

PATENT LAW INTRO AND 35 U.S.C. § 101 INVENTIONS PATENTABLE

ELLAINA SANDERS AND RICHMOND VAN WINTER

Executive Summary: The framers of the U.S. Constitution believed that codifying intellectual property (IP) rights at the federal level was important to economic independence, innovation, and domestic growth. IP rights were established in the U.S. Constitution in Article I, Section 8, which declares that Congress has the power “to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” Intellectual property in the United States encompasses four broad categories: patents, trademarks, copyrights, and trade secrets. A patent is a property right granted to an inventor that allows the inventor (or assignee) to exclude others from “making, using, offering for sale, or selling” the invention for a limited time. Patents play an essential role in the economy by creating limited legal monopolies for inventors and developers, which incentivizes investment in technological genius, creativity, innovation, and production. In exchange for these legal monopolies, patent owners disclose their inventions to the world—contributing to continued advancements in science, engineering, medicine, and more. A well-functioning and efficient patent system is critical to American invention and innovation. Thus, over time, both Congress and the Supreme Court have heavily influenced the patent doctrine. In 2011, U.S. patent laws were long overdue for a realignment to conform to modern standards and international trends. A comprehensive overhaul occurred with the passage of the Leahy-Smith American Invents Act (AIA) which sought to align the United States with existing patent regimes across the globe by switching the U.S. patent system from a “first-to-invent” to a “first-to-file” system. Today, the continuing and rapid advancements in science and technology have drawn increasing and broader attention to patent law while Federal Circuit courts struggle on how to apply unclear patent eligibility law.

I. WHAT IS A PATENT?

A patent is intended to protect new processes, machines, and/or products as codified in the 1952 Patent Act.¹ A patent is an exclusive right granted by the federal government to “exclude others from making, using, offering for sale, or selling” an invention throughout the United States and to exclude others from importing the invention into the United States.² To get a patent, technical information about the invention must be disclosed to the public in a patent application. As a reward for disclosing their invention to the public in a patent application, patent owners can obtain exclusive rights to their inventions for a certain time; however, a patent does not give the inventor an affirmative right to make, use, or sell the invention.³ After a patent term expires, the patent owner loses the legal monopoly, and the patented subject matter becomes part

¹ 35 U.S.C. § 1-390.

² 35 U.S.C. § 154.

³ CRAID ALLEN NARD, THE LAW OF PATENTS 1 (4th ed. 2017) (“A patent gives its owner the right to exclude; a patent does not provide a positive right to make, use, or sell, the invention.”).

of the public domain—meaning others are free to make, use, and sell the relevant products or process in the free market.⁴

Patents fall into one of three categories: utility patents, design patents, and plant patents.⁵ Utility patents are the concern of most patent law proceedings. Utility patents protect functional ideas (“the way an article is used and works”) and issue for a period of twenty years from the filing date of the patent application.⁶ Design patents “protect[] the way an article looks” and issues for a period of fifteen years.⁷ Plant patents generally protect “distinct and new variet[ies] of plant[s]” such as plants invented or discovered and asexually reproduced.⁸

Modern patent documents consist of two main parts: the specification and the claims.⁹ As the Federal Circuit succinctly stated, “[s]pecifications teach. Claims claim.”¹⁰ The specification contains the disclosure of the invention which is used to teach the reader about the particulars of the invention.¹¹ However, the specification is not a “how-to” guide instructing the average person how to make or perform the invention but rather contains only enough detail for a person skilled in the art to carry out the invention.¹² In contrast, claims, which are “considered to be the most important part of the patent document,” set the legal boundaries of the invention and precisely define the patentee’s property rights.¹³

II. HOW DO I GET A PATENT?

The patent application process, otherwise known as patent prosecution, starts when an inventor files a patent application with the United States Patent and Trademark Office (USPTO).¹⁴ After the application is received, it is sent to a particular art unit and Examiner who

⁴ See U.S. Patent Overview, FINDLAW (June 12, 2017), <https://corporate.findlaw.com/intellectual-property/u-s-patent-overview.html> (explaining that, once a patent expires, anyone may make, use, offer for sale, or import the invention).

⁵ U.S. Patent and Trademark Office, Manual of Patent Examining Procedure § 1502.01 (9th ed. Rev. 10, June 2020) (hereinafter MPEP).

⁶ Id.

⁷ Id.

