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ABSTRACT

Subject matter eligibility, a foundational doctrine of U.S. patent law, defines the types of inventions that are eligible for patent protection. 35 U.S.C § 101, the statutory basis for subject matter eligibility, notes four distinct categories of inventions that are eligible: processes, machines, manufactures, and compositions of matter. However, these categories are constrained by three judicial exceptions: (1) abstract ideas, (2) laws of nature, and (3) natural phenomena. These exceptions are meant to prevent inventors from patenting the basic building blocks of scientific progress.

The judiciary has attempted to mark the boundaries of these exceptions through case law since the earliest days of the American patent system. However, as technology has advanced, it has become increasingly difficult to determine whether an invention invokes one of the judicial exceptions. Four Supreme Court cases, decided between 2010 and 2014, outlined the exceptions and culminated in the *Mayo*/*Alice* test: a two-pronged approach clarifying the doctrine of subject matter eligibility. Recently, in the case of *American Axle v. Neapco Holdings*, the Court of Appeals for the Federal Circuit created uncertainty surrounding the *Mayo*/*Alice* test by invalidating a patent claim for a vibration-dampening liner. The court's ruling that a tangible product can implicitly invoke a law of nature could have wide-reaching implications for the doctrine of subject matter eligibility.

This Comment explores the history and current state of the subject matter eligibility doctrine in the U.S. patent system. It further discusses the implications of the *American Axle* decision and its potential impact on the judicial exceptions. Finally, this Comment examines the *American*

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Axle decision's potential impact on the chemical and materials industries and seeks to provide guidance to practitioners in these fields regarding what they might expect moving forward.

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I. INTRODUCTION

The American patent system has been an important aspect of the American economy since the Industrial Revolution.[1] Many of the primary doctrines within patent law were codified in the late eighteenth century, and have developed through case law and through three major statutory revisions since that time.[2] This consistency has allowed technological innovation to flourish in the United States and has attracted inventors and companies who seek to grow their businesses with the support of a robust system of intellectual property protections.[3]

Subject matter eligibility is a foundational doctrine of U.S. patent law that serves a crucial gatekeeping function by defining what is eligible for patent protection.[4] This doctrine is the bedrock of the American patent system and the predicate for all other patent doctrine inquiries.[5] Although the patent system has flourished in the last century, the question of what kinds of inventions are patentable has been "complex and theoretically challenging."[6]

The most important decisions regarding subject matter eligibility in the past century did not look to statutes, but instead outlined a series of judicially created exceptions that govern what inventions cannot be patented.[7] The judiciary has been concerned with denying patents for inventions that claim abstract ideas, laws of nature, or natural phenomena.[8] Throughout most of the judicial exceptions' history, these inquiries have been determined based on common law principles.[9] Because of the lack of statutory authority and growing technological

1. *See A Brief History of the Patent Law of the United States*, LADAS & PARRY (May 7, 2014), https://bit.ly/3BTTp0Q.

2. *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 10–12 (8th ed. 2021); *see also A Brief History of the Patent Law of the United States*, *supra* note 1 (discussing the three largest revisions to the American patent system: the Patent Act of 1836, the Patent Act of 1952, and the America Invents Act in 2012).

3. *See A Brief History of the Patent Law of the United States*, *supra* note 1.

4. *See In re* Alappat, 33 F.3d 1526, 1553 (Fed. Cir. 1994) (explaining that § 101 subject matter eligibility determinations are the predicate for analyzing the other doctrines of patent law).

5. *See id*.

6. MERGES & DUFFY, *supra* note 2, at 541.

7. *See id*.

8. *See* Diamond v. Diehr, 450 U.S. 175, 185 (1981).

9. *See* MERGES & DUFFY, *supra* note 2, at 543.

innovation across many fields, the Supreme Court has, in the past decade, taken a renewed interest in clarifying these exceptions.[10]

Through a series of four cases decided between 2010 and 2014, the Court sought to define a test for determining when inventions invoke one of these exceptions.[11] In *Mayo Collaborative Services v. Prometheus Labs*, and in *Alice Corp. v. CLS Bank International*, the Court established a standard to provide guidance in analyzing when a patent claim, across all scientific and business disciplines, invokes one of the subject matter eligibility exceptions.[12] The *Mayo*/*Alice* test has been the judiciary's guiding principle over the past seven years.[13] The Court of Appeals for the Federal Circuit recently created ambiguity through its interpretation and implementation of the test when the court applied the test to invalidate a patent claim in a utility application claiming a liner meant to reduce vibrations in an automobile's drive shaft.[14] The Federal Circuit's holding that a patent claim for a tangible product can be invalidated for implicitly invoking a law of nature could have wide-reaching implications for many industries.[15]

This Comment begins by exploring the history of the American patent system and the doctrine of subject matter eligibility.[16] This Comment then analyzes the judicial exceptions and the case law that gave rise to these controlling principles of American patent law.[17] Next, this Comment looks at the Federal Circuit's recent holding in *American Axle* and offers commentary on how the case, and the Supreme Court's decision to deny certiorari, may impact the doctrine of patentable subject matter.[18] Finally, this Comment discusses the chemical and materials industries and evaluates how the *American Axle* decision may impact these major industries in the future.[19]

10. *See id.* at 548 (explaining that the post-2010 line of § 101 cases have sought to clarify the judicial exceptions in light of two fast-growing industries: software and biotechnology).

11. *See, e.g.*, Bilski v. Kappos, 561 U.S. 593, 597 (2010); Mayo Collaborative Servs. v. Prometheus Labs., Inc. 566 U.S. 66, 70 (2012); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 579 (2013); Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 212 (2014).

12. *See Mayo*, 566 U.S. at 70; *see also Alice*, 573 U.S. at 212.

13. *See* Genetic Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369, 1374 (Fed. Cir. 2016) (stating that the *Mayo*/*Alice* test has become the "well-established two-step test for patent eligibility under § 101").

14. *See* Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1288 (Fed. Cir. 2019).

15. *See infra* Section III.C.

16. *See infra* Sections II.A–II.B.

17. *See infra* Section II.C.

18. *See infra* Section II.D.

19. *See infra* Section III.C.

II. BACKGROUND

As technology has evolved, the judiciary has been faced with evaluating patent claims for continually-advancing technologies that push the boundaries of patent law, leaving the courts to determine complex questions of patent eligibility.[20] The judiciary's determinations in this area are not trivial, and they strike at the heart of the patent system.[21] Subject matter eligibility determinations have far-reaching effects on businesses' existing intellectual property, and may potentially impact diverse sectors of the U.S. economy.[22]

A. A Brief Overview of U.S. Patent Law

To understand the evolution of patent law and its major doctrines, one must first understand how patent law was initially implemented in the United States. The structure and formation of the patent system are crucial to understanding the posture of modern patent cases and the history that has led to its major doctrines.

1. Origins

The origins of the U.S. patent system, like many sectors of American law, can largely be attributed to English Common Law.[23] Patent policy in England emerged in the sixteenth century as a strategic method to attract foreign immigrants with industrially applicable skills.[24] Early English patent policy was based on the "patent bargain": by providing an economic incentive for inventors who produce new inventions, England furthered the public's interest in luring inventors and their technological knowledge to the country.[25] As the English economy transitioned during the Industrial Revolution, this fundamental bargain's focus changed.[26] The public's incentive shifted from a desire to attract and reward new inventors to a utilitarian desire to create a repository of

20. *See* MERGES & DUFFY, *supra* note 2, at 548. *See generally* Mayo Collaborative. Servs. v. Prometheus Labs., 566 U.S. 66, 70 (2012) (demonstrating that biological technology advances have created new subject matter eligibility questions for the Court); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 579 (2013) (demonstrating the difficulty in applying traditional eligibility principles to patents claiming advanced biotechnology).

21. *See generally Intellectual Property and the U.S. Economy: 2016 Update*, U.S. PAT. & TRADEMARK OFF. (2016), https://bit.ly/3Duiikq (discussing the important role of patents and other forms of intellectual property in the American economy).

22. *See id.*

23. *See* MERGES & DUFFY, *supra* note 2, at 9.

24. *See id.* at 7.

25. *See id.*; *see also* B. Zorina Khan, *An Economic History of Patent Institutions*, ECON. HIST. ASS'N (Mar. 16, 2008), https://bit.ly/3QXO2oZ.

