COMMENT

THE CHANGING LANDSCAPE OF PATENT SUBJECT MATTER ELIGIBILITY AND ITS IMPACT ON BIOTECHNOLOGICAL INNOVATION*

ABSTRACT

Recent Supreme Court decisions and the subsequent implementation of new policies by the United States Patent and Trademark Office (USPTO) greatly diminish patent protection available to biotechnological innovation. The law recognizes these innovations as a category of subject matter that must meet a judicially-created threshold to be afforded patent protection. The threshold requirement is that technologies involving natural laws, physical phenomena, or abstract ideas must claim an inventive concept that transforms the technology into something new and useful, subject to additional evolving restrictions that remain elusive to lower courts. These evolving restrictions signal a new era where patents once granted by the USPTO involving biotechnology are now invalid. The Federal Circuit case *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* illustrates the current bleak landscape of patent protection for biotechnological inventions and highlights the judiciary's frustration with the high threshold set by the Supreme Court. Moving forward, it remains unclear what constitutes patentable subject matter under the new restrictive standards because so few rulings by the Supreme Court uphold patents challenged upon subject matter eligibility grounds. This roadblock to intellectual property protection for biotechnological inventions, due both to the recent restrictions and to the uncertain legal standard, may slow growth of the industry that relies heavily on investment.

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I. INTRODUCTION

Recent Supreme Court decisions and the subsequent implementation of new policies by the United States Patent and Trademark Office (USPTO) greatly diminish patent protection available to biotechnological innovation.[1] The law recognizes these innovations as a category of subject matter that must meet a judicially-created threshold to be afforded patent protection.[2] The threshold requirement is that technologies involving natural laws, physical phenomena, or abstract ideas must claim an inventive concept that transforms the technology into something new and useful, subject to additional evolving restrictions.[3] The recent Federal Circuit case *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* illustrates the current bleak landscape of patent protection for biotechnological inventions and highlights the judiciary's frustration with the high threshold set by the Supreme Court.[4] The recent precedent restricts patent eligibility for technologies involving natural laws, physical phenomena, and abstract ideas,[5] which could generate a stalemate in innovation in the biotechnology industry.[6] Additionally, the lack of clarity from the Supreme Court on what constitutes patent-eligible subject matter will further exacerbate the stalemate in innovation.[7]

Biotechnology encompasses technology arising from the manipulation of biological processes, often contributing to the fields of medicine, environmental science, and agricultural science.[8] One of the ultimate goals of biotechnology is to develop tools that improve the diagnosis and treatment of disease.[9] Modern scientific technology paves the way for personalized

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1. *See infra* Parts III.A, IV (discussing the restrictions on patent subject matter eligibility imposed by the Supreme Court and the USPTO).

2. The heightened threshold applies to inventions involving natural laws, physical phenomena, or abstract ideas and by their very nature, inventions involving biological discoveries will involve natural laws. *See infra* Parts II.B, III.A (discussing the judicially-created exceptions to patent subject matter eligibility).

3. Diamond v. Diehr, 450 U.S. 175, 185 (1981); *see infra* Part III.A (discussing the additional limitations recently imposed by the Supreme Court).

4. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1375–76 (Fed. Cir. 2015).

5. *See infra* Part III.A (discussing the rise in patent invalidation on grounds of subject matter ineligibility following the *Mayo* and *Alice* Supreme Court decisions).

6. *See infra* Part V (discussing the detrimental effect that uncertainty in investment return will have on future innovation).

7. *See infra* Part III.A.5 (discussing the lack of explanation of what does constitute patentable subject matter in recent Supreme Court decisions).

8. *What is Biotechnology?*, BIOTECHNOLOGY INNOVATION ORG., http://www.bio.org/articles/what-biotechnology [https://perma.cc/3NJF-6EB5].

9. *Id.*

medicine, allowing the industry to develop diagnostic tests that use the molecular profile of an individual patient to aid in diagnosis and treatment decisions.[10] However, translating an understanding of the molecular mechanisms of disease into such a "companion diagnostic" requires vast amounts of resources.[11] Novel biotechnologies can take decades to develop and commercialize, requiring substantial long-term investments.[12] According to a report by the Pharmaceutical Research and Manufacturers of America, investment in research and development of new medicines in 2014 exceeded $51 billion.[13] Some suggest the strength of protection afforded to intellectual property in the biotechnology industry to be the most important factor driving industry growth.[14] Thus, continued industry growth and the ensuing innovation is linked intricately to the patent protection of those innovations.

This Comment is divided into six parts. Following the introduction, Part II provides background on patent law, discussing the interplay between the legislative, executive, and judiciary branches and how the resulting laws impact the biotechnology industry. Part III discusses the evolving case law governing patent eligibility for inventions that involve laws of nature, physical phenomena, and abstract ideas and analyzes a few recent cases where courts inconsistently applied the governing law and voiced concern for the high threshold of patent eligibility. Part IV describes the USPTO's issuance of guidance on subject matter eligibility in an attempt to advise the community on changing eligibility requirements, highlighting the lack of continuity in court precedent. Part V examines the consequences of limited patent protection on the biotechnology industry, discussing the potential of harming society by reducing fruitful innovation. To conclude, Part VI reiterates the problems discussed throughout the Comment and proposes a solution.

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10. *See generally* Margaret A Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 NEW ENG. J. MED. 301 (2010) (providing an overview of personalized medicine successes and shortcomings).

11. *Id.* at 301–02.

12. *See, e.g.*, MATTHEW B. MCFARLANE, TARA GUFFREY SHARP & JOHN T. AQUINO, STOPPED AT THE THRESHOLD: THE PRACTICAL IMPACT OF THE SUPREME COURT'S MAYO AND MYRIAD DECISIONS ON BIOTECHNOLOGY PATENT PRACTICES S-8 (2014) (discussing the financial risks involved in biotechnology investments). The report estimates that nine out of ten drug candidates in development are never fully commercialized. *Id.*

13. PHARM. RESEARCH AND MFRS. OF AMERICA, 2015 PROFILE: BIOPHARMACEUTICAL RESEARCH INDUSTRY VI (2015), http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf [https://perma.cc/2FKV-DPPF].

14. *Id.* at 28, 56.

II. BACKGROUND

A. Sources of Patent Law

1. Statutory Basis. The U.S. Constitution proclaims that Congress "shall have 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."[15] In accordance with this constitutional grant of power, Congress promulgated laws codified in Title 35 of the United States Code to govern the grant of patents.[16] A patent represents a grant of an exclusive right to practice an invention for a limited time by the government to an inventor.[17] However, the government conditions this grant on the full disclosure of the invention.[18]

In 2011, Congress passed the America Invents Act (AIA), which superseded the Patent Act of 1952 as the ruling statutory law for patents.[19] The AIA brought a number of significant changes, perhaps the most significant being a switch from a first to invent system to a first to file system, changing the right to a patent to the first inventor to file an invention with the USPTO instead of the first to invent.[20] Section 101, governing subject matter eligibility of utility patents and the focus of this Comment, remains one of the few sections of the Act left untouched by the revision.[21] While the USPTO grants three categories of patents,[22] utility patents that encompass a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" prove the most relevant to medical diagnostics.[23] Inventors applying for patent protection must follow certain requirements for claiming the invention,[24] and the invention must qualify as subject matter eligible for receipt of a

15. U.S. CONST. art. I, § 8, cl. 8.

16. 35 U.S.C. §§ 1–390 (2012).

17. *Id.* §§ 154, 173.

18. *Id.* §§ 154, 181.

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

20. MARY ANTHONY MERCHANT, THE AMERICA INVENTS ACT (AIA) HANDBOOK: A GUIDE TO THE PATENT LAW REFORM OF 2011, at 11 (2013).

21. 35 U.S.C. § 101. The subject matter eligibility requirements in § 101 govern what inventions qualify for patent protection by the United States. *Id.*

22. *Id.* (describing utility patents); *id.* § 161 (describing plant patents); *id.* § 171 (describing design patents).

23. *Id.* § 101; Amanda Murphy et al., *Introduction to Intellectual Property: A U.S. Perspective*, *in* INTELLECTUAL PROPERTY IN MOLECULAR MEDICINE 1, 4 (Salim Mamajiwalla & Rochelle Seide eds., 2015).

24. 35 U.S.C. § 112.

patent[25] and represent a novel, nonobvious invention.[26] Once the USPTO grants a patent, the owner of the patent may enforce his right to exclusively perform the invention under the infringement provision of the AIA.[27]

2. U.S. Patent and Trademark Office. Congress created the USPTO to oversee the grant of patent rights to inventors.[28] The USPTO employs patent examiners that review patent applications and issue patents according to specific requirements.[29] Additionally, the USPTO maintains records and searchable databases of issued patents.[30] Congress granted the USPTO authority to promulgate rules "not inconsistent with law," as opposed to clear-cut substantive rulemaking authority.[31] Courts interpret this language to indicate that the USPTO must adhere to statutory law and case law when making decisions, limiting the USPTO's ability to promulgate substantive rules.[32]

3. The Judiciary's Role in Patent Law. Congress gave the Court of Appeals for the Federal Circuit exclusive jurisdiction to decide patent-related appeals from federal district courts and the USPTO.[33] Because of this grant of power, the Federal Circuit may review USPTO decisions and delineate the substantive law surrounding patents.[34] These reviews result in a power struggle between the USPTO and the Federal Circuit.[35] While an argument

25. *Id.* § 101.

