Patent-Eligible Subject Matter Reform: Background and Issues for Congress

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SUMMARY

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Patent-Eligible Subject Matter Reform: Background and Issues for Congress

The statutory definition of patent-eligible subject matter under Section 101 of the Patent Act (35 U.S.C. § 101) has remained essentially unchanged for more than two centuries. As a result, the scope of patentable subject matter—that is, the types of inventions that may be patented—has largely been left to the federal courts to develop through "common law"-like adjudication. In the 20th century, the U.S. Supreme Court established that three main types of discoveries are categorically patent-ineligible when claimed as such: laws of nature, natural phenomena, and abstract ideas.

A series of Supreme Court decisions in the 2010s broadened the scope of these three judicial exceptions to patent-eligible subject matter. Over a five-year period, the Supreme Court rejected, as ineligible, patents on a business method for hedging price-fluctuation risk (*Bilski v. Kappos*, 561 U.S. 593 (2010)); a method for calibrating the dosage of a particular drug (*Mayo Collaborative Services v. Prometheus Laboratories*, 566 U.S. 66 (2012)); isolated human DNA segments (*Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013)); and a method of mitigating settlement risk in financial transactions using a computer (*Alice Corp. Pty. v. CLS Bank International*, 573 U.S. 208 (2014)). These cases established a new two-step test, known as the *Alice*/*Mayo* framework, for determining whether a patent claims ineligible subject matter.

The first step of the *Alice*/*Mayo* test addresses whether the patent claims are "directed to" a law of nature, natural phenomenon, or abstract idea. If not, the invention is patentable. If the claims are directed to one of the ineligible categories, then the second step of the *Alice*/*Mayo* test asks whether the patent claims have an "inventive concept." To have an inventive concept, the patent claim must contain elements that transform the nature of the claim into a patent-eligible application of the ineligible concept, so that the claim amounts, in practice, to something "significantly more" than a patent on the ineligible concept itself. If the claimed invention lacks an inventive concept, then it is patent-ineligible.

The Supreme Court's decisions have been widely recognized to effect a major change in the scope of patentable subject matter, restricting the sorts of inventions that are patentable in the United States. The *Alice*/*Mayo* test has been the subject of criticism, with some stakeholders arguing that the *Alice*/*Mayo* framework is vague and unpredictable, unduly restricts the scope of patentable subject matter, reduces incentives to invest and innovate, and harms American industry's competitiveness. In particular, these stakeholders argue that the *Alice*/*Mayo* test creates uncertainty in the computer technology and biotechnology industries as to whether innovations in medical diagnostics, personalized medicine, methods of treatment, computer software, and artificial intelligence are patent-eligible. Such stakeholders—including academics, bar associations, industry representatives, judges, and former U.S. Patent and Trademark Office (USPTO) officials—have called for the Supreme Court or Congress to act to change the law of patentable subject matter.

Other stakeholders defend the legal status quo, arguing that the *Alice*/*Mayo* framework provides an important tool for combating unmeritorious patent litigation, or that the revitalized limits on patentable subject matter have important benefits for innovation. For example, some civil liberty and nonprofit organizations generally support the *Alice*/*Mayo* framework, which they argue helps foster invention and innovation by preventing monopolies on basic research tools and concepts.

The past decade has seen a number of judicial, administrative, and legislative developments in patent-eligible subject matter law and potential reforms responding to the *Alice/Mayo* decisions. On the judicial front, the Supreme Court has declined to hear further cases on the topic, despite calls by prominent stakeholders and judges on the U.S. Court of Appeals for the Federal Circuit. On the administrative front, the USPTO issued updated guidance in 2019 and 2024 to clarify and improve predictability in how USPTO patent examiners make Section 101 determinations, and released several reports on the topic. In Congress, several bills introduced in the 117th and 118th Congresses would have abrogated the Supreme Court's recent decisions on patent-eligible subject matter and otherwise reformed the statutory standards for patent-eligible subject matter.

Proposed changes to patent-eligible subject matter standards could have significant effects as to the types of technologies that are patentable. The availability of patent rights, in turn, affects incentives to invest and innovate in particular fields, as well as consumer costs and public access to technological innovation. Understanding the legal background and context of this complex issue may aid Congress as it debates the legal and practical effects that legislative Section 101 reforms would have if enacted.

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The statutory language governing patent-eligible subject matter—that is, the types of inventions that may be patented—has remained remarkably constant over the nearly 250-year history of U.S. patent law.[1] Under the Patent Act of 1793, which Thomas Jefferson authored,[2] "any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement [of the same]" was patentable.[3] Current law—Section 101 of the Patent Act of 1952—permits the patenting of "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[4] Through these four expansive statutory categories,[5] Congress sought to ensure that nearly "anything under the sun made by man" is patentable[6] if it meets all the requirements for patentability, such as novelty, enablement, and nonobviousness.[7]

Consistent with its broad statutory language, Section 101 permits patenting in fields of applied technology such as pharmaceuticals, biotechnology, chemistry, computer hardware and software, electrical engineering, agriculture, mechanical engineering, and manufacturing processes.[8] Even so, the Supreme Court has long read Section 101 as categorically prohibiting patents on three types of discoveries: "laws of nature, natural phenomena, and abstract ideas."[9] Even if "not required by the statutory text" of Section 101, the Court has held that these three judicial

[1] *See generally* Diamond v. Chakrabarty, 447 U.S. 303, 308–09 (1980) (tracing the history of statutory language on patentable subject matter). This observation—and this report more generally—is limited to traditional utility patents on useful inventions and discoveries. *See* 35 U.S.C. §§ 100–135. Congress did not provide patent protection for "original and ornamental designs for an article of manufacture" (design patents), *id.* §§ 171–173, and for "distinct and new variet[ies] of plants" (plant patents), *id.* §§ 161–164, until 1842 and 1930, respectively. *See* An Act in addition to an act to promote the progress of the useful arts, and to repeal all acts and parts of acts heretofore made for that purpose, Pub. L. No. 27-263, 5 Stat. 543 (1842); An Act to provide for plant patents, Pub. L. No. 71-245, 46 Stat. 376 (1930).

[2] Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 7 (1966) (describing Jefferson as "the author of the 1793 Patent Act").

[3] An Act to promote the progress of useful Arts; and to repeal the act heretofore made for that purpose, Pub. L. No. 2-11, § 1, 1 Stat. 318, 319 (1793). The first Patent Act, enacted in 1790, had phrased things slightly differently: "any useful art, manufacture, engine, machine, or device, or any improvement therein." *See* An Act to promote the progress of useful Arts, Pub. L. No. 1-7, § 1, 1 Stat. 109, 110 (1790). The Patent Acts of 1836 and 1870 used nearly identical language as the 1793 Patent Act. *See* An Act to promote the progress of useful arts, and to repeal all acts and parts of acts heretofore made for that purpose, Pub. L. No. 24-357, § 6, 5 Stat. 117, 119 (1836); An Act to revise, consolidate, and amend the Statutes relating to Patents and Copyrights, Pub. L. No. 41-230, § 24, 16 Stat. 198, 201 (1870). In 1952, Congress replaced the term "art," historically used to mean a process or method, with the more modern term "process," while defining "process" to mean "process, art, or method." Patent Act of 1952, Pub. L. No. 82-593, §§ 100–101, 66 Stat. 792, 797; *see also* 1 CHISUM ON PATENTS, *Overview: Historical Development of Patent Law*, § 2 n.4 (2019) ("[As used in the 1793 Patent Act, t]he term 'art' meant process or method."); Bilski v. Kappos, 561 U.S. 593, 639 (2010) (Stevens, J., concurring) ("That change [from 'art' to 'process'] was made for clarity and did not alter the scope of a patentable 'process.'" (citing Diamond v. Diehr, 450 U.S. 175, 184 (1981))); The Telephone Cases, 126 U.S. 1, 532 (1888) ("this art—or, what is the same thing under the patent law, this process . . .").

[4] 35 U.S.C. § 101.

[5] *Chakrabarty*, 447 U.S. at 308 ("In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope.").

[6] *Id.* at 309 (quoting S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)).

[7] *See* 35 U.S.C. §§ 102–103, 112; *see generally infra* "Requirements for Patentability."

[8] *See Patent Technology Centers Management*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patent/contact-patents/patent-technology-centers-management (last visited Mar. 6, 2025) (listing technological divisions for USPTO examiners).

[9] *Diehr*, 450 U.S. at 185.

exceptions "define[] the reach of the statute as a matter of statutory *stare decisis* going back 150 years."[10]

In a series of decisions in the 2010s, the Supreme Court relied on Section 101 to reject patent claims on

- a method for hedging price-fluctuation risks in commodity markets;[11]
- a method for measuring metabolites in human blood to calibrate the dosage of particular drug;[12]
- isolated human DNA segments;[13] and
- a method of mitigating settlement risk in financial transactions using a computer.[14]

These cases established a two-step test for patentable subject matter sometimes called the "*Alice/Mayo* test" or the "*Alice*/*Mayo* framework."[15] The Court's decisions have been widely recognized to effect a major change in the scope of patentable subject matter, restricting the sorts of inventions that are patentable in the United States.[16] The *Alice*/*Mayo* framework has thus shifted, for better or worse, the balance between encouraging innovation and the social costs of exclusive rights that is at the heart of patent law.[17] The effects of this change have been particularly pronounced for computer technologies and biomedical technologies.[18]

As a result, there is a significant and ongoing debate about the *Alice*/*Mayo* framework, with a number of patent law stakeholders questioning the Court's patentable subject matter rulings.[19] Critics argue that the *Alice/Mayo* framework is vague, unpredictable, and not administrable;[20]

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[10] Bilski v. Kappos, 561 U.S. 593, 602 (2010) (citing Le Roy v. Tatham, 55 U.S. (14 How.) 156, 174–75 (1853)).

[11] *Id.* at 611–12.

[12] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 77–80 (2012).

[13] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 590–94 (2013).

[14] Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 218–26 (2014).

[15] *See, e.g.*, Aatrix Software, Inc. v. Green Shades Software, Inc., 882 F.3d 1121, 1126, 1128 (Fed. Cir. 2018) (referring to the inquiry as the "*Alice*/*Mayo* test" or the "*Alice*/*Mayo* analysis"). The Supreme Court refers to the two-step process first set forth in *Mayo* as a "framework." *Alice*, 573 U.S. at 217.

[16] *See* U.S. PATENT & TRADEMARK OFF., PATENT ELIGIBLE SUBJECT MATTER: REPORT ON VIEWS AND RECOMMENDATIONS FROM THE PUBLIC 23 (2017), https://www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf [hereinafter USPTO PSM REPORT] ("In general, commentators agreed that the Court decisions in *Bilski*, *Mayo*, *Myriad*, and *Alice* have had a significant impact on the scope of patent eligible subject matter."); Jeffrey A. Lefstin et al., *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 BERKELEY TECH. L.J. 551, 555–59 (2018) [hereinafter *BCLT Report*] (describing these Supreme Court opinions as a "sea-change").

[17] *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989) ("From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy."); Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1031 (2005) ("[Traditionally,] the proper goal of intellectual property law is to give as little protection as possible consistent with encouraging innovation.").

[18] *See* USPTO PSM REPORT, *supra* note 16, at 34–35 (finding "a general consensus that two industries have been most directly affected by the recent Supreme Court jurisprudence: life sciences and computer-related technologies").

[19] *See generally id.* at 27–34 (summarizing public comments that the *Alice/Mayo* framework is legally flawed, overly broad, unpredictable, and harmful to innovation).

[20] *Id.* at 29–30 (describing public views that the Supreme Court "has failed to articulate objective, predictable criteria" for patentable subject matter); Hon. Paul R. Michel, *The Supreme Court Saps Patent Certainty*, 82 GEO. WASH. L. REV. 1751, 1758 (2014) (criticizing Court's modern Section 101 jurisprudence as "subjective," "indeterminate," and "highly (continued...)

muddies patent law by confusing patent eligibility with distinct patent law concerns, such as nonobviousness;[21] reduces incentives to innovate and invest in particular industries, such as biotechnology;[22] or puts U.S. industry at a disadvantage with international competitors.[23] Other stakeholders defend the *Alice*/*Mayo* framework, arguing that the Court's decisions are a part of the ordinary common law development of Section 101;[24] an important tool for combating unmeritorious litigation[25] or preventing overbroad or otherwise harmful patents;[26] or beneficial to American consumers by lowering prices.[27]

In response to stakeholder concerns, there have been a number of administrative and legislative developments that seek to clarify or reform the law of Section 101. In 2019, the U.S. Patent and Trademark Office (USPTO) issued Revised Patent Subject Matter Eligibility Guidance designed to assist USPTO patent examiners in determining patent eligibility with greater clarity and predictability.[28] In the 116th Congress, the Senate Judiciary Committee's Intellectual Property Subcommittee held a series of hearings on Section 101 reform, seeking input on reform proposals

unpredictable"); David O. Taylor, *Confusing Patent Eligibility*, 84 TENN. L. REV. 157, 158–60 (2016) (arguing that the Supreme Court's Section 101 jurisprudence has created a "crisis of confusion" in patent law and that the doctrine "lacks administrability").

[21] *See* USPTO PSM REPORT, *supra* note 16, at 31–32; Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591, 598–606 (2008) (arguing that patentability criteria such as obviousness, novelty, utility, inventorship, written description, and enablement motivate the Supreme Court's patentable subject matter decisions). *But see* Mark A. Lemley et al., *Life After* Bilski, 63 STAN. L. REV. 1315, 1319–32 (2011) (arguing that the preemption/overbreadth concerns driving Section 101 are distinct from disclosure and definiteness concerns under Section 112).

[22] *See, e.g.*, USPTO PSM REPORT, *supra* note 16, at 32–33, 35–38; *BCLT Report*, *supra* note 16, at 582–84; Taylor, *supra* note 20, at 240 ("[The *Alice/Mayo* framework] substantially reduces incentives to invest in research and development, particularly in the biotechnology and software technology areas.").

[23] *See* USPTO PSM REPORT, *supra* note 16, at 34; Ryan Davis, *Kappos Calls for Abolition of Section 101 of Patent* Act, LAW360 (Apr. 12, 2016), https://www.law360.com/articles/783604/kappos-calls-for-abolition-of-section-101-of-patent-act (quoting former USPTO Director David Kappos as stating that international competitors "no longer have to steal U.S. technology in [biotechnology and software], since they can now take it for free"); Robert L. Stoll, *Courts Are Making Bad Patent Law*, THE HILL (July 16, 2015), https://thehill.com/blogs/pundits-blog/the-judiciary/248054-courts-are-making-bad-patent-law ("The courts' focus on subject matter eligibility as a mechanism to deny patents for [inventions in diagnostics and personalized medicine] will drive investment into research in these technologies to other areas. We will lose our edge in the world . . . .").

[24] *See* USPTO PSM REPORT, *supra* note 16, at 23–24.

[25] *See id.* at 24; *BCLT Report*, *supra* note 16, at 555 ("Many technology companies that rely on software innovation . . . welcomed the tightening of patent eligibility standards on software claims and the opportunity to seek early dismissals of lawsuits."); Paul R. Gugliuzza, *Quick Decisions in Patent Cases*, 106 GEO. L.J. 619, 652–53 (2018) ("The invigoration of the [patent] eligibility requirement can help courts resolve infringement disputes more quickly and cheaply by allowing validity to be resolved on the pleadings as a matter of law.").

[26] *See The State of Patent Eligibility in America: Part I: Hearing Before the S. Judiciary Comm., Subcomm. on Intellectual Property*, 116th Cong. (2019) (statement of Prof. Joshua D. Sarnoff, DePaul University College of Law), at 3–8, https://www.judiciary.senate.gov/download/sarnoff-testimony [hereinafter Sarnoff Testimony]; *accord* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 86 (2012) ("[E]ven though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are the basic tools of scientific and technological work. And so there is a danger that the grant of patents that tie up their use will inhibit future innovation . . . ." (citations omitted)); Lemley et al., *supra* note 21, at 1329 (arguing that Section 101's abstract ideas doctrine is "about encouraging cumulative innovation and furthering societal norms regarding access to knowledge").

[27] USPTO PSM REPORT, *supra* note 16, at 27.

[28] Notice, 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019). The USPTO subsequently issued an update to this guidance in October 2019. *See* U.S. PAT. & TRADEMARK OFF., *October 2019 Update: Subject Matter Eligibility* (Oct. 2019), https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf.

from various patent stakeholders.[29] These efforts led to the introduction of the Patent Eligibility Restoration Act in the 117th and 118th Congresses.[30] Separately, the Restoring America's Leadership in Innovation Act has been introduced in recent Congresses and would have reformed Section 101 (along with several other changes to patent law).[31]

This report provides the necessary background and context to understand the legal and practical effects that these legislative reforms would have if enacted.[32] First, the report reviews the basic legal principles of the U.S. patent system. Second, it examines the historical development and current state of patentable subject matter law. Third, it reviews several articulated rationales for Section 101 and potential options for Section 101 reform. Finally, it examines recent judicial, administrative, and legislative developments concerning patent-eligible subject matter, including the proposed legislative reforms to Section 101.

This report focuses on patent-eligible subject matter reform from a legal perspective. For an analysis of these issues as they relate to innovation policy, see CRS Report R47267, *Patents and Innovation Policy*, by Emily G. Blevins (2022).

Patent Law Background

Congress's authority to grant patents derives from the Intellectual Property (IP) Clause of the U.S. Constitution, which grants Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[33] Patents are generally available to any person who "invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[34]

Patent rights do not arise automatically. Rather, to obtain patent protection under the Patent Act,[35] an inventor must formally apply for a patent with the USPTO, beginning a process called patent prosecution.[36] During prosecution, a USPTO patent examiner evaluates the patent application to

[29] *See generally* Sen. Chris Coons & Sen. Thom Tillis, *What Coons and Tillis Learned at Patent Reform Hearings*, LAW360 (June 21, 2019), https://www.law360.com/articles/1171672/. Video of the hearings and the written testimony are available online. *See The State of Patent Eligibility in America: Part I: Hearing Before the S. Judiciary Comm., Subcomm. on Intellectual Property*, 116th Cong. (2019), https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-i; *The State of Patent Eligibility in America: Part II: Hearing Before the S. Judiciary Comm., Subcomm. on Intellectual Property*, 116th Cong. (2019), https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-ii; *The State of Patent Eligibility in America: Part III: Hearing Before the S. Judiciary Comm., Subcomm. on Intellectual Property*, 116th Cong. (2019), https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-iii [hereinafter, collectively, *Patent Eligibility Hearings*].

[30] *See* Patent Eligibility Restoration Act of 2024, H.R. 9474, 118th Cong. (2024); Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. (2023); Patent Eligibility Restoration Act of 2022, S. 4734, 117th Cong. (2022).

[31] *See* Restoring America's Leadership in Innovation Act of 2024, H.R. 8134, 118th Cong. § 7 (2024); Restoring America's Leadership in Innovation Act of 2021, H.R. 5874, 117th Cong. § 7 (2021); Restoring America's Leadership in Innovation Act of 2020, H.R. 7366, 116th Cong. § 7 (2020); Restoring America's Leadership in Innovation Act of 2018, H.R. 6264, 115th Cong. § 7 (2018).