⁸ MPEP § 1601 (9th ed. Rev. 10, June 2020); General Information About 35 U.S.C. 161 Plant Patents, U.S. Patent and Trademark Office, <https://www.uspto.gov/patents/basics/types-patent-applications/general-information-about-35-usc-161>. Without plant patents, some kinds of agricultural development would not be cost effective, since anyone could simply get seeds of the plant and grow for free what the patent owner had spent time and effort designing.

⁹ See Nard, *supra* note 2, at 47 (noting that claims are technically part of the specification under 35 U.S.C. § 112, but that patent professionals and courts treat claims and specifications as distinct).

¹⁰ SRI Int’l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1984).

¹¹ Id. at 1122.

¹² Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005).

¹³ Id. at 1118, 1121.

¹⁴ See Joshua Scheufler, Patent, 27 TEX. INTELL. PROP. L.J. 139, 140–41 (2019) (detailing the PTO process). See Trademark, Patent, or Copyright?, U.S. PAT. & TRADEMARK OFF. (Oct. 15, 2019,

reviews the patent application for compliance with patent laws, namely, subject matter eligibility,¹⁵ novelty,¹⁶ non-obviousness,¹⁷ and sufficient disclosure.¹⁸ Patent prosecution generates a prosecution history, which refers to the record of all communications between the USPTO and the applicant regarding a particular filing.¹⁹ The USPTO awards patents for *new* inventions; that is, patents cannot be issued for concepts and objects already in the public domain.²⁰ “Prior art” is the term used to refer to all inventions, writings, and patents that came before and are related to a particular application.²¹ For the patent to be issued, it must be distinguishable from the prior art and meet all other statutory requirements.²²

Three primary statutory requirements of patent eligibility include novelty, non-obviousness, and subject matter.²³ For an invention to be novel, it cannot have been disclosed in a patent, described in a printed publication, in public use, on sale, or otherwise available to the public prior to its effective filing date.²⁴ Similarly, a patentable invention must be non-obvious—that is, readily apparent or easily conceivable to a person of ordinary skill in the relevant field.²⁵ Finally, a patentable invention must refer to patentable subject matter, which is defined by statute as a “process, machine, manufacture, or composition of matter, or any new and useful

09:54 AM), <https://www.uspto.gov/trademarks-getting-started/trademark-basics/trademark-patent-or-copyright> (explaining the difference between a patent and a copyright).

¹⁵ Four categories of invention—process, machine, manufacture, or composition of matter—are deemed by Congress to be the appropriate subject matter of a patent. 35 U.S.C. § 101.

¹⁶ The requirement for Novelty means that nothing exactly like the claimed invention can be found in the prior art. 35 U.S.C. § 102.

¹⁷ Non-obviousness requires the applicant to demonstrate that they have given society something it didn’t have before. The claimed invention must be a nonobvious solution to the person having ordinary skill in the art (PHOSITA). 35 U.S.C. § 103.

¹⁸ Sufficient disclosure requires that a patent application disclose a claimed invention in sufficient detail so that the PHOSITA could carry out that claimed invention. 35 U.S.C. § 112.

¹⁹ Karen Millane Whitney, Sources of Patent Prosecution History Must Not Violate Public Notice Requirement, 32 SETON HALL L. REV. 266, 266–68, 268 n.6 (2001).

²⁰ See Eileen M. Kane, Patent Ineligibility: Maintaining a Scientific Public Domain, 80 ST. JOHN’S L. REV. 519, 540 (2006) (explaining the public domain must be protected by not awarding patents to material already within the public domain).

²¹ Whitney, *supra* note 18, at 269–70.

²² *Id.* at 270 n.18.

²³ 35 U.S.C. §§ 101, 102, 103.

²⁴ 35 U.S.C. § 102(a).

²⁵ 35 U.S.C. § 103.

improvement thereof.”²⁶ Typically, subject matters that are not patentable include laws of nature,²⁷ natural phenomena,²⁸ and abstract ideas.²⁹

III. ORIGINS OF PATENT LAW AUTHORITY

Patent law finds its basis in the United States Constitution, which granted Congress the power “[t]o promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”³⁰ This clause, known as the Patent and Copyright Clause, is viewed both as a designation of an enumerated power to Congress and as a limitation on that power; specifically, the Constitution gave Congress the power to “grant[] exclusive rights for limited times.”³¹ This means patents only grant the right to exclude—thus giving its holder a legal monopoly—without other rights, and those rights must expire after some period of time. Congress has exercised its power to promote the sciences with many different patent laws, from the Patent Act of 1790,³² its first patent statute, to the 2013 Leahy-Smith America Invents Act (AIA),³³ the first significant overhaul to the patent system in over fifty years.