26. The novelty requirement of § 102 ensures that only new inventions will be granted patent protection by precluding protection for inventions that have previously been patented, described to the public, or otherwise available to the public. *Id.* § 102. The nonobviousness requirement of § 103 precludes inventors from obtaining patent protection for inventions that would be obvious in light of other inventions. *Id.* § 103.

27. *Id.* § 271.

28. *Id.* §§ 1–2 (establishing the USPTO and granting its powers).

29. The major requirements include subject matter eligibility in § 101, novelty in § 102, and nonobviousness in § 103. *Id.* §§ 101–103.

30. *General Information Concerning Patents*, U.S. PATENT & TRADEMARK OFFICE (Oct. 2015), http://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-1 [https://perma.cc/MU6U-PEL5].

31. 35 U.S.C. § 2(b)(2).

32. *See, e.g.*, *In re* Van Ornum, 686 F.2d 937, 945 (C.C.P.A. 1982) (stating that the USPTO's "principal business" is regulating "in a manner consistent with statutory and case law"); Herbert C. Wamsley, *The Rulemaking Power of the Commissioner of Patents and Trademarks (Part 2)*, 64 J. PAT. OFF. SOC'Y 539, 557 (1982) ("The fact that [USPTO] rules must be consistent with judge-made law as well as statutory law limits considerably the Commissioner's power to promulgate substantive rules, because a massive amount of judge-made law exists in the patent and trademark field.").

33. 28 U.S.C. § 1295(a)(4).

34. *Id.*

35. Dickinson v. Zurko, 527 U.S. 150, 158–61 (1999) (discussing the lack of deferential review granted to the USPTO by the Federal Circuit and holding that the USPTO does not

could be made that the balancing of powers between the USPTO and the judiciary upholds the separation of powers called for in the Constitution, the ultimate authority to decide the law belongs to the Supreme Court, shifting that power to the judiciary.[36] Thus, the interpretation of the AIA falls to the federal district courts, the Federal Circuit, and the Supreme Court. Since 2010, the Supreme Court has granted numerous certiorari requests on patent subject matter eligibility issues.[37] These decisions shape the subject matter eligibility requirements into a strict interpretation of § 101.[38]

B. Intellectual Property in the Biotechnology Industry

The age of biotechnology arguably began when James Watson and Francis Crick discovered the structure of DNA.[39] This discovery allowed researchers to unlock the information contained in DNA and begin harnessing that information to improve upon medicine, agriculture, and the environment.[40] In 1980, the USPTO granted the first patent on a recombinant DNA method that described introduction of foreign DNA into a microorganism to produce things like medically-useful enzymes.[41] Since 1980, the USPTO granted tens of thousands more patents claiming DNA-related inventions.[42] However, DNA-related inventions are not the only player in the biotechnology industry—inventions relating to natural correlations between a disease and a biomarker show great promise in the field of personalized medicine.[43]

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receive deferential review under the Administrative Procedure Act).

36. The Supreme Court's decisions in *Ass'n for Molecular Pathology v. Myriad Genetics* and *Mayo Collaborative Services v. Prometheus Laboratories* likely invalidated thousands of patents granted by the USPTO since the 1980s. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2011 (2013) (involving a patent of isolated DNA); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294–95 (2012) (involving a diagnostic test patent); *see infra* Part III.A. (discussing the impact of the *Mayo* and *Myriad* decisions on past and future patents involving diagnostic method claims).

37. Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014); *Myriad*, 133 S. Ct. 2107; *Mayo*, 132 S. Ct. 1289; Bilski v. Kappos, 561 U.S. 593, 601 (2010).

38. *See infra* Part III.A (discussing the limitations imposed by the Supreme Court on inventions encompassing laws of nature, physical phenomena, and abstract ideas).

39. J.D. Watson & F.H.C. Crick, *Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737, 737 (1953).

40. *Id.*; *What is Biotechnology*, *supra* note 8.

41. U.S. Patent No. 4,237,224 (filed Jan. 4, 1979); MCFARLANE, SHARP & AQUINO, *supra* note 12, at S-9.

42. MCFARLANE, SHARP & AQUINO, *supra* note 12, at S-9.

43. *See, e.g.*, Sarah E. Jackson & John D. Chester, *Personalised Cancer Medicine*, 137 INT'L J. CANCER 262, 263–64 (2015) (discussing the use of the HER2 protein in breast cancer as a biomarker predicting response to trastuzumab and other similar successful companion diagnostics).

Commercially successful companion diagnostics that make personalized medicine possible include both diagnostics related to genetics and molecular profiles.[44] These diagnostics require vast resources to generate and commercialize, and so the protection afforded by strong patent rights is crucial to secure the incentive for their development.[45]

While the Supreme Court declared that "anything under the sun that is made by man" should be patent-eligible,[46] long-standing precedent bars the grant of a patent directed to "laws of nature, physical phenomena, and abstract ideas" except for certain circumstances subject to evolving legal analysis.[47] Courts consider laws of nature and physical phenomenon to follow from the "handiwork of nature," such as the characteristic of a mixture of bacteria to enhance the inoculation of plant seeds,[48] relationships between the characteristics of a disease and the likelihood of effective treatment,[49] or the genetic information contained in a sequence of DNA.[50] Abstract ideas generally encompass things like software or mathematical equations,[51] though courts sometimes find abstract ideas in inventions that also involve natural laws.[52]

44. *Id.* at 262–64.

45. *See infra* Part V.

46. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

47. *Id.* at 309; s*ee infra* Part III.A (discussing the chain of Supreme Court cases addressing subject matter eligibility).

48. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948) ("Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect . . . is no more than the discovery of some of the handiwork of nature and hence is not patentable.").

49. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1296 (2012) ("Prometheus' patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.").

50. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013) ("To be sure, [Myriad] found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.").

51. *See, e.g.*, Parker v. Flook, 437 U.S. 584, 585 (1978) (involving technology updating alarm limits by applying a mathematical algorithm).

52. *Compare In re* BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755, 763 (Fed. Cir. 2014) ("[C]laims . . . are directed to the patent-ineligible abstract idea of comparing . . . the patient's gene with the wild-type and identifying any differences that arise."), *with Mayo*, 132 S. Ct. at 1296 ("Prometheus' patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.").

III. JUDICIAL IMPLEMENTATION OF SUBJECT MATTER ELIGIBILITY REQUIREMENTS

This section of the Comment discusses the judiciary's interpretation of the laws governing the subject matter eligibility of patents. First, discussion of the seminal Supreme Court cases establishing the legal framework for subject matter eligibility illustrates the changing landscape of subject matter eligibility for inventions that claim natural laws, physical phenomena, and abstract ideas. Second, an examination of recent lower court cases involving biotechnological patents demonstrates both the difficulty of applying the precedential framework to decide questions of subject matter eligibility and the outspoken dislike of the standard by Federal Circuit judges.

A. Precedential Decisions on Patent Subject Matter Eligibility

Section 101 of the AIA says that: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[53] Federal courts maintain three exceptions to patent-eligibility: laws of nature, natural phenomena, and abstract ideas.[54] Should an invention encompass one of the three exceptions, courts will apply additional court-made principles to determine whether that invention qualifies for patent protection afforded by the AIA.[55] This section of the Comment will address the legal framework for determining subject matter eligibility, focusing on how seminal Supreme Court cases built upon one another to arrive at the current standard.[56]

1. Diehr*: The Original Subject Matter Eligibility Standard.* Though the Supreme Court addressed subject matter eligibility as far back as the nineteenth century,[57] *Diamond v. Diehr* is an appropriate case to begin the discussion of subject matter

53. 35 U.S.C. § 101 (2012).

54. Diamond v. Chakrabarty, 447 U.S. 303 (1980); *see supra* Part II.B (discussing in greater detail the categories of natural laws, physical phenomena, and abstract ideas).

55. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

56. Diamond v. Diehr, 450 U.S. 175 (1981); Bilski v. Kappos, 561 U.S. 593 (2010); *Mayo*, 132 S. Ct. 1289; *Myriad*, 133 S. Ct. at 2107; Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).

57. *See, e.g.*, W. Elec. Mfg. Co. v. Ansonia Brass & Copper Co., 114 U.S. 447, 451 (1885) (discussing whether application of a known process resulting in nothing significantly different is eligible subject matter for a patent).

eligibility because many recent decisions reiterate some of *Diehr*'s principles, yet seemingly conflict with other principles set forth in the opinion.[58] In *Diehr*, the Supreme Court held a patent utilizing an abstract idea—a mathematical equation—patentable because the abstract idea improved the specific application—curing rubber.[59] The Court reasoned that "when a claim containing a mathematical formula . . . is performing a function . . . (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101."[60]

In other words, the standard for subject matter eligibility for a patent claiming a natural law, physical phenomenon, or abstract idea set forth by *Diehr* is that the invention must transform the non-statutory subject matter into something new and useful.[61] The Court in *Diehr* further reasoned that the conventional nature of the steps involved in curing rubber did not bar the patent from eligibility under § 101.[62] This standard prevailed for decades, allowing innovators to patent inventions involving natural laws, physical phenomena, and abstract ideas predicated upon a transformation into something new and useful, without imposition of any further limitations.[63] Part VI of this Comment proposes that courts today should revert back to this standard, affording patent rights to inventions that provide new and useful applications.[64]

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58. *See infra* Parts III.A.3, III.B.1 (distinguishing the new and useful standard laid out in *Diehr* from the *Mayo*, *Myriad*, and *PerkinElmer* opinions).

