ROLLING WITH THE PUNCHES SINCE 1793: THE PATENT SYSTEM BEFORE AND AFTER *ASSOCIATION FOR MOLECULAR PATHOLOGY V. MYRIAD GENETICS, INC.*, 133 S. CT. 2107 (2013)

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I. INTRODUCTION

Imagine discovering a genetic test that is nothing short of a medical breakthrough, and you are certain this test will change the course of cancer diagnostics. This discovery is so cutting edge that you obtain several patents to protect your interests and prevent others from infringing your legal rights. Due to the substantial time and effort put into the discovery and the exclusive patent rights, you are determined to prevent anyone else from performing the genetic diagnostic test without a patent license to do so. However, there are two sides to every story, and the other side of this story is a woman, being proactive about her health, wanting a diagnostic test to determine whether she may have a substantially higher risk of being diagnosed with cancer. Nonetheless, obtaining such diagnostic test is difficult and expensive because the creator, and now patent holder, has the exclusive right to decide by who and where it may be offered.[1]

The competing interests in this scenario highlight the underlying policy debate surrounding the patent system in our ever-advancing technological society. What qualifies as an "invention" eligible for patent protection—especially in the biotechnology and business software

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1. *See infra* text accompanying note 86; *see also* 35 U.S.C. § 154 (2012) ("Every patent shall . . . grant to the patentee [or patent owner], his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States . . . ."); U.S. PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE § 301 (9th ed. 2014) [hereinafter MPEP]. A patent owner may grant to others

> [a] patent license [which] is, in effect, a contractual agreement that the patent owner will not sue the licensee for patent infringement if the licensee makes, uses, offers for sale, sells, or imports the claimed invention, as long as the licensee fulfills its obligations and operates within the bounds delineated by the license agreement.

Id.

industries—is evolving following recent Supreme Court decisions, including *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* ("*Mayo*"), *Alice Corp. v. CLS Bank* ("*Alice*"), and, most significantly, *Association of Molecular Pathology v. Myriad Genetics* ("*Myriad Genetics*").[2] These cases have significantly changed patentable subject matter standards, which has resulted in a flood of academic, scientific, and legal speculations for the future of biotech and computer software patents.[3] With ongoing technological advances in business software and biotech industries,[4] clarity of patentable subject matter is necessary to ensure the integrity of the patent system as a whole.

This Note demonstrates that *Myriad Genetic*s partially decided patentability of all patent claims of Myriad Genetics, Inc. ("Myriad"),[5] but is still the most significant Supreme Court decision regarding patentable subject matter, having set the stage for the future of the patent protection available for biotech and pharmaceutical industries. Section II briefly introduces the requirements for obtaining a patent and provides a detailed description of patentable subject matter standards, including the judicially created exceptions to patentability as well as the historic judicial application and trends of such exceptions. Section III explores *Myriad Genetics*, explaining the Supreme Court's reasoning in reaching its decision that complementary DNA ("cDNA") is patentable but DNA are not.[6] Section IV analyzes how the Supreme Court only partially ruled on Myriad's patent claims, and thus, incompletely ruled on the matter of patentability. It argues that all existing patents related to laws of nature and natural phenomena could be challenged as a result of the *Myriad Genetics* holding. Further, it analyzes the role Congress plays in the patent system, and emphasizes the importance of consistency and thoroughness between the Supreme Court and the Federal Circuit in all decisions regarding patentability.

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2. *See* discussion *infra* Sections II.B.3, IV.A; *see also* Mayo Collaborative Serv. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012); Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014); Ass'n of Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013). This Note will cite to the Supreme Court Reporter, as the U.S. Reporter is only available through volume 564. *Bound Volumes*, U.S. SUP. CT. http://www.supremecourt.gov/opinions/boundvolumes.aspx (last visited Jan. 31, 2017).
3. *See generally*, Christopher M. Holman, *Patent Eligibility Post-Myriad: A Reinvigorated Judicial Wildcard of Uncertain Effect*, 82 GEO. WASH. L. REV. 1796 (2014); Richard H. Stern, *Alice v. CLS Bank: Are U.S. Business-Method and Software Patents Doomed? Part 1*, 34 INST. ELEC. & ELEC. ENG'RS MICRO. 64 (2014).
4. *See generally* Holman, *supra* note 3.
5. *See* discussion *infra* Section IV. Four composition of matter claims and two methods claims of patents owned by Myriad were not addressed by the Supreme Court in *Association of Molecular Pathology v. Myriad Genetics*, but were subsequently challenged and held invalid as claiming patent ineligible concepts. BRCA1- & BRCA2- Based Hereditary Cancer Test Pat. Litig. v. Ambry Genetics Corp., 774 F.3d 755, 757 (Fed. Cir. 2014).
6. *See Myriad Genetics*, 133 S. Ct. at 2107, 2119.