26. *See* MERGES & DUFFY, *supra* note 2, at 8.

innovation available to the public.[27] This bargain eventually formed the foundation of the Anglo-American patent system, and its impact is still present in international patent laws to this day.[28]

As dependents of the British Empire, the American colonies each slowly incorporated the English patent system throughout the seventeenth and eighteenth centuries.[29] In 1789, the Framers of the Constitution consolidated the U.S. patent system under federal authority by granting Congress the power to establish a new national patent system in Article I of the Constitution.[30]

2. Statutory & Constitutional Basis

Article I, Section 8, Clause 8 of the U.S. Constitution authorizes Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[31] As a result, Congress passed the U.S. Patent Statute in May of 1790. But it was not until the 1793 and 1836 revisions that the patent system began to resemble its current structure.[32] The language implemented in these early patent acts has remained largely consistent, and even Congress's revisions to the Patent Act in 1952 primarily "restated many of the fundamental principles on which American patent law has been based since 1790."[33]

The most substantive revision to the patent system in the last 70 years came in 2011 when Congress passed the America Invents Act ("AIA").[34] The AIA introduced significant changes to some of patent law's most fundamental doctrines.[35] However, to understand the importance of these statutory changes, one must first understand patent law's four fundamental doctrines.[36] For an inventor to obtain a patent, they must meet several statutory requirements set forth in Title 35 of the U.S. Code.[37]

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27. *See id* at 8–9.
28. *See id.* at 7.
29. *See id.* at 9.
30. U.S. CONST. art. I, § 8, cl. 8.
31. *Id.*
32. *See A Brief History of the Patent Law of the United States*, *supra* note 1 (explaining that the 1793 revision was notable for being the first patent act to define what constituted patentable subject matter); *see also* MERGES & DUFFY, supra note 2, at 11-12 (explaining that the 1836 act instituted the current system of examination by professional examiners and introduced the requirement for novelty to obtain a patent).
33. MERGES & DUFFY, *supra* note 2, at 13.
34. *See id.* at 18 (explaining that the AIA was the "single most important piece of legislation in patent law since the 1952 Patent Act").
35. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).
36. *See* 35 U.S.C. §§ 101–03, 112.
37. *See* 35 U.S.C. §§ 101–03, 112.

a. Subject Matter Eligibility

Subject matter eligibility is the threshold doctrine of American patent law.[38] Subject matter eligibility concerns "which *types* of inventions are eligible for patent protection."[39] The doctrine is codified in § 101 of Title 35 and has evolved since the Patent Act's inception in 1793.[40] Section 101 lists four bright-line categories of inventions that are deemed patentable: (1) machines, (2) manufactures, (3) compositions of matter, and (4) processes.[41] Based on the statutory language, one might assume that a court's subject matter eligibility determination is straightforward.[42] However, in practice, case law has demonstrated that these determinations have "not always been so simple."[43]

The complexity of these determinations stems from both the English common law and the long history of American case law that has colored these inquiries.[44] This line of cases created judicial exceptions that limit the types of inventions that may be awarded patents.[45] Namely, the judicial exceptions exclude (1) abstract ideas, (2) natural phenomena, and (3) laws of nature from being patented.[46] Because these exceptions have no statutory basis, the judiciary has justified their legitimacy based on the rationale underlying all issued patents: the patent bargain.[47] Fundamentally, this bargain in its modern form is a quid pro quo between an inventor and the U.S. government.[48] In exchange for an inventor providing new and useful technology to society, the government will award that inventor with a limited monopoly for the use and sale of their invention to incentivize further innovation.[49]

The judiciary has implemented and maintained the exceptions to prevent inventors from claiming an exclusive right to publicly available

38. *See* MPEP § 2106.03 (9th ed., rev. 10, 2019).

39. MERGES & DUFFY, *supra* note 2, at 541.

40. *See id.* at 542. *Compare* 35 U.S.C. § 101 ("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."), *with* Patent Act of 1793, § 1, 1 Stat. 318, 319 (authorizing patents for "any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter").

41. *See* 35 U.S.C. § 101.

42. *See* MERGES & DUFFY, *supra* note 2, at 542.

43. *Id.*

44. *See id.* at 542–43.

45. *See* MPEP § 2106.04 (9th ed., rev. 10, 2019).

46. *See* Diamond v. Diehr, 450 U.S. 175, 185 (1981); *see also* Parker v. Flook, 437 U.S. 584, 589 (1978).

47. *See* Thomas & Betts Corp. v. Panduit Corp., 65 F.3d 654, 660 (7th Cir. 1995).

48. *See* AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

49. *See id.*; *see also Panduit*, 65 F.3d at 660.

ideas.[50] In fact, awarding a patent to inventions that implicate the judicial exceptions may stifle innovation because these inventions are the "basic tools of scientific and technological work."[51] The judiciary has made considerable efforts to define exactly what is covered under each of these exceptions to provide clearer guidance for inventors seeking to obtain new patents and for lower courts adjudicating patent invalidity lawsuits.[52]

b. Novelty

The second statutory requirement found in Title 35 is the novelty requirement codified in § 102.[53] Novelty, unlike subject matter eligibility, is a purely statutory requirement and is thus more constrained by statutory guidelines.[54] Colloquially, one might refer to this requirement by asking whether the invention is *new*.[55] Formally, novelty under § 102 requires that the invention is a product of the inventor, the invention has not been publicly disclosed prior to one year before the filing of the application, and the elements of the invention were not described entirely by a work of prior art.[56]

The novelty requirement can also be traced back to the earliest patent acts in the late eighteenth century; however, its language has seen major revisions in the past decade.[57] Most recently, the AIA completely reshaped the novelty doctrine, primarily to comply with international patent codes.[58] The AIA changed the standard in novelty determinations

50. *See Flook*, 437 U.S. at 589.

51. *Id.*; *see also* O'Reilly v. Morse, 56 U.S. 62, 113 (1854). The Court in *Morse* used this reasoning to conclude that a claim for transmitting signals using electromagnetism should not be patentable because it would hinder scientific progress. *See id.* The Court's reluctance to allow such a broad claim would prove wise as the use of electric signals to communicate messages would explode over the next decades, and electronic signals are still the dominant form of long-distance communication. *See* Hellmut Fritzsche, *Electromagnetic Radiation: Radio Waves*, BRITANNICA (July 23, 2020), https://bit.ly/3pn4Qtz.

52. *See* Joseph Matal, *The Three Types of Abstract Ideas*, 30 FED. CIR. BAR J. 87, 88 (2021) (discussing the history of common law decisions that have led to the *Mayo/Alice* test).

53. *See* 35 U.S.C. § 102.

54. *See* MERGES & DUFFY, *supra* note 2, at 79.

55. *See id.*; *see also* 35 U.S.C. § 102 (stipulating that for an invention to be novel it must not have been previously disclosed in a patent, nor described publicly in any form of publication).

56. *See* 35 U.S.C. § 102(a)(1). Prior art is any invention or idea that has been "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." *Id.*

57. *See* MERGES & DUFFY, *supra* note 2, at 81–82.

58. *See id.* at 18–19. *See generally* Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645 (establishing requisite international standards for national patent codes for nations to participate in the treaty).

from a first-to-invent system to a first-to-file system and also alleviated administrative burdens in implementing the previous system.[59]

c. Non-Obviousness

Unlike the subject matter eligibility and novelty requirements, which have existed in some form since the origins of the patent system in the U.S., non-obviousness is a newer addition to the realm of patent law.[60] Although non-obviousness was first implemented through common-law decisions, the principles were eventually codified in § 103 of the Patent Act of 1952 and were modified only slightly by the AIA in 2011.[61] Under § 103, a patent may not be obtained if the "claimed invention and the prior art are such that the claimed invention as a whole would have been obvious . . . to a person having ordinary skill in the art."[62]

Courts have generally held that the principle question in non-obviousness decisions is whether there is a sufficient technical advancement to justify granting a patent.[63] In *Hotchkiss v. Greenwood*, the Supreme Court rejected a patent application in which an inventor merely substituted new materials into an existing mechanical design because it was "destitute of ingenuity."[64] Then, following the codification of the doctrine in § 103, the Court reiterated and expanded its original understanding of the non-obviousness doctrine in *Graham v. John Deere Co.*[65] In *Graham*, the Supreme Court held that the non-obviousness determination should be conducted by comparing the prior art and the claims in question to evaluate the level of skill required to create the invention.[66]

d. Disclosure & Enablement

Disclosure and enablement combine to form the last foundational requirement for patent eligibility.[67] These requirements are also perhaps the easiest to understand: § 112 requires that an inventor provide a "written description of the invention . . . in such full, clear, concise, and

59. *See* MERGES & DUFFY, *supra* note 2, at 85 (explaining that priority in patent applications, as a result of the AIA, was now afforded to the first inventor to file their patent application, rather than the first inventor to produce the claimed invention).