IV. THE LEAHY-SMITH AMERICA INVENTS ACT (AIA)

The AIA made significant changes to the operation of the patent system and the ways in which entities and inventors may challenge a patent’s validity. One major change was the shift from a “first-to-invent” system to a “first-to-file” system.³⁴ Under the previous system, interference proceedings resolved conflicts concerning priority to determine who conceived of an invention first. The new system eliminated interference proceedings and instead put emphasis on the inventor who filed first.³⁵

²⁶ 35 U.S.C. § 101.

²⁷ See, e.g., *O’Reilly v. Morse*, 56 U.S. 62, 113–14 (1853) (holding as ineligible a general claim for using electric current to transmit intelligible signals (telegraphy) because of its broad focus on a law of nature (electromagnetism)).

²⁸ See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980) (holding that a genetically engineered micro-organism was patentable because it did not otherwise exist in nature).

²⁹ See, e.g., *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 226–27 (2014) (rejecting a patent claim as drawn to the abstract idea of intermediated settlement because the claim merely used a generic computer implementation).

³⁰ U.S. CONST. art. I, § 8, cl. 8.

³¹ NARD, *supra* note 2, at 18.

³² Act of Apr. 10, 1790, ch. 7, 1 Stat. 109.

³³ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011)

³⁴ PRAC. L. INTELL. PROP. & TECH., LEAHY-SMITH AMERICA INVENTS ACT: OVERVIEW (2020); see NARD, *supra* note 2, at 305 (suggesting the first-inventor-to-file system is the AIA’s most significant change to the U.S. patent system).

³⁵ See PRAC. L. INTELL. PROP. & TECH., *supra* note 33 (explaining that the AIA created derivation proceedings to settle disputes about whether an inventor derived his invention from another applicant).

The AIA also expanded the scope of prior art to include any public disclosure, including use, on sale, or otherwise available to the public anywhere in the world in any language prior to the effective filing date of the claimed invention.³⁶ However, the AIA also created a statutory exception for inventor or third-party disclosures made one year or less before the effective filing date.³⁷ The AIA also created a process for anonymous third-party submissions to bring to the attention of the USPTO any printed publication prior art that bears on the patentability of a pending application.³⁸ Finally, the AIA has altered some patent infringement defenses by broadening the prior use defense, eliminating the failure to disclose the best mode as a defense, and prohibiting a failure to get advice of counsel to prove willful infringement.³⁹ In addition, the creation of the United States Court of Appeals for the Federal Circuit (Federal Circuit) as the court of appeal with exclusive subject matter jurisdiction over patents has had a profound effect on the American patent system.⁴⁰

V. PATENT LAW JUDICIAL BODIES AND PROCEEDINGS

The Federal Circuit has exclusive subject matter jurisdiction over patent appeals and hears patent appeals from federal district courts, the International Trade Commission (ITC), and the Patent Trial and Appeals Board (PTAB).⁴¹ In 2021, over fifty percent of the Federal Circuit docket consisted of patent related appeals with thirty-five percent coming from the USPTO, sixteen percent coming from district courts, and about four percent coming from the ITC.⁴²

Under the AIA, the USPTO has substantially expanded its role in adjudicating the validity of patent claims. The Act created two new types of post-grant proceedings: Post-Grant Review⁴³ (PGR) and Inter Partes Review⁴⁴ (IPR). PGRs review the validity of a patent that has recently issued, allowing anyone to challenge a patent's validity within nine months of issuance on any ground.⁴⁵ The PTAB will grant review if it believes it is "more likely than not" at least one of the

³⁶ 35 U.S.C. § 102(a)(1).

³⁷ § 102(b)(1).

³⁸ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, § 8 (2011).

³⁹ 35 U.S.C. §§ 273(a), 298 (adding manufacturing and commercial processes as viable prior use defenses, and barring failure to get advice of counsel as evidence of willful infringement).

⁴⁰ 40 U.S.C. § 1295(a).

