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Myriad and Missed Opportunity: The Role of Innovation Policy in Patent Law Jurisprudence

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MYRIAD AND MISSED OPPORTUNITY: THE ROLE OF INNOVATION POLICY IN PATENT LAW JURISPRUDENCE

I. INTRODUCTION

The latter half of the twentieth century and beginning of the twenty-first century have seen the scientific community's understanding of biological materials and processes progress at a blistering pace.[1] In the 1950s, scientists had established little more than the basic structure and function of DNA.[2] Some six decades later, it is now common practice for researchers to pinpoint the exact location of a single protein's genetic material within the human genome and isolate the corresponding segment of DNA, commonly termed a "gene," from the remainder of the genome.[3] The location and isolation of human genes has wide-ranging utility in scientific and medical communities, and is particularly valuable in

1. Elizabeth Bailey, *Products of Human Ingenuity: The Isolation and Purification of Genes Under the Natural Product Doctrine*, 32 TEMP. J. SCI. TECH. & ENVTL. L. 25, 25 (2013).

2. *Id.*

3. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCI. 239 (2005).

the domain of clinical genetic testing, where clinicians can determine patients' susceptibility to various genetically inherited diseases.[4]

Just as science has evolved, so too have the views of researchers regarding the acceptability of patenting various types of discoveries.[5] In particular, the patenting of genes has become a polarizing topic over the last several decades, garnering attention from the media and strong opinions from both supporters and opponents of the practice.[6] Tensions concerning genetic patents reached a high point with the Supreme Court case *Association for Molecular Pathology v. Myriad Genetics*.[7] In the early 1990s, Myriad Genetics ("Myriad") was one of several research groups participating in the race to locate two genes, BRCA1 and BRCA2, associated with susceptibility to breast and ovarian cancers.[8] After Myriad won this race, it procured multiple patents[9] relating to these genes and aggressively enforced its rights pursuant to those patents.[10] Myriad's actions forced several genetic testing facilities and researchers to discontinue their BRCA-related testing and research and limited patients' access to its genetic testing services.[11] Subsequently, a variety of individuals and organizations filed suit seeking invalidation of Myriad's patents.[12]

After several decisions from lower courts, including two from the Court of Appeals for the Federal Circuit, the Supreme Court accepted the case to decide one question: Are human genes patentable?[13] This issue's resolution turned primarily on whether the patents fell under the "product of nature" exception to the scope of subject matter eligible for patent according to Section 101 of the Patent Act of 1952.[14] In a landmark decision, the Court held that isolated segments of DNA are not eligible for patent, while synthetically created molecules of cDNA are patent eligible.[15]

A full discussion of the issues associated with genetic patents and the effects of the Supreme Court's decision in *Myriad* is beyond the scope of this comment, which focuses primarily on the role of innovation policy in the resolution of patent law cases.[16] In order

4. Allen C. Nunnally, *Commercialized Genetic Testing: The Role of Corporate Biotechnology in the New Genetic Age*, 8 B.U. J. SCI. & TECH. L. 306, 307 (2002).

5. Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 109-15 (1999).

6. David H. Ledbetter, *Gene patenting and licensing: the role of academic researchers and advocacy groups*, 10 GENETICS MED. 314, 314 (2008).

7. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

8. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 201 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted, judgment vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012), *opinion vacated, appeal reinstated sub nom.* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 467 F. App'x 890 (Fed. Cir. 2012), *aff'd in part, rev'd in part*, 689 F.3d 1303 (Fed. Cir. 2012), *aff'd in part, rev'd in part sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

9. U.S. Patent No. 5,693,473 (filed June 7, 1995); U.S. Patent No. 5,709,999 (filed June 7, 1995); U.S. Patent No. 5,710,001 (filed June 7, 1995); U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,753,441 (filed Jan. 5, 1996); U.S. Patent No. 5,837,492 (filed Apr. 29, 1996); U.S. Patent No. 6,033,857 (filed Mar. 20, 1998).

10. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 204-06.

11. *Id.* at 186-89.

12. *Id.*

13. *Myriad*, 133 S. Ct. at 2111.

14. 35 U.S.C. §101 (2011); *Myriad*, 133 S. Ct. at 2107.

15. *Myriad*, 133 S. Ct. at 2107-11.

16. *See generally* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003) [hereinafter Burk & Lemley, *Policy Levers*]; Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155 (2002) [hereinafter Burk & Lemley, *Technology-Specific*]; Rochelle Cooper Dreyfuss, *What the Federal Circuit Can Learn from the Supreme Court—and Vice Versa*, 59 AM. U.L.

to provide the reader with a sufficient understanding of the Court's holding in *Myriad*, Part IIA endeavors to explain some basic concepts of molecular biology and genetics.[17] Part IIB introduces the topic of United States patent law, discusses its development in relation to the biotechnology industry, and explains in further detail the Supreme Court's treatment of the "product of nature" doctrine.[18] Part IIC provides an account of the race to patent the BRCA1 and BRCA2 genes, Myriad's actions in patenting the genes and enforcing those patents, and the history of the case as it meandered through the various levels of the federal court system.[19] Part III explores the application of innovation policy to the biotechnology industry, analyzes the Federal Circuit's and Supreme Court's holdings in *Myriad*, and argues that, although *Myriad* strikes a desirable balance between the competing interests of the biotechnology research community, the Supreme Court and the Federal Circuit nevertheless missed a valuable opportunity to engage in a meaningful discourse about innovation policy and its proper role in the courts' patent law jurisprudence.[20]

II. BACKGROUND

A. Brief Introduction to Molecular Biology and Genetics

The hereditary information of every living organism on Earth is stored in molecules of deoxyribonucleic acid (DNA).[21] An organism's cells express its hereditary information through the processes of transcription and translation, by which cells synthesize ribonucleic acid (RNA) and proteins, respectively.[22] Each protein synthesized within a cell corresponds to a specific segment of DNA.[23] These specific segments of DNA are genes, and the complete DNA sequence of an organism is known as its genome.[24] The human genome contains approximately 21,500 genes.[25]

1. DNA

DNA is a chain-like molecule that takes the form of a double-helix with base pairs on the inside and a sugar-phosphate backbone on the outside.[26] The inner bases form the "cross-bars" of the double helix and pair in a specific manner—adenine with thymine and guanine with cytosine.[27] Each cross-bar is chemically connected to the sugar-phosphate

REV. 787 (2010); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827 (1999); David O. Taylor, *Formalism and Antiformalism in Patent Law Adjudication: Precedent and Policy*, 66 SMU L. Rev. 633 (2013); John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U.L. REV. 771 (2003).

17. *See infra* Part IIA.
18. *See infra* Part IIB.
19. *See infra* Part IIC.
20. *See infra* Part III.
21. BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 2 (5th ed. 2008).
22. *Id.* at 4.
23. *Id.* at 7.
24. *Id.* at 7-8.
25. *About the Human Genome Project*, HUMAN GENOME PROJECT INFO. ARCHIVE, http://web.ornl.gov/sci/techresources/Human_Genome/project/index.shtml (last visited Jan. 19, 2014).
26. ALBERTS, *supra* note 21, at 197.
27. *Id.* at 197.

backbone of the DNA double-helix.[28] DNA, as it exists in the cell, is packaged into a set of chromosomes.[29] Each person has forty-six chromosomes—twenty-three from each parent.[30] Because a chromosome consists of a long string of unbroken DNA, it is essentially a long string of genes.[31]

The nucleotide sequence of the DNA within a specific gene determines the amino acid sequence of a specific protein.[32] The amino acid sequence of a protein determines what three-dimensional structure the protein will take, and therefore, what properties it will have and what biological function it will serve.[33] Not all stretches of DNA code for amino acids; those that do are known as "exons," while those that do not are known as "introns."[34] Most human genes consist of a long string of alternating introns and exons, with introns generally making up the majority of each gene.[35] Consequently, specialized enzymes must remove substantial portions of a gene—the introns—before the gene can be "expressed" through the synthesis of a protein.[36]