60. *See id.* at 325.

61. *See id.*

62. 35 U.S.C. § 103.

63. *See* MERGES & DUFFY, *supra* note 2, at 327; *see also* Hotchkiss v. Greenwood, 52 U.S. 248, 265 (1851); Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

64. *Hotchkiss*, 52 U.S. at 266.

65. *See* MERGES & DUFFY, *supra* note 2, at 346.

66. *See Graham*, 383 U.S. at 17.

67. *See* 35 U.S.C. § 112.

exact terms as to enable any person skilled in the art to . . . make and use the [invention]."[68] The requirement of disclosure specifically pertains to the written description and asks whether the patent application is both clear and concise so that a person of ordinary skill in the art would understand what is being claimed.[69] This requirement also serves to notify potential infringers of where the boundaries of the patent's claims are.[70]

The enablement requirement asks whether the patent has sufficiently taught the public how to make and use the invention.[71] Sufficiently teaching the public how to make and use one's invention is part of the "price" an inventor pays to obtain a limited monopoly under the justification rationale of the patent bargain.[72] A patent applicant must satisfy both doctrines to meet the statutory requirements put forth in § 112.

3. Institutional Structure of American Patent Law

To understand the substantive doctrines in patent law and their evolution over time, one must also look at the institutional structure that has shaped American patent law and implements its rules in the present day. To begin, it is important to note that the federal government and the federal courts have exclusive jurisdiction over patent law.[73]

As previously mentioned, Article I of the U.S. Constitution authorizes Congress to establish a patent system for U.S. inventors.[74] Congress has enacted such a system by passing Title 35 and several major revisions over the past couple centuries.[75] Congress does not directly oversee the system created by its legislation, but instead has created an institutional structure to govern American patent law.[76] All patent proceedings, whether in the course of applying for a patent or in

68. *Id.* at § 112(a).

69. The written description requirement of § 112 requires a patent applicant to provide a written text that fully describes and enables the invention. *See* MPEP § 2163 (9th ed., rev. 10, 2019). A person of ordinary skill in the art is the objective standard by which patent examiners judge enablement to determine if an ordinarily skilled professional would understand the patent. *See* MPEP § 2141.03 (9th ed., rev. 10, 2019).

70. *See* MPEP § 608.04 (9th ed., rev. 10, 2019).

71. *See* MPEP § 2164 (9th ed., rev. 10, 2019).

72. *See* MERGES & DUFFY, *supra* note 2, at 454–55.

73. *See* 35 U.S.C. § 1.

74. *See* U.S. CONST. art. I, § 8, cl. 8.

75. *See* Patent Act of 1793, 1 Stat. 318; *see also* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

76. *See generally* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (creating the administrative framework by which patent law is governed and designating to the Patent Trial and Appeal Board the authority to officiate Inter Partes Reviews, Post-Grant Reviews, and other proceedings).

the course of patent litigation of an infringement suit, are conducted in federal courts or by administrative agencies.[77]

To lighten the burden on the federal court system, Congress initiated reform to provide alternative methods of conflict resolution in the patent system.[78] In doing so, Congress created the bureaucratic structure charged with overseeing the patent system: the United States Patent and Trademark Office ("USPTO").[79] The USPTO is principally concerned with examining patent applications according to the requirements of Title 35, issuing notices of acceptance or rejection, and publishing these documents for the benefit of the public.[80] In Title 35, Congress gave the USPTO the ability to promulgate substantive rules that supplement the scope of patent eligibility determinations subordinate to the controlling statute or case law.[81] The USPTO has expanded this authority over time by passing formal rules for inventors and its examiners in the Manual of Patent Examining Procedure ("MPEP")[82] and by establishing an appellate board capable of hearing patent suits independent of the judiciary.[83]

In addition to the USPTO, the judiciary is also a major source of American patent law.[84] The court system has exercised a tremendous amount of power in shaping the fundamental doctrines of American patent law.[85] Immediately after the inception of the first patent act, high-ranking government officials, including the Secretary of State, oversaw the patent system.[86] The 1836 revision to the Patent Act altered the structure of this system drastically by introducing professional patent examiners.[87] Over the next century and a half, this system remained largely intact as the importance of patents in American society ebbed and flowed.[88]

In 1982, Congress centralized the federal court system's role in American patent law by creating the Court of Appeals for the Federal

77. *See* 35 U.S.C. § 1.

78. *See The U.S. Patent and Trademark Office*, FINDLAW (June 20, 2016), https://bit.ly/3UCd6Ee.

79. *See id.*

80. *See* 35 U.S.C. § 2(a). *See generally* U.S. MPEP § 2106 (9th ed., rev. 10, 2019) (explaining the procedure and requirements for prosecuting and examining patents before the USPTO).

81. *See* 35 U.S.C. § 2(b)(2). For other powers granted to the USPTO, see 35 U.S.C. § 2.

82. *See, e.g.*, MPEP § 2106 (9th ed., rev. 10, 2019).

83. *See* MERGES & DUFFY, *supra* note 2, at 19.

84. *See id.* at 541 (explaining that entire doctrines like the doctrine of subject matter eligibility are almost entirely influenced by judge-made law).

85. *See id.*

86. *See id.* at 11.

87. *See id.* at 12.

88. *See id.* at 12–13.

Circuit and granting that court jurisdiction over all patent appeals from federal district courts.[89] This new court was "ostensibly formed . . . to unify patent doctrine," but many hoped it would also expand patent case law to "[enhance] the stature of the patent system."[90] Federal courts wield tremendous power to shape American patent law, and judicial precedent has implemented substantive changes throughout the history of the patent system.[91]

4. The Supreme Court's Modern Intervention in Patent Cases

United States district courts and the Court of Appeals for the Federal Circuit are the primary venues that interpret and shape patent law, but ultimate authority to interpret all patent law rests with the Supreme Court.[92] Initially, the Supreme Court was predominantly deferential to decisions of the Federal Circuit, taking only two patent cases in the Federal Circuit's first decade of existence.[93] However, the Court's involvement has steadily increased throughout the last three decades.[94] In the last 15 years, the Supreme Court has reasserted its traditional authority to shape patent law and decide cases regarding the fundamental doctrines of American patent law.[95] Perhaps no line of cases has had a bigger impact on patent law than the Court's decisions from 2010 to 2014 regarding subject matter eligibility.[96]

89. *See* Rochelle C. Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 25–26 (1989).

90. MERGES & DUFFY, *supra* note 2, at 13.

91. *See, e.g.*, O'Reilly v. Morse, 56 U.S. 62, 106 (1854); Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980); Mayo Collaborative. Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 70 (2012); MERGES & DUFFY, *supra* note 2, at 541.

92. *See* 35 U.S.C. § 1 (stating that the patent statutes are administered by federal authority).

93. *See* MERGES & DUFFY, *supra* note 2, at 14 (explaining that decisions during this time primarily "involved major issues including the scope of the court's power to construe patent claims").

94. *See id.* at 14–15. The initial period of deference, before resuming the practice of hearing patent cases, can be interpreted as the Supreme Court giving the Federal Circuit an opportunity to clarify patent law before the Supreme Court resumed its traditional appellate role. *See id.* at 15.

95. *See id.*

96. *See, e.g.*, Bilski v. Kappos, 561 U.S. 593, 597 (2010); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 70 (2012); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 579 (2013); Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 212 (2014).

B. Subject Matter Eligibility's Gatekeeping Function

Subject matter eligibility is generally the initial inquiry in all patent cases, and therefore carries a unique importance.[97] Questions of subject matter eligibility are often among the most complex and nebulous determinations in American patent law and are only growing more complex as technology advances.[98] Subject matter eligibility, as defined in § 101, serves an important gatekeeping function: determining what types of inventions may be eligible to be patented before conducting any of the other relevant inquiries.[99]

Patentable subject matter was first defined in the 1793 revision to the Patent Act.[100] That definition has remained largely the same over the past two centuries, receiving only minor amendments to its language.[101] The current definition, as found in 35 U.S.C. § 101, states: "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."[102] This formulation, at first glance, may appear simple to apply; however, case law analyzing § 101 has constrained these determinations and created tests that tend to apply a common-law analysis, as opposed to a strict textual analysis, of § 101.[103]

C. Judicial Exceptions

The judicial exceptions to subject matter eligibility have arisen from case law rather than from the text of § 101.[104] The most important decisions in the § 101 case law serve to delineate the judicial exceptions, denoting what is not eligible to be patented.[105]

1. Origins of the Judicial Exceptions

As is the case with many areas of American law, the origins of the judicial exceptions to § 101 can be traced back to English Common

97. *See* In re Alappat, 33 F.3d 1526, 1553 (Fed. Cir. 1994) (explaining that § 101 subject matter eligibility determinations are the predicate for analyzing the other doctrines of patent law).

