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## Taking Nature Back: Why Tax Strategy Law Is Relevant to Gene Patents

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## NOTE

# Taking Nature Back: Why Tax Strategy Law Is Relevant to Gene Patents

*Association for Molecular Pathology v. United States Patent and  
Trademark Office*,  
653 F.3d 1329 (Fed. Cir. 2011).

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### I. INTRODUCTION

On July 29, 2011, the United States Court of Appeals for the Federal Circuit upheld the validity of several controversial patents in *Association for Molecular Pathology v. United States Patent and Trademark Office*.<sup>1</sup> The patents, exclusively assigned to Myriad Genetics, Inc. (Myriad),<sup>2</sup> claim two human genes fundamental to understanding, researching, and diagnosing common strains of familial breast and ovarian cancers.<sup>3</sup> Patients expressed concern that Myriad's exclusivity over the two genes made diagnosis excessively expensive and precluded the availability of independent second-opinion testing.<sup>4</sup> Although the Supreme Court of the United States vacated and remanded the Federal Circuit's decision,<sup>5</sup> the Federal Circuit issued an

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\* B.S., University of Missouri, 2007; J.D. Candidate, University of Missouri School of Law, 2013; Note and Comment Editor 2012-2013, *Missouri Law Review*. Professor Dennis Crouch was influential in the writing of this case note. I am grateful for his guidance, encouragement and inspiration.

1. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Molecular Pathology II)*, 653 F.3d 1329, 1333-34 (Fed. Cir. 2011), *cert. granted, vacated sub nom.* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S.Ct. 1794 (2012).

2. *Id.* at 1334.

3. *See id.*

4. *See* Alex Philippidis, *Prometheus and Myriad Case Outcomes Will Help Shape the Future for MDx Businesses*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (Sept. 22, 2011), <http://www.genengnews.com/analysis-and-insight/em-prometheus-em-and-em-myriad-em-case-outcomes-will-help-shape-the-future-for-mdx-business/77899460/>.

5. *Ass'n for Molecular Pathology*, 132 S. Ct. 1794. The Supreme Court did not rule on the merits of the case; rather, the Court remanded to the Federal Circuit "for further consideration in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ---, 132 S. Ct. 1289, 182 L.Ed.2d 321 (2012)." *Id.*

opinion that reaffirmed the validity of Myriad's gene patents on August 16, 2012.<sup>6</sup> Despite the apparent finality of the Federal Circuit's decision, the law surrounding gene patents remains equivocal, and the American Civil Liberties Union (ACLU) recently petitioned the Supreme Court for certiorari.<sup>7</sup>

Myriad's patents will someday expire,<sup>8</sup> but cancer patients need diagnosis and treatment immediately. Moreover, the progression of science will keep the legal issues surrounding gene patents alive for many years. In particular, patents on epigenetic information<sup>9</sup> implicate many of the same legal issues as gene patents. Recent legislative solutions to problems in non-scientific realms of patent law illuminate possible methods of restructuring the patentability of human genes to better serve social concerns. Specifically, the legislation used to preempt the patentability of tax strategies provides an attractive alternative to the current law surrounding gene patents. Until Congress creates a new exception to patentability, however, courts will continue to struggle with the validity of human gene patents.

## II. FACTS AND HOLDING

Myriad's patents cover complex molecules and scientific processes. First, providing an overview of the underlying biology will assist in understanding the subtle distinctions between Myriad's various patent claims. Then, a closer examination of the patents and the dispute that arose between Myriad and the plaintiffs will provide a basis for comprehending the several arguments each party set forth at both the trial and appellate levels.

### A. Genetics and the BRCA Genes

The human genome, the entire genetic makeup of a human, contains approximately 22,000 separable sequences of molecular information called genes.<sup>10</sup> Genes are regions of deoxyribonucleic acid (DNA) that ultimately

6. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1325 (Fed. Cir. 2012).

7. Sam Favate, *ACLU Asks Supreme Court to Invalidate Gene Patents*, WALL ST. J. (Sept. 26, 2012), <http://blogs.wsj.com/law/2012/09/26/aclu-asks-supreme-court-to-invalidate-gene-patents/>.

8. Andrew Pollack, *Despite Gene Patent Victory, Myriad Genetics Faces Challenges*, N.Y. TIMES (Aug. 24, 2011), [http://www.nytimes.com/2011/08/25/business/despite-gene-patent-victory-myriad-genetics-faces-challenges.html?\\_r=1&pagewanted=all](http://www.nytimes.com/2011/08/25/business/despite-gene-patent-victory-myriad-genetics-faces-challenges.html?_r=1&pagewanted=all). Myriad's major patents will expire in 2014. *Id.*

9. The term "epigenetics" refers to "the study of changes in gene activity that do not involve alterations to the genetic code" but still have heritable qualities. John Cloud, *Why Your DNA Isn't Your Destiny*, TIME (Jan. 6, 2010), <http://www.time.com/time/magazine/article/0,9171,1952313,00.html>.

10. ROBERT A. WEINBERG, *THE BIOLOGY OF CANCER* 2-3 (2007).

code for proteins, which carry out a variety of cellular processes.<sup>11</sup> DNA, a double-stranded helical molecule contained in the nucleus of a cell, is comprised of four different molecular subunits collectively called nucleotides.<sup>12</sup> Long chains of the four nucleotides – adenine, guanine, cytosine, and thymine – pair together and form the double helix structure of DNA.<sup>13</sup> In nature, genes exist chemically bonded to each other in large, tightly packed molecules of DNA called chromosomes.<sup>14</sup>

Protein synthesis begins in the cell nucleus.<sup>15</sup> Through a process called transcription, cellular enzymes convert the nucleotide sequences in a DNA strand into a single-stranded molecule called ribonucleic acid (RNA).<sup>16</sup> At this early stage, the resulting RNA is a specific type of RNA called precursor messenger RNA (pre-mRNA).<sup>17</sup> Pre-mRNA has several regions of nucleotides that have no genetic value and do not contribute to the code of a protein.<sup>18</sup> Large molecules remove these noncoding regions, called introns, and then splice together the ends of the remaining coding regions, called exons.<sup>19</sup> The entire resulting molecule, messenger RNA (mRNA), codes for the synthesis of a protein.<sup>20</sup> Messenger RNA then exits the nucleus and enters the cytoplasm, the semifluid medium of the cell, where translation occurs.<sup>21</sup> In translation, a complex of molecules uses the nucleotide code in mRNA to create proteins.<sup>22</sup>

11. See STUART IRA FOX, HUMAN PHYSIOLOGY 43-44, 63-64 (9th ed. 2006).

12. *Id.* at 63, 65.

13. *Id.* at 44-45. In any DNA molecule the number of adenine nucleotides is equal to the number of thymine nucleotides, and the number of guanine nucleotides is equal to the number of cytosine nucleotides. *Id.* at 44-46. The reason for this phenomenon lies in the law of complementary base pairing: adenine pairs solely with thymine, and guanine pairs solely with cytosine. *Id.* As a result, only the sequence of one strand of a DNA molecule must be known in order to determine the sequence of the other strand. *Id.* at 46.

14. *Id.* at 65.

15. See *id.* at 63, 66.

16. See *id.* at 46, 66. RNA is composed of the nucleotides adenine, guanine, cytosine and uracil. *Id.* at 46. Through the law of complementary base pairing, transcription ensures that the DNA nucleotides correspond with the nucleotides in the newly synthesized RNA: enzymes bind DNA guanine to RNA cytosine, DNA cytosine to RNA guanine, DNA adenine to RNA uracil, and DNA thymine to RNA adenine. *Id.* at 66.

17. See *id.* at 66-67.

18. *Id.* at 67.

19. *Id.*

20. *Id.* at 66-67.

21. *Id.* at 68, 727.

22. *Id.* at 68. This complex reads the strand of RNA nucleotides in groups of three. *Id.* Each of these groups is called a codon and corresponds to a signal to begin translation, a signal to end translation, or a single protein building block, called an amino acid. *Id.* at 40, 68. For example, a codon consisting of the sequence “adenine-

Various mechanisms may transform the structure and sequence of genes resulting in mutations.<sup>23</sup> For example, cancer-causing agents may produce genetic substitutions, wherein a specific nucleotide in a gene is replaced by a different nucleotide.<sup>24</sup> This alteration in a DNA sequence becomes transcribed into RNA and ultimately translated into an aberrantly structured protein.<sup>25</sup> Because many proteins receive and send signals in cellular pathways, a mutant protein may alter, stop, increase, or decrease the activity of a cell pathway.<sup>26</sup> This modification of cellular activity is the basis of many types of cancer.<sup>27</sup>

Mutations in two genes, *BRCA1*<sup>28</sup> and *BRCA2*, are notoriously associated with cancer.<sup>29</sup> Individuals with certain mutations in these genes have an inherent susceptibility to breast and ovarian cancer.<sup>30</sup> Some scientists estimate that mutations of these genes cause between seventy and eighty percent of all inherited ovarian cancers.<sup>31</sup> Research indicates that normal *BRCA1* and *BRCA2* genes probably code for proteins that aid in repairing damaged DNA.<sup>32</sup> *BRCA1* and *BRCA2* mutations therefore impede a cell's ability to correct aberrant DNA.<sup>33</sup> Thus, diagnostic testing for the existence of these mutations discloses an individual's risk of ovarian and breast cancer and aids in deciding whether to take preventive steps.<sup>34</sup>

Gene cloning has enabled researchers to determine the specific nucleotide sequences of mutant genes prevalent in cancers.<sup>35</sup> This gene sequencing requires the amplification of a single DNA fragment into millions of identical

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cytosine-guanine" (transcribed from the DNA sequence "thymine-guanine-cytosine") codes for the amino acid threonine. *Id.* at 68. The codon consisting of the sequence "uracil-adenine-guanine" (transcribed from the DNA sequence "adenine-thymine-cytosine") codes for a signal to end translation, thereby terminating the synthesis of that protein. *See id.* at 68-71. When translation ends, the resulting molecule is called a polypeptide, and through further cellular processing, it becomes a functional protein. *Id.* at 69-72.