⁴¹ 28 U.S.C. § 1295(a); see *NARD*, supra note 2, at 42–43, (explaining that appeals to the Federal Circuit from PTAB may arise from the patent prosecution process, or from patent review proceedings such as Inter Partes and Post Grant Reviews).

⁴² *APPEALS FILED, BY CATEGORY, UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT (2021)*, https://cafc.uscourts.gov/wp-content/uploads/reports-stats/caseload-by-category/Caseload_by_Category_FY2021.pdf.

⁴³ 35 U.S.C. § 321.

⁴⁴ 35 U.S.C. § 311.

⁴⁵ 35 U.S.C. § 321(c).

challenged claims is unpatentable on grounds such as subject matter, novelty, public use, or sale.⁴⁶ IPRs, on the other hand, permit challenges of a patent’s validity after nine months from issuance or, if a party initiated a PGR proceeding, after the PGR terminates.⁴⁷ The scope of the challenge in an IPR is narrower than a PGR: grounds for invoking IPR are limited novelty and obviousness and with patents and printed publications.⁴⁸ Further, the court will not authorize an IPR unless there is a reasonable likelihood that the petitioner will prevail.⁴⁹ The decisions to institute both PGRs and IPRs are “final and not appealable;”⁵⁰ however, once instituted, a party may appeal an adverse result to the Federal Circuit. These two new methods of review, particularly IPRs, have been very popular due to their economy and efficiency for challenging patents.⁵¹

VI. SUBJECT MATTER ELIGIBILITY UNDER 35 U.S.C. § 101

Section 101 of Title 35 U.S.C. defines patentable subject matter as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”⁵² Until recently, these four categories were seen as essentially “all-encompassing” and included any subject matter not directed to a judicial exception, which include laws of nature, natural phenomena, and abstract ideas.⁵³ However, through a series of Supreme Court decisions from 2010 to 2014,⁵⁴ the application of what subject matter is eligible for a patent has become constrained and confused, specifically in the area of software and financial system patents as well as medical diagnostic methods.⁵⁵

After favorable Supreme Court decisions held software patents valid, the patent system experienced a flood of software and software related patents from 1981-2010.⁵⁶ After enjoying decades of flexibility in the granting of patent applications for these kinds of patents, this area of law became more restricted following a wave of additional Supreme Court decisions. In 2010, the Supreme Court held that business methods are patentable but did not explicitly state whether

⁴⁶ 35 U.S.C. § 324(a).

⁴⁷ 35 U.S.C. § 311(c).

⁴⁸ 35 U.S.C. § 311(b).

⁴⁹ 35 U.S.C. § 314(a).

⁵⁰ 35 U.S.C. §§ 324(e), 314(d).

⁵¹ CRAIG ALLEN NARD, *THE LAW OF PATENTS* 45 (5th ed. 2020).

⁵² 35 U.S.C. § 101.

⁵³ *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

⁵⁴ *Mayo Collaborative Serv. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66 (2012); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013); *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 218 (2014).

⁵⁵ Jordan Nimitz, *Shattering the Looking Glass: How Section 101 Revision Could Save FinTech from Alice*, 30 Fed. Cir. B.J. 55, 66 (2020).

⁵⁶ *Diamond*, 450 U.S. at 192 (holding that “when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect . . . than the claim satisfies the requirements of § 101”).

software is patentable subject matter.⁵⁷ Just four years later, in *Alice Corp. v. CLS Bank*,⁵⁸ the Supreme Court determined that a patent for a software designed to mitigate settlement risks was invalid as unpatentable subject matter.⁵⁹

Similarly, the Supreme Court issued rulings that disrupted the long-standing understanding of patent eligible subject matter in the life sciences industries.⁶⁰ In *Mayo*, the Court held that a method for administering a drug and determining whether to change the dosage based on detected chemical levels was directed to a law of nature and therefore not patent eligible.⁶¹ In *Myriad*, the Court found that naturally occurring DNA is not patent eligible subject matter because it is a product of nature.⁶² However, the Court noted that cDNA, which is a synthesized form of DNA, is patent eligible subject matter because it is not a naturally occurring product of nature.⁶³ After these cases, the Federal Circuit has not upheld any method of diagnosis claims that disclose natural correlations and routine scientific methods, rather it demands novel measurement and detection methods or some other inventive concept.⁶⁴