II. BACKGROUND

Biotech innovation was ignited by discovery of the double helical structure of DNA in 1953, leading to genetic technological advancements, which opened the door to vast possibilities for biotech research and innovation.[7] Similarly, computer related innovation took off following creation of the first integrated circuit around 1958, and eventually led to vast innovation in computer software and computer hardware industries.[8] Congress, through the authority granted under the United States Constitution, has guided and encouraged such innovation.[9]

Accordingly, the patent system evolved from the U.S. Constitution, which granted Congress the power to "promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[10] Since the patent system was established, it has endured numerous shifts between limited patent protection and liberally granted patent protection.[11] A shift toward limited patent protection occurred, especially in recent years, to balance societal interests in limiting the power of large businesses and their exclusive property rights while still incentivizing creation of new technologies.[12] Thus, to best understand current issues with the patent system, it is necessary to explain patents generally as well as the system's evolution, specifically since the start of the digital era.

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7. Dianne Nicol et al., *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* 17–18 (Ctr. for L. & Genetics, Occasional Paper No. 8, 2014), http://ssrn.com/abstract=2503314 (last visited Oct. 27, 2016). After the DNA structure was discovered,

> [t]he first step [toward biotechnological advancement] was the development of recombinant DNA technology, which can be thought of in quite simple terms as a process of cutting a piece out of a DNA molecule of one living cell and transferring it to another. This rapidly became the mainstream technique for manipulating the genome and immediately opened the door to a multitude of possible uses of genetic technologies, in the lab, on the farm and in the clinic.

Id.

8. Adam Mossoff, *A Brief History of Software Patents (And Why They're Valid)*, 56 ARIZ. L. REV. 65, 72–79 (2013).
9. *See* U.S. CONST. art. I, § 8, cl. 8; *see also* Diamond v. Chakrabarty, 447 U.S. 303, 308–09 (1980) (quoting 5 WRITINGS OF THOMAS JEFFERSON 75–76 (Albert Ellery Bergh ed., Washington ed. 1871) ("The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter . . . [and] embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.'").
10. U.S. CONST. art. I, § 8, cl. 8.
11. ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 127 (6th ed. 2012).
12. *Id*.

A. Patentable Subject Matter

To obtain a utility patent, an invention must be: (1) useful, (2) one of four statutory subject matter classes,[13] (3) novel,[14] (4) nonobvious,[15] and (5) enabled.[16] The statutory language of section 101 of title 35, United States Code, setting forth the four patentable subject matter classes, was first implemented in the 1952 Patent Act and was unchanged by the recent implementation of the Leahy-Smith America Invents Act (AIA), signed into law by President Barack Obama on September 16, 2011.[17] The United States Patent and Trademark Office (USPTO), through patent "examiners," is tasked with determining patentability of inventions claimed in patent applications by adhering to existing guidelines and newly created guidelines in response to changes in patentability standards set out by the legislature and judiciary.[18]

Therefore, the four classes of patentable subject matter are inherently broad and necessarily flexible to cover technological evolution occurring since the U.S. patent system was created.[19] However, to maintain the constitutionally intended boundaries of protecting inventors and their discoveries and to encourage future innovation, judicially created exceptions limit what may be patented.[20] Indeed, "laws of nature, natural phenomena, and abstract ideas" are not eligible for patent protection.[21] Moreover, the mere presence of an exception to patentability does not automatically render a patent invalid,[22] but courts consistently reason that to

13. 35 U.S.C. § 101 (2012) (describing inventions eligible for patent protection, which include "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . .").
14. *Id*. at § 102; *see also* MERGES, *supra* note 11, at 129 (meaning there is no prior art, which was "made before, or sold more than a year before a patent application was filed, or otherwise disqualified by prior use or knowledge.").
15. 35 U.S.C. § 103; *see also* MERGES, *supra* note 11, at 128 (meaning more than "a trivial step forward in the art.").
16. 35 U.S.C. § 112; *see also* MERGES, *supra* note 11, at 127–28 (citing 35 U.S.C. § 103) (meaning "disclosed and described by the [patent] application in such a way as to enable [one of ordinary skill in the art] to make and use the invention.").
17. *See* 35 U.S.C. § 101; *Leahy-Smith America Invents Act Implementation*, U.S. PAT. & TRADEMARK OFF. (last updated Oct. 29, 2014, 2:48PM EST), http://www.uspto.gov/patent/laws-and-regulations/leahy-smith-america-invents-act-implementation.
18. MPEP, *supra* note 1, at Introduction ("In addition to the statutes and rules, the actions taken by the examiner in the examination of applications for patents are to a great extent governed by decisions on prior cases.").
19. 1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.01 (2d ed. 2015).
20. *See* Diamond v. Diehr, 450 U.S. 175, 185 (1981)); *see also* Le Roy v. Tatham, 55 U.S. 156, 174–75 (1853); Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980); Ass'n of Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107, 2116 (2013).
21. *Diehr*, 450 U.S. at 185.
22. Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939) ("While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.").

preserve future innovation, such resources and abstract mental concepts and processes, which are "the basic tools of scientific and technological work[,]"[23] should be "free to all men and reserved exclusively to none."[24]

