A BRIEF INTRODUCTION TO PATENT LAW AND 35 U.S.C. § 101

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Executive Summary: A *patent is a property right granted to an inventor that allows the inventor (or assignee) to exclude others from "making, using, offering for sale, or selling" the invention for a limited time. Patents play an essential role in the economy by creating limited legal monopolies for inventors and developers, which incentivizes technological genius, innovation, and production. In exchange for these legal monopolies, patent owners disclose their inventions to the world—contributing to continued advancement in science, engineering, medicine, and more. Over the years, both Congress and the Supreme Court have heavily influenced the patent doctrine. In 2012, patent law received a comprehensive overhaul with the passage of the Leahy-Smith American Invents Act (AIA) which sought to bring America in line with international patentability standards and make the patent system more objective, transparent, and simple. Today, continuing and rapid advancements in science and technology have drawn increasing and broader attention to patent law.*

I. WHAT IS A PATENT?

A patent is an exclusive right granted by the federal government to "exclude others making, using, offering for sale, or selling" an invention throughout the United States and to exclude others from importing the invention into the United States.[1] A patent does not give the inventor an affirmative right to make, use, or sell the invention.[2] Patents fall into one of three categories: utility patents, design patents, and plant patents.[3] Utility patents, which are the concern of most patent law proceedings, "protect[] the way an article is used and works" and issue for a period of twenty years from the filing date of the patent application.[4] Design patents "protect[] the way an article looks" and issues for a period of fifteen years.[5] Plant patents generally protect "distinct and new variet[ies] of plant[s]."[6] After a patent term expires, the patent owner loses the legal monopoly, and the patented subject matter becomes part of the public domain—meaning others are free to make, use, and sell the relevant products or process in the free market.[7]

Modern patent documents consist of two main parts: the specification and the claims.[8] As the Federal Circuit succinctly stated, "[s]pecifications teach. Claims claim."[9] The specification contains the disclosure of the invention which is used to teach the

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[1] 35 U.S.C. § 154.

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

[3] MPEP 1502.01 (9th ed. Rev. 10, June 2020).

[4] *Id.*

[5] *Id.*

[6] MPEP 1601 (9th ed. Rev. 10, June 2020).

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

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

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

reader about the particulars of the invention.[10] However, the specification is not a "how-to" guide instructing the average person how to make or perform the invention but rather contains only enough detail for a person skilled in the art to carry out the invention.[11] In contrast, claims, which are "considered to be the most important part of the patent document," set the legal boundaries of the invention and precisely define the patentee's property rights.[12]

II. HOW DO I GET A PATENT?

The patent application process, which is known as patent prosecution, starts when an inventor files a patent application with the United States Patent and Trademark Office (USPTO).[13] After the application is received, it is sent to a particular art unit and Examiner who reviews the patent for compliance with the patent laws, namely, subject matter eligibility,[14] novelty,[15] nonobviousness,[16] and sufficient disclosure.[17] Patent prosecution generates a prosecution history, which refers to the record of all communications between the USPTO and the patentee regarding a particular filing.[18] The USPTO awards patents for *new* inventions; that is, patents cannot issue for concepts and objects already in the public domain.[19] "Prior art" is the term used to refer to all inventions, writings, and patents that came before and are related to a particular application.[20] For the patent to issue, it must be distinguishable from the prior art and meet all other statutory requirements.[21]

Three primary statutory requirements of patent eligibility include novelty, non-obviousness, and subject matter.[22] For an invention to be novel, it cannot have been disclosed in a patent, described in a printed publication, in public use, on sale, or otherwise available to the public prior to its effective filing date.[23] Similarly, a patentable invention must be non-obvious—that is, readily apparent or easily conceivable to a person of ordinary skill in the relevant field.[24] Finally, a patentable invention must refer