59. *Diehr*, 450 U.S. at 192–93. Courts consider mathematical equations and medical diagnostics to be abstract ideas, though the classification of medical diagnostics as abstract is inconsistent. *See, e.g.*, Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (considering a mathematical formula an abstract idea). *Compare In re* BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755, 759–65 (Fed. Cir. 2014) (considering a diagnostic that involved comparing the sequence of a patient's BRCA genes to a nonmutated control gene sequence an abstract idea), *with Mayo*, 132 S. Ct. at 1294 (considering a diagnostic test measuring levels of thiopurine metabolite levels to indicate toxicity an abstract idea).

60. *Diehr*, 450 U.S. at 192.

61. *Id.* This concept was not a novel standard for subject matter eligibility. *See, e.g.*, Parker v. Flook, 437 U.S. 584, 594–95 (1978) (holding that the discovery of a phenomenon of nature or mathematical formula "cannot support a patent unless there is some other inventive concept in its application"); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (holding that to be patent-eligible subject matter, the invention "must come from the application of the law of nature to a new and useful end").

62. *Diehr*, 450 U.S. at 188–89.

63. *Bilski v. Kappos* in 2010 was the first Supreme Court case to address the subject matter eligibility question of § 101 after *Diehr*. Bilski v. Kappos, 561 U.S. 593 (2010). Following *Bilski*, the Supreme Court backtracked on the idea that transformation into a new and useful application is sufficient for patent protection; now, patents consisting of solely conventional steps are no longer afforded subject matter eligibility. *Mayo*, 132 S. Ct. at 1298.

64. *See infra* Part VI.A.

2. Bilski*: Restricting the Standard***.** The *Bilski v. Kappos* decision in 2010 signals the start of a trend restricting patent eligibility. In *Bilski*, the Supreme Court held a patent claiming an abstract idea—a method to protect against risk in the commodities and energy markets using a mathematical formula—invalid because it did not add enough to the underlying abstract principle.[65] The Court held that the *Diehr* standard, requiring the patent to result in a transformation into something new and useful, is not the sole test for subject matter eligibility of patents claiming laws of nature, physical phenomena, or abstract ideas.[66] However, the plurality did not suggest what other factors would influence patent eligibility moving forward.[67]

The concurring opinion of *Bilski* by Justice Stevens calls out the lack of reasoning in the plurality:

> The Court . . . never provides a satisfying account of what constitutes an unpatentable abstract idea. Indeed, the Court does not even explain if it is using the machine-or-transformation criteria. . . . This mode of analysis (or lack thereof) . . . means that the Court's musings on this issue stand for very little.[68]

Commentators align with Stevens' position—the lack of a standard or explanation of reasoning by the majority in *Bilski* results in an uncertain legal standard.[69] While the *Bilski* decision did not explicitly limit subject matter eligibility requirements,[70] it signals the start of the trend limiting patent protection for inventions involving laws of nature, physical phenomena, and abstract ideas.[71]

3. Mayo *&* Myriad*: Limiting Eligibility of Biotechnological Inventions***.** Mayo Collaborative Services v. Prometheus Laboratories, Inc. and Association for Molecular Pathology v. Myriad Genetics, Inc. stand as two important cases addressing

65. *Bilski*, 561 U.S. at 611–12.

66. *Id.* at 604.

67. *Id.* at 604–57.

68. *Id.* at 621 (Stevens, J., concurring).

69. *E.g.*, Kevin Emerson Collins, Bilski *and the Ambiguity of "An Unpatentable Abstract Idea"*, 15 LEWIS & CLARK L. REV. 37, 65 (2011) ("*Bilski* offers only the roughest of sketches concerning what constitutes an unpatentable abstract idea and leaves much for further refinement.").

70. *See Bilski*, 561 U.S. at 604–57 (lacking any discussion of what will be considered subject matter eligible moving forward).

71. Following *Bilski*, three additional Supreme Court opinions limit subject matter eligibility under § 101. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013); Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).

patent eligibility of biotechnological inventions.[72] In Mayo, the Supreme Court invalidated a patent claiming a companion diagnostic used to determine the correct dosage of thiopurine drugs.[73] The patent claimed a process of administering thiopurine drugs, later measuring thiopurine metabolite levels, and then recalculating dosage based on the results.[74] The Court articulated a new standard for patent eligibility: a process involving a law of nature is not patentable "unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself."[75] The process at issue in Mayo did not meet this standard because "the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately."[76] In other words, a claim that merely applies previously known technology to a new end is not patent-eligible. While the Mayo decision does not preclude patent eligibility of all companion diagnostics, the opinion leaves the biotechnology field with little guidance moving forward.[77]

Myriad is another Supreme Court case that addresses patent eligibility of biotechnology: whether isolated DNA is patent-eligible.[78] Prior to *Myriad*, natural products isolated from their natural state qualified as patent-eligible subject matter and it was standard industry practice to claim DNA isolated from cells in a patent.[79] However, the Court in *Myriad* held a patent on isolated DNA invalid, reasoning that the isolation of naturally-occurring DNA from its natural state did not create or

72. *Myriad*, 133 S. Ct. at 2111; *Mayo*, 132 S. Ct. at 1294.

73. *Mayo*, 132 S. Ct. at 1294, 1305.

74. *Id.* at 1294–95.

75. *Id.* at 1297.

76. *Id.* at 1298. The classification of this correlative process as a law of nature is questionable. *Id.* at 1296; *see supra* Part II.B (discussing the classification system of technology as natural laws, physical phenomena, and abstract ideas).

77. *See Mayo*, 132 S. Ct. at 1296–1305 (giving no guidance on what companion diagnostic would be patent-eligible); Jennifer Gordon, *The Impact of* Myriad *and* Mayo*: Will Advancements in the Biological Sciences Be Spurred or Disincentivized? (Or Was Biotech Patenting Not Complicated Enough?)*, *in* INTELLECTUAL PROPERTY IN MOLECULAR MEDICINE, *supra* note 23, at 163, 171–72 ("We know that the language of the claims at issue in *Mayo* was considered to be too general. Unfortunately, little guidance was provided as to what level of specificity in patent claims of this nature would allay the Court's concerns.").

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

79. Gordon, *supra* note 77, at 166–67 ("[U]p until the *Myriad* case, the term 'isolated' was approved by the [USPTO] as the word that would signify that the DNA molecule being claimed was distinct from what existed in nature.").

alter the DNA.[80] The Court noted that "[t]o be sure, [the patentee] found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention."[81]

Mayo and *Myriad* stand for the rule that patents involving a naturally-occurring phenomenon or natural law must produce something altogether different than what the court classifies as natural.[82] This sounds quite similar to the *Diehr* standard set out several decades ago, with one major difference in reasoning: in *Mayo*, the Court specified that the steps in conjunction with the natural law could not be conventional or routine.[83] This difference greatly impacts patents on biotechnology, invalidating thousands of diagnostic methods and claims to isolated DNA that used wording that, up until those decisions, was industry standard.[84] A recent survey of one thousand biotechnology-related patent applications reveals that the USPTO now rejects thirty-five percent of these applications based on the *Mayo* holding alone.[85] However, rejection of patent applications is not the only effect; a recent survey by the USPTO illustrates that twenty-five out of twenty-seven holdings in the Federal Circuit after the *Mayo* decision resulted in invalidation of all claims challenged on § 101 subject matter eligibility grounds.[86] These holdings give a grim outlook for patent protection of medical diagnostics and continued innovation in the biotechnology industry.[87]

4. Alice*: Reinforcing the Limitations on Patent Subject Matter Eligibility***.** Another Supreme Court decision evaluating subject matter eligibility is Alice Corp. Pty. v. CLS Bank International.[88] The Court held a patent claiming an abstract idea—a computer-implemented scheme for mitigating settlement risk—invalid because the patent did not meet the Court's

80. *Myriad*, 133 S. Ct. at 2111, 2117.

81. *Id.* at 2117.

82. *See id.* (holding that Myriad could not patent an isolated DNA molecule because the act of isolating did not create anything new); *Mayo*, 132 S. Ct. at 1298 (holding a patent to be subject matter ineligible because the patent's "steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately").

83. *Mayo*, 132 S. Ct. at 1298; s*ee supra* Part III.A.1 (discussing the holding and reasoning of *Diehr*).

84. Gordon, *supra* note 77, at 172.

85. MCFARLANE, SHARP & AQUINO, *supra* note 12, at S-16.

86. U.S. PATENT AND TRADEMARK OFFICE, JULY 2015 UPDATE: SUBJECT MATTER ELIGIBILITY app. 3 (2015), http://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf [https://perma.cc/KC2Q-VWNM].

87. *See infra* Part III.B (discussing the recent Federal Circuit and District Court cases applying the framework provided by the Supreme Court).

88. Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).

threshold for transformation.[89] To arrive at this decision, the Court applied the test originally laid out in Diehr and applied most recently in Mayo: "we must examine the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application."[90] The Court elaborated on the meaning of transformation: "we must distinguish between patents that claim the 'buildin[g] block[s]' of human ingenuity and those that integrate the building blocks into something more."[91] Thus, the Alice decision reiterates the limitations set forth in Bilski, Mayo, and Myriad that did not exist under the Diehr decision: transformation into a new and useful application is not enough to grant patent eligibility.[92]

5. Critical Look at the Precedential Framework. The apparent shift to stricter standards for patent protection of natural laws, physical phenomena, and abstract ideas signals a new era where patents once granted by the USPTO are now invalid.[93] Empirical data of the number of patents invalidated for lack of patentable subject matter under § 101 reveals a significant rise in invalidity rulings after the *Alice* decision.[94] Additionally, following *Mayo* in 2012, the Federal Circuit invalidated the vast majority of patents challenged for their subject matter eligibility.[95]

The Supreme Court in *Alice*, *Myriad*, and *Mayo* provides reasoning for why certain subject matter is *not* patent-eligible.[96] We know theoretically what *is* patent-eligible: a natural law,

89. *Id.* at 2351–52.

90. *Id.* at 2357 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294, 1298 (2012)).

91. *Id.* at 2354 (quoting *Mayo*, 132 S. Ct. at 1303).

92. *See* discussion *supra* Part III.A.1–4. *Compare Alice*, 134 S. Ct. at 2354 (reasoning that a patent claiming the "building blocks" of ingenuity is not sufficient to meet patent eligibility requirements), Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013) (invalidating a patent because there was no perceived act of invention in isolating DNA), *Mayo*, 132 S. Ct. at 1298 (invalidating a patent because all steps consisted of "routine, conventional activity"), *and* Bilski v. Kappos, 561 U.S. 593, 604 (2010) (holding that the transformation into something new and useful is not the only test for patent subject matter eligibility), *with* Diamond v. Diehr, 450 U.S. 175, 192 (1981) (holding that transformation into something new and useful is the standard for patent subject matter eligibility).

93. *Cf.* Gordon, *supra* note 77, at 172 (noting changes to patent eligibility in the biotechnology industry after *Mayo*).

94. BRIAN C. HOWARD, LEX MACHINA, 2014 PATENT LITIGATION YEAR IN REVIEW, 20, http://pages.lexmachina.com/rs/lexmachina/images/2014%20Patent%20Litigation%20Report.pdf [https://perma.cc/HVE3-Q8CU].

95. JULY 2015 UPDATE: SUBJECT MATTER ELIGIBILITY, *supra* note 86, at app. 3.

96. *Alice*, 134 S. Ct. at 2351–52; *Myriad*, 133 S. Ct. at 2117; *Mayo*, 132 S. Ct. at 1297–98.

physical phenomenon, or abstract idea must contain an "inventive concept," a familiar requirement since the 1970s, invoked by cases such as *Mayo* and *Alice*.[97] However, it remains unclear what constitutes patentable subject matter under this test because so few rulings by the Supreme Court uphold patents challenged upon subject matter eligibility grounds.[98] This lack of clarity harms those seeking patent protection for inventions that involve a natural law, physical phenomenon, or abstract idea.[99] A major concern is in the biotechnology industry, where the *Mayo* ruling opened the door to patent application rejection and invalidation upon challenge because biotechnological inventions by their very nature will contain elements of natural laws or phenomena.[100] This uncertainty will result in patentees testing out new claim language that may very well be subject to rejection.[101] The negative impact of these limitations on incentivizing innovation leads to the proposal in Part VI of this Comment: either revert to the *Diehr* standard or push Congress to step in and assert the constitutionally-grounded right to broad patent protection.[102]

B. Lower Court Implementation of the Limited Subject Matter Eligibility Standard

The legal framework for subject matter eligibility laid out by the Supreme Court is anything but clear.[103] As a result, the Federal Circuit and lower courts have not applied any one consistent standard to decide questions on § 101, particularly in light of the *Mayo* holding.[104] This section of the Comment overviews selected

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97. *Alice*, 134 S. Ct. at 2357; *Mayo*, 132 S. Ct. at 1299; Parker v. Flook, 437 U.S. 584, 594–95 (1978).

98. The dissenting opinion in the Federal Circuit decision of *Alice* prior to its Supreme Court affirmation points out this frustration: "It has been a very long time indeed since the Supreme Court has taken a case which contains patent eligible claims." CLS Bank Int'l v. Alice Corp. Pty., 717 F.3d 1269, 1314 (Fed. Cir. 2013) (Rader, C.J., dissenting in part), *aff'd*, 134 S. Ct. 2347 (2014).

99. *See id.* at 1335.

100. Gordon, *supra* note 77, at 171–72 ("We know that the language of the claims at issue in *Mayo* was considered to be too general. Unfortunately, little guidance was provided as to what level of specificity in patent claims of this nature would allay the Court's concerns."); *see Mayo*, 132 S. Ct. at 1295–1305 (giving no guidance on what companion diagnostic would be patent-eligible); *infra* Part V (discussing the consequences of diminished patent protection in the biotechnology industry).

101. Gordon, *supra* note 77, at 172 ("The cycle of testing appropriate claim language for biological inventions in the USPTO and the courts begins anew.").

102. *See infra* Part VI.

103. *See supra* Part III.A (discussing the lack of clarity on what constitutes patentable subject matter following recent Supreme Court decisions).

104. *See infra* Part III.B. (highlighting the reasoning in recent Federal Circuit and District Court cases).

recent cases involving patents of biotechnological inventions, illustrating both the inconsistencies that arise from the confusing legal framework handed down by the Supreme Court and the expressed frustration with the restrictive standard.

1. PerkinElmer *&* Ameritox*: Conflicting Criteria of Inventiveness***.** The Federal Circuit in *PerkinElmer, Inc. v. Intema Ltd.* and the United States District Court of Wisconsin in *Ameritox, Ltd. v. Millennium Health, LLC* both use a standard for subject matter eligibility of a patent claiming a natural law that requires a specific application of an inventive concept, the former holding a patent invalid as ineligible subject matter and the latter holding a patent valid as eligible subject matter.[105] The importance of specific applications involving natural laws or other ineligible subject matter hearkens back to the *Diehr* standard that a patent involving a natural law may be patentable if it claims a new and useful application of that natural law.[106] However, as discussed below, the two courts use conflicting criteria to deem whether a process involves an inventive concept.[107]

In *PerkinElmer*, the patent at issue claimed a screening method for Down syndrome involving the measurement of two biomarkers in the first and second trimesters of pregnancy.[108] The court articulated the standard for eligibility of a patent claiming a natural correlation to be whether the patentee "added enough to the statements of ineligible subject matter to direct the claims, not to the ineligible concepts themselves, but to applications of those concepts."[109] The court ultimately held the patent invalid because the data-gathering steps were conventional,[110] as opposed to "specific inventive applications."[111] The court reasoned that the steps in the process were conventional because they could be performed "without transforming the [sample] should science develop a totally different system for [assaying for a biochemical screening marker] that did not involve such a transformation."[112]

105. PerkinElmer, Inc. v. Intema Ltd., 496 F. App'x 65, 71 (Fed. Cir. 2012), *cert. denied*, 134 S. Ct. 102 (2013); Ameritox, Ltd. v. Millennium Health, LLC, 88 F. Supp. 3d 885, 916–17 (W.D. Wis. 2015).

106. *See supra* Part III.A.1 (discussing the reasoning and holding of *Diehr*).

107. *Compare PerkinElmer*, 496 F. App'x at 72–73 (basing inventiveness on potential future scientific developments), *with Ameritox*, 88 F. Supp. 3d at 916 (basing inventiveness on the state of technology at the time of invention).

108. *PerkinElmer*, 496 F. App'x at 66–68, 73.

109. *Id.* at 70–71.

110. *Id.* at 71.

111. *Id.* at 68 (citing the *Diehr* and *Mayo* decisions).

112. *Id.* at 72 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303 (2012)).

The reasoning that someone in the future could invent a method that makes the current technology non-transformative would be a blanket preclusion to many process patents as well as an entirely subjective assessment by a judge lacking scientific credentials to make the call.[113]

The United States District Court in *Ameritox* held valid a patent claiming a protocol for detecting the amount of drugs in a patient's urine sample, adjusting the drug levels for hydration status, and comparing patient's drug levels to range of data.[114] The court upheld the patent, which admittedly had close ties to a natural law, because the court deemed the process to be a new and inventive application of the natural law.[115]

The *Ameritox* decision of patent validity hinged on the court judging the claims in light of the "scientific thought at the time of the invention,"[116] while the *PerkinElmer* court stipulated that potential future scientific developments rendering the process non-transformative pre-empted subject matter eligibility.[117] This fundamental inconsistency in application of the standard clearly affected the outcome of these two cases.[118] While the *Mayo* decision hinted that the *PerkinElmer* reasoning is the right way forward,[119] such a nebulous standard could probably render any patent invalid considering the dynamic nature of science.

