GENES AND THE SUPREMES: WILL THE SUPREME COURT UPHOLD PATENTS FOR ISOLATED GENE SEQUENCES?

Comment

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I. INTRODUCTION

"YOU, or someone you love, may die because of a gene patent that should never have been granted in the first place."[1] With these words, the late author Michael Crichton launched into a scathing attack on the practice of patenting human genes in an op-ed for the *New York Times*.[2] But does his claim have any basis in reality, or is it just hyperbolic nonsense?

Consider the plight of Ms. Patrice Fortune.[3] In 2009, doctors diagnosed forty-eight-year-old Ms. Fortune with breast cancer.[4] They recommended testing for mutations in two gene sequences, known as Breast Cancer Susceptibility Gene 1 (BRCA1) and Breast Cancer Susceptibility Gene 2 (BRCA2), which are correlated with breast cancer.[5] These tests help doctors to determine an appropriate form of cancer treatment.[6] Unfortunately, the company providing the tests, Myriad Genetics, did not accept Ms. Fortune's insurance, and she could not pay for the tests out-of-pocket.[7] Because Myriad had patented BRCA1 and BRCA2 and retained the exclusive right to their use, she had nowhere else to turn for testing.[8]

Ms. Fortune was one of many similarly situated women who were plaintiffs in a lawsuit against Myriad Genetics in 2009.[9] The women joined a collection of scientific organizations and genetic researchers who contested the validity of patents covering BRCA1 and BRCA2 by arguing that these genes were simply products of nature unchanged by their extraction from the human body.[10] The United States District Court for the Southern District of New York held that the isolated gene sequences patented by Myriad were not "markedly different" from the same gene sequences found in nature and, thus, did not constitute patentable subject matter.[11] On appeal, the United States Court of Appeals for the Federal

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1. Michael Crichton, Op-Ed., *Patenting Life*, N.Y. TIMES (Feb. 13, 2007), http://www.nytimes.com/2007/02/13/opinion/13crichton.html.

2. *Id.*

3. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 189 (S.D.N.Y. 2010), *rev'd on other grounds*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012), *remanded to* 689 F.3d 1303 (Fed. Cir. 2012).

4. *Id.*

5. *Id.*

6. *Id.* at 203.

7. *Id.* at 189. The test offered by Myriad Genetics costs over $3,000. *Id.* at 203. Myriad does offer a financial assistance program for those who are uninsured and meet certain income requirements. *See* MYRIAD FINANCIAL ASSISTANCE PROGRAM APPLICATION, http://www.myriad.com/lib/mfap/MFAP-Application.pdf (last visited Jan. 19, 2012). Most insurance companies will cover the testing if the insured is under age forty-five, which may explain why Ms. Fortune's insurance did not cover it. *See BRCA Testing*, ATLANTIC HEALTH SYS., https://atlantichealth.dnadirect.com/grc/patient-site/brca/insurance-coverage.html (last visited Jan. 20, 2012).

8. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 189.

9. *Id.* at 188-89.

10. *Id.* at 185-89.

11. *Id.* at 232.

Circuit reversed the district court's judgment, holding that the distinction between the chemical compositions of isolated gene sequences and naturally occurring gene sequences prevented BRCA1 and BRCA2 from being unpatentable natural phenomena.[12] After the Federal Circuit denied the plaintiffs' petition for rehearing, the American Civil Liberties Union (ACLU), one of the representatives of the plaintiffs, petitioned the Supreme Court of the United States.[13] On March 20, 2012, the Supreme Court decided *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, which involved a similar challenge to Prometheus's patents covering a process of administering thiopurine drugs.[14] In light of this decision, the Supreme Court remanded the *Myriad* case without writing an opinion.[15] As many commentators predicted, the Federal Circuit did not change its opinion on remand, and as a result, the case likely will return to the Supreme Court for a final decision.[16]

This Comment will attempt to predict the Supreme Court's answer to the question of whether isolated gene sequences are patent-eligible subject matter.[17] Part II will provide scientific definitions necessary to

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12. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1353 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012), *remanded to* 689 F.3d 1303 (Fed. Cir. 2012). The Court of Appeals for the Federal Circuit was created in 1982 to hear virtually all patent appeals and to alleviate the problem of inconsistent results among the regional circuit court decisions regarding patents. *See* Sapna Kumar, *Expert Court, Expert Agency*, 44 U.C. DAVIS L. REV. 1547, 1582-83 (2011). Many of the Federal Circuit judges, as well as their clerks, have backgrounds in the sciences that give them more expertise in patent cases than their counterparts in other circuits. *See* Mike Gibbons, *Patent Jurisdiction of Federal Circuit Enhanced by America Invents Act of 2011*, RUTTLER LAW (Oct. 24, 2011), http://www.ruttlerlaw.com/blog/2011/10/patent-jurisdict/.

13. *See* Sarah Roberts, *ACLU Asks Supreme Court to Hear Gene Patents Case*, ACLU BLOG OF RTS. (Dec. 7, 2011, 5:49 PM), http://www.aclu.org/blog/free-speech-womens-rights/aclu-asks-supreme-court-hear-gene-patents-case.

14. *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012).

15. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 132 S. Ct. 1794, 1794 (2012) (mem.), *vacating Ass'n for Molecular Pathology*, 653 F.3d 1329.

16. *Ass'n for Molecular Pathology*, 689 F.3d at 1325-33; *see, e.g.*, Tony Dutra, Myriad *Oral Argument Redux: Were Any Votes Changed?*, BLOOMBERG BNA (July 24, 2012), http://www.bna.com/myriad-oral-argument-b12884910784/; Daniel Fisher, Myriad *Case May Shape the Future of Medical Patents*, FORBES (July 19, 2012, 5:12 PM), http://www.forbes.com/sites/danielfisher/2012/07/19/myriad-genetics-medical-patents/; Brent Kendall, *Judges Hold the Line on Gene Patents*, WALL ST. J. LAW BLOG (July 20, 2012, 4:18 PM), http://blogs.wsj.com/law/2012/07/20/judges-hold-the-line-on-gene-patents/; Sarah A. Kagan & Lisa M. Hemmendinger, *Federal Circuit Hears Arguments in* Myriad *Genetics Case*, MONDAQ (July 26, 2012), http://www.mondaq.com/unitedstates/x/188912/Life+Sciences+Biotechnology/Federal+Circuit+Hears+Arguments+in+Myriad+Genetics+Case. On September 25, 2012, the ACLU petitioned the Supreme Court for a second time. *See* Sandra S. Park, *Supreme Court: Liberate the Human Genome!*, ACLU BLOG OF RTS. (Sept. 25, 2012, 1:14 PM), http://www.aclu.org/blog/womens-rights-free-speech/supreme-court-liberate-human-genome.

17. *See infra* Part VI. This Comment does not include a discussion of the method claims at issue in *Myriad*. *See Ass'n for Molecular Pathology*, 653 F.3d at 1355-58; Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 232-37 (S.D.N.Y. 2010), *rev'd on other grounds*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012), *remanded to* 689 F.3d 1303 (Fed. Cir. 2012). This Comment also does not address the First Amendment claim avoided by the district court. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 237-38. Additionally, a discussion of the issue

understanding the issue. Then, Part III will present the scope of patentable subject matter and the history of gene patents. Parts IV and V will examine the district court's decision invalidating gene patents and the Federal Circuit's reversal of that decision. Finally, Part VI will look at competing policy arguments and a survey of Supreme Court cases from the past decade to predict how the nine Justices will rule in the likely event that the Supreme Court grants certiorari.

II. A PRIMER ON DNA

Before delving any further into the legal issues surrounding gene patents, this Comment must define some commonly used terms. Deoxyribonucleic acid (DNA) is "a molecule consisting of a string of chemicals called *nucleotides*."[18] Most human DNA resides in tightly packed clusters known as chromosomes, which are found in the nucleus of each cell.[19] The nucleotides—containing sugar, phosphate, and a base—form a structure resembling "a ladder cut in half down the middle of the rungs."[20] The sugars and phosphates compose each side of the ladder, and the bases form the half rungs.[21] The four bases are adenine (A), guanine (G), cytosine (C), and thymine (T).[22] Bonds between A and T and between G and C connect the two halves of the ladder that are twisted into a structure known as the double-helix.[23] The order of the bases is the DNA molecule's sequence, which forms the unique genetic code of human beings and other organisms.[24] This code contains instructions for making proteins, which are "the structural components of cells and tissue and the enzymes that control biochemical reactions."[25]

Genes are segments of DNA that contain the code for specific proteins.[26] The human body contains about 20,000 to 25,000 genes.[27] The sequence of nucleotide bases in a particular gene varies from person to person, and excessive repeating of certain nucleotide bases is a mutation that can result in genetic diseases such as Huntington's disease and cystic fibrosis.[28] Scientists use these differences in gene sequences to diagnose

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of the plaintiffs' standing is not included in this Comment. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 669 F. Supp. 2d 365, 383-92 (S.D.N.Y. 2009).

18. LORI B. ANDREWS, MAXWELL J. MEHLMAN & MARK A. ROTHSTEIN, GENETICS: ETHICS, LAW AND POLICY 17 (3d ed. 2010).

19. *Id.* at 20.

20. *Id.* at 17.

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.* at 21.

26. *Id.*

27. *Id.* at 22.