98. *See* MERGES & DUFFY, *supra* note 2, at 541.

99. *See Alappat*, 33 F.3d at 1553.

100. *See* Patent Act of 1793, § 1, 1 Stat. 318.

101. *See* MERGES & DUFFY, *supra* note 2, at 542.

102. 35 U.S.C. § 101.

103. *See* MERGES & DUFFY, *supra* note 2, at 542–43.

104. *See id.* at 541. For examples of the U.S. Supreme Court's method of expounding upon the judicial exception through case law, see *Bilski v. Kappos*, 561 U.S. 593, 597 (2010); *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 70 (2012); *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 579 (2013); and *Alice Corp. v. CLS Bank International*, 573 U.S. 208, 212 (2014).

105. *See* MERGES & DUFFY, *supra* note 2, at 542–43.

Law.[106] These exceptions arose from a series of late eighteenth-century cases establishing that an inventor was not entitled to claim "principles" or other abstract ideas.[107] Later English cases expanded on this idea and formed the basis for the modern understanding of the subject matter eligibility exceptions.[108]

2. The Three Judicially Created Exceptions

Three exceptions to the subject matter eligibility doctrine originated in English Common Law and have shaped § 101 determinations throughout the past three centuries.[109] The exceptions are the concepts of "abstract ideas, laws of nature, and natural phenomenon."[110] The Supreme Court has justified the exceptions on policy grounds, stating that these three concepts are ineligible for patent protection because they "are the basic tools of scientific and technological work," and because the Court might hinder innovation by granting limited monopolies for these concepts.[111]

a. Abstract Ideas

The first of the three judicially created exceptions centers around the concept of abstract ideas. The 1978 case of *Parker v. Flook* was an important development in § 101 jurisprudence and initiated the Court's renewed interest in delineating the judicial exceptions.[112]

In *Flook,* the petitioner sought to invalidate the respondent's patent on the grounds that the patent's only novel feature was a mathematical expression applied to an existing technology.[113] The respondent had developed an alarm system that used a mathematical expression to control a chemical reaction.[114] The Court noted that the practice of using alarms to monitor the conditions of the reaction was already well-known

106. *See* H. Jared Doster, *The English Origins of the Judicial Exceptions to 35 U.S.C. § 101*, AM. BAR ASS'N (2019), https://bit.ly/3AMxhGf.

107. *See id.*

108. *See* Doster, *supra* note 106. *See generally* Neilson v. Harford, 151 Eng. Rep. 1266 (1841) (holding that the application of hot air to a furnace is ineligible for a patent because it claims a principle, but a mechanical apparatus that *applies* the principle is eligible for a patent).

109. *See* MERGES & DUFFY, *supra* note 2, at 541. *See, e.g.*, O'Reilly v. Morse, 56 U.S. 62, 106 (1854); Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 70 (2012).

110. MPEP § 2106 (9th ed., rev. 10, 2019).

111. Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 212 (2014); MPEP § 2106 (9th ed., rev. 10, 2019).

112. *See generally* Parker v. Flook, 437 U.S. 584 (1978) (revisiting the topic of subject matter eligibility for the first time before the Supreme Court since the nineteenth century).

113. *See id.* at 585.

114. *See id.* at 585–86.

and that the only question before the Court was whether applying a mathematical formula to an existing technology made the resulting invention patent eligible.[115]

The Court applied the logic laid out in *O'Reilly v. Morse* to an invention claiming an abstract idea.[116] While the Court noted that an abstract idea on its own is not patentable, it clarified that an invention that incorporates an abstract idea may be patented if it introduces some new and inventive concept.[117] However, the Court concluded that the claim at issue was nothing more than a mathematical formula that offered no new inventive concept, and merely implementing the formula with an automated alarm system was not significantly transformative to justify granting a limited monopoly on a mathematical expression.[118]

Three years later, in *Diamond v. Diehr*, the Court sought to elaborate further on its holding in *Flook* to clarify the abstract idea exception.[119] In *Diehr*, the respondent was defending a challenge to its patent that included a claim for using a mathematical formula as part of a process to control reaction parameters when synthesizing and curing rubber.[120] The Court examined whether a process claim that incorporated a mathematical formula in an industrial application constituted patentable subject matter.[121]

The Court differentiated the respondent's patent in *Diehr* from the patent in *Flook*.[122] The Court held that the patent did not claim a mathematical expression itself, like in *Flook*, but instead claimed a process for curing synthetic rubber that used a mathematical formula.[123] Accordingly, the *Diehr* Court concluded that the mathematical formula was not directly claimed but merely used as part of a broader industrial process that went beyond patenting the mathematical expression itself.[124] The Court stated that a claim containing an abstract idea can be eligible for a patent if the claim, "when considered as a whole, is performing a function which the patent laws were designed to protect (*e.g.*,

115. *See id.* at 588.

116. *See id.* at 592; *see also infra* Section II.C.2.b.

117. *See Flook*, 437 U.S. at 594.

118. *See id.* (explaining that the respondent's process is unpatentable because the process of using alarms to monitor catalytic conversion processes was well known, and the use of a mathematical algorithm to control the alarm achieved the same function).

119. *See generally* Diamond v. Diehr, 450 U.S. 175 (1981).

120. *See id.* at 177–78.

121. *See id.* at 181.

122. *See id.* at 186–87 (stating that the algorithm disclosed in *Flook* did little more than calculate an alarm limit by a different means).

123. *See id.* at 191–92.

124. *See id.* at 192.

transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101."[125]

b. Laws of Nature

The second of the three judicially created exceptions concerns the concept of laws of nature. The 1854 case of *O'Reilly v. Morse* concerned the use of a natural law to transmit messages across long distances.[126] Because the Court at the time primarily referenced electromagnetism as a law of nature, the *Morse* case provides and illustration of this exception.[127]

The patent application in *Morse* involved Samuel Morse's application for the protection of his electromagnetic telegraph.[128] Seven of Morse's eight patent claims were deemed acceptable, but the eighth claim sought to protect any means of using "electric or galvanic current . . . for marking or printing intelligible characters . . . at any distances."[129] The Court took issue with this claim and cited the English common-law doctrine that the discovery of a natural law or principle is not patentable.[130] Although the Court ultimately invalidated the claim under the requirements that are now codified as 35 U.S.C. § 112, it discussed, in dicta, the application of English Common Law exceptions to patentable inventions.[131]

The Court explained that whether the natural law exception applied to Morse's patent was a close call.[132] Under this exception, natural principles themselves are not patentable; however, inventions that exploit the natural law are.[133] Because Morse was using electromagnetism to send messages with his machine, the Court did not decide whether the claim would have invoked a law of nature, but invalidated the claim due to the clearer § 112 disclosure issue.[134] Regardless of the Court's reasoning, it clearly indicated that the English Common Law exceptions

125. *Id.*

126. *See* O'Reilly v. Morse, 56 U.S. 62, 106 (1854). It is important to note that a single invention could invoke multiple exceptions. Although the *Morse* Court primarily referenced electromagnetism as a law of nature, electromagnetism as a means of communication invokes all three exceptions: a law of nature, a natural phenomenon, and an abstract idea. *See* Matal, *supra* note 52, at 90 (explaining that the original term "abstract ideas" was used interchangeably to describe natural phenomena, laws of nature, and abstract idea).

127. *See Morse*, 56 U.S. at 106.

128. *See id.* at 112.

129. *Id.*

130. *See id.* at 116 ("[T]he discovery of a principle in natural philosophy or physical science, is not patentable.")

131. *See id.* at 116–17.

132. *See id.* at 116–18.

133. *See id.*

134. *See id.* at 117, 119–20.

to patentable subject matter applied to American patent law and would be applied in future § 101 determinations.[135]

c. Natural Phenomenon

The final judicially created exception centers around the concept of natural phenomenon. The 1980 case of *Diamond v. Chakrabarty* exemplifies this exception.[136] *Chakrabarty* was the first case to apply the judicial exceptions to genetic engineering and the growing field of biotechnology.[137] *Chakrabarty* foreshadowed the challenge of applying the judicial exceptions to emerging technological disciplines, which has characterized § 101 determinations over the past 40 years.[138]

In *Chakrabarty*, the respondent sought to defend his patent claims for a genetically engineered bacterium against the USPTO's invalidity argument.[139] This case brought into question whether an inventor may receive a patent for a living organism that had been genetically manipulated.[140] The Court focused its analysis on the fact that no other naturally-occurring bacteria contained the elements that Chakrabarty had engineered the claimed bacteria to possess.[141]

The Court held that the bacteria claimed by the patent were not natural phenomena because the claimed genetic modifications did not exist naturally, but instead were "a product of human ingenuity."[142] The Court further expressed, in dicta, that inventions that "push back the frontiers of chemistry, physics, and the like" are the most deserving of patent protection.[143] This statement created tension regarding the judicial exceptions and what the requisite amount of innovation was for an invention to qualify for a patent.[144] This question remained until the Court directly addressed it in 2010, when the Court sought to fundamentally rework the subject matter eligibility doctrine.[145]

135. *See id.* at 117–18.

