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Inter Partes Review of Patents: Innovation Issues

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Summary

The Leahy-Smith America Invents Act (AIA) of 2011 introduced inter partes review proceedings (IPRs) into the patent system. IPRs allow the U.S. Patent and Trademark Office (USPTO) to revisit—and possibly cancel—a patent the agency had previously allowed. Under these proceedings, any individual may petition the USPTO to assert that a granted patent is invalid in view of earlier patents or printed publications. A petitioner must demonstrate that there is a "reasonable likelihood" that he would prevail for the IPR to begin. Should the USPTO's Patent Trial and Appeal Board (PTAB) grant the petition, it will preside over a trial-like proceeding before a panel with at least three members. These procedures include the use of witnesses, the opportunity for limited discovery, and an oral hearing prior to a decision on the merits. IPRs must ordinarily be completed within one year and may result in patent claims being upheld, invalidated, or confirmed as amended.

IPR proceedings are arguably the most impactful of the numerous reforms made by the AIA. To many, their unexpected popularity suggests that Congress met its objectives in providing an expedient and cost-effective means for challenging patents that the USPTO erroneously issued. These proceedings potentially harness the technical expertise of the USPTO, improve patent quality, are less costly than litigation in the district courts, and can confirm the validity of patents that meet the statutory standards.

Others are critical of these proceedings. Many members of the patent community view IPRs as being biased against patent owners and believe that they have significantly eroded the confidence of innovative industry in the U.S. patent system. They observe that most patents involved in IPRs are also subject to litigation in the federal courts, a development that increases the expense and complexity of patent enforcement. They also believe that the prompt pace of these proceedings, as well as the possibility of multiple IPR petitions being filed against a single patent, may challenge patent owners.

Stakeholders have considered numerous possible reforms to the structure of IPR proceedings. In the 115th Congress, the STRONGER Patents Act of 2017 (S. 1390) would require the PTAB to give claim terms their ordinary meaning, in contrast to the "broadest reasonable interpretation" in keeping with USPTO rules. S. 1390 would also require that patent challengers prove invalidity by "clear and convincing" evidence, in contrast to the "preponderance of the evidence" standard that currently applies. And the bill would limit use of IPR proceedings to individuals and enterprises with a demonstrated adverse relationship to the challenged patent. S. 1390 was read twice and referred to the Committee on the Judiciary on June 21, 2017.

Other aspects of IPR law and practice remain topics of debate. Some stakeholders assert that even though the AIA provides patent proprietors with the opportunity to amend their claims during an IPR, the PTAB rarely allows them to do so. Others observe that the PTAB often initiates IPRs on a smaller number of claims than are challenged. They believe that such a "partial initiation" can create confusion about claims that were not considered by the PTAB. Some commentators express concern that the increased number of appeals from the USPTO to the Federal Circuit may be frustrating the congressional goal of providing the court with a well-rounded caseload. Critics of the PTAB also believe that IPRs violate the constitutional separation of powers principle and the Seventh Amendment right to a jury trial.

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Introduction

Seeking to provide a fair and effective mechanism for members of the public to challenge suspect patents, Congress has expressed interest in administrative review proceedings at the U.S. Patent and Trademark Office (USPTO) for more than four decades.[1] Most recently, the Leahy-Smith America Invents Act (AIA)[2] introduced three new avenues for patent challenges: a "transitional program for covered business methods,"[3] post-grant review,[4] and inter partes review.[5] Each of these proceedings allows the USPTO to revisit—and possibly cancel—a patent the agency had previously allowed. The third of these proceedings, commonly known as IPRs, has proven both the most widely used and the most controversial.[6]

In brief, IPR proceedings allow individuals to petition USPTO to assert that a granted patent is invalid in view of earlier patents or printed publications.[7] A petitioner must demonstrate that there is a "reasonable likelihood" that he would prevail for the IPR to begin.[8] Should the USPTO's Patent Trial and Appeal Board (PTAB) grant the petition, it will preside over the IPR and ordinarily reach a final determination,[9] which may be appealed to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit).[10] If the contested patent survives the IPR, the petitioner may not challenge it in later civil actions or other administrative proceedings based upon issues that were "raised or reasonably could have been raised" during the IPR.[11]

The unexpected popularity of IPR proceedings may suggest that Congress met its objectives in providing an expedient and cost-effective means for challenging patents that the USPTO may have issued erroneously.[12] These proceedings potentially harness the technical expertise of the USPTO, improve patent quality, are less costly than litigation, and can confirm the validity of

[1] See N. Thane Bauz, "Reanimating U.S. Patent Reexamination: Recommendations for Change Based Upon a Comparative Study of German Law," *Creighton Law Review*, vol. 27 (1993), p. 945.

[2] P.L. 112-29, 125 Stat. 284 (2011).

[3] Ibid. at §18. This provision was not codified in Title 35 of the U.S. Code.

[4] 35 U.S.C. §§321-329.

[5] 35 U.S.C. §§311-319.

[6] See, e.g., Nicholas J. Doyle, "Confirmation Bias and the Due Process of Inter Partes Review," *IDEA: The Journal of the Franklin Pierce Center for Intellectual Property*, vol. 57 (2016), p. 29. USPTO predictions about the number of IPR filings were reportedly exceed by 22.5% in 2013, 191% in 2014, and 70.6% in 2015. See Douglas B. Wenzel, "Stays Pending Inter Partes Review: Not in the Eastern District of Texas," *Journal of the Patent and Trademark Office Society*, vol. 98 (2016), pp. 120, 126. A record number of IPR and related petitions—totaling 566—were filed at the USPTO in the first three months of 2017. Michael Loney, "PTAB Q1 Rankings: 190 Petitions in March Round Out Record Quarter," *Managing Intellectual Property*, April 11, 2017, http://www.managingip.com/TopicListArticle/3709008/Trade-marks-topics/PTAB-Q1-rankings-190-petitions-in-March-round-out-record-quarter.html?TopicListId=510.

[7] 35 U.S.C. §311.

[8] 35 U.S.C. §314(a).

[9] 35 U.S.C. §§316(c), 318.

[10] 35 U.S.C. §319.

[11] 35 U.S.C. §315.

[12] See Kammie Cuneo, "A Move Towards Globalization Provides a New Tool to Defend Against Infringement: The Rise of the IPR," *Advocate (Idaho)*, vol. 59 (May 2016), p. 25 (noting that the "patent bar has filed a surprisingly large number of requests" for IPRs).

patents that meet the statutory standards.[13] IPRs have been described as the "new normal,"[14] with some believing that the principal "patent battleground" is shifting away from the federal courts into the PTAB.[15] Further, the high affirmance rate of IPR appeals at the Federal Circuit suggests to many that the PTAB is performing well.[16]

Other concerned observers have been far less sanguine about IPRs. Members of the patent community view IPRs as being "patent owner-unfriendly"[17] and having led to "swift and numerous losses of patent rights."[18] Former Federal Circuit Chief Judge Randall Rader went further, reportedly referring to the PTAB as a patent-killing "death squad."[19] Some believe that IPRs have significantly eroded the confidence of innovative industry in the U.S. patent system.[20] In 2017, the U.S. Chamber of Commerce concluded that the strength of the U.S. patent system had dropped from 1st in the world to 10th place, a shift that was attributed in part to the advent of IPR proceedings.[21]

This report surveys the patent landscape with respect to IPRs. It begins by providing a basic overview of the patent system and the different sorts of patent challenge proceedings available at the USPTO, including IPRs. The report then considers recent legislative proposals to modify the law pertaining to IPRs. It then considers additional issues pertaining to IPRs identified by stakeholders. The report closes with concluding remarks.

Patent System Fundamentals

Individuals and firms must prepare and submit applications to the USPTO if they seek to obtain patent protection.[22] USPTO officials, known as examiners, then assess whether the application merits the award of a patent. Under the Patent Act of 1952, a patent application must include a specification that so completely describes the invention that skilled artisans are able to practice it without undue experimentation.[23] The Patent Act also requires that applicants draft at least one

[13] See W. Michael Schuster, "Invalidity Assertion Entities and Inter Partes Review: Rent Seeking as a Tool to Discourage Patent Trolls," *Wake Forest Law Review*, vol. 51 (Winter 2016), p. 1163 (noting certain of these potential benefits of IPRs).

[14] Andrei Iancu, Ben Haber, and Elizabeth Iglesias, "Inter Partes Review Is the New Normal: What Has Been Lost? What Has Been Gained?," *AIPLA Quarterly Journal*, vol. 40 (Fall 2012), p. 539.

[15] Yasser El-Gamal, Ehab M. Samuel, and Peter D. Siddoway, "The New Battleground: One Year of Inter Partes Review Under the America Invents Act," *AIPLA Quarterly Journal*, vol. 42 (Winter 2014), pp. 39, 67.