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[10] *Id.* at 1122.
[11] Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005).
[12] *Id.* at 1118, 1121.
[13] *See* Joshua Scheufler, *Patent*, 27 TEX. INTELL. PROP. L.J. 139, 140–41 (2019) (detailing the PTO process). *See Trademark, Patent, or Copyright?*, U.S. PAT. & TRADEMARK OFF. (Oct. 15, 2019, 09:54 AM), https://www.uspto.gov/trademarks-getting-started/trademark-basics/trademark-patent-or-copyright (explaining the difference between a patent and a copyright).
[14] 35 U.S.C. § 101.
[15] 35 U.S.C. § 102.
[16] 35 U.S.C. § 103.
[17] 35 U.S.C. § 112.
[18] Karen Millane Whitney, *Sources of Patent Prosecution History Must Not Violate Public Notice Requirement*, 32 Seton Hall L. Rev. 266, 266–68, 268 n.6 (2001).
[19] *See* Eileen M. Kane, *Patent Ineligibility: Maintaining a Scientific Public Domain*, 80 ST. JOHN'S L. REV. 519, 540 (2006) (explaining the public domain must be protected by not awarding patents to material already within the public domain).
[20] Whitney, *supra* note 18, at 269–70.
[21] *Id.* at 270 n.18.
[22] 35 U.S.C. §§ 101, 102, 103.
[23] 35 U.S.C. § 102(a).
[24] 35 U.S.C. § 103.

to patentable subject matter, which is defined by statute as a "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[25] Typically, subject matters that are not patentable include laws of nature,[26] natural phenomena,[27] and abstract ideas.[28]

III. ORIGINS OF PATENT LAW AUTHORITY

Patent law finds its basis in the United States Constitution, which granted Congress the power "[t]o promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[29] This clause, known as the Patent and Copyright Clause, is viewed both as a designation of an enumerated power to Congress and as a limitation on that power; specifically, the Constitution gave Congress the power to "grant[] *exclusive rights* for *limited times*."[30] This means patents only grant the right to exclude—thus giving its holder a legal monopoly—without other rights, and those rights must expire after some period of time. Congress has exercised its power to promote the sciences with many different patent laws, from the Patent Act of 1790,[31] its first patent statute, to the 2013 Leahy-Smith America Invents Act (AIA),[32] the first significant overhaul to the patent system in over fifty years.

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

The AIA made significant changes to the operation of the patent system and the ways in which entities and inventors may challenge a patent's validity. One major change was the shift from a "first-to-invent" system to a "first-to-file" system.[33] Under the previous system, interference proceedings resolved conflicts concerning priority to determine who conceived of an invention first. The new system eliminated interference proceedings and instead put emphasis on the inventor who filed first.[34]

The AIA also expanded the scope of prior art to include any public disclosure, including use, on sale, or otherwise available to the public anywhere in the world in any

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[25] 35 U.S.C. § 101.

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

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

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

[29] U.S. CONST. art. I, § 8, cl. 8.

[30] NARD, *supra* note 2, at 18.

[31] Act of Apr. 10, 1790, ch. 7, 1 Stat. 109.

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

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

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

language prior to the effective filing date of the claimed invention.[35] However, the AIA also created a statutory exception for inventor or third-party disclosures made one year or less before the effective filing date.[36]

The AIA also created a process for anonymous third-party submissions to bring to the attention of the USPTO any printed publication prior art that bears on the patentability of a pending application.[37] Finally, the AIA has altered some patent infringement defenses by broadening the prior use defense, eliminating the failure to disclose the best mode as a defense, and prohibiting a failure to get advice of counsel to prove willful infringement.[38] In addition, the creation of the United States Court of Appeals for the Federal Circuit (Federal Circuit) as the court of appeal with exclusive subject matter jurisdiction over patents has had a profound effect on the American patent system.[39]

V. PATENT LAW JUDICIAL BODIES AND PROCEEDINGS

The Federal Circuit, as mentioned, has exclusive subject matter jurisdiction over patent appeals.[40] The Federal Circuit hears patent appeals from federal district courts, the International Trade Commission (ITC), and the Patent Trial and Appeals Board (PTAB).[41] In 2020, over sixty percent of the Federal Circuit docket consisted of patent related appeals with thirty-eight percent coming from the USPTO, twenty one percent coming from district courts, and four percent coming from the ITC.[42]

