the legislative process . . ."<sup>170</sup> Further, in a recent human gene patenting debate, Dr. Wendy Chung, a plaintiff in *Myriad*, stated that the real issue was not the validity of Myriad's gene patents, but exclusive licensing practices used by Myriad with these patents.<sup>171</sup> Dr. Chung further stated that there would be a "middle ground" and suggested that patent pools and non-exclusive licensing may be two alternatives to a total ban on human gene patents.<sup>172</sup> The following section advocates narrowly-tailored legislation that limits the enforcement of human gene patent rights as alternative solutions to the total ban on human gene patents. This section discusses legislation for compulsory licensing of human gene patents and exemption from patent infringement remedies for human genetic diagnostic testing as safeguards against exclusive licensing practices of human gene patents.

#### *A. Compulsory Licensing of Human Gene Patents*

This section examines three examples of compulsory licensing practices and proposes a narrowly-tailored compulsory licensing statute for human gene patents.

##### *1. Framework of Compulsory Licensing*

Three examples of compulsory licensing practices are (1) "march-in" rights under the Bayh-Dole Act;<sup>173</sup> (2) refusal of injunctive relief under 35 U.S.C. § 154(a)(1);<sup>174</sup> and (3) mandatory licensing under the Clean Air Act.<sup>175</sup>

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<sup>168</sup> Pollack, *supra* note 11, at B1.

<sup>169</sup> Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09 Civ. 4515, 2010 WL 1233416, at \*42 (S.D.N.Y. Mar. 29, 2010) (amended April 5, 2010).

<sup>170</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 316–17 (1980).

<sup>171</sup> *On Point with Tom Ashbrook, Patenting Human Genes* (Boston National Public Radio Jan 21, 2010), available at <http://www.onpointradio.org/media-player?url=http://www.onpointradio.org/2010/01/gene-patenting&title=Patenting+Human+Genes&pubdate=2010-01-21&segment=1>.

<sup>172</sup> *Id.*

<sup>173</sup> Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified at 35 U.S.C. §§ 200–212); 35 U.S.C. § 203 (2006).

<sup>174</sup> 35 U.S.C. § 154(a)(1).

The first example is “march-in” rights under the Bayh-Dole Act.<sup>176</sup> The purpose of the Bayh-Dole Act is to promote commercialization and public availability of federally-funded inventions.<sup>177</sup> For this purpose, a federal agency may exercise “march-in” rights by requiring the licensing of a funding recipient’s inventions to a third party in limited circumstances.<sup>178</sup> One of these limited circumstances occurs when such action is “necessary to alleviate health and safety needs . . . .”<sup>179</sup> The “march-in” rights, however, create a potential problem of overlapping jurisdiction between a federal agency and a court because the adversely affected party may appeal the federal agency’s decision to the Court of Federal Claims.<sup>180</sup>

The second example occurs when a court declines to enjoin patent infringement remedies.<sup>181</sup> In *eBay Inc. v. MercExchange, L.L.C.*, the Supreme Court held that a statutory right to exclude under 35 U.S.C. § 154(a)(1) alone does not justify a general rule that “a permanent injunction will issue once infringement and validity [of patents] have been adjudged.”<sup>182</sup> In *Hynix Semiconductor Inc. v. Rambus Inc.*, the United States District Court for the Northern District of California ordered compulsory licensing after finding that injunctive relief was improper.<sup>183</sup>

The final example is mandatory licensing under the Clean Air Act.<sup>184</sup> Before a court orders compulsory licensing of a patent that is critical to control air pollution, the Attorney General is required to determine that the patented invention is not reasonably available; that there are no reasonable alternatives; and that the unavailability of such rights may result in a substantial problem of competition to create a monopoly.<sup>185</sup>

## 2. Proposed Legislation of Compulsory Licensing of Human Gene Patents

The legislation proposed here for compulsory licensing of human gene patents is very narrow and its framework is based on “march-in” rights under the Bayh-Dole Act and mandatory licensing under the Clean Air Act. Unlike “march-in” rights under the Bayh-Dole Act, the proposed legislation applies to patents on inventions that did not result from federal funding.<sup>186</sup> Before a court orders compulsory licensing of specific human gene patents, the Attorney General should determine that (1) the patented human gene-related inventions are not reasonably available; (2)

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<sup>175</sup> Clean Air Act, Pub. L. No. 84-159, 69 Stat. 322 (1955) (amended by Clean Air Amendments of 1970, Pub. L. No. 91-604, 84 Stat. 1676 (codified as amended at 42 U.S.C. §§ 7401–7626)); 42 U.S.C. § 7608.