[16] See, e.g., Matt Levy, *Death to All Patents? Really? Why Inter Partes Review Shouldn't Be Controversial*, November 6, 2015, http://www.ipwatchdog.com/2015/11/06/death-to-all-patents-inter-partes-review/id=62935/.

[17] Amanda Murphy, Stacy Lewis, and Deborah Herzfeld, et al., "Adjusting for the New Normal: Thoughts on Enhancing the Possibility for Success for the Patent Owner in an AIA Post-Grant Proceeding," *Buffalo Intellectual Property Law Journal*, vol. 11 (2015), pp. 258, 259.

[18] Ibid. at 259 (noting the "unexpected boom in post-grant proceedings following the AIA").

[19] Tony Dutra, "Rader Regrets CLS Bank Impasse, Comments on the Latest Patent Reform Bill," *Bloomberg Law News*, October 29, 2013, https://www.bna.com/rader-regrets-cls-n17179879684/.

[20] Gene Quinn, *The Top 3 Reasons the U.S. Patent System in Decline*, April 26, 2017, http://www.ipwatchdog.com/2017/04/26/top-3-reasons-u-s-patent-system-decline/id=82571/ (deeming IPRs as making "infringing patents a more economical choice, while making it more costly for innovators to obtain and keep the protection they need to make innovating a worthwhile endeavor").

[21] U.S. Chamber of Commerce, *The Roots of Innovation*, U.S. Chamber International IP Index, February 2017, http://www.theglobalipcenter.com/wp-content/uploads/2017/02/GIPC_IP_Index_2017_Report.pdf.

[22] 35 U.S.C. §111.

[23] 35 U.S.C. §112(a).

claim that particularly points out and distinctly claims the subject matter that they regard as their invention.[24] The patent acquisition process is commonly known as "prosecution."[25]

While reviewing a submitted application, the examiner will determine whether the claimed invention fulfills certain substantive standards set by the patent statute. Two of the most important patentability criteria are novelty and nonobviousness. To be judged novel, the claimed invention must not be fully anticipated by a prior patent, publication, or other knowledge within the public domain.[26] The sum of these earlier materials is termed the "prior art." To meet the standard of nonobviousness, an invention must not have been readily within the ordinary skills of a competent artisan based upon the teachings of the prior art.[27]

If the USPTO allows the application to issue as a granted patent, the owner or owners of the patent obtain the right to exclude others from making, using, selling, offering to sell, or importing into the United States the claimed invention.[28] The term of the patent is ordinarily set at 20 years from the date the patent application was filed.[29] Patent title therefore provides inventors with limited periods of exclusivity in which they may practice their inventions, or license others to do so. The grant of a patent permits inventors to receive a return on the expenditure of resources leading to the discovery, often by charging a higher price than would prevail in a competitive market.

A patent proprietor bears responsibility for monitoring its competitors to determine whether they are using the patented invention. Patent owners who seek to compel others to observe their intellectual property rights must usually commence litigation in the federal courts. Although issued patents enjoy a presumption of validity, accused infringers may assert that a patent is invalid or unenforceable on a number of grounds.[30] The Federal Circuit possesses national jurisdiction over most patent appeals.[31] The U.S. Supreme Court retains discretionary authority to review cases decided by the Federal Circuit.[32]

Administrative Review Proceedings: The Basics

Once the USPTO formally issues a patent, the agency's involvement with that legal instrument ordinarily comes to a close.[33] However, the USPTO may be called upon to reconsider its initial decision to approve a patent application through several administrative review proceedings. Most of these proceedings are revocation proceedings—that is to say, they are primarily used by

[24] 35 U.S.C. §112(b).

[25] John R. Thomas, "On Preparatory Texts and Proprietary Technologies: The Place of Prosecution Histories in Patent Claim Interpretation," 47 *UCLA Law Review* (1999), p. 183.

[26] 35 U.S.C. §102.

[27] 35 U.S.C. §103.

[28] 35 U.S.C. §271.

[29] 35 U.S.C. §154(a)(2).

[30] 35 U.S.C. §282.

[31] 28 U.S.C. §1295(a)(1).

[32] 28 U.S.C. §1254(1).

[33] The USPTO does accept maintenance fees, which are due 3.5, 7.5, and 11.5 years after the grant of the patent. The patent will expire if the maintenance fees are not paid. See 35 U.S.C. §41(b).

individuals who seek to challenge the validity of an issued patent. They include reexamination,[34] inter partes review,[35] post-grant review,[36] and covered business method review.[37]

Reexamination

Under the reexamination statute, any individual, including the patentee, a competitor, and even the USPTO Director, may cite a prior art patent or printed publication to the USPTO.[38] If the USPTO determines that this reference raises a "substantial new question of patentability" with respect to the novelty or nonobviousness of an issued patent, then it will essentially reopen prosecution of the issued patent.[39] Reexamination proceedings are conducted in an accelerated fashion on an ex parte basis—that is to say, as a dialogue between applicant and examiner without extended participation by others. Reexamination may result in a certificate confirming the patentability of the original claims, an amended patent with narrower claims, or a declaration of invalidity of the patent's claims.[40]

Post-Grant Review and Inter Partes Review

The AIA established two new proceedings called post-grant review (PGR)[41] and inter partes review (IPR).[42] Petitioners may challenge validity based on any ground of patentability in a PGR, which applies only to patents with filing dates of March 16, 2013, or later. A request for a PGR must be filed within nine months of the date of patent grant.[43] To initiate a PGR, the petitioner must present information that, if not rebutted, would demonstrate that more likely than not at least one of the claims is unpatentable.[44] The USPTO charges $12,000 to consider a request for a PGR and another $18,000 if the procedure is initiated, with additional fees if a large number of claims are challenged.[45] The patent proprietor is afforded the opportunity to file a preliminary response to the petition asserting that no PGR should be instituted.[46]

If the PGR proceeds, the USPTO's Patent Trial and Appeal Board (PTAB) will conduct the proceeding and reach a final determination,[47] which may be appealed to the federal courts.[48] The patent proprietor may move to amend the patent during the proceedings.[49] A PGR must be completed within one year of its commencement, with an extension of six months possible for

[34] 35 U.S.C. §§302-307.
[35] 35 U.S.C. §§311-319.
[36] 35 U.S.C. §§321-329.
[37] P.L. 112-29 at §18.
[38] 35 U.S.C. §302.
[39] 35 U.S.C. §303.
[40] 35 U.S.C. §307.
[41] P.L. 112-29 at §6(d).
[42] P.L. 112-29 at §6(a).
[43] 35 U.S.C. §321(c).
[44] 35 U.S.C. §324.
[45] 37 C.F.R. §42.15(b).
[46] 35 U.S.C. §323.
[47] 35 U.S.C. §§326(c), 328.
[48] 35 U.S.C. §329.
[49] 35 U.S.C. §326(d).

good cause shown.[50] As well, the individual who commenced the proceeding, along with entities related to him, are barred in the future from raising issues that were "raised or reasonably could have been raised" during the PGR.[51]

IPRs operate similarly, but apply to all granted patents regardless of their filing date. These proceedings came into effect on September 16, 2012. In broad outline, any person who is not the patent owner may file a petition requesting an IPR at least nine months after a patent issues or reissues, or the conclusion of any post-grant review, whichever occurs later.[52] In contrast to a PGR, the basis for requesting an IPR is restricted to patents or printed publications. As a result, patent challenges under an IPR are limited to the patentability issues of novelty and nonobviousness.[53]

Under the AIA, the petitioner must demonstrate that there is a "reasonable likelihood" that he would prevail with respect to at least one claim in order for the IPR to begin.[54] The USPTO charges $9,000 to consider a request for an IPR and another $14,000 if the procedure is initiated, with additional fees if a large number of claims are challenged.[55] Under the time frames established, the effective result is that a patent may be challenged at the USPTO on any basis of any patentability issue within nine months from the date it was issued (via PGR). Thereafter, and throughout its entire term, the patent may be challenged at the USPTO on the grounds of novelty and nonobviousness (via IPR).

Both PGRs and IPRs operate under a trial-like procedure before a panel with at least three members.[56] These procedures include the use of witnesses,[57] the opportunity for limited discovery,[58] and an oral hearing prior to a decision on the merits.[59] In addition, the petitioner and the patent proprietor may terminate these proceedings through settlement.[60]

When establishing PGRs and IPRs, Congress was aware that patents subject to these USPTO proceedings may also be the subject of litigation in federal court. The AIA therefore establishes rules that limit the ability of petitioners to request a PGR and IPR, and also call for stays of litigation in particular circumstances. With respect to PGRs, these proceedings may not be instituted if the petitioner previously commenced litigation challenging the validity of the patent.[61] If the petitioner commences litigation challenging the validity of a patent after he files a PGR petition, that lawsuit is automatically stayed until either the patent owner moves the court to lift the stay, the patent owner asserts that the petitioner infringed the patent, or the petitioner moves the court to dismiss the case.[62] The rules with respect to IPRs are analogous, but in addition an IPR may not be instituted if the petition requesting the proceeding is filed more than

[50] 35 U.S.C. §326(a).

