**Before the**
**U.S. Patent and Trademark Office**
**600 Dulany Street**
**Alexandria, VA 22314**

**via *https://www.regulations.gov***

**December 2, 2025**

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| In the Matter of | ) | |
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| Revision to Rules of Practice | ) | Docket No. PTO-P-2025-002 |
| Before the Patent Trial and Appeal Board | ) | |
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**Submitted by**

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**On behalf of**

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The R Street Institute is a non-profit, non-partisan public policy organization whose mission is to conduct policy research and outreach that promotes free markets and limited, effective government. As part of that mission, the R Street Institute regularly advocates for the removal of arbitrary legal and regulatory barriers that threaten free and open technological innovation. With respect to patents, we are strong advocates of

reforms that ensure patents continue to "promote the Progress of Science and the useful Arts" as stipulated in the U.S. Constitution.[1]

In furtherance of that mission, we hereby submit this comment to Docket No. PTO-P-2025-002 opposing the changes introduced in the "Revision to Rules of Practice Before the Patent Trial and Appeal Board" Notice of Proposed Rulemaking (NPRM).[2] The USPTO purports that the proposed rule would promote "fairness, efficiency, and predictability" in adjudicating patent disputes.[3] Yet the revisions under consideration may have the opposite effect by systematically reducing the scope of the *inter partes review* (IPR) process established by Congress in the America Invents Act in order to rein in excessive litigation and gamesmanship in the patent system.[4]

**Proposed Revisions Protect Weak and Overly Broad Patents**

Specifically, the NPRM proposes key revisions that would fundamentally limit the IPR process. Section 42.108(d) would prohibit the institution of an IPR unless the petitioner agrees not to "raise grounds of invalidity under 35 U.S.C. 102 or 103 in any other proceeding."[5] This change forces a petitioner to choose between instituting an IPR with the PTAB and forfeiting all future rights to challenge a patent in district court, or forfeiting the IPR option and challenging the patent in district court, reverting to the pre-AIA system of more costly litigation. This forced choice limits the scope of the PTAB,

[1] U.S. CONST., art. I, Section 8, Clause 8. https://constitution.congress.gov/browse/essay/artI-S8-C8-2-1/ALDE_00013061.
[2] Federal Register, "Revision to Rules of Practice Before the Patent Trial and Appeal Board," Vol. 90, No. 199, p. 48337 (Oct. 17, 2025) https://www.federalregister.gov/documents/2025/10/17/2025-19580/revision-to-rules-of-practice-before-the-patent-trial-and-appeal-board.
[3] *Id.*, p. 48337.
[4] P.L.112 – 29, "Leahy-Smith America Invents Act," Sept. 16, 2011. https://www.congress.gov/bill/112th-congress/house-bill/1249.
[5] Federal Register, s*upra*, Note 2, p. 48341.

which was established to provide a quicker and less expensive means of dispute resolution, and increases the costs of challenging weak or overly broad patents. Restricting the use of IPRs makes it more costly to address issues such as "patent thickets," which artificially keep drug prices above market rates.[6]

In addition, Section 42.108(e) would bar institution of an IPR if a challenged claim was previously found valid or not invalid in any prior proceeding—at the district court, International Trade Commission (ITC), PTAB, or even ex parte reexamination.[7] Further, the rule makes no distinction based on "whether the prior proceeding involved the same parties, the same prior art, or the same legal arguments."[8] This change would block an IPR from a new petitioner with stronger prior art solely because an earlier challenge failed. This change can have adverse effects on innovation by making it more difficult to invalidate low-quality patents that serve as barriers to entry, even if new facts emerge demonstrating a patent's invalidity.

Section 42.108(f) would bar the institution of an IPR when it is "more likely than not" that a parallel proceeding in a district court, at the ITC, or a PTAB Final Written Decision will be concluded before the IPR can be completed.[9] In effect, this codifies guidance on discretionary denials under *Fintiv*. But it also reduces access to IPR based on court schedules, which a petitioner cannot control. In this respect, the proposed revision runs counter to the AIA, which sought to create access to more expeditious means of invalidating low-quality patents.

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[6] Wayne T. Brough, "Patent Reform and Pharmaceuticals: The Key to Lower Drug Prices," R Street Institute, Jan. 12, 2023. https://www.rstreet.org/research/patent-reform-and-pharmaceuticals-the-key-to-lower-drug-prices.
[7] Federal Register, s*upra*, Note 2, p. 48341.
[8] Dennis Crouch, "Rulemaking as Backdoor Reform: Can the USPTO Bar Whole Classes of IPR Petitions?" *Patently-O, November 10, 2025.* https://patentlyo.com.
[9] Federal Register, *supra*, Note 2, p. 48341.

Finally, Section 42.108(g) states that these new limitations on IPRs will only be waived for "extraordinary circumstances," leaving the decision to waive the new restrictions exclusively in the hands of the USPTO director.[10] It is especially concerning that the proposed rule explicitly excludes new prior art, new expert testimony, or new case law from consideration as extraordinary circumstances.[11]The fundamental purpose of IPR is to enable the USPTO to consider prior art and arguments that the original patent examiner may have overlooked. In essence, the USPTO would be ignoring dispositive new evidence simply for procedural reasons. Patent quality is not optimized under these proposed rules, nor are the benefits of patents, which are supposed to inure to the public. Instead, the changes would exacerbate the adverse economic impacts of low-quality patents by increasing the cost of invalidating them.