Under the AIA, the USPTO has substantially expanded its role in adjudicating the validity of patent claims. The Act created two new types of post-grant proceedings: Post-Grant Review[43] (PGR) and Inter Partes Review[44] (IPR). PGRs review the validity of a patent that has recently issued, allowing *anyone* to challenge a patent's validity within nine months of issuance on any ground.[45] The PTAB will grant review if it believes it is "more likely than not" at least one of the challenged claims is unpatentable on grounds such as subject matter, novelty, public use, or sale.[46] IPRs, on the other hand, permit challenges of a patent's validity after nine months from issuance or, if a party initiated a PGR

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[35] 35 U.S.C. § 102(a)(1).
[36] § 102(b)(1).
[37] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, § 8 (2011).
[38] 35 U.S.C. §§ 273(a), 298 (adding manufacturing and commercial processes as viable prior use defenses, and barring failure to get advice of counsel as evidence of willful infringement).
[39] Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982); *see* NARD, *supra* note 2,at 26–29 (discussing some of the reasons for the creation of the Federal Circuit and its impact on the American patent system, especially providing uniformity to the U.S patent system).
[40] 28 U.S.C. § 1295(a).
[41] 28 U.S.C. § 1295(a); *see* NARD, *supra* note 2, at 42–43, (explaining that appeals to the Federal Circuit fromPTAB may arise from the patent prosecution process, or from patent review proceedings such as Inter Partes and Post Grant Reviews).
[42] APPEALS FILED, BY CATEGORY, UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT (2020), http://www.cafc.uscourts.gov/sites/default/files/the-court/statistics/04_-_Caseload_by_Category.pdf.
[43] 35 U.S.C. § 321.
[44] 35 U.S.C. § 311.
[45] 35 U.S.C. § 321(c).
[46] 35 U.S.C. § 324(a).

proceeding, after the PGR terminates.[47] The scope of the challenge in an IPR is narrower than a PGR: grounds for invoking IPR are limited novelty and obviousness and with patents and printed publications.[48] Further, the court will not authorize an IPR unless there is a reasonable likelihood that the petitioner will prevail.[49] The decisions to institute both PGRs and IPRs are "final and not appealable,"[50] but once instituted, a party may appeal an adverse result to the Federal Circuit. These two new methods of review, particularly IPRs, have been very popular due to their economy and efficiency for challenging patents.[51]

VI. Subject Matter Eligibility under 35 U.S.C. § 101

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

From 1981-2010, after favorable Supreme Court decisions held software patents valid, the patent system experienced a flood of software and software related patents.[56] After enjoying decades of flexibility in the granting of patent applications for these kinds of patents, this area of law became more restricted following a wave of additional Supreme Court decisions. In 2010, the Supreme Court held that business methods are patentable but did not explicitly state whether software is patentable subject matter.[57] Just four years later, in *Alice Corp. v. CLS Bank*[58] the Supreme Court determined that a patent for a software designed to mitigate settlement risks was invalid as unpatentable subject matter.[59]

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[47] 35 U.S.C. § 311(c).
[48] 35 U.S.C. § 311(b).
[49] 35 U.S.C. § 314(a).
[50]35 U.S.C. §§ 324(e), 314(d).
[51] CRAIG ALLEN NARD, THE LAW OF PATENTS 45 (5th ed. 2020).
[52] 35 U.S.C. § 101.
[53] Diamond v. Diehr, 450 U.S. 175, 185 (1981).
[54] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013); Alice Corp. Pty. Ltd. v. CLS Bank International, 573 U.S. 208, 218 (2014).
[55] Jordan Nimitz, *Shattering the Looking Glass: How Section 101 Revision Could Save FinTech from Alice*, 30 Fed. Cir. B.J. 55, 66 (2020).
[56] *Diamond*, 450 U.S. at 192 (holding that "when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect . . . than the claim satisfies the requirements of § 101").
[57] Bilski v. Kappos, 561 U.S. 593, 606–07(2010).
[58] *Alice,* 573 U.S. at 208.
[59] *Id.* at 226–27.