23. WEINBERG, *supra* note 10, at 25-26.

24. *See id.* at 26.

25. *Id.* at 16.

26. *Id.* at 15-16.

27. *Id.*

28. "*BRCA*" in italics type refers to the gene, while "BRCA" in regular type refers to the protein.

29. *Id.* at 505.

30. *Id.*

31. *Id.*

32. *Id.*

33. *See id.*

34. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Molecular Pathology II*), 653 F.3d 1329, 1339 (Fed. Cir. 2011), *cert. granted, vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S.Ct. 1794 (2012).

35. WEINBERG, *supra* note 10, at 23-24.

copies.<sup>36</sup> To accomplish amplification, scientists use an enzyme called reverse transcriptase to synthesize complementary DNA (cDNA) from naturally-occurring mRNA.<sup>37</sup> Because mRNA lacks introns, the nucleotide sequence of the newly synthesized cDNA is not exactly identical to the nucleotide sequence of the corresponding DNA naturally found in the cell nucleus; unlike naturally existing DNA, cDNA lacks the sequences of nucleotides that code for introns.<sup>38</sup> This subtle distinction plays a critical role when parties litigate the patent eligibility of human genes.

### B. *The Parties and the Patents*

In 1991, defendant Myriad began collaborating with various research facilities to sequence the *BRCA1* gene.<sup>39</sup> Shortly after the completion of this project in September 1994, Myriad and its collaborators began sequencing the *BRCA2* gene.<sup>40</sup> As a result of these efforts, Myriad and defendant University of Utah Research Foundation hold several patents relating to the *BRCA1* and *BRCA2* genes.<sup>41</sup> Defendant United States Patent and Trademark Office (USPTO) issued the patent covering *BRCA1* in December 1997 and the patent covering *BRCA2* in November 1998.<sup>42</sup> In addition, Myriad began offering *BRCA* diagnostic testing services to women.<sup>43</sup> Several plaintiffs, including medical organizations, researchers, genetic counselors, and patients, filed suit in the United States District Court for the Southern District of New York seeking a declaratory judgment that fifteen of the claims relating to the *BRCA1* and *BRCA2* genes are drawn to patent-ineligible subject matter under 35 U.S.C. § 101.<sup>44</sup>

Myriad's contested patent claims fall into two categories: composition claims and method claims.<sup>45</sup> The composition claims are directed to "isolated" human genes with DNA sequences that code for the *BRCA1* and *BRCA2* proteins.<sup>46</sup> According to Myriad's patents, "isolated" human genes

36. *Id.*

37. *Id.* at 24.

38. *Id.*

39. See *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Molecular Pathology I)*, 702 F. Supp. 2d 181, 201 (S.D.N.Y. 2010), *rev'd in part, Molecular Pathology II*, 653 F.3d 1329, *cert. granted, vacated sub nom.* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012).

40. See *id.* at 202.

41. *Id.* at 184.

42. *Molecular Pathology II*, 653 F.3d at 1339.

43. *Id.*

44. *Id.* at 1333.

45. *Molecular Pathology I*, 702 F. Supp. 2d at 212.

46. See *id.* A representative claim of the group of composition claims is "[a]n isolated DNA coding for a *BRCA1* polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO: 2," where SEQ ID NO:2 depicts the amino

refer both to synthetic cDNA genes and to genes cleaved from a naturally occurring chromosome.<sup>47</sup> The composition claims also cover short fragments of the *BRCA1* and *BRCA2* genes, and they cover certain “isolated” *BRCA1* and *BRCA2* genes with mutations associated with breast or ovarian cancer.<sup>48</sup>

The method claims are directed to several processes that involve comparing or analyzing sequences of DNA, RNA, or cDNA associated with the *BRCA1* or *BRCA2* genes.<sup>49</sup> Some of the method claims are directed to processes that identify the existence of certain mutations in the *BRCA1* or *BRCA2* gene by “analyzing” the sequences of the corresponding DNA, RNA, or cDNA.<sup>50</sup> Other method claims are directed to processes that determine whether a human tumor sample contains a *BRCA1* or *BRCA2* gene mutation by “comparing” the DNA sequence of the tumorous sample with a normal sample from the same person.<sup>51</sup> Another method claim is directed to a process that screens potential cancer therapeutics.<sup>52</sup> The process involves growing two cultures of cells containing a mutated *BRCA1* gene that causes cancer.<sup>53</sup> One culture is grown in the presence of a suspected cancer therapeutic, and the other culture serves as the control group.<sup>54</sup> The rates of cell growth are then compared.<sup>55</sup> A slower rate of growth in the treated cell culture indicates that the treating compound is a cancer therapeutic.<sup>56</sup>

Myriad began confronting potential infringers as early as 1998, when a Myriad representative warned plaintiff Dr. Haig Kazazian, co-director of the University of Pennsylvania’s Genetic Diagnostic Laboratory (GDL), that the *BRCA1* testing services GDL offered infringed on Myriad’s patents.<sup>57</sup> GDL discontinued its testing services over a year later after Myriad repeatedly con-

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acid sequence of the *BRCA1* protein. *Molecular Pathology II*, 653 F.3d at 1334. Because different codons can translate into the same amino acid, these claims encompass several possible sequences of DNA. *Molecular Pathology I*, 702 F. Supp. 2d at 212.

47. See, e.g., U.S. Patent No. 5,747,282 col.19 ll.8-18 (filed June 7, 1995).

48. *Molecular Pathology II*, 653 F.3d at 1334.

49. *Molecular Pathology I*, 702 F. Supp. 2d at 213.

50. *Id.* A representative method claim is “[a] method for detecting a germline alteration in a *BRCA1* gene . . . 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” where SEQ ID NO: 1 depicts the cDNA nucleotide sequence of the *BRCA1* gene. *Id.*

51. *Id.*

52. *Molecular Pathology II*, 653 F.3d at 1335.

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.* at 1339.

tacted GDL regarding the alleged infringement.<sup>58</sup> As a result of Myriad's actions toward GDL and other clinical entities that provided *BRCA* testing, Myriad became the sole provider of testing services in the United States.<sup>59</sup>

The plaintiffs alleged Myriad's patents caused several injuries.<sup>60</sup> The Association for Molecular Pathology (AMP), the American Society for Clinical Pathology (ASCP), the College of American Pathologists (CAP), and the American College of Medical Genetics (ACMG) claimed that but for Myriad's patents, their members were "ready, willing, and able to engage in research and clinical practice involving the *BRCA1* and *BRCA2* genes."<sup>61</sup> Several individual physicians and scientists claimed the Myriad patents forced them to send samples to Myriad for evaluation although they had the means to do so themselves at a lesser cost.<sup>62</sup> Several cancer patients alleged that Myriad's patents prevented them from getting the *BRCA* testing they needed due to a lack of competitive pricing and Myriad's refusal to accept their medical insurance.<sup>63</sup>

At the United States District Court for the Southern District of New York, the plaintiffs moved for summary judgment to declare invalid the fifteen claims covering the *BRCA1* and *BRCA2* genes.<sup>64</sup> The plaintiffs argued Myriad's practices hindered the ability of patients to confirm Myriad's test results with second opinions.<sup>65</sup> Additionally, they claimed other facilities could provide newer testing methods with better quality and efficiency.<sup>66</sup> In response, Myriad also moved for summary judgment, seeking dismissal of the plaintiffs' complaint.<sup>67</sup> Myriad argued that to entertain the plaintiffs' claims in court would be against the policy of the USPTO and the "presumption of validity afforded to patents" under 35 U.S.C. § 282.<sup>68</sup> In addition, Myriad noted that the USPTO has historically supported the patentability of genes.<sup>69</sup>

The district court declared Myriad's human gene patent claims invalid.<sup>70</sup> First, the district court ruled that the composition claims did not constitute

58. *Id.* at 1340.

59. *Id.*

60. See Complaint, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Molecular Pathology I*), 702 F. Supp. 2d 181 (S.D.N.Y. 2009) (No. 09CV4515), 2009 WL 1343027.

61. *Id.* ¶¶ 7-10.

62. *Id.* ¶¶ 13-16.

63. *Id.* ¶¶ 21-26.

64. *Molecular Pathology I*, 702 F. Supp. 2d at 184.

65. *Id.* at 207.

66. *Id.* at 206.

67. *Id.* at 184-85.

68. *Id.* at 220; see also 35 U.S.C. § 282 (2006).