[51] 35 U.S.C. §325(e).

[52] 35 U.S.C. §311.

[53] Ibid.

[54] 35 U.S.C. §314(a).

[55] 37 C.F.R. §42.15(a).

[56] 35 U.S.C. § 6(c).

[57] 35 U.S.C. §§316(a)(5), 326(a)(5).

[58] Ibid.

[59] 35 U.S.C. §§316(a)(10), 326(a)(10).

[60] 35 U.S.C. §§317, 327.

[61] 35 U.S.C. §325(a)(1).

[62] 35 U.S.C. §325(a)(2).

one year after the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent.[63]

Transitional Program for Covered Business Method Patents

The AIA also created a post-grant review proceeding for the review of the validity of certain business method (CBM) patents.[64] This "CBM" proceeding is limited to patents that claim "a method or corresponding apparatus for performing data processing operations utilized in the practice, administration, or management of a financial product or service, except that the term shall not include patents for technological inventions."[65] Only individuals who have been either sued for infringement or charged with infringement of a business method patent may petition the USPTO to commence a CBM. The USPTO charges $12,000 to consider a request for a PGR and another $18,000 if the procedure is initiated, with additional fees if a large number of claims are challenged.[66]

In general, CBMs operate similarly to PGRs.[67] However, CBMs apply to all business method patents regardless of their date of filing or issuance. The AIA further stipulated that a party may seek a stay of litigation related to a CBM, and that the district court's decision may be subject to an immediate interlocutory appeal to the Federal Circuit.[68] This program is subject to a sunset provision that will repeal the program on September 16, 2020.[69] In addition, the statute provided that its business method patent provisions shall not be construed as amending or interpreting categories of patent-eligible subject matter.[70]

Outcomes of PTAB Proceedings

The USPTO maintains a website that presents monthly updates on a variety of statistical measures associated with PTAB trials.[71] As of March 1, 2017, the agency reported that a total of 6,139 IPR, 510 CBM, and 51 PGR petitions had been filed in total. The agency also presents running totals as to the number of petitions granted, settlements, claims confirmed or invalidated, the average length of the proceedings, and other data. The interpretation of these statistical measures has been subject to disagreement, however. Critics of these proceedings assert, for example, that:

> As of April 2016, 4,891 IPR petitions have been filed since the PTAB's inception; of the 943 that have reached a final decision, 72% resulted in every challenged claim being invalidated; 14% resulted in some claims being invalidated; and only 14% resulted in all of the challenged claims being upheld. This is far higher rate of invalidation than in federal court.... And this disparity is all the more striking because in litigation, unlike IPR review,

[63] 35 U.S.C. §315(b).

[64] P.L. 112-29 at §18. This provision was not codified in Title 35 of the U.S. Code.

[65] Ibid. at §18(d)(1).

[66] 37 C.F.R. § 42.15(b).

[67] P.L. 112-29 at §18(a).

[68] Ibid. at §18(b).

[69] Ibid. at §18(a)(2).

[70] Ibid. at §18(e).

[71] USPTO, *AIA Trial Statistics*, https://www.uspto.gov/patents-application-process/appealing-patent-decisions/statistics/aia-trial-statistics.

> patents can be invalidated on grounds aside from novelty and nonobviousness, such as inequitable conduct.[72]

As one academic observes, "[s]tudies also show that the invalidation rate in the district courts is significantly lower (46%) than the current IPR rates."[73]

On the other hand, if one accounts for denials of petitions and other dispositions such as settlement, then PTAB outcomes seem more in keeping with those of the federal courts. As one practitioner explains:

> In 2016, the PTAB instituted review in about 72% of cases, with no claims surviving final written decision in about 67% of cases. Assuming that every instituted case was instituted on every challenged claim (they are not), this would mean that every challenged claim would be killed in only about 48% of cases. Framed differently, on average, at least one challenged claim survives in about 52% of cases.[74]

Innovation Issues

After more than a half-decade of experience with IPRs, some stakeholders have called for modifications to the rules governing IPRs. Legislation introduced on June 21, 2017, the Support Technology and Research for Our Nation's Growth and Economic Resilience (STRONGER) Patents Act of 2017, proposes to make several of these changes. S. 1390 was read twice and referred to the Committee on the Judiciary on June 21, 2017. With reference to the STRONGER Patents Act of 2017 and other sources, this report reviews the principal areas of discussion and debate next.[75]

Claim Construction

Like other sorts of legal instruments, patents do not construe themselves. Patent claims may include words that are susceptible to different reasonable interpretations. Consider, for example, the term "bimonthly." "Bimonthly" may mean either "occurring twice a month" or "occurring every two months."[76] The courts and the PTO must employ an interpretational methodology when they construe terms capable of different meanings. These institutions employ different protocols when they do so, however.[77]

The courts generally attempt to discern the "ordinary and customary" meaning of terms in patent claims, most often in view of the patent's specification and its administrative record before the USPTO (the so-called "prosecution history").[78] On the other hand, during patent acquisition, the

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[72] Robert N. Schmidt and J. Carl Cecere, *MCM Portfolio, LLC v. Hewlett-Packard Co.*, Brief of Amici Curiae Gary Lauder et al. Before the Supreme Court of the United States, May 31, 2016, pp. 9-10, http://www.scotusblog.com/wp-content/uploads/2016/06/15-1330-Revised-Amici-Brief-G-Lauder-and-inventors-1.pdf.

[73] Greg Dolin, "Dubious Patent Reform," *Boston College Law Review*, May 2015, pp. 881, 927.

[74] Richard Lloyd, "Five Years of the Patent Trial and Appeal Board," *IAM*, no. 83 (May/June 2017), http://www.iam-media.com/magazine/issue/83/Roundtable/Five-years-of-the-Patent-Trial-and-Appeal-Board (remarks of attorney Joshua Goldberg).

[75] Portions of this report have been borrowed and adopted from CRS Report R43979, *Patent Litigation Reform Legislation in the 114th Congress*, by Brian T. Yeh.

[76] *Webster's New Collegiate Dictionary* (G. & C. Merriam Co., 1975), p. 110.

[77] See Jason Rantanen, *"Broadest Reasonable Interpretation" and Appellate Review*, August 3, 2016, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2816134.

[78] See, e.g., *Wasta Finance GmbH v. Continental Automotive Sys., Inc.*, 853 F.3d 1272, 1279 (Fed. Cir. 2017).

USPTO accords claim terms their "broadest reasonable interpretation." The agency does so, at least in part, because patent applicants may amend their claims during prosecution in order to achieve more precision and to eliminate ambiguities.[79] In contrast, claims in issued patents may not be amended during litigation in the federal courts.

The AIA did not specify which standard should apply during IPR proceedings. Pursuant to authority granted by the AIA,[80] however, the USPTO promulgated a regulation stating that a "claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears."[81]

In its 2016 decision in *Cuozzo Speed Technologies v. Lee*,[82] the U.S. Supreme Court upheld the USPTO's decision to adopt the "broadest reasonable interpretation" standards in IPRs. The Court observed both that the patent proprietor had the opportunity to amend claims during an IPR and that the USPTO had applied this standard for more than a century.[83] The Court acknowledged that under this bifurcated system, the courts and the USPTO could reach different constructions of the same claim term—and hence reach different conclusions as to the validity of the claim. However, the Court recognized that this possibility had long been the case and reasoned that the agency had rationally employed its rulemaking authority.[84]

In the 115th Congress, the STRONGER Patents Act of 2017 would require the PTAB, in IPR and PGR proceedings, to use the same claim construction standard as the federal courts—that is to say, a construction in accordance with "the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art to which the claimed invention pertains."[85] This legislation would also require the PTAB to consider a prior claim construction by a court in a civil action in which the patent owner was a party.

Most observers agree that the "broadest reasonable interpretation" standard makes invalidation of patents easier in the AIA-established administrative review proceedings than in the federal courts.[86] Former USPTO Director David Kappos has observed that currently, "the speed mandated for post-grant procedures is leading to greater interaction between court interpretations and USPTO interpretations of the same patent claims, and having the USPTO apply a different standard than the courts [for claim construction] is leading, and will continue to lead, to conflicting decisions."[87] However, he notes that there are valid arguments for retaining the broader standard for post-grant proceedings, such as that the "broadest reasonable interpretation" standard "requires patentees to define their claims clearly over the prior art during proceedings" before the USPTO.[88]

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[79] See Joel Miller, "Claim Construction at the PTO—The 'Broadest Reasonable Interpretation ...,'" *Journal of the Patent and Trademark Office Society*, vol. 88 (March 2006), p. 279.