28. *Id.* at 22-23.

and predict an individual's susceptibility to diseases caused by mutations.[29] Myriad Genetics used the patented BRCA1 and BRCA2 gene sequences for the same purpose.[30]

An understanding of these scientific terms is vital to comprehending the discussions in the district court and Federal Circuit decisions regarding isolated gene sequences and the policy arguments from both the plaintiffs and the defendants.

III. HISTORY OF GENE PATENTS IN THE UNITED STATES

After defining what a gene is and how gene sequences are used by scientists, the next step in the discussion is to examine what exactly is patent-eligible subject matter and how isolated gene sequences fit into this framework. This part of the Comment will also document any efforts to expand or contract the scope of patent-eligible subject matter by the courts, the Patent and Trademark Office, and Congress.

A. Statutory Language of the Patent Act and Judicially Created Exceptions

The Constitution provides that "Congress shall have power . . . to promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[31] Pursuant to this clause, Congress eventually passed the Patent Act of 1952.[32] Section 101 of the Act states that patent-eligible material includes "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[33] This Section is the first threshold that an inventor must cross before confronting the additional requirements of novelty and nonobviousness.[34]

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29. *Id.* at 23.

30. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 203 (S.D.N.Y. 2010), *rev'd on other grounds*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012), *remanded to* 689 F.3d 1303 (Fed. Cir. 2012).

31. U.S. CONST. art. I, § 8, cl. 8. The Intellectual Property Clause of the Constitution places the concept of utilitarianism higher than John Locke's labor theory of property, which emphasizes rewarding creators and inventors for the fruits of their labors. *See* Jeanne C. Fromer, *Expressive Incentives in Intellectual Property*, 98 VA. L. REV. 1745, 1753 (2012).

32. Patent Act of 1952, ch. 950, 66 Stat. 792 (codified as 35 U.S.C.).

33. 35 U.S.C. § 101 (2011). The Leahy-Smith America Invents Act, signed into law by President Barack Obama on September 16, 2011, did not alter the language of § 101. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (codified as amended in scattered sections of 35 U.S.C. (2011)); *Leahy-Smith America Invests Act Implementation*, USPTO, http://www.uspto.gov/aia_ implementation/index.jsp (last visited Oct. 2, 2011).

34. *See In re* Bergy, 596 F.2d 952, 960-61 (C.C.P.A. 1979) (describing how the patent applicant must have "the separate keys to open in succession the three doors of sections 101, 102, and 103" and noting that although the word "new" is mentioned in § 101, the requirement of novelty is not considered until § 102 (quoting *In re* Bergstrom, 427 F.2d 1934, 1401 (1970))).

In addition to these requirements, the Supreme Court has created three exceptions to patentable subject matter based on its interpretation of the statute: laws of nature, natural phenomena, and abstract principles.[35]

The Supreme Court has excluded laws of nature from patent-eligible subject matter.[36] In *Parker v. Flook*, the Court rejected the respondent's claim that a process was patentable simply because it implemented a pre-existing law of nature in a specific way.[37] The patent covered a method for calculating alarm limits used to measure temperature, pressure, and flow rates and to signal inefficiencies or danger during catalytic conversion processes.[38] The Court noted that discoveries of a law of nature are "not the kind of 'discoveries' that the statute was enacted to protect."[39] Because the scientific principle or law of nature has always existed, it is not new and, thus, does not fall under the patentable subject matter described in § 101.[40]

Similarly, the discovery of phenomena in nature is not patentable.[41] In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, the Court held that the discovery of certain strains of bacteria that exhibited a particular quality and the application of this discovery were not patentable because the useful quality of the bacteria was "part of the storehouse of knowledge of all men" and "reserved exclusively to none."[42] The use of the bacteria by the respondent simply allowed the bacteria to function as it would in nature, failing to satisfy the "new" requirement in § 101.[43]

Lastly, abstract principles are outside the scope of patentable subject matter.[44] *Gottschalk v. Benson* involved a patent for a method of "converting binary-coded decimal (BCD) numerals into pure binary numerals" on a digital computer.[45] Because the mathematical formula used in this process had no substantial application outside of a digital computer, a patent for the process would in effect cover the formula.[46] This formula was an abstract intellectual concept that constituted one of "the basic tools of scientific and technological work," and a patent for such a basic formula could stifle future inventors whose inventions involved a digital computer that used the formula.[47] Because this scientific truth had always existed, the

35. *See* Parker v. Flook, 437 U.S. 584, 593 (1978) (laws of nature); Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (abstract ideas); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (natural phenomena).

36. *See Parker*, 437 U.S. at 593.

37. *Id.*

38. *Id.* at 585-86.

39. *Id.* at 593.

40. *Id.* at 593 n.15.

41. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

42. *Id.*

43. *See id.* at 131.

44. Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

45. *Id.* at 64-65.

46. *Id.* at 67, 71-72.

47. *See id.* at 67-68.

mere mathematical expression of it was not new and could not be patented under § 101.[48]

Recently, the Supreme Court has expressed a reluctance to create more exceptions.[49] The Court has noted that the exceptions do not give "*carte blanche* to impose other limitations that are inconsistent with the text and the statute's purpose and design."[50] Thus, laws of nature, natural phenomena, and abstract ideas remain the only categorical exceptions to patentable subject matter described in § 101.[51]

B. The Chakrabarty *Decision*

The exception for natural phenomena suggests that living organisms are not patentable, and patent examiners rejected patent applications for living organisms until the landmark case of *Diamond v. Chakrabarty*.[52] Ananda Chakrabarty, a microbiologist, genetically engineered a bacterium that could break down the components of crude oil and that would be useful in cleaning up oil spills.[53] The Supreme Court held that the bacterium was a "nonnaturally occurring manufacture or composition of matter" and, thus, was patentable.[54] The Court remarked that § 101 should be given wide scope and that Congress intended to allow patents for "anything under the sun that is made by man."[55] The petitioner argued that Congress's enactment of the Plant Patent Act in 1930 and the Plant Variety Protection Act in 1970 implied that Congress did not believe living things other than plants could be patented.[56] The Court rejected this argument and reasoned that Congress used the Acts to recognize the distinction between plants found in nature and the human cultivation of plants that could not be repeated in nature.[57] Additionally, the Court rejected the argument that Congress must expressly authorize patents for microorganisms and noted that Congress's inability to foresee genetic technology at the time § 101 was drafted did not remove genetically engineered microorganisms from the scope of patentable subject matter.[58]

Although *Chakrabarty* did not specifically mention patents on isolated gene sequences, the inventing community inferred that patents on living organisms would also include the building blocks of such life, including

48. *See id.* at 67.
49. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3226 (2010).
50. *Id.*
51. *See id.*
52. *See* Diamond v. Chakrabarty, 447 U.S. 303, 306 (1980).
53. *Id.* at 305.
54. *Id.* at 309.
55. *Id.* at 308 (quoting S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).
56. *Id.* at 310-14.
57. *Id.* at 313.
58. *Id.* at 314-16.

genes.[59] In 1982, the United States Patent and Trademark Office (USPTO) issued the first "gene patent," which included the genes containing the coding for "human chorionic somatomammotropin" and "the growth hormone of an animal species."[60] After *Chakrabarty*, patent filings claiming genes rose from around 100 in 1984 to 1,600 in 1995.[61] Today, thousands of gene patents exist, covering approximately twenty percent of all human genes.[62] The *Chakrabarty* decision was instrumental in dispelling the notion that living things were unpatentable and opened the door to patents for isolated gene sequences.[63]

C. The Amgen *Decision*

While *Chakrabarty* encouraged scientists to obtain gene patents, it did not provide the reason for treating isolated gene sequences differently than gene sequences found in the human body; *Amgen, Inc. v. Chugai Pharmaceutical Co.* provided this reason over a decade later.[64] The case was a patent infringement lawsuit that involved a patent on a "purified and isolated DNA sequences encoding . . . human erythropoietin," which stimulates the production of red blood cells and is used to treat anemia and certain blood disorders.[65] In ruling on the validity of the patent, the Federal Circuit noted that "[a] gene is a chemical compound, albeit a complex one" and that an inventor must have "a mental picture of the structure of the chemical."[66] Furthermore, the inventor must be able to "envision the detailed constitution of a gene so as to distinguish it from other materials" and that this envisioning can only occur after isolating the gene from the human body.[67] Once isolated, the gene would satisfy the novelty requirement for a patent.[68] The court reasoned that a definition of the gene

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59. *See* Jonah D. Jackson, Note, *Something Like the Sun: Why Even "Isolated and Purified" Genes Are Still Products of Nature*, 89 TEX. L. REV. 1453, 1454 (2011).

60. U.S. Patent No. 4,363,877 (filed Apr. 19, 1978); Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 MINN. L. J. SCI. & TECH. 157, 176-77 (2010).

61. Torrance, *supra* note 60, at 177.

62. Andrew Pollack, *U.S. Says Genes Should Not Be Eligible for Patents*, N.Y. TIMES (Oct. 29, 2010), http://www.nytimes.com/2010/10/30/business/30drug.html.

63. *See Chakrabarty*, 447 U.S. at 310-18; Jackson, *supra* note 59, at 1454. A year after *Chakrabarty*, *Diamond v. Diehr* reinforced the broad view of patentable subject matter under § 101. *See* Diamond v. Diehr, 450 U.S. 175, 191-92 (1981) (holding that a mathematical formula contained within a structure or process that as a whole performs a function that is patentable does not render the patent invalid due to the exception for abstract ideas). Around the same time, the Bayh-Dole Act also facilitated the rise of gene patents by allowing universities to patent inventions derived from federally funded scientific research. *See* Olga Bograd, Note, *Patenting the Human Body: The Constitutionality of Gene Patents and Suggested Remedies for Reform*, 63 SMU L. REV. 1319, 1322-23 (2010).