<sup>176</sup> 35 U.S.C. § 203.

<sup>177</sup> *Id.* § 200.

<sup>178</sup> *Id.* § 203(a).

<sup>179</sup> *Id.* § 203(a)(2).

<sup>180</sup> *Id.* § 203(b); see Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 BERKELEY TECH. L.J. 1095, 1106 (1999).

<sup>181</sup> *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006); *Hynix Semiconductor Inc. v. Rambus Inc.*, 609 F.Supp.2d 951, 987 (N.D. Cal. 2009).

<sup>182</sup> 547 U.S. 388, 393–94 (2006).

<sup>183</sup> 609 F. Supp.2d 951, 987 (N.D. Cal. 2009).

<sup>184</sup> 42 U.S.C. § 7608 (2006).

<sup>185</sup> *Id.*

<sup>186</sup> See 35 U.S.C. § 203.

there are no reasonable alternatives; and (3) compulsory licensing is necessary to alleviate public health needs. Alternatively, Congress could appoint a specific federal agency for these determinations. For example, the Office of Science and Technology Policy (“OSTP”) would be a good candidate because Congress has previously directed the OSTP to determine “the impact of federal policies . . . on the innovation process for genomic technologies.”<sup>187</sup> Once the determinations have been made, the court may require compulsory licensing to allow scientists and clinical researchers to use specific human gene patents for patients’ benefit. This proposal would not be expeditious and would not address all problems associated with licensing practices. It would be prudent, however, not to alter conventional licensing practices without a determination whether it is necessary for diagnostic or therapeutic developments.

### *B. Exemption from Patent Infringement Remedies for Human Genetic Diagnostic Testing*

This section examines two examples of exemption from patent infringement remedies and proposes an exemption from patent infringement remedies for human genetic diagnostic testing.

#### *1. Framework of Exemption from Infringement Remedies for Human Genetic Diagnostic Testing*

The Patent Act of 1952 has no general statutory exemption for experimental or research use.<sup>188</sup> In *Madey v. Duke University*, the Federal Circuit held that practice of patented inventions at academic institutions does not shield these institutions from patent infringement liability regardless of commercial implications or lack thereof.<sup>189</sup> Nonetheless, Congress has provided statutory exemptions to patent infringement and patent infringement remedies.<sup>190</sup>

The first exemption is described in 35 U.S.C. § 271(e)(1).<sup>191</sup> The Supreme Court has construed this section to protect the use of patented pharmaceutical compounds for the purpose of the submission of new compounds to the Food and Drug Administration, but not for the purpose of general biomedical research.<sup>192</sup> The second exemption described in 35 U.S.C. § 287(c)(1) applies to medical practitioners’ performance of patented medical or surgical procedures on patients.<sup>193</sup> This

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<sup>187</sup> Genomic Science and Technology Innovation Act of 2002, H.R. 3966, 107th Cong. sec. 3(a).

<sup>188</sup> Act of 1952, ch. 950, 66 Stat. 792 (1952) (codified as amended under Title 35 of the United States Code); see NAT’L RESEARCH COUNCIL’S REPORT, *supra* note 15, at 144; Jordan Paradise & Christopher Janson, *Decoding the Research Exemption*, 7 NATURE REVIEW GENETICS 148, 150 (2006).

<sup>189</sup> 307 F.3d 1351, 1362 (Fed. Cir. 2002).

<sup>190</sup> 35 U.S.C. §§ 271(e)(1), 287(c)(1).

<sup>191</sup> *Id.* § 271(e)(1).

<sup>192</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 205 (2005).