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

VII. *Alice/Mayo* Framework for Deciding Patent Subject Matter Eligibility

In deciding *Mayo* and *Alice* the Supreme Court articulated a two-step test for determining whether an application is directed to a judicial exception itself, or a patent-eligible application of the judicial exception.[65] This patent-eligibility framework is commonly referred to as the *Alice/Mayo* test. Step one of this test is to determine whether the claims are directed to a patent ineligible concept or judicial exception.[66] If the claims are directed to a judicial exception, step two is to determine whether the claims recite additional elements that amount to significantly more than the judicial exception thereby transforming the nature of the claim into a patent eligible application.[67] The Supreme Court has described the second part of the test as the "search for an 'inventive concept.'"[68] Following this decision, courts have experienced great difficulty in applying the Section 101 analysis, especially to business and diagnostic method patents because of the unworkability of the test articulated by the Supreme Court.[69]

VIII. The Unpredictable and Unstable Section 101 Doctrine in Practice

The confusion in applying the *Mayo/Alice* test for patent eligible subject matter is apparent in recent Federal Circuit cases.[70] In *American Axle & Manufacturing, Inc. v.*

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[60] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
[61] *Mayo Collaborative Services*, 566 U.S. at 92.
[62] *Myriad Genetics, Inc.*, 569 U.S. at 591.
[63] *Id.* at 594–95.
[64] Joseph J. Koipally, et al, *Patent-Eligible Subject Matter in the Life Sciences in the Unites States*, 16 INTELLECTUAL PROP. J. JAPAN 20, 23 (2019).
[65] Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 217–18 (2014) (citing *Mayo*, 566 U.S. 66).
[66] *Id.* at 305.
[67] *Id.* at 217–18.
[68] *Id.* (citing *Mayo*, 566 U.S. at 72–73).
[69] Annal D. Vyas, *Alice in Wonderland v. CLS Bank: The Supreme Court's Fantastic Adventure into Section 101 Abstract Idea Jurisprudence*, 9 AKRON INTELL. PROP. J. 1, 18 (2015).
[70] Am. Axle & Mfg., Inc. v. Neapco Holdings, LLC, 967 F.3d 1285 (Fed. Cir. 2019); Illumina, Inc. v. Ariosa Diagnostic, Inc., 952 F.3d 1367 (Fed. Cir. 2020); Berkheimer v. HP Inc., 881 F.3d 1360 (Fed. Cir. 2018).

Neapco Holdings LLC,[71] the Federal Circuit examined whether a patent for manufacturing a propeller shaft with liners that attenuate vibrations is patent eligible subject matter.[72] Applying step one of the *Alice/Mayo* test, the court determined that the claim covered patent ineligible laws of nature because it was a straightforward application of Hooke's Law.[73] In applying the second step, the court found that the patent was merely a "well-understood, conventional activity already engaged in by the scientific community."[74] This case added further uncertainty to the *Alice/Mayo* framework by alluding to an enablement requirement to the section 101 inquiry, when enablement is meant to be analyzed under section 112.[75] Additionally, the Federal Circuit denied rehearing of the case *en banc* by a 6–6 split decision which illuminates the confusion that the federal circuit is experiencing in applying Supreme Court precedent.[76]

In *Illumina, Inc. v. Ariosa Diagnostics, Inc.*,[77] the court analyzed the eligibility of a patent directed to determining if a fetus has down syndrome by detecting fetal DNA in a mother's bloodstream.[78] The Court acknowledged that under *Mayo*, diagnostic methods are patent ineligible subject matter, but notes that this case is "a method of preparation case."[79] In completing the *Alice/Mayo* test, the court found that the patent was a natural phenomenon, which is patent ineligible subject matter.[80] Under the second step of the test, however, the court found the claims "are not directed to that natural phenomenon but rather to a patent eligible method that utilizes it" because the process was for more than just observing fetal DNA, it altered the DNA fragments in samples to prepare the sample for testing.[81]