The patentable subject matter classes flow from the constitutional provision "promot[ing] the progress of science and useful arts, . . ." whereby "useful" is interpreted to require useful application of the technology to be patented.[25] Thus, such exceptions must be applied in a way that affords patent protection, as recognized by Donald S. Chisum, noting: "[t]hose who articulate new problems or recognize new needs frequently make valuable contributions to society but cannot look to the patent system for reward unless they go on to find a new and specific process, machine, manufacture, or composition of matter that solves the problem or meets the need."[26]

B. Trends in Judicial Interpretation of Patentable Subject Matter

During the advancing digital era, three periods of judicially influenced patentability standards are apparent.[27] Notably, patent claims related to abstract ideas may also include laws of nature or natural phenomena; thus, Supreme Court precedent discussing the abstract idea exception is equally relevant to biotech patents.[28] This subsection describes the Supreme Court's influence on patentable subject matter during each period.

1. 1970s

Patentable subject matter was set out for the first time as a distinct element to be considered in obtaining patent protection in the 1970s.[29] At the start of the digital era, patentability of software and computer programs came to light, and the Supreme Court drew the line between what could and could not be patented with the decisions in *Gottschalk v. Benson*

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23. Gottschalk v. Benson, 409 U.S. 63, 67 (1972).
24. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).
25. U.S. CONST. art. I, § 8, cl. 8; CHISUM, *supra* note 19, at § 1.01.
26. CHISUM, *supra* note 19, at § 1.01.
27. Holman, *supra* note 3, at 1800.

> The first intervention resulted in the creation of patent eligibility as a distinct requirement of patentability, the second substantially reined in the doctrine to accommodate important new areas of technology, and the third intervention (of which we are currently in the midst) is an attempt to reinvigorate the doctrine [of patentability].

Id.

28. *See e.g.*, *Gottschalk*, 409 U.S. at 67, 71–72.
29. Holman, *supra* note 3, at 1800 (citing *Gottschalk*, 409 U.S. 63; Parker v. Flook, 437 U.S. 584 (1978)).

("*Gottschalk*")[30] and *Parker v. Flook* ("*Parker*").[31] The Supreme Court's reasoning in these decisions was based on its finding that the claimed computer programs were abstract ideas, and, thus, not eligible for patent protection because they "came too close to the sorts of activities that can be accomplished by human thought processes . . . ."[32]

In *Gottschalk*, at issue was a patent application for a computer program used to "convert[ ] binary-coded decimal (BCD) numerals into pure binary numerals."[33] The patent claims were held ineligible for patent protection, because they were directed to an abstract ideas and, thus, "were not limited to any particular art or technology, to any particular apparatus or machinery, or to any particular end use."[34]

Next, in *Parker*, at issue was patentability of a novel mathematical update to an "alarm limit" used during the process of catalytic conversion of hydrocarbons.[35] The patent claim was held ineligible for patent protection because mathematical formulas are not patentable and "post-solution activity" of adjusting the alarm according to the calculations did not transform the formula into a patent eligible concept.[36]

Thus, at the end of the first period of judicial influence, patentability meant that limiting claims to a particular field or art did not transform an unpatentable abstract concept into a patentable invention.[37]

2. 1980s

In the early 1980s, the Supreme Court expanded patentability standards with its decisions in *Diamond v. Diehr* ("*Diehr*")[38] and *Diamond v. Chakrabarty* ("*Chakrabarty*").[39] These decisions "set the patent eligibility bar at a relatively nonstringent level, such that patent protection would generally be available for practical technological innovations, particularly in computer programming and biotechnology."[40]

During this period, through split decisions, the Supreme Court vastly expanded the scope of patentable subject matter.[41] In *Diehr*, at issue were

30. *See generally Gottchalk*, 409 U.S. 63.
31. *See generally Parker*, 437 U.S. 584 (1978); *see also* Holman, *supra* note 3, at 1801.
32. Holman, *supra* note 3, at 1801 (citing *Gottchalk*, 409 U.S. at 71; *Parker*, 437 U.S. at 595).
33. *Gottchalk*, 409 U.S. at 64.
34. *Id*. at 64, 68.
35. *Id*.
36. *Id*.
37. *Parker*, 437 U.S. at 590.
38. *See generally* Diamond v. Diehr, 450 U.S. 175 (1981).
39. *See generally* Diamond v. Chakrabarty, 447 U.S. 303 (1980).
40. Holman, *supra* note 3, at 1802 (citing *Diehr*, 450 U.S. at 186–87; *Chakrabarty*, 447 U.S. at 315).
41. *Id.* (citing *Chakrabarty*, 447 U.S. at 310; *Diehr*, 450 U.S. at 192–93).

