GENE PATENTS: STRIKING THE RIGHT BALANCE BETWEEN INCENTIVE AND INNOVATION

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The U.S. Supreme Court held human genes to be unpatentable subject matter in Association for Molecular Pathology v. Myriad Genetics, Inc. *The implications from this decision were, and to a large extent still are, unclear. However, in the decade since this decision, a number of studies have begun to shed light on the fallout of* Myriad. *This Note examines such studies and finds that they suggest a decline in investment and innovation in the biotech industry. In order to promote research and innovation in the field of genetics, this Note then advocates for legislative action to reestablish the validity of gene patents. This Note concludes by proposing a novel solution to the question of gene patent eligibility, suggesting that a narrowly tailored grant of patent eligibility to mutant variants of genes can strike the right balance of incentive and innovation for gene patents.*

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INTRODUCTION

The U.S. Constitution grants Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[1] This directive underscores the basic justification for patent law: the ability to monopolize a future invention provides inventors with a strong incentive to innovate and create.[2] However, granting overly protective monopolies as incentives can have the opposite effect by stymieing research and discovery by subsequent inventors.[3] Thus, one of the key challenges of patent law is striking the right balance between incentive and innovation.[4]

Pursuant to this constitutional mandate, Congress enacted the Patent Act of 1952[5] (the "Patent Act"), now codified under title 35 of the U.S. Code. Section 101 lays out the basic requirements for an innovation to be patent-eligible, including limiting patent-eligible subject matter to "any new and

1. U.S. CONST. art I, § 8, cl. 8.
2. *See infra* Part I.B.1.
3. *See infra* Part I.B.1.
4. *See infra* Part I.B.1.
5. Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (codified as amended at 35 U.S.C. §§ 1–376).

useful process, machine, manufacture, or composition of matter."[6] Courts have read exceptions into this rule, holding that "[l]aws of nature, natural phenomena, and abstract ideas" alone cannot be patented.[7]

Patent law has had to adapt to the development of new technologies over the years. During the 1980s and 1990s, a revolution in genetic sequencing technologies occurred as researchers became capable of identifying specific genetic sequence mutations that underlie human disease.[8] Researchers and biotechs in the United States and abroad patented and monetized these genetic discoveries while advancing methods for diagnosing and treating certain diseases.[9] One such group was Myriad Genetics, who, in 1995, patented "BRCA1," a gene that, when mutated, significantly increases an individual's chances of developing breast cancer.[10]

Although biotechs utilized their "gene patents"[11] as a means to protect their investments into genetic research, others saw gene patents as a clear violation of the U.S. Supreme Court's prohibition on patenting laws of nature.[12] A group of doctors, patients, and nonprofits, backed by the American Civil Liberties Union (ACLU), sued Myriad over the right to patent genes.[13] As a result, in *Association for Molecular Pathology v. Myriad Genetics, Inc.*,[14] the Court held that gene patents fell within the laws of nature exception to patent eligibility and were thus invalid.[15] Since *Myriad*, genes are no longer valid patentable subject matter in the United States.

The initial effects of *Myriad* were unclear.[16] A decade after the decision, however, *Myriad*'s impact on the biotech industry and the development of gene-based medical diagnostics is becoming more evident.[17] Some commentators have advocated for either judicial or legislative action to overrule *Myriad* and reestablish gene patent eligibility.[18] However, ideas for restoring patent protections to genes are widely varied.[19] Some advocate for the Supreme Court to overturn *Myriad*.[20] Others have suggested a special

6. 35 U.S.C. § 101.

7. Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 70 (2012) (quoting Diamond v. Diehr, 450 U.S. 175, 185 (1981)).

8. *See* Jon F. Merz & Mildred K. Cho, *What Are Gene Patents and Why Are People Worried About Them?*, 8 CMTY. GENETICS 203, 204 (2005).

9. *See infra* Parts I.B.4–5.

10. *See* Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off., 702 F. Supp. 2d 181, 201–03 (S.D.N.Y. 2010), *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., 569 U.S. 576 (2013).

11. Gene patents are patents covering a specific genetic sequence. They often include the entirety of a gene's genetic sequence, as well as methods of assessing that gene's sequence and comparing it to a healthy reference sequence. *See* Merz & Cho, *supra* note 8, at 204.

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

13. *Id.* at 186–89.

14. 569 U.S. 576 (2013).

15. *Id.* at 580.

16. *See infra* Part II.A.

17. *See infra* Part II.A.

18. *See infra* Part II.B.

19. *See infra* Parts II.B.2.a–d.

20. *See infra* Parts II.B.2.a–b.

carveout within patent law specifically for genes.[21] Still others suggest that the United States enact a more narrow, European Union (EU)–style legislative carveout for genes by explicitly allowing for gene patents that have an industrial application.[22] This Note proposes adopting an EU-like limited exception for genes, allowing for specific disease-causing mutant variants of genes to be patent-eligible subject matter.[23] In reaching this conclusion, this Note proceeds in three parts.

First, Part I details background information necessary to understand genes, gene patents, and the Supreme Court's rationale behind its decision in *Myriad*. Next, Part II looks at some of the most pertinent studies about the aftereffects of *Myriad* and assesses arguments both for and against the need to restore gene patent eligibility. Finally, Part III advocates for a restoration of gene patents in a narrow way that minimizes issues around inhibiting genetic research and reducing incentives to innovate that a simple reversal of *Myriad* would not.

I. GENES, PATENTS, AND THE CASES THAT LED TO GENE PATENTS BEING HELD INVALID

The question of whether genes should be patentable subject matter is a complex one that requires both a basic grasp of genetics and an understanding of patent law's purpose and mechanics. To those ends, this part details the necessary background required to understand the issue of gene patents. Part I.A provides an explanation of the fundamental concepts of genetics as they relate to gene patents. Part I.B describes the theory and requirements of patent law, focusing specifically on the idea of gene patents within the United States and comparing that with gene patents in the EU. Part I.C then traces the history of patent-eligible subject matter as applied by courts within the United States with particular attention to cases that initially upheld and then ultimately overturned the validity of patents on genetic materials.

A. A Brief Overview of Genes and Genetic Diseases

*D*eoxyribo*n*ucleic *a*cid ("DNA") is a basic building block of life.[24] It can be thought of as a how-to guide that explains how to make components of a living organism. This guide can be broken down into the instructions for individual components ("genes") and even further into the words that make up those instructions ("DNA bases").[25] It is estimated that the human

21. *See infra* Part II.B.2.c.
22. *See infra* Part II.B.2.d.
23. *See infra* Part III.B.
24. ANTHONY J.F. GRIFFITHS, SUSAN R. WESSLER, RICHARD C. LEWONTIN, WILLIAM M. GELBART, DAVID T. SUZUKI & JEFFREY H. MILLER, INTRODUCTION TO GENETIC ANALYSIS 2 (Jason Noe, Susan Moran & Mary Louise Byrd eds., 8th ed. 2005).
25. *Id.* at 2–3.

genome contains about 19,000 to 22,000 genes, with an average length of about 67,000 DNA bases per gene.[26]

The specific sequence of bases within a gene determines how that gene functions.[27] In some instances, variations in gene base sequence result in rather innocuous changes to gene function—for example, differences in the sequence for the gene controlling blood type dictates whether an individual will have A, B, AB, or O blood type.[28] However, these variations can sometimes have deleterious effects on gene function—such as changes in the human *br*east *ca*ncer susceptibility gene 1 ("BRCA1").[29] Individuals who have a deleterious "mutant" variant of the BRCA1 gene are over seven times more likely to develop breast cancer by age seventy than are individuals in the general population.[30]

As is the case with BRCA1 and breast cancer, some mutant variants of genes predispose individuals to the development of certain diseases.[31] Thus, knowledge of one's own genetic sequence can be extremely useful in preventing or preparing for the onset of genetically determined diseases.[32] For example, determining that an individual carries a mutant variant of the BRCA1 gene early might prompt that individual to be proactive about screening for breast cancer.[33]

However, understanding how genetic variations result in certain diseases is not as easy as simply looking at an individual's genetic information; associating a gene with a particular disease requires a significant amount of research.[34] Even then, not all mutant variants of a gene will necessarily cause that disease.[35] Further, susceptibility to a given disease is often controlled by more than one gene.[36] And once all that research is performed, the findings must still be implemented in a way that makes them accessible to

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26. *See* Cassandra Willyard, *New Human Gene Tally Reignites Debate*, NATURE (June 19, 2018), https://www.nature.com/articles/d41586-018-05462-w [https://perma.cc/88DW-PUN8] (noting the average number of genes in a human genome is between 19,000 and 22,000); Allison Piovesan, Maria Caracausi, Francesca Antonaros, Maria Chiara Pelleri & Lorenza Vitale, *GeneBase 1.1: A Tool to Summarize Data From NCBI Gene Datasets and Its Application to an Update of Human Gene Statistics*, DATABASE, Oct. 31, 2016, at 1, 1 (estimating the average human gene to be about 67,000 bases long).

27. GRIFFITHS ET AL., *supra* note 24, at 6.

28. LAURA DEAN, BLOOD GROUPS AND RED CELL ANTIGENS 25 (2005) (ebook).

29. *See* Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off., 702 F. Supp. 2d 181, 201–02 (S.D.N.Y. 2010), *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., 569 U.S. 576 (2013).

30. *BRCA Gene Mutations*, CDC (Mar. 21, 2023), https://www.cdc.gov/cancer/breast/young_women/bringyourbrave/hereditary_breast_cancer/brca_gene_mutations.htm [https://perma.cc/GT9P-NJWJ].

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

32. *See id.*

33. *See id.*

34. GRIFFITHS ET AL., *supra* note 24, at 362–64.

35. *See id.* at 455.

36. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 203 (noting that women with mutations in both BRCA1 and BRCA2 have a higher likelihood of developing breast cancer than women with mutations in only one of the BRCA genes).

patients—for example, by developing diagnostic tests.[37] Thus, investments of considerable time and resources are needed from the initial discovery of a gene to the point where knowledge of that gene can be used in treating human disease.

B. Patents in the United States and Abroad

The drafters of the U.S. Constitution were acutely aware of this dynamic in scientific research. In fact, the Constitution explicitly gives Congress the power to grant and regulate patents.[38] This section will discuss the rationale behind the current U.S. patent law regime. It will then discuss specific requirements for patentability, claims of patent infringement, and defenses to such claims. It will conclude with an overview of the legal landscape covering the patentability of genes, within both the United States and the EU.