VII. ALICE/MAYO FRAMEWORK FOR DECIDING PATENT SUBJECT MATTER ELIGIBILITY

In deciding *Mayo* and *Alice* the Supreme Court articulated a two-step test for determining whether an application is directed to a judicial exception itself, or a patent-eligible application of the judicial exception.⁶⁵ This patent-eligibility framework is commonly referred to as the *Alice/Mayo* test. Step one of this test is to determine whether the claims are directed to a patent ineligible concept or judicial exception.⁶⁶ If the claims are directed to a judicial exception, step two is to determine whether the claims recite additional elements that amount to significantly more than the judicial exception thereby transforming the nature of the claim into a patent eligible application.⁶⁷ The Supreme Court has described the second part of the test as the “search for an ‘inventive concept.’”⁶⁸ Following this decision, courts have experienced great difficulty in

⁵⁷ *Bilski v. Kappos*, 561 U.S. 593, 606–07(2010).

⁵⁸ *Alice*, 573 U.S. at 208.

⁵⁹ *Id.* at 226–27.

⁶⁰ *Mayo Collaborative Serv. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66 (2012); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

⁶¹ *Mayo*, 566 U.S. at 92.

⁶² *Myriad Genetics, Inc.*, 569 U.S. at 591.

⁶³ *Id.* at 594–95.

⁶⁴ Joseph J. Koipally, et al, Patent-Eligible Subject Matter in the Life Sciences in the Unites States, 16 INTELL. PROP. J. JAPAN 20, 23 (2019).

⁶⁵ *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 217–18 (2014) (citing *Mayo*, 566 U.S. 66).

⁶⁶ *Id.* at 305.

⁶⁷ *Id.* at 217–18.

⁶⁸ *Id.* (citing *Mayo*, 566 U.S. at 72–73).

applying the Section 101 analysis, especially to business and diagnostic method patents because of the unworkability of the test articulated by the Supreme Court.⁶⁹

VIII. THE UNPREDICTABLE AND UNSTABLE SECTION 101 DOCTRINE IN PRACTICE

The confusion in applying the *Alice/Mayo* test for patent eligible subject matter is apparent in recent Federal Circuit cases.⁷⁰ In *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*,⁷¹ the Federal Circuit examined whether a patent for manufacturing a propeller shaft with liners that attenuate vibrations is patent eligible subject matter.⁷² Applying step one of the *Alice/Mayo* test, the court determined that the claim covered patent ineligible laws of nature because it was a straightforward application of Hooke's Law.⁷³ In applying the second step, the court found that the patent was merely a "well-understood, conventional activity already engaged in by the scientific community."⁷⁴ This case added further uncertainty to the *Alice/Mayo* framework by alluding to an enablement requirement to the section 101 inquiry, when enablement is meant to be analyzed under section 112.⁷⁵ Additionally, the Federal Circuit denied rehearing of the case en banc by a 6–6 split decision which illuminates the confusion that the federal circuit is experiencing in applying Supreme Court precedent.⁷⁶

In *Illumina, Inc. v. Ariosa Diagnostics, Inc.*,⁷⁷ the court analyzed the eligibility of a patent directed to determining if a fetus has down syndrome by detecting fetal DNA in a mother's bloodstream.⁷⁸ The Court acknowledged that under *Mayo*, diagnostic methods are patent ineligible subject matter, but notes that this case is "a method of preparation case."⁷⁹ In completing the *Alice/Mayo* test, the court found that the patent was a natural phenomenon, which is patent ineligible subject matter.⁸⁰ Under the second step of the test, however, the court found the claims "are not directed to that natural phenomenon but rather to a patent eligible method that

⁶⁹ Annal D. Vyas, *Alice in Wonderland v. CLS Bank: The Supreme Court's Fantastic Adventure into Section 101 Abstract Idea Jurisprudence*, 9 AKRON INTELL. PROP. J. 1, 18 (2015).

⁷⁰ *Am. Axle & Mfg., Inc. v. Neapco Holdings, LLC*, 967 F.3d 1285 (Fed. Cir. 2019); *Illumina, Inc. v. Ariosa Diagnostic, Inc.*, 952 F.3d 1367 (Fed. Cir. 2020); *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018).

⁷¹ 967 F.3d 1285 (Fed. Cir. 2019).

⁷² *Id.* at 1289.

⁷³ *Id.* at 1291.

⁷⁴ *Id.* (quoting *Mayo*, 566 U.S. at 79–80).

⁷⁵ Daryl Lim, *The Influence of Alice*, 105 MINN. L. REV. 345, 359–60 (2021).