<sup>193</sup> 35 U.S.C. §§ 287(c)(1)-(c)(2)(A).

exemption, however, does not include the use of a patented composition of matter, and a patented use of a composition of matter.<sup>194</sup>

In 2002, Rep. Lynn Rivers introduced the Genomic Research and Diagnostic Accessibility Act of 2002 “to provide for non-infringing uses of patents on genetic sequence information for purposes of research and genetic diagnostic testing” but this bill received little support.<sup>195</sup> Section 2 of this proposed Act provided a non-commercial research exemption, and section 3 provided exemption for medical practitioners performing genetic diagnostic testing.<sup>196</sup>

## *2. Proposed Legislation for Exemption from Patent Infringement Remedies for Human Genetic Diagnostic Testing*

The legislation proposed here for exemption from patent infringement remedies is very narrow and applies only to medical practitioners’ performance of human genetic diagnostic testing that constitutes an infringement.<sup>197</sup> The term “medical practitioner” means “any natural person who is licensed by a State to provide medical activity . . . or who is acting under the direction of such person in the performance of the medical activity.”<sup>198</sup> The proposed legislation adopts section 3 of the Genomic Research and Diagnostic Accessibility Act of 2002.<sup>199</sup> This section amends 35 U.S.C. § 287(c)(2)(A) by redefining the term “medical activity” to include “performance of a genetic diagnostic, prognostic, or predictive test or a medical or surgical procedure.”<sup>200</sup> The term “genetic diagnostic, prognostic, or predictive test” is defined as “any test, designed to detect disease, to predict the potential for a medical disorder, or to predict the effectiveness of therapeutics, which uses either an ordered listing of nucleotides comprising a portion of a human or human pathogen genetic code or the proteins encoded by such nucleotides.”<sup>201</sup> Similarly, the Secretary’s Advisory Committee on Genetics, Health and Society (“SACGHS”) distinguished the use of human gene patents in genetic testing from use in therapeutics and recommended that gene patent rights should not be enforced in genetic testing.<sup>202</sup> The SACGHS reasoned that “[t]he existence of multiple providers for a particular testing would permit second-opinion testing and the sharing of samples to ensure the quality of testing.”<sup>203</sup> Because the statutory change applies only to human genetic diagnostic testing, human gene patents would remain enforceable for therapeutic use and would serve to stimulate investment in the biotechnology industry.<sup>204</sup>

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<sup>194</sup> *Id.* § 287(c)(2)(A).

<sup>195</sup> Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. pmbl.

<sup>196</sup> *Id.* §§ 2-3.

<sup>197</sup> *See* 35 U.S.C. § 287(c).

<sup>198</sup> *See id.* § 287(c)(2)(B).

<sup>199</sup> H.R. 3967 § 3.

<sup>200</sup> *Id.* § 3(a)(1).

<sup>201</sup> *See id.* § 3(a)(3).

<sup>202</sup> SACGHS Report, *supra* note 2, at 88.

<sup>203</sup> *Id.*

<sup>204</sup> *See id.*

## CONCLUSION

The Supreme Court previously concluded that Congress intended statutory subject matter under 35 U.S.C. § 101 “to include anything under the sun that is made by man” and that the proper forum for excluding a specific technology from patent-eligible subject matter lies within the legislative body.<sup>205</sup> Congress has previously considered, but failed to statutorily exclude human genes under section 101.<sup>206</sup> Despite this background, in *Myriad*, the United States District Court for the Southern District of New York ruled that human gene patents are not patent-eligible subject matter under 35 U.S.C. § 101.<sup>207</sup> However, this district court’s decision does not lead to automatic invalidation of all existing human gene patents.<sup>208</sup>

On June 16, 2010, Myriad filed a Notice of Appeal to the Federal Circuit.<sup>209</sup> On appeal, the Federal Circuit should uphold the validity of human gene patents including Myriad’s patents-in-suit in view of long-standing legal precedent that a new and useful composition of matter isolated from natural substances is patent-eligible.<sup>210</sup> Myriad’s claims on isolated DNA molecules encoding normal or mutant forms of human BRCA1/2 are directed to compositions of matter.<sup>211</sup> These claims may also be considered as manufactures because the claimed isolated DNA molecules do not exist in nature and significantly differ in structure, function and utility from the naturally-occurring human BRCA1/2 genes.<sup>212</sup> Further, Myriad’s diagnostic method claims for determining a predisposition to breast cancer using isolated DNA molecules encoding human BRCA1/2 should be patent-eligible processes in view of *Prometheus*.<sup>213</sup>