1. Patent Law Theory

The rationale that underlies patent law is relatively simple: encourage innovation by rewarding inventors for their efforts.[39] Advances in science and technology can be thought of as public goods that benefit society at large and should therefore be promoted.[40] However, the process of innovation can be costly and time-consuming.[41] Thus, to get individuals to engage in this process, they must be offered some form of incentive.[42] One possible incentive is to grant an inventor the exclusive right to make, sell, and profit from their invention.[43] However, as essentially all scientific progress builds off of prior scientific advances, granting the inventor overly protective rights might ultimately hinder scientific progress by limiting further, or "follow-on," innovations.[44] Thus, a balance must be struck: inventors must be incentivized to invent, but that incentive must be limited so as not to unnecessarily hinder scientific progress.[45]

Patent law attempts to strike this balance by granting inventors limited-time monopolies over their inventions.[46] An inventor is given the right to exclude others from making, using, selling, or importing their patented invention for a set amount of time.[47] In exchange, the inventor must

37. *See* Merz & Cho, *supra* note 8, at 204.
38. U.S. CONST. art. I, § 8, cl. 8.
39. *See* PETER S. MENELL, ROBERT P. MERGES, MARK A. LEMLEY & SHYAMKRISHNA BALGANESH, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE: 2023, at 22 (2023).
40. *See id.* at 21.
41. *See id.* at 20.
42. *See id.*
43. *See id.* at 23.
44. *See id.* at 24. Follow-on innovations are subsequent innovations that build off of the work of prior patents. *See* Janet Freilich & Sepehr Shahshahani, *Measuring Follow-On Innovation*, RSCH. POL'Y, Nov. 2023, at 1, 1.
45. *See id.* at 25.
46. *See id.*
47. 35 U.S.C. §§ 271(e)(1), 154. In the United States, the patent protection period is currently twenty years. *Id.* § 154.

disclose the details of their patented invention so that, once their patent expires, the public can make use of the innovation.[48]

2. Patent Requirements

In order to acquire a patent in the United States, an inventor must show that their invention or discovery meets certain requirements laid out by the Patent Act.[49] Specifically, they must show that their innovation falls within the realm of patent-eligible subject matter[50] and that it is useful,[51] novel,[52] nonobvious,[53] and adequately disclosed.[54] Patent applications are filed with the United States Patent and Trademark Office (USPTO) and, if denied, are appealable to the Patent Trial and Appeal Board (PTAB) and the U.S. Court of Appeals for the Federal Circuit.[55]

Important to the balancing act discussed above[56] is the idea that some, but not all, discoveries or innovations should be patentable.[57] The Patent Act designates four categories of patent-eligible subject matter: processes, machines, manufactures, and compositions of matter.[58] However, courts have read three exceptions into this list, holding that patents claiming laws of nature, natural phenomena, and abstract ideas are not patent-eligible.[59] Courts have held that these exceptions are so foundational to scientific progress that no one individual should have exclusive control over them.[60] However, courts have held that inventions that fall within one of the three exceptions might still be patent-eligible if the claimed patent applies the basic scientific principle in some inventive way.[61]

In addition to subject matter, for an innovation to be patentable, it must also be useful,[62] novel,[63] nonobvious,[64] and adequately disclosed.[65]

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48. *See id.* § 112; *see* MENELL ET AL., *supra* note 39, at 23.
49. 35 U.S.C. §§ 1–390.
50. *Id.* § 101.
51. *Id.*
52. *Id.* § 102.
53. *Id.* § 103.
54. *Id.* § 112.
55. *Id.* §§ 134, 141.
56. *See supra* Part I.B.1.
57. *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (holding that certain things, like the laws of nature, do not belong to any one person and thus cannot be patented).
58. 35 U.S.C. § 101.
59. Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 70 (2012).
60. *See, e.g.*, *Funk Bros.*, 333 U.S. at 130. For example, the invention of a rubber-molding machine might qualify for patent protection, as it falls within the four approved subject matter categories. *See* Diamond v. Diehr, 450 U.S. 175, 192–93 (1981). Meanwhile, the discovery of a basic scientific idea, such as a mathematical formula that a rubber-molding machine uses to calculate the temperature it should operate at, might alone not warrant patent protection, as the underlying abstract idea falls within the three subject matter exceptions. *See id.* at 186.
61. Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 217 (2014); *see also infra* Part I.C.4.a.
62. 35 U.S.C. § 101.
63. *Id.* § 102.
64. *Id.* § 103.
65. *Id.* § 112.

Usefulness requires that the innovation serve some specific, presently known purpose.[66] Novelty requires that the innovation cannot have already been discovered and disclosed.[67] Nonobviousness requires that the innovation represents a significant advancement in science or technology.[68] Finally, disclosure requires the inventor to stake out exactly what they are claiming to have discovered or invented and to divulge the specifics of their innovation in enough detail so that others in the field can replicate their work.[69]

3. Patent Infringement and Defenses

A patent grants the holder the right to prevent others from making, using, or selling their patented invention.[70] When another does so, the patent holder may sue them for infringement.[71] The patent holder must then demonstrate that the accused infringement falls within the scope of the patent.[72]

Accused infringers have several available defenses to claims of infringement.[73] Among their options, they can argue that the patent is invalid for failing to meet the patentability requirements discussed above.[74] For example, if an alleged infringer can demonstrate that the patent actually covers unpatentable subject matter, a court will hold that no infringement has occurred and that the patent is invalid.[75]

Additionally, an accused infringer can argue that their use is covered by the research use exception, which permits certain uses of a patented innovation that would otherwise constitute infringement.[76] Such uses include those undertaken "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry"—often uses associated with academic pursuits[77]—as well as some limited statutorily authorized exceptions.[78] However, courts have traditionally construed the research use exception narrowly, for example, holding that the use of patented materials by universities to conduct research furthers the university's business objective by enhancing its status and thus does not fall under the exception.[79] Such a

66. *See* Brenner v. Manson, 383 U.S. 519, 534–35 (1966).

67. 35 U.S.C. § 102; *see* Rosaire v. Baroid Sales Div., Nat'l Lead Co., 218 F.2d 72, 73, 75 (5th Cir. 1955).

68. 35 U.S.C. § 103; *see* Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 15 (1966).

69. 35 U.S.C. § 112; *see* Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 472 (1895).

70. *See* 35 U.S.C. § 271(a).

71. *See id.*

72. *Id.*

73. *Id.* §§ 271, 282.

74. *Id.* § 282.

75. *See, e.g.*, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

76. *See, e.g.*, Alicia A. Russo & Jason Johnson, *Research Use Exemptions to Patent Infringement for Drug Discovery and Development in the United States*, COLD SPRING HARBOR PERSPS. MED., Feb. 2015, at 1, 1 (summarizing the research use exemption).

77. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984).

78. *See, e.g.*, 35 U.S.C. § 271(e)(1) (authorizing specific uses of patented pharmaceuticals in order to develop generic alternatives that comply with federal regulations).

79. Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002).

narrow scope for the research use exception has led some to suggest that—outside of statutory exceptions—there is effectively no research exception in the United States.[80]

4. Gene Patents in the United States

Human genes are among the many innovations that have received patent protection in the United States over the years.[81] As described above, specific mutations of certain human genes can predispose individuals to particular diseases.[82] However, the process of discovering a gene, linking that gene to a disease of interest, and then developing methods for diagnosing and treating that disease based on a patient's underlying genetic information can be costly and time-consuming.[83] As DNA-sequencing technologies advanced in the 1980s and 1990s, researchers working to understand such genetic linkages often sought to patent their discoveries and use the resulting "gene patent" to raise the capital needed to further exploit their discovery—for example, by creating diagnostic tests.[84]

One such company who followed this pattern was Myriad Genetics.[85] While working to discover the genetic sequence of BRCA1 at the University of Utah, Dr. Mark Skolnick recognized the need for greater investment in the project than could be acquired from within an academic institution.[86] He thus founded the biotech Myriad Genetics with the purpose of raising the money needed to uncover and exploit the BRCA1 genetic sequence.[87] Myriad was ultimately successful, and it patented the BRCA1 gene.[88] Myriad went on to identify and patent another gene, "BRCA2," that, when mutated, also predisposes an individual to breast cancer.[89] Myriad used their BRCA gene patents to develop medical diagnostic test kits that allowed doctors to sequence a patient's BRCA1 and BRCA2 genes and identify

80. *See, e.g.*, Freilich & Shahshahani, *supra* note 44, at 10.

81. *See* Merz & Cho, *supra* note 8, at 1.

82. *See supra* Part I.A.

83. *See* Paul Michel, David Kappos, Corey Salsberg & Matthew Dowd, *Presenting the Evidence for Patent Eligibility Reform: Part II—Harm to R&D Investment, Innovation and U.S. Interests*, IPWATCHDOG (Oct. 11, 2022, 4:15 PM), https://ipwatchdog.com/2022/10/11/presenting-evidence-patent-eligibility-reform-part-ii-harm-rd-investment-innovation-u-s-interests/id=151960/ [https://perma.cc/LBF6-CUY4].

84. *See, e.g.*, Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off., 702 F. Supp. 2d 181, 200–03 (S.D.N.Y. 2010), *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., 569 U.S. 576 (2013).

85. *See id.* (summarizing Myriad Genetics' discovery and patenting of the BRCA1 and BRCA2 genes).

86. *Id.* at 201.

87. *See id.*

88. *Id.*; U.S. Patent No. 5,747,282 (filed June 7, 1995).

89. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 202; U.S. Patent No. 5,837,492 (filed Apr. 29, 1996) (BRCA2 sequence patent). Myriad also patented the process of comparing patient BRCA1 and BRCA2 sequences to healthy references as part of its diagnostic testing. *See* U.S. Patent No. 5,753,441 (filed Jan. 5, 1996) (BRCA1); U.S. Patent No. 6,033,857 (filed Mar. 20, 1998) (BRCA2).

mutations that warranted heightened breast cancer screening for affected patients.[90]

Between the 1980s and early 2000s, numerous gene patents were granted, including patents for: the DNA sequence of "APC," mutations of which predispose an individual to colon cancer;[91] the sequence and diagnostic tests relating to "MLH1" and "MSH2," genes that, when mutant, cause Lynch Syndrome;[92] and the sequence and right to test "CFTR," mutations of which predispose an individual to developing cystic fibrosis.[93] However, in 2013, these and other such gene patents were invalidated in the United States by the landmark Supreme Court decision *Association for Molecular Pathology v. Myriad Genetics, Inc*.[94]

5. Gene Patents in the European Union

Unlike the United States, some other countries continue to permit the patenting of human genes. The EU, for example, explicitly allows for the patenting of genes.

In the EU, patents are processed by the European Patent Office (EPO) in compliance with the European Patent Convention (EPC).[95] The EPC dictates that "any invention" may be patented,[96] but it restricts this broad grant with specific limitations—for example, by indicating that "discoveries, scientific theories and mathematical methods" do not qualify as inventions.[97] However, directives passed by the EU create carveouts to these restrictions. A 1998 directive of the European Parliament, for example, clarifies that DNA sequences are to be considered inventions—and not unpatentable discoveries—so long as the claimed sequence has an industrial application, such as use in the diagnosis of disease.[98] Thus, in the EU, genes qualify as valid patentable subject matter through a narrowly tailored exception to a more general bar on patenting abstract scientific principles.[99]

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

91. U.S. Patent No. 5,352,775 (filed Aug. 8, 1991).

92. U.S. Patent No. 5,922,855 (filed Mar. 8, 1994); U.S. Patent No. 5,693,470 (filed June 1, 1995).

93. U.S. Patent No. 5,407,796 (filed Jan. 4, 1991).

94. *See* 569 U.S. 576, 579 (2013).

95. *See, e.g.*, Christina Gates, *Patenting the Life Sciences in the European Patent Office*, COLD SPRINGS HARBOR PERSPS. MED., Dec. 2014, at 1 (summarizing differences between U.S. and EU patent systems).

96. Convention on the Grant of European Patents art. 52, Oct. 5, 1973, 1065 U.N.T.S. 255.

97. *Id.* art. 52(2)(a). The EU's restrictions on patenting discoveries and scientific principles are reminiscent of the United States's patentable subject matter exceptions for laws of nature, natural phenomena, and abstract ideas. *See supra* Part I.B.2.

98. Directive 98/44/EC, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13–21.

99. *See, e.g.*, Paul Cole, *Patentability of Genes: A European Union Perspective*, COLD SPRING HARBOR PERSPS. MED., May 2015, at 1, 2. Still other countries, such as Japan, continue to allow for the patenting of specific types of genetic elements that have industrial and research applications. *See* Asako Saegusa, *Japanese Guidelines Specify the Terms of Gene Patents*, 401 NATURE 731 (1999) (detailing that cDNA, single nucleotide polymorphisms (SNPs), and

With the above backdrop of what gene patents are and how they fit into the broader field of patent law, this part next turns to the legal history of gene patents in the United States that led courts to initially permit and subsequently invalidate the patenting of genes.

C. A History of Gene Patents in the United States

Although the United States once upheld the validity of human genes as patentable subject matter, in 2013 the Supreme Court overturned this precedent in *Association for Molecular Pathology v. Myriad Genetics, Inc.*[100] To help better understand the rationale behind this decision, this section traces the history of the patentability of biologics in the United States. Part I.C.1 discusses older cases that demonstrated the Supreme Court's general willingness to allow natural principles to be patented so long as they were applied to something practical. Next, Part I.C.2 describes cases in which the Court pulled back from this low bar for patent eligibility of natural principles. Then, Part I.C.3 discusses important decisions from the 1980s to the early 2000s coinciding with the rise of gene sequencing technologies that helped establish the patentability of genes. Finally, Part I.C.4 details a series of landmark Supreme Court decisions in the early 2010s that upended patent subject matter jurisprudence and found that genes were unpatentable under the "laws of nature" exception.