[32] For a succinct overview of this topic, see CRS In Focus IF12563, *Patent-Eligible Subject Matter Reform: An Overview*, by Emily G. Blevins and Kevin J. Hickey (2024).

[33] U.S. CONST. art. I, § 8, cl. 8.

[34] 35 U.S.C. § 101.

[35] *See* Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (codified as amended at 35 U.S.C. §§ 1–390).

[36] *See Applying for Patents*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/basics/apply (last visited Mar. 6, 2025).

ensure that it meets all the applicable legal requirements to merit the grant of a patent.[37] To be patentable, an invention must be (1) directed at patent-eligible subject matter, (2) useful, (3) new, (4) nonobvious, and (5) adequately disclosed and claimed in the patent application.[38] If the USPTO finds these requirements met, it will issue (i.e., grant) the patent.[39] Patents typically expire 20 years after the initial patent application.[40]

The current law of patent-eligible subject matter will be discussed separately in detail below.[41] The remainder of this section briefly reviews the other requirements for patentability, the scope and effect of patent claims, and the legal rights granted to the holder of a valid patent.

Requirements for Patentability

Section 101: Utility

Along with its subject matter requirements, Section 101 contains a requirement that a patented invention must be "useful."[42] In particular, courts have held that an invention must have both a specific and substantial utility to be patentable.[43] The utility requirement derives from the Constitution's command that patent laws exist to "promote the Progress of . . . *useful* Arts."[44] The constitutional purpose of patent law thus requires a "benefit derived by the public from an invention with substantial utility," where the "specific benefit exists in currently available form."[45] This standard for utility is low, however, requiring only that the claimed invention have some "significant and presently available benefit to the public" that "is not so vague as to be meaningless."[46]

Section 102: Novelty

Perhaps the most fundamental requirement for patentability is that the claimed invention must be *new*. The USPTO will not issue a patent if "the claimed invention was 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."[47] In other words, if every element of the claimed invention is already disclosed in the "prior art"—the information available to the public at the time of the patent application—then the alleged inventor "has added nothing to the total stock of knowledge," and no valid patent may issue to her.[48]

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[37] 35 U.S.C. § 131.

[38] *See id.* §§ 101–103, 112.

[39] *Id.* § 131.

[40] *Id.* § 154(a)(2).

[41] *See infra* "The Law of Section 101."

[42] 35 U.S.C. § 101.

[43] Brenner v. Manson, 383 U.S. 519, 534–35 (1966); *In re* Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

[44] Stiftung v. Renishaw PLC, 945 F.2d 1173, 1180 (Fed. Cir. 1991) (citing *Brenner*, 383 U.S. at 528–29).

[45] *Brenner*, 383 U.S. at 534–35.

[46] *In re* Fisher, 421 F.3d at 1371–72.

[47] 35 U.S.C. § 102(a)(1). There are certain exceptions to this requirement when, for example, the prior-art disclosure derives from the inventor and the patent application is made within one year of the disclosure. *Id.* § 102(b)(1).

[48] Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 153 (1950); Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 6 (1966) ("Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.").

Section 103: Nonobviousness

Even if a claimed invention is novel in the narrow sense that it is not "identically disclosed" in a prior-art reference (such as an earlier patent or publication), the invention must further be *nonobvious* to be patentable.[49] Specifically, an invention cannot be patented if "the differences between 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 relevant technology.[50] When determining obviousness, courts also evaluate secondary considerations (also known as "objective indicia") of nonobviousness such as "commercial success, long felt but unsolved needs, [or] failure of others . . . to give light to the circumstances surrounding the origin of the subject matter sought to be patented."[51] By its nature, obviousness is an "expansive and flexible" inquiry that cannot be reduced to narrow, rigid tests.[52] Nonetheless, if an invention merely combines "familiar elements according to known methods," yielding only "predictable results," it is likely to be obvious.[53]

Section 112(a): Written Description, Enablement, Best Mode

Finally, the Patent Act imposes several requirements relating to the technical disclosures in the patent application. These provisions are intended to ensure that the patent adequately describes the invention such that the public can use the invention after the expiration of the patent term.[54] Section 112(a) of the Patent Act requires that patents must contain a "specification" that includes

> a *written description* of the invention, and of the manner and process of making and using it, *in such full, clear, concise, and exact terms as to enable* any person skilled in the art to . . . make and use the same, and shall set forth *the best mode* contemplated by the inventor or joint inventor of carrying out the invention.[55]

This statutory language yields three basic disclosure requirements for patentability.[56] First, to satisfy the *written description requirement*, the specification must "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date" of the patent application.[57] Second, to satisfy the *enablement requirement*, the specification must contain enough information to teach a person skilled in the art how "to make and use the invention without undue experimentation."[58] Finally, to satisfy the *best mode requirement*, if the inventor knew of a preferred way of practicing her invention at the time of the patent application, the specification must disclose that "preferred embodiment[]" of the invention.[59]

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[49] 35 U.S.C. § 103.

[50] *Id.* Patent law often relies on the concept of a "person having ordinary skill in the art," a "hypothetical person" with a typical level of skill in the relevant technology who is "presumed to be aware of all the pertinent prior art" in the particular field. *See* Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985).

[51] *Graham*, 383 U.S. at 17–18; *see also* Apple Inc. v. Samsung Elecs. Co., 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) ("Objective indicia of nonobviousness must be considered in every case where present.).

[52] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415–19 (2007).

[53] *Id.* at 416.

[54] *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974).

[55] 35 U.S.C. § 112(a) (emphases added).

[56] *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002); Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc).

[57] *Ariad*, 598 F.3d at 1351.

[58] *In re* Wands, 858 F.2d 731, 735 (Fed. Cir. 1988).

[59] Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 963 (Fed. Cir. 2001). Failure to disclose the best mode is not a basis on which a patent claim can be invalidated in subsequent patent infringement proceedings. 35 U.S.C. § 282(b)(3)(A).

Patent Claims

Section 112(b): Definiteness

If granted, the legal scope of the patent is defined by the *patent claims*, a sequence of statements that formally set forth the patentee's asserted rights. In essence, while the specification explains the invention in a technical sense, the claims set forth the *legal* effect of the patent.[60] Much as a deed may describe the boundaries of a tract of land, the claims define the "metes and bounds" of the patent right.[61] Patent claims must be sufficiently *definite* to be valid—that is, they must "particularly point[] out and distinctly claim[] the subject matter which the inventor . . . regards as the invention."[62] In other words, when the claims are read in context, they must "inform, with reasonable certainty, those skilled in the art about the scope of the invention."[63]

Section 112(f): Functional Claiming

For the most part, the current Patent Act uses a system *of peripheral claiming*, in which the patent claims formally set out the outer boundaries of the patentee's rights.[64] However, the Patent Act still retains elements of its former system of *central claiming*, in which the patentee would describe the core principles or examples of what he had invented, but need not formally delineate the outer boundaries of his rights.[65] For example, under the doctrine of equivalents, an accused infringer may be found liable even if his product does not literally meet every element of the patent claims, if the differences between a claim element and its alleged equivalent in the accused product are "insubstantial."[66]

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[60] *See Ariad*, 598 F.3d at 1347 (Fed. Cir. 2010); *In re* Vamco Mach. & Tool, Inc., 752 F.2d 1564, 1577 n.5 (Fed. Cir. 1985).

[61] Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989).

[62] 35 U.S.C. § 112(b); Laitram Corp. v. NEC Corp., 163 F.3d 1342, 1347 (Fed. Cir. 1998) ("[I]t is the *claims*, not the written description, which define the scope of the patent right.").

[63] Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901 (2014).

[64] *See* 35 U.S.C. § 112(b); Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 WIS. L. REV. 905, 911 (2013) ("Today, peripheral claiming is universal [in patent law]; patentees write claims in an effort to define the outer boundaries of their invention."); Jeanne C. Fromer, *Claiming Intellectual Property*, 76 U. CHI. L. REV. 719, 725–30 (2009) (explaining the distinction between peripheral and central claiming systems for intellectual property). Until the late 19th century, however, central claiming prevailed: the patentee had only to describe the core principle or an example of his invention, and courts would decide whether the accused infringer's product or method was sufficiently similar to the patentee's invention to infringe the patent. *See* Lemley, *supra*, at 910–11; Fromer, *supra*, at 731–33. Peripheral claiming began as a defensive strategy by patentees to describe their invention at a higher level of generality, and the gradual switch toward the modern patent claiming was eventually codified in the Patent Act in 1870. *See* An Act to revise, consolidate, and amend the Statutes relating to Patents and Copyrights, Pub. L. No. 41-230 § 26, 16 Stat. 198, 201 (1870) (requiring patent applicant to "particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery"); *see generally* Fromer, *supra*, at 731–35 (reviewing American patent law's historical shift from central to peripheral claiming); Dan L. Burk & Mark A. Lemley, *Fence Posts or Sign Posts? Rethinking Patent Claim Construction*, 157 U. PA. L. REV. 1743, 1766–71 (2009) (same). This account of patent-claiming history is somewhat simplified: notably, despite the 1870 statutory shift, the Patent Act retained (and retains) features of central claiming. *See* Burk & Lemley, *supra*, at 1771 ("[I]t may be fairer to say that during the twentieth century we had not a peripheral-claiming system, but a hybrid peripheral claiming system.").

[65] *See* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 520 U.S. 17, 27 n.4 (1997) ("[T]he abandonment of 'central' claiming [in American patent law] may be overstated."); Fromer, *supra* note 64, at 735–41 (describing "vestiges" of central claiming in the modern Patent Act).

[66] *See Warner-Jenkinson*, 520 U.S. at 39–40; Graver Tank & Mfg. Co. v. Linde Co., 339 U.S. 605, 608–09 (1950) (laying out factors to consider in determining equivalence).

A potential danger of a peripheral claiming system is that patentees may seek to claim more than they invented by couching the patent claims in broad, functional language—that is, by claiming a result or goal without limitation to any specific structure or device that accomplishes the result.[67] In *Halliburton Oil Well Cementing Co. v. Walker*, the Supreme Court limited this practice, invalidating as indefinite a "functional" patent claim, in which the invention—an apparatus for determining the location of an obstruction in an oil well—was claimed not in terms of specific machinery, but instead as a "means for" performing various functions.[68]

Functional claims (also known as "means-plus-function" claims) such as those in *Halliburton* may be convenient for the patentee, who can express a claim element in terms of a general end, rather than an "exhaustive list" of every possible apparatus that could be used to perform that goal.[69] On the other hand, as *Halliburton* recognized, functional claims may be overbroad and ambiguous, or permit the patentee to claim more than he actually invented.[70] In the Patent Act of 1952, Congress enacted current Section 112(f) as a compromise for functional claims, overruling *Halliburton*[71] but providing a standard to make functional claims more definite.[72]

Under Section 112(f), a patentee may opt to express a claim element as "a means or step for performing a specified function without the recital of structure, material, or acts in support thereof."[73] If the patentee chooses to claim functionally, however, the claim is construed not to cover *all* possible means of performing the function, but only "the corresponding structure, material, or acts *described in the specification* and equivalents thereof."[74] Courts have held that a patentee is presumed to invoke Section 112(f) when the term "means" is used in the claims.[75] Conversely, there is a presumption that the patentee does *not* invoke Section 112(f) if she does not use the term "means," but that presumption may be overcome, such that Section 112(f) will apply to any claim that fails to recite a "sufficiently definite structure" for performing a function.[76]

Rights of Patent Holders

With some exceptions, a patent is generally granted "for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was

[67] *See* Lemley, *supra* note 64, at 911–13. Such claiming should in theory be prohibited on novelty or enablement grounds, *see* 35 U.S.C. §§ 102, 112(a), but the problem persists, for example, in modern software patents. *See* Lemley, *supra* note 64, at 921–23 (citing examples).

[68] *See* 329 U.S. 1, 8–9, 12–13 (1946).

[69] Stephen Winslow, *Means for Improving Modern Functional Patent Claiming*, 98 GEO. L.J. 1891, 1892 (2010) ("A patent can be clearer, more concise, and more comprehensible when the patentee drafts her claims using language describing what a particular element does, rather than giving an exhaustive list of the various structures that could provide that function within her invention.").

[70] *See Halliburton*, 329 U.S. at 12.

[71] *See* Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1347 (Fed. Cir. 2015) (en banc) ("In enacting [§ 112(f)], Congress struck a balance in allowing patentees to express a claim limitation by reciting a function to be performed rather than by reciting structure for performing that function, while placing specific constraints on how such a limitation is to be construed . . . ."); P.J. FEDERICO, COMMENTARY ON THE NEW PATENT ACT (West 1954), *reprinted in* 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 186 (1993) (observing that "[t]he last paragraph of section 112" means that "decisions such as that in [*Halliburton Oil*] are modified or rendered obsolete . . . .").

[72] Valmont Indus. v. Reinke Mfg. Co., 983 F.2d 1039, 1042 (Fed. Cir. 1993).

[73] 35 U.S.C. § 112(f).

[74] *Id.* (emphasis added).

[75] *Williamson*, 792 F.3d at 1348 (quoting Watts v. XL Sys., Inc., 232 F.3d 877, 880 (Fed. Cir. 2000)).

[76] *Id.*

filed."[77] The Patent Act includes provisions that may modify the 20-year term, including to account for excessive delays in patent examination at the USPTO,[78] or delays associated with obtaining marketing approval from other federal agencies.[79]

Once granted, a valid patent gives the patent holder the exclusive right to make, use, offer to sell, sell, or import the invention in the United States until the patent expires.[80] Any other person who practices the invention (i.e., makes, uses, offers to sell, sells, or imports it) without permission from the patent holder infringes the patent and may be liable for monetary damages and injunctive relief if sued by the patentee.[81] To obtain relief from infringement, the patentee must generally sue in court.[82] Patent law is an area of exclusive federal jurisdiction,[83] and the traditional forum for most patent disputes is federal district court.[84] Although patent suits may be filed in any district court across the country with jurisdiction over the defendant and proper venue,[85] a single specialized court, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), hears all appeals in patent cases.[86]

Defending Against Patent Suits

Parties accused of patent infringement may defend on several grounds. First, the accused infringer may claim an "absence of liability" because of *noninfringement*.[87] In other words, even presuming the patent is valid, the patentee may fail to prove that the activities of the accused infringer fall within the scope of the patent claims—that is, the accused infringer is not making, using, selling, or importing the patented invention.[88] Second, although patents benefit from a

[77] 35 U.S.C. § 154(a).

[78] *Id.* § 154(b)(1).

[79] *Id.* § 156. In the pharmaceutical context, patents claiming a drug product or medical device (or a method of using or manufacturing the same) may be extended for up to five years to account for delays in obtaining regulatory approval, if certain statutory conditions are met. *See* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 670–71 (1990); Merck & Co. v. Hi-Tech Pharmacal Co., 482 F.3d 1317, 1320–21 (Fed. Cir. 2007); Stephanie Plamondon Bair, *Adjustments, Extensions, Disclaimers, and Continuations: When Do Patent Term Adjustments Make Sense?*, 41 CAP. U. L. REV. 445, 460 (2013).

[80] 35 U.S.C. § 271(a).

[81] *Id.* §§ 271, 281, 283–85.

[82] 35 U.S.C. § 281.

[83] 28 U.S.C. § 1338.

[84] In 2023, roughly 3,108 patent lawsuits were filed in federal district courts, as compared to 1,192 petitions filed before the Patent Trial and Appeal Board (PTAB). *See 2023 Patent Dispute Report: Year in Review*, UNIFIED PATENTS (Jan. 8, 2024), https://www.unifiedpatents.com/insights/2024/1/8/patent-dispute-report-2023-in-review. The third main forum for patent disputes is the International Trade Commission (ITC), which has authority to conduct administrative trials (called "Section 337 investigations") into whether imported goods violate patent and other intellectual property rights. *See* 19 U.S.C. § 1337. The ITC usually receives fewer than 100 complaints per year (and not all of these are patent cases). *See Section 337 Statistics: Number of New, Completed, and Active Investigations by Fiscal Year (Updated Quarterly)*, ITC, https://www.usitc.gov/intellectual_property/337_statistics_number_new_completed_and_active.htm (last updated Feb. 3, 2025).

[85] *See generally* TC Heartland LLC v. Kraft Foods Grp., 137 S. Ct. 1514, 1518–21 (2017) (addressing scope of patent venue statute); Gunn v. Minton, 568 U.S. 251 (2013) (addressing scope of federal patent subject matter jurisdiction); Xilinx, Inc. v. Papst Licensing GmbH & Co. KG, 848 F.3d 1346 (Fed. Cir. 2017) (addressing personal jurisdiction in patent dispute).

[86] 28 U.S.C. § 1295(a)(1).

[87] 35 U.S.C. § 282(b)(1).

[88] To prove direct infringement, the plaintiff must show that each element contained in a patent claim is practiced by (continued...)

presumption of validity, the accused infringer may assert that the patent is *invalid*.[89] To prove invalidity, the accused infringer must show, by clear and convincing evidence, that the USPTO should not have granted the patent because it failed to meet the requirements for patentability.[90] Thus, for example, the accused infringer may argue that the invention lacks novelty, is obvious, or claims nonpatentable subject matter; that the patent fails to enable the invention; or that the patent claims are indefinite.[91] Finally, the accused infringer may assert as a defense that the patent is *unenforceable* based on the inequitable or illegal activities of the patent holder, such as obtaining the patent through fraud on the USPTO.[92] While the patent holders bears the burden of proving infringement,[93] the accused infringer bears the burden of proving invalidity or inequitable conduct.[94]

Following the passage of the 2011 Leahy-Smith America Invents Act (AIA),[95] the Patent Trial and Appeal Board (PTAB) has become an increasingly important forum for patent disputes.[96] The AIA created several new administrative procedures for challenging patent validity, including (1) *post-grant review* (PGR), which allows any person to challenge patent validity based on any of the requirements of patentability if the PGR petition is filed within nine months of the patent's issuance;[97] (2) *inter partes review* (IPR), which allows any person other than the patentee to challenge patent validity on limited grounds (novelty or obviousness based on prior patents or printed publications) at any time more than nine months following the patent's issuance;[98] and (3) a transitional program for *covered business method patents* (CBM), a PGR-like process limited to certain patents claiming "business methods" that was available only through September 2020.[99] Of these procedures, IPR is by far the most widely used.[100] IPRs can only be used to seek cancellation of patents based on a lack of novelty or nonobviousness, and not on Section 101 grounds (i.e., claiming ineligible subject matter).[101]

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the alleged infringer, either literally or by an equivalent. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29–30 (1997). Often, whether or not the accused infringer's activities fall within the patent claims depends upon *claim construction*: how the words used in the patent claims are interpreted. *See generally* Markman v. Westview Instruments, Inc., 517 U.S. 370, 372–74 (1996); Phillips v. AWH Corp., 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc).

[89] 35 U.S.C. § 282(a), (b)(2)–(3).

[90] *Id.* § 282(b)(2)–(3); Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 95–96 (2011).

[91] *See supra* "Requirements for Patentability."

[92] 35 U.S.C. § 282(b)(1); Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1285, 1290–91 (Fed. Cir. 2011) (en banc).

[93] Medtronic, Inc. v. Mirowski Fam. Ventures, LLC, 571 U.S. 191, 193 (2014).

[94] 35 U.S.C. § 282(a); *Therasense*, 649 F.3d at 1291.

[95] Pub. L. No. 112-29, 125 Stat. 284 (2011).