69. See *Molecular Pathology I*, 702 F. Supp. 2d at 220-21.

70. *Id.* at 238. See generally Alex Osterlind, Note, *Staking a Claim on the Building Blocks of Life: Human Genetic Material Within the United States Patent System*, 75 Mo. L. REV. 617 (2010).



patentable subject matter.<sup>71</sup> In reaching this conclusion, the district court reasoned that Supreme Court precedent requires a product of nature to possess “markedly different characteristics in order to satisfy the patentability requirements of [35 U.S.C. §] 101.”<sup>72</sup> The district court explained that “none of the structural and functional differences cited by Myriad between native *BRAC1/2* DNA and the isolated *BRAC1/2* DNA . . . render the claimed DNA ‘markedly different.’”<sup>73</sup>

Second, the district court rejected Myriad’s method claims.<sup>74</sup> Specifically, the district court determined that Myriad’s claims for “analyzing” or “comparing” nucleotide sequences constituted mere mental processes unpatentable under section 101.<sup>75</sup> Additionally, the district court explained that Myriad’s patent claim for comparing the growth rates of cell cultures to screen potential cancer therapeutics was a “basic scientific principle: that a slower rate of cell growth in the presence of a compound indicates . . . a cancer therapeutic.”<sup>76</sup>

On appeal to the United States Court of Appeals for the Federal Circuit, Myriad argued that both its composition claims and method claims constituted patentable subject matter.<sup>77</sup> The Federal Circuit held that Myriad’s composition claims directed to isolated DNA and method claims directed to a procedure for screening potential cancer therapeutics were patentable, but that Myriad’s method claims directed to comparing or analyzing nucleotide sequences did not constitute patentable subject matter.<sup>78</sup>

On March 26, 2012, the Supreme Court of the United States issued a one sentence opinion that vacated and remanded the Federal Circuit’s decision.<sup>79</sup> The Court instructed the Federal Circuit to reconsider its holding in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,<sup>80</sup> a

71. *Molecular Pathology I*, 702 F. Supp. 2d at 227-28.

72. *Id.* at 227.

73. *Id.* at 229.

74. *Id.* at 236-37.

75. *Id.* at 236.

76. *Id.* at 237.

77. See Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office (*Molecular Pathology II*), 653 F.3d 1329, 1333 (Fed. Cir. 2011), *cert. granted, vacated sub nom.* Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012).

78. *Id.* at 1334.

79. Ass’n for Molecular Pathology v. Myriad Genetics, 132 S.Ct. 1794 (2012). The opinion reads: “Petition for writ of certiorari granted. Judgment vacated, and case remanded to the United States Court of Appeals for the Federal Circuit for further consideration in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ---, 132 S. Ct. 1289, 182 L.Ed.2d 321 (2012).” *Id.*

80. 132 S.Ct. 1289 (2012); see also *infra* notes 144-49 and accompanying text.

recent Supreme Court case that provided a detailed analysis of subject matter patentability.<sup>81</sup>

Accordingly, the Federal Circuit reexamined Myriad's patent claims and issued its opinion on August 16, 2012.<sup>82</sup> Before assessing subject matter patentability, the court cautioned that its opinion would not address "whether it is desirable for one company to hold a patent or license covering a test that may save people's lives."<sup>83</sup> Rather, the court explained that "disapproving of patents on medical methods and novel biological molecules are policy questions best left to Congress" and that its opinion would only focus on whether Myriad's various patent claims "meet the threshold test for patent-eligible subject matter under 35 U.S.C. § 101 in light of various Supreme Court holdings, particularly including *Mayo*."<sup>84</sup>

Turning to the patent claims, the court first upheld Myriad's composition claims, finding that the isolated DNA claims constituted "products of man" not found in nature.<sup>85</sup> The court explained that "[w]hile [the isolated DNA molecules] are prepared from products of nature, so is every other composition of matter."<sup>86</sup> Second, the court found that the patent claims directed to "comparing" or "analyzing" nucleotide sequences constituted patent-ineligible subject matter.<sup>87</sup> As in its prior opinion, the Federal Circuit explained that these method claims "recite[] nothing more than the abstract mental steps necessary to compare two different nucleotide sequences[.]"<sup>88</sup> Finally, the court upheld the method claim of screening for potential cancer therapeutics, rejecting the plaintiffs' argument that this method claim constituted a mere abstract idea based on a basic scientific principle.<sup>89</sup> The court stated that while "all activity, whether chemical, biological, or physical, relies on natural laws[.]" this particular method claim "does do more."<sup>90</sup> Specifically, the court noted that the method claim involved the step of "growing host cells *transformed* with an altered *BRCA1* gene."<sup>91</sup> Thus, the ultimate

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81. See *Prometheus Laboratories, Inc.*, 132 S.Ct. at 1295-1303.

82. See *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012).

83. *Id.* at 1324.

84. *Id.* at 1324-25.

85. See *id.* at 1325-31.

86. *Id.* at 1325. The court elaborated: "For example, virtually every medicine utilized by today's medical practitioners, and every manufactured plastic product, is either synthesized from natural materials (most often petroleum fractions) or derived from natural plant materials. But, as such, they are different from natural materials, even if they are ultimately derived from them." *Id.* at 1325.

87. See *id.* at 1333-35.

88. *Id.* at 1334.

89. *Id.* at 1335-37.

90. *Id.* at 1336.

91. *Id.*

results of the Federal Circuit's most recent decision coincided with its original opinion regarding both the composition claims and the methods claims.

Despite the Federal Circuit's recent decision, the Myriad narrative lives on. In September 2012, the ACLU petitioned the Supreme Court to review Myriad's patents,<sup>92</sup> and scholars seem to believe that the Court will grant certiorari.<sup>93</sup>

### III. LEGAL BACKGROUND

The United States Constitution bestows upon 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 Writings and Discoveries."<sup>94</sup> Congress has exercised this constitutional authority by establishing the USPTO to manage and issue patents<sup>95</sup> and by mandating in 35 U.S.C. § 101 that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter" may obtain a patent.<sup>96</sup> Patents, mechanisms through which Congress enforces this intellectual property right, provide their holders with the exclusive right to make, use, offer to sell, and sell their inventions for twenty years from the patent application filing date.<sup>97</sup>

This section will provide a synopsis of subject matter patentability as it relates to gene patents. First, an overview of case law regarding subject matter patentability will show how the courts have struggled to apply judicially created exceptions to 35 U.S.C. § 101 and how heavily the courts weigh social utility when determining the patentability of a naturally occurring substance. Then, an examination of law and policy surrounding gene patents will provide an understanding of the current legal status of gene patents and the criticism and praise they receive from various scholars.

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92. Lisa Shuchman, *Advocacy Groups Making IP Litigation Waves*, LAW.COM (Oct. 4, 2012), [http://www.law.com/corporatecounsel/PubArticleCC.jsp?id=1202573593552&Advocacy\\_Groups\\_Making\\_IP\\_Litigation\\_Waves&slreturn=20120907100237](http://www.law.com/corporatecounsel/PubArticleCC.jsp?id=1202573593552&Advocacy_Groups_Making_IP_Litigation_Waves&slreturn=20120907100237).

93. *See, e.g.*, Dennis Crouch, *Gene Patent Debate Continues: Federal Circuit Finds Isolated Human Genes Patentable*, PATENTLYO (Aug. 16, 2012), <http://www.patentlyo.com/patent/2012/08/gene-patent-debate-continues-federal-circuit-finds-isolated-human-genes-patentable.html>; Harold C. Wegner, *Why the Myriad Petition May Be Granted: A Fundamental Misunderstanding of "Experimental Use"*, L.A. INTELL. PROP. L. ASS'N (Sept. 27, 2012), <http://www.laipla.net/wp-content/uploads/2012/09/Myriad-September-27-2012.pdf>.

94. U.S. CONST. art. I, § 8, cl. 8.

95. 35 U.S.C. § 1(a) (2006).

96. *Id.* § 101.

97. *Id.* § 154(a)(1)-(2).

### A. Patentable Subject Matter

Courts consistently hold that the broad language of 35 U.S.C. § 101 reflects a congressional intent to give patent laws wide interpretation.<sup>98</sup> In drafting this statute, Congress wished to ensure that “ingenuity should receive a liberal encouragement.”<sup>99</sup> Even under such a far-reaching construal, however, courts have recognized substantial limitations on patentable subject matter.<sup>100</sup> Section 101 qualifies its broad language by subjecting inventions to other “conditions and requirements of this title.”<sup>101</sup> Title 35 imposes prerequisites of newness and usefulness on patentable subject matter; it precludes patents on subject matter that “as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which” the claim pertains.<sup>102</sup>

Beyond statutory restraints, courts have imposed three common law restrictions on patentable subject matter: laws of nature, abstract ideas, and physical phenomena.<sup>103</sup> Although Title 35 lacks explicit language describing these limitations, these exceptions to the generally broad statutory language are consistent with the concept that patentable inventions must encompass “new and useful” subject matter.<sup>104</sup> Courts have implicitly and explicitly upheld these restraints for over 150 years.<sup>105</sup>

An early case regarding patentable subject matter of biological matter was *Parke-Davis & Company v. H. K. Mulford Company*.<sup>106</sup> In that case, an inventor sued the defendant for infringement of a patent claiming a purified form of adrenaline, extracted from the suprarenal glands of animals.<sup>107</sup> In response, the defendant challenged the validity of the patent on the grounds of subject matter patentability.<sup>108</sup> In the Circuit Court for the Southern District of New York, Judge Learned Hand upheld the validity of the patent, reasoning that “while it is of course possible logically to call [the invention] a

98. See, e.g., *Bilski v. Kappos (Bilski II)*, 130 S. Ct. 3218, 3225 (2010); *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (“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.”).