2. Protein Synthesis: RNA Transcription and Translation

The creation of proteins from DNA takes place through two major steps—transcription and translation.[37] During transcription, enzymes unwind DNA and use it to create a strand of complimentary RNA.[38] Like DNA, RNA is also a chain-like molecule composed of nucleotide subunits.[39] Unlike DNA, however, RNA utilizes the base uracil (U) instead of thymine and its sugar-phosphate backbone is chemically different from the sugar-phosphate backbone of DNA.[40] The RNA molecule produced from transcription is known as pre-messenger RNA, or pre-mRNA, and contains both introns and exons, like its parent strand of DNA.[41] A process called splicing removes the introns from the pre-mRNA molecule and produces a molecule known as final messenger RNA, or mRNA.[42] During translation, an enzyme reads the nucleotide sequence of the mRNA in groups of three, known as codons, and translates the codons into amino acids, which the enzyme links together to form a protein.[43] Often, cells are capable of splicing a segment of DNA in more than one way, allowing a single segment of DNA to contain genes coding for several different proteins.[44]

28. *Id.*
29. *Id.* at 202.
30. *Id.*
31. *Id.* at 204.
32. *Id.* at 199.
33. *Id.*
34. *Id.* at 206.
35. *Id.*
36. *Id.*
37. *Id.* at 4.
38. *Id.*
39. *Id.* at 332.
40. *Id.*
41. *Id.* at 347.
42. *Id.*
43. *Id.* at 367.
44. *Id.* at 348.

3. DNA Extraction, Purification, and Synthesis

A variety of well-established laboratory techniques allow laboratory technicians to extract DNA from its cellular environment and manipulate it.[45] For example, a scientist can produce a purified version of a specific segment of DNA by excising the specific segment from a sample of extracted DNA.[46] The purified segment of DNA may then be amplified, or cloned, in unlimited amounts directly through processes such as polymerase chain reactions or indirectly using a self-replicating element such as a virus or a plasmid.[47] Additionally, highly automated DNA sequencing techniques can rapidly and accurately determine the nucleotide sequence of a molecule of DNA.[48]

Complimentary DNA, or cDNA, is a laboratory-synthesized molecule created using the process of reverse transcription.[49] Reverse transcription is the process of extracting an mRNA molecule from a cell and using it as a template to create a complementary chain of single-stranded DNA, which cellular enzymes then convert into double stranded DNA.[50] Genomic DNA primarily differs from cDNA in that cDNA contains the uninterrupted coding sequence of a gene.[51] This is because cDNA's synthesis from mRNA molecules occurs after splicing, leaving only a particular gene's exons remaining.[52] For this reason, cDNA is the molecule of choice when analyzing a gene's protein product.[53]

A laboratory can use purified and amplified segments of DNA to detect a particular nucleotide sequence of interest—most often a gene.[54] For example, a scientist can insert a radioactive or chemical isotope—a marker—into a single stranded sequence of nucleotides.[55] The scientist can then use the sequence as a "probe" to find a complimentary sequence within a sample of DNA.[56] The scientific community widely utilizes this type of probe for the localization, purification, and characterization of nucleic acid sequences corresponding to specific genes.[57]

B. Patent Law Introduction

United States patent law dates back to 1790, when the First Congress passed House Resolution 10—our nation's first patent bill.[58] Congress passed House Resolution 10 in accordance with Article I, Section 8 of the United States Constitution, which bestowed 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 respective

45. *See, e.g.*, *id.* at 532-48.
46. *Id.* at 552.
47. *Id.*
48. *Id.* at 553.
49. *Id.* at 542.
50. *Id.*
51. *Id.* at 544.
52. *Id.*
53. *Id.* at 552.
54. *Id.*
55. *Id.*
56. *Id.*
57. *Id.*
58. S. REP. NO. 82-1979, at 2396 (1952).

Writings and Discoveries."[59] Congress promptly revised the bill in 1793 to make the granting of patents essentially automatic so long as the applicant filed the necessary papers and fees.[60] In 1836, dissatisfaction with the ease at which patents were obtained prompted Congress to enact a new bill.[61] This new bill created a patent office with the power to refuse patents if the inventor did not meet certain requirements.[62] Congress substantially revised patent laws again in 1870 and a final time in 1952, when it codified the Patent Act still in effect today.[63]

As noted above, the founding fathers recognized early in our nation's existence that a patent system was vital to the advancement of technology and innovation.[64] According to traditional patent doctrine, patents incentivize innovation by rewarding an inventor with the right to exclude others from the use of his invention for a specified period of time.[65] In the absence of a patent system, imitators could lie in wait for new inventions and appropriate them with a marginal expenditure of resources, while the inventor would lose the full benefit of his ingenuity and labor.[66] Consequently, inventors would be less likely to expend time and energy innovating, and the technological progress of society as a whole would proceed at a slower pace.[67] Additionally, by giving inventors legal protection from those who would exploit their inventions in the absence of patent rights, patent law encourages the prompt disclosure of new discoveries to the public.[68] Public disclosure of inventions is desirable because it provides opportunity for improvement on the original invention and for further discovery—both subject to the patent holder's rights, of course.[69]

Unfortunately, some patents may actually impede the development of "downstream" innovations that are contingent on the use of a subsequent "upstream" innovation.[70] This distinction between upstream and downstream resources plays a vital role in the success of the patent system.[71] The traditional doctrine is built on a system in which innovators utilize a freely available pool of upstream resources to develop new downstream technologies eligible for patent protection.[72] Accordingly, a patent system's effectiveness in promoting innovation relies on its ability to maintain accessibility to requisite upstream resources while providing innovators with sufficient patent protection for downstream technologies.[73] In the words of the Supreme Court, "patent protection strikes a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention.'"[74]

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59. U.S. CONST. art I, § 8, cl. 8.
60. S. REP. NO. 82-1979, at 2397.
61. *Id.*
62. *Id.*
63. *Id.* at 2395; *see also* Burk & Lemley, *Technology-Specific*, *supra* note 16, at 1159.
64. S. REP. NO. 82-1979, at 2396.
65. JOHN GLADSTONE MILLS III ET AL., PATENT LAW BASICS § 1:2 (2013).
66. *Id.*
67. *Id.*
68. *Id.*
69. *Id.*
70. Peter Lee, *Towards a Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917, 929-30 (2009).
71. Peter Yun-Hyoung Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine to Constrain Patents on Biotechnology Research Tools*, 19 HARV. J. L. & TECH. 79, 81 (2005).
72. *Id.*
73. *Id.*
74. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013) (quoting Mayo

The scenario in which a patentable downstream technology also serves as an upstream resource for further innovation and discovery often complicates the balance between these two pools of resources.[75] This scenario is particularly common in the biotechnology setting, where patents on groundbreaking discoveries have the potential to inhibit the development of downstream technologies.[76] For example, a patent on recombinant gene technology—developed using basic upstream scientific knowledge and techniques—might inhibit the development of medicines and treatments derived from subsequent use of the technology if the patent holder actively enforces his patent rights.[77]

Another factor that further complicates the intellectual property landscape of the biotechnology industry is the growing tension between the for-profit and not-for-profit sectors of the research community.[78] For the better part of the twentieth century, the academic community, which highly valued the sharing of scientific knowledge and generally frowned upon claiming property rights in scientific discoveries, conducted the vast majority of scientific research.[79] Although the market applicability of fields such as molecular biology rapidly increased throughout the century, the lack of any meaningful property rights in research results warded off privatization of scientific research until the late 1970s.[80] Around that time, the prevailing view of the legal and economic community shifted in favor of stronger intellectual property rights.[81]

In an attempt to create incentives for private firms to develop university-based discoveries into marketable products, and also to protect American discoveries from foreign exploitation, Congress passed the Bayh-Dole Act in 1980.[82] The Bayh-Dole Act gave universities the option to seek patent rights for discoveries made as a result of federally funded research.[83] The Act's purpose was to stimulate economic growth by giving private firms the opportunity to obtain exclusive licenses to develop commercial applications of university-owned technologies.[84] The Act facilitated the development of a "technology transfer industry" in which universities encourage researchers to pursue commercialization of their discoveries.[85] Universities now file patent applications on many of these discoveries—which often serve as valuable inputs into further research—then negotiate licensing agreements that allow private firms to make use of patented discoveries in exchange for royalties.[86]

Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1305 (2012)).