[80] 35 U.S.C. §316(a)(4).

[81] 37 C.F.R. §42.100(b).

[82] 136 S.Ct. 2131 (2016).

[83] Ibid. at 2145.

[84] Ibid. at 2146.

[85] See S. 1390 at §§102(a)(4),103(a)(4).

[86] See, e.g., Tara Feld, "States Hold the Sword to Force "Patent Trolls" Back Under Their Bridges," *University of Illinois Law Review*, 2016, p. 1123.

[87] Statement of David J. Kappos, Former Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, House Committee on the Judiciary, *The "Innovation Act*," hearing on H.R. 3309, 113th Cong., 1st sess., 2013, at 8.

[88] Ibid.

However, some groups oppose the inclusion of these changes to the IPR/PGR claim construction standard in the patent litigation reform bills, arguing that they "will undermine post grant review procedures that have proven to be an effective and useful tool in weeding out the weak patents that are often asserted in the most abusive of patent cases."[89] Technology companies have explained their opposition to the IPR/PGR amendments as follows:

> [T]he changes to the claim construction standard in IPR proceedings ... would eliminate a necessary and significant difference between the court system and USPTO standards for claim construction. In district court, the purpose is to determine liability for patent infringement; whereas the purpose of an IPR proceeding is for the USPTO to ensure its decision to issue a patent was, in fact, correct. The IPR process was amended in the AIA to provide a more streamlined, cost-effective method to challenge patent validity outside the court system. The proposed changes to this process endanger the meaningful progress Congress has made in reducing the burden invalid patents pose to our industry and will only make the process more costly and complex.[90]

Presumption of Validity

Section 282 of the Patent Act affords issued patents a presumption of validity.[91] As a result, patent proprietors do not have to prove that their patents are valid when they assert them in court. Rather, the accused infringer must identify and prove the statutory requirements—such as novelty or nonobviousness—that the asserted patent allegedly does not fulfill. Although the statute does not stipulate the burden of proof to be borne by patent challengers, the courts have set the standard as "clear and convincing evidence."[92] "Clear and convincing evidence" must leave the factfinder with "an abiding conviction" that the truth of the factual contentions is "highly probable."[93] Courts deem this standard to amount to "the deference that is due to a qualified government agency presumed to have properly done its job."[94]

The rules differ in IPR and PGR proceedings. Under the AIA, "the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence."[95] The term "preponderance of the evidence" generally refers to the "degree of relevant evidence that a reasonable person, considering the record as a whole, would accept as sufficient to find that a contested fact is more likely to be true than untrue."[96] This standard reportedly allows patent challengers a greater opportunity for success than would be the case in federal court.[97]

In the 115th Congress, the STRONGER Patents Act proposes to establish a presumption of validity for a previously issued claim during an IPR or PGR proceeding.[98] The STRONGER

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[89] Business Software Alliance (BSA) Letter to Speaker Boehner and Minority Leader Pelosi, July 9, 2015, available at http://www.bsa.org/~/media/Files/Policy/SoftwareInnovation/Letters/07092015InnovationActLetter.pdf, at 1.

[90] Information Technology Industry Council Letter to Senate Judiciary Committee Chairman Grassley and Ranking Member Leahy, June 3, 2015.

[91] 35 U.S.C. §282.

[92] *ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 1354 (Fed. Cir. 2015).

[93] *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984) (citation omitted).

[94] *Forest Laboratories Holdings Ltd. v. Mylan Inc.*, 206 F.Supp.3d 957, 982 (D. Del. 2016) (citation omitted).

[95] 35 U.S.C. §§316(e), 326(e).

[96] *Dominco v. Office of Personnel Management*, 626 Fed. Appx. 270, 271 (Fed. Cir. 2015).

[97] See Aashish Kapadia, "Inter Partes Review: A New Paradigm in Patent Litigation," *Texas Intellectual Property Law Journal*, vol. 23 (2015), pp. 113, 119.

[98] See S. 1390 at §§102(b), 103(b).

Patents Act would also require that the IPR or PGR petitioner demonstrate unpatentability "by clear and convincing evidence."[99]

Standing

Administrative review proceedings that allow patent validity challenges address an issue that some perceive as a shortcoming in the patent system. Absent such proceedings, interested individuals would be unable to challenge the validity of a patent unless they became involved in a "substantial controversy" with the patent's proprietor.[100] The requirement that an immediate, concrete dispute occur between the patent owner and another individual arises because the Constitution vests the federal courts with jurisdiction only where a "case or controversy" exists.[101] This concept is known as the "standing" doctrine.[102]

The "case or controversy" requirement significantly limits the ability of members of the public to challenge the USPTO's decision to grant a patent. Unless the patent proprietor becomes involved in an actual, continuing controversy with another person, that person cannot successfully request that a court determine whether the patent is valid or not. Reticent patent proprietors may therefore potentially create uncertainty in the marketplace. Manufacturers, researchers, investors, and others who question the validity of a patent, but possess no forum to address their concerns, may be unable to make informed decisions regarding the subject matter of that patent.[103] Administrative review proceedings address this perceived gap by allowing any interested person to challenge any U.S. patent at the USPTO. Because IPRs and PGRs are administrative in nature, the constitutional "case or controversy" requirement does not apply to them.[104]

Some commentators believe that the absence of a standing requirement for IPRs and PGRs should be reconsidered.[105] If IPRs and PGRs were meant to serve as low-cost alternatives to determine the validity of patent claims, then some believe that only those parties who could have brought litigation should be able to initiate an IPR or PGR.[106] Others have suggested that "reverse trolling"—the practice of demanding payments from patent proprietors in exchange for not filing petitions for review or settling cases that have been filed[107]—might have less impact if a standing requirement applied. Another possible concern associated with the absence of a standing requirement is the use of these new proceedings by "interest groups making ... challenges for ideological, political, or policy reasons ... rather than weaknesses specific to a given invention."[108]

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[99] Ibid.

[100] *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

[101] U.S. Constitution, Article III, Section 2, clause 1.

[102] See *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1171 (Fed. Cir. 2017) (explaining the standing doctrine).

[103] See *Tyco Fire Prods. LP v. Victaulic Co.*, 2012 WL 39956 (E.D. Pa. 2012).

[104] Kenneth J. Costa, "Patent System Manipulation: Hedge Funds Abusing IPR, Poor Patent Quality & Pharmaceutical Monopolies," *Cardozo Arts & Entertainment Law Journal*, vol. 35 (2016), pp. 177, 184.

[105] Feng Ye, "Trading on the Outcomes of Patent Challenges: Short-Selling Petitioners and Possible Modifications to the Inter Partes Review Process," *Journal of the Patent & Trademark Office Society*, vol. 98 (2016), pp. 557, 567 (noting these critiques).

[106] Gene Quinn, *Patent Abuse or Genius? Is Kyle Bass Abusing the Patent System?*, April 8, 2015, http://www.ipwatchdog.com/2015/04/08/is-kyle-bass-abusing-the-patent-system/id=56613/.

[107] Rochelle Cooper Dreyfuss, "Giving the Federal Circuit a Run for Its Money: Challening Patents in the PTAB," *Notre Dame Law Review*, vol. 91 (November 2015), pp. 235, 285.

[108] Karen A. Lorang, "The Unintended Consequences of Post-Grant Review of Patents," *UCLA Journal of Law & Technology*, vol. 17 (Spring 2013), pp. 1, 19.

Still others have expressed concern over the strategic use of IPRs in an attempt to profit from the short selling of pharmaceutical stocks.[109] The pharmaceutical industry deemed this practice an abuse of process and encouraged the PTAB to sanction those who used this strategy.[110] However, the PTAB declined to do so.[111]

In the 115th Congress, the STRONGER Patents Act would provide that in order to have standing to file a petition with the USPTO to institute an IPR or PGR, a person, or a real party in interest or privy of the person, must have been charged with infringement of the challenged patent.[112]

Claim Amendments

As noted, Congress afforded patent proprietors the opportunity to amend their claims in both IPR and PGR proceedings. In particular, the relevant IPR statute provides:

> (d) Amendment of the patent.—
>
> (1) In general.—During an inter partes review instituted under this chapter, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:
>
> (A) Cancel any challenged patent claim.
>
> (B) For each challenged claim, propose a reasonable number of substitute claims.
>
> (2) Additional motions.—Additional motions to amend may be permitted upon the joint request of the petitioner and the patent owner to materially advance the settlement of a proceeding under section 317, or as permitted by regulations prescribed by the Director.
>
> (3) Scope of claims.—An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.[113]

The ability to amend claims underlies other parameters of these proceedings, including the presumption of validity and claim construction standard. Yet some stakeholders believe that, in practice, the PTAB rarely allows motions to amend claims.[114] They assert that motions to amend are denied for failure to show patentability over the prior art; failure to discuss where substitute claims finds support in the original written description; failure to provide a clear claim construction; and failure to discuss the level of ordinary skill in the art.[115] The Supreme Court, in *Cuozzo Speed Technologies, LLC v. Lee*,[116] appears to have concurred with this assessment, as it observed that the PTAB granted only 5 out of the first 86 motions it received to amend claims.