2. The Classen *Litigation.* The patent at issue in Classen Immunotherapies, Inc. v. Biogen IDEC (Classen) is a rare example of a diagnostic patent that meets the subject matter eligibility threshold post-Mayo.[120] In Classen, the United States District

113. *See* CLS Bank Int'l v. Alice Corp. Pty., 717 F.3d 1269, 1335 (Fed. Cir. 2013) (Rader, C.J., dissenting in part), *aff'd*, 134 S. Ct. 2347 (2014) ("Moreover, to inject the patentability test of 'inventiveness' into the separate statutory concept of subject matter eligibility makes this doctrine again 'the plaything of the judges who, as they became initiated into its mysteries, delighted to devise and expound their own ideas of what it meant; some very lovely prose resulting.'" (internal citation omitted)).

114. Ameritox, Ltd. v. Millennium Health, LLC, 88 F. Supp. 3d 885, 890, 916 (W.D. Wis. 2015).

115. *Id.* at 916 ("Because the inventors cut against scientific thought at the time of the invention, and because the invention targeted a specific problem in the field . . . the court finds that there is sufficient inventive concept . . . for the purposes of meeting the threshold test of section 101.").

116. *Id.*

117. *PerkinElmer*, 496 F. App'x at 72 (quoting *Mayo*, 132 S. Ct. at 1303).

118. *Compare id.* (holding the patent invalid, basing inventiveness on potential future scientific developments), *with Ameritox*, 88 F. Supp. 3d at 916 (holding the patent valid, basing inventiveness on the state of technology at the time of invention).

119. *See Mayo*, 132 S. Ct. at 1302 (suggesting that "later discovered processes" may render a patent invalid for consisting of only conventional elements).

120. Classen Immunotherapies, Inc. v. Biogen IDEC, No. WDQ-04-2607, 2012 WL 3264941, at *5 (D. Md. Aug. 9, 2012).

Court in Maryland ultimately held a patent claiming a method of choosing immunization schedule to minimize negative health impacts based on previous data collection to be patentable by meeting § 101 requirements.[121]

The procedural history of *Classen* illustrates the changing landscape of the legal framework for analyzing subject matter eligibility.[122] On appeal in 2008, the Federal Circuit held the method patent invalid.[123] However, in 2010, the Supreme Court vacated the Federal Circuit's judgment and remanded the case back to the Federal Circuit in light of the Court's *Bilski* decision, where the Federal Circuit once again held the patent invalid.[124] Under the *Bilski* decision, the court reasoned that the patent was invalid because it did not involve a practical application.[125] However, after the Supreme Court's 2012 *Mayo* decision, the District Court granted reconsideration of the *Classen* case and reversed, holding the patent valid under *Mayo*.[126]

Using *Mayo* as a guide, the court reasoned that the patentee's claims fell within patentable subject matter, unlike those in *Mayo*, because the claims did not build upon "well-understood, routine, [or] conventional activity."[127] The court distinguishes between *Classen* and *Mayo* by reasoning that the technology in *Classen* involves compiling information from a public database and synthesizing it into a new and useful application, whereas the technology in *Mayo* involved taking information from a single patient, and using that information to aid in triage

121. *Id.*

122. The *Classen* litigation began in 2006 and went up to the Federal Circuit on appeal in 2008, where the court held the patent invalid, only to be remanded in 2010 by the Supreme Court because of the *Bilski* opinion. Classen Immunotherapies, Inc. v. Biogen IDEC, No. WDQ-04-2607, 2006 WL 6161856 (D. Md. Aug. 16, 2006), *aff'd*, 304 F. App'x 866 (Fed. Cir. 2008), *cert. granted*, *judgment vacated*, 561 U.S. 1040 (2010). On remand, the Federal Circuit reversed, holding the patent valid, but after the Supreme Court's *Mayo* decision in 2012, the District Court heard the issue again, resulting in an invalidated patent. Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2011); Classen Immunotherapies, Inc. v. Biogen IDEC, No. WDQ-04-2607, 2013 WL 680379 (D. Md. Feb. 22, 2013).

123. Classen Immunotherapies, Inc. v. Biogen IDEC, 304 F. App'x 866, 867 (Fed. Cir. 2008), *cert. granted*, *judgment vacated*, 561 U.S. 1040 (2010).

124. Classen Immunotherapies, Inc. v. Biogen IDEC, 561 U.S. 1040, 1040 (2010); Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1065 (Fed. Cir. 2011).

125. Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1067–68 (Fed. Cir. 2011) (speculating that actually immunizing a patient rather than merely identifying the proper immunization schedule would meet the threshold for § 101 subject matter eligibility).

126. Classen Immunotherapies, Inc. v. Biogen IDEC, No. WDQ-04-2607, 2012 WL 3264941, at *2, *5 (D. Md. Aug. 9, 2012).

127. *Id.* at *4 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1298 (2012)).

decision-making.[128] However, both technologies arguably synthesize the information into a new and useful application.[129]

3. Ariosa*: Frustration with the Restrictions***.** The June 2015 *Ariosa* decision is a recent example of the broad *Mayo* rule precluding subject matter eligibility of a patent claiming an invention of a promising medical diagnostic—detecting the presence of Down syndrome.[130] The patent at issue claimed a specific application of known techniques and involved the isolation and analysis of DNA to make a diagnosis of fetal characteristics.[131] The patentees argued that use of the mother's blood to isolate fetal DNA transformed the routine steps into an inventive concept worthy of a patent; prior to the patentee's discovery of the method, fetal DNA samples could only be obtained using invasive methods.[132] However, the court invalidated the patent, concluding that "the practice of the method claims does not result in an inventive concept that transforms the natural phenomenon of [fetal DNA in the mother's blood] into a patentable invention," reasoning that the only thing new and useful about the invention is the novel discovery of the fetal DNA in the mother's blood.[133]

In the concurrence, Circuit Judge Linn concedes that under *Mayo*, the diagnostic patent must be invalid.[134] However, Judge Linn gives a scathing critique of *Mayo's* broad rule: "This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain."[135] Distinguishing *Mayo* from *Ariosa*, Judge Linn states that the steps taken in *Mayo* consisted of a routine practice with thiopurine drug dosage, whereas in *Ariosa*, the use of fetal DNA from the mother's

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128. The court cites to the Federal Circuit's distinction of *Classen* from *Mayo*: *Mayo* deals with "a method of controlling individualized dosages of a specific drug by measuring its metabolic products in the blood of individual patients, while the Classen patents operate on published information to determine general immunization schedules." Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1068 (Fed. Cir. 2011); Classen Immunotherapies, Inc. v. Biogen IDEC, No. WDQ-04-2607, 2012 WL 3264941, at *4 (D. Md. Aug. 9, 2012).

129. *Mayo*, 132 S. Ct. at 1294 (selecting correct dosage as the ultimate application of the technology); Classen Immunotherapies, Inc. v. Biogen IDEC, No. WDQ-04-2607, 2012 WL 3264941, at *5 (D. Md. Aug. 9, 2012) (indicating that selecting an immunization schedule is the ultimate application of the technology).

130. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1373, 1376, 1380 (Fed. Cir. 2015).

131. *Id.* at 1373.

132. U.S. Patent No. 6,258,540 col 1 l. 11–17 (filed Nov. 29, 1999).

133. *Ariosa*, 788 F.3d at 1376–77.

134. *Id.* at 1380 (Linn, J., concurring).

135. *Id.*

blood embodied an entirely new test with a new step.[136] The Federal Circuit addressed the petition for a rehearing en banc of the June 2015 *Ariosa* decision, ultimately denying a rehearing but aligning with Judge Linn's critique:

> In sum, it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts. But I agree that the panel did not err in its conclusion that under Supreme Court precedent it had no option other than to affirm the district court.[137]

Shortly after denial of a rehearing en banc, Sequenom filed petition for writ of certiorari with the Supreme Court, only to be denied in June 2016.[138]

Ariosa and the other recent cases discussed in this section have spurred a lot of criticism from both scientists and the judiciary.[139] Rigid application of Supreme Court holdings to new technologies may not be the best way forward.[140] Critic Kevin Noonan argues "the Court itself has on many occasions made it clear that they view their role (in patent law and otherwise) as setting forth the broad contours of the law that they expect the inferior courts to use to develop the law properly."[141] Additionally, some argue that the level of novelty that *Ariosa* and the broad application of *Mayo* suggest may "call into question nineteenth-century patented innovation the Supreme Court deemed valid."[142] The uncertainty of what constitutes eligible

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136. *Id.* at 1381 ("[The patentee] 'effectuate[d] a practical result and benefit not previously attained,' so its patent would traditionally have been valid.") (quoting Le Roy v. Tatham, 63 U.S. (22 How.) 132, 135–36 (1859)).

137. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1287 (Fed. Cir. 2015).

138. Petition for a Writ of Certiorari, Sequenom, Inc. v. Ariosa Diagnostics, Inc., 136 S. Ct. 2511 (2016) (No. 15-1182), 2016 WL 1105544, at *1 (petitioning the court to answer: "Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?"); Sequenom, Inc. v. Ariosa Diagnostics, Inc., 136 S. Ct. 2511 (2016) (denying certiorari).

139. *E.g.*, *Ariosa*, 809 F.3d at 1287; Kevin E. Noonan, Ariosa Diagnostics, Inc. v. Sequenom, Inc. (Fed. Cir. 2015), PATENT DOCS (June 22, 2015), http://www.patentdocs.org/2015/06/ariosa-diagnostics-inc-v-sequenom-inc-fed-cir-2015.html [https://perma.cc/SZ64-VFP4].