75. *See, e.g.*, Peter Lee, *Contracting to Preserve Open Science: Consideration-based Regulation in Patent Law*, 58 EMORY L. J. 889, 895 (2009).

76. *See generally*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

77. *See* Lee, *supra* note 70, at 80.

78. Case Comment, *Patent Act of 1952 – Patentable Subject Matter – Association for Molecular Pathology v. Myriad Genetics*, 127 HARV. L. REV. 388, 388 (2013) [hereinafter *Patent Act*].

79. Rai, *supra* note 5, at 89-90; Eisenberg, *supra* note 16, at 1046-48.

80. Rai, *supra* note 5, at 93.

81. *Id.* at 94.

82. Bayh-Dole Act, Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (1994)); Rai, *supra* note 5, at 95-97.

83. *See* Ledbetter, *supra* note 6, at 315.

84. *See* Rai, *supra* note 5, at 96-97.

85. Anna Bartow Laakman, *Restoring the Genetic Commons: A "Common Sense" Approach to Biotechnology Patents in the Wake of KSR v. Teleflex*, 14 MICH. TELECOMM. & TECH. L. REV. 43, 48 (2007).

86. *Id.*

Two years after the Bayh-Dole Act was passed, Congress created the Court of Appeals for the Federal Circuit to address growing concerns about the negative effects of inconsistent patent decisions in the regional circuit courts.[87] Although the Federal Circuit does not exclusively hear patent cases, it has exclusive appellate jurisdiction over the nation's patent appeals.[88] The Federal Circuit substantially strengthened patent rights in basic research discoveries by liberalizing the utility requirement and holding that DNA discoveries satisfy the "nonobviousness" requirement.[89] This increase in the patentability of basic research, coupled with the effects of the Bayh-Dole Act, led to a marked increase in the commercialization of biotechnology research.[90]

Consequently, substantial tension developed between the growing private sector and its not-for-profit counterparts.[91] The private sector maintains that strong patent rights are necessary for the attraction of capital investors, who have little incentive to allocate resources to the development of new technologies if those new technologies are readily available to competing firms.[92] In response, the not-for-profit sector argues that the free flow of information best encourages innovation.[93]

To settle these conflicting interests, many commentators have argued that substantial changes to current patent law are necessary.[94] Some have suggested alternatives to traditional patent rights, including monetary prizes for discoveries, completely new forms of intellectual property, compulsory licensing to ensure access at reasonable costs, tax incentives for donations of intellectual property to non-profit organizations, and codification of common law safe harbor provisions for non-profit research entities.[95] However, until further legislative action resolves the complex policy issues associated with biotechnology patents, federal courts must resolve highly technical patent law claims within the statutory framework of the current patent act.[96]

Under the Patent Act of 1952, an invention must meet several statutory requirements to be eligible for patent protection.[97] First, the invention must concern patentable subject matter, a concept discussed in further detail below.[98] It must also have utility and novelty, it must not be obvious, and it must be properly disclosed.[99] The utility requirement derives from the language of § 101, which allows the United States Patent and Trademark Office (USPTO) to issue patents to "[w]hoever invents or discovers any new and *useful* process,

87. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25; Rai, *supra* note 5, at 102-03.

88. *See* S. Jay Plager, *The Federal Circuit As an Institution: On Uncertainty and Policy Levers*, 43 LOY. L.A. L. REV. 749, 750 (2010).

89. *See* Rai, *supra* note 5, at 103-09; *see also* Laakman, *supra* note 85, at 43, 48-49. An invention satisfies the nonobviousness requirement if a person having ordinary skill in the art to which the invention pertains would not consider the invention to be an obvious change from the prior state of the art. *See infra* note 103 and accompanying text.

90. *See* Rai, *supra* note 5, at 110.

91. Indeed, this is precisely the scenario that played out in *Myriad*. *See Patent Act*, *supra* note 78, at 388.

92. *Id.*; Rai, *supra* note 5, at 95-96.

93. *See Patent Act*, *supra* note 78, at 388.

94. *See id.* at 397.

95. *Id.*

96. *Id.*

97. 35 U.S.C. §§ 101-03, 112.

98. 35 U.S.C. § 101.

99. 35 U.S.C. §§ 101-03, 112; *see also* Rai, *supra* note 16, at 829-31.

machine, manufacture, or composition of matter."[100] Utility is generally the easiest requirement to satisfy, since courts merely require the invention to have some form of specific benefit to the public.[101] Novelty requires, quite simply, that others did not know of or use the invention prior to its discovery by the patentee.[102] An invention is obvious if a person having ordinary skill in the art to which the invention pertains would consider the invention to be an obvious change from the prior state of the art.[103] Section 112 of the patent act requires the patent specifications to contain an adequate written description of the invention, which must be sufficiently clear and concise to allow others to make use of the invention.[104]

The Supreme Court's decision in *Myriad* concerns itself only with the question of whether the contested patents related to patentable subject matter.[105] In fact, the question presented in the Association for Molecular Pathology's petition for writ of certiorari was likely one of the most concise in the history of the Supreme Court: Are human genes patentable?[106]

C. The Supreme Court's "Product of Nature" Jurisprudence

The Supreme Court has long recognized an implicit exception to the scope of patentable subject matter for "laws of nature, natural phenomena, and abstract ideas."[107] Scholars and commentators refer to the exception as the "natural products" or "product of nature" doctrine.[108] Two Supreme Court cases, *Funk Brothers Seed Company v. Kalo Inoculant Company*[109] and *Diamond v. Chakrabarty*,[110] provide an adequate introduction to the Court's "product of nature" doctrine.

In *Funk Brothers*, the petitioner contested a patent relating to a bacterial mixture used for inoculating plants.[111] Prior to the patentee's discovery of this mixture, the mutually inhibitory effects of various species of bacterial inoculants on one another necessitated the manufacture and sale of each species of inoculant separately.[112] However, the patentee discovered particular strains of each species that did not exert these mutually inhibitive effects.[113] He isolated these superior strains of bacteria and used them to create mixed cultures suitable for use on a much wider variety of crops than was possible with existing inoculants.[114]

Although the Court recognized the advantage provided by the discovery and the ingenuity of its creator, it struck down the patent on the ground that the patented mixture

100. 35 U.S.C. §101 (emphasis added).
101. WILLIAM C. HOLMES, INTELLECTUAL PROPERTY AND ANTITRUST LAW § 1:12 (West 2014).
102. JAMES BUCHWALTER ET AL., C.J.S. *Patents* §34 (2014).
103. HOLMES, *supra* note 101, § 1:14.
104. 35 U.S.C. § 112; HOLMES, *supra* note 101, § 1:15.
105. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2120 (2013).
106. Petition for Writ of Certiorari, *Myriad*, 133 S. Ct. 2107 (2011) (No. 11-725).
107. Diamond v. Diehr, 450 U.S. 175, 185 (1981).
108. Bailey, *supra* note 1, at 30-31.
109. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).
110. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
111. *Funk Bros.*, 333 U.S. at 130.
112. *Id.* at 129.
113. *Id.* at 130.
114. *Id.*

was merely a discovery of "some of the handiwork of nature."[115] The patentee's isolation of the bacterial strains did not "improve in any way their natural functioning;" the bacteria still "serve[d] the ends nature originally provided and act[ed] quite independently of any effort of the patentee."[116] Accordingly, the Court determined that the patented mixture fell squarely within the product of nature exception to the § 101 definition of patentable subject matter and, thus, was not patentable.[117]

In *Diamond v. Chakrabarty*, the Court further explained its position on the "product of nature" doctrine.[118] In *Chakrabarty*, the patentee was a microbiologist who created, through genetic engineering, a bacterium that was capable of chemically degrading several components of crude oil.[119] The bacterium's value was in the treatment of oil spills, and no known naturally occurring organism possessed the same capability.[120] The Court reasoned that because the genetically engineered bacterium was different from any found in nature, it was patent eligible.[121]

The Court distinguished the case from *Funk Brothers* by explaining that in that case, the patentee had simply discovered a strain of bacteria that previously existed in nature.[122] In contrast, the patentee in *Chakrabarty* created a new bacterium with "markedly different characteristics from any found in nature."[123] The Court emphasized that patent protection is appropriate only for inventions that are products of human ingenuity.[124] Although the Court decided the two cases differently, the reasoning of the decisions is consistent and provides the relevant standards for determining when an invention falls within the "product of nature" exception to the scope of patentable subject matter.[125]

