

Lowering Prescription Drug Costs by Removing Barriers to Challenging Patents

Introduction

I-MAK's mission is to build a more just and equitable medicines system. Our solutions recognize that patent quality, achieved through a high patentability standard and more public participation¹ in the patent system are key to achieving that mission. In the United States, unfortunately, it is clear that the Patent and Trademark Office (PTO) issues many patents that do not meet even today's low bar of patentability, creating thickets of invalid patents that contribute to overpatenting². However, since 2011 the patent system has included an important tool that allows the public to challenge patent validity in an administrative proceeding before the PTO called inter partes review (IPR) that provides some relief. Unfortunately, IPR's efficiency in weeding out invalid patents led to attacks against it and significant PTO action to weaken it during the last administration. Improving IPR is an important step toward raising the bar through public participation. Two tools currently under discussion for accomplishing that goal are PTO action under a new Director and passage of S.2891, the Restoring the America Invents Act.

The America Invents Act of 2011

In the fall of 2011, Congress passed the America Invents Act (AIA) with overwhelming bipartisan support after six hard-fought years of negotiation with a broad range of stakeholders having different views of the patent system, including the pharmaceutical industry, hi-tech companies and the patent bar. The AIA was seen as the most significant legislative change to the Patent Act since its modern reformulation in 1952. It contained many significant provisions, such as the change from a "first-to-invent" to a "first-to-file" system necessary to harmonize the U.S patent system with the rest of the world; protection of PTO's funding mechanism that would give the agency more control over the fees it collects; and the creation of post-grant opposition proceedings that allow increased participation by the public in patent

¹ <https://www.i-mak.org/public-participation-blueprint/>

² <https://www.i-mak.org/overpatented/>

validity challenges before the PTO.³ As with most legislation of this size and complexity, the final bill represented a carefully-crafted compromise.

Ten years after passage, the AIA's post-grant opposition proceedings have become its most impactful provision. The PTO's improper issuance of large numbers of invalid patents had led a chorus of stakeholders, including the PTO itself, the Federal Trade Commission, the National Academies of Sciences, the American Intellectual Property Law Association, the biotechnology and pharmaceutical industries and many technology companies to endorse the creation of an efficient system to allow the expert administrative law judges at the PTO to review the validity of issued patents challenged by the public.⁴

Operation of the Post-Grant Opposition Proceedings of the AIA

The AIA created two new post-grant opposition procedures at the PTO, post-grant Review (PGR) and inter partes review (IPR). PGR allows the public to challenge the validity of a patent at the Patent Trials and Appeal Board (PTAB) of the PTO on any grounds, but only in the first nine months after a patent issues. IPR allows the public to challenge the validity of a patent at the PTAB at any time after the first nine months from issuance, but the arguments are limited to lack of novelty and obviousness based on printed publications. One caveat on timing is that if the patent owner previously sued the challenger, the challenger must file the IPR within one year of being sued. The details of how the two procedures operate and the differences between them resulted from negotiation with stakeholders and multiple compromises.

IPR has been used more extensively than PGR⁵ and, consequently, has been the subject of more controversy and change over the past ten years. This memo, therefore, focuses on IPR although many of the points also apply to PGR. IPR has been a popular and powerful tool for challenging patents and improving patent quality for several reasons:

- It is faster than litigation and has predictable timing. The AIA requires that the PTAB complete its review in 18 months.

³ H.R. Rep. No. 98, 112th Cong., 1st Sess. 39-40 (2011).

⁴ See, e.g., Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, (Oct. 2003) available at <https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf>; National Academies of Sciences, A Patent System for the 21st Century (2004) available at <https://www.nap.edu/catalog/10976/a-patent-system-for-the-21st-century> (reporting testimony in support of recommendation to create a post-grant review system).

⁵ During FY 2021, 93% of petitions filed were for IPR, and 7% were for PGR. USPTO PTAB Trial Statistics, Fiscal Year 2021, available at https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2021_roundup.pdf. The difference is certainly due to the restricted window in which a PGR may be filed, within nine months of a patent's issuance.