⁷⁶ Lim, *supra* note 75, at 360 ("When the Federal Circuit, an appeals court created to develop consistent interpretations and applications of patent law, is itself divided on how to apply Supreme Court subject matter eligibility precedent, a fundamental aspect of the U.S. patent system is at risk.").

⁷⁷ 952 F.3d 1367 (Fed. Cir. 2020).

⁷⁸ *Id.* at 1369.

⁷⁹ *Id.* at 1371.

⁸⁰ *Id.*

utilizes it” because the process was for more than just observing fetal DNA, it altered the DNA fragments in samples to prepare the sample for testing.⁸¹

Additionally, recent Federal Circuit cases have altered the early pleading stages of a trial.⁸² In *Berkheimer v. HP, Inc.*,⁸³ the Federal Circuit held that a determination of whether a claim is well-understood and conventional under step two of the *Alice/Mayo* framework is a question of fact.⁸⁴ The court in *Aatrix Software Inc. v. Green Shades Software, Inc.*,⁸⁵ found that the second step of the *Alice/Mayo* test “cannot be answered adversely to the patentee based on the sources properly considered in a motion to dismiss.”⁸⁶ These cases have led to factual determinations taking a more prominent role in determining patentable subject matter and made the application of the Federal Rules of Civil Procedure more standard in pretrial motions for summary judgment or judgment as a matter of law.⁸⁷ These cases have caused a significant reduction in the granting of summary judgment motions and motions to dismiss in cases where patentable subject matter is at issue.⁸⁸

IX. CURRENT PATENT NEWS & FURTHER READING

The Supreme Court denied certiorari in *American Axle*, leaving it up to Congress and USPTO to restore any semblance of clarity on patent eligibility law. The Court also denied certiorari in *Spireon, Inc. v. Procon Analytics, Inc.*,⁸⁹ which presented identical questions to *American Axle*. The United States Solicitor General recommended that The Court grant certiorari because inventions like the one at issue in *American Axle* have “[h]istorically...long been viewed as paradigmatic examples of the ‘arts’ or ‘processes’ that may receive patent protection if other statutory criteria are satisfied” and that the U.S. Court of Appeals for the Federal Circuit

⁸¹ *Id.* at 1372.

⁸² *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018); *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121 (2018).

⁸³ 881 F.3d 1360 (Fed. Cir. 2018).

⁸⁴ *Id.* at 1368.

⁸⁵ 882 F.3d 1121 (Fed. Cir. 2018).

⁸⁶ *Id.* at 1128.

⁸⁷ Li Zhang, *Alice Gets a Haircut: Berkheimer and Aatrix Restore Factual Inquiry to Patent Subject Matter Eligibility Under Section 101*, 101 *BERKELEY TECH. L. J.*, 1081, 1099 (2019).

⁸⁸ Paul D. Ackerman, *Six Years After Alice, Are We Any Closer to Clarity on Patent Eligibility?*, *THOMAS REUTERS WESTLAW* (Nov. 30, 2020) (noting that the granting of motions to dismiss has dropped from a 70% success rate to a 45% success rate).

⁸⁹ 142 S. Ct. 2904 (2022); See also Brief for Petitioner, *Spireon, Inc. v. Procon Analytics, Inc.*, 142 S. Ct. 2904 (2022) (“This case relates to a new inventive method for vehicles. Despite the invention here improving both the functioning of (i) vehicles and (ii) “location devices” used for tracking vehicles, the district court below found the patent-in-suit invalid as an “abstract idea” under 35 U.S.C. § 101, without factual development, on a motion for judgment on the pleadings, and the Federal Circuit affirmed without opinion.”).

“erred in reading this Court’s precedents to dictate a contrary conclusion.”⁹⁰ The Supreme Court’s denial of certiorari leaves it up to Congress and the USPTO to take action to fix the unpredictability in patent eligibility laws.⁹¹