64. *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991).

65. *Id.* at 1204.

66. *Id.* at 1206.

67. *Id.*

68. *See id.*

solely concerned with "its principal biological property, *e.g.,* encoding human erythropoietin," would be insufficient for the purposes of a patent.[69] A purely biological definition could also cover any material with the same biological property, such as a gene native to the human body, which is not patentable.[70]

The *Amgen* decision was crucial in explaining how isolated gene sequences fit into the scheme of patentable subject matter.[71] The distinction between a gene's chemical and biological compositions would later feature prominently in the *Myriad* case.[72]

D. The USPTO Speaks Out

Though *Amgen* explained how an isolated gene sequence was patent-eligible subject matter, questions and concerns about the validity of gene patents persisted.[73] In 2001, the USPTO issued an updated set of guidelines that addressed these questions and confirmed the validity of gene patents.[74] In countering claims against validity, the USPTO noted that "an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature."[75] The USPTO also noted that patents for compositions or compounds isolated from nature are not new.[76] In 1873, Louis Pasteur received a patent for "[y]east, free from organic germs of disease, as an article of manufacture."[77] Another example is a patent for adrenaline removed from a gland-tissue from the early twentieth century.[78] The USPTO quoted Judge Learned Hand, who noted that "even if it were merely an extracted product without change, there is no rule that such products are not patentable."[79] The USPTO guidelines affirmed the holding in *Amgen* and reinforced the validity of patents for isolated gene sequences.[80]

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69. *Id.*
70. *Id.*
71. *See id.*
72. *See infra* Part IV-V.
73. *See* USPTO Utility Examination Guidelines, 66 Fed. Reg. 1,092, 1,093 (Jan. 5, 2001).
74. *See id.* at 1,093-95.
75. *Id.* at 1,093.
76. *Id.*
77. *Id.* (alteration in original) (quoting U.S. Patent No. 141,072 (issued July 15, 1873)).
78. *See* U.S. Patent No. 730,176 (issued June 6, 1903); USPTO Utility Examination Guidelines, 66 Fed. Reg. at 1,093.
79. USPTO Utility Examination Guidelines, 66 Fed. Reg. at 1,093 (quoting Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (C.C.S.D.N.Y. 1911)).
80. *See id.* at 1,093-95. Additionally, the USPTO rejected comments arguing that it needed further congressional authorization to issue gene patents; that gene patents inhibit research; that isolated gene sequences have little utility; that patents should be limited to applications and methods of using DNA; and that patents should be limited to the uses disclosed in the applications. *See id.* The USPTO also

E. Virtual Silence from Congress

While only the USPTO has the power to administer patent laws, Congress has the ultimate authority to include or exclude isolated gene sequences from the realm of patentable subject matter.[81] In 2007, Congress attempted to specifically address the validity of gene patents with the Genomic Research and Accessibility Act (GRAA), which was sponsored by Representative Xavier Becerra.[82] The GRAA amended the Patent Act to state that "no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies."[83] Universal heritage theorists, such as Michael Crichton, adamantly supported the bill because it expressed their core belief that "genes are the product of millions of years of evolution and are thus the property of all mankind, not any one individual."[84] Representative Becerra argued that gene patents impede, rather than encourage, innovation by allowing patent holders to withhold research data from other scientists working toward the same end.[85] He also rejected the holding in *Amgen* that isolated gene sequences were novel compositions of matter and, thus, eligible subject matter for a patent.[86] Despite the deep convictions behind the GRAA, the bill surprisingly died in committee.[87]

More recently, Congress had another opportunity to address the validity of gene patents with the Leahy-Smith America Invents Act, which was designed to modernize the Patent Act.[88] As noted earlier, Congress declined to change the language of § 101 or amend any other section to expressly exclude gene patents.[89] The Act does place a limitation on § 101 by mandating that "no patent may issue on a claim directed to or encompassing a human organism."[90] This limitation appears to be a poorly drafted attempt to inject one representative's pro-life sentiments into the bill.[91] In addition, the Act echoes the concern behind the GRAA by

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emphasized that patents do not give true ownership of human genes, only the right to exclude others for a limited time. *See id.* at 1093-94.

81. *See id.* at 1095.

82. Genomic Research and Accessibility Act, H.R. 977, 110th Cong. § 2 (2007), *available at* http://www.govtrack.us/congress/bill.xpd?bill=h110-977.

83. *Id.*

84. James DeGiulio, Comment, *The Genomic Research and Accessibility Act: More Science Fiction Than Fact*, 8 NW. J. TECH. & INTELL. PROP. 292, 297 (2010).

85. *Id.* at 298.

86. *Id.*

87. *See* H.R. 977, § 2.

88. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (to be codified as amended in scattered sections of 35 U.S.C. (2011)).

89. *See id.*

90. *Id.* § 33.

91. *See Patents Directed to Human Organisms*, PATENTLY-O (Sept. 9, 2011), http://www.patentlyo.com/patent/2011/09/patents-directed-to-human-organisms.html (asking the befuddling question, "When is a patent claim 'directed . . . to a human organism?'" (alteration in original)). Despite the

requiring a study to determine "[t]he effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test."[92] This study only provides a vague hint of some future action by Congress.[93] Aside from the failed GRAA and a study required by the America Invents Act, Congress has remained silent on the patentability of isolated gene sequences.[94]

The Supreme Court's broad interpretation of § 101 in the *Chakrabarty* decision, the legal reasoning in the *Amgen* decision, the USPTO's affirmation of *Amgen*, and Congress's unwillingness to alter the language of § 101 all helped to cement the practice of granting patents for isolated gene sequences. Despite the weight of authority behind the practice,[95] challenges to these patents continued and culminated in the lawsuit against Myriad Genetics in 2009.[96]

IV. THE SOUTHERN DISTRICT OF NEW YORK SAYS NO TO GENE PATENTS

After failing to achieve results in Congress, opponents of gene patents found another avenue of attack in 2009 with *Association for Molecular Pathology v. U.S. Patent & Trademark Office*, commonly known as the *Myriad* case.[97]

A. The Facts

In 1990, Dr. Mary-Claire King, a genetic researcher at the University of California, Berkeley, published a paper announcing that a gene linked with breast cancer was located somewhere in chromosome 17.[98] In that same year, Dr. Mark Skolnick founded Myriad Genetics, which began to

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vagueness of the limitation, the USPTO issued a memo stating that this limitation simply affirms its longstanding policy that human beings are not patentable. Memorandum from Robert W. Bahr, Acting Assoc. Comm'r for Patent Exam. Policy, to Patent Examination Corps (Sept. 20, 2011), *available at* http://www.uspto.gov/aia_implementation/human-organism-memo.pdf.

92. Leahy-Smith America Invents Act § 27.

93. *See id.*

94. *See id.*; H.R. 977, 110th Cong. (2007), *available at* http://www.govtrack.us/congress/bill.xpd?bill=h110-977. Congress held the required hearings on second opinion genetic testing on February 16, 2012, and March 9, 2012, but the USPTO's report on the subject has been delayed. *See* Kevin E. Noonan, *USPTO Holds First Hearing on "Second Opinion" Genetic Testing*, PATENT DOCS (Feb. 16, 2012), http://www.patentdocs.org/2012/02/uspto-holds-hearing-on-second-opinion-genetic-testing.html; Kevin E. Noonan, *USPTO Report on Genetic Testing Delayed*, PATENT DOCS (June 18, 2012), http://www.patentdocs.org/2012/06/uspto-report-on-genetic-testing-delayed.html.

95. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 184 (S.D.N.Y. 2010), *rev'd on other grounds*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012), *remanded to* 689 F.3d 1303 (Fed. Cir. 2012).

96. USPTO Utility Examination Guidelines, 66 Fed. Reg. 1,092, 1,093 (Jan. 5, 2001).

97. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 184.

98. *Id.* at 201.

search for the exact gene sequence that correlated with breast cancer.[99] In 1994, Myriad finally discovered the gene sequence, which became known as BRCA1, and quickly patented the isolated BRCA1.[100] Myriad discovered a second gene sequence linked to breast cancer, which became known as BRCA2, and soon filed for a patent.[101] Myriad used its patented BRCA1 and BRCA2 to develop genetic testing to predict and diagnose breast cancer and offered its services to the general public.[102]

Through the University of Pennsylvania's Genetic Diagnostic Laboratory, Drs. Haig Kazazian and Arupa Ganguly offered a cheaper alternative to Myriad's testing, which was also based on BRCA1 and BRCA2.[103] After failing to reach a license agreement with the doctors in 1998, Myriad sent a cease and desist letter to Dr. Kazazian and later sued the University of Pennsylvania for patent infringement.[104] Drs. Kazazian and Ganguly, along with a host of other scientists, scientific organizations, and cancer patients unable to afford Myriad's testing, sought a declaratory judgment invalidating the patents for BRCA1 and BRCA2.[105] They argued that the patents for BRCA1 and BRCA2 were granted for natural phenomena and, thus, were not valid.[106] They shared the belief of many other scientists that the isolation-and-purification doctrine espoused in the *Amgen* decision and by the USPTO is simply a "lawyer's trick" that allows for the patenting of otherwise unpatentable subject matter.[107] The case generated considerable interest, as evidenced by the army of amici curiae who wrote briefs both for and against gene patents.[108]

B. The Holding

The *Myriad* case garnered even more attention when District Judge Sweet delivered his opinion siding with the plaintiffs and shattering the status quo of the inventing community.[109] Before reaching the substance of his opinion, Judge Sweet construed the term "isolated DNA" to mean "a

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99. *Id.*

100. *Id.* at 201-02; U.S. Patent No. 5,747,282 (filed June 7, 1995).

101. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 202; U.S. Patent No. 5,837,492 (filed Apr. 29, 1996). Utility patents, such as the BRCA1 and BRCA2 patents, last for twenty years. 35 U.S.C. § 154 (2011).

102. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 203.

103. *Id.* at 187, 204.

104. *Id.* at 205.

105. *Id.* at 184-90.

106. *Id.* at 184.

107. *See id.* at 185 (quoting John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 301, 305 (2003)).

108. *See id.* at 190-92. Notable amici include the American Medical Association, the March of Dimes Foundation, Greenpeace, and the Boston Patent Law Association. *See id.*

109. *See id.* at 232; John Schwartz & Andrew Pollack, *Judge Invalidates Human Gene Patent*, N.Y. TIMES (Mar. 29, 2010), http://www.nytimes.com/2010/03/30/business/30gene.html.

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."[110] He also remarked that even though patents issued by the USPTO have a presumption of validity, the Federal Circuit is not required to defer to the USPTO, and 40% of all patents challenged have been found invalid.[111]

In considering the patentability of the isolated gene sequences, Judge Sweet returned to the *Chakrabarty* decision and focused on the "markedly different" nature of the bacterium from other bacteria found in nature.[112] He then noted that in a past case, the mere purification of a product of nature did not result in patent-eligible subject matter.[113] He also noted that the Judge Hand opinion, relied on by Myriad and the USPTO, was a question of novelty rather than patentable subject matter and that Judge Hand's statement—that "even if it were merely an extracted product without change, there is no rule that such products are not patentable"—was only dicta.[114]

Like the purified tungsten before them, the isolated gene sequences were not markedly different from those occurring in nature and, thus, were unpatentable according to Judge Sweet.[115] DNA is unique and unlike other chemical compounds in that it carries coded information and should not be characterized as any other chemical compound.[116] When examining DNA as the "physical embodiment of information," no difference exists between the isolated BRCA1 and BRCA2 and the native BRCA1 and BRCA2.[117] Judge Sweet rejected Myriad's view that any identifiable difference from the natural gene sequences would be sufficient, reasoning that under this view, no invention could fail the test.[118] The claimed invention must be considered as a whole rather than simply examining the differences.[119]

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110. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 217. Patent claim construction is a question of law for the judge to decide. *See* Markman v. Westview Instruments, Inc., 517 U.S. 370, 378-91 (1996) (using the history of patent cases, the greater expertise of judges over jurors, and a concern for uniformity to reach its conclusion).

111. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 220-21.

112. *Id.* at 223 (citing Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980)).

113. *Id.* at 224 (citing Gen. Elec. Co. v. De Forest Radio Co., 28 F.2d 641, 642-43 (3d Cir. 1928) (holding that a purified form of tungsten was not patentable because the supposed inventor did not create or give the claimed qualities to the purified tungsten)).

114. *Id.* at 225 (quoting Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 101, 103 (C.C.S.D.N.Y. 1911) (holding a patent for isolated adrenaline valid)); *accord* Jon M. Harkness, *Dicta on Adrenalin(e): Myriad Problems with Judge Learned Hand's Product-of-Nature Pronouncements in* Parke-Davis v. Mulford, 93 J. PAT. & TRADEMARK OFF. SOC'Y 363, 368 (2012).

115. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 232.

116. *Id.* at 228.

117. *Id.* at 229.

118. *Id.*

119. *Id.*

When viewed as a whole, the isolated gene sequences were not sufficiently different to put them within the confines of patentable subject matter.[120]

V. THE FEDERAL CIRCUIT REVERSES

After the shocking decision of the district court, Myriad appealed to the Federal Circuit, and the panel rejected the district court's reasoning and held two-to-one that isolated gene sequences are patent-eligible subject matter.[121]

A. The Holding

Judge Lourie's opinion took the exact opposite approach from the one employed by Judge Sweet; Judge Lourie focused on the "distinctive chemical identity" of isolated gene sequences.[122] He noted that genes are best described "by their structures rather than their functions."[123] From this perspective, isolated gene sequences are markedly different from native gene sequences because of the differences in their chemical structures.[124] This chemical difference results when native gene sequences are "chemically cleaved from their combination with other genetic materials" found in the body during the process of isolation.[125] This process breaks covalent bonds, which are the "defining boundary between one molecule and another" and "separate one chemical species from another."[126] Judge Lourie also noted that an isolated gene sequence is not simply a purified form of native gene sequences.[127] The isolation of a particular gene sequence is an "act of human invention" that renders the isolated gene sequence patentable subject matter.[128]

Judge Lourie also rejected the government's "magic microscope" test.[129] The test focused in on the BRCA1 and BRCA2 sequences as they are found in the human body and compared them to the isolated BRCA1 and BRCA2 sequences.[130] If the natural BRCA1 and BRCA2 were exactly the same as the isolated BRCA1 and BRCA2, then the isolated gene sequences were not patentable.[131] He noted that "[t]he ability to visualize a

120. *Id.* at 232.

121. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1333, 1350 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012), *remanded to* 689 F.3d 1303 (Fed. Cir. 2012).

122. *See id.* at 1351-53.

123. *Id.* at 1353.

124. *Id.*

125. *Id.* at 1352.

126. *Id.* at 1352-53.

127. *Id.* at 1352.

128. *Id.* at 1353-54.

129. *Id.* at 1350, 1353.

130. *Id.* at 1350.

131. *Id.*

DNA molecule through a microscope, . . . when it is bonded to other genetic material, is worlds apart from possessing an isolated DNA molecule that is in hand and usable."[132] This test could prevent a patent for any claimed portion of a complex molecule, even if that portion could never exist on its own in nature.[133] Such a test would stifle innovation.[134]

Finally, Judge Lourie highlighted the thirty-year practice of the USPTO in granting patents for isolated gene sequences.[135] Congress has never assailed this practice, and any change to patentable subject matter that would disrupt the expectations of the inventing community should come from Congress rather than the courts.[136]

B. Judge Moore's Concurring Opinion

Like Judge Lourie, Judge Moore acknowledged that the chemical differences between a gene sequence found in human chromosomes and the same isolated gene sequence prevent the isolated gene sequence from falling into the unpatentable natural phenomena category.[137] She also derided the magic microscope test for its "child-like simplicity."[138] She differed from Judge Lourie in her unwillingness to declare that the chemical differences render isolated gene sequences patentable subject matter per se.[139]

Instead of relying solely on the chemical differences, Judge Moore examined the utility of the isolated gene sequences and how they serve a different function from those same gene sequences in the body.[140] The shorter isolated gene sequences are used for diagnostic testing, which is not a function that the body can perform using native genes.[141] Longer isolated gene sequences that contain most or all of an entire gene cannot be used for genetic testing and have more limited utility.[142] As a result, their patent eligibility is more questionable.[143] When viewed on "a blank canvas," these longer isolated gene sequences might not qualify as patentable subject matter.[144] But when "both settled expectations and extensive property rights are involved," the court should be wary in creating any more

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132. *Id.* at 1353.
133. *Id.*
134. *See id.*
135. *See id.* at 1354-55.
136. *See id.* at 1355.
137. *See id.* at 1364-65 (Moore, J., concurring).
138. *Id.* at 1368.
139. *Id.* at 1364-65.
140. *See id.* at 1365-67.
141. *Id.* at 1365.
142. *Id.* at 1366.
143. *See id.*
144. *See id.*

exceptions to patentable subject matter.[145] For Judge Moore, the policy concerns "tip[ped] the scale in favor of patentability."[146]

C. Judge Bryson's Dissenting Opinion

Judge Bryson employed a wide array of analogies to explain why Judge Lourie and Judge Moore were wrong and why isolated gene sequences should not be patentable subject matter.[147]

First, Judge Bryson likened isolated gene sequences to minerals extracted from the earth.[148] Minerals, like isolated gene sequences, can be used for many more purposes than they could if they were not removed from their natural setting.[149] Minerals also change physically and chemically when removed from nature just as gene sequences do when isolated from the human body.[150] Yet minerals cannot be patented and isolated gene sequences can.[151]

Next, Judge Bryson compared isolated gene sequences to the element lithium.[152] In nature, lithium does not exist alone; it is a part of a chemical compound.[153] Lithium can be isolated by breaking the ionic bonds that connect it to the chemical compound.[154] The isolated lithium then has many industrial uses, but unlike isolated gene sequences, it cannot be patented.[155]

Another analogy imagined a leaf on a tree.[156] Eventually the leaf will fall off the tree, but at all times, it is a product of nature.[157] The premature plucking of the leaf from the tree by a human being does not change the fact that it is a product of nature.[158] The minor differences between the plucked leaf and the fallen leaf are not enough to make the plucked leaf a patentable human invention.[159]

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145. *Id.* at 1367.
146. *Id.*
147. *See id.* at 1375-77 (Bryson, J., dissenting).
148. *Id.* at 1375.
149. *Id.*
150. *Id.*
151. *See id.*
152. *Id.* at 1376.
153. *Id.*
154. *Id.*
155. *See id.*
156. *Id.* at 1377.
157. *Id.*
158. *See id.*
159. *See id.* In its amicus brief, the Department of Justice cited a similar example from *Ex parte Latimer*, in which a patent for a fiber taken from a pine needle was rejected for being a product of nature. Brief for the United States as Amici Curiae in Support of Neither Party at 25, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2012 WL 2884115 (citing *Ex parte* Latimer, 46 O.G. 1638, 1889 Dec. Comm'r Patent 123 (1889)).