Additionally, recent Federal Circuit cases have altered the early pleading stages of a trial.[82] In *Berkheimer v. HP, Inc.*,[83] the Federal Circuit held that a determination of whether a claim is well-understood and conventional under step two of the *Alice/Mayo* framework is a question of fact.[84] The court in *Aatrix Software Inc. v. Green Shades Software. Inc.*[85] found that the second step of the *Alice/Mayo* test "cannot be answered adversely to the patentee based on the sources properly considered in a motion to dismiss."[86] These cases have led to factual determinations taking a more prominent role in determining patentable subject matter and made the application of the Federal Rules of Civil

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[71] 967 F.3d 1285 (Fed. Cir. 2019).
[72] *Id.* at 1289.
[73] *Id.* at 1291.
[74] *Id.* (quoting *Mayo*, 566 U.S. at 79–80).
[75] Daryl Lim, *The Influence of* Alice, 105 MINN. L. REV. 345, 359–60 (2021).
[76] Lim, *supra* note 75, at 360 ("When the Federal Circuit, an appeals court created to develop consistent interpretations and applications of patent law, is itself divided on how to apply Supreme Court subject matter eligibility precedent, a fundamental aspect of the U.S. patent system is at risk.").
[77] 952 F.3d 1367 (Fed. Cir. 2020).
[78] *Id.* at 1369.
[79] *Id.* at 1371.
[80] *Id.*
[81] *Id.* at 1372.
[82] Berkheimer v. HP Inc., 881 F.3d 1360 (Fed. Cir. 2018); Aatrix Software, Inc. v. Green Shades Software, Inc., 882 F.3d 1121 (2018).
[83] 881 F.3d 1360 (Fed. Cir. 2018).
[84] *Id.* at 1368.
[85] 882 F.3d 1121 (Fed. Cir. 2018).
[86] *Id.* at 1128.

Procedure more standard in pretrial motions for summary judgment or judgment as a matter of law.[87] These cases have caused a significant reduction in the granting of summary judgment motions and motions to dismiss in cases where patentable subject matter is at issue.[88]

IX. Recent Cases & Further Reading

The Supreme Court recently found a portion of the AIA unconstitutional under the Appointments Clause. In *Arthrex, Inc. v. Smith & Nephew, Inc.*,[89] the Court determined that the PTAB's Administrative Panel Judges (APJ's) are principal officers, and because the President does not appoint these officers the position violates the Appointment Clause.[90] To remedy this constitutional violation, the Court held that the Director of the USPTO, a principal officer that the President appoints and the Senate confirms, must be able to review any and overturn any APJ decision, making them more directly accountable.[91]

In 2020, the PTAB issued a precedential decision, *Apple v. Fintiv*,[92] which set forth six factors to guide the PTAB's discretion to deny institution of an IPR.[93] In patent litigations, a patent owner generally files an infringement case against an alleged infringer in district court. The alleged infringer will frequently file a request with the PTAB to institute an IPR to review the patent-in-suit's validity in parallel with the district court proceedings. District courts may or may not stay the district court case pending institution and final written decision from the PTAB. The PTAB has discretion to deny institution of an IPR, and *Apple v. Fintiv* provides guidance on when that discretion should be exercised.[94] The six factors that the PTAB applies are: (1) whether the district court granted a stay or may grant a stay if the Board institutes the IPR, (2) the proximity of the district court's trial date to the Board's issuance of a final written decision, (3) investment in the district court proceeding by the court and both parties, (4) overlap between the issues raised in the petition for IPR and the district court proceeding, (5) whether the petitioner and defendant are the same in the district court proceeding, and (6) other circumstances that influence the Board's exercise of discretion.[95] These factors focus on what stage the district court proceeding is in at the time of institution with the goal of preventing judicial inefficiency by trying the same case in multiple forums.