[96] *See generally* CRS Report R48016, *The Patent Trial and Appeal Board and Inter Partes Review*, by Christopher T. Zirpoli and Kevin J. Hickey (2024); Rochelle Cooper Dreyfuss, *Giving the Federal Circuit a Run for Its Money: Challenging Patents in the PTAB*, 91 NOTRE DAME L. REV. 235, 249 (2015).

[97] 35 U.S.C. §§ 321–329.

[98] *Id.* §§ 311–319.

[99] Pub. L. No. 112-29, § 18, 125 Stat 284, 329–30 (2011) (not codified in U.S.C.).

[100] *See PTAB Trial Statistics: FY23 End of Year Outcome Roundup*, USPTO, https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2023__roundup.pdf (last visited Mar. 6, 2025), at 3 (98% of petitions filed with PTAB in FY2023 were IPRs).

[101] 35 U.S.C. § 311(b).

The Law of Section 101

At a general level, there are two basic requirements for an invention to claim patent-eligible subject matter. First, the invention must fit into one or more of the four statutory categories in Section 101—the claimed invention must be a (1) process, (2) machine, (3) manufacture, or (4) composition of matter.[102] Given the (intentionally) expansive nature of these terms, nearly all claimed inventions will satisfy this requirement.[103] Still, exceptions to this rule do exist. For example, in *In re Nuijten*, the Federal Circuit held that a transitory electromagnetic signal was neither a process, machine, manufacture, or composition of matter, and was therefore not patent-eligible subject matter.[104]

Because most claimed inventions fit into one of the four statutory categories, the second requirement tends to be more practically important, and receives more attention.[105] The second patentable subject matter requirement is that the invention cannot claim one of the judicially created categories of ineligible subject matter. That is, the claimed invention must *not* be a (1) law of nature, (2) natural phenomenon, or (3) abstract idea.[106] As explained below, the modern Supreme Court has articulated a two-step test for this second requirement, known as the *Alice*/*Mayo* framework.[107]

The Supreme Court has justified the three ineligible categories as necessary to prevent patent monopolies on the "'basic tools of scientific and technological work,'" which "might tend to impede innovation more than it would tend to promote it."[108] Thus, the Court has explained that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have

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[102] 35 U.S.C. § 101.

[103] *See* Lemley et al., *supra* note 21, at 1328 ("[P]atent claims almost never fall *outside* of the four fundamental categories of § 101 . . . .").

[104] 500 F.3d 1346, 1354–57 (Fed. Cir. 2007).

[105] *See* Kevin Emerson Collins, *Patent-Ineligibility As Counteraction*, 94 WASH. U. L. REV. 955, 968 (2017) ("Contemporary debates over patent-ineligibility rarely parse the plain meanings of [the four statutory categories]. They focus instead on a set of judicial exclusions from patent-eligibility that are not expressly codified in the statute: laws of nature, products of nature, and abstract ideas . . . .").

[106] Diamond v. Diehr, 450 U.S. 175, 185 (1981). *Diehr*'s modern distillation of patentable subject matter doctrine to these three categories is a somewhat simplified version of the doctrine's historical development, which often identified patent-ineligible categories in addition to these three. *See, e.g.*, Daniel J. Klein, *The Integrity of Section 101: A 'New and Useful' Test for Patentable Subject Matter*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 287, 288 (2011) (listing eight terms that the Court has used to denote patent-ineligible subject matter); Michel, *supra* note 20, at 1757 (counting six categories of patent-ineligible subject matter); *accord* Emily Michiko Morris, *Intuitive Patenting*, 66 S.C. L. REV. 61, 66 n.31 (2014) (describing the Supreme Court's patentable subject matter jurisprudence as "insolubly murky").

In addition to the three modern patent-ineligible categories and their close variants (such as "products of nature" or "physical phenomena" as synonyms for natural phenomena, see Diamond v. Chakrabarty, 447 U.S. 303, 309, 313 (1980), or "scientific truth" as a synonym for a law of nature, see Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939)), courts have at times referenced "principles," "natural agencies," "functions of a machine," "effects of a machine," "mathematical formulas," "algorithms," "mental processes," "mental steps," and "printed matter" as patent-ineligible categories. *See* Le Roy v. Tatham, 55 U.S. 156, 175 (1852) ("principle[s]" and "natural agencies"); Corning v. Burden, 56 U.S. 252, 268 (1853) ("function or abstract effect of a machine"); Gottschalk v. Benson, 409 U.S. 63, 67, 72 (1972) ("mathematical formula," "algorithm," "mental processes"); Diamond v. Diehr, 450 U.S. 175, 195–200 (1981) (Stevens, J., dissenting) (reviewing history of "mental steps" doctrine that prohibited patents on "processes involving mental operations"); Praxair Distribution, Inc. v. Mallinckrodt Hosp. Prod. IP Ltd., 890 F.3d 1024, 1031–33 (Fed. Cir. 2018) ("printed matter").

[107] *See infra* "The Modern *Alice*/*Mayo* Framework."

[108] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012) (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)).

patented the law of gravity."[109] At the same time, the Court has said that even if a mathematical formula or law of nature is not patentable "in the abstract," a practical application of such a principle or law "to a new and useful end" is patent-eligible.[110]

Beyond such broad illustrations, it is not easy to define what an "abstract idea," "law of nature," or "natural phenomenon" is.[111] Because these exceptions to patent-eligible subject matter are judicially created, they have no formal statutory definition; their meaning has instead been developed through two centuries of case-by-case "common law" adjudication in the federal courts.[112] As a result, the scope of patentable subject matter has waxed and waned over time, depending on the trends in judicial decisions.[113]

This section overviews the leading Supreme Court cases addressing patent-eligible subject matter, beginning with formative cases from the 19th century and culminating in the series of 2010s Supreme Court decisions that have led some to call for legislative reform of Section 101.[114]

Historical Development of the Judicial Exceptions to Patent-Eligible Subject Matter

Nineteenth Century

The 1853 case of *Le Roy v. Tatham*, the "fountainhead" of American patentable subject matter jurisprudence,[115] concerned a patent on machinery to manufacture metal pipes that exploited a

[109] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

[110] *See, e.g.*, *Diehr*, 450 U.S. at 187; Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); Mackay Radio & Telegraph Co. v. Radio of Am., 306 U.S. 86, 94 (1939); *Le Roy*, 55 U.S. at 174–75.

[111] *See* Morris, *supra* note 106, at 62 (describing the Supreme Court's patentable subject matter jurisprudence as "insolubly murky"); Klein, *supra* note 106, at 289 (describing the three categories of nonpatentable subject matter as "metaphysically vague and extra-statutory"); *Funk Bros.*, 333 U.S. at 134–35 (Frankfurter, J., concurring) ("It only confuses the issue, however, to introduce such terms as 'the work of nature' and the 'laws of nature.' For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.'").

[112] *See, e.g.*, Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land:* Bilski*'s Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289, 1307 (2011) ("Since the founding of our nation, courts have evolved [patentable subject matter limits] within a hybrid constitutional/common law tradition."); Lemley et al., *supra* note 21, at 1325 (describing the three judicially created ineligible categories as "common law exceptions" to patentable subject matter).

[113] The evolving standards applied to the patentability of computer software over the last 50 years are just one notable example. *See generally* Lemley et al., *supra* note 21, at 1317–19 (reviewing the "tortured history" of the patentability of software). *Compare*, *e.g.*, *Benson*, 409 U.S. 63 (method for converting binary-coded decimal numerals into pure binary numerals on computer is not patentable subject matter) *with* State Street Bank v. Signature Fin. Grp., 149 F.3d 1368, 1373 (Fed. Cir. 1998) (Rich, J.) (transformations of data are patentable so long as they produce "a useful, concrete and tangible result"), *abrogated by In re* Bilski, 545 F.3d 943, 960 (Fed. Cir. 2008) (en banc) *and* Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 224–26 (2014) (computer-implemented business method not patentable because it is an abstract idea lacking an "inventive concept"). For a broader review of the history of patentable subject matter jurisprudence, see, e.g., Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 570–645 (2015); Max Stul Oppenheimer, *Patents 101: Patentable Subject Matter and Separation of Powers*, 15 VAND. J. ENT. & TECH. L. 1, 5–28 (2012); Joshua D. Sarnoff, *Patent-Eligible Inventions After* Bilski*: History and Theory*, 63 HASTINGS L.J. 53, 63–90 (2011); John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609, 623–46 (2009).

[114] *See infra* **Table 1.**

[115] *See, e.g.*, Lefstin, *supra* note 113, at 594 (describing *Le Roy* as "the fountainhead of subject-matter exclusion in American patent law"); Menell, *supra* note 112, at 1296 (describing *Le Roy* as "the foundation for much patentable subject matter jurisprudence").

newly developed property of lead.[116] Although the Court ultimately did not decide the case on subject matter grounds,[117] *Le Roy* relied on influential English patent cases[118] to set forth a basic distinction between abstract "principles" and natural laws (which may not be patented) and *practical applications* of those principles (which may be patented).[119] The Court stated that "[a] principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."[120] On the other hand, a "new property discovered in matter, when practically applied, in the construction of a useful article of commerce or manufacture, is patentable," for the "invention is not in discovering [the natural principles], but in applying them to useful objects."[121]

In its next term, the Court applied this rule to Samuel Morse's patent on the telegraph in the famous case *O'Reilly v. Morse*.[122] Although the Court found that Morse was the first inventor of the telegraph and sustained much of his patent,[123] the Court rejected Morse's eighth claim to any "use of the motive power of the electric or galvanic current . . . however developed for marking or printing intelligible characters, signs, or letters, at any distances, being a new application of that power of which I claim to be the first inventor or discoverer."[124] Observing that "the discovery of a principle in natural philosophy or physical science, is not patentable,"[125] Chief Justice Roger Taney's majority opinion held that Morse's eighth claim was "too broad" because he had not discovered "that the electric or galvanic current will always print at a distance, no matter what may be the form of the machinery" used, but only that the specific machinery disclosed in the patent specification would do so.[126]

In the second half of the 19th century, the Court issued a series of important decisions on the patentability of processes. The result of these cases was a move away from an earlier rule that prohibited "pure" method patents as ineligible (i.e., a process claimed independently of the specific machinery used to accomplish the method) either by construing nominal process patents as claiming a machine or limiting the process patents to the machinery disclosed and its equivalents.[127] In *Cochrane v. Deener*, which involved a patent on an improved manufacturing process for flour, the Court defined a patentable process as "a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing."[128] *Cochrane* held that such

[116] 55 U.S. (14 How.) 156, 176–77 (1853).

[117] The dispositive issue in the case was the scope of the patent claims. *See infra* note 181; Lefstin, *supra* note 113, at 595 ("The outcome in *Le Roy* therefore turned entirely on the Court's narrow construction of the claim.").

[118] For a full historical account of these English cases and how they shaped the Supreme Court's jurisprudence, see Lefstin, *supra* note 113, at 577–644.

[119] *Le Roy*, 55 U.S. at 174–75.

[120] *Id.* at 175.

[121] *Id.*

[122] 56 U.S. 62 (1853).

[123] *Id.* at 111–12, 123–24.

[124] *Id.* at 112–20.

[125] *Id.* at 116.

[126] *Id.* at 117, 119.

[127] *See, e.g.*, Corning v. Burden, 56 U.S. (15 How.) 252, 268–70 (1853) (construing "equivocal" patent to claim a machine, and not a process, to save its validity because a "process" in the sense of "the function of a machine, or the effect produced by it" cannot be patented); *see generally* Sarnoff, *supra* note 113, at 67 ("[A]t the end of the eighteenth century, pure method patents—methods claiming all future applications and not merely those substantially similar to the disclosed implementing machinery and their equivalents—were ineligible for protection and remained so until the late nineteenth century.") & *id.* n. 88 (collecting cases).

[128] 94 U.S. 780, 788 (1876).

methods are patentable "irrespective of the particular form of the instrumentalities used."[129] Similarly, in *Tilghman v. Proctor*, the Court held that a method for separating fat into glycerin and fatty acids using water, pressure, and heat was patentable.[130]

In *The Telephone Cases*, the Court distinguished *Morse* to allow Alexander Graham Bell's patent claim on a "method of and apparatus for transmitting vocal or other sounds telegraphically, as herein described, by causing electrical undulations, similar in form to the vibrations of the air accompanying the said vocal or other sounds, substantially as set forth."[131] Chief Justice Edward Douglass White interpreted *Morse* as holding that "the use of magnetism as a motive power, without regard to the particular process with which it was connected in the patent, could not be claimed, but that its use in that connection could."[132] The Court found that Bell's claim, unlike Morse's, did not reach uses of electricity to transmit speech that are "distinct from the particular process with which it is connected in [Bell's] patent," and upheld the claim, so construed.[133]

Twentieth Century

In the first half of the 20th century, the Court decided two major cases on the patentability of natural phenomena. In *American Fruit Growers v. Brogdex Co.*, the Court rejected patent claims on citrus fruit treated with a solution of borax to render it resistant to mold.[134] The Court held that treated fruit was not a "manufacture" under Section 101, but a patent-ineligible "natural article"; treatment with borax did not effect a "change in the name, appearance, or general character of the fruit" or imbue it with a "new or distinctive form, quality, or property."[135] In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, the Court rejected patent claims on an inoculant for leguminous plants consisting of multiple species of bacteria, where the particular bacterial strains were selected to avoid inhibiting each other (as prior multispecies combinations had).[136] Because the patentee's combination "produces no new bacteria [and] no change in the six species of bacteria," Justice William Douglas's majority opinion held that it was only "the discovery of some of the handiwork of nature and hence is not patentable."[137]

From 1972 to 1981, the Supreme Court decided four patentable subject matter cases.[138] In *Gottschalk v. Benson*, the Court held that an algorithm for converting binary-coded decimal numerals into pure binary numerals (either by hand, or, more practically, on a computer) was patent-ineligible.[139] Justice Douglas reasoned that "one may not patent an idea" and that upholding this patent would "wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself."[140] Second, in *Parker v. Flook*, the Court rejected a

[129] *Id.* at 787.

[130] 102 U.S. 707, 728–30 (1880).

[131] Dolbear v. Am. Bell Tel. Co. (The Telephone Cases), 126 U.S. 1, 531, 534–35 (1888).

[132] *Id.* at 534.

[133] *Id.* at 534–35.

[134] 283 U.S. 1, 6, 11–12 (1931).

[135] *Id.* at 11–12.

[136] 333 U.S. 127, 130–32 (1948).

[137] *Id.*

[138] Three of these four (*Benson, Flook,* and *Diehr*), which concern the patentability of inventions relating to mathematical formulas and computers, are often referred to as a "trilogy." *See, e.g.*, Michel, *supra* note 20, at 1755; Menell, *supra* note 112, at 1290. This usage leaves out *Chakrabarty*, which was also decided in the same time frame, because that case concerned the exception for products of nature.

[139] 409 U.S. 63, 64, 71–73 (1972).

[140] *Id.* at 71–72.

patent on a method for updating alarm limits during catalytic conversion of hydrocarbons (such as petroleum), which relied in part on a mathematical formula, because the only novel feature of the method was the mathematical formula.[141] Third, in *Diamond v. Chakrabarty*, the Court upheld a patent on a genetically engineered bacterium useful in breaking down oil (e.g., in cleaning up oil spills).[142] Chief Justice Warren Burger distinguished *American Fruit Growers* and *Funk Brothers* because this bacterium, although a living organism, was human-made and possessed "markedly different characteristics from any [bacteria] found in nature."[143] Finally, in *Diamond v. Diehr*, the Court distinguished *Flook* to uphold a patent on a process for molding synthetic rubber that relied on a mathematical formula (the Arrhenius equation).[144] Justice William Rehnquist's majority opinion reached back to *Cochrane v. Deener*, holding that the process at issue was patentable because it transformed an article (uncured rubber) into a different state or thing.[145] Even though the method used a mathematical formula, the patent in *Diehr* did not claim the formula itself and would not "pre-empt the use of that equation" in other fields.[146]

After *Diehr*, the Court did not decide a major patentable subject matter case for nearly 30 years.[147] Development of patent-eligible subject matter law was mainly left to the Federal Circuit, whose decisions generally expanded patent-eligible subject matter,[148] such that by the late 1990s Section 101 became perceived as "a dead letter."[149]

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[141] 437 U.S. 584, 585, 591–92 (1978).

[142] 447 U.S. 303, 305, 309–10 (1980).

[143] *Id.* at 310.

[144] 450 U.S. 175, 177, 183–93 (1981).

[145] *Id.* at 184.

[146] *Id.* at 187. In the view of many commentators, *Diehr* effectively overturned *Flook* (or at least some statements in *Flook*) without explicitly saying so. *See, e.g.*, Michel, *supra* note 20, at 1756 ("*Diehr*, to my eye, overruled *Flook* five to four."); Menell, *supra* note 112, at 1298 ("Justice Rehnquist [in *Diehr*] effectively overrode *Flook*'s statutory subject matter test."); *BCLT Report*, *supra* note 16, at 554 ("*Flook* was effectively overruled three years later in *Diamond v. Diehr* . . . ."); Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 927 F.3d 1333, 1346 (Fed. Cir. 2019) (Chen, J., concurring in the denial of rehearing en banc) ("Given *Diehr*'s evident disagreement with *Flook*'s analysis, *Diehr*, as the later opinion, was widely understood to be the guiding, settled precedent on § 101 for three decades."); Dennis Crouch, *Revival of* Parker v. Flook *II*, PATENTLYO (Jan. 4, 2018), https://patentlyo.com/patent/2018/01/revival-parker-flook.html (presenting data showing that courts rarely cited *Flook* between 1982 and 2007).

The Supreme Court does not appear to view matters this way, however—it continues to cite and rely on *Flook* as good law. *See, e.g.*, Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 218, 222 (2014).

[147] *See* Lemley et al., *supra* note 21, at 1317; Menell, *supra* note 112, at 1298. There are two partial exceptions to this generalization. The first is *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, in which the Court held that human-made plant varieties were patentable under Section 101. 534 U.S. 124, 127 (2001). However, that case turned not on general patent-eligibility principles, but on whether two specialized statutes for protection of plant varieties precluded utility patents on plants under the general provisions of Section 101. *Id.* at 132–44. Second, although the Supreme Court ultimately did not decide the case, Justice Breyer's 2006 dissent from the dismissal of a writ of certiorari as improvidently granted in *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, served as an important signal of the Court's renewed interest in patentable subject matter. *See* 548 U.S. 124 (2006). *Metabolite* involved claims for diagnosing vitamin deficiencies, much like the claims the Supreme Court would address years later in *Mayo*, when the Court largely adopted the reasoning of Justice Breyer's *Metabolite* dissent. *See id.* at 129, 135–38.

[148] *See generally* Menell, *supra* note 112, at 1298–99; Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 9–14 (2001). The canonical examples are *In re Alappat*, 33 F.3d 1526, 1542–45 (Fed. Cir. 1994) (en banc) (permitting software claims if tied to a machine, including a programmed general-purpose computer) and *State Street Bank v. Signature Financial Group*, 149 F.3d 1368, 1373 (Fed. Cir. 1998) (Rich, J.) (holding that computer-implemented business methods are patentable if tied to a machine that produces "a useful, concrete and tangible result"). Both cases were later abrogated. *See In re* Bilski, 545 F.3d 943, 959–60 (Fed. Cir. 2008) (en banc), *aff'd, sub nom.* Bilski v. Kappos, 561 U.S. 593 (2010).