> These decisions laid the groundwork for a subsequent dramatic expansion in the recognized scope of patent-eligible subject matter, based on the holding in

claims to an algorithm used to calculate temperature and completion time for a process of "curing" synthetic rubber.[42] There, the Court found the claims valid because the process considered as a whole, including an unpatentable mathematical algorithm, involved "transformation of an article" which afforded patent protection.[43] In *Chakrabarty*, the Court found valid claims for "human-made, genetically engineered bacterium . . . capable of breaking down multiple components of crude oil[,]" as the bacterium created had "significant utility" and were "markedly different" than any bacterium existing naturally.[44]

Subsequent to these expansive decisions, through enactment of the Federal Courts Improvement Act of 1982, Congress created the United States Court of Appeals for the Federal Circuit; this gave one court the exclusive jurisdiction to hear patent related appeals for all U.S. District Courts, which incidentally established a powerful pro-patent advocate.[45] Consequently, the Federal Circuit adopted a number of tests to handle the influx of patents claiming new technological advancements following the judicially expanded scope of patentability.[46]

One particular test provided that an abstract idea may be patentable if, as a whole, it produced a "useful, concrete, and tangible result."[47] First introduced in *Alappat*, the Federal Circuit found the process claims at issue eligible for patent protection, reasoning that the computer program performed mathematical calculations for converting "waveform data samples into anti-aliased pixel illumination intensity data to be displayed on a display means."[48] The Court found the process as more than a mere abstract idea, but "a specific machine to produce a useful, concrete, and

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> *Chakrabarty* that any product of human intervention—even living organisms—is patent eligible, and *Diehr*'s holding that a computer program is patent eligible so long as it provides a sufficiently tangible practical outcome.

Id.

42. *Diehr*, 450 U.S. at 177.
43. *Id*. at 184, 187.
44. *Chakrabarty*, 447 U.S. at 305, 310.
45. Federal Courts Improvement Act of 1982 § 127, 28 U.S.C. § 1295 (2012); *see also* Holman, *supra* note 3, at 1802.
46. *See e.g.*, *In re* Alappat, 33 F.3d 1526, 1544-45 (Fed. Cir. 1994); *see also* State St. Bank & Tr. Co. v. Signature Fin. Grp., Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998) (applying the test adopted in *Alappa*).
47. *See Alappat*, 33 F.3d at 1544.

> [T]he claimed invention as a whole is directed to a combination of interrelated elements which combine to form a machine for converting discrete waveform data samples into anti-aliased pixel illumination intensity data to be displayed on a display means. This is not a disembodied mathematical concept which may be characterized as an 'abstract idea,' but rather a specific machine to produce a useful, concrete, and tangible result.

Id.

48. *Id*.

tangible result."[49] Subsequently, in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, highlighting the reasoning of *Alappat*, the Federal Circuit held claims related to a machine were directed to a patent eligible mathematical algorithm, because the algorithm, though an abstract idea on its own, was "applied in a 'useful' way."[50]

3. 2006 - Present

A noteworthy decision, which likely initiated the third and current period of Supreme Court influence on patentable subject matter, was *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc*. ("*LabCorp*"). At issue in *LabCorp* was a method claim related to "testing homocysteine levels using gas chromatography and mass spectrometry[,]"[51] which the Federal Circuit found valid, even though the patent at issue claimed laws of nature.[52] Dissenting from the Court's dismissal of certiorari, Justice Breyer discussed several policy arguments and noted policy concerns over the patent system and its influence on innovation.[53] Addressing the concern that "*too much*" patent protection may hinder the constitutional grant of promoting progress, Justice Breyer stated:

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49. *Id*.

50. *State St. Bank*, 149 F.3d at 1373-75.

> [H]old[ing] that the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces "a useful, concrete and tangible result"—a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades.

Id. at 1373.

51. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 128 (2006) (Breyer, J., dissenting) (disagreeing with the Supreme Court's decision to dismiss the writ of cert.) (per curiam); *see also* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004).

52. *LabCorp*, 548 U.S. at 125.

> This case involves a patent that claims a process for helping to diagnose deficiencies of two vitamins, folate and cobalamin. The process consists of using any test (whether patented or unpatented) to measure the level in a body fluid of an amino acid called homocysteine and then noticing whether its level is elevated above the norm; if so, a vitamin deficiency is likely. The lower courts held that the patent claim is valid.

Id.

53. Holman, *supra* note 3, at 1798 (citing *LabCorp*, 548 U.S. at 137–39 (Breyer, J., dissenting)).

> [T]he expansion in the recognized scope of patentable subject matter that had occurred under the watch of the Federal Circuit had resulted in substantial negative public policy consequences. The dissent . . . essentially called for a more vigorous enforcement of the patent eligibility requirement as a significant doctrinal tool for weeding out ill-advised and unwarranted patents.

Id.