1. Early Cases on Subject Matter Eligibility Establish a Low Bar

As with many areas of U.S. law, U.S. patent law was heavily influenced by English law at its outset. In 1841, the English Court of the Exchequer was presented with the question of whether a new method of heating blast furnaces was patentable.[101] The court indicated that a claim of not just an abstract principle, but rather an application of that principle, could be patentable.[102]

The Supreme Court followed suit twelve years later in *Le Roy v. Tatham*.[103] There, the Court faced a patent claiming a new method for manufacturing lead pipes.[104] The Court held that while the principle underlying the creation of these pipes—that is, the idea of how to create stronger metals through heat and pressure—might be abstract, the application of this principle into a specific context made it patent-eligible.[105] The Supreme Court carried on with this lenient view of patent eligibility through

expressed sequence tags (ESTs)—all types of genetic materials commonly used in research—are patentable in Japan).

100. *See* 569 U.S. 576, 579 (2013).

101. *See* Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 83–84 (2012) (summarizing Neilson v. Harford, Webster's Patent Cases 295 (1841)).

102. *See id.* at 83.

103. 55 U.S. 156 (1852).

104. *See id.* at 159.

105. *See id.*

the end of the nineteenth and into the early twentieth centuries, only requiring that abstract principles be applied to something specific.[106]

2. The Supreme Court Raises the Bar for Subject Matter Eligibility

The Court began retreating from this lax view of patent eligibility in the mid-twentieth century. In *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,[107] the Court was faced with the question of the patentability of a natural product.[108] Kalo developed a mix of naturally occurring bacteria that could be applied as fertilizer to leguminous plants.[109] Prior to Kalo's innovation, fertilizers containing multiple different species of bacteria were not used, as the different species of bacteria often inhibited one another's growth.[110] Kalo discovered a mixture of several species that avoided this problem and patented the idea of combining multiple non-inhibitory strains together.[111] The Court invalidated this patent, holding that Kalo had attempted to patent a law of nature—that certain bacteria do not inhibit each other's growth—that belonged to the "storehouse of knowledge of all men."[112] In a shift away from its jurisprudence of the nineteenth century, the Court found that Kalo's limited application of this law of nature was not enough to make it patent-eligible.[113]

The Court continued this trend with a pair of cases in the late 1970s and early 1980s. In *Parker v. Flook*,[114] the Court struck down a patent that applied a mathematical algorithm to set a temperature alarm on a device.[115] The Court held that the algorithm was not patentable subject matter, as it lacked some "inventive concept in its application."[116] By contrast, in *Diamond v. Diehr*,[117] the Court upheld a patent for a device utilizing a mathematical algorithm to set multiple different parameters in the production of molded rubber.[118] The Court reasoned that the device, and by extension the algorithm, was patentable because the algorithm was applied in a way that transformed it "to a different state or thing."[119] These cases illustrate the mid-twentieth century Court's willingness to find abstract ideas and natural principles to be patentable subject matter so long as they were applied in an inventive and concrete way. By contrast, the Court rejected efforts to patent

106. *See, e.g.*, DAVID FULTON, THE LAW AND PRACTICE RELATING TO PATENTS, TRADE MARKS AND DESIGNS 41 (2d ed. 1902) (noting that patenting of a principle simply required carrying "the principle into effect, however simple and self-evident such means may be").
107. 333 U.S. 127 (1948).
108. *Id.*
109. *Id.* at 130.
110. *See id.* at 129–30.
111. *Id.* at 130.
112. *Id.*
113. *Id.*
114. 437 U.S. 584 (1978).
115. *Id.* at 594.
116. *Id.*
117. 450 U.S. 175 (1981).
118. *Id.*
119. *Id.* at 192.

principles alone and, by extension, rejected the patenting of basic applications of a principle that did little more than simply state the principle.

3. Subject Matter Eligibility from the 1980s to the Early 2000s: Biological Products and Gene Patents

The Court applied the idea of an inventive application of natural principles to a biological organism in 1980. In *Diamond v. Chakrabarty*,[120] the Court was faced with the question of whether a genetically engineered bacterium was patentable subject matter.[121] Chakrabarty developed and attempted to patent a genetically modified strain of bacteria that could metabolize crude oil products as a means of helping clean up oil spills.[122] A patent examiner rejected Chakrabarty's claim, reasoning that bacteria are "products of nature" and thus unpatentable.[123] Chakrabarty appealed the decision, ultimately ending up before the Supreme Court.[124] The Court upheld its stance that "laws of nature, physical phenomena, and abstract ideas" were not patentable subject matter.[125] However, it found that Chakrabarty's bacterium fell outside of these categories.[126] The Court reasoned that even though bacteria were biological products, Chakrabarty had made a type of bacteria that did not occur in nature and thus was not excluded from patent eligibility.[127] The Court further indicated that the bounds of patentable subject matter were to be construed broadly and that "anything under the sun that is made by man" would likely qualify.[128]

Although the Supreme Court did not rule on the issue of patentable subject matter as it related to biologics for the next three decades, the USPTO and the Federal Circuit continued to confront the issue. In *Amgen, Inc. v. Chugai Pharmaceutical Co.*,[129] the Federal Circuit considered whether a patent covering the isolated DNA sequence of erythropoietin, a gene important in the production of red blood cells, was patentable.[130] Although the patent was challenged on grounds of novelty, nonobviousness, and disclosure, neither the plaintiff nor the Federal Circuit even considered the idea that an isolated DNA sequence was not patentable subject matter.[131] Likewise, in *In re Deuel*,[132] the Federal Circuit heard a challenge over the nonobviousness of a patent claiming an isolated DNA molecule encoding heparin-binding growth factor, a gene that plays a role in muscle repair.[133] As in *Chugai*, neither the

120. 447 U.S. 303 (1980).
121. *Id.* at 309.
122. *Id.* at 305.
123. *Id.* at 306.
124. *Id.* at 306–07.
125. *Id.* at 309.
126. *Id.*
127. *Id.* at 310.
128. *Id.* at 309 (quoting S. Rep. No. 82-1979, at 5 (1952)).
129. 927 F.2d 1200 (Fed. Cir. 1991).
130. *Id.* at 1202–04.
131. *See id.* at 1202.
132. 51 F.3d 1552 (Fed. Cir. 1995).
133. *Id.* at 1553–54.

USPTO nor the Federal Circuit even contemplated whether an isolated DNA sequence might not be patentable subject matter.[134] As evidenced through omissions in these cases, the fact that both the USPTO and the Federal Circuit ignored subject matter as a potential issue with gene patents demonstrates that they appeared to have accepted the validity of genes as patent-eligible subject matter.

The USPTO made such a view explicit in a set of federal regulations in 2001.[135] The USPTO clarified that genetic sequences isolated from their natural environment qualified as patentable subject matter.[136] Although the USPTO further clarified that gene sequences with no known function would not be patentable under the usefulness inquiry,[137] it found the act of isolating DNA from its natural environment to be enough to make it a nonnaturally occurring product and thus valid subject matter.[138] Much like in the EU, U.S. patent law in the late 1900s and early 2000s allowed for the patenting of genes through a specific exception for genetic materials.[139]

4. The Supreme Court Strikes Down Gene Patents

The Supreme Court, largely silent on the issue of patentable subject matter from the 1980s until the early 2000s, upended subject matter eligibility jurisprudence in a series of cases in the early 2010s. This section briefly summarizes *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[140] and *Alice Corp. v. CLS Bank International*,[141] two seminal cases in modern patent subject matter eligibility. It then examines in detail *Association for Molecular Pathology v. Myriad Genetics, Inc.*,[142] in which the Court held that isolated genetic sequences were naturally occurring products and thus not patent-eligible subject matter.[143]

a. Mayo *and* Alice*: The Court Takes a Hard Stance on Laws of Nature and Abstract Ideas*

The Court reassessed its position on patent subject matter exclusions in *Mayo*.[144] In that case, Prometheus Laboratories devised and patented a method for calibrating drug dosage in patients being treated for autoimmune diseases, such as Crohn's disease.[145] Typical treatment of these diseases includes administration of thiopurine, an immunosuppressant.[146] However,

134. *See id.*
135. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).
136. *Id.* at 1093.
137. *Id.*
138. *Id.*
139. *See supra* Part I.B.5.
140. 566 U.S. 66 (2012).
141. 573 U.S. 208 (2014).
142. 569 U.S. 576 (2013).
143. *Id.* at 591.
144. 566 U.S. at 66.
145. *Id.* at 73.
146. *See id.*

as different individuals metabolize thiopurine at different rates, finding an effective dosage of the drug can prove tricky.[147] Prometheus developed a method for administering thiopurine to patients and then measuring thiopurine metabolites in a patient's blood to see how they metabolized the drug.[148] Thiopurine dosage could then be adjusted in a patient-specific manner based on an individual's metabolism.[149] The Supreme Court found that Prometheus's patent attempted to claim an underlying law of nature and was thus outside the realm of patentable subject matter.[150] Specifically, the Court found that Prometheus's patent effectively restated a natural law—that the level of metabolites in a person's blood reflect the rate at which they metabolize something—and then said to "apply it."[151] Absent some additional inventive step that transforms the "laws of nature, natural phenomena, [or] abstract ideas" into something more concrete, the Court held that such applications were not patentable.[152]

The Court solidified their stance two years later in *Alice Corp. v. CLS Bank International*. In *Alice*, the Court was faced with assessing whether a computer program implementing an abstract idea to facilitate financial transactions was sufficiently inventive to make it patentable subject matter.[153] The Court reiterated its holding in *Mayo*, finding that mere application of an abstract idea without a more inventive step did not make the idea patentable subject matter.[154] The Court further formalized the test first laid down in *Mayo*, holding that, for inventions directed to the three excluded categories of laws of nature, natural phenomena, and abstract ideas, a court must ask whether the claimed patent transforms the unpatentable principle into something patentable through an inventive step.[155] If such a transformation occurs, the claim can be considered eligible subject matter despite being a natural or abstract principle.[156] Alternatively, if the claim merely says to apply the principle, such an application does not transform the principle and the claim should not be considered valid subject matter.[157]

b. Myriad*: The Downfall of Gene Patents*

Between the *Mayo* and *Alice* decisions, the Court heard a case on the patentability of genetic sequences.[158] In the 1990s, Myriad Genetics patented the sequences for BRCA1 and BRCA2, genes that, when mutated,

147. *See id.*
148. *Id.* at 74.
149. *Id.* at 74–75.
150. *Id.* at 77.
151. *Id.* at 72.
152. *Id.* at 82.
153. *See* Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 212 (2014).
154. *Id.* at 217.
155. *See id.* at 217–18.
156. *See id.* at 221.
157. *See id.* at 221–22.
158. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

predispose an individual to developing breast cancer.[159] Myriad directly offered testing for BRCA1 and BRCA2 mutations to patients, as well as offering licensing agreements to other medical groups to allow these groups to test patients in-house for such mutations.[160] However, Myriad's licensing agreements were limited in terms of the number of mutations and identity of patients that could be tested.[161] These limitations meant that, in effect, if a patient wanted to be screened for BRCA mutations, they had to go through Myriad.[162] Myriad actively enforced its patents over BRCA1 and BRCA2 to prevent others from infringing by offering their own BRCA tests.[163]

In 2009, a group of plaintiffs sued Myriad, alleging that its patents over the BRCA1 and BRCA2 gene sequences, and by extension the right to test patients for mutations thereof, were invalid for covering unpatentable subject matter.[164] Among the plaintiffs were a number of doctors who had been blocked from administering their own BRCA tests by Myriad; patients who either could not afford Myriad's tests or who desired a second opinion of their results but could not get it, as Myriad was the sole provider of BRCA testing; and nonprofit groups dedicated to advocating for women's health or to advancing medical research, such as the Association for Molecular Pathology (AMP).[165] The plaintiffs were further backed by groups, such as the ACLU, who saw the issue of gene patents as a civil rights issue over bodily autonomy.[166] The plaintiffs sued the USPTO and Myriad Genetics, alleging that Myriad's BRCA patents were invalid for attempting to patent a law of nature.[167] With the backing of amici across the biotech industry, academia, and the patent bar, the defendants argued that the process of isolating DNA from its natural environment turned it into something made by man and thus transformed it into patent-eligible subject matter.[168]

The U.S. District Court for the Southern District of New York found that Myriad's BRCA patents covered ineligible subject matter.[169] The court considered both the nature of the isolated DNA itself and the process of comparing isolated BRCA sequences to a healthy reference when checking for mutations.[170] Concerning its nature, the court noted that DNA was a composition of matter with special properties as both a chemical substance

159. *See* Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off., 702 F. Supp. 2d 181, 203 (S.D.N.Y. 2010), *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., 569 U.S. 576 (2013); *see supra* Part I.B.4.

160. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 203–05.

161. *Id.* at 205.

162. *See id.*

163. *Id.* at 205–06.

164. *Id.* at 184.

165. *Id.* at 186–89.

166. *See* Jorge L. Contreras, *The Civil Rights Challenge to Gene Patenting*, HARV. L. PETRIE-FLOM CTR. (Oct. 19, 2021), https://blog.petrieflom.law.harvard.edu/2021/10/19/myriad-gene-patenting-civil-rights/ [https://perma.cc/V3ZQ-Z56Z].

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

168. *Id.* at 189–92.

169. *Id.* at 232, 236–37.

170. *Id.* at 220.

and a carrier of information.[171] The court observed that although isolation of a specific gene sequence might chemically alter the substance, it does nothing to change the "defining characteristic"—that is, the genetic information—of the DNA.[172] The court reasoned that Myriad's patents covering isolated BRCA sequences were effectively equivalent to claiming naturally occurring biologics akin to the claims in *Funk Bros.*[173] The court thus found that Myriad's patented claims to the BRCA gene sequences themselves covered unpatentable subject matter and were thus invalid.[174]

The district court further held that Myriad's claims over comparing patient BRCA sequences to healthy references were likewise ineligible for patent protection.[175] Drawing parallels to cases such as *Diehr* and *Flook*, the court held that the process of comparing genetic sequences was a mental process that, absent something more, was too abstract to be patent-eligible.[176]

On appeal, the Federal Circuit reversed the district court's ruling on isolated DNA sequences, holding that the process of isolating DNA from a patient rendered it "not a purified form of a natural material, but a distinct chemical entity" that is "markedly different . . . from the native DNA . . . [and], therefore, patentable subject matter."[177] The Federal Circuit, however, affirmed the district court's invalidation of the claim over comparing and analyzing patient DNA sequences, finding that this claim covered an unpatentable mental process.[178] Thus, even though Myriad no longer had the exclusive right to analyze patients' BRCA sequences, these rulings effectively upheld Myriad's monopoly on testing BRCA mutations because Myriad maintained the exclusive right to isolate the genes for sequencing.[179] On remand from the Supreme Court to reconsider its findings in light of *Mayo*, the Federal Circuit maintained that isolated DNA was patent-eligible and the process of comparing DNA sequences was not.[180]

Both the plaintiffs and Myriad appealed the Federal Circuit's ruling.[181] The Supreme Court assessed the nature of Myriad's isolated BRCA gene

171. *Id.* at 228.

172. *Id.* at 229. The alteration of the substance that the court referred to occurs when the chemical bonds of a DNA molecule are physically broken as part of the isolation process. *Id.*

173. *Id.*

174. *Id.* at 232.

175. *Id.* at 236–37.

176. *Id.* at 233. The district court case was decided before *Mayo* and thus the court did not engage in *Mayo*'s inventive step analysis.

177. Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off., 653 F.3d 1329, 1333, 1352–54 (Fed. Cir. 2011), *cert. granted, judgment vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 566 U.S. 902 (2012), *opinion vacated, appeal reinstated*, 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. 569 U.S. 576 (2013).

178. *See id.* at 1355.

179. *Id.*

180. Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off., 689 F.3d 1303, 1308 (Fed. Cir. 2012), *aff'd in part, rev'd in part sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

181. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 586 (2013).

sequences and came down on the same side as the district court.[182] Finding that DNA must be thought of in its dual role as a chemical composition of matter and carrier of information, the Court agreed with the district court that isolation of a DNA sequence did not render the underlying information contained therein distinct from its naturally occurring counterpart and that "separating that gene from its surrounding genetic material is not an act of invention."[183] The Court held that Myriad's claim of isolated DNA fell squarely within the "laws of nature" exception to patentable subject matter and that Myriad's patents were thus invalid.[184] As an aside, the Court also held that Myriad's claims over synthetically created "cDNA," included in the BRCA patents, were valid patent subject matter because the cDNA was not naturally occurring.[185] Thus, the Court indicated that although genetic material itself might be patent-eligible, genetic information based on the isolation of an individual's DNA alone was no longer valid subject matter for patents.[186]

The Supreme Court upended decades of practice in the biotech industry when it invalidated gene patents in *Myriad*.[187] Although the Court did not issue a categorical ban on patenting genetic material—thus allowing some niche uses to still be patent-eligible[188]—at the time, its decision in *Myriad* seemed likely to have profound effects on the research and commercialization of genetic information.

II. THE FALLOUT FROM *MYRIAD* AND DEBATE OVER THE PATENTABILITY OF GENES

Although many strongly believed that *Myriad* signaled a sea change in patent law and the biotech industry,[189] the initial effects were not necessarily clear. This part explores studies conducted since *Myriad* that have tried to make sense of its ramifications. Part II.A details several studies that inform the debate over the patent eligibility of genes. Part II.B traces arguments that proponents of gene patent eligibility have raised in response to such studies and details several proposals put forward for reestablishing gene patentability. Part II.C presents arguments from opponents of gene patents.

182. *Id.* at 580.
183. *Id.* at 591.
184. *Id.* at 591.
185. *Id.* at 594–95.
186. *See id.* at 596.
187. *See, e.g.*, Gene Quinn, *Why SCOTUS* Myriad *Ruling Overrules* Chakrabarty, IPWATCHDOG (July 14, 2013, 8:30 AM), https://ipwatchdog.com/2013/07/14/why-scotus-myriad-ruling-overrules-chakrabarty/id=43249/ [https://perma.cc/A49Y-BHJJ] (speculating about what *Myriad* would mean for the biotech industry).
188. *See, e.g.*, Illumina, Inc. v. Ariosa Diagnostics, Inc., 967 F.3d 1319, 1321 (Fed. Cir. 2020) (indicating that the process of isolating fetal DNA from a mother based on size is patent-eligible subject matter but noting that the phenomenon of difference in DNA size between mother and child is not); Oxford Immunotec Ltd. v. Qiagen, Inc., No. 15-13124, 2016 U.S. Dist. LEXIS 135971, at *5 (D. Mass. Sep. 30, 2016) (indicating that a genetically modified protein used in a diagnostic kit might be patent-eligible subject matter).
189. *See, e.g.*, Quinn, *supra* note 187; Shahrokh Falati, *Patent Eligibility of Disease Diagnosis*, 21 N.C. J.L. & TECH. 63, 66–67 (2020).

A. Studies Assessing the Aftermath of Myriad

Although the implications of *Myriad* appeared significant at the outset, the specific consequences of the decision were, and to a substantial degree still are, unclear. This section highlights some of the most salient issues concerning gene patents, including investments in the biotech industry, continued research into medical diagnostics, and the impact that gene patents had on follow-on innovation.

1. *Myriad* Discourages Investment in Biotechs

One of the main disputes following *Myriad* was over what effect the decision would have on investments within the biotech industry. Although some argued that *Myriad* would open up the industry to greater collaboration,[190] others saw *Myriad* as a harbinger of the downfall of American biotechs.[191]

Several studies have tried to get a handle on what impact *Myriad* actually had on the biotech industry. In "Patent Eligibility and Investment," Professor David O. Taylor surveyed 475 venture capital and investment firms to find out.[192] Taylor found that investors were generally less willing to invest in biotechs that did not have patent protection covering their most important products.[193] He further found that almost 40 percent of investors who were aware of the Supreme Court's decisions in *Myriad*, *Mayo*, and *Alice* believed that the decisions had negative effects on the firm's existing investments; additionally, approximately 33 percent of firms indicated that these decisions caused them to shift investments away from impacted industries—especially biotechs and pharmaceutical companies.[194] As a whole, the study indicated a general hesitancy of investment firms to back biotechs following *Myriad*.[195]

In similar studies, others have found that, although investment in the biotech field continues to grow, it has done so at a slower rate after *Myriad*. Looking at venture capital investment data, A. Sasha Hoyt found that although investments in the biotech industry were higher than before *Myriad*, they were growing at a slower rate compared to other industries.[196] Hoyt concluded that, had the Court not upended subject matter eligibility in *Myriad*, *Mayo*, and *Alice*, investments in disease diagnostic technologies would be $9.3 billion greater than their current level.[197] Likewise, from

190. *See, e.g.*, Stephanie Huang, Note, *Silly Gene Patent Is Not My Lover: A Retrospective Analysis of* Myriad, 34 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 160, 191 (2023).

191. *See, e.g.*, Quinn, *supra* note 187.

192. David O. Taylor, *Patent Eligibility and Investment*, 41 CARDOZO L. REV. 2019, 2027 (2020).

193. *Id.*

194. *Id.* at 2028–29.

195. *See id.* at 2030.

196. A. Sasha Hoyt, Note, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 79 WASH. & LEE L. REV. 397, 445–46 (2022).

197. *Id.* at 446.

analyzing venture capital data from 2004 to 2017, Professor Mark F. Schultz found that although venture capital investments have expanded in recent years, biotech's share of those investments dropped significantly following *Myriad*.[198] Although biotechs and pharmaceutical companies constituted over 50 percent of the market share of startup investment in 2004, by 2017 their share had fallen to about 28 percent.[199] Schultz determined that, absent some change in patent policy, a shift in investments away from biotechs would have a profound impact on the industry.[200]

Attempting to view the issue from a different angle, Professors Jay Kesan and Runhua Wang examined the impact of *Myriad* from the USPTO's perspective.[201] They found that, following *Myriad*, *Mayo*, and *Alice*, the USPTO experienced both a lower rate of patent applications and a higher rate of rejection of those applications than before these decisions.[202] This effect was disproportionately felt in the fields most affected by the Supreme Court's decisions, such as the biotech industry.[203] Kesan and Wang concluded that both the greater uncertainty around patent approval and the increase in time and resources necessary to get a patent approved led to a reduction in the number of patent applications from biotechs.[204]

Collectively, these studies indicate that the Supreme Court's decisions in *Myriad*, *Mayo*, and *Alice* have had a general chilling effect on investments in the biotech industry. They suggest that increased difficulties and uncertainties in the ability of biotechs to obtain patents has led to fewer biotechs patenting their inventions which in turn has led to less investment from venture capital firms.

2. *Myriad* Caused Multiple Genetic Diagnostics to Be Abandoned

Another major concern following *Myriad* was that it would stifle the development of medical diagnostics and treatments. Although some believed that *Myriad* would lead to decreased costs for consumers due to greater competition in the marketplace for gene-based medicines,[205] others feared that the decision could lead to an overall decrease in the research that made these diagnostics and treatments possible.[206]

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198. MARK F. SCHULTZ, ALL. FOR U.S. STARTUPS & INVENTORS FOR JOBS, EXECUTIVE SUMMARY: THE IMPORTANCE OF AN EFFECTIVE AND RELIABLE PATENT SYSTEM TO INVESTMENT IN CRITICAL TECHNOLOGIES 4 (2020).