- It is less expensive than litigation because the validity arguments are based on printed publications and extensive discovery is not involved.
- It places the validity review with capable experts—dedicated administrative law judges with both legal and patent expertise who work in panels of three to produce careful opinions. The PTAB judges have significant expertise compared to lay juries and generalist judges.
- IPR allows any member of the public to challenge patent validity. A plaintiff in district court must have standing under Article III of the U.S. Constitution to bring a validity challenge, meaning the challenger must demonstrate that it faces a concrete threat from the patent,⁶ but IPR is an administrative proceeding without this limitation.

Since the AIA procedures came on-line in September 2012, more than 1010 challenges have been brought against pharmaceutical and biologic patents.⁷ The large number of patents that often cover important drug products and block less expensive generic or biosimilar products from the market make IPR and PGR important tools for clearing patent thickets and lowering drug costs.

Challenges to IPR

Despite initial broad, cross-industry support for the AIA, the success of IPR in efficiently weeding out invalid patents led to criticism that IPR is unfair to patent owners from the pharmaceutical industry and those that benefit from invalid patents. There have been challenges to IPR, some of which could have effectively eliminated the procedure but failed, and others that have weakened it. For example, legislation had been introduced in both houses of Congress during 2019 called “The Stronger Patents Act” that would undermine the usefulness of IPR through multiple constraints, including by imposing a standing requirement similar to that required in district court, limiting challenges to one per patent, and raising the standard for showing invalidity to “clear and convincing evidence.”⁸

The constitutionality of the PTAB and the IPR proceeding has been challenged in court, but the Supreme Court has upheld the program. In the 2018 case, *Oil States v. Greene’s Energy Group*,⁹ the Supreme Court rejected the argument that IPR violated Article III of the Constitution because it constituted

⁶ *MedImmune, Inc. v. Genentech, Inc.* 127 S.Ct. 764 (2006); see Michael J. Burstein, “Rethinking Standing in Patent Challenges,” 83 *Geo. Washington L.R.* 498 (2015) (discussing the standing limits on public challenges to patent validity in district court). Available at <https://www.gwlr.org/wp-content/uploads/2015/05/83-Geo-Wash-L-Rev-498.pdf>.

⁷ PTAB Trial Statistics FY21 End of Year Outcome Roundup, available at https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2021_roundup.pdf; and USPTO Trial Statistics: IPR, PGR, CBM (September 2020), available at https://www.uspto.gov/sites/default/files/documents/trial_statistics_20200930.pdf.

⁸ Stronger Patents Act of 2019, H.R. 3666, S. 2082; see *Stronger Patents Act of 2019*, Patently-O Blog (Sept. 10, 2019), available at <https://patentlyo.com/patent/2019/09/stronger-patents-2019.html> (describing provisions).

⁹ *Oil States Energy Serv. v. Greene’s Energy Group, LLC*, 138 S.Ct.1365 (2018).

improper judicial activity by an administrative agency. In *United States v. Arthrex*,¹⁰ the Court held that the procedure for naming administrative law judges to the PTAB violated the Appointments Clause of the Constitution, but it also issued a fix that gave the Senate-confirmed Director of the Patent Office a right to review PTAB decisions and, therefore, sufficient control to satisfy the Constitution.

Substantial Weakening of IPR by the Patent Office

The most consequential changes made to IPR thus far have been promulgated by the last administration's PTO Director, Andre Iancu – changes he described as “a new day at the PTAB.”¹¹

Discretionary Denials: One threat to the efficacy of IPR is the PTO's new policy of discretionary denials. An IPR challenge begins when a member of the public files a petition with the PTAB arguing that the patent is invalid. Based on that petition and the patent owner's optional response, the PTAB should decide whether to institute a full IPR proceeding and more careful review based on whether the petition demonstrates there is a “reasonable likelihood” that at least one patent claim is invalid. The AIA requires that a petition not meeting the “reasonable likelihood” standard be dismissed.¹²

Over the past few years, however, the PTO has steadily and deliberately expanded the circumstances in which it will deny institution of an IPR based on procedural grounds divorced from the merits of the invalidity arguments. Such grounds include whether the original patent examiner considered similar references, whether another petition has been filed against the same patent, and whether there is a co-pending district court challenge to the patent. These so-called “discretionary denials” can leave invalid patents standing and unchallengeable, and they often do so for reasons that Congress rejected in drafting the AIA.¹³ The PTO now claims complete and unreviewable discretion over its decisions to deny institution on procedural grounds, arguing that Supreme Court precedent supports that interpretation.¹⁴

The actions of former Director Iancu in pushing forward this policy of discretionary denials has led to dramatic changes in the availability of IPR. Discretionary denials, which were once rare (only 6 during

¹⁰ *United States v. Arthrex, Inc.*, 141 S.Ct. 1970 (2021).