Lastly, Judge Bryson contrasted the making of a baseball bat to the isolation of a gene sequence.[160] The wood used to make a baseball bat is extracted from a tree, and it is transformed into something with an entirely different form and function from the tree.[161] As a result, it is a patentable human invention.[162] On the contrary, a gene sequence is extracted "along lines defined by nature so as to preserve the structure and function that the gene possessed in its natural environment."[163] The gene sequence's ability to produce proteins remains intact.[164] Its isolation does not create a human invention.[165] This is akin to chopping out a section of a tree but not changing its nature, form, and use by turning it into a baseball bat.[166]

In addition to these analogies, Judge Bryson downplayed the importance of the USPTO's proclamations regarding gene patents.[167] He noted that the USPTO lacks "substantive rulemaking authority" and that the court should only defer to it to the extent its reasoning is valid.[168] He also noted that the USPTO's position was substantially undermined by the Department of Justice, which filed a brief arguing against the validity of Myriad's patents.[169] Finally, Judge Bryson turned to the *Chakrabarty* decision to point out that before its holding, microorganisms were patentable despite the fact that the USPTO had determined that microorganisms were not patent-eligible subject matter.[170] The Supreme Court gave no deference to the USPTO in its landmark decision.[171] Likewise, the Federal Circuit should not have to defer to the USPTO in this case.[172]

Although the Federal Circuit upheld the validity of gene patents, its panel was far from unanimous. Judge Moore was not entirely comfortable with Judge Lourie's focus on the chemical aspect of isolated gene sequences and was more persuaded by policy arguments.[173] Judge Bryson utilized some powerful analogies to explain why gene sequences are unpatentable and trivialized the significance of the USPTO's policy on the subject.[174]

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160. *See Ass'n for Molecular Pathology*, 653 F.3d at 1377 (Bryson, J., dissenting).
161. *Id.*
162. *Id.*
163. *Id.*
164. *Id.*
165. *Id.*
166. *See id.*
167. *See id.* at 1380.
168. *Id.*
169. *See id.*
170. *Id.* at 1381.
171. *See id.*
172. *Id.* at 1380.
173. *See id.*at 1365-67 (Moore, J., concurring).
174. *See id.* at 1375-81 (Bryson, J., dissenting).

On remand, the reasoning of *Prometheus* failed to change the minds of the judges on the Federal Circuit.[175] Judge Lourie noted that "the compositions here are not natural products" but rather "products of man, albeit following, as all materials do, laws of nature."[176] Judge Moore restated that she could not decide the case on a blank canvas and refused to "strip an entire industry of the property rights it has invested in, earned, and owned for decades unchallenged."[177] Judge Bryson maintained that isolation of the gene sequence and the chemical change it undergoes in the process are not inventive contributions that render the gene sequence patentable.[178] Now, the case awaits a definitive answer from the Supreme Court.

VI. HOW WILL THE SUPREME COURT DECIDE?

In Judge Moore's concurring opinion, she stated that she could not decide the case in a vacuum; policy concerns ultimately persuaded her to uphold the validity of the patents.[179] The first part of this section will examine themes gleaned from several recent Supreme Court decisions and how they will affect the Court's decision in *Myriad*. Then, the second part will consider weighty policy concerns that the *Myriad* case will present to the Court. The final part will examine *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, which prompted the Court to send the *Myriad* case back to the Federal Circuit for reconsideration.

A. Recent Supreme Court Decisions

Several Supreme Court cases from the last decade are illustrative of how the nine Justices will decide the fate of gene patents.[180] Several themes have emerged from these cases.

175. *See, e.g.*, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1325 (Fed. Cir. 2012) ("*Mayo* does not control the patent-eligibility of such claims.").

176. *Id.* at 1331.

177. *Id.* at 1343, 1348 (Moore, J., concurring).

178. *Id.* at 1354-55 (Bryson, J., dissenting).

179. *See Ass'n for Molecular Pathology*, 653 F.3d at 1366-67 (Moore, J., concurring).

180. *See* Wal-Mart Stores, Inc. v. Dukes, 131 S. Ct. 2541, 2552-57 (2011); Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2251-52 (2011); Bilski v. Kappos, 130 S. Ct. 3218, 3225-29 (2010); Citizens United v. Fed. Election Comm'n, 130 S. Ct. 876, 913 (2010); Ledbetter v. Goodyear Tire & Rubber Co., 550 U.S. 618, 642-43 (2007); Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 125 (2006); Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 737 (2002); J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 127 (2001).

1. The Court Prefers a Flexible Approach to Patent Cases

One case that exemplifies the Court's flexible approach in patent cases is *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*[181] *Festo* concerned the doctrine of equivalents and prosecution history estoppel.[182] While these concepts are not at issue in *Myriad*, the Court's handling of the case is instructive.[183] The Court held that prosecution history estoppel is a flexible bar to patentability, rather than a complete bar.[184] In doing so, the Court rejected the Federal Circuit's bright-line rule for the more balanced approach of the USPTO.[185] *Festo* was a unanimous opinion, and it indicates that the Court likely would disfavor a per se rule banning all isolated gene sequences from the scope of patentable subject matter and prefer a more nuanced solution provided by Congress.[186]

Another more recent example of the Court's preference for flexibility in patent cases is *Bilski v. Kappos*.[187] *Bilski* concerned a patent for a process of hedging risk against price fluctuations.[188] While the Court agreed with the Federal Circuit that the process was not patent-eligible subject matter, it rejected the Federal Circuit's reasoning in arriving at this conclusion.[189] Though they disagreed on other issues in the case, all of the Justices agreed that the machine-or-transformation test should not be the exclusive test, indicating, as they did in *Festo*, that the Court should use a flexible approach in patent cases.[190] These cases suggest that the Court likely will not adopt a bright-line rule to assess the patentability of isolated gene sequences.

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181. *See Festo*, 535 U.S. at 737-38.

182. *Id.* at 726. The doctrine of equivalents extends patent protection against other inventions that, although they do not literally copy the patented claims, perform "substantially the same function in substantially the same way to obtain the same result." Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950) (quoting Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42 (1929)). When an inventor must narrow the claims in his patent application, the rule of prosecution history estoppel may prevent the inventor from later claiming the removed elements using the doctrine of equivalents. *See Festo*, 535 U.S. at 739-40 (2002).

183. *See Festo*, 535 U.S. at 737-42.

184. *Id.* at 737-38.

185. *See id.* at 739 (citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 32 (1997)).

186. *See id.*; *see also* Eldred v. Ashcroft, 537 U.S. 186, 212 (2003) (noting that "it is generally for Congress, not the courts, to decide how best to pursue the [Intellectual Property] Clause's objectives" (citing Stewart v. Abend, 495 U.S. 207, 230 (1990))).

187. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3225-29 (2010).

188. *Id.* at 3223-24.

189. *See id.* at 3225-29, 3231.

190. *See id.* at 3231-32 (Stevens, J., concurring); *Festo*, 535 U.S. at 737.

2. The Court Is Reluctant to Create New Exceptions to § 101

J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc. is a recent example of the Court's unwillingness to create new, categorical exceptions to § 101.[191] In an opinion written by Justice Thomas, the Court upheld the validity of these patents and reiterated its statement in *Chakrabarty* that the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970 do not remove plants from the realm of patentable subject matter.[192] The Court "decline[d] to narrow the reach of § 101 where Congress has given us no indication that it intends this result."[193] Of the Justices who currently sit on the Court, Justices Scalia, Kennedy, and Ginsburg joined the opinion, and Justice Breyer was the lone dissenter.[194] This case suggests that the Court would adhere to an expansive reading of § 101 and decline to categorically exclude isolated gene sequences from the realm of patentable subject matter.

In a similar way, the Court in *Bilski* refused to categorically exclude business method patents from the scope of § 101.[195] Instead, the Court held that the process fit into the category of abstract ideas, one of the judicial exceptions to patentable subject matter established long ago in *Gottschalk v. Benson*.[196] Justice Kennedy wrote the opinion, and Justices Roberts, Thomas, Alito, and Scalia joined it.[197] Justices Breyer, Ginsburg, and Sotomayor joined Justice Stevens's concurring opinion, which used a combination of textual, historical, constitutional, and policy analyses to conclude that business method patents are excluded from patentable subject matter.[198]

Bilski suggests that Justices Kennedy, Roberts, Thomas, Alito, and Scalia are very reluctant to create new categories of unpatentable subject matter and would probably reject an argument to establish a new exception for gene patents.[199] Justices Ginsburg, Sotomayor, and Breyer, on the other hand, might be more willing to create a categorical exception for gene

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191. *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 145-46 (2001).

192. *Id.* at 129, 131-44 (discussing Diamond v. Chakrabarty, 447 U.S. 303, 311-14 (1980)).

193. *J.E.M. Ag Supply*, 534 U.S. at 145-46.