199. *Id.*

200. *Id.*

201. Jay P. Kesan & Runhua Wang, *Eligible Subject Matter at the Patent Office: An Empirical Study of the Influence of* Alice *on Patent Examiners and Patent Applicants*, 105 MINN. L. REV. 527 (2020).

202. *Id.* at 593.

203. *Id.* at 589.

204. *Id.* at 604.

205. *See, e.g.*, Jorge Contreras, *Another Legislative Attempt to Revive Gene Patenting*, HARV. L. PETRIE-FLOM CTR. (Aug. 4, 2022), https://blog.petrieflom.law.harvard.edu/2022/08/04/another-legislative-attempt-to-revive-gene-patenting/ [https://perma.cc/3ZX3-LPNA].

206. *See, e.g.*, Paul Michel, David Kappos, Corey Salsberg & Matthew Dowd, *Presenting the Evidence for Patent Eligibility Reform: Part III—Case Studies and Litigation Data*

Case studies of specific instances of research abandoned post-*Myriad* abound. In *Is the Sky Really Falling?:* Myriad *and Its Impact on Therapeutic Development*, Taylor Beardall details the story of Mambalgin-1, a snake toxin with potential application as a painkiller that could serve as an opioid alternative in development at the time of *Myriad*.[207] Following *Myriad*, the researchers attempting to develop Mambalgin-1 were unable to patent their discoveries and, in the absence of patent protection, were unable to secure investments necessary to continue their work.[208] The team ultimately determined Mambalgin-1 was commercially unviable and abandoned the project.[209]

Many similar stories exist. Retired Judge Paul Michel, former Director of the USPTO David Kappos, and others detail a number of these, including: patents for genes that could predict flare-ups of Lupus that were invalidated and abandoned post-*Myriad*; a patent for the diagnosis of Noonan syndrome—a rare genetic disorder in infants that causes developmental abnormalities and heart defects—that was held invalid post-*Myriad* and led to the patent holders abandoning efforts to improve testing; and a gene-based Schizophrenia diagnostic that was so limited in scope by *Mayo* and *Myriad* that it failed to attract investment.[210] Likewise, in a 2017 study, Kevin Madigan and Professor Adam Mossoff found that of 1,310 patent applications rejected by the USPTO since 2014 but approved by either the EPO or Chinese Patent Office, nearly half related to the diagnostics of diseases such as cancer, Alzheimer's, and diabetes.[211] Although largely anecdotal, these stories demonstrate that biotechs were compelled to abandon their research into disease diagnostics and treatments in the wake of *Myriad* for fear of an inability to procure the funding needed to see their work through to completion.

On the other side of this issue, Professor Jorge Contreras argues that *Myriad* helped to significantly reduce the costs of gene-based diagnostics like Myriad's BRCA testing.[212] Although Myriad's BRCA testing could cost upwards of $3,000 when Myriad was the exclusive provider, modern consumers can test their BRCA genes for around $100.[213] Organizations such as the ACLU have likewise suggested that *Myriad* led to a decrease in

Highlight Additional Evidence of Harm, IPWATCHDOG (Oct. 18, 2022, 12:15 PM), https://ipwatchdog.com/2022/10/18/presenting-evidence-patent-eligibility-reform-part-iii-case-studies-litigation-data-highlight-additional-evidence-harm/id=152193/# [https://perma.cc/8D6V-BYQG].

207. Taylor Beardall, Note, *Is the Sky Really Falling?:* Myriad *and Its Impact on Therapeutic Development*, 34 STAN. L. & POL'Y REV. 311 (2023).

208. *Id.* at 334–35.

209. *Id.* at 335.

210. *See* Michel et al., *supra* note 206.

211. *See* Michel et al., *supra* note 83 (describing the results of Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939 (2017)).

212. *See* Contreras, *supra* note 205.

213. *Id.*

healthcare costs.[214] However, it should be noted that the cost of sequencing a human genome has dropped dramatically in the past two decades, largely due to advances in sequencing technologies.[215] Thus, the extent to which *Myriad* and the invalidation of gene patents were responsible for this drop in gene-based diagnostic healthcare costs is unclear.

Collectively, these examples suggest that although *Myriad* might have contributed to the reduction in DNA sequencing costs for existing genetic diagnostics, it also stymied the introduction of new diagnostics into the marketplace.

3. *Myriad* Did Not Have as Profound an Impact on Research as Was Speculated

The impetus for the plaintiffs to bring suit in *Myriad* was partially due to concerns over the effect gene patents had on research related to patented genes.[216] The plaintiffs' contention, among other things, was that gene patents like those held by Myriad limited academic investigation into the underlying patented material.[217] Several studies after *Myriad* have analyzed the problem of what effect gene patents had on research.

In 2019, Professors Bhaven Sampat and Heidi Williams performed a comprehensive study in which they asked if gene patents actually suppressed follow-on innovations.[218] They looked at both accepted and rejected gene patent applications from 2000 to 2013 and tracked subsequent academic and commercial uses of the corresponding genes.[219] Professors Sampat and Williams found that patenting did not seem to have a substantial effect on the rate that a gene was used for research or commercial purposes.[220] They also found that most follow-on innovations were performed by someone other than the patent holder, suggesting that, before *Myriad*, licensing agreements worked well enough to provide access to patented genetic information.[221] In sum, the authors concluded that gene patents did not have as strong an

214. Press Release, ACLU, ACLU Condemns Congressional Bill to Patent Human Genes, Nature, and Abstract Ideas (June 23, 2023), https://www.aclu.org/press-releases/aclu-condemns-congressional-bill-to-patent-human-genes-nature-and-abstract-ideas [https://perma.cc/T2JJ-778V].

215. *The Cost of Sequencing a Human Genome*, NAT'L HUM. GENOME RSCH. INST. (Nov. 1, 2021), https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost [https://perma.cc/D68X-BCT5] (indicating that the cost of sequencing a human genome has fallen from approximately $14 million in 2006 to just below $1,500 in 2016).

216. Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off., 702 F. Supp. 2d 181, 208 (S.D.N.Y. 2010), *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., 569 U.S. 576 (2013).

217. *See supra* notes 164–67 and accompanying text.

218. *See generally* Bhaven Sampat & Heidi L. Williams, *How Do Patents Affect Follow-On Innovation?: Evidence From the Human Genome*, 109 AM. ECON. REV. 203 (2019).

219. *Id.* at 209.

220. *Id.* at 229.

221. *Id.* at 206.

inhibitory effect on follow-on innovations as assumed by the Court in *Myriad*.[222]

These results have recently been corroborated by Professors Janet Freilich and Sepehr Shahshahani.[223] In their study, the authors replicated the analysis performed by Professors Sampat and Williams while further disaggregating follow-on innovations into those that infringed on existing gene patents and those that did not.[224] They found that 87 percent of follow-on innovations did not infringe existing patents.[225] They further found that gene patents that were not expiring soon had a positive correlation with non-infringing follow-on innovation, implying that patenting a gene might have actually increased research into that gene by others.[226] This study demonstrated that gene patents had a relatively limited effect on follow-on innovation, as most follow-on innovations did not infringe and thus were not affected by the patent.[227]

Collectively, these studies belie the notion that gene patents like those in *Myriad* had a significant inhibitory effect on subsequent research. Instead, they suggest that, in practice, gene patents had a negligible impact on outside research into the patented genes.

B. Proponents of Gene Patents Argue for the Reversal of Myriad

Fierce debate has sprung up in the wake of *Myriad* over whether the Supreme Court was correct in holding genes unpatentable and whether someone—either the Court or Congress—needs to fix gene patentability. Proponents of gene patents argue that *Myriad* has had devastating effects on the American biotech industry and that something must be done to salvage the situation.[228] This section first details some of the arguments proponents of gene patents have put forward to justify a reintroduction of genes as patent-eligible subject matter. It then outlines several proposed solutions for achieving this goal.

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222. *Id.*
223. Freilich & Shahshahani, *supra* note 44, at 1.
224. *Id.* at 4–5.
225. *Id.* at 5.
226. *Id.* at 8–9.
227. *Id.* at 11.
228. *See, e.g.*, Emily M. Morris, *A Response to 'Another Legislative Attempt to Revive Gene Patenting'*, HARV. L. PETRIE-FLOM CTR. (Aug. 26, 2022), https://blog.petrieflom.law.harvard.edu/2022/08/26/a-response-to-another-legislative-attempt-to-revive-gene-patenting/ [https://perma.cc/Y6L6-JXD8]; Paul Michel, David Kappos, Corey Salsberg & Matthew Dowd, *Presenting the Evidence for Patent Eligibility Reform: Part IV—Uncertainty Is Burdening Litigants and Courts, Threatening U.S. Competitiveness and National Security*, IPWATCHDOG (Oct. 26, 2022, 3:15 PM), https://ipwatchdog.com/2022/10/26/presenting-evidence-patent-eligibility-reform-part-iv-uncertainty-burdening-litigants-courts-threatening-u-s-competitiveness-national-security/ [https://perma.cc/2B23-GRAW].

1. Arguments in Favor of Reestablishing Gene Patents

Proponents of gene patent eligibility have raised several concerns that argue for the ability to patent genes. Chief among them are fears that the lack of gene patentability is (1) eroding America's place in the world market for biotech innovation and (2) on balance, harming access to healthcare.[229]

Those who support the ability to patent genes are troubled by the shift in capital investment away from the biotech industry.[230] Studies like Professor Taylor's have caused them to raise the alarm over the United States's place as a global leader in biotech.[231] Their basic argument is that, if genes cannot be patented, investment firms will be less willing to invest in biotechs working on gene-based technologies since such investments will be riskier.[232] This lack of investment, in their view, will lead to an overall dampening effect on the industry.[233] Meanwhile, other countries, such as the EU, Japan, and China, continue to uphold the validity of gene patents.[234] Investment firms will thus be motivated to shift resources abroad.[235] The United States has enjoyed a place of prominence in the biotech industry for the last half century.[236] Some attribute this in part to the United States's liberal grant of gene patent rights pre-*Myriad* that spurred the creation of some of the United States's major biotechs.[237] Proponents argue that, if the Court's ban on gene patents is not overcome soon, the United States will lose its position in the global biotech marketplace and that, if this were to happen, it might never be able to catch back up to other countries.[238]

Proponents further contend that gene patents ultimately do serve the purpose of promoting access to healthcare.[239] They argue that the lack of development of gene-based diagnostics and therapeutics actually deprives people of the ability to test and treat diseases because less research is going into developing those tests and treatments.[240] Noting examples like the Lupus flare-up indicator or the Noonan syndrome diagnostic,[241] proponents argue that *Myriad* has had the effect of killing development of these and other technologies that, had *Myriad* been decided differently, might be on the market today.[242] Proponents further note that although patented gene technologies can lead to prohibitively high costs for some, as was the case with Myriad and BRCA testing, this issue is actually one of insurance

229. *See* Michel et al., *supra* note 228.
230. *See id.*
231. *See id.*
232. *See id.*
233. *See id.*
234. *See id.*
235. *See id.*
236. *See* David S. Olson & Fabrizio Ducci, *Patenting Genetic Information*, 98 IND. L.J. 1181, 1210 (2023).
237. *See id.* at 1205, 1210.
238. *See* Michel et al., *supra* note 228.
239. *See* Morris, *supra* note 228.
240. *See id.*
241. *See* Michel et al., *supra* note 206.
242. *See id.*

coverage, not gene patentability.[243] They suggest that issues over specific individuals being unable to afford tests or treatment because insurance will not cover it should not be grounds to deny the general public access to potentially lifesaving technologies.[244]

2. Proposed Solutions to Reestablish Gene Patents

Proponents have proposed a variety of ways to reintroduce gene patents. These proposals vary considerably—both over who should promote the patentability of genes and what additional restrictions, if any, should be placed on gene patents. This section briefly details several such proposals.

a. Wait for the Supreme Court to Reverse Myriad

Perhaps the most jurisprudentially simple solution to the issue of gene patents is to wait for the Supreme Court to reverse *Myriad* and related patent subject matter eligibility cases. This solution would leave the majority of patent law jurisprudence in place and, depending on how the Court crafts its decision, could be tailored to fit specific issues like gene patents, while leaving broader prohibitions on patenting laws of nature in place.[245]

b. Congressional Legislation: The Patent Eligibility Restoration Act of 2023

Many have implored Congress to fix American patent law.[246] Senators Thom Tillis and Chris Coons have taken up this call to arms, proposing a legislative amendment to the Patent Act.[247] Their bill, known as the Patent Eligibility Restoration Act of 2023, would amend 35 U.S.C. § 101 to overrule several of the Court's recent holdings.[248] As it specifically pertains to gene patents, the bill would prohibit the patenting of unmodified human genes but then clarify that the process of isolating a human gene from an individual's body counts as modifying it.[249] The bill further maintains exceptions to patent eligibility, including restricting the patenting of mathematical

243. *See* Morris, *supra* note 228.