Senators Leahy and Cornyn recently introduced a new bill, the Restoring the American Invents Act, which is intended to make the patent system more transparent and

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[87] Li Zhang, *Alice Gets a Haircut: Berkheimer and Aatrix Restore Factual Inquiry to Patent Subject Matter Eligibility Under Section 101*, 101 BERKLEY TECH. L. J., 1081, 1099 (2019).
[88] Paul D. Ackerman, *Six Years After* Alice*, Are We Any Closer to Clarity on Patent Eligibility?*, THOMAS REUTERS WESTLAW (Nov. 30, 2020) (noting that the granting of motions to dismiss has dropped from a 70% success rate to a 45% success rate).
[89] 141 S. Ct. 1970 (2021).
[90] *Id.* at 1982.
[91] *Id.* at 1987–88.
[92] IPR2020-00019, Paper 11 (Mar. 20, 2020) (precedential).
[93] *Id.* at 6.
[94] *Apple*, IPR 2020-00019, Paper 11 at 6.
[95] *Id.*

accessible for both small businesses and large manufacturers.[96] One of the biggest changes set forth in this bill is the elimination and replacement of the *Fintiv* factors with a new statutory framework for instituting IPRs.[97] The bill would require the USPTO to institute an IPR if it meets the statutory standards set forth in the bill, while allowing discretion to deny institution only in narrow circumstances.[98] Given that the PTAB has used *Fintiv* to discretionarily deny institution for about forty percent of petitions in 2021, this change in institution requirements would have a major impact on the IPR process.[99]

The *Fintiv* ruling has also been challenged in appeals to the Supreme Court.[100] In Apple's Supreme Court appeal, it argues that the *Fintiv* rule that allows discretionary denials of IPR institution "undermines the role of IPR in Congress's effort to improve the integrity of the patent system" and leads to arbitrary results based on PTAB speculation.[101] Apple argues that the practice is unlawful under the AIA and was adopted without the proper notice-and-comment rulemaking that is required under the Administrative Procedure Act (APA).[102] Mylan also petitioned the Supreme Court on similar grounds, arguing that the *Fintiv* factor test is unlawful because the USPTO Director exceeds the authority delegated to him by Congress under the AIA.[103] The future of the *Fintiv* rule is unclear in light of these petitions and recently introduced Restoring the America Invents Act bill.

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[96] *Leahy and Cornyn Introduce Bipartisan Bill to Support American Innovation and Reduce Litigation*, PATRICK LEAHY (Sept. 29, 2021) https://www.leahy.senate.gov/press/leahy-and-cornyn-introduce-bipartisan-bill-to-support-american-innovation-and-reduce-litigation.

[97] Josh Landau, *Leahy and Cornyn Introduce Bill to Restore the America Invents Act*, PATENT PROGRESS (Oct. 1, 2021), https://www.patentprogress.org/2021/10/01/leahy-and-cornyn-introduce-bill-to-restore-the-america-invents-act.

[98] IPWatchdog, *Looming Leahy Bill Would End* Fintiv *Practice at PTAB*, IPWATCHDOG (Sept. 23, 2021) https://www.ipwatchdog.com/2021/09/23/looming-leahy-bill-end-fintiv-practice-ptab/id=138020/.

[99] *PTAB Uses Discretion*, Fintiv *to Deny Petitions 38% in 2021 to Date*, UNIFIED PATENTS (Sept. 22, 2021), https://www.unifiedpatents.com/insights/2021/9/22/an-early-look-at-the-ptabs-use-of-fintiv-and-discretion-discretionary-denials-through-september-2021.

[100] Petition for Writ of Certiorari at 2, *Apple Inc. v. Optis Cellular Tech., LLC*, 2020 WL 7753630 (Dec. 21, 2020) (No. 2021-1043). Petition for Writ of Certiorari at 21–26, *Mylan Lab'ys. Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375 (2021) (No. 2021-1071).

[101] *Id.*

[102] *Id.* at 3.

[103] Petition for Writ of Certiorari at 21–26, *Mylan Lab'ys. Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375 (2021) (No. 2021-1071).