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[109] See J. Gregory Sidak and Jeremey O. Skog, "Attack of the Shorting Bass: Does the Inter Partes Review Process Enable Petitioners to Earn Abnormal Returns?," *UCLA Law Review Discourse*, vol. 63 (2015), p. 120.

[110] See Yishi Yin, "Avenues for Addressing the Exploitation of Inter Partes Review Process by Third Parties," *North Carolina Journal of Law & Technology Online Edition*, vol. 17 (January 2016), pp. 107, 120-121.

[111] *Coalition for Affordable Drugs VI, LLC v. Celgene Corp.*, Decision Denying Sanctions Motion, IPR2015-01092 (PTAB Sept. 25, 2015).

[112] See S. 1390 at §§102(c), 103(c).

[113] 35 U.S.C. §316(d).

[114] See Stacy Lewis and Tom Irving, "Amending Rather Than Cancelling Claims in Inter Partes Reviews," *Buffalo Intellectual Property Law Journal*, vol. 11 (2015), pp. 178, 195 (referring to the patent proprietor's ability to amend claims during an IPR as "virtually nonexistent.").

[115] Kia L. Freeman, Andrej Barbic, and Heath T. Misley, "Change Anticipated in Uncertain Requirements for Motions to Amend Claims in Inter Partes Review," *Intellectual Property & Technology Law Journal*, vol. 28, no. 12 (December 2016), pp. 3, 4.

[116] 136 S. Ct. 2131 (2016).

The Court was unmoved, however, explaining that "these numbers may reflect the fact that no amendment could save the inventions at issue.... "[117]

Judicial developments may potentially alter this situation. The Federal Circuit, sitting *en banc*,[118] recently heard oral argument in *In re Aqua Products, Inc.*[119] The Court of Appeals requested that the parties and *amici curiae* address two questions:

> (1) When the patent owner moves to amend its claims under 35 U.S.C. §316(d), may the PTO require the patent owner to bear the burden of persuasion, or a burden of production, regarding patentability of the amended claims as a condition of allowing them? Which burdens are permitted under 35 U.S.C. §316(e)?
>
> (2) When the petitioner does not challenge the patentability of a proposed amended claim, or the Board thinks the challenge is inadequate, may the Board *sua sponte* raise patentability challenges to such a claim? If so, where would the burden of persuasion, or a burden of production, lie?[120]

Issuance of the *Aqua Products* case, which is expected during the summer of 2017, could potentially impact USPTO practices regarding claim amendments. In addition, the STRONGER Patents Act of 2017 would establish an alternative procedure for amending the claims of a patent challenged before the PTAB. The patent owner could request an "expedited patentability report" from a patent examiner on a substitute claim. The legislation would afford the PTAB the discretion to allow this alternative amendment pathway upon the request of the patent owner.[121]

PTAB Panel Composition

IPR and PGR proceedings are currently conducted by panels consisting of at least three members of the PTAB. The STRONGER Patents Act of 2017 would additionally stipulate that the PTAB members who participated in the initial decision to permit a post-grant proceeding cannot be the same persons to reach the final decision in that proceeding.[122]

The Federal Circuit's Docket

Although the Federal Circuit hears virtually every patent appeal in the United States,[123] it also accepts cases involving veterans' rights, government contracts, federal taxation, takings, vaccine compensation, government employment, customs and tariffs, and other matters.[124] Congress established this "hodgepodge"[125] of jurisdiction purposefully. Prior to the formation of the Federal Circuit in 1982,[126] opponents voiced concern that a patent specialty court would be susceptible to

[117] Ibid. at 2145.

[118] The term "*en banc*" refers to a special proceeding where all the active members of the Federal Circuit sit to hear a case. See 28 U.S.C. §46(c).

[119] 833 F.3d 1335 (Fed. Cir. 2016).

[120] Ibid. at 1336.

[121] See S. 1390 at §§102(i), 103(i).

[122] Ibid at §104.

[123] 28 U.S.C. §1295(a)(1).

[124] See Paul R. Gugliuzza, "Rethinking Federal Circuit Jurisdiction," *Georgetown Law Journal*, vol. 100 (June 2012), p. 1437.

[125] Matthew R. Huppert, "Commercial Purpose as Constitutional Purpose: Reevaluating *Asahi* through the Lens of International Patent Litigation," *Columbia Law Review*, vol. 111 (April 2011), pp. 624, 628 n.28.

[126] Federal Courts Improvement Act of 1982, P.L. 97-164, 96 Stat. 25.

influence by special interests, stand outside the mainstream of legal developments, and be prone to "tunnel vision."[127] In response to this objection, proponents of the Federal Circuit "stressed that the range and variety of its jurisdiction would necessarily avoid the risks of specialized courts."[128]

Possibly in combination with other trends, the introduction of IPRs has altered the balance of the Federal Circuit's docket by bringing a "massive influx of new appeals" from the USPTO.[129] As two patent practitioners recently explained:

> As of Oct. 31, 2016, there are 586 pending appeals before the Federal Circuit from proceedings at the USPTO, with 48 appeals being docketed between Oct. 1, 2016, and Oct. 31, 2016, alone.... To put the immensity of the current appellate docket in perspective, on Oct. 31, 2012, the period just after the post-grant proceedings began but before any decisions would have reached the Federal Circuit, there were only 93 pending appeals before the Federal Circuit for proceedings at the USPTO, with only 4 appeals being docketed between Oct. 1, 2012, and Oct. 31, 2012.[130]

As of April 30, 2017, the Federal Circuit reported a total of 1,526 pending cases, with 636 arising from the USPTO. It also reported 478 cases coming from the district courts, 116 from the U.S. Court of Federal Claims, and 17 from the International Trade Commission—the great majority of them involving patent matters.[131] Of course, the Federal Circuit docket may possibly be transitioning to a period where USPTO appeals replace those arising from the federal district courts, as patent disputes are increasingly addressed by the agency rather than the judiciary.[132]

Judicial Review of the PTAB

The landmark Supreme Court decision in *Chevron v. Natural Resources Defense Council* has governed Federal Circuit review of USPTO regulations concerning the PTAB.[133] The *Chevron* case announced a two-part test that establishes the relationship between the courts, federal agencies, and Congress in drafting, administering, and interpreting statutes:

> First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.[134]

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[127] Pauline Newman, "The Federal Circuit—A Reminiscence," *George Mason University Law Review*, vol. 14 (Summer 1992), pp. 513, 520.

[128] Ibid.

[129] Jason Mock, "Post-Grant Proceedings at the USPTO and the Rising Tide of Federal Circuit Appeals," *Federal Circuit Bar Journal*, vol. 25 (2015), pp. 15, 16.

[130] Rachel C. Hughey and Joseph W. Dubis, "Navigating Post-Grant Proceedings: What Two Years of Federal Circuit Decisions and the Supreme Court's *Cuozzo* Decision Tell Us About Post-Grant Proceedigns Before the PTAB," *Federal Lawyer*, vol. 64 (January/February 2017), pp. 70, 71.

[131] U.S. Court of Appeals for the Federal Circuit, *Year-to-Date Activity*, April 30, 2017, http://www.cafc.uscourts.gov/sites/default/files/the-court/statistics/YTD_Activity_4.30.17.pdf.

[132] See Mock, *supra*, at 16.

[133] 467 U.S. 837 (1984).

[134] Ibid. at 842-43.

The *Chevron* test established what many commentators have considered to be a highly deferential judicial role when faced with a challenge to an agency's interpretation of its own authorizing statute or a statute it administers.[135] The USPTO has successfully relied upon *Chevron* deference in a variety of respects regarding IPRs,[136] including rules that designate the "broadest reasonable interpretation" standard for claim construction,[137] allow decisions regarding preliminary institution of review and final decisions to be made by the same panel,[138] and permit the PTAB to institute a review on only some of the claims in the petition.[139]

In the 115th Congress, both the Regulatory Accountability Act of 2017, H.R. 5; and the Separation of Powers Restoration Act of 2017, H.R. 76; are widely viewed as proposing to overturn *Chevron* deference. H.R. 5, which passed the House on January 11, 2017, would do so by directing courts to:

> decide *de novo* all relevant questions of law, including the interpretation of constitutional and statutory provisions, and rules made by agencies. If the reviewing court determines that a statutory or regulatory provision relevant to its decision contains a gap or ambiguity, the court shall not interpret that gap or ambiguity as an implicit delegation to the agency of legislative rule making authority and shall not rely on such gap or ambiguity as a justification either for interpreting agency authority expansively or for deferring to the agency's interpretation on the question of law.[140]

H.R. 76 is worded similarly.[141] If enacted, some commentators believe that, despite the ruling of the Supreme Court in *Cuozzo v. Lee*,[142] "it will be an open question whether the Patent Office may use [the broadest reasonable interpretation standard] within IPR proceedings. That is because the law will have changed over what deference a court must give Patent Office regulations."[143] The same result would seemingly hold for other aspects of USPTO rulemaking regarding the new administrative review procedures as well.