194. *Id.* at 126. Justice Scalia also wrote a concurring opinion, noting that repeals by implication are disfavored and that *Chakrabarty* had already resolved any ambiguity in the language of the Plant Patent Act. *See id.* at 146-47 (Scalia, J., concurring). In his dissent, Justice Breyer argued that the legislative history of the Plant Patent Act and the Plant Variety Protection Act showed that Congress intended plants to be outside of the scope of § 101. *See id.* at 147-56 (Breyer, J., dissenting).

195. *See Bilski*, 130 S. Ct. at 3225-29. The machine-or-transformation test states that a process is patent-eligible if either of the following applies: "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." *In re* Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008). The Court criticized the Federal Circuit's approach as both "broad and atextual." *Bilski*, 130 S. Ct. at 3229.

196. *See Bilski*, 130 S. Ct. at 3225-29; Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

197. *Bilski*, 130 S. Ct. at 3223.

198. *See id.* at 3231-57 (Stevens, J., concurring).

199. *See id.* at 3225-29.

patents if it can be justified using the text of the Patent Act, the history of patent law, the Intellectual Property Clause of the Constitution, and policy considerations.[200]

3. The Court Often Defers to Those with More Patent Expertise

In both *J.E.M. Ag Supply* and *Festo*, the Court emphasized that its decision coincided with the practices of the USPTO and Congress's acquiescence in those practices.[201] In *J.E.M. Ag Supply*, the Court acknowledged the particular expertise of the USPTO in patent issues and its unbroken practice of granting plant patents for the past sixteen years, which remained uncontested by Congress or the Department of Agriculture.[202] Likewise, *Festo* criticized the Federal Circuit's interpretation of prosecution history estoppel as contrary to the holding in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.* and also the practice of the USPTO.[203] The Court stated that any fundamental changes to settled patent law should emanate from Congress rather than the courts.[204]

A more recent example of this type of deference in patent cases is *Microsoft Corp. v. i4i Ltd. Partnership*.[205] The case involved the interpretation of § 282 of the Patent Act, which establishes a presumption of validity for patents.[206] In her opinion, Justice Sotomayor upheld the clear and convincing evidence standard for proving a patent invalid by examining the history of patent cases.[207] In particular, she pointed to the Federal Circuit's consistent interpretation of § 282 over the past thirty years and Congress's silence in the face of this interpretation.[208] Justices Scalia, Kennedy, Ginsburg, Breyer, Alito, and Kagan all joined the opinion, and Chief Justice Roberts was not a part of the decision.[209]

The *Microsoft* decision echoed the Federal Circuit's deference to Congress and reluctance to depart from longstanding practices in the

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200. *See id.* at 3231-57 (Stevens, J., concurring).

201. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 739 (2002); J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 144-45 (2001).

202. *See J.E.M. Ag Supply*, 534 U.S. at 144-45.

203. *See Festo*, 535 U.S. at 739 (citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 32 (1997)).

204. *See id.* at 739. It is important to note that Justice Kennedy, the crucial swing vote in contentious cases, penned this opinion. *Id.* at 726; *see* Jeffrey Toobin, *Power in the Court*, NEW YORKER (Nov. 15, 2011), http://www.newyorker.com/online/blogs/comment/2011/11/power-in-the-court.html.

205. *See* Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2252 (2011).

206. *See id.* at 2242.

207. *Id.* at 2245-51.

208. *See id.* at 2252.

209. *Id.* at 2241. Additionally, Justice Breyer wrote a concurring opinion, noting that the clear and convincing evidence standard only applied to questions of fact. *See id.* at 2253 (Breyer, J., concurring). Justice Thomas also concurred, stating that Congress never codified the clear and convincing evidence standard in § 282 but that it should prevail because it is the common law rule. *See id.* at 2253-54 (Thomas, J., concurring).

Myriad case.[210] The unwillingness of the Court to change the accepted meaning of § 282 without guidance from Congress suggests that it, likewise, will be hesitant to modify the meaning of § 101 to specifically exclude gene patents.[211] This case expressed the view that the more prudent course is to allow Congress to debate the merits of significant changes to the Patent Act rather than allow abrupt and ill-informed changes by the courts.[212]

4. The Court Is Sensitive to Its Effect on Commerce

Like the Federal Circuit, the Supreme Court has recognized the potential adverse effects on commerce that its decisions in patent cases may cause, and as a result, it is cautious in making fundamental alterations to settled patent law. In *Festo*, the Court claimed that the Federal Circuit ignored its holding in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, which warned against "adopting changes that disrupt the settled expectations of the inventing community."[213]

A number of recent cases unrelated to patents have led some observers to question whether the Supreme Court disproportionately favors businesses over individuals.[214] Commentators highlight the appointments of Justice Roberts and Justice Alito as the starting point of the Court's more business-friendly demeanor.[215] A study conducted by Lee Epstein, William Landes, and Richard Posner noted a statistically significant difference between the Rehnquist Court and the Roberts Court in the percentage of cases each

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210. *See id.* at 2252; Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1355 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012), *remanded to* 689 F.3d 1303 (Fed. Cir. 2012).

211. *See Microsoft*, 131 S. Ct. at 2252.

212. *See id.* This case is part of a larger trend of courts to view themselves as "legally and practically incompetent to process arguments based on the practical benefits or costs expected to result from patenting a particular type of subject matter." John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1085 (2011). This trend has led one scholar to advocate for giving the USPTO the authority to develop legal doctrine on subject matter eligibility. *See id.* at 1075-1111 (explaining why the USPTO has greater competence on subject matter eligibility than Congress or the courts).

213. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 739 (2002) (citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 28 (1997)).

214. *See, e.g.*, Wal-Mart Stores, Inc. v. Dukes, 131 S. Ct. 2541, 2552-57 (2011) (declining to certify a class of 1.5 million female employees alleging employment discrimination); Citizens United v. Fed. Election Comm'n, 130 S. Ct. 876, 913 (2010) (holding that political speech cannot be suppressed based on the corporate identity of the speaker); Ledbetter v. Goodyear Tire & Rubber Co., 550 U.S. 618, 642-43 (2007) (refusing to deviate from the time period allowed for an employee to file an unlawful employment practice); *Corporations and the Court*, ECONOMIST (June 23, 2011), http://www.economist.com/node/18866873 [hereinafter *Corporations and the Court*].

215. *See Corporations and the Court*, *supra* note 214 (noting that between 1994 and 2005, 56% of the parties supported by the U.S. Chamber of Commerce prevailed and that this figure rose to 68% between 2006 and 2010).

decided in favor of business interests.[216] These statistics indicate that the Court might favor the interests of genetic research corporations like Myriad by upholding the validity of gene patents.

Others argue that a closer look reveals that these numbers do not evidence a pro-business tilt.[217] One commentator noted that in the 2007 term, parties supported by the U.S. Chamber of Commerce lost five out of seven labor and employment cases and that the Court has decided 79% of the cases involving the Chamber by lopsided margins that do not conform to the ideological divisions among the Justices.[218] An alternative explanation to a seemingly pro-business bias is that the Court shares the business community's desire for legal uniformity and predictable legal rules.[219] Chief Judge Rader of the Federal Circuit has expressed a similar concern in his views about the rising challenges to patentable subject matter and the uncertainty they may create.[220] The Court also expressed this desire for uniformity and predictability in the *Microsoft* case.[221] While the existence of a pro-business bias in the Court is questionable, recent cases do evidence a reluctance to create uncertainty in the business world, which could be the result of adding more categorical exceptions to § 101.[222]

But what do all of these cases suggest about how the Court would handle the *Myriad* case? The Court has two camps with differing ideas on subject matter eligibility. Justices Kennedy, Roberts, Alito, Thomas, and Scalia are unlikely to deviate from the three core judicial exceptions to patentable subject matter and would probably only invalidate Myriad's patents if they could fit them into the natural phenomena exception.[223] The other camp consists of Justices Ginsburg, Sotomayor, and Breyer, who are more willing to establish new exceptions using textual, historical, and constitutional support, as well as policy considerations, and they might be more amenable to removing isolated gene sequences from the realm of patentable subject matter.[224]

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216. LEE EPSTEIN, WILLIAM M. LANDES & RICHARD A. POSNER, IS THE ROBERTS COURT PRO-BUSINESS? 13-14 (2010), *available at* http://epstein.usc.edu/research/RobertsBusiness.pdf (finding that among cases categorized as "Economic Activity Plus," the Rehnquist Court ruled in favor of business interests in 46% of these cases in its last five years while the Roberts Court did so in 61% of these cases in its first five years).

217. *See, e.g.*, Robin S. Conrad, *The Roberts Court and the Myth of a Pro-Business Bias*, 49 SANTA CLARA L. REV. 997, 1000-15 (2009).

218. *Id.* at 1005, 1009.

219. *See id.* at 1011-14.

220. *See* Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1075 (Fed. Cir. 2011) (additional views of Chief Judge Rader).

221. *See* Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2250 (2011) (rejecting the notion that Congress would "take the unusual and impractical step of enacting a variable standard of proof that must itself be adjudicated in each case").

222. *See, e.g.*, *id.* at 2550-51.

223. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3225-29 (2010); J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 129, 131-44 (2001).

224. *See Bilski*, 130 S. Ct. at 3231-57 (Stevens, J., concurring).