[149] Lemley et al., *supra* note 21, at 1318 ("[A]fter 1998, patentable subject matter was effectively a dead letter").

The Modern *Alice*/*Mayo* Framework

In 2010, the Supreme Court reentered the field of patent-eligible subject matter, deciding four cases on the issue within five years.[150] These cases established the two-step *Alice*/*Mayo* test for patentable subject matter.

The first step of the *Alice*/*Mayo* test addresses whether the patent claims are "directed to" an ineligible concept: a law of nature, a natural phenomenon, or an abstract idea.[151] The inquiry at step one focuses on the "claim as whole."[152] To be "directed to" an eligible concept at step one of *Alice*/*Mayo*, the claims must not simply *involve* a patent-ineligible concept.[153] Rather, the "focus of the claims" must be a patent-ineligible concept, and not the improvement of a technological process.[154] If the patent claims are not directed to an ineligible concept, then the subject matter is patent-eligible.[155]

If the claims are directed to an ineligible category, then the invention is not patentable unless the patent claims have an "inventive concept" under the second step of the *Alice*/*Mayo* test.[156] Step two of *Alice*/*Mayo* considers the elements of each patent claim both individually and as an ordered combination in the search for an "inventive concept"—additional elements that "transform the nature of the claim" into a patent-eligible application of an ineligible concept.[157] To have an "inventive concept," the patent claims must contain elements "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself."[158] Claim limitations that are "conventional, routine and well understood," such as generic computer implementation, cannot supply an inventive concept.[159]

Bilski v. Kappos, the first in the series of Supreme Court cases that developed what became known as the *Alice*/*Mayo* framework, concerned a patent on a business method for hedging against price-fluctuation risks in energy and commodity markets.[160] The Federal Circuit had held that this method was not patentable as a "process" under Section 101 because it failed the "machine-or-transformation test"—that is, it was neither "tied to a particular machine or apparatus" nor "transform[ed] a particular article into a different state or thing."[161] All nine members of the Supreme Court agreed with that result—that the business method at issue was not

[150] Bilski v. Kappos, 561 U.S. 593 (2010); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013); Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208 (2014).

[151] *Alice*, 573 U.S. at 217.

[152] Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 915 F.3d 743, 750 (Fed. Cir. 2019) (citing Elec. Power Grp., v. Alstom S.A., 830 F.3d 1350, 1353 (Fed. Cir. 2016)).

[153] Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1335–36 (Fed. Cir. 2016).

[154] *Id.*; *see also Athena*, 915 F.3d at 750 ("To determine whether a claim is directed to an ineligible concept, we have frequently considered whether the claimed advance improves upon a technological process or merely an ineligible concept, based on both the written description and the claim.") (citations omitted).

[155] *Alice*, 573 U.S. at 217.

[156] *Id.*

[157] *Alice*, 573 U.S. at 217–28 (quotations omitted).

[158] *Id.* (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 73 (2012)).

[159] Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1378 (Fed. Cir. 2015); *accord Alice*, 573 U.S. at 225; *Mayo*, 566 U.S. at 79 ("Purely 'conventional or obvious' '[pre]-solution activity' is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." (quoting Parker v. Flook, 437 U.S. 584, 590 (1978))).

[160] *Bilski*, 561 U.S. at 598–99.

[161] *In re* Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc) (Michel, C.J.).

patent-eligible—but differed significantly as to their reasoning. Writing for five Justices, Justice Anthony Kennedy held that the machine-or-transformation test was not the "sole test" for determining whether a process is patent-eligible but still "a useful and important clue."[162] While the majority rejected the "atextual" notion that business methods were categorically unpatentable under Section 101,[163] it relied on *Benson* and *Flook* to conclude that this particular patent attempted to claim an unpatentable abstract idea: the "concept of hedging risk."[164] Concurring only in the judgment, Justice John Paul Stevens wrote for four Justices who would have held, based on the history of the Patent Act and its constitutional purpose, that business methods were always patent-ineligible.[165]

In *Mayo Collaborative Services v. Prometheus Laboratories*, the Court addressed the scope of the "law of nature" exception.[166] The patent in *Mayo* claimed a method for measuring metabolites in human blood in order to calibrate the dosage of thiopurine drugs in the treatment of autoimmune disorders.[167] Writing for a unanimous Court, Justice Stephen Breyer's opinion held that the patent claims were addressed to a law of nature: "namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm."[168] Because the claims were little "more than an instruction to doctors to apply the applicable laws when treating their patients," the patent lacked any inventive concept and was held to be patent-ineligible.[169]

The next case, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, concerned the applicability of the "natural phenomena" exception to the patentability of human DNA.[170] The inventor in *Myriad* had discovered the precise location and genetic sequence of two human genes associated with an increased risk of breast cancer.[171] Based on this discovery, the patentee claimed two molecules associated with the genes: (1) an isolated DNA segment and (2) a complementary DNA (cDNA) segment, in which the nucleotide sequences that do not code for amino acids were removed in the laboratory.[172] Justice Clarence Thomas's unanimous opinion in *Myriad* held that isolated DNA segments were nonpatentable products of nature because the patent claimed naturally occurring genetic information.[173] The Court held, however, that cDNA, as a synthetic molecule distinct from naturally occurring DNA, was patentable even though the underlying nucleotide sequence was dictated by nature.[174]

Most recently, *Alice Corp. v. CLS Bank International* examined the scope of the "abstract idea" category of nonpatentable subject matter.[175] *Alice* concerned a patent on a system for mitigating

[162] *Bilski*, 561 U.S. at 604.

[163] *Id.* at 609.

[164] *Id.* at 609–12.

[165] *Id.* at 626–57 (Stevens, J., concurring in the judgment).

[166] 566 U.S. 66, 77 (2012).

[167] *Id.* at 73–75.

[168] *Id.* at 77.

[169] *Id.* at 79.

[170] 569 U.S. 576 (2013).

[171] *Id.* at 579.

[172] *Id.* at 580–85.

[173] *Id.* at 591–94. Justice Antonin Scalia joined the opinion save for the "fine details of molecular biology," as he found himself "unable to affirm those details on my own knowledge or even my own belief." *Id.* at 596 (Scalia, J., concurring in part and in the judgment).

[174] *Id.* at 594–95.

[175] 573 U.S. 208 (2014).

"settlement risk"—the risk that only one party to a financial transaction will pay what it owes—using a computer as an intermediary.[176] The Court first held, relying on *Bilski*, that the invention was directed at "the abstract idea of intermediated settlement."[177] Although this idea was implemented on a computer (which is, of course, a physical machine), the patent lacked an inventive concept because the claims merely "implement[ed] the abstract idea of intermediated settlement on a generic computer."[178]

Table 1 summarizes the facts and holding of the Supreme Court's major patentable subject matter cases, in reverse chronological order.

Table 1. Major Supreme Court Decisions on Patentable Subject Matter

Case Citation	Claimed Inventions	Holding and Rationale
Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208 (2014)	Computer-implemented method and system for mitigating settlement risk in financial transactions using a third-party intermediary	**Ineligible**: The claims are drawn to the abstract idea of intermediated settlement; implementation on a generic computer does not transform an ineligible abstract idea into a patent-eligible invention.
Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013)	Isolated human DNA segments and exon-only complementary DNA (cDNA) segments corresponding to genes discovered to be linked to an increased risk of breast cancer	**Certain Claims Ineligible**: Isolated human DNA segments are patent-ineligible because the nucleotide sequence is a product of nature and isolation from the rest of the genome is insufficient to render them patentable; however, cDNA is patentable because it is not naturally occurring.
Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012)	Method for optimizing dosage of thiopurine drugs for treating autoimmune disease, by administering the drug, measuring a metabolite, and adjusting the dosage based on the measurement	**Ineligible**: The relationship between the concentration of particular metabolites in the blood and a drug's effectiveness is directed to a law of nature, and the claims lack an inventive concept beyond conventional post-solution activity.
Bilski v. Kappos, 561 U.S. 593 (2010)	Business method for hedging against price-fluctuation risks in energy and commodity markets	**Ineligible**: Although business methods are not categorically patent-ineligible, the process at issue was not patentable because it claimed the abstract idea of hedging risk.
J.E.M. Ag. Supply v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001)	Human-developed inbred and hybrid corn plant varieties and seeds	**Eligible**: Newly developed plant varieties are human-made manufactures or compositions of matter, even though protection may also be available under the Plant Patent Act or the Plant Variety Protection Act.
Diamond v. Diehr, 450 U.S. 175 (1981)	Process for molding raw, uncured synthetic rubber into cured products, relying on the Arrhenius equation and a programmed computer to calculate the curing time	**Eligible**: The invention does not claim a mathematical formula or a law of nature as such, but applies a natural law to a particular industrial process that transforms an article into a different state or thing.
Diamond v. Chakrabarty, 447 U.S. 303 (1980)	Genetically engineered bacterium capable of breaking down components in crude oil	**Eligible:** The genetically engineered bacterium was not naturally occurring and possessed markedly different characteristics from any bacteria found in nature.

[176] *Id.* at 212.

[177] *Id.* at 221.

[178] *Id.* at 225.

Case Citation	Claimed Inventions	Holding and Rationale
Parker v. Flook, 437 U.S. 584 (1978)	Method of updating alarm limits used in catalytic conversion of hydrocarbons (e.g., in oil refining) relying on a mathematical formula	**Ineligible:** The only novel feature of the invention was a mathematical formula, conventionally applied to a specific field.
Gottschalk v. Benson, 409 U.S. 63 (1972)	Method for converting binary-coded decimal numerals into pure binary numerals on digital computer	**Ineligible**: The patent claims cover all practical uses of a mathematical algorithm and would, in effect, amount to a patent on the algorithm itself.
Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948)	Inoculant for leguminous plants comprising several strains of mutually noninhibitive species of bacteria to improve nitrogen fixation	**Ineligible**: Each bacterial strain is naturally occurring, and discovery of the noninhibitive qualities of certain strains was not invention but merely the discovery of a nonpatentable natural phenomenon.
Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86 (1939)[179]	Radio antenna in which the angle of the wires and their length are determined by a mathematical formula	**Assumed to be patentable**: Although a mathematical expression of a scientific truth is not patentable, a novel and useful structure created with the aid of knowledge of scientific truth may be patentable.
Am. Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931)	Citrus fruit treated with borax solution to render it resistant to mold	**Ineligible**: Treatment with borax did not transform the fruit (a product of nature) into a manufacture with a new or distinctive form, quality, or property.
The Telephone Cases, 126 U.S. 1 (1888)	Method and apparatus for transmitting sound telegraphically by causing electrical undulations, similar to air vibrations accompanying speech and other sounds	**Eligible**: The patentee did not claim all uses of electricity to transmit speech at a distance, but only the particular process and apparatus disclosed in the patent.
Tilghman v. Proctor, 102 U.S. 707 (1881)	Process for separating fat into glycerin and fatty acids using water, pressure, and heat	**Eligible**: New and useful manufacturing processes are "arts" that may be patented independently of the apparatus used.
Cochrane v. Deener, 94 U.S. 780 (1877)	Improved industrial process for manufacturing flour	**Eligible**: A process ("a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing") is patentable independent of the machinery used.
Rubber-Tip Pencil Co. v. Howard, 87 U.S. (20 Wall.) 498 (1874)	Rubber cap with cavity designed to be attached to lead pencils for convenient use as an eraser	**Ineligible**: An "idea of itself" (here, the idea of attaching a piece of rubber to the end of a pencil for use as an eraser) is not patentable.
Corning v. Burden, 56 U.S. (15 How.) 252 (1854)	Machine for rolling puddle balls and other masses of iron used in the manufacture of iron products	**Eligible**: The patentee did not claim the function or abstract effect of a machine, but only the machine that produced the result.

[179] Although *Mackay Radio* is widely quoted in subsequent jurisprudence for the proposition that useful applications of laws of nature are patentable, see, for example, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012); Diamond v. Diehr, 450 U.S. 175, 188 (1981), Justice Harlan Stone's statement is dicta because the Court merely "assume[d], without deciding" that the invention was patentable, ruling instead on grounds of noninfringement, see *Mackay Radio*, 306 U.S. at 94, 101.

Case Citation	Claimed Inventions	Holding and Rationale
O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1854)[180]	Any use of electro-magnetism for printing intelligible characters, signs, or letters, at a distance	**Ineligible**: The discovery of a scientific principle is not patentable, nor can a patentee claim a useful result in the abstract, apart from the particular process or machine by which the result is accomplished.
Le Roy v. Tatham, 55 U.S. (14 How.) 156 (1853)[181]	Machinery for manufacturing wrought metal pipes exploiting a newly discovered property of lead	**Potentially patentable**: Although a principle in the abstract is not patentable, a practical application of such a principle to a new and useful end is patentable.

Source: CRS.

The Debate Over *Alice*/*Mayo* and Section 101 Reform

A substantial group of patent law stakeholders, including inventors, academics, industry representatives, patent attorneys, current and former Federal Circuit judges, and former USPTO officials, has criticized the *Alice*/*Mayo* framework on various grounds.[182] Other patent law stakeholders defend the Supreme Court's Section 101 decisions.[183]

Criticisms of the *Alice*/*Mayo* Framework

Generally, critics of the Court's patentable subject matter jurisprudence raise four principal concerns. First, the *Alice*/*Mayo* framework is criticized as excessively vague, subjective, and unpredictable in application. For example, the Federal Circuit has stated that when determining whether a patent claim is "directed to" an ineligible concept at step one, courts must determine whether the "focus" of the claims is on that concept.[184] At the same time, the Federal Circuit has cautioned that this "focus" must be articulated "with enough specificity to ensure the step one

[180] The specific doctrinal basis of *O'Reilly v. Morse* is unclear, as the Court speaks in language that, when cast in modern terms, sounds at times like enablement and at times like patentable subject matter. *Compare* 56 U.S. at 113 ("The court is of opinion that the claim is too broad . . . .") *with id.* at 116 ("[T]he discovery of a principle in natural philosophy or physical science, is not patentable."). Many patent scholars regard *Morse* as a case not about Section 101 but about enablement under Section 112 of the modern Patent Act. *See, e.g.*, Taylor, *supra* note 20, at 205 ("In modern terms, it is quite clear that the problem with Claim 8 in *Morse*'s patent was based on the enablement and written description requirements located in § 112 and not in § 101."); Lefstin, *supra* note 113, at 597 ("*Morse* is about disclosure and scope, not patent-eligible subject matter."). The Supreme Court, however, appears to regard *Morse* as primarily a subject matter decision. *See, e.g.*, *Mayo*, 566 U.S. at 70, 73 (citing to *Morse* to support notion that "laws of nature" or claims that "preempt the use of a natural law" are "not patentable").

[181] Statements in *Le Roy* to the effect that a "principle, in the abstract" is not patentable, but a practical application of such a principle may be patentable, 55 U.S. at 174–75, are widely quoted and influential in subsequent American jurisprudence. *See supra* note 115. Nonetheless, because the result in *Le Roy* turned primarily on claim construction, *see* 55 U.S. at 176, these general statements were dicta and did not entail the holding of the case.

[182] *See infra* "Criticisms of the *Alice*/*Mayo* Framework."

[183] *See infra* "Defenses of the *Alice*/*Mayo* Framework."

[184] Elec. Power Grp. v. Alstom S.A., 830 F.3d 1350, 1353 (Fed. Cir. 2016).

inquiry is meaningful."[185] The appropriate level of specificity can vary from patent to patent and from judge to judge.[186]

Thus, in the view of many stakeholders, the Supreme Court's patentable subject matter case law and the Federal Circuit's implementation of the *Alice*/*Mayo* framework fail to articulate "objective, predictable criteria" for making patent-eligibility determinations.[187] Key terms, such as what an "abstract idea" is, or precisely how claim elements can make an invention "significantly more" than an ineligible category (the "inventive concept"), are largely left undefined, making it difficult for patent applicants and litigants to know whether their patent claims will survive judicial scrutiny.[188] Moreover, the Federal Circuit has explicitly recognized that the two steps of the analysis are not clearly defined and may overlap.[189] As a result, many observers characterize the court's Section 101 jurisprudence as a "highly subjective," "I know it when I see it" approach.[190] This subjectivity, in the view of critics, injects unpredictability and uncertainty into whether an invention is of a type that is patentable.[191]

Second, the *Alice*/*Mayo* framework is criticized as legally flawed on various grounds. Some stakeholders argue that the *Alice*/*Mayo* framework misinterprets Section 101, imposing "extra-statutory" requirements for patent eligibility, contrary to congressional intent or the constitutional purpose of patent law.[192] Others argue that *Mayo*'s requirement of an "inventive concept" rests on a historically inaccurate understanding of 19th century English patent law, first imported into

[185] Thales Visionix Inc. v. United States, 850 F.3d 1343, 1347 (Fed. Cir. 2017).

[186] *See* Visual Memory LLC v. NVIDIA Corp., 867 F.3d 1253, 1262 (Fed. Cir. 2017) (Hughes, J., dissenting) (disagreeing with the majority over whether characterizing the claims as directed to "categorical data storage" views the invention "at an unduly 'high level of abstraction'") (quoting Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1337 (Fed. Cir. 2016)).

[187] USPTO PSM REPORT, *supra* note 16, at 29.

[188] *See id*. at 30 (describing comments that the *Alice*/*Mayo* test "fails to define crucial terms, such as 'abstract' and 'substantially more'"); Taylor, *supra* note 20, at 231 ("[N]o one really knows what an inventive concept is."); Lemley et al., *supra* note 21, at 1316 ("[N]o one understands what makes an idea 'abstract,' and hence ineligible . . . ."); Morris, *supra* note 106, at 68 (arguing that the judicially created patentable subject matter decisions are "merely post hoc rationalizations"). Some Supreme Court Justices have echoed this criticism. *See, e.g.*, Bilski v. Kappos, 561 U.S. 593, 621 (2010) (Stevens, J., concurring in the judgment) ("The Court . . . never provides a satisfying account of what constitutes an unpatentable abstract idea."); Fred Funk Seed Bros. Co. v. Kalo Inoculant Co., 333 U.S. 127, 134–35 (1948) (Frankfurter, J., concurring) ("It only confuses the issue, however, to introduce such terms as 'the work of nature' and the 'laws of nature.' For these are vague and malleable terms infected with too much ambiguity and equivocation."). To some extent, uncertainty in Section 101 is not a new phenomenon. *See, e.g.*, Duffy, *supra* note 113, at 623–38 (reviewing history of failed patentable subject matter rules and observing that "instability in the law of patentable subject matter" is a recurring issue). However, at least in the decade before *Mayo*, uncertainty was less practically important for patentees because courts and the USPTO only "rarely" rejected patents based on Section 101. *See BCLT Report*, *supra* note 16, at 575–76 (reviewing data showing a "dramatic" increase in the number of Section 101 district court decisions following *Mayo*, with a "10-fold" increase following *Alice*).

[189] *Elec. Power Grp.*, 830 F.3d at 1353 ("[T]he two stages are plainly related: not only do many of our opinions make clear that the two stages involve overlapping scrutiny of the content of the claims, but we have noted that there can be close questions about when the inquiry should proceed from the first stage to the second.") (citations omitted).