Article III and the Seventh Amendment

Article III of the U.S. Constitution establishes the federal court system and in part provides that the "judicial Power shall extend to all Cases, in Law and Equity, arising under ... the Laws of the United States."[144] The Seventh Amendment to the U.S. Constitution provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

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[135] See, e.g., Connor N. Raso and William N. Eskridge, Jr., "*Chevron* as a Canon, Not a Precedent: An Empirical Study of What Motivates Justice in Agency Deference Cases," *Columbia Law Review*, vol. 110 (November 2010), p. 1727.

[136] See Stuart Minor Benjamin and Arti K. Rai, "Administrative Power in the Era of Patent Stare Decisis," *Duke Law Journal*, vol. 65 (May 2016), p. 1563.

[137] *Cuozzo Speed Technologies v. Lee*, 136 S.Ct. 2131 (2016) (discussed infra).

[138] *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023 (Fed. Cir. 2016).

[139] *Synopsis, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309 (Fed. Cir. 2016).

[140] H.R. 5 at §202.

[141] H.R. 76 at §2.

[142] *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131 (2016).

[143] Robert P. Greenspoon, *Conservative Ideology Will Rebuild the Patent System*, January 30, 2017, http://www.ipwatchdog.com/2017/01/30/conservative-ideology-rebuild-patent-system/id=77717/.

[144] U.S. Constitution, Art. III, §2.

In keeping with the Seventh Amendment, patent cases in federal court are often tried before juries.[145]

In *MCM Portfolio LLC v. Hewlett-Packard Co*.,[146] an IPR petitioner unsuccessfully argued to the Federal Circuit that IPRs violated Article III by delegating issues to the PTAB that should be adjudicated by a federal court. In addition, the petitioner asserted that IPRs violated the Seventh Amendment because juries play no role in these proceedings. The Federal Circuit held that IPR proceedings were consistent with the Constitution:

> Here ... the agency's sole authority is to decide issues of federal law. The patent right "derives from an extensive federal regulatory scheme," ... and is created by federal law. Congress created the PTO, "an executive agency with specific authority and expertise" in the patent law ... and saw powerful reasons to utilize the expertise of the PTO for an important public purpose—to correct the agency's own errors in issuing patents in the first place.... There is notably no suggestion that Congress lacked authority to delegate to the PTO the power to issue patents in the first instance. It would be odd indeed if Congress could not authorize the PTO to reconsider its own decisions.[147]

Critics of the *MCM v. HP* opinion assert in part that patents qualify as property rights whose disposition must be tried before an Article III court and that a jury must be available to decide factual issues as mandated by the Seventh Amendment.[148] On the other hand, because similar challenges were made to the reexamination statute in 1985 and were also rejected,[149] the use of administrative proceedings to decide patent validity has a history of many decades.

On June 12, 2017, the Supreme Court of the United States agreed to hear the matter of *Oil States Energy Services LLC v. Greene's Energy Group LLC*.[150] The question before the Court is:

> Whether inter partes review—an adversarial process used by the Patent and Trademark Office (PTO) to analyze the validity of existing patents—violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury.

Decisions to Institute IPRs

Under current law, the USPTO Director may not institute an IPR or PGR unless he determines that "it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable."[151] Similarly, he may not authorize an IPR unless he concludes that "there is a reasonable likelihood that the petitioner would prevail.... "[152]

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[145] See Daniel P. Sullivan, "Must the Jury Reach a Verdict? The Constitutionality of Eliminating Juries in Patent Trials by Creating an Article I Tribunal," *John Marshall Review of Intellectual Property Law*, vol. 7 (Summer 2008), p. 754.

[146] 812 F.3d 1284 (Fed. Cir 2015).

[147] Ibid. at 1290-91 (citations omitted).

[148] See, e.g., *Brief of 13 Law Professors as Amici Curiae in Support of Petitioner*, MCM Portfolio LLC v. Hewlett-Packard Co., May 27, 2016.

[149] See, e.g., *Patlex Corp. v. Mossinghoff*, 771 F.3d 480 (Fed. Cir. 1985).

[150] 2017 WL 2507340 (2017).

[151] 35 U.S.C. §324(a).

[152] 35 U.S.C. §314(a).

The STRONGER Patents Act of 2017 would authorize the USPTO to initiate an IPR or PGR with respect to a particular patent claim only once. Under this legislation, if a patent claim has been previously challenged in an IPR or PGR, it may not be so challenged again.[153]

Partial Institution of IPRs

The USPTO has established a regulation that allows it to initiate an IPR "on all or some of the challenged claims."[154] As a result, the agency may institute an IPR on only a subset of the claims identified in a petition. Although one petitioner challenged that regulation as inconsistent with the AIA, the Federal Circuit disagreed.[155] The Court of Appeals instead concluded that the "statute strongly implies that the initiation decision be made on a claim-by-claim basis and that the Board can pick and choose among the claims in the decision to institute."[156]

On May 22, 2017, the Supreme Court agreed to hear a case involving partial institution. In *SAS Institute Inc. v. Lee*,[157] the petitioner presented the following issue to the Court:

> Does 35 U.S.C. §318(a), which provides that the [PTAB] in an inter partes review "shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner," require [the PTAB] to issue a final written decision as to every claim challenged by the petitioner, or does it allow [the PTAB] to issue a final written decision with respect to the patentability of only some of the patent claims challenged by the petitioner, as the Federal Circuit held?[158]

The ruling of the Supreme Court is expected by the end of 2017. Given that the AIA stipulates that the USPTO's decision to institute an IPR is "final and non-appealable,"[159] some are concerned that partial institution may create hardships for both the petitioner and patent proprietor. Even after completing an IPR, a petitioner may still need to address claims that were challenged but not subject to the proceeding. As well, when some claims of a patent are challenged and invalidated via an IPR, but other similar claims were entirely unaddressed, there are concerns that the patent's owner may hold a legal instrument of dubious value. The cloud on that patent's title may make licensing or enforcement of the remaining claims uncertain. Another concern of some is that piecemeal institution decision may also not serve the congressional purpose of establishing an administrative substitute for litigation.[160]

On the other hand, the AIA charges the PTAB with administering IPRs within a one-year period.[161] Thus, others argue that partial institution provides the agency with a valuable tool for managing its workload within this time frame.[162] In addition, litigation in the federal courts often

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[153] See S. 1390 at §§2(d), 3(d).

[154] 37 C.F.R. §42.108(a).

[155] *Synopsis, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309 (Fed. Cir. 2016).

[156] Ibid. at 1316.

[157] 2017 WL 468440 (2017).

[158] John A. Marlott and Gregory A. Castanias, *SAS Institute Inc. v. Lee*, Petition for a Writ of Certiorari, January 31, 2017, p. i, https://cdn.patentlyo.com/media/2017/05/SAS-Petition.pdf.

[159] 35 U.S.C. §314(d). See *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131, 2139-42 (2016) (upholding the USPTO's interpretation of this statute).

[160] The dissenting decision of Judge Newman in *Synopsis v. Mentor*, 814 F.3d at 1328-31, addresses these points.

[161] 35 U.SC. §316(a)(11).

[162] USPTO, "Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board," 80 *Federal Register* 50720, 50739, August 20, 2015.

involves the assertion of a modest number of "representative" claims, even though the relevant patents may have dozens or even hundreds of claims.[163]

Repetitive Invalidity Arguments and Estoppel

Under current law, individuals who commence either an IPR or PGR that results in a final written decision are barred—or "estopped"—from raising in a later civil action issues that they raised in these proceedings—as well as any issue that "reasonably could have been raised."[164] The STRONGER Patents Act of 2017 would create an exception to this rule when "after the filing of the initial petition, the petitioner, or the real party in interest or privy of the petitioner, is charged with infringement of additional claims of the patent."[165]

Hatch-Waxman and the BPCIA

Congress has enacted legislation linking the patent laws with the food and drug laws. One such statute is the Drug Price Competition and Patent Term Restoration Act of 1984,[166] more commonly known as the Hatch-Waxman Act.[167] This legislation established specialized pharmaceutical patent infringement litigation procedures between companies producing generic drugs and those producing brand-name drugs. In very broad outline, these procedures include the identification of relevant patents to the Food and Drug Administration (FDA), publication of the patents in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), the opportunity for generic drug companies to state their views about the validity and scope of those patents, the ability of brand-name firms to sue generics that have done so, and an obligatory 30-month stay of marketing approval for the generic firm should the brand-name company do so.[168]

Another statute, the Biologics Price Competition and Innovation Act (BPCIA), established a distinct but equally elaborate patent dispute resolution procedure for "biologics"—a category of medical preparations derived from a living organism.[169] In brief, the so-called "Patent Dance" calls for (1) the follow-on biologic applicant to disclose its FDA licensing application to the brand-name firm; (2) each party to identify pertinent patents; (3) the parties to exchange briefings on the validity and possible infringement of those patents; (4) the parties to negotiate which patents will be subject to litigation; and (5) simultaneously to exchange a list of patents designated for litigation in the event the parties could not reach agreement.[170]

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[163] For example, in *Motorola Mobility, Inc. v. Apple Inc.*, Case 1:12-cv-20271-SCOLA (April 9, 2013), the litigants proposed that the court adjudicate "over 180 claims asserted from ... 12 patents.... " The court warned the parties that it would stay the litigation unless the case were simplified. Similarly, in *Stamps.com Inc. v. Endicia, Inc.*, 437 Fed.Appx. 897, 900 (Fed. Cir. 2011), the Federal Circuit affirmed a judgment which involved the reduction from 629 asserted claims to 15 due to the encouragement of the district court.