> The problem arises from the fact that patents do not only encourage research by providing monetary incentives for invention. Sometimes their presence can discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented information, sometimes prohibitively so. Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten.[54]

Subsequently, in *Bilski v. Kappos* ("*Bilski*"), the Supreme Court determined whether business methods may be patented.[55] The patent claims at issue in *Bilski* "explain[ed] how buyers and sellers of commodities in the energy market can protect, or hedge, against the risk of price changes."[56] Applying *Gottchalk*, *Parker*, and *Diehr*, the Court ultimately found the claims invalid as an abstract idea,[57] but noted that business methods may be patentable in limited capacity.[58] In reaching this decision, the Court overturned the Federal Circuit's attempt to create a test for determining patent eligibility and held the machine-or-transformation test was merely an investigative tool, not the sole test to be applied because it violates the text of the statute.[59] Thus, there is nothing in the language of section 101 that requires a process be "tied to a machine or transform an article" to be patent eligible.[60]

After the Supreme Court declined to endorse the Federal Circuit's machine-or-transformation test in *Bilski*, courts were left to rely on the language of section 101 and precedent in determining whether patent protection was appropriate.[61] The Supreme Court next addressed patentability in *Mayo*.[62] There, the Court invalidated patent claims on methods for determining proper drug dosage based on differing metabolic

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54. *LabCorp*, 548 U.S. at 127 (Breyer, J., dissenting).
55. *See* Bilski v. Kappos, 561 U.S. 593, 606–13 (2010).
56. *Id*. at 599.
57. *Id*. at 609 ("[T]he Patent Act leaves open the possibility that there are at least some processes that can be fairly described as business methods that are within patentable subject matter under [section] 101.")
58. *Id*. at 608–13; *see* ERIC E. BENSEN, PATENT LAW PERSPECTIVES § 1.1[1][b][ii] n.23 (2d ed. 2015) (discussing cases in which business method patents were found patent eligible).
59. *Bilski*, 561 U.S. at 597, 603–05. "As numerous *amicus* briefs argue[d], the machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals." *Id*. at 605.
60. *Id*. at 603–04; *see also* 35 U.S.C. § 101 (2012).
61. BENSEN, *supra* note 58, at § 1.1[1][b][i].
62. *See generally* Mayo Collaborative Serv. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2013).

rates of patients with autoimmune diseases.[63] The Court reasoned such invalidation was necessary, as differing human metabolization is a naturally occurring phenomenon and not eligible for patent protection because it lacked an "inventive concept."[64]

Accordingly, the Court set out a test for determining patent validity, including: (1) Is there a law of nature, natural phenomena, or abstract idea being claimed?[65] (2) If so, is there an "inventive concept" observed by examining each claim independently and all the claims as a whole?[66] If an inventive concept exists, the patent will be found valid so long as it meets all other patentability requirements.[67] The court noted that "to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'"[68]

The test set out in *Mayo* was further extended by the decision in *Alice*, which applied the test to business method patent claims.[69] In *Alice*, at issue were claims for a computer system that monitored bank accounts of all parties to a financial transaction.[70] At the close of the business day, the system would only permit transactions allowing both parties to maintain their end of the financial obligation.[71] While at the Federal Circuit, the judges differed in their interpretations of how to apply the *Mayo* test.[72] Judge Lourie, writing for the plurality, found the claims invalid by applying the two-part test from *Mayo*, holding the abstract idea of "settlement risk" was not transformed enough by the claims to amount to "significantly more" as required for patent protection.[73] The plurality also found the system claims invalid, as they claimed an abstract idea and included the words "apply it" on a computer.[74]

Subsequently, the Supreme Court invalidated the patent on mitigating settlement risk, reasoning the patent claimed "intermediated settlement," which the Court held was an abstract idea, and, thus, not eligible for patent protection.[75] In reaching this conclusion, the Court applied the two-step

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63. *Id*. at 1294.
64. *Id*.
65. *Id*. at 1293–94; *see also* Parker v. Flook, 437 U.S. 584, 594 (1978)
66. *Id*.
67. *Id*. *See* 35 U.S.C. §§ 101-103, 112 (2012).
68. *Id*. (citing Gottschalk v. Benson, 409 U.S. 63, 71–72 (1972)).
69. *See generally* Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).
70. *Id*. at 2352.
71. *Id*.
72. BENSEN, *supra* note 58, at § 1.1[1][b][iii] (citing CLS Bank Int'l v. Alice Corp. Pty. Ltd., 717 F.3d 1269, 1286–87, 1301, 1312–13 (Fed. Cir. 2013) ((Lourie, J., concurring, Rader, J., concurring in part, dissenting in part) (per curiam), *aff'd sub nom*., 134 S. Ct. 2347 (2014)).
73. *CLS Bank*, 717 F.3d at 1286–87 (Lourie, J., concurring).
74. *Id*. at 1291; *see also* BENSEN, *supra* note 58, at § 1.1[1][b][iii].
75. Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2351–52 (2014).

analysis set out in *Mayo* for determining patentability where an exception to patentability is present in a claimed invention.[76] Since the Court found that intermediated settlement was an abstract idea, it applied step two of the analysis, and determined the method claim adding computer implementation did not "transform that abstract idea into a patent-eligible invention."[77]

4. Response by the USPTO

Following the *Alice* decision, the USPTO published guidance in the Federal Register to assist patent examiners in evaluating patent applications in terms of patentable subject matter.[78] After the public comment period, the USPTO published updated guidelines on implications of the recent Supreme Court decisions regarding patentable subject matter.[79] Most notably, the guidelines offer information of recognizing abstract ideas and provide examples of claims containing the laws of nature, natural phenomena, and abstract ideas exceptions to patentability. [80]