[190] *See, e.g.*, USPTO PSM REPORT, *supra* note 16, at 30 (quoting stakeholder view that *Alice*/*Mayo* is "hopelessly subjective"); Taylor, *supra* note 20, at 227–30 (arguing that *Alice*/*Mayo* framework has "no objective guidance" and "leaves the determination of eligibility to the unconstrained, subjective opinion of a patent examiner or judge"); Klein, *supra* note 106, at 288 (criticizing patentable subject matter case law as amounting to "an 'I know it when I see it' approach").

[191] *See, e.g.*, *BCLT Report*, *supra* note 16, at 561 (describing "uncertainty and confusion resulting from the Court's recent [patentable subject matter] jurisprudence"); *accord* USPTO PSM REPORT, *supra* note 16, at 30–31 (describing views that the *Alice*/*Mayo* test yields "unpredictable" and "inconsistent" results).

[192] *See* USPTO PSM REPORT, *supra* note 16, at 28; Klein, *supra* note 106, at 289–91 (criticizing the three judicially created categorical exclusions as "extra-statutory" and proposing test that focuses on text of Section 101).

American jurisprudence in cases such as *Le Roy* and *Morse*.[193] Finally, many commentators and stakeholders argue that the *Alice*/*Mayo* framework confuses patent law by conflating eligibility under Section 101 with policy concerns—such as the obviousness of the invention and claim breadth—that are better addressed by other provisions in the Patent Act, such as Sections 102, 103, and 112.[194] For example, patent claims have been found to lack an inventive concept at *Alice*/*Mayo* step two where they implement an abstract idea on conventional computer hardware.[195] Issues about what was "conventional" or "well-understood" at the time of the invention, however, are questions usually reserved for novelty or nonobviousness analysis.[196]

Third, the *Alice*/*Mayo* framework is alleged to have detrimental effects on incentives to innovate, especially in the biotechnology and computer software industries. Given the patent claims at issue in *Alice* (a computer-implemented business method), *Myriad* (an isolated human DNA segment), and *Mayo* (a drug dose optimization method), most observers agree that these two industries have been the most affected by the Supreme Court's Section 101 rulings.[197] In the biotechnology industry, stakeholders argue that the *Alice*/*Mayo* framework has limited their ability to obtain patents on diagnostic methods and kits, personalized medicine, and isolated natural substances.[198] Views in the computer industry are "sharply divided," but at least some stakeholders argue that *Alice* has devalued their patents and created uncertainty for their business.[199] In both fields, some stakeholders argue that the law of Section 101 is reducing incentives to innovate in these areas and driving investment elsewhere.[200]

Finally, the uncertainty and unpredictability caused by *Alice/Mayo* is alleged to put the United States at a disadvantage relative to international competitors. Some stakeholders argue that U.S. competitiveness may be harmed because a lack of patent availability will drive investment in certain industries to other countries where such inventions are more clearly patent-eligible.[201]

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[193] Lefstin, *supra* note 113, at 565 (arguing that *Alice*/*Mayo* test's "inventive application" requirement rests on a "basic misapprehension" of the 19th century English case cited by the Supreme Court); USPTO PSM REPORT, *supra* note 16, at 27–28 (same).

[194] *See* USPTO PSM REPORT, *supra* note 16, at 31–32; Taylor, *supra* note 20, at 157 ("[T]he current approach to determining patent eligibility confuses the relevant policy concerns underlying numerous discrete patent law doctrines."); *see also* Risch, *supra* note 21, at 594 (arguing that the Court's patentable subject matter doctrine would be more consistent and rigorous if replaced with a strict application of other patentability doctrines such as obviousness, novelty, utility, inventorship, written description, and enablement). This criticism has been echoed by Supreme Court Justices. *See* Parker v. Flook, 437 U.S. 584, 600 (1978) (Stewart, J., dissenting) ("[The majority] strikes what seems to me an equally damaging blow at basic principles of patent law by importing into its inquiry under 35 U.S.C. § 101 the criteria of novelty and inventiveness.").

[195] *See, e.g.*, *Elec. Power Grp.*, 830 F.3d at 1355.

[196] *See, e.g.*, Berkheimer v. HP Inc., 881 F.3d 1360, 1368–69 (Fed. Cir. 2018) (noting that *Alice*/*Mayo* step two determination of whether claims are "well-understood, routine and conventional" overlaps with Section 102 novelty inquiry).

[197] USPTO PSM REPORT, *supra* note 16, at 34–35 ("Among members of the public, there was a general consensus that two industries have been most directly affected [by the *Alice*/*Mayo* framework]: life sciences and computer-related technologies."); *see also BCLT Report*, *supra* note 16, at 582–85 (examining the *Alice*/*Mayo* framework's effects on diagnostics, personalized medicine, biosciences, software, and information technology).

[198] *See* USPTO PSM REPORT, *supra* note 16, at 34–35; *BCLT Report*, *supra* note 16, at 582–84.

[199] *See* USPTO PSM REPORT, *supra* note 16, at 37–38 (characterizing the views on *Alice*/*Mayo* in the computer industry as "sharply divided"); *BCLT Report*, *supra* note 16, at 582–84.

[200] *See* USPTO PSM REPORT, *supra* note 16, at 35, 38; *BCLT Report*, *supra* note 16, at 583.

[201] *See, e.g.*, Stoll, *supra* note 23 ("The courts' focus on subject matter eligibility as a mechanism to deny patents for [inventions in diagnostics and personalized medicine] will drive investment into research in these technologies to other areas. We will lose our edge in the world . . . ."); *accord* USPTO PSM REPORT, *supra* note 16, at 34; Kevin Madigan & Adam Mossoff, *Turning Gold into Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in*
(continued...)

Others argue that one effect of *Alice*/*Mayo* is a loss of any patent protection for certain inventions, which will enable competitors to "free ride" off of American innovation.[202]

Defenses of the *Alice*/*Mayo* Framework

Defenders of the current law of Section 101 respond that these criticisms of *Alice*/*Mayo* are overstated, or that the Supreme Court's reinvigoration of Section 101 has important benefits for the patent system. As to the subjective or unpredictable nature of Section 101 doctrine, there is some empirical evidence that the *Alice*/*Mayo* framework is not as unpredictable as is sometimes claimed.[203] Some commentators also observe that uncertainty in patentable subject matter law is hardly a new phenomenon,[204] and may even be "inevitable."[205] A subjective or "amorphous" approach to patentable subject matter, on this view, may have certain benefits, including flexibility and adaptability to new technologies.[206] Moreover, even if one views the current state of the law as unacceptably vague, courts may eventually clarify or change Section 101 doctrine in line with the long history of common law development in this area.[207]

As to the legal correctness of *Alice*/*Mayo*, defenders of the framework note that while the judicially created categories are not directly grounded in the text of Section 101, they have been treated as part of the law "as a matter of statutory *stare decisis* going back 150 years."[208] As to *Mayo*'s reliance on 19th century English patent law, some commentators defend the Supreme Court's "inventive application" requirement as a faithful reading of this precedent.[209] Finally, although the *Alice*/*Mayo* framework may overlap with other patent law doctrines, several commentators and judges of the Federal Circuit argue that Section 101 serves purposes distinct

Innovation, 24 GEO. MASON L. REV. 939, 942–44 (2017) (expressing "concern about the U.S. conceding its gold standard patent system to China and Europe" because of the uncertainty of the *Alice*/*Mayo* framework).

[202] *See, e.g.*, Davis, *supra* note 23 (quoting former USPTO Director David Kappos as stating that international competitors "no longer have to steal U.S. technology in [biotech and software], since they can now take it for free").

[203] *See* Jason D. Reinecke, *Is the Supreme Court's Patentable Subject Matter Test Overly Ambiguous? An Empirical Test*, 2019 UTAH L. REV. 581, 583 (2019) (empirical study indicating that while "the [*Alice*/*Mayo*] test is likely not a beacon of absolute clarity, it is not completely amorphous," as patent prosecutors correctly predicted judicial results 67.3% of the time based only on claim language).

[204] *See, e.g.*, Duffy, *supra* note 113, at 623–38 (reviewing 100-year history of failed rules and tests for patentable subject matter and observing that "instability in the law of patentable subject matter" is a recurring issue) & *id.* at 616 (citing 19th century treatise writers noting difficulty and complexity of the patentable subject matter); Risch, *supra* note 21, at 591 (criticizing, in 2008, the "currently confused and inconsistent jurisprudence of patentable subject matter"); Donald S. Chisum, *The Patentability of Algorithms*, 47 U. PITT. L. REV. 959, 992 (1986) (noting "confusion and arbitrary distinctions" in the law of the patentability of computer software resulting from the *Benson* decision).

[205] Morris, *supra* note 106, at 107 (arguing that the Court's "intuitive" approach to patentable subject matter determinations is "inevitable").

[206] *Id.* at 107–09 (arguing that intuitive approach to Section 101 may be "desirable" because "there is simply no other more rigorous and yet durable way of identifying the proper boundaries for patentable subject matter" and "vagueness provides the flexibility necessary to adjust future technological developments"); Duffy, *supra* note 113, at 639 ("[T]he traditional doctrines of patentable subject matter—the prohibition against patenting abstract ideas, natural phenomena, and principles of nature—have survived because . . . they have been amorphous.").

[207] *See* USPTO PSM REPORT, *supra* note 16, at 23–24 (expressing stakeholder views that the Court's decisions are part of the normal common law development of Section 101, and that the Federal Circuit's subsequent development of the law may be "headed in the right direction").

[208] Bilski v. Kappos, 561 U.S. 593, 602 (2010) (citing Le Roy v. Tatham, 55 U.S. (14 How.) 156, 174–75 (1853)).

[209] *See* Brief of Nine Law Professors as *Amicus Curiae* in Support of Petitioners at 8–16; Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012) (No. 10-1150), 2011 WL 4071921.

from Sections 102, 103, and 112.[210] For example, even if the invention in *Myriad*—an isolated human DNA sequence discovered to be linked to increased breast cancer risk—was novel, nonobvious, and sufficiently disclosed, some commentators would still argue that the invention should not be patented based on harm to future innovation or moral concerns about patenting human DNA.[211]

Regarding the alleged detrimental effects of the Court's Section 101 decisions on innovation, some stakeholders point to countervailing benefits either generally or in certain industries. In particular, some stakeholders in industries (such as computer software) affected by litigation by patent assertion entities[212] argue that Section 101 is a useful and important tool for weeding out overly broad or vague patents at the outset of litigation.[213] Other commentators point to general utilitarian or moral benefits of robust exclusions for patents on basic discoveries in science and nature.[214]

Lastly, in response to concerns about the *Alice*/*Mayo* framework's effect on international competitiveness, some commentators assert that these changes are good for the United States as a geopolitical matter.[215] In particular, restricted patent-eligibility standards may benefit U.S. consumers if a lack of patent protection leads to increased competition and lower prices for certain products without harming innovation.[216]

Views on the Purposes of Section 101

There is a long-running debate over the functions and purposes that Section 101 serves in the patent system. For its part, the modern Supreme Court has largely settled on the "preemption rationale" for the judicially created subject matter exclusions. These decisions assert that abstract ideas, laws of nature, and natural phenomena should not be patentable because permitting a monopoly on the "'basic tools of scientific and technological work' . . . might tend to impede innovation more than it would tend to promote it,"[217] in that such patents would "significantly impede future innovation."[218] The gist of the preemption rationale is that Section 101 functions to

[210] *See, e.g.*, Morris, *supra* note 106, at 113 ("To be sure, patentable subject matter overlaps with and serves some of the same purposes as the other patentability requirements . . . . But only patentable subject matter serves to distinguish patentable technology from unpatentable discoveries, information, and human thought and activity."); Lemley et al., *supra* note 21, at 1330–32 (distinguishing purpose of Section 101 from Section 112); *accord Mayo*, 566 U.S. at 90–91; Athena Diag., Inc. v. Mayo Collaborative Servs., 927 F.3d 1333, 1337–39 (Fed. Cir. 2019) (Dyk, J., concurring in the denial of rehearing en banc).

[211] *See generally infra* "Views on the Purposes of Section 101."

[212] A patent assertion entity, sometimes called a nonpracticing entity or (pejoratively) a "patent troll," is a loose term for an individual or organization that seeks to license or litigate patents, but does not itself practice the patented invention. *See* Colleen V. Chien, *From Arms Race to Marketplace: The Complex Patent Ecosystem and Its Implications for the Patent System*, 62 HASTINGS L.J. 297, 326–27 (2010) (discussing distinction among various types of nonpracticing patent entities).

[213] USPTO PSM REPORT, *supra* note 16, at 24–26; *BCLT Report*, *supra* note 16, at 596; Gugliuzza, *supra* note 25, at 652–53.

[214] Sarnoff, *supra* note 113, at 106–24 (reviewing asserted utilitarian and moral benefits of robust Section 101 exclusions); *see generally infra* "Views on the Purposes of Section 101."

[215] USPTO PSM REPORT, *supra* note 16, at 27.

[216] *Id.*

[217] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012) (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)); Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 216 (2014) ("We have described the concern that drives [the ineligible categories of patentable subject matter] as one of pre-emption.").

[218] *Mayo*, 566 U.S. at 91.

prevent patents that reach so broadly that they "threaten downstream innovation" by preempting all uses of a natural law, abstract idea, or fundamental research tools.[219]

The preemption rationale is not the only potential justification for Section 101, however. Although a complete survey of the various rationales proffered for Section 101 is beyond the scope of this report, at least four broad categories of rationales for Section 101 have been proposed.[220]

First, some commentators argue that Section 101's purpose is to identify certain patents or categories of patents that should not be granted because their economic harms exceed their benefits—that is, their net social costs are negative for innovation, or more generally.[221] Preemption theory, which claims that certain overbroad patents should be denied patent protection under Section 101 because of their negative effects on downstream innovation, is an example from this group.[222]

Second—in what is in some sense a special case of the first rationale—other commentators assert that Section 101's purpose is to identify and deny patents to categories of inventions that would have been developed even without a patent incentive.[223] For example, several commentators have argued the patents on business methods should be excluded under Section 101 either because they affirmatively harm innovation and the economy, or because they are simply unnecessary because sufficient incentives to create business methods would exist even if patents are unavailable.[224]

Third, some commentators assert that Section 101 (or elements of Section 101 doctrine) are based not on economic considerations but on moral or ethical concerns.[225] For example, the judicial prohibition on patenting products of nature—such as human DNA sequences—may be motivated

[219] *See, e.g.*, Lemley et al., *supra* note 21, at 1346–47; *accord Benson*, 409 U.S. at 72 (rejecting patent because it would "wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself"). *But see* Katherine J. Strandburg, *Much Ado About Preemption*, 50 HOUS. L. REV. 563, 566 (2012) (critiquing preemption rationale's "sole focus on broad downstream impact" as not providing a satisfactory explanation for the Supreme Court's Section 101 case law).

[220] *See generally* J. Jonas Anderson, *Applying Patent-Eligible Subject Matter Restrictions*, 17 VAND. J. ENT. & TECH. L. 267, 269–40, 279–86 (2015) (surveying the "diverse set of proposed theories" of Section 101 and categorizing them into several broad categories).

[221] *See* Anderson, *supra* note 220, at 284–85 (overviewing this group of theories); *see, e.g.*, David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181, 184 (2009) (arguing that patentable subject matter doctrine should be driven by looking at when "granting a patent right for this type of innovation causes more loss to society than gain").

[222] *See supra* note 219 and accompanying text.

[223] *See* Anderson, *supra* note 220, at 285–86 (overviewing this group of theories); *see, e.g.*, Pamela Samuelson, Benson *Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions*, 39 EMORY L.J. 1025, 1136 (1990) (arguing that software should not be patentable in part because "the fact that this growth [in the software industry] has occurred without the aid of patent protection is powerful evidence that patent protection is not necessary for the software industry to thrive").

[224] *See, e.g.*, Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263, 274 (2000) (arguing that business method patents are unwise because they "adversely affect innovation, and worse, the economy"); *accord* Bilski v. Kappos, 561 U.S. 593, 651 (2010) (Stevens, J., concurring in the judgment) (arguing that business methods should not be patentable because there are "ample incentives to develop business methods even without patent protection" (quoting Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1618 (2003))).

[225] *See* Anderson, *supra* note 220, at 286 (overviewing this group of theories); *see, e.g.*, Sarnoff, *supra* note 113, at 84–90 (surveying religious and deontological bases for prohibition on patenting science, nature, and ideas); Tun-Jen Chiang, *Competing Visions of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1858, 1860 (2014) (arguing that Section 101 determinations are "often about noneconomic moral values").

by noneconomic, deontological notions of human dignity, or the inviolability of natural creation.[226]

Finally, some commentators believe that Section 101 serves no independent purpose in patent law not already better served by other patentability requirements.[227] On this view, Section 101's judicially created exceptions to patentable subject matter should simply be eliminated as an independent requirement for patentability, in favor of a rigorous application of the other patentability requirements in Sections 102, 103, and 112 of the Patent Act.[228]

Potential Options for Section 101 Reform

Before examining the particular approaches used in USPTO guidance and proposed legislative reforms, this section reviews some of the general ways in which Section 101 may or may not be reformed. These different paths are introduced to contextualize the current Section 101 reform proposals within the universe of possible reforms. This list is not exhaustive, nor are each of these options necessarily mutually exclusive.

At a general level, most of the proposed paths forward for Section 101 fall into one of four categories.[229] First, some oppose any legislative intervention, proposing instead to allow the courts to continue to develop and refine the standards for patent eligibility.[230] Second, some propose replacing the *Alice*/*Mayo* framework with an explicit list of subject matter that is patent-eligible or -ineligible, similar to the approach that is used for European patents.[231] Third, some propose replacing the *Alice*/*Mayo* framework with a different, usually lower, standard for patent eligibility, such as a requirement that the invention result from human effort, exist outside the human mind, or contribute to the technological arts.[232] Fourth, some propose to do away with any limitations on patentable subject matter, beyond the four statutory categories and other existing statutory patentability requirements.[233]

Continued Common Law Judicial Development

Congress could leave Section 101 as it is, and allow the courts and the USPTO to continue developing the law of patent-eligible subject matter. Stakeholders and commentators may support this option for several different reasons. Some may disagree that the *Alice*/*Mayo* framework is as

[226] Chiang, *supra* note 225, at 1873–81.

[227] *See* Anderson, *supra* note 220, at 280 (overviewing this group of theories).

[228] *See, e.g.*, Risch, *supra* note 21, at 591–94 (articulating this view); Davis, *supra* note 23 (quoting former USPTO Director David Kappos as calling for abolishing Section 101 and instead "faithfully applying other areas of patent law to ensure that patents are not obvious or anticipated or lacking in written description").

[229] *See* David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2149, 2189–2211 (2017) (listing proposed Section 101 reforms, including a European-style "laundry list" of exclusions, a new "workable eligibility standard," or the elimination of the judicially created ineligible categories); USPTO PSM REPORT, *supra* note 16, at 39–46 (reviewing proposed Section 101 recommendations, including continued judicial and/or administrative development, codification of explicitly defined Section 101 exceptions, or new standards for patent eligibility); *BCLT Report*, *supra* note 16, at 562–66 (same).

[230] *See* USPTO PSM REPORT, *supra* note 16, at 39–41; *BCLT Report*, *supra* note 16, at 566.