140. *See* Noonan, *supra* note 139.

141. *Id.* (noting that "[i]n view of the lack of clarity in the *Mayo* opinion, a third year law student could distinguish [*Ariosa*] from [*Mayo*] in arriving at the correct conclusion of patent eligibility").

142. Brief of Amicus Curiae Twenty-Three Law Professors in Support of Appellants' Petition for Rehearing *En Banc* at 2, Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015) (Nos. 14-1139, 14-1144).

subject matter for patents covering natural laws, physical phenomena, or abstract ideas likely contributes to the difficulty the Federal Circuit and lower courts have had in applying the legal framework handed down by the Supreme Court.[143] However, the Court refrained from revisiting or clarifying the issues by denying certiorari to Sequenom, leaving this issue to be resolved by the lower courts or Congress.[144]

IV. U.S. PATENT AND TRADEMARK OFFICE GUIDANCE ON SUBJECT MATTER ELIGIBILITY

The USPTO periodically issues guidelines on patent subject matter eligibility in an attempt to address the new standards imposed by the judiciary.[145] While the guidance documents purport to guide patent examiners and applicants on acceptable subject matter for patent protection, courts are not bound by the guidance.[146] The unfortunate result is that even if an applicant follows the current USPTO guidance and obtains a patent, there is uncertainty as to whether the patent will be upheld if challenged in a court. The guidelines therefore represent unreliable sources of subject matter eligibility requirements because of the frequent revision to keep up with court decisions; the USPTO revised their guidelines on subject matter eligibility six times since 2012.[147] The

143. *See supra* Part III.A (discussing the lack of clarity on what constitutes patentable subject matter).

144. Sequenom, Inc. v. Ariosa Diagnostics, Inc., 136 S. Ct. 2511 (2016).

145. *See, e.g.*, John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1047 (2011) ("No matter how incoherent or tortured relevant judicial precedent is, the USPTO must try to distill it into a set of comprehensible guidelines for several thousand patent examiners, each of whom must ultimately rule on the patentability of claims in a sample of the hundreds of thousands of applications that the USPTO receives annually.") (footnote omitted).

146. *See, e.g.*, U.S. PATENT AND TRADEMARK OFFICE, GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PHENOMENA, & NATURAL PRODUCTS (2014), http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf [https://perma.cc/Y5EE-T4Y5] (stating that the guidance is to assist examiners in determining whether a patent claims eligible subject matter).

147. U.S. PATENT AND TRADEMARK OFFICE, 2012 INTERIM PROCEDURE FOR SUBJECT MATTER ELIGIBILITY ANALYSIS PROCESS CLAIMS INVOLVING LAWS OF NATURE (2012) http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf [https://perma.cc/U3XM-QPZ7] (in response to *Mayo*); Memorandum from Andrew H. Hirshfeld, Deputy Commissioner for Patent Examination Policy to Patent Examining Corps (June 13, 2013), http://www.uspto.gov/sites/default/files/patents/law/exam/myriad_20130613.pdf [https://perma.cc/RLX5-85ES] (in response to *Myriad*); GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PHENOMENA, & NATURAL PRODUCTS, *supra* note 146 (in response to *Myriad*, expanding upon the June 2013 document); 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) (in response to *Alice*); JULY 2015 UPDATE: SUBJECT MATTER

frequent change does not necessarily indicate the USPTO's inability to interpret court holdings, but rather reflects the ongoing evolution of the legal framework for subject matter eligibility laid out by the Supreme Court.[148]

Additionally, the USPTO guidelines represent unreliable sources of subject matter eligibility because the guidelines do not follow logically from the court decisions. Again, this is not necessarily the fault of the USPTO—recent precedent lacks clear standards for patents involving natural laws, physical phenomena, or abstract ideas.[149] The March 2014 Guidance addresses changes in the law of subject matter eligibility of inventions involving natural laws, physical phenomena, or abstract ideas after the Supreme Court decided *Myriad*.[150] Because the Court provides no explicit guidance on what constitutes eligible subject matter in recent decisions, this guidance merely represents the agency's predictions of what the courts will construe as eligible considering the precedent.[151] The guidance set out a "substantially different" test: "the claim only qualifies as eligible subject matter if the claim as a whole recites something significantly different than the judicial exception itself."[152] While this test seems to logically follow from precedent,[153] the test is broader than anything laid out by the Supreme Court by purporting to apply to all claims involving laws of nature, natural phenomena, or natural products.[154]

ELIGIBILITY, *supra* note 86 (in response to negative comments of the December 2014 document and the ongoing change of precedent).

148. *See, e.g.*, Golden, *supra* note 145, at 1074 ("[G]iven the coarse-grained nature of the subject-matter inquiry, the USPTO seems the best place to locate primary responsibility for the inquiry's scope and structure. The courts appear inherently ill-suited to the task, and their long-standing struggles with subject-matter inquiries corroborate this appearance.").

149. *See supra* Part III.A (discussing the lack of clarity on what constitutes patentable subject matter).

150. GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PHENOMENA, & NATURAL PRODUCTS, *supra* note 146.

151. Michele Wales & Eddie Cartier, *The Impact of* Myriad *on the Future Development and Commercialization of DNA-Based Therapies and Diagnostics*, *in* INTELLECTUAL PROPERTY IN MOLECULAR MEDICINE, *supra* note 23, at 175, 178 ("In this guidance, the USPTO attempts to synthesize a cohesive regulation, extrapolating from the various Supreme Court decisions, in order to determine patent eligibility based on predictions about what the court might say in future cases.").

152. GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PHENOMENA, & NATURAL PRODUCTS, *supra* note 146, at 3.

153. *See supra* Part III.A.3 (synthesizing the rule for subject matter eligibility from *Mayo* and *Myriad*).

154. GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PHENOMENA, & NATURAL PRODUCTS, *supra* note 146, at 1.

Comments received by the USPTO in response to the March 2014 Guidance illustrate the shortcomings of the "substantially different" test.[155] First, many commentators pointed out that the test broadens the legal framework beyond explicit limitations on holdings that the Supreme Court laid out.[156] Second, the March 2014 Guidance results in invalidating many claims that the USPTO granted over the last century.[157] Critic Sherry Knowles estimates that nearly half of all drugs approved by the Food and Drug Administration from 1981–2010 that once were patent-eligible would no longer be patentable under the new guidelines set forth by the USPTO.[158]

In December 2014 the USPTO released a proposal for an updated guidance document on subject matter eligibility, proposing changes to the March 2014 Guidance document in light of the *Alice* decision by the Supreme Court and other court decisions after *Mayo* and *Myriad*.[159] The proposal in the Federal Register for comments set out a "significantly more" test: "The

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155. *See Public Comments on Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products*, U.S. PATENT AND TRADEMARK OFFICE, http://www.uspto.gov/patent/laws-and-regulations/comments-public/public-comments-guidance-determining-subject-matter [https://perma.cc/99K4-W6J3] (inviting members of the public to submit comments if they believe "that the Supreme Court decisions could be implemented in an alternative manner from the approach taken in the [March 2014] Guidance").

156. *See, e.g.*, Letter from David E. Korn, on behalf of the Pharmaceutical Research and Manufacturers of America, to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration (July 31, 2014), http://www.uspto.gov/sites/default/files/patents/law/comments/mm-a-phrma20140731.pdf [https://perma.cc/9T3P-4NQ8] ("The Guidance also fails to heed the Supreme Court's own warnings about the limits of the *Myriad* and *Mayo* holdings and instead improperly elevates and expands the Court's *dicta* statements, and takes them out of context."); Letter from William T. Tucker, on behalf of the University of California, to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration (July 29, 2014), http://www.uspto.gov/sites/default/files/patents/law/comments/mm-c-ucalifornia20140729.pdf [https://perma.cc/Z4KD-8472] ("We believe that the USPTO has overreached its authority through inappropriately and unjustifiably broad interpretation of the Supreme Court decisions."). In *Myriad* the Court states "what is not implicated by this decision . . . this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes." Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119–20 (2013).

157. *See, e.g.*, Letter from Society Fellows of the American Society of Pharmacognosy to the Commissioner for Patents (July 28, 2014) http://www.uspto.gov/sites/default/files/patents/law/comments/mm-c-sfasp20140728.pdf [https://perma.cc/4EZV-CSYC] ("Harnessing the forces and products of Nature has been inextricably intertwined with the development of modern human society, and the list of patents for ways in which to use these products is extensive.").

158. Sherry Knowles, *Guest Post: Sherry Knowles Responds to USPTO Comments on New Myriad Guidelines*, MANAGING INTELL. PROP.: THE GLOBAL IP RESOURCE (Apr. 24, 2014), http://www.managingip.com/Article/3334160/Managing-Patents-Archive/Guest-post-Sherry-Knowles-responds-to-USPTO-comments-on-new-myriad-guidelines.html.

159. 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618, 74,619 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1).