136. *See* Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980).

137. *See* MERGES & DUFFY, *supra* note 2, at 543.

138. *See id.* at 547–48.

139. *See Chakrabarty*, 447 U.S. at 305–06. The USPTO primarily argued against the genetically-engineered bacteria because they were naturally occurring. *See id.* at 306.

140. *See id.* at 307.

141. *See id.* at 310.

142. *Id.* at 309*; see also* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 590-91 (2013) (confirming the *Chakrabarty* decision but elaborating that merely isolating a naturally occurring gene is not enough to distinguish the innovation from a natural phenomena).

143. *Chakrabarty*, 447 U.S. at 316 (quoting Great A. & P. Tea Co. v. Supermarket Corp., 340 U.S. 147, 154 (1950)).

144. *See* MERGES & DUFFY, *supra* note 2, at 547.

145. *See id.* at 548.

Ultimately, these twentieth-century subject matter eligibility cases can be understood as the Court's attempt to establish rules to govern each of the judicial exceptions. The Court ultimately abandoned the search for a bright line rule in favor of a more flexible approach, which the Court established in a quadrilogy of subject matter eligibility cases between 2010 and 2014.[146]

3. Twenty-First Century Amendments to the Judicial Exceptions

In 2010, the Supreme Court took up a renewed interest in questions of subject matter eligibility.[147] Notably, the Court's focus centered on clarifying the doctrines of the three statutory exceptions.[148] The Supreme Court took four subject matter eligibility cases between 2010 and 2014 to clarify the doctrine and establish a test for lower courts to use when applying the judicial exceptions.[149]

The first in this series of decisions was the 2010 case of *Bilski v. Kappos*.[150] The Court granted certiorari in *Bilski* to issue a decision on the trend in the early twenty-first century of granting patents for business operations and procedures that were commonly referred to as business method patents.[151] These types of patents had sparked debate among patent practitioners, with many commentators calling for a categorical ban on business method patents.[152] The chief issue in such cases was whether business method patents merely claimed abstract ideas and thus were patent ineligible under the judicial exceptions.[153]

In *Bilski*, the patent at issue claimed a method of hedging risk when purchasing commodities in fixed-price contracts.[154] These types of purchases incur risk because the value of the commodity can decrease between the time the fixed-price contract is agreed to and the time when the actual transaction takes place.[155] Although the concept of risk hedging was not new, the patent holder in *Bilski* claimed novelty due to the expression of the method as a mathematical formula.[156]

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146. *See infra* Section II.C.3.
147. *See* MERGES & DUFFY, *supra* note 2, at 548.
148. *See id.*
149. *See, e.g.*, Bilski v. Kappos, 561 U.S. 593, 597 (2010); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 70 (2012); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 579 (2013); Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 212 (2014).
150. *See Bilski*, 561 U.S. at 597.
151. *See* MERGES & DUFFY, *supra* note 2, at 548.
152. *See Bilski*, 561 U.S. at 602.
153. *See id.* at 597–98.
154. *See id.* at 599.
155. *See id.*
156. *See id.*

The Court ultimately held that business method patents were not categorically banned.[157] The Court refused the opportunity to establish any per se rules limiting the scope of subject matter eligibility.[158] However, the Court did lean on the precedent established in both *Dier* and *Flook* when it held that the business method claimed in *Bilski* did nothing but claim an abstract idea.[159] The Court stated that Bilski's mathematical expression was insufficient to allow the petitioner to receive a patent that would "effectively grant a monopoly over an abstract idea" because the claim did not include an additional inventive step that would distinguish it from one of the exceptions.[160] While this decision reaffirmed existing principles, it left the door open for the expansion of the judicial exceptions.[161]

The second subject matter eligibility case the Court agreed to hear was the 2012 case of *Mayo Collaborative Services v. Prometheus Labs, Inc*.[162] In contrast to *Bilski*, the Court in *Mayo* was concerned with providing clarity in applying the natural law exception to § 101.[163] The patents at issue in this case claimed a method for administering appropriate doses of a pharmaceutical drug that could treat autoimmune disorders.[164] This method claimed the detection of naturally occurring chemicals in a patient's blood that correlated with these disorders and necessarily implicated a natural biological response.[165]

The Court held that the patents were ineligible for patent protection due to the natural law exception.[166] The Court concluded that an invention must have "additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself" even though the invention may use a natural law to achieve the result.[167] The *Mayo* Court stated that a method of identifying the correlation between metabolites and drug dosages added no additional features to the natural law and instead merely instructed a user to apply the natural principle.[168] This requirement of an "inventive

157. *See id.* at 609.
158. *See id.*
159. *See id.* at 611.
160. *Id.* at 612.
161. *See* MERGES & DUFFY, *supra* note 2, at 557.
162. *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 70 (2012).
163. *See id.* at 70–72.
164. *See id.* at 72.
165. *See id.*
166. *See id.* at 73.
167. *Id.* at 77.
168. *See id.* at 78–80.

application" has become a governing principle in subject matter eligibility determinations.[169]

The third case in the Court's string of subject matter eligibility determinations was the 2013 case of *AMP v. Myriad Genetics*.[170] This case gave the Court an opportunity to provide clarity in cases concerning natural phenomena.[171] In *Myriad*, the patent at issue concerned the isolation and synthesis of DNA associated with common forms of ovarian and breast cancers.[172] Myriad had discovered the precise location of two sequences of human DNA, in which the presence of mutations could indicate an individual's risk for developing cancer.[173] Myriad had obtained multiple patents for (1) the isolation of the DNA sequence, which merely isolated existing, naturally-occurring compounds; and (2) the synthesis of complementary DNA ("cDNA"), which required lab technicians to synthetically create a derivative form of DNA.[174]

Ultimately, the Court delivered a split holding.[175] The Court reasoned that the isolation of naturally-occurring DNA was not patentable because "Myriad did not create anything," and there was no "act of invention."[176] Instead, the Court reasoned that there was no act of invention because Myriad merely identified the location of a naturally-occurring gene.[177] However, the Court held that Myriad's claim for the synthesis of cDNA was patentable.[178] Even though cDNA is "dictated by nature," it took the work of a lab technician to create the new genetic product.[179] Therefore, cDNA was not a natural phenomenon but rather a product of ingenuity.[180] This reasoning ultimately mirrored the *Mayo* rationale, which required some inventive step or inventive application to transform a naturally occurring law or product into patent-eligible subject matter.[181]

The fourth and final case in the Supreme Court's line of recent subject matter eligibility precedent was the 2014 case of *Alice Corp. v.*

169. *See* Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 217–18 (2014) (implementing the *Mayo* Court's requirement for an inventive application into the Court's newly formulated *Mayo/Alice* test).

170. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 579 (2013).

171. *See id.* at 590.

172. *See id.* at 580.

173. *See id.* at 579–80.

174. *See id.* at 580.

175. *See id.*

176. *Id.* at 591.

177. *See id.*

178. *See id.* at 595.

179. *Id.*

180. *See Myriad*, 569 U.S. at 590.

181. *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 78 (2012).