III. EXPOSITION OF THE CASE

In *Myriad Genetics*, the Supreme Court considered the validity of nine composition of matter claims of three patents owned by Myriad.[81] The Supreme Court ultimately held that cDNA is patentable while DNA are not.[82]

A. Facts and Procedural History

Myriad, a medical research laboratory, located and identified the genetic sequence of two human genes ("BRCA1" and "BRCA2"), which allowed isolation of the DNA segment.[83] This medical breakthrough was significant, as mutations of these genes are directly related to an individual's increased risk of breast and ovarian cancer.[84] Myriad obtained several patents related to this discovery, giving Myriad the "exclusive right

76. *Id*. at 2355–57.
77. *Id*. at 2357–58.
78. 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1).
79. *July 2015 Update: Subject Matter Eligibility*, U.S. PAT. & TRADEMARK OFF. 1, http://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf.
80. *Id*.
81. Ass'n of Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2113 (2013).
82. *Id*. at 2111.
83. *Id*. at 2112.
84. *Id*.

to isolate an individual's BRCA1 and BRCA2 genes . . ." and "to synthetically create BRCA cDNA."[85] Isolation of the BRCA DNA is necessary to perform genetic testing, which reveals whether a woman possesses the precise genetic sequence associated with an increased risk of breast and ovarian cancer.[86]

Myriad sent letters to a number of entities that offered BRCA testing to assert patent infringement; as a result, facilities stopped offering the genetic testing, and Myriad was the only entity offering BRCA testing until this lawsuit ensued.[87] Patients, physicians, and advocacy groups brought suit against Myriad, seeking declaratory judgment to invalidate Myriad's nine composition of matter claims, arguing the claims were for non-patentable subject matter pursuant to section 101.[88]

The district court granted Association of Molecular Pathology's motion for summary judgment, concluding all claims at issue were invalid as they claimed "products of nature."[89] Myriad appealed to the federal circuit, which reversed the district court's invalidation of Myriad's patent claims.[90] Subsequently, the Supreme Court granted Association of Molecular Pathology's petition for certiorari but vacated the judgment and remanded the case to the federal circuit due to the decision of *Mayo*.[91] On remand, writing three separate opinions, the federal circuit held the DNA and cDNA claims valid under section 101, but the judges disagreed on whether isolation of DNA was an inventive act and entitled to patent protection.[92] Certiorari was again granted.[93]

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85. *Id*. at 2113. ("At issue [were] claims 1, 2, 5, 6, and 7 of U.S. Patent 5,747,282 (the '282 patent) [granted in 1978], claim 1 of U.S. Patent 5,693,473 (the '473 patent) [granted in 1997], and claims 1, 6, and 7 of U.S. Patent 5,837,492 (the '492 patent) [granted in 1998]." *Id.* at 2113 n.2; *Google Patents*, GOOGLE, https://patents.google.com (search in search bar for each patent's application number) (last visited Oct. 1, 2015)).
86. *Myriad Genetics*, 133 S. Ct. at 2112.
87. *Id*. at 2114. As mentioned in the introductory hypothetical, patent owners have the exclusive right to control use of their patent. By prohibiting others from offering their diagnostic test, this essentially limited the ability of women to obtain their genetic information in seeking proactive healthcare. *See* Sandra S. Park, *Gene Patents and the Public Interest: Litigating Association for Molecular Pathology v. Myriad Genetics and Lessons Moving Forward*, 15 N.C. J.L. & TECH. 519, 520 (2014).
88. *Myriad Genetics*, 133 S. Ct. at 2114.
89. *Id*.
90. *Id*.
91. *Id*.
92. *Id*. at 2114–15.
93. *Id*.

B. Majority Opinion

The Supreme Court addressed whether Myriad's patent claims met the patentability requirement set out in section 101.[94] The Court began by setting out the exceptions to patentable subject matter under section 101,[95] reiterating that exceptions exist to prevent "tying up" resources, which could discourage innovation.[96] The Court also noted that there are limits to the exceptions to prevent evisceration of the patent system.[97] The Court pointed to language in the patents' detailed descriptions describing their extensive efforts, but held such efforts did not equate to patent protection.[98] Further, the Court noted that Myriad's DNA patent claims were not drafted in a way to emphasize severing chemical bonds, which occurs during the isolation process and is a chemical change that results in a nonnaturally occurring molecule.[99]

Nevertheless, the Court reasoned that "genes and the information they encode are not patent eligible under section 101 simply because they have been isolated from the surrounding genetic material."[100] Recognizing that claims applying newly discovered knowledge would likely be eligible for patent protection, as set out in the second step of the *Mayo* framework, the Court held the claims at issue did not meet requirements for application of the inventive concept test.[101]

Ultimately, the Court held that DNA is a naturally occurring product of nature, and mere location and isolation of a naturally occurring product does not make it patentable.[102] However, cDNA is not naturally occurring in the human body, so creation of BRCA cDNA is patentable under section 101.[103]

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94. *Id*. at 2116.
95. *Id*.
96. *Id*.
97. *Id*. (citing Mayo Collaborative Serv. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012)).
98. *Myriad Genetics*, 133 S. Ct. at 2118.
99. *Id*. at 2118.