[164] 35 U.S.C. §325(e).

[165] See S. 1390 at §§2(f), 3(f).

[166] P.L. 84-417.

[167] See CRS Report R44643, *The Hatch-Waxman Act: A Primer*, by John R. Thomas.

[168] Ibid. at 6-8.

[169] CRS Report R44173, *Follow-On Biologics: Intellectual Property Issues*, by John R. Thomas.

[170] Ibid. at 7. The Supreme Court is currently interpreting these provisions. See *Sandoz Inc. v. Amgen Inc.*, 137 S.Ct. 808 (2017).

Some commentators believe that IPRs and related proceedings present a poor fit with the Hatch-Waxman Act and BPCIA.[171] John Castellani of the Pharmaceutical Manufacturer's Association and James Greenwood of the Biotechnology Industry Organization have collectively asserted:

> Under the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA), Congress crafted a carefully calibrated system that ensured the continued development and introduction of new and innovative medicines and, at the same time, facilitated the timely introduction of generic and biosimilar medicines. This system has worked well for over 30 years. Because IPR challenges arise outside these carefully designed legal regimes, they threaten to disrupt the delicate balance that has served patients so well.[172]

On the other hand, membership of the United States in the World Trade Organization (WTO) includes the obligation to ensure that "patents shall be available and patent rights enjoyable without discrimination as to the ... field of technology.... "[173] Exempting medical patents from IPR and related procedures may be deemed to violate this commitment.

Commentators have also encouraged the consideration of IPRs as a possible forfeiture event with respect to the regulatory exclusivity period associated with generic drugs. As originally enacted, the Hatch-Waxman Act provided prospective manufacturers of generic pharmaceuticals with a reward for challenging patents associated with a brand-name product. That reward, granted to the first generic firm to challenge a patent, consists of a 180-day exclusivity period that prevents other generic firms from entering the market.[174]

With the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),[175] Congress established various "forfeiture events" that, if triggered, cause a generic firm to lose its 180-day exclusivity.[176] In general, a generic manufacturer can lose its exclusivity at such times that one of dates (1)-(2) and one of dates (3)-(5) comes to pass:

> (1) 75 days after the FDA finally approves the generic firm's application;
>
> (2) 30 months after the generic submits its application to the FDA;
>
> (3) 75 days after a court judgment that the challenged patent is invalid or not infringed;
>
> (4) 75 days after a suit over the challenged patent is settled favorably to the generic firm; or
>
> (5) 75 days after the challenged patent is removed from the Orange Book.[177]

None of the statutory forfeiture events refer to IPRs and related provisions, at the very least because enactment of the MMA preceded that of the AIA by eight years. Commentators have suggested that Congress should consider how IPRs should interact with the forfeiture events identified in the MMA.[178]

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[171] See Joanna Shepherd, "Disrupting the Balance: The Conflict Between Hatch-Waxman and *Inter Partes* Review," *NYU Journal of Intellectual Property and Entertainment Law*, vol. 6 (Fall 2016), p. 14.

[172] Jim Greenwood and John Castellani, "Congress Must Keep Trolls Away from Medical Patents," *The Hill*, July 20, 2015, http://thehill.com/opinion/op-ed/248567-congress-must-keep-trolls-away-from-medical-patents.

[173] Agreement on Trade-Related Aspects of Intellectual Property, Art. 27, April 15, 1994, 33 I.L.M. 1197.

[174] 21 U.S.C. §355(j)(5)(B)(iv).

[175] P.L. 108-173, 117 Stat. 2066 (2003).

[176] 21 U.S.C. §355(j)(5)(D)(i).

[177] *Teva Pharmaceuticals USA, Inc. v. Sebelius*, 595 F.3d 1303, 1316 (D.C. Cir. 2010).

[178] See Brian T. Apel, "An Administrative Meter Maid: Using *Inter Partes* Review and Post-Grant Review to Curb

Concluding Observations

Patents derive their value from the rights they confer to exploit proprietary technologies. The increased focus on intellectual property in our information-based, knowledge-driven economy has arguably caused industry to raise its expectations with respect to the quality, timeliness, and efficiency of the granting of patents. As the USPTO currently employs approximately 8,000 patent examiners with varying degrees of experience, legal training, and technical education,[179] maintaining consistency in patent grant determinations presents a challenging task for USPTO management.

By recruiting members of the public to act as "private patent examiners," post-grant proceedings allow the USPTO to confirm its earlier determinations regarding that subset of patents that prove to be of marketplace significance.[180] In this respect, it should be noted that the validity of only a relatively small subset of issued patents is ever called into question. For example, one commentator estimated that about 5% of issued patents are litigated or licensed.[181] Post-grant proceedings may therefore direct the attention of the USPTO to those patents that industry believes to be of particular significance and arguable validity.

In addition, an administrative process for reassessing patentability determinations in a reliable, cost-effective, and timely manner could potentially allow members of the public to make commercial decisions with more certainty over the impact of patent rights. Reduction of litigation costs could also channel resources that innovative firms currently spend on defending their patent rights in the courts into further research and development.[182]

The perception of a high percentage of invalidity rulings at the PTAB may be due in part to the fact that, over the past decade, the Supreme Court has revisited a number of the requirements for patenting and made them more difficult to satisfy.[183] Patents granted under earlier, more lenient requirements remain subject to the new, more stringent standards and may therefore be invalid. This trend may also be due to petitioners, at the outset, pursuing "low-hanging fruit"[184]—that is to say, weak patents that have been asserted via licensing demands or litigation.

Exclusivity Parking Via the "Failure to Market" Provision of the Hatch-Waxman Act," *Michigan Law Review*, vol. 114 (October 2015), p. 107; Jaimin Shah, "Pulling the 'Trigger' on the Hatch-Waxman Act's 180-Day Exclusivity Using Inter Partes Review," *John Marshall Intellectual Property Law Review*, vol. 14 (2015), p. 453.

[179] See Michael Macagnone, "Patent Office Head Defends Examiners' Work at House Panel," *Law360*, September 13, 2016.

[180] See John R. Thomas, "Collusion and Collective Action at the Patent Office: A Proposal for Patent Bounties," *University of Illinois Law Review*, 2001, pp. 305, 343.

[181] Mark A. Lemley, "Rational Ignorance at the Patent Office," *Northwestern University Law Review*, vol. 95 (Summer 2001), pp. 1495, 1507.

[182] See John R. Thomas, "Collusion and Collective Action at the Patent Office: A Proposal for Patent Bounties," *University of Illinois Law Review*, 2001, pp. 305, 343.

[183] See, e.g., *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120 (2014) (claim definiteness); *Alice Corp. v. CLS Bank Int'l*, 134 S.Ct. 2347 (2014) (patent eligibility of software and business methods); *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013) (patent eligibility of naturally derived substances); *KSR Int'l Inc. v. Teleflex Inc.*, 550 U.S. 398 (2007).

[184] Stacy Lewis and Tom Irving, "Very Few Appreciated Just How Bad AIA Inter Partes Reviews (IPRs) Would Be for Patent Owners, Although IPR Denials Have Been, for Patent Owners, a Glimmer of Hope," *Buffalo Intellecutal Property Law Journal*, vol. 11 (2015), pp. 28, 38.

Another reason for the perception of a high invalidation percentage is that "petitioners are choosing which patents to challenge fairly well."[185] Although IPRs are significantly less expensive than litigation, they remain a costly venture. The average cost for one party to participate in an IPR has been estimated at approximately $200,000.[186] Indeed, the cost of challenging an issued patent from the USPTO is usually much greater than the cost of obtaining one in the first place.[187] Further, the possible penalty of a loss—being barred from challenging the validity of the claims in the future—could prove consequential.[188] Most petitioners may therefore be cautious and selective in choosing patents to challenge via an IPR.