[231] *See* Taylor, *supra* note 229, at 2198–2201; USPTO PSM REPORT, *supra* note 16, at 43–45; *BCLT Report*, *supra* note 16, at 564.

[232] *See* Taylor, *supra* note 229, at 2202–06; USPTO PSM REPORT, *supra* note 16, at 41–43; *BCLT Report*, *supra* note 16, at 563–65.

[233] *See, e.g.*, Risch, *supra* note 21, at 591–94; *see generally* "Requirements for Patentability" (reviewing requirements for patentability under Sections 102, 103, and 112 of the Patent Act).

indeterminate or as harmful to innovation as the critics claim.[234] Other commentators, even if they accept the criticisms directed at *Alice*/*Mayo*, believe that the courts will eventually refine, clarify, or otherwise improve the law of patentable subject matter given more time for judicial development.[235] Still other commentators support the current law of Section 101 as affirmatively good for innovation and society because it precludes property rights in fundamental aspects of science, nature, and ideas,[236] or serves as an important mechanism to weed out overly broad patents or obtain early dismissal of unmeritorious patent litigation.[237]

Supporters of continued judicial development may point to the administrative guidance put forth by the USPTO[238] and significant Section 101 decisions of the Federal Circuit[239] as promising steps in the development of Section 101 after the *Alice*, *Mayo*, and *Myriad* decisions. Opponents of maintaining the legal status quo, for their part, observe that the Supreme Court has not shown much interest in revisiting its Section 101 jurisprudence despite many opportunities,[240] and that the USPTO and the Federal Circuit are bound by the Court's decisions.

Specific Statutory List of Included or Excluded Subject Matter Categories

Another potential option would be for Congress to amend Section 101, replacing the *Alice*/*Mayo* framework with a more specific list of subject matter that is patent-eligible or ineligible. Currently, Section 101 contains a broad list of included subject matter categories (processes, machines, manufactures, and compositions of matter), and most of the doctrine focuses on the three judicially created ineligible categories: laws of nature, natural phenomena, and abstract ideas.[241] The "laundry list" approach would seek to make Section 101 clearer and more predictable by more specifically defining categories of eligible or ineligible subject matter.[242] Depending on how this sort of proposal is structured, it would retain the notion of ineligible classes of subject matter, but define such categories differently, more precisely, and perhaps more narrowly than the common law exceptions under the *Alice*/*Mayo* framework.

The European Patent Convention's (EPC's) approach to patent eligibility offers a potential model for this type of approach.[243] Under EPC article 52(1), patent-eligible subject matter reaches "all

[234] *See BCLT Report*, *supra* note 16, at 566.

[235] *See* USPTO PSM REPORT, *supra* note 16, at 39.

[236] Sarnoff Testimony, *supra* note 26, at 1.

[237] *See Patent Eligibility Hearings*, *supra* note 29 (statement of Prof. Paul R. Gugliuzza, Boston University School of Law), at 1, https://www.judiciary.senate.gov/imo/media/doc/Gugliuzza%20Testimony.pdf [hereinafter Gugliuzza Testimony] ("[T]he eligibility requirement, though imperfect, plays a crucial role in reducing litigation costs by giving courts a mechanism to quickly dismiss infringement claims that plainly lack merit.").

[238] *See infra* "Administrative Developments in the USPTO ."

[239] *See, e.g.*, Am. Axle & Mfg. v. Neapco Holdings, 967 F.3d 1285 (Fed. Cir. 2020); Yu v. Apple Inc., 1 F.4th 1040 (Fed. Cir. 2021); Chamberlain Grp., Inc. v. Techtronic Indus. Co., 935 F.3d 1341 (Fed. Cir. 2019); ChargePoint, Inc. v. SemaConnect, Inc., 920 F.3d 759 (Fed. Cir. 2019); Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019); Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018); Aatrix Software v. Green Shades Software, 882 F. 3d 1121 (Fed. Cir. 2018); Berkheimer v. HP Inc., 881 F.3d 1360 (Fed. Cir. 2018); Enfish, LLC v. Microsoft Corp., 822 F.3d 1327 (Fed. Cir. 2016); Finjan, Inc. v. Blue Coat Systems, Inc., 879 F.3d 1299 (Fed. Cir. 2018); McRO, Inc. v. Bandai Namco Games Am. Inc., 837 F.3d 1299 (Fed. Cir. 2016); Bascom Global Internet Services, Inc. v. AT&T Mobility LLC, 827 F.3d 1341 (Fed. Cir. 2016); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015); DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245 (Fed. Cir. 2014).

[240] *See infra* "Judicial Developments."

[241] *See supra* "The Law of Section 101."

[242] *See* Taylor, *supra* note 229, at 2198, 2200 (coining this term).

[243] *BCLT Report*, *supra* note 16, at 564.

fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application."[244] At the same time, EPC article 52(2) defines specific subject matter that is *not* patentable when claimed "as such":

> (a) discoveries, scientific theories and mathematical methods;
>
> (b) aesthetic creations;
>
> (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
>
> (d) presentations of information.[245]

EPC article 53 further denies patents on inventions that are "contrary to [public order] or morality," claim "plant and animal varieties," or claim "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body."[246]

Assuming that the new statutory categories are more clearly defined than existing judicial categories, a potential virtue of the laundry-list approach is greater clarity and predictability in the sort of inventions that are patentable.[247] This approach would also more firmly ground subject matter determinations in the statutory text. On the other hand, the list-of-specific-exclusions approach might be less flexible and less able to adapt to unforeseen new technologies than other options.[248] It might also, to some degree, replace case-by-case judicial judgments of eligibility with more categorical legislative ones, which may be a virtue or a vice depending on one's perspective.[249]

Replace Judicial Exceptions with a Different Standard

A third group of proposed Section 101 reforms seeks to replace the *Alice*/*Mayo* framework with a new statutory standard for assessing patent eligibility.[250] Proposals in this category are fairly diverse, but common elements in proposed new standards would limit patent eligibility to inventions that

- result from human effort;[251]
- contribute to the technological arts;[252]
- have practical utility or application;[253]

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[244] Convention on the Grant of European Patents art. 52(1), Oct. 5, 1973, 1065 U.N.T.S. 254 (as amended), https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/EPC_conv_20190401_en_20190326.pdf.

[245] *Id.* art. 52(2)–(3).

[246] *Id.* art. 53.

[247] *See* Taylor, *supra* note 229, at 2200.

[248] *See id.* at 2201.

[249] *Compare id.* at 2193–97 (arguing that judicial "policymaking" under Section 101 should be constrained), *with* Morris, *supra* note 106, at 107–17 (arguing that a subjective, intuitive, case-by-case, judgment-based approach to Section 101 is inevitable and "perhaps even desirable").

[250] For examples of this sort of proposal, see Taylor, *supra* note 229, at 2202–07; USPTO PSM REPORT, *supra* note 16, at 42–43, 59–62; *BCLT Report*, *supra* note 16, at 563–65.

[251] *See, e.g.*, Taylor, *supra* note 229, at 2202–05; *BCLT Report*, *supra* note 16, at 563.

[252] *See, e.g.*, USPTO PSM REPORT, *supra* note 16, at 42, 64.

[253] *See, e.g.*, USPTO PSM REPORT, *supra* note 16, at 43; *BCLT Report*, *supra* note 16, at 563–64; Taylor, *supra* note 229, at 2205–07.

- cannot be solely performed in the human mind;[254]
- do not preempt all practical uses of a law of nature, abstract idea, or natural phenomenon.[255]

Usually, the proposed new patentability standard would supersede the three judicially created subject matter exclusions and the two-step *Alice*/*Mayo* test.[256]

Several proposed new standards blend more than one of these elements. For example, the American Intellectual Property Law Association has submitted a Section 101 reform proposal that replaces the *Alice/Mayo* framework with a single exception to patent eligibility if an invention "exists in nature independently of and prior to any human activity" or "is performed solely in the human mind."[257] A 2017 proposal by the American Bar Association (ABA) would explicitly allow patenting "practical applications" of laws of nature, natural phenomena, and abstract ideas, so long as the patent claim does not "preempt the use by others of all practical applications of the law of nature, natural phenomenon, or abstract idea."[258]

It is difficult to generalize given the significant differences among the various proposals in this category, but stakeholders may wish to consider whether proposed new standards would provide greater clarity and predictability in patent-eligibility law, while still being flexible enough to adapt to new technologies.[259]

Eliminate Implied Patentable Subject Matter Limits

Another option would be for Congress to eliminate the *Alice*/*Mayo* framework and judicially created exceptions to patent eligibility altogether, without replacing them with a new standard or statutory exceptions.[260] Several commentators have argued that patent-eligibility doctrine serves no purpose that is not already served by the existing statutory patentability requirements of utility, novelty, obviousness, written description, definiteness, and enablement.[261] On this view, the appropriate course would be for Congress to simply eliminate the nonstatutory eligibility requirements (i.e., the judicial prohibitions on patenting laws of nature, natural phenomena, and abstract ideas) in favor of the application of the patentability requirements of Sections 102, 103, and 112 of the Patent Act.[262]

Supporters of this approach argue that it advances the policy concerns motivating Section 101 law, but does so in a "more consistent and more rigorous" manner.[263] Opponents argue that

[254] *See, e.g.*, *BCLT Report*, *supra* note 16, at 563.

[255] *See, e.g.*, USPTO PSM REPORT, *supra* note 16, at 60–61.

[256] *See, e.g.*, *BCLT Report*, *supra* note 16, at 563–65.

[257] Am. Intellectual Prop. Law Ass'n, *Joint AIPLA-IPO Proposal on Patent Eligibility* (May 2018), https://www.aipla.org/policy-advocacy/legislative/joint-aipla-ipo-proposal-on-patent-eligibility.

[258] *See* USPTO PSM REPORT, *supra* note 16, at 60.

[259] *See* Taylor, *supra* note 229, at 2189–97 (articulating general principles for evaluating proposed Section 101 reforms).

[260] *See BCLT Report*, *supra* note 16, at 565.

[261] *See* Risch, *supra* note 21, at 594, 606–09; Taylor, *supra* note 229, at 2171–89.

[262] Risch, *supra* note 21, at 606–09.

[263] *Id.* at 594; *accord* Taylor, *supra* note 229, at 2211.

Section 101 serves important purposes that are distinct from the other patentability requirements, which would be lost if the judicial exceptions were eliminated.[264]

Post-*Alice* Developments in Patent-Eligible Subject Matter Law and Proposed Reforms

The Supreme Court's modern patentable subject matter jurisprudence has led to responses from the courts, the USPTO, and Congress. This section reviews recent judicial, administrative, and legislative developments on patent-eligible subject matter standards and proposed reforms.

Judicial Developments

Since its 2014 decision in *Alice*, the Supreme Court has denied dozens of petitions for certiorari (i.e., requests that the Court hear an appeal) on Section 101 issues, despite calls from some patent law stakeholders asking the Court to revisit its patent-eligible subject matter jurisprudence.[265] For example, in *Sequenom v. Ariosa Diagnostics, Inc.*,[266] the Supreme Court denied certiorari despite 22 amicus briefs supporting certiorari and calls from commentators, stakeholders, and Federal Circuit judges urging the Court to take the case to clarify Section 101.[267] Similarly, in opinions concerning rehearing en banc in *Athena Diagnostics, Inc. v. Mayo Collaborative Services*,[268] all of the active judges on the Federal Circuit called upon the Supreme Court (or Congress) to change Section 101 law to clearly allow for the patenting of diagnostic methods.[269] The Supreme Court nonetheless denied certiorari in *Athena* and again declined to revisit its Section 101 case law.[270]

Another prominent Section 101 case that the Court declined to hear was *American Axle & Manufacturing v. Neapco Holdings*.[271] That case was thought by some observers to be an ideal vehicle for the Court because the patented technology—a method for manufacturing driveline shafts for automotive vehicles—was tangible and relatively straightforward, yet the lower courts held it ineligible as directed to a law of nature.[272] As in *Athena*, the Federal Circuit was closely

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[264] *See, e.g.*, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 91 (2012) (relying on concerns about preemption to "decline the Government's invitation to substitute §§ 102, 103, and 112 inquiries for the better established inquiry under § 101"); *see supra* note 210 (citing academic sources); *see generally* "Views on the Purposes of Section 101."

[265] *See* Burman York Mathis III, *Supreme Court Denies 43rd Petition for Cert on 101 Grounds in* Villena v. Iancu, IPWATCHDOG (Sept. 3, 2019), https://www.ipwatchdog.com/2019/06/16/supreme-court-denies-43rd-petition-cert-101-grounds-villena-v-iancu/id=110425/.

[266] *See* 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 579 U.S. 928 (2016).

[267] *BCLT Report*, *supra* note 16, at 577 (describing *Sequenom* as a "case that many Federal Circuit jurists, scholars, and practitioners regarded as an ideal vehicle for [the Court to] clarify[] patent eligibility standards"); USPTO PSM Report, *supra* note 16, at 11 (same); SCOTUSBLOG, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, https://www.scotusblog.com/case-files/cases/sequenom-inc-v-ariosa-diagnostics-inc/ (last visited Mar. 31, 2025) (linking to 22 amicus briefs in support of the petition for certiorari).

[268] Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019), *cert. denied*, 140 S. Ct. 855 (2020).

[269] *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1335 (Fed. Cir. 2019) (opinions regarding the denial of rehearing en banc); CRS Legal Sidebar LSB10344, *Judges Urge Congress to Revise What Can Be Patented*, coordinated by Kevin J. Hickey (2020) (reviewing the Federal Circuit's opinions in *Athena Diagnostics*).

[270] 140 S. Ct. 855 (2020).

[271] 967 F.3d 1285 (Fed. Cir. 2020), *cert. denied*, 142 S. Ct. 2902 (2022).

[272] *Id.* at 1292–99.

divided with respect to rehearing *American Axle* en banc, dividing 6-6, with 5 judges averring that "[Federal Circuit] rulings on patent eligibility have become so diverse and unpredictable as to have a serious effect on the innovation incentive in all fields of technology."[273] Many stakeholders again supported the petition for certiorari in *American Axle*, including a brief filed jointly by Senator Tillis, the Hon. Paul R. Michel (a former Chief Judge of the Federal Circuit), and David J. Kappos (a former USPTO Director).[274] The Supreme Court invited the views of the Solicitor General, who filed a brief supporting a partial grant of certiorari in *American Axle*.[275] The Supreme Court declined to hear the case in 2022.[276]

In light of the Supreme Court's apparent reluctance to revisit Section 101, the Federal Circuit has continued to develop the law of Section 101 within the constraint of the Supreme Court's precedents,[277] deciding many significant cases applying the *Alice*/*Mayo* framework.[278] The Supreme Court's inaction on Section 101 post-*Alice* has also led some stakeholders to call for Congress to intervene on the issue.[279]

Administrative Developments in the USPTO

The 2019 Revised Patent Subject Matter Eligibility Guidance

In 2019, the USPTO issued Revised Patent Subject Matter Eligibility Guidance (the 2019 Guidance) to assist USPTO patent examiners in determining subject matter eligibility for patent applications.[280] The USPTO noted that the "legal uncertainty" surrounding the *Alice*/*Mayo* framework "poses unique challenges" for the agency, which has thousands of patent examiners who must make patent-eligibility determinations on hundreds of thousands of applications each

[273] Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 966 F.3d 1347, 1357 (Fed. Cir. 2020) (Newman, J., dissenting from the denial of rehearing en banc).

[274] *See* Am. Axle & Mfg. v. Neapco Holdings LLC (U.S. No. 20-891), https://www.supremecourt.gov/search.aspx?filename=/docket/docketfiles/html/public/20-891.html (Supreme Court docket linking to amicus briefs).

[275] *See* Brief for the United States as Amicus Curiae, Am. Axle & Mfg. v. Neapco Holdings LLC, No. 20-891 (U.S. May 24, 2022), https://www.supremecourt.gov/DocketPDF/20/20-891/226156/20220524150114156_20-891%20-%20American%20Axle%20CVSG.pdf.

[276] 142 S. Ct. 2902 (2022).

[277] *See, e.g.*, Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1337 (Fed. Cir. 2019) (Hughes, J., concurring in the denial of rehearing en banc) (noting that "we are bound by the Supreme Court['s]" precedent even if the result is "problematic" for diagnostic patents in the view of some Federal Circuit judges).

[278] *See, e.g.* Trinity Info Media, LLC v. Covalent, Inc., 72 F.4th 1355 (Fed. Cir. 2023); CardioNet, LLC v. InfoBionic, Inc, 955 F.3d 1358 (Fed. Cir. 2020); Illumina, Inc. v. Ariosa Diagnostics, Inc., 967 F.3d 1319 (Fed. Cir. 2020); Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019); Endo Pharms. Inc. v. Teva Pharms. USA, Inc., 919 F.3d 1347, 1348 (Fed. Cir. 2019); Cellspin Soft, Inc. v. Fitbit, Inc., 927 F.3d 1306 (Fed. Cir. 2019); Aatrix Software, Inc. v. Green Shades Software, Inc., 882 F.3d 1121 (Fed. Cir. 2018); Berkheimer v. HP Inc., 881 F.3d 1360, 1363 (Fed. Cir. 2018); Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018); Enfish, LLC v. Microsoft Corp., 822 F.3d 1327 (Fed. Cir. 2016); McRO, Inc. v. Bandai Namco Games Am. Inc., 837 F.3d 1299 (Fed. Cir. 2016); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015); DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245 (Fed. Cir. 2014).

[279] *See infra* "Legislative Developments" (reviewing congressional proposals to amend Section 101).

[280] Notice, 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019) [hereinafter 2019 Guidance]. USPTO subsequently issued an update to this guidance in October 2019. *See* U.S. PAT. & TRADEMARK OFF., *October 2019 Update: Subject Matter Eligibility* (Oct. 2019), https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf [hereinafter the October 2019 Update]. These guidance documents have been incorporated in the USPTO's Manual of Patent Examining Procedure.

year.[281] Accordingly, the USPTO issued revised guidance to its patent examiners to provide "more clarity and predictability" in their Section 101 determinations.[282]

The USPTO subsequently incorporated the 2019 Guidance into the Manual of Patent Examining Procedure (MPEP), which guides USPTO patent examiners in their review of patent applications.[283] The 2019 Guidance made at least two major changes to how patent examiners evaluate whether a patent application claims patent-ineligible subject matter. First, the Guidance seeks to provide a clearer definition of what constitutes an ineligible "abstract idea."[284] Previously, examiners would make that determination by comparing the patent claim at issue to those found to be ineligible "abstract ideas" in previous judicial cases.[285] The USPTO found that this approach had become "impractical" because of an expanding volume of sometimes contradictory Section 101 case law.[286] The 2019 Guidance "distills" the case law into three categories that examiners will treat as "abstract ideas":

> 1) Mathematical concepts—mathematical relationships, mathematical formulas or equations, mathematical calculations;
>
> 2) Certain methods of organizing human activity – fundamental economic principles or practices (including hedging, insurance, mitigating risk); commercial or legal interactions (including agreements in the form of contracts; legal obligations; advertising, marketing or sales activities or behaviors; business relations); managing personal behavior or relationships or interactions between people (including social activities, teaching, and following rules or instructions); and
>
> 3) Mental processes – concepts performed in the human mind (including an observation, evaluation, judgment, opinion).[287]

Under the Guidance, patent claims that do not recite matter that falls into one of these three groupings should not be treated as an "abstract idea" except in "rare circumstance[s]."[288]

Second, the 2019 Guidance clarifies when examiners will treat a patent claim as "directed to" an ineligible category (abstract ideas, laws of nature, or natural phenomena) under step one of the *Alice*/*Mayo* test.[289] In particular, the USPTO will *not* treat a claim as "directed to" an ineligible concept if "the claim as a whole integrates the recited judicial exception into *a practical application of the exception*."[290] If the claim does integrate a practical application—such as

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[281] *See* 2019 Guidance, *supra* note 280, at 50 ("The legal uncertainty surrounding Section 101 poses unique challenges for the USPTO, which must ensure that its more than 8500 patent examiners and administrative patent judges apply the *Alice/Mayo* test in a manner that produces reasonably consistent and predictable results across applications, art units and technology fields."); *see also* U.S. PAT. & TRADEMARK OFF., *U.S. Patent Statistics Chart Calendar Years 1963–2015*, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last visited Mar. 5, 2025) (indicating that the USPTO received 589,410 applications in 2015).