Of this group, Justice Breyer seems the most likely to invalidate gene patents.[225] His dissent in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.* also reflected this propensity.[226] The petitioner in that case challenged the validity of patents covering a process for diagnosing vitamin deficiencies, arguing that the patent impermissibly sought to claim a "basic scientific relationship."[227] The Court dismissed the writ as improvidently granted.[228] Justice Breyer found no reason to refuse to decide the case and argued that the patent merely covered a correlation between homocysteine and vitamin deficiency, which is a natural relationship that is not patentable.[229] Additionally, he noted that "[p]atent law seeks to avoid the dangers of overprotection" and that patents "can discourage research by impeding the free [flow] of information," which ultimately stifles the purpose of the Intellectual Property Clause.[230]

Justice Kagan's position remains relatively unknown, having only joined the majority opinion in *Microsoft* and the unanimous opinion in *Prometheus*, but her first year on the Court indicated that she is ideologically similar to her predecessor, Justice Stevens.[231] Assuming Justice Kagan joins Justices Ginsburg, Sotomayor, and Breyer, the question for the other five Justices becomes the following: Do isolated gene sequences fall into the natural phenomena exception?

Though the Court has insisted on not deviating from the three judicial exceptions, it has provided little clarity in defining what exactly each exception encompasses.[232] Although *Chakrabarty* established that the invention must be markedly different from natural phenomena, the exact degree of difference required remains ambiguous.[233] This ambiguity reflects the Court's preference for a flexible approach in patent cases, as displayed in *Festo*.[234] In light of this preference and the Court's disdain for per se rules in the patent arena, the Court is unlikely to lay down a definite

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225. *See J.E.M. Ag Supply*, 534 U.S. at 147-56 (Breyer, J., dissenting).

226. *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 127 (2006) (Breyer, J., dissenting).

227. *Id.* at 125.

228. *Id.* at 125-26.

229. *See id.* at 133, 135.

230. *Id.* at 126-27; *see* U.S. CONST. art. I, § 8, cl. 8.

231. *See, e.g.*, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1292 (2012); Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2241 (2011); Robert Barnes, *Verdict on Kagan's First Year on Supreme Court*, WASH. POST (Sept. 25, 2011), http://www.washingtonpost.com/politics/verdict-on-kagans-first-year-on-supreme-court/2011/09/21/gIQAnJ14wK_story.html (noting that retired Justice Stevens could only think of a few cases where Justice Kagan voted differently than he would have).

232. *See* Golden, *supra* note 212, at 1077-83 (lamenting the Court's lack of coherence on subject matter eligibility and noting the Federal Circuit's attempts to bring clarity by creating bright-line rules).

233. *See* Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980); Golden, *supra* note 212, at 1079.

234. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 737 (2002).

rule regarding what exactly fits the natural phenomena exception.[235] In this situation, subject matter eligibility largely becomes a game of semantics.[236] Even if one finds the chemical differences between isolated gene sequences and native gene sequences insufficient, one could still argue that isolated gene sequences do not exist in nature and exist at all only because of human ingenuity.[237] The absence of a definite rule and an inclination toward an expansive view of patentable subject matter suggest that the five Justices may turn to policy arguments to help in answering the question, just as Judge Moore did.[238]

B. Policy Arguments

The policy arguments for and against gene patents present a wide array of interests from the business, legal, and medical communities.[239] Opponents use practical, philosophical, ethical, and even religious arguments to explain why gene patents should no longer be granted. Proponents focus on economics and innovation in justifying the continued existence of gene patents.

1. Opponents of Gene Patents

One of the practical concerns of opponents is the gene patent's deleterious effect on scientific research.[240] In his opinion, Judge Sweet noted that gene patents can create a situation similar to "the tragedy of the anti-commons," in which a resource is underused because too many have

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235. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3225-29 (2010). The Court expressly refused to take a position on the appropriate balance between protecting inventors and ensuring the progress of science and the useful arts. *See id.* at 3228.

236. *See* Allen K. Yu, *Within Subject Matter Eligibility—A Disease and a Cure*, 84 S. CAL. L. REV. 387, 417-18 (2011). The majority and dissent in the Federal Circuit's *Myriad* decision engaged in this same kind of semantic debate over whether the chemical or informational quality of the DNA molecule should matter. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1351-53 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012), *remanded to* 689 F.3d 1303 (Fed. Cir. 2012).

237. *See* Yu, *supra* note 236, at 418.

238. *See Ass'n for Molecular Pathology*, 653 F.3d at 1366-67 (Moore, J., concurring).

239. *See, e.g.*, Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1073-75 (Fed. Cir. 2011) (additional views of Chief Judge Rader); Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 208-11 (S.D.N.Y. 2010); David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1681 (2007); Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 624 (1998); Pilar N. Ossorio, *The Human Genome as Common Heritage: Common Sense or Legal Nonsense?* 35 J.L. MED. & ETHICS 425, 425 (2007); Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 19, 30 (2011); Timothy M. Todd, Note, *Patenting the Fingerprint of God: How Gene Patents Violate the Products of Nature Doctrine*, 5 LIBERTY U. L. REV. 77, 106-09 (2010).

240. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 208.

the right to exclude others from that resource.[241] Studies show that gene patents have decreased public knowledge of the BRCA1 and BRCA2.[242] Among laboratory directors across the country, nearly half of them believed that gene patents had delayed or limited their research.[243] Another study shows that over half of the laboratory directors decided against developing new clinical tests because of gene patents and that among them, the largest number had stopped using tests involving BRCA1 and BRCA2.[244] In the end, the right to exclude granted by a patent may prevent people like Ms. Fortune from getting the testing required to combat breast cancer and other diseases.[245]

This limited access to, and sometimes outright unavailability of, treatment caused by gene patents has raised ethical concerns for some in the medical profession, including the American Medical Association (AMA).[246] Under the AMA Code of Medical Ethics, one of the ethical duties of physicians is "to contribute to the total store of scientific knowledge" and to "make their achievements known through publication or other means of disseminating such information."[247] The Code condemns the use of patents to "limit the availability of medical procedures," which results in "significant limitation on the dissemination of medical knowledge."[248] Patients are best served when BRCA1 and BRCA2 testing is available from multiple providers using different methodologies, rather than from a single provider such as Myriad.[249] The availability of testing from multiple providers ensures that the patient will receive accurate results that will allow for proper treatment.[250]

Dissemination of knowledge is also important to those who view human genes as part of mankind's common heritage.[251] Followers of the Common Heritage Property Doctrine (CHPD) share four core principles:

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241. *Id.* (citing Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998)); *see* Heller, *supra* note 239, at 679 n.259. A real-world example of the tragedy of the anticommons is the many empty storefronts in Moscow shortly after the end of the Soviet Union in the early 1990s. *See id.* at 633-35. Because title to the stores was either not clearly defined or remained in the hands of inactive state entities, merchants sold their wares in kiosks on the street while the stores remained empty and useless. *See id.*

242. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 208.

243. *Id.*

244. *Id.* at 208-09. *But see* Adelman & DeAngelis, *supra* note 239, at 1684-94 (challenging the application of the anticommons theory to biotechnology patents and failing to find a loss of innovation).

245. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 188-89.

246. *See id.* at 209.

247. COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, AM. MED. ASS'N, CODE OF MEDICAL ETHICS: OPINION 9.095 (2007), *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/9095b.pdf.

248. *Id.*

249. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 210.

250. *See id.*

251. Ossorio, *supra* note 239, at 427.

> (1) no single entity can have sovereignty over, or unilaterally appropriate, the resource or territory in question; (2) all countries will share in a management authority of some sort, which will manage the resource or territory for the "benefit of all humanity"; (3) benefits from the exploitation of the territory or resource will be actively shared among nations; and (4) the area will be used only for peaceful purposes.[252]

International agreements involving land use in Antarctica and resources in outer space have manifested these beliefs, and believers seek to treat the human genome as property owned by all humans.[253] While CHPD would not ban all commercial exploitation of human genes, it would take measures to ensure that the economically disadvantaged could enjoy the fruits of genetic research, such as BRCA1 and BRCA2 testing.[254]

In addition to the common heritage philosophy, some religious groups are opposed to gene patents.[255] They believe that the human body is a "special divine work" and that gene patents impermissibly allow "transferring ownership of the creation from the Creator (God) to the creation (man)."[256] This transfer of ownership permits the "commodification" of the human body, which denigrates the body's divine character.[257]

2. Proponents of Gene Patents

On the other side of the debate, Myriad rebutted the charge that its patents on BRCA1 and BRCA2 stifled research and development by pointing to its contributions to the scientific community.[258] Myriad claimed that it had made over 20,000 submissions to the Breast Cancer Information Core, an open database available to scientists worldwide, and that it is the largest contributor to this database.[259] It also noted that data about BRCA1

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252. *Id.* Dr. James D. Watson, one of the scientists who discovered DNA's double-helix structure, has expressed similar views about gene patents. *See* Torie Bosch, *DNA Structure Co-Discoverer James Watson Weighs In on Ongoing Gene Patent Case*, SLATE (July 19, 2012, 5:48 PM), http://www.slate.com/blogs/future_tense/2012/07/19/james_d_watson_files_amicus_brief_in_case_over_myriad_genetics_brca_patent_.html.

253. Ossorio, *supra* note 239, at 427, 429. In its utility guidelines, the USPTO explicitly rejected the application of this philosophy to gene patents. *See* USPTO Utility Examination Guidelines, 66 Fed. Reg. 1,092, 1,093-94 (Jan. 5, 2001).

254. *See* Ossorio, *supra* note 239, at 429.