99. *Bilski II*, 130 S.Ct. at 3225 (quoting *Chakrabarty*, 447 U.S. at 308-09).

100. See *id.*; *Chakrabarty*, 447 U.S. at 309.

101. 35 U.S.C. § 101.

102. *Id.* § 103(a).

103. *Bilski II*, 130 S. Ct. at 3225. Courts have also referred to these restraints as “phenomena of nature,” “mental processes,” and “products of nature,” respectively. See *Chakrabarty*, 447 U.S. at 313; *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

104. *Bilski II*, 130 S. Ct. at 3225.

105. *Id.*; see also *Le Roy v. Tatham*, 55 U.S. 156, 174-75 (1852).

106. 189 F. 95 (S.D.N.Y. 1911), *aff’d in part, rev’d in part*, 196 F. 496 (2d Cir. 1912).

107. *Id.* at 95.

108. See *id.* at 103.

purification . . . it became for every practical purpose a new thing commercially and therapeutically.”<sup>109</sup> On appeal, the Second Circuit affirmed Judge Hand’s ruling on patentability, giving deference to his “most exhaustive” opinion.<sup>110</sup>

In 1948, the Supreme Court of the United States addressed subject matter patentability when it clarified the meaning of the “natural phenomena” exception to patentability in the landmark case, *Funk Brothers Seed Company v. Kalo Inoculant Company*.<sup>111</sup> In *Funk Brothers*, the inventor discovered that several strains of root-nodule bacteria could be applied in aggregate to inoculate the seeds of several leguminous plants.<sup>112</sup> In rejecting the inventor’s patent claim, the Court reasoned that the patent claim was merely the discovery of a process of nature already in existence and therefore not patentable subject matter.<sup>113</sup> The Court noted that the bacteria’s use in combination did not change their natural function, and explained that “[t]he qualities of [the] bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men.”<sup>114</sup> Discoveries such as this “are manifestations of laws of nature, free to all men and reserved exclusively to none.”<sup>115</sup>

In the 1970s and 1980s, the Supreme Court decided four landmark cases on the topic of subject matter patentability. The first, *Gottschalk v. Benson*, involved the validity of a method claim directed to an algorithm “converting binary-coded-decimal . . . numerals into pure binary numerals.”<sup>116</sup> Because the process claims “were not limited to any particular art or technology, to any particular apparatus or machinery, or to any particular end use,” the Court struck down the patents.<sup>117</sup> The majority reasoned that because the claims contemplated practical use with no “particular” machine, granting a patent would have preempted the practical use of the algorithm in any context and effectively patent the algorithm, a mere “idea,” itself.<sup>118</sup>

A few years later, the Supreme Court struck down another algorithm patent in *Parker v. Flook*.<sup>119</sup> The inventor claimed a “Method for Updating Alarm Limits,”<sup>120</sup> in which the sole novel element of the claim constituted an

109. *Id.*

110. *Parke-Davis & Co. v. H. K. Mulford & Co.*, 196 F. 496, 497 (2d Cir. 1912).

111. 333 U.S. 127 (1948).

112. *Id.* at 130.

113. *Id.* at 130-31.

114. *Id.* at 130.

115. *Id.*

116. 409 U.S. 63, 64 (1972).

117. *Id.* at 64.

118. *Id.* at 71-72.

119. 437 U.S. 584 (1978).

120. An alarm limit is a number that represents the level at which an abnormal condition, such as a high temperature, will cause an alarm to sound. *Id.* at 585.

algorithm used to calculate the alarm limit.<sup>121</sup> The claims covered “a broad range of potential uses of the method,” but unlike the claims in *Benson*, did not preempt “every conceivable application of the formula.”<sup>122</sup> However, the Court nevertheless rejected the patent, holding that attaching an abstract idea to other known or obvious steps cannot transform an otherwise unpatentable idea into a patentable process.<sup>123</sup> The patent did not “purport to contain any disclosure relating to the chemical processes at work. . . . All that it provide[d] was] a formula for computing an updated alarm limit.”<sup>124</sup>

In 1980, the Supreme Court held that a human-made organism constituted patentable subject matter under 35 U.S.C. § 101.<sup>125</sup> The inventor, Chakrabarty, applied for a patent that claimed a genetically engineered bacterium containing certain bacterial hereditary units called plasmids, which enable the bacterium to break down multiple components of crude oil.<sup>126</sup> The Court looked to the broad language of section 101 and the legislative history of patentable subject matter and concluded that Congress intended to allow patents on “anything under the sun that is made by man[,]” excepting “laws of nature, physical phenomena, and abstract ideas.”<sup>127</sup> Following this rule, the Court held that Chakrabarty’s claim clearly fell into a patentable category, because it was directed to a “nonnaturally occurring manufacture or composition” and constituted a “product of human ingenuity.”<sup>128</sup> The Court distinguished *Funk Brothers*, explaining that while the patentee in *Funk Brothers* had merely discovered a natural phenomenon already in existence, Chakrabarty “produced a new bacterium with markedly different characteristics from any found in nature.”<sup>129</sup>

Only a year later, the Supreme Court upheld the validity of a patent directed to a process for curing rubber in *Diamond v. Diehr*.<sup>130</sup> Several steps of the claimed process involved temperature regulation through the use of a mathematical equation programmed into a computer.<sup>131</sup> The Court first noted that the process involved the transformation of rubber from a raw state to a cured state.<sup>132</sup> Distinguishing *Benson* and *Flook*, the Court explained that the inventor of the process did not desire to patent the formula itself; rather, the inventor implemented the formula and computer use in the process to signifi-

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121. *Id.* at 585-86.

122. *Id.* at 586.

123. *See id.* at 590.

124. *Id.* at 586.

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

126. *Id.* at 305.

127. *Id.* at 307-09.

128. *Id.* at 309.

129. *Id.* at 310.

130. 450 U.S. 175, 192-93 (1981).

131. *Id.* at 178-79.

132. *Id.* at 184.

cantly improve the accuracy of curing rubber.<sup>133</sup> In holding for the inventor, the Court asserted that its reasoning was consistent with the precedential principle that “[a] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer.”<sup>134</sup>

After *Diehr*, the Supreme Court did not address the patentability of processes under 35 U.S.C. § 101 again until 2010 when it decided *Bilski v. Kappos*.<sup>135</sup> In *Bilski*, an inventor sought protection for a method of “instructing buyers and sellers [of commodities] how to protect against the risk of price fluctuations.”<sup>136</sup> The Court of Appeals for the Federal Circuit held the claims unpatentable, applying and extracting the “machine-or-transformation” test<sup>137</sup> from *Benson* and *Diehr*.<sup>138</sup> Under the machine-or-transformation test, “[t]ransformation and reduction of an article ‘to a different state or thing’ is the clue to patentability of a process claim that does not include particular machines.”<sup>139</sup> The Federal Circuit asserted that the ma-

133. *Id.* at 185-87.

134. *Id.* at 187.

135. Sharon Barkume, *Bilski’s Effect on Patent Law: Patentable Processes Under 35 U.S.C. § 101*, 27 *TOURO L. REV.* 379, 383 (2011). See also Mark A. Lemley et al., *Life After Bilski*, 63 *STAN. L. REV.* 1315, 1317-22 (2011) (discussing the Supreme Court’s near thirty-year delay in addressing subject matter patentability and the rise and fall of the Federal Circuit’s machine-or-transformation test).

136. 130 S. Ct. 3218, 3223 (2010). A representative claim reads:

A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of: (a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer; (b) identifying market participants for said commodity having a counter-risk position to said consumers; and (c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

*In re Bilski (Bilski I)*, 545 F.3d 943, 949 (Fed. Cir. 2008), *aff’d sub nom. Bilski v. Kappos (Bilski II)*, 130 S. Ct. 3218 (2010).

137. The “machine-or-transformation” test dictates that a process is only subject-matter patentable “if it is tied to a machine or transforms an article into a different state or thing.” *Bilski II*, 130 S. Ct. at 3232.

138. *Bilski I*, 545 F.3d at 956.

139. *Id.* at 955-56 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972)).

chine-or-transformation test constituted the sole relevant test in determining whether a process is patent-eligible under 35 U.S.C. § 101, and because the claimed processes failed that test, the court held them unpatentable.<sup>140</sup>

The Supreme Court agreed that the process claims were drawn to patent-ineligible subject matter but declined to recognize the machine-or-transformation test as the only applicable analysis for the patentability of processes.<sup>141</sup> Rather, the Court likened the concept of “hedging”<sup>142</sup> to the algorithms in *Benson* and *Flook* and held the claims unpatentable as abstract ideas under *Benson*, *Flook*, and *Diehr*.<sup>143</sup>

The Supreme Court most recently addressed the issue of subject matter patentability in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*<sup>144</sup> In a unanimous opinion, the Court invalidated several patents directed to processes that identified “relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug

140. *Id.* at 966.