[282] *See* 2019 Guidance, note 280, at 50.

[283] *See* U.S. PATENT & TRADEMARK OFF., *Subject Matter Eligibility*, https://www.uspto.gov/patents/laws/examination-policy/subject-matter-eligibility (last visited Mar. 6, 2025); U.S. PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE §§ 2103–2106 (last revised Jan. 2024), *available at* https://www.uspto.gov/web/offices/pac/mpep/index.html [hereinafter MPEP].

[284] *Id.* at § 2106.04(a).

[285] 2019 Guidance, note 280, at 51.

[286] *Id.* at 52.

[287] MPEP § 2106.04(a) (internal cross-references omitted).

[288] *Id.*

[289] *Id.* at § 2106.04. The USPTO calls the *Alice*/*Mayo* test's first step "Step 2A" of its Section 101 examination process. *See id.*

[290] *Id.* at § 2106.04(d) (emphasis added).

improving the functioning of a computer, effecting a particular treatment for a disease, or implementing the exception into a particular machine or manufacture—then the USPTO will treat the claim as patent-eligible, without having to examine the patent application for an "inventive concept" under step two of the *Alice*/*Mayo* framework.[291]

The 2019 Guidance was generally perceived as lowering Section 101 barriers to patentability, especially for computer-related inventions.[292] Some commentators praised the Guidance for providing greater clarity to patent examiners, while other stakeholders criticized the Guidance as inconsistent with the Supreme Court's Section 101 decisions.[293]

Although the USPTO's 2019 Guidance changes how USPTO examiners review new patent applications, the Guidance is not binding on the courts when patents are challenged in litigation (unlike decisions of appellate courts or statutes). The USPTO lacks general substantive rulemaking authority,[294] and the Guidance itself states that it is only a "tool for internal USPTO management" that lacks "the force and effect of law."[295] Although the Federal Circuit has issued somewhat contradictory signals on this point,[296] courts would only follow the Guidance if they found its reasoning to be persuasive and agreed that it was the "best reading" of Section 101.[297]

[291] *Id.* at §§ 2106, 2106.04(d).

[292] *See, e.g.*, James J. DeCarlo & George David Zalpea, *The USPTO's New § 101 Guidance: Progress or Pitfall?*, N.J. LAW J. (May 13, 2019), https://www.gtlaw.com/en/insights/2019/5/published-articles/the-usptos-new-101-guidance-progress-or-pitfall ("In practice, many applicants are seeing a noticeable decrease of rejections under § 101 [after the 2019 Guidance.]"); Michelle Holoubeck & Lestin Kenton, *5 Things to Know About USPTO's New Eligibility Guidance*, LAW360 (Jan. 8, 2019), https://www.law360.com/articles/1116262/5-things-to-know-about-uspto-s-new-eligibility-guidance ("The [PTO's] new guidance eases the burden on patenting computer-implemented invention.").

[293] *See generally* Stuart P. Meyer, *No Shortage of Viewpoints on New USPTO Eligibility Guidelines*, BILSKI BLOG (Mar. 26, 2019), https://www.fenwick.com/bilski-blog/no-shortage-of-viewpoints-on-new-uspto-patent-eligibility-guidelines (reviewing comments received by USPTO on the 2019 Guidance and noting that "both the 'new Guidance is great' and the 'new Guidance doesn't follow *Alice*' camps are very well represented").

[294] Merck & Co. v. Kessler, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996) (holding that while the USPTO may promulgate regulations directed to the conduct of its own proceedings, it lacks authority to "issue substantive rules" under the Patent Act); Ass'n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1357 (Fed. Cir. 2012) (Bryson, J., concurring in part and dissenting in part) ("As we have recognized, the PTO lacks substantive rulemaking authority as to issues such as patentability."); *see generally* Melissa F. Wasserman, *The Changing Guard of Patent Law:* Chevron *Deference for the PTO*, 54 WM. & MARY L. REV. 1959, 1962 (2013) ("[The USPTO] lacks robust substantive rule-making authority and receives no judicial deference for its legal interpretations of the Patent Act.").

[295] 2019 Guidance, *supra* note 280, at 51.

[296] *Compare* Nat. Alternatives Int'l, Inc. v. Creative Compounds, LLC, 918 F.3d 1338, 1346 n.2 (Fed. Cir. 2019) (noting that "[t]he parties dispute the persuasiveness of this document and the weight we should afford it under [*Skidmore*]," but declining to decide whether the 2019 Guidance should receive any deference), *with* Cleveland Clinic Found. v. True Health Diagnostics LLC, 760 F. App'x 1013, 1020 (Fed. Cir. 2019) ("While we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance."). *See generally* Andrew Michaels, *How Much Deference Courts Owe to USPTO Guidance*, LAW360 (June 20, 2019), https://www.law360.com/ip/articles/1171217/how-much-deference-courts-owe-to-uspto-guidance.

[297] *See* Loper Bright Enters. v. Raimondo, No. 22-451, slip op. at 23 (U.S. June 28, 2024); United States v. Mead Corp., 533 U.S. 218, 234 (2001) ("[A]n agency's interpretation [of a statute] may merit some deference whatever its form, given the specialized experience and broader investigations and information available to the agency, and given the value of uniformity in its administrative and judicial understandings of what a national law requires.") (citations omitted); Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) ("The weight of [an informal agency] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.").

Following the 2019 Guidance, the USPTO has continued efforts to increase clarity and consistency in its Section 101 determinations.[298] In 2020, the USPTO Office of the Chief Economist issued a report on patent examination outcomes following *Alice*.[299] That study found that while Section 101 rejections in certain technological fields increased by 31% in the 18 months after *Alice*, the rejection rate decreased by 35% after issuance of the 2019 Guidance, with less variability in outcomes across examiners.[300] In response to a 2021 letter from Senators Tillis and Cotton,[301] the USPTO launched the Deferred Subject Matter Eligibility Response Pilot Program, which invites selected patent applicants to defer consideration of subject-matter eligibility issues until other patentability issues (such as those under Sections 102, 103, and 112) are resolved.[302]

2022 USPTO Report on Stakeholder Views

In 2022, at the urging of a group of Senators,[303] the USPTO solicited public comment and published a report for Congress summarizing stakeholder views on current patent-eligible subject matter law.[304] While the report found a consensus that patent-eligibility law should be "clear, predictable, and consistently applied," stakeholders differed on whether current Section 101 law achieved that ideal.[305] Finding a "continuing divide" on the issue, the USPTO report indicated that defenders of the *Alice*/*Mayo* framework (primarily from the computer technology industry) found current law to be sufficiently clear and an important tool for addressing overbroad patents and abusive lawsuits.[306] On the other side, critics of the *Alice*/*Mayo* framework (especially life-science industries) found the current law to be unpredictable and to have detrimental effects on innovation and investment in the development of new technologies.[307]

2024 Artificial Intelligence Eligibility Guidance

Patent applications relating to artificial intelligence (AI) technologies doubled between 2002 and 2018.[308] Some stakeholders worry that patents on AI inventions are at risk under the *Alice*/*Mayo*

[298] *See generally* Kathy Vidal, *Providing Clear Guidance on Patent Subject Matter Eligibility*, U.S. PAT. & TRADEMARK OFF. (July 25, 2022), https://www.uspto.gov/blog/director/entry/providing-clear-guidance-on-patent.

[299] ANDREW A. TOOLE & NICHOLAS A. PAIROLERO, *ADJUSTING TO* ALICE (U.S. Pat. & Trademark Off. April 2020), https://www.uspto.gov/sites/default/files/documents/OCE-DH_AdjustingtoAlice.pdf.

[300] *Id.* at 1.

[301] Letter from Sens. Thom Tillis and Tom Cotton to Drew Hirschfeld (Mar. 22, 2021), https://www.uspto.gov/sites/default/files/documents/sens-sequencedexam-20210322.pdf.

[302] USPTO, Deferred Subject Matter Eligibility Response Pilot Program, 87 Fed. Reg. 776 (Jan. 6, 2022). This pilot program is "designed to evaluate how deferred applicant responses to subject matter eligibility (SME) rejections affect examination efficiency and patent quality." U.S. PAT. & TRADEMARK OFFICE, *Deferred Subject Matter Eligibility Response (DSMER) Pilot Program*, https://www.uspto.gov/patents/initiatives/patent-application-initiatives/deferred-subject-matter-eligibility-response (last visited Mar. 31, 2025).

[303] *See* Letter from Sens. Thom Tillis, Mazie Hirono, Tom Cotton and Christopher Coons to Drew Hirschfeld (Mar. 5, 2021), https://www.tillis.senate.gov/services/files/04D9DCF2-B699-41AC-BE62-9DCA9460EDDA.

[304] U.S. PAT. & TRADEMARK OFF., PATENT ELIGIBLE SUBJECT MATTER: PUBLIC VIEWS ON THE CURRENT JURISPRUDENCE IN THE UNITED STATES (June 2022), https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf [hereinafter 2022 PUBLIC VIEWS REPORT].

[305] *Id.* at ii, 41.

[306] *Id.* at 41.

[307] *Id.*

[308] *See* USTPO, Off. of the Chief Economist, *Inventing AI: Tracing the Diffusion of Artificial Intelligence with U.S. Patents* (Oct. 2020), at 3, https://www.uspto.gov/sites/default/files/documents/OCE-DH-AI.pdf.

framework because they might be characterized as claiming abstract ideas.[309] In 2024, USPTO issued updated guidance on patent eligibility focusing on AI-related inventions.[310]

USPTO's 2024 AI Eligibility Guidance supplements its general 2019 Guidance on patent-eligible subject matter. As explained above, under the 2019 Guidance, claims are eligible under *Alice/Mayo* step one if the claim either (1) does not "recite" a judicial exception, or (2) has additional elements that "integrate" the judicial exception into a practical application of ineligible subject matter.[311] The 2024 AI Eligibility Guidance focuses on this step, giving several examples designed to illustrate when claims on AI inventions recite or "merely involve" abstract ideas, and when claims integrate an abstract idea into a practical application by improving the functioning of a computer or another technology.[312]

As an example, the 2024 AI Eligibility Guidance explains that a claim on an application-specific integrated circuit for an artificial neural network comprising synaptic circuits, a microprocessor, and an array of organized "neurons" is patent-eligible because it is directed to specific hardware components and thus does not recite an abstract idea.[313] By contrast, a general method of using a deep neural network to analyze a speech sample with multiple sources is ineligible because it claims a mathematical process.[314] However, a specific method of using a deep neural network to separate a mixed speech sample, generate separate waveforms for each speech source, and recombine them into a new mixed sample without unwanted sources is eligible as a practical application of an abstract idea.[315]

While some stakeholders appreciated USPTO's efforts to provide more guidance on how examiners will approach patent eligibility issues for AI-related inventions,[316] others asserted that the 2024 AI Eligibility Guidance should have done more to clarify the application of the *Alice/Mayo* framework for such inventions.[317]

[309] *See* 2022 PUBLIC VIEWS REPORT, *supra* note 304, at 8.

[310] USPTO, 2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence, 89 Fed. Reg. 58,128 (July 17, 2024) [hereinafter 2024 AI Eligibility Guidance]. Another CRS product reviews USPTO's 2024 AI Eligibility Guidance in more detail. *See generally* CRS Legal Sidebar LSB11251, *Artificial Intelligence and Patent Law*, by Kevin J. Hickey and Christopher T. Zirpoli (2024).

[311] *See* MPEP § 2106.05

[312] 2024 AI Eligibility Guidance, 89 Fed. Reg. at 58,134–38.

[313] *See* USPTO, *July 2024 Subject Matter Eligibility Examples*, https://www.uspto.gov/sites/default/files/documents/2024-AI-SMEUpdateExamples47-49.pdf (last visited Mar. 11, 2025), at 5.

[314] *Id.* at 18–21.

[315] *Id.* at 21–24.

[316] *See, e.g.*, PhRMA, *Comments of the Pharmaceutical Research and Manufacturers of America in Response to the USPTO's 2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence* (Oct. 16, 2024), https://www.regulations.gov/comment/PTO-P-2024-0026-0018 ("PhRMA appreciates USPTO's efforts to streamline interpretation of [patent-eligible subject matter] jurisprudence and application to pending matters before the Office so as to create a more predictable landscape for patent applicant.").

[317] *See, e.g.*, Eileen McDermott & Steve Brachmann, *IP Organizations Want More on USPTO's AI Patent Eligibility Guidance*, IPWATCHDOG, https://ipwatchdog.com/2024/10/20/ip-organizations-want-usptos-ai-patent-eligibility-guidance/id=182378/ (Oct. 20, 2024) (summarizing public comments on the 2024 AI Eligibility Guidance).

Legislative Developments

The 116th Congress

The 116th Congress saw one formal proposal to reform Section 101 introduced in the House. In the Senate, the Chairman and Ranking Member of the Subcommittee on Intellectual Property of the U.S. Senate Committee on the Judiciary held a series of hearings on Section 101 issues and circulated several informal draft proposals to amend Section 101. Ultimately, these Members did not introduce formal legislation in the 116th Congress.

The Restoring America's Leadership in Innovation Act of 2020

In the House, Representative Massie introduced H.R. 7366, the Restoring America's Leadership in Innovation Act of 2020 (RALIA 2020).[318] Alongside provisions designed to reverse many of the changes in patent law enacted through the 2011 America Invents Act,[319] Section 7 of RALIA 2020 would have responded to the Supreme Court's Section 101 decisions. Expressing the view that the Court's recent Section 101 jurisprudence "has harmed the progress of science and the useful arts," RALIA 2020 would have "effectively abrogate[d]" those decisions (specifically, *Alice* "and [its] predecessors").[320]

To "ensure that life sciences discoveries, computer software, and similar inventions and discoveries are patentable," RALIA 2020 would have replaced the three judicially created exceptions to patent-eligible subject matter with a single narrow statutory exception.[321] Under RALIA 2020, any new and useful process, machine, manufacture, or composition of matter would have been patent-eligible unless "the claimed invention as a whole, as understood by a person having ordinary skill in the art, exists in nature independently of and prior to any human activity, or exists solely in the human mind."[322] RALIA 2020 would have thus expanded the types of inventions that are patentable compared to the status quo under *Alice/Mayo.* RALIA 2020 would have also established that eligibility determinations under Section 101 shall be made "without regard as to the requirements or conditions of sections 102, 103, and 112 of this title, or the claimed invention's inventive concept."[323] This provision would have sought to separate eligibility questions under Section 101 from issues of novelty, nonobviousness, enablement, and disclosure more specifically addressed in other provisions of the Patent Act.

The First Tillis-Coons Proposal

In April 2019, Senators Tillis and Coons—joined by Representatives Collins (GA), Johnson (GA), and Stivers—released a framework for legislative Section 101 reform (the First Tillis-Coons Proposal).[324] The framework's release followed multiple roundtables with patent law

[318] H.R. 5874, 117th Cong. (2021).

[319] *See, e.g.*, *id.* §§ 4–5 (abolishing the PTAB and the IPR/PGR procedures).

[320] *Id.* § 7(b).

[321] *Id.* § 7(a).

[322] *Id.*

[323] *Id.*

[324] *See* Press Release, Office of Sen. Thom Tillis, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework (Apr. 17, 2019), https://www.tillis.senate.gov/2019/4/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-section-101-patent-reform-framework [hereinafter Sen. Tillis April 17 Press Release]; Sen. Tillis et al., Draft Outline for Section 101 Reform,
(continued...)

stakeholders on Section 101 and the effect of the *Alice/Mayo* framework on, for example, innovation in artificial intelligence, medical diagnostics, and personalized medicine.[325]

The First Tillis-Coons Proposal would have retained the four current statutory categories of patentable inventions, but removed the requirement that the invention or discovery be "new and useful" from Section 101.[326] Patent eligibility would have instead been determined "by considering each and every element of the claim as a whole and without regard for considerations properly addressed by [Sections] 102, 103 and 112 [of the Patent Act]."[327]

In place of the judicially created exceptions to patent eligibility, which the First Tillis-Coons Proposal would have abrogated by statute, the proposal listed five "exclusive" categories of patent-ineligible subject matter: (1) fundamental scientific principles; (2) products that exist solely and exclusively in nature; (3) pure mathematical formulas; (4) economic or commercial principles; and (5) mental activities.[328] Effectively, this would have codified aspects of the judicial exceptions in a narrower form, with the first two ineligible categories roughly corresponding to the "law of nature" and "natural product" judicial exceptions, and the final three to the types of "abstract ideas" identified by the USPTO in its 2019 Guidance.[329] The First Tillis-Coons Proposal thus blended elements of the USPTO's 2019 Guidance with a list of specific ineligible categories, plus new statutory standards for how to apply the list of exceptions to patentable subject matter.[330] The overall effect would be to lower Section 101 barriers to patentability, while still retaining more narrowly defined classes of ineligible subject matter.[331]

Reactions to the First Tillis-Coons Proposal were mixed.[332] Some commentators argued that the draft proposal was a promising start for much-needed congressional intervention.[333] Some critics of the *Alice/Mayo* framework argued that the First Tillis-Coons Proposal did not go far enough,

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https://www.tillis.senate.gov/services/files/3491a23f-09c3-4f4a-9a93-71292704c5b1 [hereinafter First Tillis-Coons Proposal].

[325] *Id.*; *see generally* "The Debate Over *Alice*/*Mayo* and Section 101 Reform."

[326] *See* First Tillis-Coons Proposal, *supra* note 324.

[327] *Id.*

[328] *Id.*

[329] *See* Phillip M. Nelson & Bridget A. Smith, *Legislators Propose "Section 101 Reform,"* KNOBBE MARTENS (Apr. 18, 2019), https://www.knobbe.com/blog/legislators-propose-section-101-reform/ ("[The First Tillis-Coons Proposal] would codify several of the judicial exceptions. The last three categories correspond to those enumerated in the USPTO's recent guidance.").

[330] *See supra* "Specific Statutory List of Included or Excluded Subject Matter Categories"; "Administrative Developments in the USPTO "; *see also* Nelson & Smith, *supra* note 329 ("[The First Tillis-Coons Proposal] includes some aspects of the proposals from several patent specialty associations, including those from the AIPLA/IPO, IPLAC, and the ABA-IPL section.").