If the Federal Circuit affirms the district court’s decision that invalidated Myriad’s gene patents-in-suit, this decision would have negative repercussions.<sup>214</sup> While statutory exclusion of human gene patents would not apply to patents issued before the date of the enactment of the legislation, judicial exclusion would lead to the invalidation of all human gene patents, which could unravel the foundation of biotechnology industry.<sup>215</sup> Such a ruling would destroy not only decades of

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<sup>205</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 308, 318 (1980).

<sup>206</sup> Genomic Research and Accessibility Act, H.R. 977, 110th Cong. § 2 (2007).

<sup>207</sup> *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 WL 1233416, at \*42, \*49 (S.D.N.Y. Mar. 29, 2010) (amended April, 5, 2010).

<sup>208</sup> See Press Release, Myriad Genetics, Inc., Federal District Court Rules Isolated DNA Claims are Not Patentable: Myriad to Appeal Decision to the Federal Circuit Court of Appeals (March 30, 2010), available at <http://investor.myriad.com/releasedetail.cfm?ReleaseID=455348> (emphasizing that the district court’s decision was limited to 15 claims in seven patents and that 164 claims in those seven patents and additional 16 patents covering Myriad’s BRCA tests were not challenged).

<sup>209</sup> Notice of Appeal to the Federal Circuit, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515 (S.D.N.Y. June 16, 2010).

<sup>210</sup> See *In re Bergstrom*, 427 F.2d 1394, 1402 (C.C.P.A. 1970); *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 162–63 (4th Cir. 1958); *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911).

<sup>211</sup> See *Ass’n for Molecular Pathology*, 2010 WL 1233416 at \*31–32 (construing DNA as a “tangible, chemical compound”).

<sup>212</sup> See Myriad’s brief, *supra* note 65, at 30, 31.

<sup>213</sup> See *id.*

<sup>214</sup> Pollack, *supra* note 11, at B1.

<sup>215</sup> See Genomic Research and Accessibility Act, H.R. 977, 110th Cong. § 2 (2007); Sherry M. Knowles, *Fixing the Legal Framework for Pharmaceutical Research*, 327 SCIENCE 1083, 1084 (2010).

investment of capital and research, undertaken in reliance on the validity of human gene patents, but also incentives for future innovation to translate the basic research into diagnostics and therapeutics.<sup>216</sup>

Nonetheless, the district court's decision reflects the concern about the possible adverse impact of human gene patents on patients' access to genetic testing.<sup>217</sup> It is difficult to balance the public's interest in access to human gene patents and the biotechnology industry's incentive to invest capital to translate basic research to commercial products that ultimately benefit the public. As an alternative to a total ban on human gene patents, this comment has proposed narrowly tailored legislation to achieve this balance. Under the proposal, a court may grant compulsory licensing in limited circumstances to stimulate commercialization of human gene-related inventions such as diagnostics and therapeutics that benefit the public. In addition, a court would prohibit enforcement of human gene patents related to diagnostic genetic testing against medical practitioners. Thus, the proposed legislation would safeguard patients' access to human gene patents related to genetic diagnostic testing, and it would encourage reasonable licensing policies that maximize commercial development of diagnostics and therapeutics to benefit the public.

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(indicating that retroactive judicial invalidation of patent could constitute taking and suggesting that "Congress should pass a law that gives an appellate court discretion to mark a decision for prospective only, if it overrules a prior interpretation of patent statutory law.").

<sup>216</sup> Stott & Valentine, *supra* note 35, at 364; Nunnally et al., *supra* note 35, at 215.

<sup>217</sup> *Sitting Up and Taking Notice*, 28 NATURE BIOTECHNOLOGY 381, 381 (May, 2010); *Testing Time for Gene Patents*, 464 NATURE 957, 957 (April, 2010).