> Myriad's claims [are not] saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes.

Id.

100. *Id*.
101. *Id*. at 2119.
102. *Id*.
103. *Id*.

IV. ANALYSIS

In *Myriad Genetics*, the Supreme Court essentially applied long-standing judicially created exceptions to patentability, but the issue was only partially decided, as the Court did not address patentability of all claims of Myriad's patents.[104] It was the most significant Supreme Court decision in recent years, as it made a definitive determination for patents claiming natural phenomena and laws of nature.[105] This differs from the reasoning in *Mayo* and *Alice*, which applied a complex, subjective legal framework to ultimately find that claims directed to such long-standing exceptions to patentability were not transformative enough to create an "inventive concept."[106]

A. Post-*Myriad Genetics* and *Alice* Case Law

Because the Supreme Court addressed only nine composition claims for three of Myriad's patents, there were six remaining claims, four composition claims and two method claims, related to the genetic tests for which Myriad was able to assert infringement.[107] Less than one month after the Supreme Court decided *Myriad Genetics*, a number of generic medical supply companies began manufacturing "medical kits" using the cancer screening technology claimed in Myriad's remaining patent claims.[108] When Myriad learned of the generic medical kits, they brought suit against Ambry Genetics Corp ("Ambry"), requesting a preliminary injunction.[109]

The Court for the District of Utah held that Myriad's claim would not likely succeed because the claims allegedly being infringed were drawn to subject matter not eligible for patent protection.[110] The court insightfully noted that the decision would likely harm Myriad irreparably, but noted that the "public interest was in equipoise . . . [and] the balance of hardships slightly favored Ambry."[111] On appeal, the Federal Circuit affirmed that the method and composition claims were invalid, but disagreed with Ambry's contention that *Mayo* was the proper test for assessing the method claims as containing laws of nature.[112] The Court applied the *Mayo*

104. *Id*. at 2116. *See infra* Section IV.A.
105. *See supra* Section III.B.
106. *See generally* Mayo Collaborative Serv. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012); Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).
107. BRCA1- & BRCA2- Based Hereditary Cancer Test Patent Litig. V. Ambry Genetics Corp., 774 F.3d 755, 757 (Fed. Cir. 2014). The composition claims were related to primers, which are naturally occurring. *Id.* at 761.
108. *Id*. at 757.
109. *Id*. at 758.
110. *Id.*
111. *Id*.
112. *Id.* at 762.

framework, but applied step one of *Mayo* to the claims comparing "wild-type genetic sequences," and then applied step two to the medical techniques or methods for comparing the sequences.[113]

Thus, the lower courts' fragmented application and failure to apply the framework, demonstrates the technicality of specific industry patents and the complexity of *Mayo*'s two-part test.[114] Presumptively, some believe the future is unclear for medical diagnostic and biotech patents and may demonstrate the Supreme Court's ambiguous understanding of the technicality these industries.[115]

B. Policy Debate

For the patent system generally, there are conflicting policies among specific industries.[116] Some believe that "patents are choking cumulative innovation and commercialization, such that lawmakers should discard or radically restructure the system[;]" while others believe "that the patent regime is [essential to] industrial research and development . . . , such that any change in the law would have disastrous repercussions."[117] Likewise, there are differing opinions among specific industries. For example, some in the information technology industries favor limited patent rights to prevent restraints on their business models and limit patent owners' exclusive rights; comparably, some in the pharmaceutical industry lean more toward broad patent protection and prefer greater difficulty

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> Ambry argues that *Mayo* is directly on point because the method claims here, as there, simply identify a law of nature (the precise sequence of the BRCA genes, and comparisons of the wild-type BRCA sequences with certain mutations of those gene sequences found in the test subject) and apply conventional techniques. We need not decide if *Mayo* is directly on point here because the method claims before us suffer from a separate infirmity: they recite abstract ideas.

Id.

113. *Id.* at 762–63.

114. *Id*.

115. Holman, *supra* note 3, at 1799.

116. Alan Devlin, *Systemic Bias in Patent Law*, 61 DEPAUL L. REV. 57, 58 (2012); *see also* Mayo Collaborative Serv. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1305 (2012).

> Patent protection is, after all, a double-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements. At the same time, patent law's general rules must govern inventive activity in many different fields of human endeavor, with the result that the practical effects of rules that reflect a general effort to balance these considerations may differ from one field to another.

Id.

117. Devlin, *supra* note 116, at 57.

challenging patents in court.[118] The conflicting policy arguments are problematic "because of the lack of information necessary to resolve it and the absence of an objective framework within which to craft policy prescriptions."[119]

Patent law jurisprudence during the third period of judicial intervention expresses concern for over-patenting, especially in regard to laws of nature, natural phenomena, and abstract ideas.[120] This concern has led to increased speculation over the future of the patent system.[121] The increased use of new patentability standards as a "pragmatic tool for economically disposing of an adversary's allegedly infringed patent"[122] evidences conflict among industries. However, there is inconsistency among lower courts and USPTO examiners, leading to discrepancies in application of the new patentability doctrine, further leading to difficulties for patent attorneys, patent holders, and inventors seeking patent protection.[123] Thus, inventions related to laws of nature and natural phenomena that do not meet the recently imposed patentability requirements could be challenged under *Myriad Genetics*.