¹¹ Remarks by Director Iancu at the American Intellectual Property Law Association Annual Meeting, Oct. 25, 2018, available at <https://www.uspto.gov/about-us/news-updates/remarks-director-iancu-american-intellectual-property-law-association-annul>.

¹² 35 U.S.C. § 314(a).

¹³ See *Congress Urged to Investigate PTAB Discretionary Denials*, Patents Post-Grant (June 30, 2020) available at <https://www.patentspostgrant.com/congress-urged-to-investigate-ptab-discretionary-denials/>.

¹⁴ See *Thryv, Inc. v. Click-to-Call Tech.*, 140 S. Ct. 1367 (2020) (holding that PTAB's decision on whether the one-year time bar to IPR institution applied was unappealable).

2016) have exploded, reaching 84 in 2019 and 167 in 2020.¹⁵ That means that the PTAB is taking a closer look at a declining number of challenged patents, leaving many intact.

Other Changes: The new policy of discretionary denials comes on top of many other changes to IPR that the PTO implemented through regulation during the last administration, including:

- reversing the PTO’s established policy of viewing issues of fact raised by a petition in the light most favorable to the petitioner prior to institution;¹⁶
- reversing the PTO’s established policy of interpreting patent claims in IPR using the same standard applied by examiners--the broadest reasonable interpretation;
- giving patent owners multiple opportunities to amend claims during IPR; and
- requiring the petitioner to show that the amended claims are unpatentable rather than conducting an independent assessment.

Cumulatively, these changes plus discretionary denials have weakened IPR by decreasing the number of patents reviewed. In FY2014, the PTAB instituted 75% of filed petitions. For FY2021, the PTAB instituted petitions at a rate of only 59%, and that followed a historical low of 56% for FY2020.¹⁷ Having so many fewer petitions instituted necessarily means that IPR proceedings will be taking a closer look at fewer patents and weeding out fewer bad patents.

Restoring IPR

The PTO announced and implemented its new policy of discretionary denials through a self-defined process of designating chosen PTAB decisions as “precedential” and requiring all future PTAB panels to follow the designated decisions. The key PTAB decisions are known as *NHK Spring*¹⁸ and *Fintiv*.¹⁹ A court challenge to the policy recently failed. A district court reasoned that because the AIA bars appeals

¹⁵ *PTAB Discretionary Denials Up 60% in 2020: Fueled Entirely by 314(a) Denials*, Unified Patents (January 5, 2021) (“Unified Patents Report”), available at <https://www.unifiedpatents.com/insights/2020-ptab-discretionary-denials-report>.

¹⁶ 85 Fed. Reg. 79120 (Dec. 9, 2020).

¹⁷ PTAB Trial Statistics FY21 End of Year Outcome Roundup, available at https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2021_roundup.pdf.

¹⁸ *NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc.*, No. IPR2018-00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018).

¹⁹ *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020) (“Fintiv”).

over PTAB decisions to grant or deny institution, stakeholders could not challenge in court how the PTO established its policy governing discretionary denials or the content of that policy.²⁰

With the courts unable to review the discretionary denial policy, change must come from either the PTO itself or legislation. A new PTO Director, working with the PTAB, could reverse its position on discretionary denials by simply withdrawing the precedential designation of the *NHK Spring* and *Fintiv* decisions. But the agency would need to do more to restore IPR to its former efficacy, thereby bringing its policies in line with the AIA's goals of improving patent quality and protecting the integrity of the patent system by making IPR a robust tool for weeding out invalid patents. For instance, the PTO could engage in rulemaking to undo the most recent regulations that weaken IPR, and it could confirm through regulation and precedential PTAB opinions that the merits of a petition and the reasonable likelihood that at least one patent claim is invalid is the preeminent factor in deciding whether or not to institute an IPR petition.