D. Development of Myriad's Patents

Throughout the 1980's, organizations devoted to breast cancer awareness spurred an increase in public and governmental attentiveness to the disease.[126] In response to this increased awareness, scientists from many developed countries sought to identify the DNA sequences associated with breast cancer.[127] In 1990, a group of researchers at the University of California, Berkeley, led by Doctor Mary-Claire King, published a paper linking a gene located on a specific region of chromosome 17 to breast and ovarian cancer.[128] Dr. King's group had not yet determined the sequence of the gene, which was later designated

115. *Id.* at 131.
116. *Funk Bros.*, 333 U.S. at 131.
117. *Id.*
118. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
119. *Id.* at 305.
120. *Id.*
121. *Id.* at 310.
122. *Id.*
123. *Chakrabarty*, 447 U.S. at 310.
124. *Id.* at 309-10.
125. *See* Bailey, *supra* note 1, at 32.
126. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 200 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted, judgment vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012), *opinion vacated, appeal reinstated sub nom.* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 467 F. App'x 890 (Fed. Cir. 2012), *aff'd in part, rev'd in part*, 689 F.3d 1303 (Fed. Cir. 1012), *aff'd in part, rev'd in part sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).
127. *Id.* at 201.
128. *Id.*

Breast Cancer Susceptibility Gene, or BRCA1.[129] This discovery led research teams around the world to intensify their research concerning the specified region of chromosome 17.[130] Dr. Mark Skolnick, a co-founder of Myriad Genetics, led one of these groups.[131]

While earning his Ph.D. in genetics, Dr. Skolnick met three Mormons who introduced him to the Utah Genealogical Society's resources.[132] In 1973, Dr. Skolnick recommended linking the genealogical society's database to the Utah Cancer Registry's database to analyze occurrences of cancer within families.[133] Dr. Skolnick furthered this effort by developing a familial cancer-screening clinic, which his group used to study a variety of familial cancers.[134] After Dr. King's research group announced the BRCA1 gene's linkage to chromosome 17, Dr. Skolnick created Myriad Genetics in 1991 after his research group's attempts to obtain government funding were not as successful as he hoped they would be.[135]

Scientists at Myriad located the BRCA1 gene using linkage analysis, meaning that the group "mapped" the physical location of the gene within the human genome using correlations between the inheritance of certain DNA markers and the occurrence of cancer.[136] After pinpointing the location of the BRCA1 gene, Myriad's scientists analyzed the sequence of the gene and identified the nucleotides that comprise it.[137] Following the discovery, scientists raced to locate a second gene also thought to be associated with breast and ovarian cancer.[138] Utilizing the same form of analysis it used to locate BRCA1, Myriad discovered the BRCA2 gene.[139] However, a substantial portion of the scientific community holds the view that Dr. Michael Stratton of London's Institute for Cancer Research was actually the first to sequence the BRCA2 gene.[140] When all was said and done, Myriad obtained seven patents on the BRCA1 and BRCA2 genes, which gave it the option to exercise the exclusive right to perform research and clinical testing on the genes.[141]

E. The Importance of the BRCA1 and BRCA2 Genes

The BRCA1 and BRCA2 genes produce tumor suppressor proteins that ensure the stability of a cell's genetic material by facilitating the repair of damaged DNA.[142] Inherited

129. *Id.*
130. *Id.*
131. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 201.
132. Declaration of Dr. Mark Skolnick at ¶ 7, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (2009) (No. 09 Civ. 4515).
133. *Id.* ¶¶ 7-8.
134. *Id.* ¶ 10.
135. *Id.* ¶¶ 14-15.
136. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 201; *see also* U.S. Patent No. 5,747,282 (filed June 7, 1995).
137. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 201; see also U.S. Patent No. 5,747,282.
138. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 202.
139. *Id.*
140. *Id.*
141. U.S. Patent No. 5,693,473 (filed June 7, 1995); U.S. Patent No. 5,709,999 (filed June 7, 1995); U.S. Patent No. 5,710,001 (filed June 7, 1995); U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,753,441 (filed Jan. 5, 1996); U.S. Patent No. 5,837,492 (filed Apr. 29, 1996); U.S. Patent No. 6,033,857 (filed Mar. 20, 1998).
142. BRCA1 and BRCA2: Cancer Risk and Genetic Testing, NAT'L CANCER INST., http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA (Last visited Mar. 14, 2014).

mutations in the BRCA1 and BRCA2 genes can lead to an increased risk of female breast and ovarian cancers.[143] Together, mutations in these two genes are responsible for twenty to twenty-five percent of hereditary breast cancers and fifteen percent of all ovarian cancers.[144] The existence of mutated BRCA1 or BRCA2 genes, therefore, contains important implications for the prevention and detection of breast and ovarian cancers.[145]

A patent holder has the option to grant licenses to others for the use of the patented item in exchange for an up-front payment or royalty payments.[146] In the context of gene patents, the patent holder has the option to grant licenses to other entities for the use of the gene in diagnostic testing.[147] Myriad, however, chose to retain the exclusive right to perform diagnostic testing on the BRCA1 and BRCA2 genes—a decision the scientific community met with extensive opposition and criticism.[148]

Opponents of Myriad's patents raised the objection that Myriad's effective monopoly on BRCA testing allows it to raise the cost of the test to unreasonable levels.[149] Myriad offered testing at a cost of over $3,000, while a public healthcare plan in Ontario—which chose to ignore Myriad's patents—offered the testing at approximately one third of Myriad's price.[150] Insurance companies often do not cover BRCA testing, and some of Myriad's testing options impose extra fees on patients who are not "high risk."[151] Another concern involves the lack of options for consumers; if Myriad is the only choice for BRCA testing, a patient who desires a second opinion is simply out of luck.[152] During the late 1990s and early 2000s, Myriad actively enforced its BRCA patents, sending cease and desist letters and filing lawsuits against various parties who offered BRCA testing in violation of Myriad's patents.[153] In May 2009, the Association for Molecular Pathology ("AMP") filed suit against the United States Patent and Trademark Office ("USPTO") and Myriad in the United States District Court for the Southern District of New York seeking invalidation of Myriad's patents.[154] A substantial number of clinical physicians, researchers, cancer patients, and public interest groups joined as plaintiffs in the case.[155]

143. *Id.*

144. *Id.*; *see also* Douglas F. Easton, *How Many More Breast Cancer Predisposition Genes are There?*, 1 BREAST CANCER RES. 14, 15 (1999); Pal T et al., *BRCA1 and BRCA2 Mutations Account for a Large Proportion of Ovarian Carcinoma Cases*, 104 CANCER 2807, 2812 (2005).

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

146. Ledbetter, *supra* note 6, at 317.

147. See *id.*

148. *Id.* at 314; *see generally* T. Caulfield, *Myriad and the Mass Media: The Covering of a Gene Patent Controversy*, 9 GENETICS MED. 850 (2007); Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 J. AMER. MED. ASS'N 1379 (2006).

149. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 203-04.

150 *Id.*

151. *Id.* at 204.

152. A related concern is that Myriad's monopoly over BRCA testing leaves it with little incentive to improve upon its original test. *See* Ledbetter, *supra* note 6, at 314.

153. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 204-06.

154. *Id.* at 186-89.