141. *Bilski II*, 130 S. Ct. at 3226.

142. “Hedging” is an economic practice that insulates market participants from adverse price fluctuations. See *Bilski I*, 545 F.3d at 949-50. The Federal Circuit provided the following illustration:

[C]oal power plants (i.e., the “consumers”) purchase coal to produce electricity and are averse to the risk of a spike in demand for coal since such a spike would increase the price and their costs. Conversely, coal mining companies (i.e., the “market participants”) are averse to the risk of a sudden drop in demand for coal since such a drop would reduce their sales and depress prices. The claimed method envisions an intermediary, the “commodity provider,” that sells coal to the power plants at a fixed price, thus isolating the power plants from the possibility of a spike in demand increasing the price of coal above the fixed price. The same provider buys coal from mining companies at a second fixed price, thereby isolating the mining companies from the possibility that a drop in demand would lower prices below that fixed price. And the provider has thus hedged its risk; if demand and prices skyrocket, it has sold coal at a disadvantageous price but has bought coal at an advantageous price, and vice versa if demand and prices fall.

*Id.*

143. *Bilski II*, 130 S. Ct. at 3229-31.

144. 132 S. Ct. 1289 (2012).



will prove ineffective or cause harm.”<sup>145</sup> Aside from identifying these correlations, each claim also included a step for “administering” the drug to the patient and a step for “determining” the blood metabolite levels in the patient.<sup>146</sup>

First, the Court found that the claimed correlation between blood metabolite levels and the effects of a thiopurine drug constituted a law of nature, explaining that “[w]hile it takes human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action.”<sup>147</sup> Then, the Court identified the remaining “administering” and “determining” steps in the processes as “well-understood, routine, conventional activity already engaged in by the scientific community.”<sup>148</sup> Thus, the Court concluded that these additional steps were insufficient to transform the law of nature into patentable subject matter, stating that *Flook* and *Diehr* require patentable processes to entail elements that “ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.”<sup>149</sup>

### B. Gene Patents

As technology advanced, the courts’ stringent refusal to allow patents on the mere purification of a preexistent substance gained flexibility under the consideration of the overwhelming social benefits some of these inventions encompassed.<sup>150</sup> This case law, accompanied by USPTO policy, opened the door for gene patents.

A few years after *Diamond v. Chakrabarty*, the USPTO began to issue human gene patents.<sup>151</sup> As a result of an enormous influx of gene and gene fragment patent applications in the 1990s, the USPTO issued new utility examination guidelines in December 1999.<sup>152</sup> Facing an overwhelming amount of applications for random and functionless DNA sequences called expressed sequence tags,<sup>153</sup> the USPTO affirmed the general patentability of isolated

145. *Id.* at 1296-97. The Court explained, “Claim 1, for example, states that *if* the levels of 6-TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per 8x10 red blood cells, *then* the administered dose is likely to produce toxic side effects.” *Id.* at 1297.

146. *Id.* at 1290.

147. *Id.* at 1297.

148. *Id.* at 1298.

149. *Id.* at 1294.

150. *See, e.g., Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911), *aff’d in part, rev’d in part*, 196 F. 496 (2d Cir. 1912).

151. Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 319 (2002).

152. *Id.* at 325-27.

153. *See id.* at 323.

DNA, but required that a patentable isolated DNA molecule have “specific, substantial, and credible” utility under the new guidelines.<sup>154</sup> The USPTO gave two reasons for allowing the patentability of DNA molecules: “(1) an excised gene is eligible for a patent . . . because that DNA molecule does not occur in that isolated form in nature, [and] (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.”<sup>155</sup> The USPTO also asserted that longstanding precedential guidelines have established the patentability of isolated DNA.<sup>156</sup>

Proponents of gene patents argue that these patents have no more negative impact on society than other types of patents, and gene patents “provide a meaningful incentive for the development, improvement, and commercialization of research tools and genetic testing.”<sup>157</sup> Gene patents often enable innovator companies to perform research; without the benefits of holding a patent, innovator companies could not recapture costs relating to research and development.<sup>158</sup> Additionally, gene patents induce innovation by incentivizing competing researchers to “design around” a claimed gene.<sup>159</sup> Thus, proponents argue gene patents increase public access to genetic information and testing.<sup>160</sup> Furthermore, courts rarely find infringement in gene patent litigation cases, suggesting that gene patents do not have an overly preemptive effect.<sup>161</sup>

In recent years, gene patents have received heavy criticism. Social concerns regarding gene patents align with those of monopolies and include limited access to genetic testing, lack of opportunities to obtain second opinions, decreased price competition, and reduced incentive to improve the quality of services provided.<sup>162</sup> The monopolistic prices caused by patents on medical treatments exclude some patients from receiving the benefits of medical innovation.<sup>163</sup>

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154. *Id.* at 327, 329.

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

156. *Id.* (citing *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912); *In re Bergstrom*, 427 F.2d 1394 (C.C.P.A. 1970)).

157. *See, e.g.*, 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, 360-61 (2007).

158. *Id.* at 356.

159. Amanda Wilson, *Gene Patents “Like Trying to Keep Water in a Sieve,”* INTER PRESS SERVICE (Oct. 21, 2011), <http://ipsnews.net/news.asp?idnews=105570>.

160. Holman, *supra* note 157, at 356.

161. *Id.* at 356-57.

162. David H. Ledbetter, *Gene Patenting and Licensing: The Role of Academic Researchers and Advocacy Groups*, 10 GENETICS IN MED. 314, 315 (2008).

163. *See* Margaret Kubick, Comment, *An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States*, 9 NW. J. TECH. & INTELL. PROP. 280, \*48 (2010).

Opponents of gene patents generally raise two arguments.<sup>164</sup> First, some critics contend that isolating genes involves routine scientific processes necessary to researching and clinically testing genes.<sup>165</sup> They argue that products of nature extracted from known and customary procedures should not be patent-eligible.<sup>166</sup> Other critics contend that courts and the USPTO should view DNA sequences not as chemicals, but as information.<sup>167</sup> This argument rests on the presumption that society values genes not for their physical structures, but for the clinical information they provide.<sup>168</sup> Moreover, critics assert a change in the DNA sequence during the extraction process would render the isolated molecule completely useless, as isolated genes “are valued precisely for the faithful copies of naturally occurring information contained within.”<sup>169</sup>

Some scholars suggest mandating nonexclusive licenses as a way to mitigate the threat of patent monopolies.<sup>170</sup> Nonexclusive licenses allow the patent holder to offer multiple licenses to genetic testing facilities and can curb the possible negative impacts resulting from the issuance of gene patents.<sup>171</sup> The patent holder can collect royalties from its licensees while preserving competition among genetic testing facilities and maintaining the availability of second opinions for patients.<sup>172</sup> The National Institutes of Health has recommended nonexclusive licensing of gene patents whenever possible to maximize access to the patents.<sup>173</sup>

#### IV. INSTANT DECISION

In the instant decision, the United States Court of Appeals for the Federal Circuit assessed the patentability of both the composition claims and the method claims.<sup>174</sup> The court began by analyzing the composition claims.<sup>175</sup> In addressing the method claims, the court first discussed the methods of

164. Allen K. Yu, *Within Subject Matter Eligibility – A Disease and a Cure*, 84 S. CAL. L. REV. 387, 409 (2011).

165. *Id.* at 409.

166. *Id.* at 410.

167. *Id.*

168. *Id.*

169. *Id.* at 410-11.

170. Miri Yoon, Comment, *Gene Patenting Debate: The Meaning of Myriad*, 9 J. MARSHALL REV. INTELL. PROP. L. 953, 969 (2010).

171. Ledbetter, *supra* note 162, at 316.

172. *Id.*

173. Yoon, *supra* note 170, at 957.

174. *See* Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office (*Molecular Pathology II*), 653 F.3d 1329, 1333 (Fed. Cir. 2011), *cert. granted, vacated sub nom.* Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 132 S.Ct. 1794 (2012).

175. *See id.* at 1349-55.

“comparing” or “analyzing” nucleotide sequences and then discussed the method of screening potential cancer therapeutics.<sup>176</sup>

### A. Composition Claims

The United States Court of Appeals for the Federal Circuit concluded that the claimed “isolated” DNA did not fall under the “products of nature” exception to patentability and thus upheld the validity of Myriad’s patents.<sup>177</sup>

Myriad argued that its composition claims constituted patentable subject matter because “isolated” DNA is “a nonnaturally occurring manufacture or composition of matter” with “a distinctive name, character and use.”<sup>178</sup> Myriad asserted that the claimed DNA does not exist in nature, and unlike DNA found in nature, “can be used as primers and probes for diagnosing cancer.”<sup>179</sup> Finally, Myriad argued that the “products of nature” exception is inherently problematic because “every composition of matter is, at some level, composed of natural materials,” and excepting Myriad’s claims from patentability “would be contrary to [the Federal Circuit’s] precedents, the [USPTO’s] *Utility Examination Guidelines*, and Congress’s role in enacting the patent laws.”<sup>180</sup>

The plaintiffs responded that Myriad’s claims constituted unpatentable subject matter because they fell under the “natural phenomena” and “products of nature” exceptions.<sup>181</sup> The plaintiffs argued that Supreme Court precedent demonstrated that products of nature are not patentable, regardless of whether they have “undergone some highly useful change.”<sup>182</sup> The plaintiffs further alleged that because the claimed DNA retained the same nucleotide sequence as DNA found in nature, the claimed DNA was not “markedly different” than a product of nature.<sup>183</sup> Finally, the plaintiffs noted the preemptive effect Myriad’s patents had on entities that desire to work with the *BRCA1* and *BRCA2* genes.<sup>184</sup>

The government, as amicus curiae, distinguished between two types of “isolated” DNA: cDNA and DNA isolated from natural chromosomes.<sup>185</sup> The government asserted that the claimed synthetic cDNA constituted patentable subject matter because it does not occur in nature, but that DNA mole-

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176. See *id.* at 1355-58.