Legislation. One tool currently being discussed as a way to improve the efficacy of IPR is bipartisan legislation recently introduced by Senators Leahy and Cornyn, S.2891, Restoring the America Invents Act (RAIA).²¹ Key provisions of the bill would:

- Limit discretionary denials of institution in IPRs by making the reasonable likelihood that a claim is invalid paramount in the institution decision;
- Permit discretion in denials only when the same or substantially same arguments were previously before the PTO;
- Require a patent owner to demonstrate the patentability of any new or amended claims that it seeks during the IPR proceeding, and allow the PTAB to refer newly offered claims for examination; and
- Establish a presumption that petitioners who lose an IPR challenge before the PTAB have suffered an “injury-in-fact,” which may help give them standing to appeal that loss.

The Problem of Standing to Appeal IPR Losses

This last provision of the RAIA requires further explanation. As mentioned above, one powerful advantage of IPR and PGR is that any member of the public can challenge a patent's validity in these administrative proceedings. But challengers and patent owners are not on equal footing when it comes to the ability to appeal a loss before the PTAB, and that imbalance disadvantages and discourages

²⁰ Apple Inc., et al. v. Iancu, No. 5:20-cv-06128-EJD (N.D. Cal. Nov. 10, 2021), available at <https://storage.courtlistener.com/recap/gov.uscourts.cand.365219/gov.uscourts.cand.365219.133.0.pdf> (citing *Thrv, Inc. v. Click-To-Call Technologies*, 140 S. Ct. 1367 (2020)).

²¹ See Press Release, Leahy and Cornyn Introduce Bipartisan Bill to Support American Innovation and Reduce Litigation (Sept. 29, 2021), available at <https://www.leahy.senate.gov/press/leahy-and-cornyn-introduce-bipartisan-bill-to-support-american-innovation-and-reduce-litigation>.

public participation in this important procedure. The AIA explicitly allows that decisions of the PTAB may be appealed to the Court of Appeals for the Federal Circuit, but that court has ruled that the ability to appeal is governed by the requirements for standing under the Constitution.²²

A patent owner that loses before the PTAB and whose patent is invalidated will always have standing to appeal that adverse decision because of the injury it suffers from the invalidation. But under current law, the same is not true for challengers that lose when the PTAB upholds a patent. Those being sued by the patent owner in district court have standing to appeal, but beyond that the law becomes murky. The Federal Circuit has held that the fact of losing before the PTAB is insufficient to confer standing to appeal.²³ Members of the public who file IPRs and lose their challenge at the PTAB do not have standing to appeal that decision unless they have suffered an injury-in-fact, which has been narrowly defined as being sued or threatened with suit by the patent holder.²⁴ The RAIA broadens the definition of “injury-in-fact” beyond that currently recognized by the courts in a way that could give more of the public the ability to appeal an IPR loss and level the playing field with patent owners.

About I-MAK

The Initiative for Medicines, Access, and Knowledge (I-MAK) is a 501(c)(3) organization with a mission to build a more just and equitable medicines system. Our framework integrates deep analytical research to influence policy, education to activate change, and partnerships to drive solutions. We bring decades of private-sector expertise and an evidence-based approach to this mission, spanning 50 countries and including engagement with patients, drug manufacturers, patent offices, community leaders, public health professionals, policymakers, scientists, economists, and more. I-MAK’s work on structural change in the patent system is featured regularly in the national and global press, as well as Congressional hearings and Committee reports. In early 2021, I-MAK proposed a 10 point plan²⁵ to increase equity and competition through the patent system to help inform policy solutions.

Learn more about I-MAK’s work at <https://www.i-mak.org/>

²² *Consumer Watchdog v. WARF*, 753 F.3d 1258 (Fed. Cir. 2014).

²³ *General Electric Co. v. United Technologies Corp.*, 928 F.3c 1349 (Fed. Cir. 2019).

²⁴ Richard Stark, *Standing to Appeal IPR Decisions of the PTAB: Article III and the Federal Circuit*, *Landslide* (Mar./Apr. 2020), available at https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2019-20/march-april/standing-appeal-ipr-decisions-ptab-article-iii-federal-circuit/

²⁵ P Krishtel and T Amin. 10 Steps The Biden-Harris Administration Should Take To Bring Equity To Our Patent System. 17 Mar 2021. <https://medium.com/i-mak/10-steps-the-biden-harrisadministration-should-take-to-bring-equity-to-our-patentsystem-a50304bfe228>.