155. *Id.*

III. ANALYSIS

A. Innovation Policy in Biotechnology

Although scholars widely agree that the basic goal of patent law is to promote innovation, legal and economic theorists often fundamentally disagree on how to best implement that goal.[156] The application of the patent system's general rules to the unique qualities of diverse industries and technologies complicates this debate substantially.[157] For example, the cost of research and development varies widely across industries.[158] Pharmaceutical companies often invest millions of dollars and spend several years developing a new drug, while software companies can develop a new program for a fraction of that cost.[159] Consequently, those industries that require vast expenditures for research and development will generally covet patent rights more fiercely than those that require comparatively modest expenditures.[160]

There are several unique qualities of biotechnology that complicate the debate on how to best implement the patent system's goals.[161] Biotechnology research is expensive, takes place over an extended period of time, and often involves a high degree of uncertainty.[162] Even when biotechnology research yields exciting new discoveries, the market value of those discoveries is often difficult to ascertain.[163] Also, imitators face substantially lower risks and costs than original innovators do.[164] For example, an imitator can easily replicate a particular molecule of cDNA once the original innovator locates and isolates the underlying DNA sequence.[165] The combination of these two factors lends support to the private sector's argument that the industry requires strong patent rights to entice investment in important research.[166]

However, a countervailing argument is that the field of biotechnology research offers a wealth of alternative incentives that motivate researchers to innovate.[167] Whereas the patent system incentivizes innovation with monetary rewards, many leading researchers—often funded by government grants and nonprofit organizations—are motivated by alternative incentives, such as prestige, prizes, academic tenure, altruism, or mere scientific curiosity.[168] In the field of biotechnology, then, it is not unreasonable to argue that a substantial amount of scientific progress would continue even in the absence of the patent system's incentives.[169] Put more generally, an industry with an abundance of alternative incentives to innovate should require fewer incentives from the patent system.[170] After all,

156. Burk & Lemley, *Policy Levers*, *supra* note 16, at 1597-99.
157. *Id.* at 1581.
158. *Id.*
159. *Id.* at 1581-82.
160. *Id.* at 1582.
161. *Id.* at 1676-77.
162. See *id.*
163. *Id.*
164. *Id.* at 1677.
165. *Id.*
166. *See* Brief for Respondents at 5, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 12398).
167. Burk & Lemley, *Policy Levers*, *supra* note 16, at 1586.
168. *Id.*
169. *Id.*
170. *See id*.

why should society pay the patent system's price if a steady supply of inventors not seeking patent exclusivity is available to provide the scientific progress the patent system seeks to promote?[171]

Such a question depends in part on what kind of scientific progress patent exclusivity seeks to promote.[172] Under the more traditional account of the patent system, patent exclusivity provides ex-ante incentives that operate prior to the issuance of the patent.[173] In other words, society benefits from the inventor's discovery and disclosure of the patented invention, and the inventor's right to exclude others from the use of his invention is the price society must pay to hold up its end of the bargain.[174] This traditional account of the patent system was likely effective when inventions were primarily mechanical in nature, but it is problematic when applied to modern sciences such as biotechnology, where an initial patented invention often has no market value in and of itself, and further investment is necessary to develop commercial applications of the initial invention.[175] Furthermore, researchers motivated by alternative incentives to innovate, especially those in academia, often do not direct their research toward the pursuit of such commercial applications.[176]

An alternative theory holds that patents also provide incentives that operate subsequent to the issuance of the patent.[177] These ex-post incentives motivate the inventor to invest in the development of commercial applications of the invention during the patent term, or in the alternative, to entice others to invest in developing commercial applications through licensing.[178] This alternative theory was apparently espoused by Congress when it passed the Bayh-Dole Act.[179] Congress passed the Act because it determined that federally funded researchers were not efficiently developing their basic research discoveries into commercial applications.[180] Its solution to the problem, as noted above, was to nudge the biotechnology industry towards commercialization by allowing universities and nonprofit organizations to patent their basic research discoveries and encouraging them to subsequently license their patents to private firms, who could develop them into commercial applications.[181]

Professors Arti Rai and Rebecca Eisenberg have argued that the Bayh-Dole Act's failure to distinguish fundamental research discoveries that enable further scientific investigation from downstream inventions that translate directly into commercial products caused the patent system to encroach too far into the domain of open science, which may impede rather than promote the progress of science.[182] This concept is directly applicable

171. *See* Eisenberg, *supra* note 16, at 1037.

172. *See id.* at 1024, 1037.

173. *Id.*

174. *Id.*

175. Burk & Lemley, *Technology-Specific*, *supra* note 16, at 1155; *see also* Rai, *supra* note 5, at 96. Some scholars distinguish invention from innovation; notable economist Joseph Schumpeter, for example, has argued that invention produces "no economically relevant effect at all," while innovation brings about constant change in the economic system. 1 JOSEPH A. SCHUMPETER, BUSINESS CYCLES 84-87 (1939).

176. Gina A. Kuhlman, *Alliances for the Future: Cultivating a Cooperative Environment for Biotech Success*, 11 BERKELY TECH. L.J. 311, 314 (1996).

177. Eisenberg, *supra* note 16, at 1036-38.

178. *Id.*

179. H.R. Rep. No. 96-1307, pt. 1, at 3 (1980).

180. Rai, *supra* note 5, at 95.

181. Brian Zadorozny, *The Advent of Gene Patenting: Putting the Great Debate in Perspective*, 13 SMU SCI. & TECH. L. REV. 89, 92-93 (2009).

182. Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW &

to *Myriad*; the question of whether DNA patents encroach too far into the domain of open science—so as to impede the progress of science rather than promote it—is the overarching question of innovation policy presented by the case.[183]

In an attempt to aid and influence the courts in their resolution of *Myriad*, both parties to the case and numerous amici offered a plethora of policy arguments.[184] Myriad and similarly situated amici, largely consisting of for-profit entities, argued that Myriad and its investors relied on strong patent rights when they "risked billions of dollars" to research the BRCA genes, and therefore, Myriad needed patent exclusivity in order to recover its investment in the molecules.[185] Other amici warned that a holding in the plaintiffs' favor would have significant negative effects on America's economy and on its position as a leader in the biotechnology industry.[186]

Plaintiffs and their amici, consisting primarily of not-for-profit members of the research community, offered a variety of arguments to the contrary.[187] First, they argued that the incentivization of innovation does not always require patent exclusivity, especially in the context of genetic research.[188] For example, scientists have developed genetic testing for an assortment of diseases without pursuing patent rights, and Myriad's competition in the race to discover the BRCA genes came from scientists claiming to have no intention of seeking patents on the genes.[189]

Also, plaintiffs and associated amici argued that patent exclusivity impedes progress by preventing further downstream research and discovery.[190] Myriad's amici responded by arguing that members of the biotechnology industry rarely enforce patents against researchers, but the argument fell on deaf ears.[191] Plaintiffs and their amici asserted that the mere threat of litigation—and the resulting attorney's fees and court costs—often prevents researchers from taking the risk, especially those employed by non-profit entities.[192] In Myriad's case, the fact that several plaintiffs ceased BRCA testing and research to settle

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CONTEMP. PROBS. 289, 290-91 (2003).

183. Unfortunately, both the Supreme Court and the Federal Circuit largely avoided addressing this question. *Patent Act*, *supra* note 78, at 397.

184. *See generally* Brief of Amici Curiae American Medical Association, American Society of Human Genetics, American College of Obstetricians and Gynecologists, American Osteopathic Association, American College of Legal Medicine, and the Medical Society of the State of New York in Support of Petitioners, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 12-398) [hereinafter AMA Brief]; Brief for Amicus Curiae Eric S. Lander in Support of Neither Party, 133 S. Ct. 2107 (2013) (No. 12-398) [hereinafter Lander Brief]; Brief of the American Bar Association as Amicus Curiae in Support of Respondents, 133 S. Ct. 2107 (2013) (No. 12-398).

185. Brief for Respondents at 5, *Myriad*, 133 S. Ct. 2107 (2013) (No. 12-398); see also *Patent Act*, *supra* note 78, at 394.

186. Brief for Amicus Curiae the Biotechnology Industry Organization in Support of Respondents at 3, *Myriad*, 133 S. Ct. 2107 (2013) (No 12-398) [hereinafter Biotechnology Brief]; *see also Patent Act*, *supra* note 78, at 394.

187. *Patent Act*, *supra* note 78, at 394.

188 *See, e.g.*, AMA Brief, *supra* note 184, at 16 (stating that "[t]he majority of geneticists are willing to undertake the research to discover genes and develop genetic tests without the possibility of a patent").

189. *See id.* at 16; *see also* Reply Brief for Petitioners at 21, *Myriad*, 133 S. Ct. 2107 (2013) (No. 12-398).

190. *See* Brief for Petitioners at 42, *Myriad*, 133 S. Ct. 2107 (2013) (No. 12-398); Brief Amici Curiae of the National Women's Health Network et al. in Support of Petitioners at 12-14, *Myriad*, 133 S. Ct. 2107 (2013) (No. 12-398).