Supreme Court has identified a number of considerations for determining whether a claim with additional elements amounts to *significantly more* than the judicial exception itself."[160] The USPTO received over sixty comments in response to its December 2014 Interim Guidelines and generated a July 2015 Updated Guidance to respond to the themes of the comments.[161] In the July 2015 Updated Guidance, the USPTO acknowledges the ever-changing precedent: "Since . . . 2014 . . . the Federal Circuit has issued a number of decisions on eligibility, including several very recent precedential decisions, such as *Ariosa Diagnostics v. Sequenom* . . . [t]hese recent decisions, which may be subject to further judicial developments, are being reviewed closely to determine whether any changes in guidance are warranted."[162]

The USPTO guidelines on subject matter eligibility serve as a reference to inventors on what sorts of claims the USPTO will accept.[163] However, after each Supreme Court decision since 2012 addressing subject matter eligibility, the USPTO has been forced to revise their guidelines, indicating that the USPTO is a step behind the courts and can only predict what will come. It is clear that many disagree with the liberties taken by the USPTO in setting forth what it will consider eligible subject matter for patents encompassing natural laws, physical phenomena, or abstract ideas.[164] However, given the lack of clarity in Supreme Court decisions, it seems unfair to fault the USPTO.[165] The revised guidelines on subject matter eligibility will result in rejected patent applications, followed by appeals to the Patent Trial and Appeal Board, resulting in costly defense of technologies that were once deemed protected under the US patent laws.[166] The next section of this Comment will address the consequences of such endeavors on the biotechnology industry.

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160. *Id.* at 74,624 (emphasis added).

161. JULY 2015 UPDATE: SUBJECT MATTER ELIGIBILITY, *supra* note 86, at 1.

162. *Id.*

163. *See, e.g.*, GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PHENOMENA, & NATURAL PRODUCTS, *supra* note 146 (serving the purpose of assisting examiners in evaluating subject matter eligibility). The guidances also provide various examples of claims that are and are not within the bounds set by the USPTO interpreting court precedent. *E.g.*, *id.* at 5–18.

164. *See supra* text accompanying notes 155–58 (discussing the critical comments received by the USPTO regarding the March 2014 guidance).

165. *See supra* Part III.A (discussing the lack of clarity on what constitutes patentable subject matter following recent Supreme Court decisions).

166. Knowles, *supra* note 158 ("The guidelines are already being implemented to reject pending US patent applications, which will get stuck in years of appeals, chilling any ability to attract venture capital and stripping the value of numerous emerging life science companies.").

V. CONSEQUENCES OF LIMITED PATENT PROTECTION ON THE BIOTECHNOLOGY INDUSTRY

The Constitution proclaims that Congress "shall have 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."[167] Congress interprets the clause to grant inventors the right to exclude others from using their inventions for a set period of time.[168] A monopoly is by definition the "exclusive possession or control of the trade in a commodity, product, or service."[169] So, the patent system promotes monopolies on technology, with an overarching objective of promoting "the Progress of Science and useful Arts."[170]

In deciding patent eligibility, the courts attempt to find a balance between maximizing incentives to innovate and allowing the free flow of information to the public to promote innovation.[171] The *Mayo* decision expresses concern for excessive patent protection that may impede the flow of information.[172] While *Mayo* does not explicitly delineate the objectives of patent law it contends to uphold—the Court's opinion merely references "patent law's objectives"—some argue those objectives to be promoting innovation that would benefit society in the form of researching cures for diseases and other important technological advances.[173] The high threshold for subject matter eligibility of patents involving natural laws, physical phenomena, or abstract ideas will reduce patent protection granted to the biotechnology industry, conflicting with the desire to incentivize innovation that would benefit society.[174]

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167. U.S. CONST. art. I, § 8, cl. 8.

168. *General Information Concerning Patents*, *supra* note 30.

169. *Monopoly*, OXFORD ENGLISH DICTIONARY ONLINE (Oxford University Press, 2016), http://www.oed.com [https://perma.cc/Z3NR-4KFX].

170. U.S. CONST. art. I, § 8, cl. 8.

171. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013) (discussing the balance between incentivizing innovation and impeding the flow of information).

172. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1301 (2012) ("And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them . . . .").

173. *Id*. at 1299; *see, e.g.*, *In re* Bilski, 545 F.3d 943, 1014 (Fed. Cir. 2008) (Rader, J., dissenting) (suggesting patent law's objective to be "incentiviz[ing] research for cures and other important technical advances"); Brief for the Biotechnology Industry Organization (BIO) and Pharmaceutical Research and Manufacturers of America (PhRMA) as *Amici Curiae* Supporting Appellants and in Favor of En Banc Reconsideration at 8, Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015) (Nos. 14-1139, 14-1144) ("the objectives of patent law . . . clearly encompass providing adequate patent protection for meritorious inventions . . . .").

174. *See supra* Parts III.A, III.B (discussing the invalidation of various patents claiming biotechnological inventions).

Intellectual property protection is crucial to spur investment and industry growth.[175] The uncertainty of patent protection for biotechnological inventions[176] makes investment return less likely, casting doubt on the future of innovation in biotechnology.[177] The Biotechnology Industry Organization and Pharmaceutical Research and Manufacturers of America, two advocates of strong patent protection for biotechnology, argue that:

> Patents on diagnostics . . . play a critical role as the necessary incentive for the substantial investment required for commercialization activities such as clinical studies in support of regulatory approval, insurance reimbursement, and even the necessary studies to ensure healthcare providers and patients have sufficient information to avail themselves of the technology.[178]

Without strong patent protection, investors will not have the confidence to invest; the risk will outweigh the benefits.[179]

Unfortunately for society as a whole, a loss of investment in the biotechnology industry will result in less research, ultimately resulting in a loss of benefits that research and commercialization of that research gives society.[180] Circuit Judge Rader of the Federal Circuit argues that courts should be mindful of the innovation that spurs breakthroughs in medicine and other technological advancement, otherwise the "court inadvertently advises investors that they should divert their un-protectable investments away from discovery of 'scientific relationships' within the body that diagnose breast cancer or Lou Gehrig's disease or Parkinson's or whatever."[181] A Bureau of National Affairs report of biotechnology after the *Myriad* and *Mayo* Supreme Court decisions acknowledges the same danger:

> Life science companies, facing the possibility that U.S. patent law will not allow them to recoup the millions of dollars and years of research spent on getting a life-changing

175. *See supra* Parts I, II.B.

176. *See supra* Part III.A.5 (discussing the uncertainty of what constitutes patentable subject matter following the *Mayo* decision).

177. *See, e.g.*, MCFARLANE, SHARP & AQUINO, *supra* note 12, at S-8.

178. Brief for the Biotechnology Industry Organization (BIO) and Pharmaceutical Research and Manufacturers of America (PhRMA) as *Amici Curiae* Supporting Appellants and In Favor of En Banc Reconsideration, *supra* note 173, at 6–7.

179. Wales & Cartier, *supra* note 151, at 176 ("[E]fforts by Congress, the courts, and now even the U.S. Patent and Trademark Office (USPTO) that limit the ability to obtain strong patent protection for biotech products have the potential to undermine investor confidence . . . .").

180. *See generally* Hamburg & Collins, *supra* note 10 (discussing some of the successes of personalized medicine).

181. *In re* Bilski, 545 F.3d 943, 1014 (Fed. Cir. 2008) (Rader, J., dissenting).

therapy from lab to market, may be less likely to pursue innovative technology or may take it to other countries where the technology more easily could find patent protection.[182]

VI. CONCLUSION

The laws governing patents are complex: the Constitution grants Congress the power to promote the useful arts, and Congress accordingly codified the patent laws in the United States Code.[183] Those laws remain subject to interpretation by both the judiciary and the USPTO.[184] Popular interpretation of Congress's grant of power to the USPTO forces the USPTO to heed the common law holdings decided by the judiciary.[185] The courts, faced with the ever-changing and dynamic nature of science and technology—and arguably ill-equipped to understand the facets of some patents—have restricted what qualifies as patent-eligible.[186]

The shift in legal analysis of patent-eligible subject matter lacks clarity.[187] The judiciary's take on subject matter eligibility recently evolved in a restrictive manner, yet the Court takes no steps to reconcile current ideology with prior holdings.[188] Additionally, only in rare circumstances does the Court provide direction on what will be considered patent-eligible moving forward, despite invalidating many patents for lacking eligible subject matter.[189] The USPTO, in an attempt to fill the gaps left by the Supreme Court, issues guidance documents that serve to inform their patent examiners what will qualify for a patent.

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182. MCFARLANE, SHARP & AQUINO, *supra* note 12, at S-31.

183. U.S. CONST. art. I, § 8, cl. 8; 35 U.S.C. §§ 1–390 (2012).

184. 28 U.S.C. § 1295; 35 U.S.C. §§ 1–2.

185. *See supra* Part II.A.2 (discussing the interpretation of the statute granting USPTO authority).

186. *See supra* Part III.A (discussing the trend of Supreme Court cases that restrict patent protection of natural laws, physical phenomena, and abstract ideas).

187. *See supra* Parts III.A–B (discussing legal precedent and recent inconsistencies in its application).

188. For example, the technology in *Diehr*—curing rubber—existed prior to the patent at issue. Diamond v. Diehr, 450 U.S. 175, 177–78 (1981). This stands in conflict with *Alice*, *Myriad*, and *Mayo*, all of which held that a patent involving a natural law, physical phenomenon, or abstract idea may not consist merely of conventional or routine steps, yet none reconciled their holding with the tension in *Diehr*. Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347, 2359–60 (2014); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119–20 (2013); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1302 (2012).