255. *See, e.g.*, Todd, *supra* note 239, at 106-07.

256. *Id.*

257. *See id.*

258. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 210 (S.D.N.Y. 2010), *rev'd on other grounds*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012), *remanded to* 689 F.3d 1303 (Fed. Cir. 2012).

259. *Id.* at 209, 211. Recently, however, Myriad has stopped contributing to this database. *See* Andrew Pollack, *Despite Gene Patent Victories, 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.

and BRCA2 is available on the company's website, where it can be accessed by all.[260] Finally, Myriad highlighted the fact that the primary purpose of obtaining a patent is to disclose new discoveries so that others may improve upon them.[261]

In addition to its contributions, Myriad and other proponents of gene patents argue that the financial incentive provided by patents is necessary to spur new research.[262] Although the federal government does provide some funding for genetic research, the majority of the funding comes from private investors.[263] Without the exclusive rights provided by patents, these investors would be unwilling to provide the capital necessary to fund companies like Myriad, and the useful products and services they create would never exist.[264]

A related concern with the invalidation of gene patents is the resulting loss of innovation in the United States.[265] Chief Judge Rader of the Federal Circuit acknowledged that the increasing number of challenges to patents under § 101 threatens to frustrate patent protection and push investors to find other countries that do not create obstacles to patents.[266] Judge Rader used Europe as an example of a region that has suffered a loss of innovation by placing impediments to obtaining patents.[267] These impediments included delays by the patent office, challenges to patent eligibility, increases in cost to obtain a patent, and legal uncertainties about patents.[268] Many investors left Europe and invested in companies in the United States, which offered greater patent protection.[269] As a result, the United States became a world leader in biotechnology innovation.[270] Judge Rader warned that the United States could suffer the same fate as Europe if it were to adopt harsher eligibility restrictions.[271]

Another policy argument in favor of gene patents is a desire to preserve the status quo among genetic researchers.[272] Some argue that if the Court invalidated gene patents, it would disrupt the settled expectations of the inventing community, which has relied on the USPTO's thirty-year

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260. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 211.
261. *Id.* at 210.
262. *See id.* at 191, 211.
263. *See id.* at 211.
264. *Id.*
265. *See* Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1073-75 (Fed. Cir. 2011) (additional views of Chief Judge Rader).
266. *Id.*
267. *Id.* at 1075.
268. *See id.*
269. *Id.*
270. *See id.*
271. *Id.*
272. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1355, 1367 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012), *remanded to* 689 F.3d 1303 (Fed. Cir. 2012).

practice of granting these patents, and would result in too much chaos.[273] Justice Oliver Wendell Holmes famously remarked that "[i]t is revolting to have no better reason for a rule of law than that so it was laid down in the time of Henry IV," but the Supreme Court has stated that an unbroken practice of many years is not to be set aside lightly.[274] Thirty years is a relatively short period, but in this time, the USPTO has granted patents for over four thousand genes, which comprise approximately twenty percent of the human genome.[275] While this argument alone is insufficient, its combination with other arguments may "tip the scale in favor of patentability," as it did for Judge Moore.[276]

The proponents' emphasis on economics, innovation, and the status quo stands in stark contrast with the opponents' utilitarian, ethical, philosophical, and religious reasons for invalidating gene patents. But which of these policy arguments will the Court find most persuasive? Before answering this question, it is important to examine the case that led the Court to remand the *Myriad* case, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[277]

C. The Impact of the Prometheus *Decision*

Of all of the patent cases decided by the Court in the past decade, the most recent and most instructive on the issue of subject matter eligibility is *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[278] This decision is especially significant because it was unanimous and involved the same underlying policy concerns as those found in the *Myriad* case.[279] The contested patents covered processes used to help doctors determine the correct dosage of thiopurine drugs in treating patients with autoimmune diseases.[280] The processes consisted of "relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm."[281] Because the patent claims did not add enough to these natural relationships to render them patent-eligible subject matter, the Court held that the patents constituted an impermissible monopolization of the laws of nature.[282] The

273. *See id.*

274. Oliver Wendell Holmes, *The Path of the Law*, 10 HARV. L. REV. 457, 469 (1897). *But see* Walz v. Tax Comm'n of New York, 397 U.S. 664, 678 (1970).

275. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 208 (S.D.N.Y. 2010), *rev'd on other grounds*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012), *remanded to* 689 F.3d 1303 (Fed. Cir. 2012).

276. *Ass'n for Molecular Pathology*, 653 F.3d at 1367 (Moore, J., concurring).

277. *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012).

278. *See id.*

279. *See id.* at 1292, 1301-02, 1304-05.

280. *Id.* at 1294.

281. *Id.* at 1296.

282. *Id.* at 1297.

added steps merely consisted of "well-understood, routine, conventional activity previously engaged in by scientists who work in the field."[283]

Not surprisingly, Justice Breyer wrote the opinion.[284] He expressed concerns similar to those voiced in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, namely that patents, if improperly granted, could inhibit the use of laws of nature in future scientific research and monopolize "the basic tools of scientific and technological work."[285] Despite expressing this concern, Justice Breyer declined to comment on the broader policy question of the desirability of increased patent protection for inventors.[286] He also noted that Congress has a special role "in crafting more finely tailored rules where necessary," echoing similar statements the Court made in earlier cases.[287]

The *Prometheus* decision suggests that policy arguments regarding the appropriate level of patent protection do not carry as much weight with the Supreme Court as they do with the Federal Circuit.[288] Despite expressing a concern for the settled expectations of the inventing community in earlier cases, the Court was unwilling to entertain policy arguments when the patents at issue covered processes that were thinly disguised laws of nature.[289] Unlike Judge Moore, the Court refused to allow policy concerns to "tip the scales in favor of patentability."[290] Even Justices Kennedy, Roberts, Alito, Thomas, and Scalia, who seemed more willing to protect the inventing community and the businesses behind it, were not sympathetic to Prometheus's policy arguments.[291] The Court had no qualms about deciding Prometheus's patent claims on a blank canvas.[292] Without the support of policy arguments in favor of patentability, Prometheus's patent claims could not stand on their own because the additional steps were simply not transformative enough to bring the claims into the realm of patentable subject matter.[293]

Although *Prometheus* involved method patents, the Court most likely will apply the same reasoning to Myriad's utility patents.[294] Judges Lourie

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283. *Id.* at 1298-99.

284. *See id.* at 1293.

285. *Id.* at 1301 (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)); *see* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 126-27 (2006) (Breyer, J., dissenting).

286. *See Prometheus*, 132 S. Ct. at 1304-05.

287. *Id.* at 1305; *see* Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2252 (2011); Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 739 (2002); J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 144-45 (2001).

288. *See Prometheus*, 132 S. Ct. at 1304-05.

289. *See id.* at 1304-05; discussion *supra* Part VI.A.4.

290. *Prometheus*, 132 S. Ct. at 1304-05; *accord* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1367 (Fed. Cir. 2011) (Moore, J., concurring).

291. *See Prometheus*, 132 S. Ct. at 1304-05; discussion *supra* Part VI.A.4.

292. *See Prometheus*, 132 S. Ct. at 1305.

293. *See id.* at 1302-03.

294. *See id.* at 1294-95.

and Moore were content that the chemical changes that occurred when isolating BRCA1 and BRCA2 from the body were enough to separate these gene sequences from their counterparts in nature; the Court, however, is unlikely to share this view.[295] Like the additional steps added to Prometheus's patent claims, the chemical changes touted by Myriad and Judges Lourie and Moore are only superficial changes; the molecular composition of the gene sequences remains intact.[296] The lack of anything markedly different between isolated BRCA1 and BRCA2 and their naturally occurring forms will most likely prevent the Court from even reaching the policy arguments that saved Myriad's patents from invalidation by the Federal Circuit.[297]

VII. CONCLUSION

The *Myriad* case is likely to join *Bilski* and *Prometheus* in a trilogy of cases representing the Supreme Court's efforts to tighten restrictions on patentable subject matter. If the Supreme Court reverses the Federal Circuit and declares Myriad's patents for BRCA1 and BRCA2 invalid as products of nature, Michael Crichton's doomsday prophecy will have been averted. The availability and affordability of BRCA1 and BRCA2 testing likely would grow, and Ms. Patrice Fortune and those in her predicament could receive the testing they so desperately need.

But would the future still be grim despite the Court's invalidation of Myriad's patents? What about the dire predictions made by Chief Judge Rader of the Federal Circuit?[298] Might investors flee to other countries more hospitable to inventors and innovation?[299] These are questions Congress must ultimately answer.

Because the Court has indicated it will not create a test for what is a product of nature or what steps must be taken to render an isolated gene sequence patentable generally, Congress will have the task of defining the limits of gene patents.[300] But as Justice Breyer noted in *Prometheus*, patent protection is "a two-edged sword," and Congress should proceed carefully, lest it upset the delicate balance between public access to an invention and an inventor's rights secured by patents.[301]

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295. *See Prometheus*, 132 S. Ct. at 1302-03; discussion *supra* Part V.A-B.

296. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1377 (Fed. Cir. 2011) (Bryson, J., dissenting), *vacated*, 132 S. Ct. 1794 (2012), *remanded to* 689 F.3d 1303 (Fed. Cir. 2012).

297. *See id.*

298. *See supra* notes 266-71 and accompanying text.

299. *See supra* notes 268-70 and accompanying text.

300. *See* discussion *supra* Part VI.A.1-3.

301. *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1305 (2012).