191. *See, e.g.*, Biotechnology Brief, *supra* note 186, at 33 (stating that, in the biotechnology industry, "rational forbearance against researchers is the norm").

192. Brief of Amicus Curiae AARP in Support of Petitioners at 4, 133 S. Ct. 2107 (No 12-398); *see also Patent Act*, supra note 78, at 395.

pending lawsuits, while others did so to avoid litigation altogether, gave credence to the argument.[193] Lastly, plaintiffs and their amici argued that communication and collaboration, not exclusivity, are vital to scientific discovery.[194] To foster innovation, the scientific community needs certain basic tools and scientific knowledge to remain in the public domain.[195] For example, Myriad built its discovery of the BRCA genes on the work of other scientists, including that of the Human Genome Project and Dr. King's University of California, Berkeley research team.[196]

B. The Litigation Saga

In March of 2010, the United States District Court for the Southern District of New York invalidated all seven of Myriad's patents.[197] In doing so, the court split the patents into two categories and struck each category down for a different reason.[198] One category of patent claims pertained to "isolated DNA containing all or portions of the BRCA1 and BRCA2 gene sequence[s]."[199] The court found these "composition of matter" claims unpatentable based on the product of nature exception to 35 U.S.C. § 101.[200] The second category of patents were those based on "methods for 'comparing' or 'analyzing' BRCA1 and BRCA2 gene sequences to identify the presence of mutations correlating with a predisposition to breast or ovarian cancer."[201] The court invalidated this second category of patents because it found that they were abstract mental processes, which are also not eligible for patent under § 101.[202]

On July 29, 2011, Myriad appealed and brought the case before the United States Court of Appeals for the Federal Circuit.[203] The Federal Circuit presented a three-part decision: (1) "isolated" DNA molecules do not exist in nature and are thus patent-eligible, (2) Myriad's claim to a method for screening potential cancer therapeutics is not an abstract mental process and is also patent-eligible, and (3) Myriad's method claims pertaining to "comparing" or "analyzing" DNA sequences are patent-ineligible abstract mental

193. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 204-06 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted, judgment vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012), and *opinion vacated, appeal reinstated*, 467 F. App'x 890 (Fed. Cir. 2012), and *aff'd in part, rev'd in part*, 689 F.3d 1303 (Fed. Cir. 1012), *aff'd in part, rev'd in part sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

194. *Patent Act, supra* note 78, at 396.

195. Brief of Professor Eileen M. Kane as Amicus Curiae in Support of Petitioners at 5, 133 S. Ct. 2107 (2013) (No. 12-398).

196. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 201; *see also Patent Act, supra* note 78, at 396.

197. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 238.

198. *See id.* at 185.

199. *Id.*

200. *Id.* at 185, 220.

201. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 185.

202. Myriad, relying on the Federal Circuit's decision in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, argued that the method claims were not abstract mental processes because they incorporated a transformation step and therefore passed the "machine or transformation" test from *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). *Id.* at 233-37. The district court disagreed, holding there was no transformative step involved in Myriad's "comparing" and "analyzing" method claims. *Id.* at 234-37; *see also infra* notes 208-16 and accompanying text.

203. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted, judgment vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012), and *opinion vacated, appeal reinstated*, 467 F. App'x 890 (Fed. Cir. 2012), and *aff'd in part, rev'd in part*, 689 F.3d 1303 (Fed. Cir. 1012), *aff'd in part, rev'd in part sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

processes.[204] The plaintiffs filed a petition for a writ of certiorari, which asked the Supreme Court to review the Federal Circuit's decision relating to the patentability of isolated human genes.[205] The Court issued a summary disposition[206] that granted the plaintiffs' petition for writ of certiorari, vacated the Federal Circuit's judgment, and remanded the case to the Federal Circuit for further consideration in light of the Court's recent decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*.[207]

In *Mayo*, the patents at issue related to methods for determining, in a patient-specific manner, the most effective dose of thiopurine drugs used for the treatment of autoimmune diseases.[208] The method used correlations between metabolite levels in a patient's blood and the likelihood of ineffectiveness or negative side effects to precisely establish the proper dose.[209] *Mayo*, interestingly, was itself a case in which the Supreme Court granted certiorari, vacated a Federal Circuit decision, and remanded for reconsideration in light of a recently decided case—*Bilski v. Kappos*.[210] The Federal Circuit's pre-remand decision in *Mayo* determined that the claims at issue were eligible for patent under the "machine or transformation" test.[211] In *Bilski v. Kappos*, however, the Supreme Court held that the machine or transformation test was not "a definitive test of patent eligibility, but only an important and useful clue."[212] The Court seemed to be hinting that it wanted the Federal Circuit to incorporate some form of policy into its analysis of patent eligibility.[213] On remand, the Federal Circuit determined that, even if the machine or transformation test was not the definitive test of patent eligibility, its application to the claims in *Mayo* led to a clear and compelling conclusion that the claims at issue were eligible for patent.[214] The Supreme Court granted certiorari a second time and reversed the Federal Circuit's decision.[215] Although the Court purported to rely on established general legal rules and case law precedent, it also referenced its own repeated emphasis on the concern that patent law

204. *Id.* at 1334.

205. Plaintiffs also requested Supreme Court review of the Federal Circuit's holding on an issue of standing, but the Court chose not to disturb the Federal Circuit's decision in that regard. Petition for Writ of Certiorari, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012) (No. 11-725).

206. Summary Disposition, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012).

207. *See generally* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2011).

208. *Id.* at 1290.

209. *Id.* at 1290-91.

210. *Id.* at 1296; *see generally* Bilski v. Kappos, 130 S. Ct. 3218 (2010).

211. Prometheus Labs., Inc. v. Mayo Collaborative Servs., 581 F.3d 1336, 1342-43, 1350 (Fed. Cir. 2009), *cert. granted, judgment vacated*, 130 S. Ct. 3543 (2010), *rev'd*, 628 F.3d 1347 (Fed. Cir. 2010), *rev'd*, 132 S. Ct. 1289 (2012). The machine or transformation test, first articulated by the Supreme Court in *Gottschalk v. Benson*, attempts to ascertain whether a process or method claim is tailored narrowly enough to embody a particular application of a fundamental principle without pre-empting the principle itself; a claimed process or method is sufficiently narrow if "(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), aff'd but criticized sub nom. Bilski v. Kappos, 130 S. Ct. 3218 (2010); *see also* Gottschalk v. Benson, 409 U.S. 63, 70 (1972).

212. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. at 1296 (explaining the significance of its holding in *Bilski*); *see also Bilski*, 130 S. Ct. at 3227.

213. The Court's reiteration that its holding in *Bilski* stood for the proposition that the machine or transformation test was not the sole test for determining the patent eligibility of process or method claims suggests that its remand of *Mayo* was effectively an invitation for the Federal Circuit to engage in a more flexible, policy-inclusive analysis of whether the claims in dispute were eligible for patent. *See Mayo Collaborative Servs*., 132 S. Ct. at 1296.

214. Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347, 1355 (Fed. Cir. 2010), *rev'd*, 132 S. Ct. 1289 (2012).