In March 2021, Senators Thom Tillis (R-N.C.), Mazie Hirono (D-HI), Tom Cotton (R-AR) and Chris Coons (D-DE) highlighted their concerns about the lack of consistency and clarity in the United States’ patent eligibility laws since the Supreme Court’s landmark decisions in *Alice* and *Mayo*.⁹² In response to the Senators’ letter, the USPTO released an in-depth June 2022 report on patent eligibility jurisprudence.⁹³ Director of the USPTO Kathy Vidal then followed up with a blog post which provided some early statistics behind the recently closed Deferred Subject Matter Eligibility Response pilot program, which was designed to evaluate whether examination efficiency and patent quality can be improved by delaying the complete evaluation of subject matter eligibility until other patentability criteria are evaluated.⁹⁴ After a summary of the USPTO’s work to date, the post recognized that “[d]espite this progress to achieve a more consistent examination under Section 101, there is more work to be done” and made an explicit request for comments on the guidance currently found in Section 2106 of the Manual of Patent Examining Procedure – the roadmap for patent examiners and practitioners. Given the overwhelming interest in the guidance, the USPTO extended its September 15, 2022, deadline, and accepted feedback until October 15, 2022.

⁹⁰ Brief for Elizabeth B. Prelogar & Brian M. Boyton et al., as Amici Curae, *Am. Axle & Mfg., Inc. v. Neapco Holdings, LLC*, 142 S.Ct. 2902, (No. 20-891).

⁹¹ Eileen McDermott, COTUS Kicks Patent Eligibility Cases to the Curb in Last Move of the Term, IPWATCHDOG (June 30, 2022), <https://www.ipwatchdog.com/2022/06/30/scotus-kicks-patent-eligibility-cases-curb-last-move-term/id=149928/>.

⁹² Gene Quinn, Tillis’ Promised Patent Eligibility Bill Would Overrule Myriad, Mayo, IPWATCHDOG (Aug. 3, 2022), <https://www.ipwatchdog.com/wp-content/uploads/2022/08/Patent-Eligibility-Restoration-Act-One-Pager-Final.pdf> (citing Thom Tillis’ Patent Eligibility Restoration Act One Pager “patent eligibility law in the United States has become confused, constricted, and unclear in recent years. This has led to inconsistent case decisions, uncertainty in innovation and investment communities, and unpredictable business outcomes.”)

⁹³ Katherine K. Vidal, Patent Eligible Subject Matter: Public Views on the Current Jurisprudence in the United States, UNITED STATES PATENT & TRADEMARK OFFICE (June 24, 2022), <https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf>.

⁹⁴ Katherine K. Vidal, Providing Clear Guidance on Patent Subject Matter Eligibility, UNITED STATES PATENT & TRADEMARK OFFICE DIRECTOR’S BLOG: THE LATEST FROM USPTO LEADERSHIP (Jul. 25, 2022), <https://www.uspto.gov/blog/director/entry/providing-clear-guidance-on-patent-Deferred-Subject-Matter-Eligibility-Response-Pilot-Program>, UNITED STATES PATENT & TRADEMARK OFFICE (Feb. 1, 2022), <https://www.uspto.gov/patents/initiatives/patent-application-initiatives/deferred-subject-matter-eligibility-response>.

A new bipartisan bill currently pending in the U.S. Senate could have significant implications on what can and can't be patented in the United States.⁹⁵ The Patent Eligibility Restoration Act of 2023,⁹⁶ introduced by Senators Tillis and Coons on June 22, 2023, addresses patent subject matter eligibility by rewriting 35 U.S.C. Section 101. In this bill, the original statutory language stays much the same so that “[w]hoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefore.”⁹⁷ However, the new Section 101 provides explicit exclusions to patentable subject matter that will replace the previous judicial exceptions, problematic for some in the biotechnology space, including the Supreme Court decisions of *Mayo*, *Alice*, and their descendants. One of the goals of the bill is to override case law that has made it difficult to receive patents on diagnostics inventions and otherwise blurred the line between what inventions are considered abstract.⁹⁸ The bill further states that genes or natural material that are “purified, enriched, or otherwise altered by human activity, or otherwise employed in a useful invention or discovery,” would not be considered unmodified and would be eligible for patents.⁹⁹

While the USPTO has taken steps to make the eligibility analysis easier for examiners, the courts remain at a loss on how to apply the law in patent eligibility cases.¹⁰⁰ However, potential remains for the Supreme Court to reconsider. Currently, there are two cases that address the eligibility requirement pending certiorari in the Supreme Court: *CareDx v. Natera*¹⁰¹ and *Killian v. Vidal*.¹⁰² In *CareDx*, the Federal Circuit analyzed the eligibility of a series of patents describing methods of diagnosing or predicting organ transplant status by detecting, collecting, and measuring cell-free DNA.¹⁰³ Under the first step of the *Alice/Mayo* test, the court directly analogized the claimed methods to those held ineligible in *Mayo*, rejecting *CareDx's* argument that the claims describe an improved measurement method.¹⁰⁴ Under the second step of the test, the court found the claims did not include an inventive concept because, as the specification confirms, the steps in the claims “appl[ied] standard techniques in a standard way to observe natural phenomenon.”¹⁰⁵ In its petition for certiorari, *CareDx* asks the Supreme Court to address