244. *See id.*

245. *See* Olson & Ducci, *supra* note 236, at 1216.

246. *See, e.g.*, Berkheimer v. HP Inc., 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie, J., concurring); *The State of Patent Eligibility in America: Part I Before the S. Comm. on Intell. Prop.*, 116th Cong. 1 (2019) (statement of Hon. Paul R. Michel (Ret.)).

247. Press Release, Sen. Thom Tillis, Tillis, Coons Introduce Landmark Legislation to Restore American Innovation (June 22, 2023), https://www.tillis.senate.gov/2023/6/tillis-coons-introduce-landmark-legislation-to-restore-american-innovation [https://perma.cc/5URX-2Y66]. Several other proposed legislative amendments seeking to amend 35 U.S.C. § 101 exist. *See, e.g.*, *Joint AIPLA-IPO Proposal on Patent Eligibility*, AM. INTELL. PROP. L. ASS'N (May 2018), https://www.aipla.org/advocacy/legislative/joint-aipla-ipo-proposal-on-patent-eligibility [https://perma.cc/AB4A-GYFM]. For simplicity, this Note will only focus on the June 2023 version of the Patent Eligibility Restoration Act.

248. Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. (2023).

249. *Id.* §§ 101(b)(1)(D), 101(b)(2)(A).

formulas, mental processes, and natural materials.[250] Thus, in the context of human genes, the bill would essentially overrule *Myriad* and restore gene patents to their pre-2013 status as potentially valid so long as an isolated gene is claimed.

c. Generate a New Field of Law for Gene Patents

Another proposed solution includes creating a special section in the Patent Act for genes.[251] Precedent exists in other fields of U.S. intellectual property law for such a solution, including a special subsection of copyright law created by Congress to regulate computer silicon chip design[252] and another for ship vessel hull design.[253] Proponents of such an idea argue that genes do not fit neatly into patent law and, as such, Congress should consider creating a new, special carveout of patent law specifically for gene patents.[254] They argue that it can be crafted to fit the specific needs and concerns around gene patents more closely than current patent law, thus creating fewer issues than overruling *Myriad* would.[255] Opponents of such an idea argue that the area of copyright law regulating computer chips failed to keep up with rapidly developing technologies and, as a result, such a regime ultimately failed.[256] They further indicate that the special copyright laws were too narrow in scope and thus had limited applicability to the computer chip industry.[257]

d. Passing a Narrow Amendment Inspired by Foreign Patent Regimes

Some have advocated for a more narrowly tailored exception to patent subject matter explicitly permitting the patenting of genetic materials akin to the EU patent regime.[258] Advocates of this position argue that such a system continues to work in the EU and that the EU biotech industry is starting to outpace the U.S. biotech industry due to greater economic incentives in Europe.[259]

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250. *Id.* § 101(b)(1). These exceptions are roughly analogous to the Court's current "laws of nature, natural phenomena, and abstract ideas" exceptions.

251. *See* Olson & Ducci, *supra* note 236, at 1221–22.

252. 17 U.S.C. §§ 901–14.

253. *Id.* §§ 1301–32.

254. *See* Olson & Ducci, *supra* note 236, at 1221.

255. *See id.* at 1221–22.

256. *See* Simone A. Rose, *Semiconductor Chips, Genes, and Stem Cells: New Wine for New Bottles?*, 38 AM. J.L. & MED. 113, 145 (2012).

257. *See* Timothy T. Hsieh, *A Bridge Between Copyright and Patent Law: Towards a Modern Day Reapplication of the Semiconductor Chip Protection Act*, 28 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 729, 734 (2018).

258. *See, e.g.*, Benjamin Foote-Huth, *Biomarkers as Subject Matter: A Tailored Solution for Patent Ineligibility in Medical Diagnostics*, 73 CASE W. RES. L. REV. 139 (2022); Ilija Ilijovski, *Perfecting U.S. Patentable Subject Matter—Merging the European Approach and the American Principles*, 19 CHI.-KENT J. INTELL. PROP. 178, 182 (2020).

259. *See* Ilijovski, *supra* note 258, at 207; Jessica C. Lai, Myriad Genetics *and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision*, 5 U.C. IRVINE L. REV. 1041, 1067 (2015).

However, the EU system is not free of issues. Much like the U.S. system before *Myriad*, EU patents protecting gene-based diagnostics have the potential to limit healthcare access due to increased costs.[260] Research into this issue has indicated that, although gene patents do lead some labs in the EU to decline offering certain tests to patients, such restrictions are rare under the EU system and occur at a much lower rate than was typical in the United States at the time the *Myriad* case was brought.[261] Additionally, like the U.S. system, the EU legislative grant for gene patents is still subject to judicial determinations of which patents qualify.[262] However, given the narrow scope of the EU gene patent grant, judicial interpretation tends to be limited in nature and has not had as seismic an effect in the EU as decisions like *Myriad* have had in the United States.[263]

Given similarities between the current EU system and the pre-*Myriad* U.S. system, advocates argue that a narrow, EU-style exception would successfully restore gene patents and bring the United States back in line with other major gene patent regimes around the world.[264]

C. Opponents of Gene Patents Think Myriad *Was Correctly Decided*

Opponents of gene patentability see *Myriad* as a huge win for individual rights. This section details arguments that opponents of gene patents have raised in support of continuing to hold genes as invalid patent subject matter. It then briefly summarizes the state of intellectual property protections for genetic information since *Myriad*, including why opponents of gene patents think gene-based diagnostics are adequately protected under trade secret law.

1. Arguments Against Gene Patents

Opponents of gene patents contend that the Supreme Court was correct in holding genes to be invalid patent subject matter and that its decision in *Myriad* should be left undisturbed.[265] They argue that to overturn *Myriad* would (1) be to deny individuals the rights to access information in their own body, (2) again deprive the poorest the ability to receive diagnoses and treatment for their diseases, and (3) stymie research into genetics that is more important than ever in the wake of COVID-19.[266]

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260. *See, e.g.*, Johnathon Liddicoat, Kathleen Liddell, Arlie H. McCarthy, Stuart Hogarth, Mateo Aboy, Dianne Nicol, Simon Patton & Michael M. Hopkins, *Continental Drift?: Do European Clinical Genetic Testing Laboratories Have a Patent Problem?*, 27 EUR. J. HUM. GENETICS 997 (2019).

261. *See id.* at 1002.

262. *See, e.g.*, Lai, *supra* note 259, at 1049–50 (summarizing some of the types of cases EU courts have heard in addressing gene patent issues).

263. *See, e.g.*, *id.* (discussing EU cases in which the courts debated whether an industrial application of a gene required some financial benefit to qualify for patentability).

264. *See* Ilijovski, *supra* note 258, at 207.

265. *See, e.g.*, Contreras, *supra* note 205.

266. *See, e.g.*, Press Release, ACLU, *supra* note 214; Contreras, *supra* note 205; Jorge L. Contreras, *COVID-19 as an Example of Why Genomic Sequence Data Should Remain Patent Ineligible* (Univ. of Utah Coll. of L. Rsch. Paper No. 432, 2021), https://ssrn.com/abstract=3808319 [https://perma.cc/V6R3-4C8U].

Opponents of gene patents are as concerned with the implications of patenting a human gene now as when they brought suit in the first place.[267] Specifically, they raise concerns over gene patents depriving individuals of the right to know their own genetic information.[268] They argue that the right to know one's genetic information is a basic human right and that gene patents would effectively strip this right away and hand it to corporations.[269] Thus, in their view, gene patents are an issue of bodily autonomy.[270]

Opponents are also concerned with healthcare costs.[271] Noting that a number of plaintiffs in the original *Myriad* suit were women who could not afford Myriad's BRCA testing due to a lack of insurance coverage,[272] they argue that reversing *Myriad* would reintroduce monopolies over genetic testing and drive up healthcare costs.[273] They argue that *Myriad* opened the market to competition over genetic testing and that, as a result, the sequencing of BRCA mutations dropped from over $3,000 before the lawsuit to around $100 today.[274]

Opponents are further concerned with the implications of reversing *Myriad* for genetic research.[275] They argue that *Myriad* helped promote more open access to genetic information that helped to spur research into genetic diseases and that overturning *Myriad* could dampen research endeavors.[276] They are especially concerned with research into viruses like SARS-CoV-2.[277] COVID-19 testing and vaccines were developed at astonishing speed largely because researchers from around the world openly shared information about the virus, including its genetic sequence.[278] Opponents of gene patents fear that, had gene patents been allowed at the time, an unscrupulous researcher or biotech that was the first to sequence the viral genome could have patented it and then blocked research into the virus by others while they tried to develop a vaccine.[279] Had they ultimately been

267. *See* Press Release, ACLU, *supra* note 214.

268. *See id.*

269. *See id.* Although instances of gene patents totally prohibiting an individual from sequencing their own genetic information were rare, in the case of Myriad and BRCA testing, patients were unable to have their BRCA genes sequenced unless they went through either Myriad or someone who licensed Myriad's tests. *See* Merz & Cho, *supra* note 8, at 205–06.

270. *See* Press Release, ACLU, *supra* note 214.

271. *See id.*; Contreras, *supra* note 205.

272. *See* Contreras, *supra* note 205; *see also* Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off., 702 F. Supp. 2d 181, 186–89 (S.D.N.Y. 2010), *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., 569 U.S. 576 (2013) (reciting plaintiffs in the *Myriad* suit).

273. *See* Press Release, ACLU, *supra* note 214.

274. *See* Contreras, *supra* note 205.

275. *See* Press Release, ACLU, *supra* note 214.

276. *See id.*

277. *See* Contreras, *supra* note 266, at 139.

278. *See id.* at 138–39; *see also Can Open Science Speed Up the Search for a COVID-19 Vaccine?: 5 Things You Need to Know*, U.N. NEWS (Nov. 10, 2020), https://news.un.org/en/story/2020/11/1077162 [https://perma.cc/3PBU-7ZE5].

279. *See* Contreras, *supra* note 266, at 139.

unsuccessful, as many who tried to develop COVID-19 vaccines were,[280] progress toward overcoming the COVID pandemic could have been significantly hampered.[281] Thus, they argue that, in light of the COVID pandemic, the idea of patenting genes is now more untenable than ever.[282]

In sum, opponents of gene patents contend that the Supreme Court's decision in *Myriad* had a net positive effect on healthcare and human rights. As such, they argue that it should be allowed to stand.