177. *Id.* at 1350.

178. Brief for the Appellants at 41-42, *Molecular Pathology II*, 653 F.3d 1329 (No. 2010-1406), 2010 WL 4600106, at \*47 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980)).

179. *Molecular Pathology II*, 653 F.3d at 1349.

180. *Id.*

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.*

185. *Id.* at 1349-50.

cules isolated from chromosomes do not constitute patentable subject matter because “their nucleotide sequences exist because of evolution, not man.”<sup>186</sup> At oral argument, the government proposed a “magic microscope” test for deciding whether a claim is drawn to patent ineligible subject matter.<sup>187</sup> The test contemplated a microscope that could focus in closely on DNA in the human body.<sup>188</sup> Under the “magic microscope” test, cDNA is patentable because the microscope could not focus in on this synthetic molecule in a living organism.<sup>189</sup> Conversely, the hypothetical microscope could focus in on *BRCA1* and *BRCA2* sequences found in nature, meaning DNA isolated from naturally occurring chromosomes are patent-ineligible under the government’s test.<sup>190</sup>

The Federal Circuit upheld Myriad’s composition claims, declining to hold separately on the issues of cDNA and DNA isolated from naturally occurring chromosomes.<sup>191</sup> First, the court examined *Chakrabarty* and *Funk Brothers*, and concluded that the distinction between a product of nature and a human-made invention “turns on a change in the claimed composition’s identity compared with what exists in nature.”<sup>192</sup> The court reasoned that Myriad’s claimed molecules have characteristics “markedly different” from molecules that exist in nature.<sup>193</sup> The court noted that isolated DNA is a free-standing molecule, unlike DNA in the human body, which exists in large, tightly-packed chromosomes.<sup>194</sup> The chemical bonds that attach genes to chromosomes in nature have been cleaved in isolated DNA.<sup>195</sup> Additionally, the court focused on the different sizes of naturally occurring DNA and Myriad’s patented DNA.<sup>196</sup> For example, while the *BRCA1* gene naturally exists in a chromosome approximately eighty-million nucleotides long, the *BRCA1* gene itself consists of approximately eighty thousand nucleotides.<sup>197</sup> Thus, the court concluded that the structural differences in Myriad’s patents amounted to more than a purification of a substance already existing in nature.<sup>198</sup>

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186. *Id.*

187. *Id.* at 1350.

188. *Id.*

189. *Id.* Because cDNA lacks introns, the sequences of nucleotides found in cDNA are unidentical to the sequences of nucleotides found in naturally occurring genes. *Id.* at 1363 (Moore, J., concurring).

190. *Id.* at 1350.

191. *Id.*

192. *Id.* at 1351.

193. *Id.*

194. *Id.* at 1351-52.

195. *Id.*

196. *Id.*

197. *Id.* Without introns, the *BRCA1* gene is even smaller: approximately 5,500 nucleotides long. *Id.* at 1352.

198. *Id.* at 1352.

Next, the court rejected the plaintiffs' argument that, because "isolated DNAs retain the same nucleotide sequence" as naturally occurring DNA, the claimed subject matter was not "markedly different" from a product of nature.<sup>199</sup> The court explained that the proper test to apply does not involve looking to similarities, but rather looking to significant differences between the claimed subject matter and the product of nature.<sup>200</sup> The court rejected the district court's focus on the patented molecules' function, explaining "it is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility rather than their physiological use or benefit."<sup>201</sup>

The court also rejected the government's "magic microscope" test, explaining that merely visualizing the claimed DNA sequence through a microscope fails to consider the cleavage of chemical bonds necessary to create isolated DNA from naturally occurring DNA, and "[o]ne cannot visualize a portion of a complex molecule . . . and will it into isolation as a unique entity."<sup>202</sup>

Finally, the court noted that upholding Myriad's patents comports with the "longstanding practice" of the USPTO.<sup>203</sup> For nearly thirty years, the USPTO has granted patents directed to DNA molecules, and in that time, Congress has declined to take action inconsistent with this practice.<sup>204</sup> The Federal Circuit explained that the Supreme Court has consistently held that changes to USPTO practice should come from Congress, not the courts.<sup>205</sup>

Due to Supreme Court precedent, customary USPTO procedures, and structural differences between isolated DNA and naturally occurring DNA, the United States Court of Appeals for the Federal Circuit held that Myriad's patents fell outside the judicially created exceptions to patentability and thus upheld the validity of all of Myriad's composition claims.<sup>206</sup>

## B. Method Claims

### 1. Methods of "Comparing" or "Analyzing" Nucleotide Sequences

Of the two types of method claims, the Federal Circuit looked first to the methods of "comparing" or "analyzing" nucleotide sequences.<sup>207</sup> Myriad argued that its method claims satisfied the machine-or-transformation test

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199. *Id.* at 1353.

200. *Id.*

201. *Id.*

202. *Id.*

203. *Id.* at 1354.

204. *Id.* at 1355.

205. *Id.* at 1354.

206. *Id.* at 1351.

207. *Id.* at 1355.

because they require a “transformation – extracting and sequencing DNA molecules from a human sample – before the sequences can be compared or analyzed.”<sup>208</sup> Moreover, Myriad claimed the patent specifications demonstrated that the claim term “sequence” “refers not to information, but rather to a physical DNA molecule, whose sequence must be determined before it can be compared.”<sup>209</sup>

The plaintiffs responded by asserting that the methods constituted abstract ideas, and merely limiting them to a certain technological field did not render them patentable.<sup>210</sup> The plaintiffs further alleged that the claims did not satisfy the machine-or-transformation test<sup>211</sup> because the language of the claims included only one step: “comparing” or “analyzing” the relevant nucleotide sequences.<sup>212</sup>

The court concluded that these method claims merely constituted single-step mental processes, rejecting Myriad’s attempt to read into the claims additional steps, such as extracting DNA from a human sample and sequencing the *BRCA1* or *BRCA2* genes.<sup>213</sup> Rather, the court asserted that both the claims and the patent specifications supported the plaintiffs’ contention that the method claims consisted of single-step mental processes.<sup>214</sup> In rejecting Myriad’s proposed definition of “sequence,” the court observed several figures in Myriad’s patent that Myriad labeled or described as nucleotide “sequence[s]”; rather than depicting a physical molecule, the figures contained only letters representing the sequence of nucleotides Myriad claimed.<sup>215</sup> Furthermore, the court agreed with the plaintiffs that simply limiting the scope of these patents to the *BRCA* genes failed to render the claimed process patentable, and held that because the methods could “be accomplished by mere

208. *Id.*

209. *Id.* at 1356.

210. *Id.* at 1355.

211. *See supra* note 137.

212. *Id.*

213. *Id.* at 1355-56. The court explained that the claims “[recite] nothing more than the abstract mental steps necessary to compare two different nucleotide sequences: look at the first position in a first sequence; determine the nucleotide sequence at that first position; look at the first position in a second sequence; determine the nucleotide sequence at that first position; determine if the nucleotide at the first position in the first sequence and the first position in the second sequence are the same or different, wherein the latter indicates an alteration; and repeat for the next position.” *Id.* at 1356.

214. *Id.*

215. *Id.* For example, one figure shows a list of “a series of letters (Gs, As, Ts, and Cs) corresponding to the nucleotides guanine, adenine, thymine, and cytosine.” *Id.* The patent specification describes the figure as showing “the ‘genomic sequence of *BRCA1*.’” *Id.* (quoting U.S. Patent No. 5,693,473 col.5 1.66 (filed June 7, 1995)).

inspection alone,” they failed to claim patentable subject matter under 35 U.S.C. § 101.<sup>216</sup>

## 2. Method of Screening Potential Cancer Therapeutics

Finally, the court turned to Myriad’s single method claim directed to screening potential cancer therapeutics.<sup>217</sup> The plaintiffs argued that the claim constituted an “abstract idea of comparing the growth rates of two cell populations and . . . preempt[ed] a basic scientific principle.”<sup>218</sup>

The Federal Circuit found that the claims directed to screening potential cancer therapeutics constituted patentable subject matter.<sup>219</sup> Applying the machine-or-transformation test, the court explained that the method claim included the steps of growing host cells with a *BRCA1* mutation, determining the growth rate of the cells, and comparing the growth rate of the cells.<sup>220</sup> The court observed that the steps of “growing” and “determining” both involved physical manipulation of the cells, and thus amounted to more than abstract ideas.<sup>221</sup> After noting that the claim presented “functional and palpable applications” in the biotechnology field, the court held that the method claim was directed to patent-eligible subject matter under 35 U.S.C. § 101 and therefore allowed.<sup>222</sup>

## V. COMMENT

Before the issue of gene patentability escalated, patents on tax strategies peaked and then faced legislative demise.<sup>223</sup> Tax strategy patents are a division of the broad category of business method patents. In court, inventors seeking patent protection of business methods have often struggled to demonstrate that their claims avoided the mental steps exception to patentable subject matter.<sup>224</sup> Understanding how these tax strategy patents achieved judicial endorsement and subsequently collapsed under Congress illuminates legal issues and possible future solutions to the problems surrounding the patentability of human genes.