**Economic Impact**

The NPRM's economic reasoning is premised on a fundamental flaw, stating that "the licensing fees or judgments that a patent challenger may avoid paying are reduced compensation for innovators whose patent claims have already been adequately tested."[12] However, the IPR process was created precisely to weed out erroneously granted patents. In such instances, licensing fees are more akin to monopoly rents that contribute little to innovation; rather, they are a deadweight loss that reduces social welfare. This is why

[10] *Id.*
[11] *Id.*
[12] FR, *supra,* Note 2, p. 48337.

patent quality remains a significant concern. In fact, a recent GAO report highlights the need for reform of "persistent examination and quality challenges" at the USPTO.[13]

Framing the economic calculation as merely a dispute between the petitioner and the patent owner overlooks the substantial costs placed on the broader public. For example, patent thickets can prevent lower-cost generic drugs from reaching the market.[14] One study found that the one-year cost from delayed competition due to patent thickets surrounding just one drug—Humira—amounted to $7.6 billion.[15] Drug pricing is an essential issue for this administration, and such patent thickets contribute to higher costs that have significant adverse impacts on patients, healthcare systems, and federal healthcare programs.

More generally, one study has identified a correlation between administrative patent challenges—of which IPRs are the most prominent—and lower drug prices.[16] The study found that the most challenges involved secondary patents of low quality and little, if any, innovation. Removing these patents facilitates generic manufacturers' entry, and this competition substantially lowers prices. Another study found that prices fall by over 50 percent in the first year of generic competition and by more than 80 percent within five years.[17]

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[13] GAO, "Intellectual Property: Patent Office Should Strengthen Its Efforts to Address Persistent Examination and Quality Challenges," GAO-25-107218**,** April, 2025. https://www.gao.gov/products/gao-25-107218.

[14] Kaitlin Carroll, "Patents over Patients: How Pharmaceutical Companies Use the Patent System to Keep Drug Costs High," *Journal of Law and Technology.* https://jolt.richmond.edu/2023/11/27/patents-over-patients-how-pharmaceutical-companies-use-the-patent-system-to-keep-drug-costs-high.

[15] Alex Brill and Christy Robinson, "Patent Thickets and Lost Drug Savings," Matrix Global Advisors, January 2023. https://getmga.com/new-report-from-mga-examines-the-one-year-cost-savings-lost-due-to-patent-thickets.

[16] Charles Duan, "On the Appeal of Drug Patent Challenges," *American University Law Review* 2 (March 31, 2023). https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4406404.

[17] "Price Declines after Branded Medicines Lose Exclusivity in the U.S.," IMS Institute for Health Care Informatics, January 2016. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf.

The proposed revisions invert the incentive for innovation by prioritizing the collection of fees on patents of questionable quality over the harms to social welfare generated by weak and overly broad patents. Studies have demonstrated the benefits of the IPR process for addressing the social welfare losses from low-quality patents.[18] One researcher found that the PTAB IPR process generated $2.6 billion in savings from 2014 to 2019, primarily due to lower dispute-resolution costs.[19]

Adopting the proposed rule would, by definition, reduce the availability of IPRs at the PTAB and therefore reduce these benefits, directly contradicting congressional intent in the America Invents Act, which sought to provide an expeditious, lower-cost mechanism for challenging weak and low-quality patents.[20]

**Conclusion**

The revisions included in the NPRM would hamper innovation, increase litigation, harm consumers, and reduce the global competitiveness of American companies. Moreover, the proposed changes also contravene the America Invents Act, which, among other things, was enacted to specifically facilitate less costly and more timely resolution of patent disputes.

The NPRM's economic analysis is built on the false premise that challenged patent claims have already been adequately tested. It ignores the substantial public costs from invalid patents, mischaracterizes monopoly rents as innovation incentives, and would foreclose market entry for the very innovators it claims to protect.

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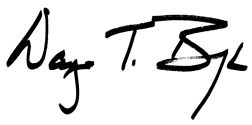
[18] Korok Ray, "The Economic Impact of Codifying Fintiv," February 3, 2023. https://ssrn.com/abstract=4346836 or http://dx.doi.org/10.2139/ssrn.4346836.
[19] "An Assessment of the Impact of the America Invents Act and the Patent Trial and Appeal Board on the US Economy," The Perryman Group, June 2020.
[20] AIA, *supra*, Note 4.

The proposed revisions also raise substantial questions about the scope of the USPTO's statutory authority. While the statute allows the USPTO Director to decline to institute IPRs on a case-by-case basis, it is not evident that it grants the authority to exclude entire classes of petitions. [21]

Moreover, the USPTO characterizes the revisions as procedural rather than policy changes, thereby eliminating the need for notice-and-comment rulemaking.[22] Yet the substantive restrictions included in the revisions have significant economic impacts, suggesting that the NPRM is more indicative of a policy change than a procedural or administrative change. Given changes to petitioners' statutory rights before the PTAB, a complete notice-and-comment rulemaking is necessary, including a Regulatory Impact Analysis.

I urge the USPTO to withdraw this proposed rule in its entirety. A complete regulatory impact analysis that fully accounts for the rule's impact on patent quality, innovation, competition, and consumer welfare is necessary before any such rulemaking can proceed.

Respectfully submitted,



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[21] Dennis Crouch, *supra*, Note 8.
[22] F.R., *supra*, Note 2, p. 48338.