2. Protection of Genetic Research Under Trade Secret Law

Opponents of gene patents further contend that biotechs are able to still protect their interests in genetic research through trade secret law. Trade secrets are a form of intellectual property that, so long as the holder makes reasonable efforts to keep them secret, are protectable by law.[283] Opponents of gene patents argue that not only can trade secret law suffice to protect genetic technologies in the absence of patent law, but that trade secret law actually confers two big advantages.[284]

First, trade secret law protects a narrower scope of information than does patent law, thus limiting issues concerning overbroad monopolies within genetic research that might exist under gene patents.[285] Patent law protects an invention or innovation, regardless of how the inventor comes to it.[286] For example, under the pre-*Myriad* regime of gene patents, if a scientist discovered a new mutation in a gene patented by another, the scientist could not make and sell diagnostic tests for their new mutation without the patent holder's permission to sequence the gene. By contrast, trade secret law allows for independent discovery of protected materials.[287] Thus, in the same example, the discovery of a new mutation in a gene covered by trade secret law would not prevent the scientist from making and selling diagnostics for the independently discovered mutation. Opponents argue that trade secret

280. *See, e.g.*, *Merck Discontinues Development of SARS-CoV-2/COVID-19 Vaccine Candidates*, MERCK (Jan. 25, 2021, 6:45 AM), https://www.merck.com/news/merck-discontinues-development-of-sars-cov-2-covid-19-vaccine-candidates-continues-development-of-two-investigational-therapeutic-candidates/ [https://perma.cc/AY3K-FAW8].

281. *See* Contreras, *supra* note 266, at 139.

282. *See id.*

283. *Trade Secrets/Regulatory Data Protections*, U.S. PATENT & TRADEMARK OFF., https://www.uspto.gov/ip-policy/trade-secret-policy [https://perma.cc/JN64-TZCL] (last visited Apr. 3, 2024) (summarizing trade secret requirements and contrasting with patents).

284. *See* Jill M. Robinson, *A "Myriad" of Controversy over the Question of Human Gene Patent Eligibility: A Comparison of the Differing Approaches in the United States and Australia*, 38 HOUS. J. INT'L L. 913, 931 (2016) (summarizing arguments in favor of trade secrets).

285. *See id.*

286. *See* Darren M. Franklin, *Choosing Between Trade Secret and Patent Protection: A Primer for Businesses*, LAW.COM (May 12, 2022, 9:50 AM), https://www.law.com/2022/05/12/choosing-between-trade-secret-and-patent-protection-a-primer-for-businesses/ [https://perma.cc/G2SR-KAY4] (contrasting the protections granted by trade secret and patent law).

287. *See id.*

law thus can still incentivize research into genes without being as restrictive to follow-on innovations.[288]

Second, opponents argue that trade secret practice is much cheaper and easier to implement than patent law and that such savings might further encourage investment into the field.[289] The process of applying for a patent is costly.[290] By contrast, trade secrets do not have a complicated registration process.[291] This lower barrier to entry for genetic research might thus help drive more research in the field.[292]

Collectively, opponents of gene patents argue that trade secret law offers sufficient protections for genetic research. Combined with the shortcomings of gene patents, opponents contend that a reversal of *Myriad* is not necessary or even desirable.

The above studies and arguments illustrate the overarching conflict of gene patents: whether, post-*Myriad*, sufficient incentives to invent gene-based diagnostics exist in the absence of gene patents or whether stronger incentives, such as those offered under patent law, are necessary.

III. PROMOTING INNOVATION THROUGH REASSERTING THE RIGHT TO PATENT GENES

The debate over whether genes should be patent-eligible subject matter rages on. The question is not only if genes should be patentable, but, if so, what form such patents should take. This part argues for genes being held as patentable subject matter, though with practical limitations intended to address some of the most poignant concerns voiced by opponents of gene patents. Part III.A argues that, in order to encourage innovation in the field of medical diagnostics, genes should be considered valid patent subject matter. Part III.B advocates for the position that legislative action is required to reintroduce gene patents to U.S. patent law, but that it should be narrowly tailored to minimize economic uncertainty and thus reinvigorate investment and ultimately promote progress in medical diagnostics research. Part III.C compares this proposal against other suggested solutions.[293]

A. Patent Law Theory Argues for Allowing Genes to Be Patented

The debate over whether genes should be patent-eligible centers around the rationale for patents: can gene patents strike the right balance between *promoting* access to innovations in order to advance scientific progress and the need to *limit* access to innovations so as to incentivize active participation in the necessary work? This section first assesses whether, based on the principles of patent law, genes should be patent-eligible subject matter. After concluding that they should, this section evaluates the concerns that both

288. *See* Robinson, *supra* note 284, at 931.
289. *See id.*
290. *See id.*
291. *See id.*
292. *See id.*
293. *See supra* Part II.B.2.

sides of the argument have voiced around reestablishing gene patents so that further discussions over the form gene patents should take might be sensitive to potential pitfalls.

1. Gene Patents Strike the Right Balance of Incentive and Innovation

The issue of whether genes should be patentable subject matter hinges first on whether gene patents serve the purpose of incentivizing innovation. Studies assessing this issue are compelling; they demonstrate a clear, quantifiable reduction in investments into the biotech industry in the wake of *Myriad*.[294] This reduction of investment correlates neatly with the abandonment of numerous gene-based diagnostics in development at the time of the *Myriad* decision.[295] Thus, gene patents seem to incentivize innovation.

Provided that gene patents incentivize innovation, the issue then becomes whether they do so in a way that is on balance desirable or whether they are too restrictive to justify.[296] This in turn hinges on the amount of incentive required to spur innovation in the biotech industry and the costs of limiting access to genetic research.

The development of gene-based diagnostics is a difficult process that requires considerable investments in time and resources.[297] Associating human genes to human diseases is not at all straightforward.[298] The human genome has been sequenced for two decades, yet the exact number of genes it contains is still unknown.[299] It will take many more years of intense research just to fully map out what diseases are related to what genes and many more beyond that to determine how specific mutations of such genes cause disease. Even once such a connection is understood, researchers will still need to develop diagnostics and treatments based on that genetic information. Thus, considerable incentives to drive innovation of gene-based diagnostics are clearly required.[300]

However, allowing inventors to patent gene-based diagnostics also carries considerable costs. Patents by their very nature drive down competition and increase costs for consumers by giving the patent holder a monopoly over the patented subject matter.[301] In the instance of Myriad's BRCA patents, numerous individuals were unable to afford Myriad's price for testing and, as a result, were denied access to their own health information.[302] Gene patents are tricky because they limit access to key information that tells us about ourselves and our health. Thus, the question here—and really, the key question behind patent law—is whether the benefits outweigh the costs.

294. *See supra* Part II.A.1.
295. *See supra* Part II.A.2.
296. *See supra* Part I.B.1.
297. *See supra* Part I.B.4.
298. *See supra* notes 34–37 and accompanying text.
299. *See* Willyard, *supra* note 26 and accompanying text.
300. *See supra* Part II.A.1.
301. *See supra* Part I.B.1.
302. *See supra* notes 165–68 and accompanying text.

This Note argues that, although the costs of gene patents are great, the benefits ultimately are greater. Gene-based diagnostics are difficult and costly to develop and thus require considerable incentives to encourage people to do so. Numerous studies have demonstrated that, in the absence of such incentives, individuals will not engage in the hard work required to develop these diagnostics.[303] Although patents will limit access to such inventions once developed, the incentive to invent them is insufficient without patent protection. Considering Myriad's BRCA patents, individuals were only able to argue that there was uneven access to such tests because the tests were developed by Myriad in the first place. Had Myriad or others not been incentivized to do so, it is possible that no BRCA test would ever have been developed, meaning that no one would have been able to have their BRCA genes tested, regardless of cost. Thus, gene patents are necessary to promote progress in human health and medicine. Although the cost implications of such patents are high, they are overshadowed by the benefits patents confer to scientific progress in human genetics. As such, this Note advocates for allowing genes to be patent-eligible subject matter.

2. Considerations in Reestablishing Gene Patents

Assuming that genes should be valid subject matter for patents, it is not immediately obvious how the U.S. patent system should implement gene patent protections. To assess this issue, this section considers the concerns of both sides of the debate over gene patents.

Proponents of gene patents are primarily concerned with the economic uncertainty produced by the prohibition on gene patents.[304] They argue that *Myriad* disrupted the biotech industry in a significant way and that, as a result, investment firms have been reluctant to invest in biotechs at the same levels as before.[305] Any reimplementation of gene patents must be sensitive to this issue and attempt to minimize further economic uncertainty in the biotech industry.

Opponents of gene patents have also raised several concerns associated with gene patents, including issues over bodily autonomy, healthcare costs, and effects on subsequent research.[306] Similarly, any future regime of gene patents should attempt to address the most pressing of these concerns.

First, opponents argue that gene patents limit bodily autonomy by blocking individuals from knowing their genetic information without paying for it.[307] However, opponents seem to misunderstand how accessible one's genetic information is. Although it is true that a gene patent might mean that an individual has to pay a specific company to sequence one of their genes, the absence of a gene patent does not mean that that individual can sequence that gene for free. Regardless of who owns what with regards to a gene,

303. *See supra* Parts II.A.1–2.
304. *See supra* Part II.B.1.
305. *See supra* notes 192–200 and accompanying text.
306. *See supra* Part II.C.1.
307. *See supra* notes 267–70 and accompanying text.

individuals are incapable of knowing their own genetic sequence without outside help. Just as one cannot know their weight without a scale or cannot tell their blood pressure without a blood pressure cuff, an individual cannot know their own genetic information without the tools required to sequence it. Such tools are prohibitively expensive for most individuals,[308] and thus the only practical way for someone to sequence their own genetic information is to pay a company to do it for them. Although it is true that gene patents might affect price, gene patents do not determine if one ultimately has access to their own genetic information.

Second, and related, is the concern that gene patents will drive up the price of genetic testing.[309] Although an admirable concern, it misses the basic principle of patent law. Patents exist to promote innovation.[310] The underlying tradeoff is that patents grant innovators a limited monopoly to profit from—and thus encourage—such innovation.[311] Although the consumer might suffer increased costs as a result, such a tradeoff is needed to encourage innovation *in the first place*. The alternative—cheaper prices but little to no gene diagnostic development—is out of step with the basic premises of patent law.

As it pertains to genetic sequencing itself, the actual cost of sequencing a human genome has dropped dramatically in the last two decades.[312] Thus, even if gene patents drive up the cost of sequencing certain genes, it is unclear if prices will ever again be as prohibitively expensive as they were at the time of *Myriad*.

Finally, opponents raise a salient point on the effect of gene patents as they relate to research, particularly in light of the recent COVID-19 pandemic.[313] As noted, research that infringes on patents can sometimes defeat claims of infringement through the research use exception.[314] However, courts have construed this exception narrowly, meaning that even basic research into a patented gene by a nonprofit group, such as a university, might still be considered infringement.[315] Although several studies have found that gene patents did not actually have a strong impact on follow-on innovation,[316] the concern still exists that patent holders who aggressively enforce their patents might stymie research into important genetic information. This concern is particularly acute given the recent COVID-19 pandemic and the fact that many who were on the forefront of researching SARS-CoV-2 were

308. *See, e.g.*, Michael A. Quail, Miriam Smith, Paul Coupland, Thomas D. Otto, Simon R. Harris, Thomas R. Connor, Anna Bertoni, Harold P. Swerdlow & Yong Gu, *A Tale of Three Next Generation Sequencing Platforms: Comparison of Ion Torrent, Pacific Biosciences and Illumina MiSeq Sequencers*, 13 BMC GENOMICS, July 2012, at 1, 2 (indicating that sequencers used for sequencing human genomes cost between $80,000 and $695,000).

309. *See supra* notes 271–74 and accompanying text.

310. *See supra* Part I.B.1.

311. *See supra* Part I.B.1.

312. *See The Cost of Sequencing a Human Genome*, supra note 215.

313. *See supra* notes 275–82 and accompanying text.

314. *See* Freilich & Shahshahani, *supra* note 44, at 10.

315. *See supra* Part I.B.3.

316. *See supra* Part II.A.3.

companies attempting to profit through the development of tests and vaccines.[317] Clearly, some protection must be afforded to safeguard research into topics of global significance like viral genomes. This concern weighs in favor of a more limited scope of viable subject matter for gene patents than was previously enjoyed before *Myriad*.

In sum, any future regime of gene patent eligibility in the United States must address the dual concerns of encouraging investments by promoting economic stability and avoiding placing unreasonable limits on genetic research. Properly balancing these concerns will ultimately prove vital to the success of any future gene patent regime.