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216. *Id.* at 1356-57.

217. *Id.* at 1357.

218. *Id.*

219. *Id.*

220. *Id.*

221. *Id.*

222. *Id.* at 1358 (quoting *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 868 (Fed. Cir. 2010)).

223. *See infra* Part V.A.

224. *See infra* Part V.A.



### A. *The Rise and Fall of Tax Strategy Patents*

The mental steps doctrine is a judicially created exception to statutory patentable subject matter.<sup>225</sup> The doctrine dictates that “mental processes – or processes of human thinking – standing alone are not patentable even if they have practical application.”<sup>226</sup> Despite a plausible physical manifestation, often by “pencil and paper” calculation, these processes generally implement human thought outside the realm of patentable subject matter, such as “‘determining,’ ‘registering,’ ‘counting,’ ‘observing,’ ‘measuring,’ ‘comparing,’ ‘recording,’ and ‘computing.’”<sup>227</sup> Courts have frequently used this doctrine to strike down patents for business methods that are not tied to any particular technology.<sup>228</sup>

Throughout the twentieth century, judicial ambiguity existed as to whether business methods constituted unpatentable subject matter per se.<sup>229</sup> Courts often gave equivocal explanations for their holdings in opinions invalidating business method patents.<sup>230</sup> For example, in *Hotel Security Checking Co. v. Lorraine Co.*, the Circuit Court of Appeals for the Second Circuit invalidated a claim directed to a “‘method of and means for cash-registering and account-checking’ designed to prevent frauds and speculation by waiters and cashiers in hotels and restaurants.”<sup>231</sup> The court suggested that all claims directed to business methods constitute unpatentable subject matter when it explained that a “‘system of transacting business . . . is not, within the most liberal interpretation of the term,’ a patentable art.”<sup>232</sup> On the other hand, the court appeared to focus on the doctrine of obviousness when it asserted that the subject matter in the patent at issue “would occur to anyone conversant with the business.”<sup>233</sup>

225. See *In re Comiskey*, 554 F.3d 967, 979 (Fed. Cir. 2009).

226. *Id.*

227. Debra Greenfield, *Intangible or Embodied Information: The Non-Statutory Nature of Human Genetic Material*, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 467, 518-19, 525 (2009); see also Jeffrey A. Simenauer, Note, *Patentability of Computer-Related Inventions: A Criticism of the PTO's View on Algorithms*, 54 GEO. WASH. L. REV. 871, 885-86 (1986).

228. See, e.g., *In re Comiskey*, 554 F.3d at 980 (“It is thus clear that the present statute does not allow patents to be issued on particular business systems – such as a particular type of arbitration – that depend entirely on the use of mental processes.”).

229. JOHN R. THOMAS, CONG. RESEARCH SERV., RL 34221, PATENTS ON TAX STRATEGIES: ISSUES IN INTELLECTUAL PROPERTY AND INNOVATION 5-6 (2010).

230. *Id.*

231. 160 F. 467 (2d Cir. 1908) (quoting U.S. Patent No. 500,071 (filed July 21, 1890)); see also THOMAS, *supra* note 229, at 5.

232. *Hotel Sec. Checking Co.*, 160 F. at 469; see also THOMAS, *supra* note 229, at 5.

233. *Hotel Sec. Checking Co.*, 160 F. at 471; see also THOMAS, *supra* note 229, at 5-6.

In 1998, the United States Court of Appeals for the Federal Circuit ended the ambiguity surrounding business methods when it explicitly endorsed their patentability in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*<sup>234</sup> State Street Bank & Trust Company (State Street) brought a declaratory judgment action against Signature Financial Group (Signature), the assignee of a patent directed to a data processing system designed to facilitate an investment “structure whereby mutual funds . . . pool their assets in an investment portfolio . . . organized as a partnership.”<sup>235</sup> The claimed investment plan provided “the administrator of a mutual fund with the advantageous combination of economies of scale in administering investments coupled with the tax advantages of a partnership.”<sup>236</sup> Seeking to invalidate Signature’s patent, State Street argued that the patent fell into the business method exception to patentable subject matter.<sup>237</sup> The Federal Circuit upheld Signature’s patent and rejected the business method exception, reasoning that the exception had roots in the “requirement for invention,” an antiquated prerequisite for patentability eradicated by the 1952 Patent Act.<sup>238</sup> Since *State Street Bank & Trust Co.*, the USPTO has issued numerous business method patents.<sup>239</sup>

Judicial validation of business method patents invited an influx of tax strategy patents filed and issued.<sup>240</sup> Tax strategies are the “purposeful arrangement of financial transactions so as to reduce tax liability.”<sup>241</sup> Patents that claim tax strategies are typically directed to methods of manipulating tax loopholes and tax havens.<sup>242</sup> As of January 6, 2010, the USPTO granted ninety patents and published 136 patent applications in the tax strategy category.<sup>243</sup> These patents subjected tax practitioners to infringement liability if the practitioners, at a minimum, recommended the patented strategies to their clients.<sup>244</sup> Opponents of tax strategy patents equated them with “private toll-booths that block tax compliance options and . . . cost Americans more money.”<sup>245</sup> Moreover, the “nonobviousness” requirement for patentability

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234. 149 F.3d 1368, 1377 (Fed. Cir. 1998), *arbrograted by* *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2010).

235. *Id.* at 1370.

236. *Id.*

237. *Id.* at 1375-76.

238. *Id.* at 1375.

239. THOMAS, *supra* note 229, at 7.

240. *Id.* at 8.

241. See Christopher A. Cotropia & James Gibson, *The Upside of Intellectual Property's Downside*, 57 UCLA L. REV. 921, 940 (2010).

242. *Id.* at 941.

243. THOMAS, *supra* note 229, at 8.

244. Michael Cohn, *Obama Signs Ban on Tax Strategy Patents*, ACCOUNTING TODAY (Sept. 19, 2011), <http://www.accountingtoday.com/news/Obama-Signs-Ban-Tax-Strategy-Patents-60016-1.html>.

245. *Id.*

illuminates the fact that patent law inherently incentivized the most unwelcome form of tax law manipulation;<sup>246</sup> tax strategy patents “represent behavior that could not have been intended by Congress because, if it had been, the tax planning would be predictable and thus unpatentable.”<sup>247</sup> The American Institute of Certified Public Accountants and state certified public accountant societies lobbied for five years to enact legislation banning the practice of tax strategy patents.<sup>248</sup>

Congress resolved this issue when it passed the Leahy-Smith America Invents Act. Signed into law September 16, 2011, the Leahy-Smith America Invents Act renders tax strategies unpatentable.<sup>249</sup> The Act dictates that “any strategy for reducing, avoiding, or deferring tax liability” is “insufficient to differentiate a claimed invention from the prior art.”<sup>250</sup> Under the new law, “tax liability” broadly refers to “any liability for a tax under any [f]ederal, [s]tate, or local law.”<sup>251</sup> Although the act has no effect on patents filed, pending or issued before September 16, 2011, it effectuates a fiat that bans the patentability of future tax strategies.<sup>252</sup>

### B. Nucleotide Sequences As Prior Art

Like tax strategy patents, human gene patents can lead to adverse social effects. Just as tax strategy patents inhibit basic functions in the tax practitioner industry,<sup>253</sup> Myriad’s patents bar researchers and medical professionals from performing elementary tasks in relation to the *BRCA* genes. In addition, the exclusivity attained by Myriad allows it to maximize profits at the cost of independent research and broader access to testing. Opponents of Myriad’s patents have criticized Myriad’s testing services as “technologically outmoded, incomplete and too costly.”<sup>254</sup>

Myriad’s test sequences patients’ *BRCA1* and *BRCA2* genes and screens them for cancer-causing mutations, but soon, others will have the ability to sequence a person’s entire 22,000-gene genome for less than \$3,340 – the

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246. Cotropia & Gibson, *supra* note 241, at 942.

247. *Id.* at 943.

248. *President Signs Patent Reform Bill Banning New Tax Strategy Patents*, AM. INST. OF CPAS (Sept. 16, 2011), <http://www.aicpa.org/interestareas/tax/newsandpublications/taxnews/pages/20110916.aspx>.

249. Leahy-Smith America Invents Act, Pub. L. No. 112-29 § 14(a), 125 Stat. 284 (2011); *see also* *President Signs Patent Reform Bill Banning New Tax Strategy Patents*, *supra* note 248.

250. Leahy-Smith America Invents Act § 14(a).

251. *Id.* § 14(b).

252. *President Signs Patent Reform Bill Banning New Tax Strategy Patents*, *supra* note 248.

253. *See supra* notes 240-52 and accompanying text.