CLS Bank International.[182] In *Alice*, the Court revisited the issue of business method patents.[183] The patent at issue in *Alice* claimed a method for mitigating risk in a business transaction by using a "shadow" account to facilitate and verify the transaction.[184] This process was a well-established method of conducting transactions, but Alice claimed that the novelty stemmed from the implementation of this method using a computer system.[185]

The Court held that this method claimed an abstract idea that served as a "building block of the modern economy."[186] However, unlike in past rulings, the Court set out to delineate an explicit two-step framework to distinguish between inventions that invoke a judicial exception and those that constitute eligible subject matter based on the framework set forth in *Mayo*.[187] Under the Court's new *Mayo*/*Alice* test, a court should conduct a two-step inquiry: (1) first, the court should "determine whether the claims at issue are directed to one of [the judicial exceptions]," and (2) if so, the court should ask if the claims demonstrate an "inventive concept" that amounts to more than merely claiming a patent-ineligible concept.[188] The Court has defined an "inventive concept" as "an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'"[189] This test has been the governing legal standard in subject matter eligibility determinations since 2014, but it is not always obvious how it should be applied.[190]

Ultimately, the Court moved away from rigid rules prevalent in twentieth-century subject matter eligibility determinations to a more flexible, case-by-case analysis in the *Mayo*/*Alice* test.[191] The two-step *Mayo*/*Alice* test provided a mechanism for determining whether an invention invoked one of the judicial exceptions.[192] This approach provided far more flexibility for the judiciary to evaluate claims, specifically with respect to the interpretation of what it means for an invention to be "directed to" one of the judicial exceptions.[193]

182. *See* Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 212 (2014).
183. *See* MERGES & DUFFY, *supra* note 2, at 585.
184. *Alice*, 573 U.S. at 213–14.
185. *See id.* at 214.
186. *Id.* at 220.
187. *See id.* at 217.
188. *Id.*
189. *Id.* at 217–18 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 73 (2012)).
190. *See infra* Section II.D.
191. *See Alice*, 573 U.S. at 217–18.
192. *See id.* at 217.
193. *Id.*

D. The Current State of Subject Matter Eligibility Exceptions

Since the establishment of the *Mayo/Alice* test in 2014, the Court has not granted certiorari to any subject matter eligibility cases.[194] The Court has primarily left the implementation of this test to the Federal Circuit.[195] The 2019 case of *American Axle v. Neapco Holdings* presented the Court with a clear opportunity to provide needed clarification to the *Mayo*/*Alice* test. However, the Court denied certiorari, creating even more uncertainty surrounding subject matter eligibility.[196]

1. *American Axle*

American Axle is an automobile parts manufacturer that produces propeller shafts ("prop shafts").[197] Because prop shafts are made of thin steel, they are subjected to various stresses and vibrations, which can damage the vehicle or cause an unpleasant ride.[198] To dampen vibrations, prop shaft manufacturers often use physical methods involving weights, dampers, and hollow liners.[199] Nonetheless, current technology limits the effectiveness of these traditional methods.[200] American Axle filed the patent at issue, which claimed a novel method of attenuating these vibrations that was more efficient than other, existing means.[201]

The primary claim at issue in the case was claim 22, which teaches a method of "tuning a mass and a stiffness of at least one liner" to dampen vibrations within a vehicle's driveshaft.[202] The Federal Circuit ultimately decided the case under § 101 and held that this claim was "directed to" Hooke's law—a natural law that explains the elastic behavior of solid materials.[203] The court held, applying the *Mayo*/*Alice* test, that the claim was "directed to" one of the judicial exceptions, and that it did not possess an additional inventive concept.[204] The court reasoned that claiming a tuned liner that mitigated vibrations did nothing

194. *See* Bryan Nese & Alison Gelsleichter, *High Court is Poised to Un-Muddy the Section 101 Waters Nearly Seven Years After Alice*, IPWATCHDOG (May 4, 2021, 1:15 PM), https://bit.ly/3Sqh3dq.

195. *See id.*

196. *See* Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1288 (Fed. Cir. 2019), *cert. denied*, 142 S. Ct. 2901 (2022).

197. *See id.* at 1289.

198. *See id.*

199. *See id.* at 1290 (discussing how current methods of attenuation can address only one of the three modes of vibration in solid materials: bending, shell, or torsion).

200. *See id.* (explaining that the *American Axel* patent claims to dampen two modes of vibration at a time).

201. *See id.*

202. *Id.* at 1290.

203. *See id.* at 1291; *see also What is Hooke's Law?*, KHAN ACADEMY, https://bit.ly/3BZYRzX (last visited Jan. 9, 2022).

204. *See Am. Axle*, 967 F.3d at 1298.

more than invoke Hooke's law because claiming a liner that dampens vibration without describing the specific method amounted to claiming Hooke's law itself.[205] While the application did not disclose what steps would be made to tune the liner, the patent application also did not explicitly claim Hooke's law anywhere in the document.[206]

In her dissent, Judge Moore argued that the majority misapplied step one of the *Mayo/Alice* test, effectively creating a new "Nothing More" test to determine if a claim is "directed to" a natural law.[207] She argued that this new test asks whether a claim invokes a natural law and nothing more to determine its eligibility, which implicitly expands the "directed to" inquiry of the *Mayo/Alice* test.[208] According to the dissent, this new formulation improperly expands the scope of the first prong of the *Mayo/Alice* analysis because any claim that claims a function attributable to a physical law can now be said to implicitly invoke the law itself.[209] Furthermore, the dissent argued that *American Axle* was improperly decided under § 101, and the majority's underlying issue with claim 22 was that it did not fully disclose how the claimed functional result was accomplished.[210] However, due to the Supreme Court's refusal to take up *American Axle*, the majority's "Nothing More" test will stand as the new guiding principle in *Mayo*/*Alice* inquiries for the foreseeable future.[211]

2. Potential Consequences

The *American Axle* appeal eventually reached the Supreme Court, but the Court denied the opportunity to take up its first subject matter eligibility case since *Alice*.[212] The Federal Circuit's decision in *American Axle* primarily focused on what it means for a claim to be "directed to" one of the natural exceptions.[213] Traditionally, for a claim to be "directed to" a natural law, the patent application had to explicitly claim or reference a natural law. But *American Axle* seems to have expanded that inquiry to include any claim that can be said to implicitly rely on a natural law.[214] This issue presented new questions distinct from the

205. *See id.*
206. *See id.*
207. *Id.* at 1305 (Moore, J., dissenting).
208. *See id.* at 1307–08.
209. *See id.* at 1307.
210. *See id.* at 1316.
211. *See* Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 142 S. Ct. 2902 (2022) (denying a petition for writ of certiorari).
212. *See id.*
213. *See Am. Axle*, 967 F.3d at 1292.
214. *See id.* at 1304 (Moore, J., dissenting).

Court's previous decisions regarding the natural law exception.[215] Undoubtedly, the Court's deferral to the Federal Circuit's holding will have a major effect on subject matter eligibility and the *Mayo/Alice* framework.[216]

E. Subject Matter Eligibility and the Chemical & Materials Industries

Few industries stand to be more affected by this decision than the chemical and materials industries.[217] After all, the claim at issue in *American Axle* was centered on a method for achieving a specific result by tuning a material's properties.[218] This is fundamentally the goal that chemical and materials researchers strive to achieve when designing new materials.[219] Whether it is a new chemical compound or a new material structure, these new products are designed by manipulating natural laws to exhibit unique properties capable of achieving a specific goal.[220]

The value of this type of chemical and materials innovation can be seen in global economic markets.[221] Intellectual Property portfolios have become increasingly important for the nation's largest chemical companies.[222] The United States is one of the world's largest chemical producers, and, as of 2021, the chemical and materials industries accounted for $768 billion annually.[223] Uncertainty in U.S. patent policy regarding subject matter eligibility to chemical and materials patents could have drastic and unintended consequences to the U.S. economy by directly undermining chemical and materials companies' patent holdings and further complicating patent prosecution.[224] The *American Axle* decision has clouded subject matter eligibility determinations in the U.S. and may adversely affect the chemical and materials industries moving

215. *See id.*

216. *See infra* Section III.A.

217. *See generally* Dirk Caspary, *A Brief Patent Landscape of Chemical Companies*, PATENTSIGHT IP ANALYTICS BLOG (June 24, 2021), https://bit.ly/3HQoRQ2 (discussing the IP holdings of the nation's largest chemical companies).

218. *See Am. Axle*, 967 F.3d at 1290.

219. *See Research & Development: Careers & the Chemical Sciences*, AM. CHEM. SOC'Y, https://bit.ly/3t8APAA (last visited Jan. 9, 2022).

220. *See id.*

221. *The Top 5 Biggest Chemical Exporters in the World*, NES FIRCROFT (Dec. 12, 2021, 3:46 PM), https://bit.ly/3hnHeAY.

222. *See* Caspary, *supra* note 217.

223. *See Chemical Sector Profile*, U.S. DEP'T OF HOMELAND SEC. (May 2019), https://bit.ly/3Hs0veT.