⁹⁵ Press Release, Tillis, Coons Introduce Landmark Legislation to Restore American Innovation (June 22, 2023), <https://www.tillis.senate.gov/2023/6/tillis-coons-introduce-landmark-legislation-to-restore-american-innovation>.

⁹⁶ Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. (2023).

⁹⁷ *Id.*

⁹⁸ See Press Release, *supra* note 95.

⁹⁹ S. 2140.

¹⁰⁰ Eileen McDermott, With Congress and Courts at Standstill, IPWatchdog LIVE 2022 Panel Says Upcoming ‘Action’ on 101 Will Be at USPTO, IPWATCHDOG (Sept. 13, 2022), <https://www.ipwatchdog.com/2022/09/13/congress-courts-standstill-ipwatchdog-live-2022-panel-says-upcoming-action-101-will-uspto/id=151348/>.

¹⁰¹ *CareDx, Inc. v. Natera, Inc.*, 40 F.4th 1371 (Fed. Cir. 2022).

¹⁰² *In re Killian*, 45 F.4th 1373 (Fed. Cir. 2022).

¹⁰³ *CareDx*, 40 F.4th at 1372, 1377.

¹⁰⁴ *Id.* at 1378-79.

¹⁰⁵ *Id.* at 1380.

the question of whether an improvement upon methods for measuring natural phenomenon is patentable subject matter as a “new and useful improvement” of an existing “process.”¹⁰⁶

While *CareDx* provides an opportunity for the Court to clarify patentable subject matter under the *Alice/Mayo* test, *Killian* asks the Court to consider questions that get to the very heart of issues surrounding section 101. In *Killian*, the Federal Circuit analyzed the eligibility of a patent relating to a system and method of using a computer network to determine social security disability insurance eligibility.¹⁰⁷ The court held that the patent was ineligible under the *Alice/Mayo* test because it described an abstract idea without an inventive step.¹⁰⁸ The court also dismissed arguments that the *Alice/Mayo* test is indefinite, allowing the USPTO to violate the Administrative Procedure Act¹⁰⁹ (APA) by making “arbitrary” and “capricious” decisions.¹¹⁰ In its petition for certiorari, *Killian* asks the Supreme Court to reconsider arguments that the Federal Circuit’s indefinite application of the *Alice/Mayo* test allows the USPTO to violate the APA as well as consider whether the judicially created exceptions to section 101 exceeds the powers given to courts in Article III of the Constitution.¹¹¹

Although both *CareDx* and *Killian* are on the conference list for September 26, 2023, the Court’s decade long pattern of denying certiorari for section 101 cases, even against the recommendations of the Solicitor General, suggests patent eligibility will continue to be unpredictable.¹¹² As the Supreme Court remains reluctant to reassess and the pending legislation continues to stall in the Senate, lower courts are left to apply the ambiguous *Alice/Mayo* test in subject matter eligibility determinations.¹¹³

¹⁰⁶ 35 U.S.C. § 101; Petition for Writ of Certiorari, *CareDx, Inc. v. Natera, Inc.*, 40 F.4th 1371 (Fed. Cir. 2022) (No. 22-1066).

¹⁰⁷ *Killian*, 45 F.4th at 1376.

¹⁰⁸ *Id.* at 1380.

¹⁰⁹ Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

¹¹⁰ *Id.*; *Killian*, 45 F.4th at 1381, 1383.

¹¹¹ Petition for Writ of Certiorari, *In re Killian*, 45 F.4th 1373 (Fed. Cir. 2022) (No. 22-1220).

¹¹² See CertPool, Conference of September 26, 2023 in the United States Supreme Court, <https://certpool.com/conferences/2023-09-26>.

¹¹³ See *Ficep Corp. v. Peddinghaus Corp.*, No. 2022-1590, 2023 WL 5346043, at *1, *3 (Fed. Cir. Aug. 21, 2023).