254. Pollack, *supra* note 8.

price Myriad charges for sequencing two genes.<sup>255</sup> In 2006, Mary-Claire King, a professor of genome sciences and medicine at the University of Washington, published a paper showing that Myriad's main test "failed to detect a significant number of" mutations in the *BRCA1* and *BRCA2* genes.<sup>256</sup> In response, Myriad developed a supplemental test, available to patients for an additional \$700.<sup>257</sup> Because of the expense and the fact that most insurance companies do not cover it, many women do not receive supplemental testing.<sup>258</sup> Critics urge that this problem would not exist absent Myriad's exclusivity, and over 200 health care professionals have exhorted Myriad to incorporate the supplemental test into its original *BRCA1* and *BRCA2* sequencing test.<sup>259</sup>

Although patent protection exists to promote innovation and to reward research, gene patents can have the opposite effect.<sup>260</sup> Entities with gene patents may hinder "the next generation of innovation in genetic" medicine.<sup>261</sup> Firms developing new technologies must contend with "thicket[s] of patents," and "[i]n order to sequence an entire genome, a firm would have to license thousands of patents from many different licensors."<sup>262</sup> Even if a competing firm reasonably believed a court would strike down such a patent as anticipated or obvious, the costs of filing suit alone may prohibit judicial inquiry.<sup>263</sup> Such adverse effects may not generate much concern in most fields of patentable technology, but where human lives depend on the efficient function of the industry, the implications of these problems swell.

To address these issues, Congress could apply the method used against tax strategy patents to gene patents by enacting legislation that deems all natural DNA sequences to be prior art.<sup>264</sup> Patentable subject matter must claim a novel element, and the sole novel element of a gene patent is its

255. *Id.*

256. *Id.*; Tom Walsh, et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 J. AM. MED. ASS'N 1379, 1379 (2006).

257. Pollack, *supra* note 8.

258. *Id.*

259. *Id.*

260. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Molecular Pathology II)*, 653 F.3d 1329, 1379-80 (Fed. Cir. 2011) (Bryson, J., dissenting), cert. granted, vacated sub nom. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S.Ct. 1794 (2012).

261. *Id.* at 1380.

262. *Id.*

263. *Id.*

264. Likewise, to combat cDNA patents, Congress could simply enact legislation that deems nucleotide sequences complementary to naturally-occurring mRNA sequences to be prior art.

newly mapped nucleotide sequence.<sup>265</sup> The proposed legislation would eliminate the sole novel element of gene patents by deeming natural human DNA sequences to be prior art. Accordingly, natural human genes would become unpatentable, because they could not claim a novel element.

The proposed legislation is not implausible because critics of gene patents have long objected to the courts' and the USPTO's endorsement of nucleotide sequences as novel.<sup>266</sup> Although researchers may develop new methods of sequencing and isolating genes, "the information of a genetic sequence . . . is not new, but has pre-existed in the natural environment."<sup>267</sup> Companies like Myriad distinguish isolated genes from genes found in nature on the basis that isolated genes result only when the inventor cleaves their covalent bonds from other genes.<sup>268</sup> However, chemical bonds are "merely a force between two atoms . . . strong enough 'to make it convenient for the chemist to consider [the aggregate] as an independent molecular species.'"<sup>269</sup> Furthermore, cleaving these bonds is not unique to Myriad's *BRCA1* and *BRCA2* patents; it is an element necessary to the existence of any isolated gene.

Aside from minimizing the anticompetitive harms of gene patents, the proposed legislation would end decades of common law ambiguity. *Parke-Davis*, *Funk Brothers*, and *Chakrabarty* demonstrate how courts have struggled to separate products of nature and mere purifications from compositions of matter with markedly different characteristics and social utility.<sup>270</sup> Although the Supreme Court's opinion in *Prometheus* attempts to clarify and limit the scope of patentable subject matter,<sup>271</sup> its holding leaves ample room for interpretation and inconsistency. Specifically, the *Prometheus* decision "does not appear to consider administrative practicality" and leaves "an ongoing open question as to whether the USPTO will be able to successfully implement the proffered rule of subject matter eligibility."<sup>272</sup> Additionally, the decision arguably "creates a framework for patent eligibility in which almost

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265. See generally Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 19 (2011) (discussing the scope and validity of gene patents).

266. See, e.g., Greenfield, *supra* note 227, at 498.

267. *Id.*

268. See *Molecular Pathology II*, 653 F.3d at 1375 (Bryson, J., dissenting).

269. *Id.* (quoting LINUS PAULING, *THE NATURE OF THE CHEMICAL BOND* 6 (3d ed. 1960)).

270. See *supra* notes 106-115, 151-56 and accompanying text.

271. See *supra* notes 144-49 and accompanying text.

272. Dennis Crouch, *Examining Subject Matter Eligibility Under Mayo v. Prometheus*, PATENTLYO (Mar. 23, 2012), <http://www.patentlyo.com/patent/2012/03/examining-subject-matter-eligibility-under-mayo-v-prometheus.html>.

any method claim can be invalidated” because the holding allows courts to explain away their decisions merely through artful language.<sup>273</sup>

In light of the confusion surrounding subject matter patentability, the patentability of human gene sequences is an issue better suited for policy makers, not the courts. Deeming gene sequences to be prior art would reduce court costs. Moreover, this legislation would provide competing firms with unequivocal boundaries on research and medical practices; because competing firms would no longer have to guess about the outcome of a lawsuit, they would be more apt to challenge a patent of dubious patentability.

In the Leahy-Smith America Invents Act, Congress clearly contemplated that conceiving new tax strategies from a set of laws already in existence constitutes sufficient grounds to declare such strategies prior art.<sup>274</sup> Certainly then Congress could find that a newly mapped sequence of DNA found in nature is insufficient to differentiate the claimed gene from the prior art. If Congress enacted legislation regarding gene patents similar to the new law regarding tax strategies, companies like Myriad would have to create new ways to differentiate their claims in order to avoid rejection by the USPTO or face judicial invalidation.

Because scientists have now mapped the entire human genome,<sup>275</sup> and because the only new element of a gene patent is its nucleotide sequence,<sup>276</sup> the USPTO likely will not issue any more human gene patents claiming naturally occurring genes. However, the legal issues surrounding gene patents will remain ripe for years due to advances in science and medicine. Particularly, the field of epigenetics continues to grow.<sup>277</sup> Like gene sequence abnormalities, epigenetic abnormalities often lead to cancer.<sup>278</sup> Thus, the sense of urgency surrounding gene patents will not die with their expiration. Epigenetic researchers have filed recent applications for patent applications,<sup>279</sup>

273. Robert R. Sachs, *Punishing Prometheus: The Supreme Court's Blunders in Mayo v. Prometheus*, PATENTLYO (Mar. 26, 2012), <http://www.patentlyo.com/patent/2012/03/punishing-prometheus-the-supreme-courts-blunders-in-mayo-v-prometheus.html>.

274. See *supra* notes 249-52 and accompanying text.

275. See *Human Genome Project Information*, U.S. DEP'T OF ENERGY, [http://www.ornl.gov/sci/techresources/Human\\_Genome/home.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml) (last visited July 26, 2011).

276. See *supra* note 265 and accompanying text.

277. See Cloud, *supra* note 9. The term “epigenetics” refers to “the study of changes in gene activity that do not involve alterations to the genetic code” but still have heritable qualities. *Id.*

278. Danielle Simmons, *Epigenetic Influences and Disease*, SCITABLE <http://www.nature.com/scitable/topicpage/epigenetic-influences-and-disease-895> (last visited July 26, 2012). Epigenetic abnormalities can also lead to mental retardation. *Id.*

279. See *Recent Patent Applications in Epigenetics*, NATURE BIOTECHNOLOGY, [http://www.nature.com/nbt/journal/v28/n6/fig\\_tab/nbt0610-560\\_T1.html](http://www.nature.com/nbt/journal/v28/n6/fig_tab/nbt0610-560_T1.html) (last visited July 26, 2012).

and the USPTO has already granted patents claiming epigenetic methods or compositions of matter.<sup>280</sup> Since these patents have the same preemptive effect as gene patents, the USPTO and courts could be facing Myriad's legal and ethical dilemma for years.

## VI. CONCLUSION

Myriad's major patents will expire in 2014,<sup>281</sup> but cancer patients need competent, affordable medical treatment now. Moreover, the legal issues encompassing gene patents remain ripe with the advent of epigenetic information. With these matters on the horizon, eradicating the ambiguity surrounding subject matter patentability becomes even more imperative. The Framers of the Constitution stated their intent simply: "[t]o promote the Progress of Science and useful Arts."<sup>282</sup> For years the courts have had the burden of determining how best to achieve that goal with respect to gene patents, and the Supreme Court of the United States may have to reassess an exigent dilemma: the validity of Myriad's patent claims and investments against the distress of patients seeking affordable quality health care in a monopolist's market. In one act of legislation Congress can relieve the Supreme Court of this onus, clarify decades of judicial ambiguity, and give cancer patients the access to health care they deserve.

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280. See, e.g., U.S. Pat. No. 7,723,565 (filed Jan. 7, 2005) (issued May 25, 2010).

281. Pollack, *supra* note 8.

282. U.S. CONST. art I, § 8, cl. 8.