[331] *See* Daniel T. Taskalos, *Returning to the Status Quo?—Proposed Outline for Section 101 Reform*, NAT'L L. REV. (Apr. 22, 2019), https://www.natlawreview.com/article/returning-to-status-quo-proposed-outline-section-101-reform ("In all, the proposed framework appears to focus on returning the 101 analysis to its previous status as more of a low hurdle to patentability, but a hurdle nonetheless.").

[332] *See generally* Eileen McDermott, *Reactions Roll in on Congress's Proposed 101 Framework: 'The Right Approach' or 'a Swing and a Miss"?*, IPWATCHDOG (Apr. 18, 2019), https://www.ipwatchdog.com/2019/04/18/reactions-roll-in-on-congresss-proposed-101-framework-the-right-approach-or-a-swing-and-a-miss/id=108407/ (surveying positive and negative reactions to the First Tillis-Coons Proposal).

[333] *See, e.g.*, Antoinette F. Konski, *Is 101 Relief in Sight?*, FOLEY & LARDNER LLP (Apr. 17, 2019), https://www.foley.com/en/insights/publications/2019/04/is-101-relief-in-sight (calling the First Tillis-Coons Proposal "a step in the right direction"); McDermott, *supra* note 332 (quoting stakeholder comment that the First Tillis-Coons Proposal is "exactly the right approach" to bring predictability to Section 101).

and urged elimination of any ineligible categories of patentable subject matter.[334] On the pro-*Alice* side of the debate, the Electronic Frontier Foundation, for example, criticized the First Tillis-Coons Proposal as detrimental to innovation because it would eliminate a powerful tool to combat bad patents and patent troll litigation.[335]

The Second Tillis-Coons Proposal

Following feedback on their first draft framework, the same group of Members released a "draft bill" to reform Section 101 (the Second Tillis-Coons Proposal).[336] The Second Tillis-Coons Proposal was released before a series of three public hearings held in the 116th Congress before the Senate Judiciary Committee's Subcommittee on Intellectual Property, which solicited feedback on the draft legislative language.[337] In these hearings, 45 witnesses testified over three days, with representatives from industry, academia, bar associations, and trade groups; former Federal Circuit Judges and USPTO Directors; and other patent law stakeholders expressing various views on Section 101 reform.[338]

As compared to the first proposal, the Second Tillis-Coons Proposal would have made more sweeping changes to Section 101 to expand patent eligibility. Like the First Tillis-Coons Proposal, the draft bill had several provisions that attempted to separate the Section 101 inquiry from other patentability requirements. Specifically, the draft bill would have struck the word "new" from Section 101 and established that patent subject matter eligibility must be determined "considering the claimed invention as a whole" and without regard to "considerations relating to section 102, 103, or 112 of [the Patent Act]."[339] The Second Tillis-Coons Proposal provided that eligibility determinations would not depend on the "manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; [or] the state of the art at the time of the invention."[340] The draft bill also explicitly provided that Section 101 "shall be construed in favor of eligibility."[341]

Rather than narrow the judicial exceptions to patentability, the Second Tillis-Coons Proposal would have eliminated those exceptions altogether. The draft bill provided that

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[334] *See, e.g.*, Mark Marrello, *Urge the Drafters of the New Section 101 to Support Inventor-Friendly Reform*, IPWATCHDOG (May 13, 2019), https://www.ipwatchdog.com/2019/05/13/urge-drafters-new-section-101-support-inventor-friendly-reform/id=109206/.

[335] Alex Moss, *The Tillis-Coons Patent Bill Will Be a Disaster for Innovation*, ELECTRONIC FRONTIER FOUND. (Apr. 24, 2019), https://www.eff.org/deeplinks/2019/04/tillis-coons-patent-bill-will-be-disaster-innovation.

[336] *See* Press Release, Office of Sen. Thom Tillis, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act (May 22, 2019), https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act.

[337] *Id.*

[338] *See generally* Coons & Tillis, *supra* note 29. For a succinct summary of the main views expressed at the hearings, see Bruce M. Wexler et al., *Senate Hearing on "The State of Patent Eligibility in America": Analysis of Viewpoints on Looming Section 101 Change*, PAUL HASTINGS (June 25, 2019), https://www.paulhastings.com/publications-items/details/?id=c58c536d-2334-6428-811c-ff00004cbdedl. For a more detailed witness-by-witness breakdown, see Stuart M. Meyer, *Still No Shortage of Viewpoints as Eligibility Debate Moves to the Hill*, BILSKI BLOG (June 27, 2019), https://www.fenwick.com/bilski-blog/still-no-shortage-of-viewpoints-as-eligibility-debate-moves-to-the-hill.

[339] *See* Sen. Tillis et al., Draft Bill for Section 101 Reform, https://www.tillis.senate.gov/services/files/E8ED2188-DC15-4876-8F51-A03CF4A63E26 (proposed § 101(a)–(b) and "Additional Legislative Provisions") [hereinafter Second Tillis-Coons Proposal].

[340] *Id.* ("Additional Legislative Provisions").

[341] *Id.*

> No implicit or other judicially created exceptions to subject matter eligibility, including "abstract ideas," "laws of nature," or "natural phenomena," shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated.[342]

This language would have overturned by statute not only the *Alice*/*Mayo* framework, but over two centuries of judicial decisions interpreting the "common law" exceptions to Section 101.[343]

The Second Tillis-Coons Proposal would have replaced the judicial exceptions with a new statutory definition of utility that incorporated elements of various prior proposals for a new Section 101 standard.[344] To be patent-eligible subject matter under the Second Tillis-Coons Proposal, the invention would need to fit into one of the four statutory categories of eligible subject matter (which remain unchanged) and be "useful."[345] To be "useful," an invention or discovery would need to provide "specific and practical utility in any field of technology through human intervention."[346]

Finally, to combat overbroad patent claims, the Second Tillis-Coons Proposal would have altered the functional claiming rules under Section 112(f), which permits patentees to claim their invention in functional terms as opposed to reciting specific physical structures.[347] Consistent with decisions of the Federal Circuit,[348] the proposal would have clarified that Section 112(f) applies to any claim element that fails to sufficiently recite a structure for performing a function.[349] This change could have arguably made it tougher for a patentee to avoid the limiting effects of Section 112(f), even if the words "means for" are not used in the claim language.[350]

As with the first proposal, reactions to the Second Tillis-Coons Proposal from patent law stakeholders were mixed.[351] Critics of the *Alice/Mayo* framework generally applauded the draft bill as bringing much needed clarity and certainty to the law of patent eligibility,[352] particularly

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[342] *Id.*

[343] *See supra* "Historical Development of the Judicial Exceptions to Patent-Eligible Subject Matter."

[344] *See supra* "Replace Judicial Exceptions with a Different Standard"; "Section 101: Utility."

[345] *See* Second Tillis-Coons Proposal, *supra* note 339 (proposed § 101(a)).

[346] *See id.* (proposed § 100(k)). The draft bill did not further define "practical utility," "field of technology," or "human intervention."

[347] *See* Coons & Tillis, *supra* note 29 (indicating that the Section 112(f) amendments were intended "to guard against . . . overly broad, functional patent claims"); *see generally* "Section 112(f): Functional Claiming" (summarizing current law of functional claiming).

[348] Williamson v. Citrix Online, LLC, 792 F.3d 1339 (Fed. Cir. 2015) (en banc).

[349] *Compare* Second Tillis-Coons Proposal, *supra* note 339 (proposed § 112(f)), *with* 35 U.S.C. § 112(f). *See also Patent Eligibility Hearings*, *supra* note 29 (statement of Christopher A. Mohr, Vice President for Intellectual Property and General Counsel, Software and Information Industry Association), at 11, https://www.judiciary.senate.gov/download/mohr-testimony ("[The proposed § 112(f) language appears to do little more than cement the Federal Circuit's *Williamson v. Citrix* decision . . . .").

[350] *See Patent Eligibility Hearings*, *supra* note 29 (statement of David W. Jones, Executive Director, High Tech Inventors Alliance), at 12, https://www.judiciary.senate.gov/download/06/05/2019/jones-testimony [hereinafter Jones Testimony] ("[The proposed Section 112(f)] amendment represents a modest improvement over the current language and will eliminate lingering arguments about the effect of inclusion or omission of the words 'means for' and whether particular terms should be interpreted as functional in the wake of [*Williamson v. Citrix*].").

[351] *See generally* Wexler et al., *supra* note 338 (summarizing arguments made by supporters and opponents of the Second Tillis-Coons Proposal).

[352] *See, e.g.*, *Patent Eligibility Hearings*, *supra* note 29 (statement of Judge Paul R. Michel (Ret.), U.S. Court of Appeals for the Federal Circuit), at 1, https://www.judiciary.senate.gov/download/michel-testimony (praising the Second Tillis-Coons Proposal as "a very good starting point [that] represents an enormous improvement over the present, intolerable chaos [in Section 101 law]"); *Patent Eligibility Hearings*, *supra* note 29 (statement of Q. Todd (continued...)

for biotechnology innovation.[353] Opponents of the draft bill expressed concern that changes to the *Alice*/*Mayo* framework would eliminate an important tool against unmeritorious patent litigation.[354] Critics also questioned the necessity and advisability of such a sweeping change to Section 101 law.[355] Both supporters and opponents raised concerns about potential ambiguities in the proposed definition of "useful," particularly the terms "human intervention," "practical utility," and "field of technology."[356]

Stakeholders also debated the specific practical effects of the legislative changes at the hearings, such as the effect of elimination of the judicial exceptions on basic scientific research.[357] One concern, raised by the American Civil Liberties Union in opposition to the draft bill, was that the Second Tillis-Coons Proposal, by abrogating the *Myriad* decision,[358] would permit the patenting of human genes.[359] Several witnesses denied that the draft bill would lead to that result because of the bill's "human intervention" requirement or other patent law principles.[360] For their part, Senators Tillis and Coons made clear that they had "no intention" of overruling the result in *Myriad* that no one may patent "genes as they exist in the human body."[361]

The 117th Congress

The 117th Congress saw two introduced bills that proposed reforms to Section 101, one in the House and one in the Senate.

Dickinson, former Director of the USPTO), at 36, https://www.judiciary.senate.gov/download/dickinson-testimony [hereinafter Dickinson Testimony] (expressing "general support for this positive proposal that should go far in clarifying and resolving several major issues . . . particularly the interpretation and use of § 101 . . . .").

[353] *See, e.g.*, *Patent Eligibility Hearings*, *supra* note 29 (statement of Laurie Hill, Vice President, Intellectual Property, Genentech, Inc.), at 8, 15–16, https://www.judiciary.senate.gov/download/hill-testimony (supporting the Second Tillis-Coons Proposal as "a strong step in the right direction" because of the "present uncertainty surrounding Section 101 [that] threatens to disrupt the development of a wide range of important medicines, diagnostics, treatments, and other innovations that benefit society").

[354] *See, e.g.*, Gugliuzza Testimony, *supra* note 237, at 6–7 (arguing that "completely dismantling the eligibility requirement would take away a crucial tool courts can use to end, at relatively low cost, patent cases that plainly lack merit.").

[355] *See, e.g.*, Jones Testimony, *supra* note 350, at 7 ("The evidence and arguments that have been advanced by proponents [of Section 101 reform] simply do not provide any reasonable justification for . . . the complete abrogation of two centuries of eligibility case law.").

[356] *See, e.g.*, Dickinson Testimony, *supra* note 352, at 33–34; Jones Testimony, *supra* note 350, at 10–11.

[357] *See, e.g.*, *Patent Eligibility Hearings*, *supra* note 29 (statement of Charles Duan, Director, Technology & Innovation Policy, R Street Institute), at 13–18, https://www.judiciary.senate.gov/download/duan-testimony.

[358] *See supra* notes 170–174 and accompanying text (discussing the Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*).

[359] *See, e.g.*, *Patent Eligibility Hearings*, *supra* note 29 (statement of Kate Ruane, Senior Legislative Counsel, Washington Legislative Office, ACLU) at 3, https://www.judiciary.senate.gov/download/ruane-testimony (arguing that the Second Tillis-Coons Proposal "would clearly make human genes, isolated from the rest of the genome, patent-eligible again").

[360] *See, e.g.*, *Patent Eligibility Hearings*, *supra* note 29 (statement of Corey Salsberg, Vice President and Global Head Intellectual Property Affairs for Novartis), at 6, https://www.judiciary.senate.gov/download/salsberg-testimony; *Patent Eligibility Hearings*, *supra* note 29 (statement of Philip S. Johnson, Chair, Coalition for 21st Century Patent Reform), at 8, https://www.judiciary.senate.gov/download/06/05/2019/johnson-testimony.

[361] Sen. Chris Coons & Sen. Thom Tillis, *It's Time to Restore America's Patent System*, THE HILL (June 10, 2019), https://thehill.com/blogs/congress-blog/technology/447666-its-time-to-restore-americas-patent-system.

The Restoring America's Leadership in Innovation Act of 2021

In the House, Representative Massie introduced H.R. 5874, the Restoring America's Leadership in Innovation Act of 2021 (RALIA 2021). Like RALIA 2020, the eligibility provisions of RALIA 2021 would have abrogated the *Alice/Mayo* framework and replaced the judicially created exceptions to patent-eligible subject matter with a single exception for inventions that "exist[] in nature independently of and prior to any human activity, or exist[] solely in the human mind."[362]

The Patent Eligibility Restoration Act of 2022

In the Senate, Senator Tillis introduced S. 4734, the Patent Eligibility Restoration Act of 2022 (PERA 2022). PERA 2022 would have retained the four statutory categories of eligible subject matter, deleted the word "new" in Section 101, and added a statutory definition of "useful."[363] PERA 2022's utility definition would have required that "the invention or discovery has a specific and practical utility from the perspective of a person of ordinary skill in the art."[364] In addition, PERA 2022 would have changed the definition of "process" to clarify that "a use, application, or method of manufacture of a known or naturally-occurring process" is patent-eligible.[365] Like RALIA, PERA 2022 would have established that patent eligibility determinations should be made without regard to "any consideration in [35 U.S.C.] section 102, 103, or 112" including "whether a claim element is known, conventional, routine, or naturally occurring."[366]

As in First Tillis-Coons proposal in the 116th Congress, PERA 2022 contains a closed list of the types of inventions that would not be patent-eligible when claimed "as such," specifically:

> (A) A mathematical formula, apart from a useful invention or discovery.
>
> (B) A process that—
>
> (i) is a non-technological economic, financial, business, social, cultural, or artistic process;
>
> (ii) is a mental process performed solely in the human mind; or
>
> (iii) occurs in nature wholly independent of, and prior to, any human activity.
>
> (C) An unmodified human gene, as that gene exists in the human body.
>
> (D) An unmodified natural material, as that material exists in nature.[367]

In effect, PERA would have abrogated the *Alice/Mayo* framework, and replaced the three judicially created ineligible categories with this closed statutory list of narrower ineligible categories.[368]

While both PERA 2022 and RALIA 2022 would have expanded the scope of patent-eligible subject matter, PERA's changes are generally more limited than RALIA's. This is because the list of patent-ineligible categories in PERA 2022 (mathematical formulae, non-technological

[362] H.R. 5874, 117th Cong. § 7.

[363] S. 4734, 117th Cong. § 2.

[364] *Id.* § 2(a)(1)(B).

[365] *Id.* § 2(a)(1)(A).

[366] *Id.* § 2(a)(2).

[367] *Id.* For the ineligible "non-technological" processes, PERA 2022 further provided that they would have been eligible if the process was meaningfully "embodied in a machine or manufacture." *Id.* PERA 2022 also explained that a human gene or natural material would have been considered "modified" (and thus patent-eligible) if it was "isolated, purified, enriched, or otherwise altered by human activity." *Id.*

[368] *See id.* (providing that the four statutorily eligible categories would be "subject only to the [listed] exclusions").

processes, et al.) was broader than RALIA 2021's single exception to patent eligibility (for wholly mental or naturally occurring inventions). In other words, while both bills would have resulted in more patent-eligible inventions than current law, the increase would have been greater under RALIA 2021. For example, a non-technological business method would have been eligible under RALIA 2021, but ineligible under PERA 2022.

The 118th Congress

In the 118th Congress, new versions of RALIA and PERA were introduced. In the House, Representative Massie introduced the Restoring America's Leadership in Innovation Act of 2024 (RALIA 2024), which proposed to amend Section 101 in the same way as the earlier versions of RALIA discussed above.[369]

In the Senate, Senator Tillis introduced S. 4734, the Patent Eligibility Restoration Act of 2023 (PERA 2023).[370] PERA 2023 added a new findings section expressing the view that patent-eligible subject matter law "requires significant modification and clarification" and that the legal status quo is marked by "confusion and a lack of consistency."[371]

Like PERA 2022, PERA 2023 would have added a new definition of utility and provided that Section 101 determinations should be made independently of considerations under Sections 102, 103, and 112 of the Patent Act.[372] PERA 2023 would have (like PERA 2022) effectively abrogated the *Alice*/*Mayo* framework, providing that "any useful process, machine, manufacture, or composition of matter" is patent-eligible subject only to a closed statutory list of ineligible categories.[373] PERA 2023's patent-ineligible categories also remained mostly the same as the previous version. Specifically, mathematical formulae, purely mental or natural processes, unmodified human genes, and unmodified natural material would have been ineligible under both versions of PERA.[374]

PERA 2023's provisions on ineligible processes varied from those in PERA 2022. The earlier bill would have prohibited patenting a "non-technological economic, financial, business, social, cultural, or artistic process" unless that process "is embodied in a machine or manufacture," but not if "the machine or manufacture is recited in a patent claim without integrating . . . the steps of the process that the machine or manufacture perform."[375] PERA 2023 would have made patent-ineligible any "process that is *substantially* economic, financial, business, social, cultural, or artistic," even if a step in the process "refers to a machine or manufacture."[376] That said, if the process "cannot practically be performed without the use of a machine or manufacture" then it would have been patent-eligible.[377]

[369] Restoring America's Leadership in Innovation Act of 2024, H.R. 8134, 118th Cong., § 7 (2024).

[370] Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. (2023).

[371] *Id.* § 2.

[372] *Id.* § 3(a).

[373] *Id.* § 3(a)(2).

[374] *Compare id.* with S. 4734, 117th Cong. § 2(a)(2). Like PERA 2022, PERA 2023 made clear that—contrary to the result in the *Myriad* case—isolation, purification, or other human alteration sufficed to make natural material and human genes "modified" and therefore patent eligible. *See* S. 2140, 118th Cong. § 3(a)(2).

[375] *See* S. 4734, 117th Cong. § 2(a)(2).

[376] *See* S. 2140, 118th Cong. § 3(a)(2) (emphasis added).

[377] *Id.*

Representative Kiley introduced a bill substantially identical to PERA 2023 in the House as the Patent Eligibility Restoration Act of 2024.[378]

Conclusion

The Supreme Court's 2010s decisions on patent-eligible subject matter have inspired a robust debate among patent law stakeholders as to whether the Court's jurisprudence in this area advances or harms innovation. Actions by lower federal courts, the USPTO, and Congress have responded to the Supreme Court's decisions in various ways, including proposed statutory reforms introduced in the 116th and subsequent Congresses.

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Disclaimer

[378] H.R. 9474, Patent Eligibility Restoration Act of 2024, 118th Cong. (2024).