Commentators have also lauded the PTAB for its expertise and thoroughness. Each PTAB member is an experienced patent practitioner.[189] Further, the USPTO attempts to have at least one Administrative Patent Judge on the panel with relevant technical expertise. In contrast, most federal district judges and jurors have not received a technical patent-related education and possess little, if any, experience in the patent law. As explained by one practitioner, if "you read PTAB decisions in IPRs, you'll find that they're typically very thorough and well-reasoned, much better reasoned than district court opinions."[190]

On the other hand, critics of IPRs assert that "Congress erected a heavily slanted administrative regime that invalidates patents by design, even when those same patents would be upheld by district court."[191] These features reportedly include a more capacious claim construction, which renders patents more susceptible to a validity attack; a lower burden of proof upon the patent challenger than would be the case in district court litigation; and the absence of a jury and a "disinterested, life-appointed judge."[192] They also note that the one-year deadline for completing an IPR may render patent proprietors "ill-prepared for the speed of the fight," in contrast to the challenger who may "methodically prepare a petition and set up a strategy for the proceedings" in advance.[193]

In addition, some patents have been subject to multiple, serial IPR petitions on different grounds of patent validity.[194] Some patent owners have been subject to dozens of IPR petitions since

[185] Matt Levy, *Death to All Patents? Really? Why Inter Partes Review Shouldn't Be Controversial*, November 6, 2015, http://www.ipwatchdog.com/2015/11/06/death-to-all-patents-inter-partes-review/id=62935/.

[186] See Aashish Kapadia, "Inter Partes Review: A New Paradigm in Patent Litigation," *Texas Intellectual Property Law Journal*, vol. 23 (2015), pp. 113, 133.

[187] See Gene Quinn, *The Cost of Obtaining a Patent in the US*, April 4, 2015, http://www.ipwatchdog.com/2015/04/04/the-cost-of-obtaining-a-patent-in-the-us/id=56485/.

[188] 35 U.S.C. §315(b).

[189] Michael Wagner, "An Introduction to Administrative Patent Judges at the Patent Trial and Appeal Board," *Federal Lawyer*, vol. 62 (May 2015), p. 36.

[190] See Levy, *supra.*

[191] Robert N. Schmidt and J. Carl Cecere, *MCM Portfolio, LLC v. Hewlett-Packard Co.*, Brief of Amici Curiae Gary Lauder et al. Before the Supreme Court of the United States, May 31, 2016, p. 4, http://www.scotusblog.com/wp-content/uploads/2016/06/15-1330-Revised-Amici-Brief-G-Lauder-and-inventors-1.pdf.

[192] Ibid.

[193] Rob Sterne and Gene Quinn, *PTAB Death Squads: Are All Commercially Viable Patents Invalid?*, March 24, 2014, http://www.scotusblog.com/wp-content/uploads/2016/06/15-1330-Revised-Amici-Brief-G-Lauder-and-inventors-1.pdf.

[194] Judge Paul Michel, *Torpedoing Patent Rights*, July 10, 2011, http://www.ipwatchdog.com/2011/07/10/torpedoing-patent-rights/id=18022/.

2012.[195] This possibility, which increases the cost and length of participation, may be exacerbated because current law permits one individual to file multiple IPR petitions against a single patent.[196]

Statistics with respect to IPRs also suggest that most patents in these proceedings have been subject to contemporaneous litigation. In one recent study, three legal academics recently identified each of the 24,162 patent cases filed between September 16, 2011, and June 30, 2015.[197] As they explain:

> During this time, a total of 14,218 patents were either challenged in an IPR or CBM petition, asserted in litigation, or both. A subset of 13,557 patents [was] involved in litigation alone; 298 patents were involved in a USPTO proceeding alone; and 1,968 patents were involved in both. Accordingly, about 12.7% of litigated patents are also being challenged in the PTAB, and about 86.8% of IPR- or CBM-challenged patents are also being litigated in the federal courts.[198]

These statistics suggest that "PTAB-only cases are relatively rare.... "[199] One could infer from this account that rather than serving as a low-cost litigation substitute, IPRs now form an additional, parallel track that potentially increases the expense and complexity of patent enforcement.[200]

Other observers have discerned that the PTAB grants few motions to amend claims; indeed, some assert that despite "the statutory approval of amending claims in IPRs, in reality, Patent Owners' ability to amend claims has been virtually nonexistent so far."[201] The relatively tight statutory deadlines to complete an IPR, as well as an unexpected demand for these proceedings, have been cited as contributing to the PTAB's reluctance to allow amended claims in view of newly cited prior art.[202] Congress intended IPRs to improve patent quality. But, for some, IPRs appear to do so by invalidating individual patents altogether, rather than by allowing inventors to obtain appropriate claim scope in view of the prior art on a case-by-case basis.[203]

Critics of IPRs further observe that, due to the absence of a standing requirement, anyone may file an IPR petition. According to some observers, experience "from only the first few years of IPR proceedings shows that they are frequently utilized by larger competitors to weaken smaller, more innovative ones, as well as by vultures seeking to extract nuisance settlements."[204] In addition, the "absence of a discrete set of potential petitioners" reportedly "makes it difficult for

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[195] See Pedram Sameni, *Top 10 Patent Owners in IPR Petitions*, March 1, 2017, https://www.patexia.com/feed/weekly-chart-30-top-10-patent-owners-in-ipr-petitions-20170228.

[196] Courtney Dabbiere and Allison Dobson, *How Does the PTAB Evaluate Follow-On IPR Petitions?*, April 24, 2017, http://ncbarblog.com/2017/04/how-does-the-ptab-evaluate-follow-on-ipr-petitions/.

[197] Saurabh Vishnukbhakat, Arti K. Rai, and Jay P. Kesan, "Strategic Decision Making in Dual PTAB and District Court Proceedings," *Berkeley Technology Law Journal*, vol. 31 (2016), p. 45.

[198] Ibid. at 69.

[199] Ibid. at 83.

[200] See Jonathan Stroud, Linda Thayer, and Jeffrecy C. Totten, "Stay Awhile: The Evolving Law of District Court Stays in Light of Inter Partes Review, Post-Grant Review, and Covered Business Method Post-Grant Review," *Buffalo Intellectual Property Law Journal*, vol. 11 (2015), pp. 226, 231-232.

[201] Stacy Lewis and Tom Irving, "Amending Rather Than Cancelling Claims in Inter Partes Review," *Buffalo Intellectual Property Law Journal*, vol. 11 (2015), pp. 178, 196.

[202] Ibid.at 197.

[203] See Gene Quinn, *Taking Stock of the Health of the American Patent System, a System in Crisis*, March 27, 2017, http://www.ipwatchdog.com/2017/03/27/health-american-patent-system-crisis/id=80720/.

[204] Schmidt and Cecere, supra, p. 7.

inventors and potential investors to adjust their behavior to avoid a potential IPR, as they might do to avoid litigation."[205]

Some observers believe that the creation of IPRs has had a significant deleterious impact upon the innovation environment of the United States. For some, these proceedings can increase the cost and uncertainty associated with patent ownership, "measurably diminishing their utility as a durable asset on which new businesses, new industries—and indeed, the entire American economy—all depend."[206] Lack of predictability and stability of patent rights might also discourage the injection of venture capital into start-ups and high-technology products.[207] IPRs may work especially to the detriment of individual inventors and small firms that lack the resources enjoyed by incumbents.[208]

Critics and supporters of IPRs alike tend to agree that these proceedings have emerged as the most prominent component of the entire AIA.[209] Detractors assert that IPRs have had a negative impact upon the U.S. patent system and innovation environment, while proponents believe that they have largely met the congressional goal of developing an effective mechanism for challenging suspect patents. As Congress potentially revisits IPR reform proposals, five years of experience with these proceedings may prove helpful to policymakers weighing these competing views.

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[205] Ibid. at 8.

[206] Ibid. at 4.

[207] Letter from Life Sciences Venture Capital Community to The Honorable Chuck Grassley et al., Chairman, Senate Committee on the Judiciary, September 9, 2015, https://califesciences.org/wp-content/uploads/2015/09/VC-Letter-on-IPR-Reform-H-R-9_FINAL.pdf.

[208] Adrian Pelkus, *Patents Used to Be a Property Right, Now a Patent Is a Liability*, November 12, 2016, http://www.ipwatchdog.com/2016/11/12/patents-property-right-now-patent-liability/id=74679/.

[209] Amanda Murphy, Stacy Lewis, and Deborah Herzfeld, et al., "Adjusting for the New Normal: Thoughts on Enhancing the Possibility for Success for the Patent Owner in an AIA Post-Grant Proceeding," *Buffalo Intellectual Property Law Journal*, vol. 11 (2015), pp. 258, 259.

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