B. Patents of Mutant Variants of Genes Properly Balance Innovation and Access

In determining what form gene patents should take, this Note argues that Congress should adopt narrow legislation that amends patentable subject matter as dictated by 35 U.S.C. § 101 to explicitly allow for gene patents, in a manner similar to the EU regime.[318] Part III.B.1 explains the rationale for supporting a narrower legislative amendment. Part III.B.2 then proposes such an amendment and explains how it addresses the economic and research concerns surrounding gene patents.

1. Congress Should Pass a Narrow Amendment to Allow for the Patenting of Genes

One of the major ramifications of *Myriad* was the uncertainty that the investment world felt after the Supreme Court's decision.[319] This uncertainty led to an unwillingness among investors to invest in biotechs that relied on gene patents, thus hindering ongoing research and development of gene-based diagnostics.[320] Although big, sweeping changes like those proposed by Senator Tillis or those that would see gene patents split off into their own field of patent law might ultimately be able to address the gene patent problem,[321] they are unlikely to foster the economic certainty needed to stabilize the U.S. biotech industry. Such drastic solutions will likely only serve to increase uncertainty around gene patents as biotechs, investors, and courts try to sort out the implications of such moves.

As such, this Note advocates for a more incremental change effected through amending subject matter eligibility to allow for specific types of gene patents, without totally upending gene patent jurisprudence. Such an

317. *See, e.g.*, Jaimy Lee, *These 23 Companies Are Working on Coronavirus Treatments or Vaccines—Here's Where They Stand*, MARKETWATCH (May 6, 2020, 2:50 PM), https://www.marketwatch.com/story/these-nine-companies-are-working-on-coronavirus-treatments-or-vaccines-heres-where-things-stand-2020-03-06 [https://perma.cc/TH6J-EQBJ].

318. *See supra* Part I.B.5.

319. *See supra* Part II.B.1.

320. *See supra* Part II.A.

321. *See supra* Part II.B.2.b.

approach would likely not have as unsettling an effect on the biotech industry and, if well-crafted, could quickly inspire the confidence needed to get investment, and thus scientific progress, into genetic diseases back on track.[322] This approach could further be crafted to protect access of genetic research into important topics like viruses, thus achieving the right balance of incentive and innovation.

2. Mutant Variants of Human Genes Should Be Patent-Eligible Subject Matter

The issue then becomes what nature such an amendment should take. This Note advocates for the rather simple solution of creating an exception within § 101 that recognizes *mutant variants* of human genes as patent-eligible subject matter. This exception will promote investment and progress into gene-based diseases while avoiding concerns over access to research into nonhuman genomes.

Permitting the patenting of mutant variants of human genes would allow inventors to once again patent genes that they have discovered to be associated with particular diseases.[323] This would give researchers the necessary protection to develop diagnostic tests and treatments for specific genes that they have shown to be associated with a disease in question. Further, this requirement would not impose additional burdens on inventors in acquiring gene patents as compared to before *Myriad*. Before *Myriad*, patent applicants were still required to demonstrate that a gene patent had utility by showing that a specific mutation of the gene in question was related to a disease of interest.[324] The requirement to patent specific mutations rather than whole genes would require no additional effort on the part of researchers and would afford comparable protections to pre-*Myriad* gene patents, though with two important exceptions.

First, gene patents based on specific mutations would prevent inventors from patenting entire genes simply because they found a single mutation in that gene. As noted, many different types of mutations within a gene can lead to gene dysfunction and ultimately disease.[325] The knowledge of a single mutation that affects a gene's function is far from a complete understanding of the gene itself. Thus, one of the major concerns with *Myriad* was that an inventor could discover a single mutation in a gene that resulted in some disease, patent the entire gene, and prevent further research into that gene.[326] By only allowing the patenting of individual mutations, inventors would be limited to claiming specific mutations in the gene that they have shown to be clinically relevant. Other groups would be free to continue researching the gene broadly and, if additional distinct mutations are discovered that lead to disease, they are likewise free to patent them. This

322. *See supra* Part II.A.1.
323. *See supra* Part I.A.
324. *See supra* notes 135–38 and accompanying text.
325. *See supra* notes 34–36 and accompanying text.
326. *See supra* Part II.C.1.

solution allows researchers to patent, and thus profit from, individual discoveries of genetic mutations that are important for diagnosing and treating disease while still allowing other researchers to continue studying that gene as a whole. It further does not depend on unreliable exemptions like the research use exception to allow further research, thus removing another source of uncertainty in gene patents.

Second, the proposal to only allow patenting of *human* genetic mutations circumvents issues over both basic scientific research as well as concerns over gene patents exacerbating the next global pandemic. The majority of basic research in the field of genetics involves the study of animal genes that, through evolution, share a function with human genes.[327] By preventing animal genes from qualifying as patentable subject matter, basic genetic research can continue unobstructed. Likewise, by limiting gene patents to human genes, the genomes of pathogens like that of the SARS-CoV-2 virus would be ineligible for patent protection. Were the world to face another viral pandemic, no single researcher could attempt to patent the virus's genome and then block others from working on it.

Collectively, this approach would seek to protect individual incentives to research and develop gene-based disease diagnostics while avoiding some of the more significant concerns associated with such patents. By taking a narrower approach and designating a specific type of genetic element that is patentable, this solution avoids issues of uncertainty—and the resulting depressive effects uncertainty has on investment and innovation—that would likely plague more sweeping alternatives, as argued below.

C. Other Potential Methods for Reestablishing Gene Patents Fall Short

Various other proposals for incentivizing genetic research have been suggested.[328] This section briefly evaluates key proposals in light of the dual concerns of encouraging investment through economic stability and limiting restrictions on research.[329]

1. Trade Secrets Are a Poor Fit for Genetic Technologies

Opponents of gene patents maintain that trade secret law adequately incentivizes genetic research.[330] However, trade secret law actually exacerbates the more pressing issues of genetic research for two reasons. First, trade secret protections are unstable, as they only exist so long as the underlying information is kept secret.[331] It is unlikely that investors would feel more confident investing in intellectual properties like trade secrets that could disappear at any moment—especially when compared to patents that

327. *See* GRIFFITHS ET AL., *supra* note 24, at 13–15. Given the shared function, a better understanding of animal genes can inform our understanding of related human genes and ultimately lead to the development of medical diagnostics and therapeutics for humans. *Id.*

328. *See supra* Parts II.B.2, II.C.2.

329. *See supra* Part III.A.2.

330. *See supra* Part II.C.2.

331. *See* Robinson, *supra* note 284, at 926.

carry a set, guaranteed term of protection.[332] Second, the nature of trade secrets actively discourages the dissemination of research, as trade secret protections are predicated on keeping information secret.[333] Unlike patents, which explicitly require the disclosure of discoveries, trade secret law incentivizes researchers to prevent others from learning about their discoveries for as long as possible.[334] Collectively, trade secret law is a poor fit for genetic research, as it would fail either to provide economic stability or to encourage the sharing of genetic discoveries. The lack of trade secret protections as a viable alternative adds to the argument that patent law is the best available solution for human genetic technologies.

2. The Supreme Court Is Unlikely to Reverse *Myriad*

Among the proponents of gene patents, some suggest that waiting for the Supreme Court to overturn *Myriad* might be the simplest solution.[335] However, this method runs into a serious problem: the Supreme Court has not indicated that it is dissatisfied with the current state of patent subject matter eligibility and has repeatedly denied certiorari on issues that might address such concerns.[336] These signs suggest that the Court is unlikely to act on the matter in the near future.[337] Given that concerns over the current state of gene patents suggest a need to act *now*,[338] waiting for the Supreme Court to act seems like folly. And even if the Court were to reverse *Myriad*, it is unclear what the resulting legal landscape would look like in the wake of such a decision. Such uncertainty does not meet the needs of the moment for gene patents.

3. Broad Congressional Overhauls Would Introduce Too Much Economic Instability

Some have advocated for sweeping congressional legislation to overturn *Myriad*, such as Senator Tillis's Patent Eligibility Restoration Act.[339] The bill would effectively reverse *Myriad* and set gene patents back to pre-2013 status.[340] However, gene patents were not perfect before *Myriad*.[341] The *Myriad* suit was brought over very real concerns about the effects that gene

332. *See id.* at 926–27.
333. *See* Franklin, *supra* note 286.
334. *See id.*
335. *See supra* Part II.B.2.a.
336. *See* Blake Brittain, *US Supreme Court Rejects Two Appeals over Patent Eligibility*, REUTERS (May 15, 2023, 3:41 PM), https://www.reuters.com/legal/litigation/us-supreme-court-rejects-two-appeals-over-patent-eligibility-2023-05-15/ [https://perma.cc/4DL4-F7AB].
337. *See id.*
338. *See supra* Part II.B.1.
339. *See supra* Part II.B.2.b.
340. *See supra* Part II.B.2.b.
341. *See generally* Julia Carbone, E. Richard Gold, Bhaven Sampat, Subhashini Chandrasekharan, Lori Knowles, Misha Angrist & Robert Cook-Deegan, *DNA Patents and Diagnostics: Not a Pretty Picture*, 28 NATURE BIOTECHNOLOGY 784 (2010) (arguing that the field of gene patents needs to change).

patents had on healthcare costs and access by researchers.[342] The bill, if enacted, would likely reopen those issues and reignite a number of debates over gene patents that would once again require judicial interpretation. Given the Supreme Court's stance that genes should not be patentable, it is unclear whether those debates would lead to a different result. Such a move would likely provoke even greater uncertainty within the biotech industry and might ultimately prove counterproductive to the goal of reinvigorating investment in the field.

4. Genetic Technologies Are Too Complex and Too Dynamic for Their Own Area of Patent Law

Others have suggested creating a special statutory regime for gene patents akin to what has been done for computer chips within copyright law.[343] However, this proposal would likely run into many of the same issues that plagued the computer chips legislation. Specifically, critics point out that copyright law was too slow to adapt to computer chip technology and was ultimately a poor fit.[344] This shortcoming seems almost certain to also apply to the complex and rapidly developing field of human genetics. Further, whatever regime Congress could manage to craft may then immediately be open to challenges as the specifics of this new field of law are fleshed out, likely requiring years of litigation and uncertainty before a semblance of stability emerges for gene patents.

Collectively, the above proposals seem incapable of meeting the moment for gene patents. Big, sweeping changes are likely to exacerbate issues over uncertainty and thus discourage investment and innovation. Further, a mere reversal of *Myriad* does not address concerns over access to genetic information by researchers. A narrower solution, such as that in effect in the EU and as proposed by this Note, is the best resolution for the issue of gene patents.

CONCLUSION

The issue of gene patents is a complex and technical one. A decade ago, the Supreme Court came down squarely against such patents in *Myriad*. Since then, a number of studies have started to reveal the impact *Myriad* has had on the U.S. biotech industry. Specifically, *Myriad* has led to a decreased willingness of investors to risk capital in the biotech industry, which in turn has led to fewer gene-based diagnostics being developed and brought to market. Such effects have fed the debate over whether the Supreme Court was correct in holding genes to be unpatentable products of nature or whether Congress must step in to correct the Court's mistake.

342. *See supra* Part I.C.4.b.
343. *See supra* Part II.B.2.c.
344. *See supra* notes 256–57 and accompanying text.

This Note advocates for congressional intervention. The point of patents is to "promote the progress of science and useful arts."[345] Without some protection of genetic discoveries, such progress will likely be inhibited, if not outright halted. To serve the ultimate goal of promoting scientific innovation, Congress should act to allow genes to be patent-eligible subject matter. However, this interest would be best served by Congress acting in a narrow manner to only allow the patenting of specific mutations of human genes. By restricting gene patents to specific mutations, Congress could promote open access to genetic research while still providing sufficient incentives to stimulate scientific innovation. This Note asserts that such a narrowly tailored solution for gene patents achieves the balancing act that is the ultimate challenge of patent law by incentivizing individuals to innovate while still protecting the public interest.

345. U.S. CONST. art. I, § 8, cl. 8.