224. See Eileen McDermott, *American Axle Denied: Patent Stakeholders Sound Off on SCOTUS' Refusal to Deal with Eligibility*, IPWATCHDOG (July 4, 2022, 1:15 PM), https://bit.ly/3cvd13Z.

forward by introducing uncertainty into both patent prosecution and litigation proceedings.[225]

III. ANALYSIS

Subject matter eligibility has been the cornerstone of the American patent system over the past couple centuries, but its proper role and scope has been debated for decades.[226] The doctrine categorically restricts certain types of inventions that would be antithetical to the patent system's purpose of awarding a limited monopoly in exchange for the public disclosure of a useful invention.[227] Various threshold determinations, found both in Title 35 and the common law, may make an invention unpatentable.[228] The most controversial and frequently-litigated areas of ineligible subject matter center on the three judicially created exceptions to subject matter eligibility: (1) abstract ideas, (2) laws of nature, and (3) natural phenomena.[229]

These judicial exceptions categorically ban certain types of inventions, barring some additional inventive concept.[230] This gatekeeping determination was originally made based on whether an invention should benefit from the patent bargain.[231] However, to clarify § 101 determinations, the Court's implementation of the judicial exceptions grew more formulistic in an attempt to establish bright-line rules.[232] Yet, formulistic approaches proved difficult to apply as subject matter eligibility determinations grew more complex during the Information Age.[233]

225. *See infra* Section III.A.

226. *See supra* Sections II.B–II.C.

227. *See supra* Section II.A.1; *see also* Maayan Perel, *Reviving the Gatekeeping Function: Optimizing the Exclusion Potential of Subject Matter Eligibility*, 23 ALB. L.J. SCI. & TECH. 237, 240 (2013).

228. *See* MPEP § 2106 (9th ed., rev. 10, 2019). The MPEP instructs examiners that "[t]he § 101 patent-eligibility inquiry is only a threshold test. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the Patent Act's protection the claimed invention must also satisfy 'the conditions and requirements of this title.'" *Id.*

229. *See supra* Section II.C.

230. *See* David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 1, 26 (2009).

231. *See id.*

232. *See* Perel, *supra* note 227, at 241–42. The judiciary employed various formulations of bright-line rules to make § 101 determinations, including "the physical transformation test, the mental steps doctrine, the mathematical algorithm test, and the machine-or-transformation test." *Id.* at 242.

233. *See id.* (explaining how bright-line rules were inadequate for Information Age innovations and courts ultimately replaced them with more flexible standards, like the *Mayo*/*Alice* test).

The complexity in making determinations regarding subject matter eligibility is evident in the *American Axle* decision. The Federal Circuit's reading of claim 22 seems to imply that any claims which state a function could be interpreted as merely claiming the natural law which produces the functional result.[234] The properties of any chemical or material in the natural world are intrinsically the functional result of a chemical or material structure.[235] American Axle has claimed a method of dampening vibration using a tuned material liner.[236] American Axle is not claiming every application of Hooke's law that would attenuate vibrations in a drive shaft; rather, it is claiming a physical liner that has been tuned to reduce vibration, which inevitably must obey the laws of physics—including Hooke's law.[237] The Federal Circuit's ruling potentially creates a gray area in the application of the *Mayo*/*Alice* test, which could invalidate previously accepted patents just because they implicitly rely on the laws of physics (as all physical objects must).[238] This Comment's Analysis discusses the potential impact of the Federal Circuit's decision as it stands, as well as potential theories for clarifying the *Mayo*/*Alice* framework moving forward.[239] The Analysis concludes by predicting how the decision may affect the chemical and materials industries, and by providing suggestions to practitioners in these fields as they approach patent claim drafting.[240]

A. Subject Matter Eligibility After American Axle

The Supreme Court has passed on the opportunity to hear *American Axle*, instead deferring to the Federal Circuit's interpretation of § 101.[241] Practitioners have heavily criticized the *American Axle* decision for muddling the already complicated application the *Mayo*/*Alice* test.[242] Questions remain regarding how USPTO examiners and lower courts will construe the Federal Circuit's holding moving forward, and whether the judiciary will be convinced to provide much-needed clarification to § 101 in the future.

234. *See* Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1302 (Fed. Cir. 2019).

235. *See* Lous A. Girifalco et al., *Materials Science*, BRITANNICA, https://bit.ly/3RiI428 (last updated Aug. 2, 2022) (explaining that the molecular structure of a chemical compound is what produces its resulting properties).

236. *See Am. Axle*, 967 F.3d at 1290.

237. *See id*. at 1307 (Moore, J., dissenting).

238. *See id.* at 1305.

239. *See infra* Sections III.A, III.B.

240. *See infra* Section III.C.

241. *See* McDermott, *supra* note 224.

242. *See id.*

1. The *Mayo*/*Alice* Framework Following *American Axle*

The Court's refusal to grant certiorari to hear an appeal of the Federal Circuit's decision has created significant uncertainty surrounding § 101.[243] The Federal Circuit's interpretation of the *Mayo*/*Alice* test has expanded the first step of the analysis, making satisfying § 101 more burdensome and potentially bringing into question many patent claims that have traditionally been deemed acceptable.[244] Previously, for a claim to be "directed to" one of the judicial exceptions, the claim must explicitly invoke a law of nature, natural phenomenon, or abstract idea.[245] Such was the case in *Flook*, where the mathematical formula being claimed was explicitly recited within the patent claims.[246] While *Flook* is one of the principal cases on which the *American Axle* majority relied, the claims at issue in each case are not directly analogous.[247] The court in *American Axle* inferred that claim 22 implicates a natural law, which expands the definition of what it means for a claim to be "directed to" one of the judicial exceptions in step one of the *Mayo*/*Alice* test.[248] In both *Mayo* and *Alice*, the patent holders explicitly invoked the natural laws at issue within their respective patent applications.[249] In *American Axle*, the petitioner made no explicit mention of Hooke's law in its patent, yet the court inferred that the claim sought to effectively monopolize the natural law anyway.[250]

The *American Axle* majority argued that the "claim on its face clearly invokes a natural law, and nothing more, to achieve the claimed result."[251] The majority's "Nothing More" test is a far broader interpretation of the "directed to" requirement because this was previously understood to mean an explicit invocation of the natural law in question.[252] However, as Justice Moore points out in her dissenting opinion, "every invention at some level operates according to natural

243. *See* Jonathan P. Osha, *American Axle: The Latest Twist of Patent Eligibility*, OSHA BERGMAN WATANABE BURTON NEWSL. (Oct. 17, 2019), https://bit.ly/3homWam.

244. *See* Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1305 (Fed. Cir. 2019) (Moore, J., dissenting).

245. *See id.* at 1304–05.

246. *See id.* at 1298 (majority opinion); *see also* Parker v. Flook, 437 U.S. 584, 586 (1978).

247. *Compare Am. Axle*, 967 F.3d at 1292 (demonstrating that claims 1 and 22 of the patent at issue in *American Axle* do not explicitly claim Hooke's Law), *with Flook*, 437 U.S. at 588 (demonstrating that the mathematical formula was explicitly recited in the claims of the patent at issue in *Flook*).

248. *See Am. Axle*, 967 F.3d at 1298.

249. *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 72 (2012); *see also* Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 213–14 (2014).

250. *See Am. Axle*, 967 F.3d at 1307 (Moore, J., dissenting).

251. *See id.* at 1298 (majority opinion).

252. *See id.* at 1303.

laws."[253] Any claim that recites a functional result necessarily invokes a natural law because all real-world inventions must obey the laws of physics.[254] Expanding the "directed to" inquiry in the first step of the *Mayo*/*Alice* test to include any claims which depend on a law of physics would increase the scope of the inquiry such that "every patent is in ineligibility jeopardy."[255] Thus, the Federal Circuit's ruling has created doctrinal uncertainty surrounding future § 101 determinations and has potentially opened the door for a flood of invalidity challenges to previously accepted patents.[256]

2. Future Avenues that Could Clarify the *Mayo/Alice* Framework

Although *American Axle* is settled law for now, many are still calling for the Supreme Court or the Federal Circuit to revisit § 101 to provide more clarity.[257] American Axle's primary argument was that the Federal Circuit improperly applied the first prong of the *Mayo*/ *Alice* test.[258] The judiciary could choose to clarify the *Mayo*/*Alice* test under two avenues. First, the judiciary could reverse the Federal Circuit's ruling and attempt to clarify the relatively ambiguous language currently present in the *Mayo*/*Alice* test.[259] There is no defined method for determining what it means to be "directed to" one of the judicial exceptions.[260] If the Supreme Court is content with the broad language of the *Mayo*/*Alice* test, it could keep the test in place and merely provide guidance for lower courts to make the determination in step one. The USPTO publishes fact patterns to provide guidance for the application of the test; however, the Court has yet to provide any precedential clarity on how the broad language of the *Mayo*/ *Alice* test should be interpreted.[261] Should the Court take up a future § 101 case, it would have its first real opportunity to provide a concise definition of the "directed to" language

253. *Id.* at 1306 (Moore, J., dissenting) (quoting Ryan Davis, *Drive Shaft Ruling May Expand Challenges to Patent Eligibility*, LAW 360 (Oct. 24, 2019), https://bit.ly/3en7Kfw).