189. *See, e.g.*, *Alice*, 134 S. Ct. at 2352 (reasoning that "merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible invention," yet omitting what would transform the idea); Parker v. Flook, 437 U.S. 584, 594 (1978) (suggesting what would not be patent-eligible under the court's holding but omitting what would be patent-eligible).

However, these guidance documents undergo frequent revision and reissuance because of the change in legal analysis handed down by the judiciary.[190]

An unfortunate result to the ever-changing legal framework for what constitutes eligible subject matter for a patent involving a natural law, physical phenomenon, or abstract idea is uncertainty for inventors, investors, and others with vested interests in the biotechnology industry. Patents play a crucial role in securing money to fund the continuing research that, in the past, has transformed the disciplines of medicine, environmental science, and agricultural science. Without well-defined patent protection, it is unclear whether these endeavors can continue to flourish and better society.[191]

A. Proposed Reversion to the Diehr *Standard of Subject Matter Eligibility*

Many scientists, myself included,[192] favor strong patent rights for the research community.[193] Reversion to the standard for subject matter eligibility set forth in *Diehr* would ease the tension created by the recent limitations and resulting uncertainty. In *Diehr*, the Supreme Court held that an application of natural laws, physical phenomena, or abstract ideas to a new and useful end can qualify as patent-eligible subject matter, regardless of the conventional nature of steps.[194] In glaring contrast to the reasoning in *Mayo*, the *Diehr* Court explained:

> It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim

190. *See supra* Part IV (discussing the different guidance documents released by the USPTO from 2012 onwards).

191. *See supra* Part V (discussing the potential impact of uncertain investment return on the biotechnology industry).

192. Prior to law school, I earned a Ph.D. in Experimental Pathology from Yale University, focusing on the improvement of breast cancer diagnostics. Hallie Wimberly, Validation and Assessment of Breast Cancer Biomarkers Estrogen Receptor Beta and Programmed-Death-1 Ligand-1 (May 2014) (unpublished Ph.D. dissertation, Yale University) (on file with author). My research involved correlative relationships between molecules and cancer, akin to the technology underlying those patents deemed patent-ineligible in *Mayo*. *See, e.g.*, Hallie Wimberly et al., *PD-L1 Expression Correlates with Tumor-Infiltrating Lymphocytes and Response to Neoadjuvant Chemotherapy in Breast Cancer*, 3 CANCER IMMUNOLOGY RES. 326 (2015); Hallie Wimberly et al., *ERβ Splice Variant Expression in Four Large Cohorts of Human Breast Cancer Patient Tumors*, 146 BREAST CANCER RES. & TREATMENT 657 (2014).

193. Dorothy Nelkin, *Living Inventions: Animal Patenting in the United States and Europe*, 4 STAN. L. & POL'Y REV. 203, 207 (1993); Randall W. Schwartz, *Patent Reform and the Perception of A Broken System*, J. KAN. B. ASS'N, Nov./Dec. 2010, at 22, 23.

194. *See supra* Part III.A.1 (discussing the holding and reasoning of *Diehr*).

> because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.[195]

A benefit of the *Diehr* standard is that it leaves the door open for creativity in solving problems, a large part of scientific endeavor in the modern laboratory.[196] Under the current framework, because inventions consisting of conventional steps would be simple to copy, inventors who make an innovative leap by combining existing technologies to a ground-breaking end would have little incentive to disclose their invention to the public.[197]

Reversion to the *Diehr* standard would not necessarily overrule the recent Supreme Court decisions on subject matter eligibility. The Supreme Court in *Mayo* notes that the patent at issue, consisting of solely conventional steps, "when viewed as a whole, add[s] nothing significant beyond the sum of [its] parts taken separately."[198] So, assuming the *Mayo* patent really did lack any significant contribution or transformation, under the *Diehr* standard, the *Mayo* patent would fail regardless of whether the steps used were conventional.[199] Reconciling *Myriad* with the *Diehr* standard is trickier: the *Myriad* patent involved conventional steps and involved isolation of two genes from their natural state using routine steps, and use of that product could potentially revolutionize the diagnosis of breast cancer.[200] However, the patent claims at issue in *Myriad* only included the isolation of the genes from an individual.[201] The claims involving specific applications of the isolated genes to a new and useful end

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195. Diamond v. Diehr, 450 U.S. 175, 188 (1981). *But cf.*, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1298 (2012) (holding the patent invalid because steps in addition to the law of nature consist of "well-understood, routine, conventional activity already engaged in by the scientific community").

196. Brief for the Biotechnology Industry Organization (BIO) and Pharmaceutical Research and Manufacturers of America (PhRMA) as *Amici Curiae* Supporting Appellants and In Favor of En Banc Reconsideration, *supra* note 173, at 6 ("It will often be the case that an otherwise novel and nonobvious biotechnology invention can be deconstructed into a mere combination of natural phenomena and known techniques. But biotechnology has advanced through inventions of this type . . . .").

197. *See id.* at 6–7 (discussing the crucial role of diagnostic patents as financial incentives to partake in the research).

198. *Mayo*, 132 S. Ct. at 1298.

199. *See Diehr*, 450 U.S. at 188 (reasoning that the process resulting in a "more efficient solution" is not barred from patent eligibility by § 101).

200. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2112, 2114 (2013).

201. *Id.* at 2114.

were not challenged for subject matter eligibility.[202] Thus, while some of the reasoning in recent Supreme Court decisions stands in conflict with the *Diehr* standard, reversion to the *Diehr* standard would not necessarily negate the recent Supreme Court holdings relating to biotechnology patents.

Under the *Diehr* standard, *Ariosa* would likely come out different. The court in *Ariosa* held the patent at issue invalid on the grounds that it consisted of conventional steps that built upon the discovery of a natural law or physical phenomenon.[203] However, the conventional steps of the patent combined into something new and truly useful—the first non-invasive diagnostic test for Down syndrome of an unborn fetus.[204] Had *Mayo* and *Myriad* been decided under the *Diehr* framework, rather than precluding subject matter eligibility to those methods using only conventional steps, the Federal Circuit likely would have upheld the patent at issue in *Ariosa* as eligible subject matter.[205]

B. Should Congress Step in?

Congress has not passed legislation to limit the wide scope of subject matter eligibility afforded in § 101, which could be read to mean either Congress' view has not changed or that Congress acquiesces with the Supreme Court's interpretation of § 101 to limit patentable subject matter involving natural laws, physical phenomena, and abstract ideas, and recent additional restrictions upon those limits.[206] The legislative history of the laws governing patents reflects Congress's stance that "anything under the sun . . . made by man" should be eligible for a patent.[207] On many occasions, the Supreme Court has proclaimed that only Congress should propose limitations on the laws governing patents.[208] Some

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202. *Id.* at 2120 ("[T]his case does not involve patents on new *applications* of knowledge about the . . . genes. . . . '[A]s the first party with knowledge of the [genes], Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications.'") (quoting Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1349 (Fed. Cir. 2012)).

203. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1376 (Fed. Cir. 2015).

204. U.S. Patent No. 6,258,540 col. 1 l. 11-17 (filed Nov. 29, 1999).

205. *See supra* Part III.B.3 (reconciling a more lenient standard for subject matter eligibility with the *Myriad* and *Mayo* holdings).

206. U.S. CONST. art. I, § 8, cl. 8; *see supra* Part III.A (discussing the trend of reducing patent protection for patents involving natural laws, physical phenomena, or abstract ideas).

207. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 5 (1952), *as reprinted in* U.S.C.C.A.N 1952, 2394, 2399).

208. Diamond v. Diehr, 450 U.S. 175, 182 (1981) ("'[C]ourts 'should not read into the patent laws limitations and conditions which the legislature has not expressed.'" (quoting *Chakrabarty*, 447 U.S. at 308)).

proponents of strong patents rights propose that it may be prudent for Congress to step in and reiterate their stance of strong patent rights, correcting the line of precedent from the Supreme Court that endangers the future of biotechnology research.[209] The *Ariosa* opinions from the Federal Circuit demonstrate that even the judiciary recognizes the high burden placed on biotechnological inventions by the subject matter eligibility framework handed down from the Supreme Court.[210] Considering the outspoken dissatisfaction with the strict standard, the time is apt for either the Supreme Court to revisit the matter and broaden the scope of patent subject matter eligibility or for Congress to step in and reiterate the idea that patentable subject matter should be given broad scope.

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209. *See, e.g.*, Gordon, *supra* note 77, at 173 ("Perhaps the so-last-century, strict ban on patenting laws of nature and natural phenomena needs to be loosened. A legislative fix may well be in order. As if to suggest that that might be the case, the court in *Mayo* noted: '[W]e must recognize the role of Congress in crafting more finely tailored rules where necessary.'"); *see supra* Part III.A (discussing the recent Supreme Court cases that restrict patent eligibility of inventions involving natural laws, physical phenomena, or abstract ideas).

210. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1287 (Fed. Cir. 2015) (referring to the current subject matter eligibility rule as "unsound"); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1380 (Fed. Cir. 2015) (Linn, J., concurring) (referring to unintended consequences of the broad *Mayo* holding precluding patent protection of inventions like the diagnostic test at issue).