C. Complexity of Patents and Congress's Role

There has been some debate among the judiciary regarding patentable subject matter and whether Congress or the judiciary should decide what may be patented, due to the complexity of biotech and computer program patent claims. As far back as 1972, during the first period of judicial intervention,[124] the Supreme Court noted the complexity of certain industries' products, such as computer programs, and opined that Congress holds the authority of determining patentability in such industries.[125] For example, in *Chakrabarty*, the Supreme Court discretionarily found the patent claims valid for a newly created bacterium, stating "[i]n choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."[126] However, the dissenting opinion in *Chakrabarty* disagreed, and reasoned that it should be left to Congress to make such determinations.[127]

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118. *Id*. at 58.
119. *Id*.
120. *See* discussion *supra* Section II.C.3.
121. *See* discussion *supra* Section II.C.3.
122. Holman, *supra* note 3, at 1798.
123. *Id*.
124. *See supra* Section II.
125. Gottschalk v. Benson, 409 U.S. 63, 72–73 (1972).
126. Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980); 35 U.S.C. § 101 (2012).
127. *Id*. at 322 (Brennan, J., dissenting).

However, the second period of judicial intervention was defined by a broad scope of patentability and wide judicial discretion, especially with the creation of the Federal Circuit.[128] Congress essentially established a powerful, specialized court for the development and harmonization of patent law.[129] Thus, instead of overruling *Chakrabarty* and *Diehr*,[130] Congress seemingly created the Federal Circuit specifically to deal with the significant judicial expansion of patentability as a result of these decisions.[131] In the years following creation of the Federal Circuit, the number of business methods and biotech patents increased exponentially, likely due to adherence by the USPTO and the lower courts in adopting of the Federal Circuit's broad tests for patentability.[132]

It may be inferred that Congress makes changes to the patent system out of necessity to ensure fulfillment of its constitutional duty,[133] and the rest of the system adapts accordingly. This necessary adaptability is further emphasized by the Supreme Court in *Mayo*; while hesitant to depart from established rules for patentability and recognizing the unique rules for plant patents, the Court noted that Congress intervenes with patent laws only when it deems necessary.[134] Most recently, the AIA substantially changed several provisions of the patent statutes.[135] AIA created specific guidelines for U.S. Patent Office officials and examiners, but did not address or change patentable subject matter standards.[136] For example, in one newly added section related to business method patents, it states "[n]othing in this section shall be construed as amending or interpreting

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128. *See supra* Section II; *see also* Holman, *supra* note 3, at 1802.
129. *See* Holman, *supra* note 3, at 1802.
130. *See supra* Section II.
131. Holman, *supra* note 3, at 1802.
132. *Id*. at 1802–03; *see also* discussion *supra* Section II.C.2.
133. *See* U.S. CONST. art. I, § 8, cl. 8.
134. *See* Mayo Collaborative Serv. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1305 (2012).

> In consequence, we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary. Cf. 35 U.S.C. §§ 161–164 (special rules for plant patents). We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable.

Id.

135. The patent system was changed from a first-to-invent to a first-to-file system; first-to-file means the first person to file an application with the USPTO is potentially entitled to patent protection, as opposed to the first person to "invent" under the prior system. *First Inventor to File (FITF) Comprehensive Training*, U.S. PATENT & TRADEMARK OFF. 4, http://www.uspto.gov/sites/default/files/aia_implementation/fitf_comprehensive_training_prior_art_under_aia.pdf (last visited Nov. 19, 2015).
136. 35 U.S.C. § 321 (2012); Leahy-Smith America Invents Act, H.R. 1249, 112th Cong. (2011); *see also* CHISUM, *supra* note 19, at § 1.01.

categories of patent-eligible subject matter set forth under section 101 of title 35, United States Code."[137]

Therefore, as mentioned *supra*, presumptively fulfilling its constitutional duty and acting in the best interests of the patent system, Congress has played an active role in shaping patentability since the system was created.[138] Therefore, until Congress enacts legislation speaking specifically to the current policy debate, lower courts, judges, patent attorneys, and inventors must adapt to the newly shaped system.

V. CONCLUSION

The patent system is an essential part of the industrial progression of the United States, and it has withstood numerous changes since first implemented. Recent Supreme Court decisions will continue to shape the future of patent protection, especially for biotech and computer program industries. Thus, while biotech and computer program innovation has become increasingly complex and discrepancies between the Supreme Court and Federal Circuit exist, Congress has seemingly left patentable subject matter for the courts to decide. Accordingly, in the interest of maintaining the integrity of the patent system, it is crucial for the Supreme Court and the Federal Circuit to thoroughly and consistently decide all matters related to patentable subject matter.

137. 35 U.S.C. § 321.

138. *See* discussion *supra* Sections II.A, II.B.2, IV.C.