254. *See id.* at 1307.

255. *Id.* at 1306.

256. *See id.*

257. *See* McDermott, *supra* note 224.

258. *See* Petition for Writ of Certiorari at 21–23, Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285 (Fed. Cir. 2019) (No. 20-891).

259. *See supra* Section II.C.3.

260. *See* Dominic Frisina, *American Axle is the Supreme Court's Chance to Give Patent Eligibility a Tune-Up*, IPWATCHDOG (June 16, 2021, 4:15 PM), https://bit.ly/3f4Kekn.

261. *See id.*

to provide examiners and lower courts with the proper construction of the ambiguous terms of the test.[262]

The judiciary could also take an opportunity to replace the *Mayo*/*Alice* test and revert to a more formulistic standard for applying the § 101 judicial exceptions.[263] However, this outcome is less likely, considering that the Court finalized the test only eight years ago.[264] Given the Court's and the Federal Circuit's lengthy history of moving away from rigid subject matter eligibility determinations toward a more flexible, case-by-case approach, it would be surprising for the Court to change direction after the relatively short period that the *Mayo*/*Alice* has been in effect.[265] Thus, it is likely that if the Court seeks to revisit § 101 in the future, it would do so to amend or clarify the *Mayo*/*Alice* test.

B. Future Clarification of Subject Matter Eligibility by Distinguishing § 101 and § 112

The judiciary could also revisit and clarify subject matter eligibility by deciding ambiguous claim language under § 112, rather than deciding problematic claims under a *Mayo*/*Alice* analysis. Because the judiciary has trended toward establishing more flexible standards in its subject matter eligibility determinations, the judiciary could continue to embrace the less rigid formulation of the *Mayo*/*Alice* test and further promulgate a proper construction of the test's language.[266] Meanwhile, courts could still deal with claims that appear to broadly claim natural laws under a theory of inadequate enablement under § 112 rather than further expanding and muddling § 101.[267]

As Justice Moore noted in her dissent to the Federal Circuit's decision in *American Axle*, the majority's real issue with claim 22 was that it did not properly enable a person of ordinary skill in the art to tune the liner to achieve the claimed properties.[268] The majority compared the broadness of claim 22 in *American Axle* to the broadness of claim 8 in *Morse* in order to argue for invalidity under § 101.[269] However, *Morse* was decided under § 112, and the majority sought to use it as precedent

262. *See id.*

263. *See supra* Section II.C.

264. *See generally* Alice Corp. v. CLS Bank Int'l, 573 U.S. 208 (2014) (demonstrating that the *Alice* decision is the last guidance the Court has given regarding the application of the judicial exceptions).

265. *See* Perel, *supra* note 227, at 241–42.

266. *See supra* Section II.C.3.

267. *See* Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1316 (Fed. Cir. 2019) (Moore, J., dissenting); *see also supra* Section II.C.3.

268. *See Am. Axle*, 967 F.3d at 1316; *see also supra* Section II.A.2.d.

269. *See Am. Axle*, 967 F.3d at 1297 (majority opinion).

to decide *American Axle* under § 101.[270] The majority in *American Axle* appears to have blended § 101 with § 112 to make a muddled argument of invalidity.[271]

The judiciary could focus on this ambiguity to provide future clarity of a different kind. The petitioner, in its patent application, explained what it means to tune a liner, but never provided any step-by-step method to do so.[272] The question remains whether disclosure of the steps to achieve this outcome is necessary to satisfy § 112's enablement requirements.[273] Thus, *American Axle* demonstrates a need to provide clarity to an entirely different doctrine of patent law. The judiciary could build upon *American Axle* by stating that issues invoking enablement concerns are more appropriately decided under § 112 and should not be imported into the already complicated landscape of § 101 inquiries.

C. Impacts on the Chemical and Materials Industries

Due to the chemical and materials industries' reliance on intellectual property, a dramatic change in U.S. patent doctrine could have a significant effect on the U.S. economy.[274] Therefore, it is important for practitioners who work in these fields to be cognizant of the potentially changing landscape of subject matter eligibility.

First, it is important to take note of the potential impacts of the *American Axle* decision.[275] As noted previously, the Federal Circuit's decision could create uncertainty regarding what kinds of claims are deemed to be "directed to" one of the judicial exceptions.[276] The majority's "Nothing More" test seems to create a great amount of leeway for examiners or courts to conclude that broad claims or functional result claims necessarily invoke their underlying natural laws.[277] In the case of chemical and materials patents, an applicant is typically claiming a material or chemical property, a material's structure or chemical formulation, or methods that produce these results.[278] Under the *American Axle* holding, all claims to properties and structures may invite rejection or invalidity challenges because of the underlying natural laws

270. *See* O'Reilly v. Morse, 56 U.S. 62, 105 (1854); *Am. Axle*, 967 F.3d at 1308–09 (Moore, J., dissenting); *see also supra* Section II.C.2.b.

271. *See Am. Axle*, 967 F.3d at 1316 (Moore, J., dissenting).

272. *See id.* at 1315.

273. *See* Frisina, *supra* note 260.

274. *See* Caspary, *supra* note 217.

275. *See supra* Section III.A.1.

276. *See* Frisina, *supra* note 260.

277. *See* Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1304–05 (Fed. Cir. 2019) (Moore, J., dissenting).

278. *See* Mike Zammit, *Common Types of Patent Claims in the Field of Chemical Sciences*, SPRUSON & FERGUSON (Oct. 11, 2018), https://bit.ly/3SCp7Yx.

that give these materials or chemical compounds their properties.[279] Practitioners can avoid these challenges by explicitly claiming an applied use to demonstrate an inventive contribution to satisfy step two of the *Mayo*/*Alice* test.[280] Traditionally, this has been unnecessary for physical products that demonstrate a claimed function, but practitioners would be wise to draft claims cautiously. Ultimately, it would be good practice to avoid functional claims that merely state the effect of a claimed method or process whenever possible.[281]

IV. CONCLUSION

Subject matter eligibility determinations have had a profound effect on the scope of American patent law.[282] The Supreme Court has made various efforts over the past two centuries to clarify the judicial exceptions and their application for lower courts.[283] The Court has moved away from formulistic rules toward more malleable standards in order to provide greater flexibility in applying the judicial exceptions to advancing technologies.[284] This move toward flexible standards has come with a cost, and the *American Axle* decision illustrates the confusion with which the judiciary still grapples when applying the Court's current formulation in judicial exception inquiries: the *Mayo*/*Alice* test.[285]

The *American Axle* decision could have far-reaching consequences and could reopen invalidity debates on countless previously accepted patents.[286] The Federal Circuit's broad interpretation of the first prong of the *Mayo*/*Alice* test provides support for the idea that any functional claim implicitly invokes the underlying natural laws that produce its claimed properties.[287] The effect of the decision will be felt throughout the industries subject to patent law, most notably in the chemical and materials industries.[288] Intellectual property is an important economic asset to these industries, and threats to previously accepted patents could have devastating consequences on a material or chemical company's financial outlook.[289]

279. *See Am. Axle*, 967 F.3d at 1306.
280. *See supra* Section II.C.3.
281. *See Am. Axle*, 967 F.3d at 1302 (majority opinion).
282. *See supra* Sections II.B–II.D.
283. *See supra* Sections II.B–II.C.
284. *See* Perel, *supra* note 227, at 241–42.
285. *See supra* Section II.D.1.
286. *See supra* Sections III.A–III.B.
287. *See* Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1319 (Fed. Cir. 2019) (Moore, J., dissenting).
288. *See supra* Section III.C.
289. *See supra* Section III.C.

Patents in these fields claim unique material or chemical structures.[290] An extremely broad application of the first prong of the *Mayo*/*Alice* test, like the Federal Circuit asserts, may lead to the conclusion that any claim for a structure's resulting properties is merely a claim for the laws that govern molecular structures themselves.[291] This would negate the tremendous effort of researchers in these fields, the massive cost of research and development, and the value of the intellectual property holdings that these companies currently possess.[292] The *American Axle* case demonstrates a clear need for the judiciary to reexamine subject matter eligibility once again and clarify the proper scope of the *Mayo*/*Alice* test to avoid these unintended effects.

290. *See* Zammit, *supra* note 278.
291. *See supra* Section III.A.1.
292. *See supra* Section III.C.