215. *Mayo Collaborative Servs*., 132 S. Ct. at 1305.

should not "inhibit further discovery by improperly tying up the future use of laws of nature" as reinforcement of its decision.[216]

After reconsideration of its *Myriad* holding in light of the Supreme Court's decision in *Mayo*, the Federal Circuit produced a carbon copy of its prior holding.[217] The Federal Circuit reasoned that *Mayo* was not controlling on the issue of patent-eligible subject matter under § 101.[218] It further explained that while *Mayo* "provide[d] valuable insights and illuminate[d] broad, foundational principles," the *Chakrabarty* and *Funk Brothers* cases set out the framework for determining patent-eligibility of composition of matter claims.[219] Accordingly, the court held that *Mayo* did not affect its prior holding that isolated DNA molecules are within the realm of patent-eligible subject matter.[220] The Federal Circuit then moved on to Myriad's method claims; it determined that *Mayo* reinforced its previous holding that the method claims directed to "comparing" or "analyzing" DNA sequences were patent-ineligible and that the method claim for screening potential cancer therapeutics was patent-eligible.[221] Plaintiffs again filed a petition for writ of certiorari, asking the Supreme Court to determine whether human genes are patent eligible and whether the Federal Circuit erred in upholding Myriad's method patent for screening potential cancer therapeutics.[222]

The Supreme Court granted certiorari only on the question of whether human genes are eligible for patent.[223] Although the Court received a substantial number of policy-based arguments from the case's numerous amici, it largely evaded the policy issue by basing its decision on rules developed in its previous case law.[224] The Court offered a narrow, two-part holding: (1) a segment of DNA is a product of nature which is not patent-eligible by virtue of its isolation from the human genome, and (2) cDNA is not naturally occurring and is therefore patent-eligible.[225] To arrive at this decision, the Court compared Myriad's patents to those in *Chakrabarty* and *Funk Brothers*, examined the focus of the patents, and determined that the past practice of the USPTO in granting patents for isolated genes was not entitled to deference.[226]

The Court began its analysis by distinguishing Myriad's isolated DNA patents from the patent in *Chakrabarty*.[227] In *Chakrabarty*, the genetically engineered bacterium had "markedly different characteristics from any found in nature."[228] In contrast, the Court determined that Myriad did not create anything; the separation of the BRCA genes from

216. *Id.* at 1301-02, 1305.

217. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1309 (Fed. Cir. 2012), *aff'd in part, rev'd in part sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

218. *Id.* at 1325.

219. *Id.* at 1326.

220. *Id.* at 1333.

221. *Id.* at 1326.

222. Plaintiffs again included the standing question in its petition, and the Supreme Court again ignored it. Petition for Writ of Certiorari, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 11-725).

223. *Ass'n for Molecular Pathology*, 133 S. Ct. at 695.

224. *Myriad*, 133 S. Ct. at 2116-17.

225. *Id.* at 2109.

226. *Id.* at 2116-19.

227. *Id.* at 2116-17.

228. *Id.* at 2117 (internal quotation marks omitted) (quoting Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980)).

the human genome may have been a groundbreaking discovery, but it was no act of invention.[229] The Court found the subject matter of Myriad's isolated DNA patents to be more analogous to the subject matter of the patent considered in *Funk Brothers*.[230] In *Funk Brothers*, the Court's primary objection to the patent was that its mixture of bacterial strains did not alter the bacteria in any way.[231] Similarly, the Court found that Myriad did not create or alter the BRCA1 and BRCA2 genes in any way.[232] Rather, Myriad's contribution was "uncovering" the location and sequence of the genes within their respective chromosomes.[233]

Myriad attempted to distinguish its isolated DNA patents from the *Funk Brothers* patent by emphasizing that isolating DNA from the human genome requires severance of chemical bonds, resulting in a non-naturally occurring molecule.[234] The Court acknowledged and dismissed this argument, stating that Myriad had not expressed its patent claims in terms of chemical composition.[235] Rather, the isolated DNA claims primarily focused on the genetic information encoded in the patented genes, which existed without any contribution from Myriad.[236] The Court illustrated this point by explaining that, if Myriad's patents depended on the creating a unique molecule, a patent infringer could avoid Myriad's patent claims by isolating a DNA sequence containing the BRCA1 or BRCA2 gene and one additional nucleotide pair.[237] Such an outcome would obviously frustrate the purpose of Myriad's patents, because its claims concerned the information encoded within the genes, not their chemical composition.[238] Myriad's final argument on the issue was that the USPTO's past practice of awarding patents on genes was entitled to deference.[239] The Court quickly dispatched this argument, noting that the United States itself, as *amicus curiae*, argued against the practice of granting patents on isolated DNA sequences.[240] Ultimately, the Court held that Myriad's isolated DNA patents fell squarely within the product of nature exception, rendering them invalid.[241]

The Supreme Court addressed Myriad's cDNA patent claims much more concisely.[242] The AMP conceded that cDNA is in no way a naturally occurring molecule, but argued that it should not be eligible for patent because its nucleotide sequence is dictated by nature and not by the laboratory technician.[243] The Court acknowledged the truth of the premise underlying the AMP's argument, but reasoned that the laboratory technician still

229. *Myriad*, 133 S. Ct. at 2117.
230. *Id.*
231. *Id.*
232. *Id.* at 2116.
233. *Id.*
234. *Myriad*, 133 S. Ct. at 2118. However, Dr. Eric Lander asserted in his amicus brief that the scientific community has long been aware of the occurrence of isolated DNA fragments in the human body. Lander Brief, *supra* note 184, at 12. The Court gave considerable attention to Dr. Lander's brief on this point during oral argument. Transcript of Oral Argument at 38-40, *Myriad*, 133 S. Ct. 2107 (2013) (No. 12-398).
235. *Id.*
236. *Id.*
237. *Id.*
238. *Myriad*, 133 S. Ct. at 2118.
239. *Id.*
240. The Court provided further support for its conclusion by discussing Congress' failure to legislatively endorse the USPTO's longstanding practice of granting genetic patents. *Id.* at 2118-19.
241. *Id.* at 2117.
242. *See id.* at 2119.
243. *Myriad*, 133 S. Ct. at 2119; Brief for Petitioner at 49, 133 S. Ct. 2107 (2013) (No. 12-398).

unquestionably creates something new when he synthesizes cDNA.[244] The Court held that a molecule of cDNA is distinct from the molecule of DNA from which it was created.[245] Consequently, cDNA is not a product of nature, making it patent eligible under Section 101 of the Patent Act.[246]

C. Policy Avoidance and Missed Opportunity

The Supreme Court asserted in *Mayo* that Congress holds the responsibility of crafting finely tailored rules to resolve industry-specific issues of patent policy.[247] While Congress has shown a tepid willingness to pass industry-specific patent legislation, it has done so in a piecemeal fashion rather than promulgating comprehensive statutes to fully address the needs of any one industry.[248] Some commentators have suggested that the biotechnology industry should have its own sui generis patent system, but Professor Rai argues the legislature is as ill-equipped as the courts to provide a permanent solution to the industry's ever-changing and amorphous patent needs.[249] Unless Congress chooses to undertake this seemingly herculean task, the courts must resolve patent disputes by interpreting the existing Patent Act, which remains largely unchanged since 1952.[250] However, if the last six decades of technological advancements and emerging industries have not prompted Congress to make any substantial changes to update patent law, it is plausible that Congress is satisfied with the ability of the federal courts to adapt their reading of the Patent Act to accommodate the unique demands of diverse industries and technologies.[251]

Unfortunately, the institutional constraints faced by the federal courts leave them ill equipped to reconcile the disparate interests held by different sectors of the biotechnology industry.[252] One such constraint the federal courts face is that of limited resources.[253] Another is that federal courts often lack technical competence.[254] For example, judges on the Court of Appeals for the Federal Circuit, which was created primarily to adjudicate patent cases, are not required to have technical backgrounds—and most do not.[255] Even a judge with a technical background, however, could not hope to be technically competent in the all of the vastly diverse disciplines within the scope of the Patent Act.[256]

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244. *Myriad*, 133 S. Ct. at 2119.
245. *Id.*
246. *Id.*
247. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1304-05 (2011).
248. For example, Congress has extended the patent term for many pharmaceutical patents, 35 U.S.C. §§ 155-56 (2000), prohibited enforcement of medical procedure patents against doctors, *id.* § 287 (2000), and relaxed the obviousness standard as it applies to biotechnology processes, *id.* § 103(b) (2000). *See also* Burk & Lemley, *Policy Levers*, *supra* note 16, at 1631.
249. Professor Rai argues that the difficulties associated with biotechnology arise not from legal standards themselves, but instead from the courts' faulty application of the standards. Rai, *supra* note 16, at 841-42. She then provides three objections to the promulgation of a sui generis regime for biotechnology patents: (1) special interest groups may have substantial influence over the resultant legislation, (2) the administrative costs would be significant, and (3) there is no reason to believe that a sui generis approach would provide sufficient flexibility to accommodate the ever-changing nature of the biotechnology industry. *Id.* at 842.
250. *See generally*, 35 U.S.C. §§ 101-212.
251. Burk & Lemley, *Policy Levers*, *supra* note 16, at 1674.
252. Rai, *supra* note 99, at 837.
253. *Id.*
254. *Id.* at 837-38.
255. *Id.* at 838.
256. *Id.* at 837-38.

The proper role of the Court of Appeals for the Federal Circuit and the Supreme Court in their interpretation of the Patent Act is the subject of much debate.[257] Some commentators adhere to the view that, in light of the complex nature of patent law, the courts should avoid policy considerations altogether and implement a formalistic and rule-based approach to their intellectual property jurisprudence.[258] Indeed, the judges of the Federal Circuit have generally indicated that they should avoid expressing their own policy views in written opinions.[259] This view is in accord with the traditional notion that the judiciary should exercise restraint against implementing its own policy preferences when interpreting statutory language.[260] On the other hand, a seemingly overwhelming portion of the academic community advances the view that the Federal Circuit and Supreme Court should more actively analyze innovation policy in patent cases.[261]

Rather conveniently, professor David Taylor recently published a thoughtful article that neatly gathered the critical views of several notable professors on the perceived formalistic nature of the Federal Circuit's jurisprudence.[262] Professor Rochelle Dreyfuss, for example, has argued that the Patent Act requires "common law elaboration," and that Federal Circuit judges should consider "whether the law is developing in a manner that reflects policies that meet the needs of the creative sector and further federal interests in promoting technological progress."[263] Professor Rai has also criticized the Federal Circuit's formalism.[264] She has advanced the argument that the history and language of the Patent Act suggest that Congress intended to delegate patent law policymaking to the judiciary, which should accept this responsibility by incorporating innovation policy into its patent law jurisprudence.[265] Several other professors have expressed similar views,[266] and although each has his or her own unique take on the Federal Circuit's appropriate role, a common thread exists: the Federal Circuit should do a better job of articulating policy-based justifications for its holdings in patent cases.[267]

Although commentators have directed the bulk of their criticisms toward the Federal Circuit, the Supreme Court has not altogether escaped similar scrutiny.[268] However, the general consensus among commentators is that the Supreme Court has been much more open to discussing innovation policy in its patent cases.[269] Perhaps more importantly, the

257. *See, e.g.*, Taylor, *supra* note 16, at 640-52.

258. *See* Burk & Lemley, *Policy Levers*, *supra* note 16, at 1673-74.

259. Taylor, *supra* note 16, at 640-45.

260. *See* Burk & Lemley, *Policy Levers*, *supra* note 16, at 1673-74.

261. This criticism is more often aimed at the Federal Circuit; some commentators argue the specialized nature of the court and the failure of other institutions to take responsibility for establishing patent policy make it the best option to articulate substantive patent policy. *See, e.g.*, Taylor, *supra* note 16, at 645.

262. *Id.* at 645-52.

263. With respect to patent law's need for "common law elaboration," Professor Dreyfuss compares the Patent Act to the Sherman Act. Rochelle Cooper Dreyfuss, *In Search of Institutional Identity: The Federal Circuit Comes of Age*, 23 BERKELY TECH. L. J. 787, 800, 801 (2008); *see also* Taylor, *supra* note 16, at 648.

264. *See* Arti K. Rai, *Engaging in Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1101-03 (2003); *see also* Taylor, *supra* note 16, at 649.

265. Rai, *supra* note 264, at 1040-41.

266. *See generally* Lucas S. Osborn, *Instrumentalism at the Federal Circuit*, 56 ST. LOUIS U. L.J. 419 (2012); Thomas, *supra* note 16; Burk & Lemley, *Policy Levers*, *supra* note 16.

267. Taylor, *supra* note 16, at 652.

268. *Id.* at 672.

269. *See, e.g.*, KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 419 (2007) (explaining why the nonobviousness standard needed to be raised); Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 732-35 (2002) (justifying retention of the doctrine of equivalents); Lab. Corp. of Am. Holdings v. Metabolite Labs., 548

Supreme Court has expressed a willingness to engage in a discourse with the Federal Circuit on how to best implement innovation policy in patent cases.[270] Unfortunately, the Federal Circuit has not consistently expressed the same willingness to participate in this discourse.[271]

Similar to its remand in *Mayo*, the Supreme Court's remand of *Myriad* presented a prime opportunity for the Federal Circuit to implement innovation policy into its opinion.[272] That the doctrine at issue—subject-matter eligibility—was one not closely circumscribed by the language of the Patent Act ads weight to this argument.[273] This is not necessarily to say that the result would have been different if the Federal Circuit had done so; even if it determined that innovation policy discouraged DNA patents, it might have been constrained by the doctrine of stare decisis.[274] By engaging in a reasoned analysis of innovation policy, though, the Federal Circuit could have framed the issues more thoroughly for the Supreme Court, enabling it to make effective use of the Federal Circuit's expertise without necessarily deferring to its judgment.[275] Additionally, such a policy analysis would have supplied the district courts with a better understanding of how to address subject-matter eligibility in the future.[276]

Unfortunately, the Supreme Court responded to the Federal Circuit's avoidance of innovation policy with its own avoidance of the same.[277] This is especially surprising given that the Court's opinion in *Mayo* seemingly took a step toward incorporating innovation policy into its subject-matter eligibility analysis.[278] Its subsequent avoidance of innovation policy in *Myriad* will likely foster uncertainty in the lower courts about the proper role of innovation policy in the nation's patent law jurisprudence moving forward.[279] Thus, although the Supreme Court's holding in *Myriad* appears to strike a desirable balance between the competing interests of the biotechnology community, the Supreme Court and the Federal Circuit nevertheless missed a valuable opportunity to engage in a meaningful discourse about innovation policy and its proper role in the courts' patent law jurisprudence.

A possible justification for the Court's avoidance of innovation policy in *Myriad* is its lack of expertise and experience with patent law.[280] It may have decided that avoiding a policy analysis altogether was a better alternative to a possibly faulty or incomplete policy analysis, especially given the controversial nature of the patent claims at hand.[281] In-

U.S. 124, 126-27 (2006) (per curiam) (Breyer, J., dissenting) (arguing that granting too much patent protection can run counter to the constitutional objective of patent protection); *see also* Dreyfuss, *supra* note 16, at 801-03; Taylor, *supra* note 16, at 637.

270. Dreyfuss, *supra* note 16, at 801-02.

271. *See, e.g.*, Taylor, *supra* note 16, at 674.

272. *See supra* nn.208-16 and accompanying text.

273. Subject matter eligibility is not closely circumscribed by statute because the language of 35 U.S.C. § 101 leaves much of the doctrine's application to the discretion of the courts. *See* Taylor, *supra* note 16, at 678.

274. *See id.* It is important to note, however, that the en banc Federal Circuit is not bound by its own precedent. *Id.* at 656.

275. *See id.*; Dreyfuss, *supra* note 16, at 796.

276. Dreyfuss, *supra* note 16, at 805.

277. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116-20 (2013).

278. *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1304-05 (2011).

279. *Myriad*, 133 S. Ct. at 2116-20.

280. *See* Dreyfuss, *supra* note 16, at 802.

281. *See Myriad*, 133 S. Ct. at 2116-20.

deed, some might applaud the Supreme Court's abstention from articulating issues of innovation policy that the Federal Circuit could arguably address more effectively.[282]

IV. CONCLUSION

The application of the patent system to biotechnology discoveries presents complex issues of innovation policy.[283] Legal and economic theorists rarely agree on how to best resolve these issues, but a substantial portion of commentators agree that the Court of Appeals for the Federal Circuit and the Supreme Court should incorporate some form of reasoned policy analysis in their patent law jurisprudence.[284] Although *Myriad* presented a clear opportunity for the two courts to engage in a discourse about the proper role of innovation policy in the resolution of patent cases, neither court took advantage of this opportunity. Unless such a discourse is established in the future, innovation policy's place in United States patent law jurisprudence will remain a question mark.

—*Dru Prosser*[*]

282. Dreyfuss, *supra* note 16, at 802.

283. *See generally* Burk & Lemley, *Technology-Specific*, *supra* note 63; Rai, *supra* note 5, at 95-96.

284. *See* Taylor, *supra* note 16, at 645-52.

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