

[Docket No. PTO-P-2025-0025], for “Revision to Rules of Practice Before the Patent Trial and Appeal Board”

Dear Director Squires,

Thank you for providing us with the opportunity to submit comments and to share how revising the rules of practice before the Patent Trial and Appeal Board will negatively impact our young adult patient community. Generation Patient is an organization created by and for young adult patients living with chronic and rare medical conditions such as lupus, inflammatory bowel disease, tuberous sclerosis, Lyme disease, and rheumatoid arthritis. We seek to ensure a better future for our generation of patients by providing direct support through peer-support groups while driving systems-level change through policy work, leadership programming, and advocacy initiatives. Through our direct support work, we have led over 650 peer support meetings and continue to build the evidence base to build holistic support for young adults with chronic and rare conditions.

Our organization does not accept funding from the pharmaceutical, insurance, pharmaceutical benefit managers, or related healthcare industries. We are among a small group of patient advocacy organizations that are completely **free of industry influence**; we are solely beholden to the interests of our patient community. We believe strongly in programs advancing transparency and conflict of interest disclosures. We hope that this administration will invite more independent patient advocacy organizations to this important conversation.

Our young adult patient community strongly opposes the United States Patent and Trademark Office (USPTO) proposed rule governing the institution of Inter Partes Review (IPR) proceedings. The proposed rule would tarnish the IPR system, a tool to ensure patent quality that has proven essential for promoting competition, innovation, and our community’s access to affordable generic pharmaceutical options. This rule would shield invalid patents from review, expand monopolies, and lead to higher prices for the life-saving medications we desperately need to thrive into adulthood. This outcome is directly contrary to the America Invents Act’s (AIA) purpose and would cause severe, tangible harm to patients across the country.

We urge the USPTO to consider the impact of this proposal on the ability of young adult patients to access life-saving prescription medicines.

The Proposed Rules will Make Medications Inaccessible

Over half of all young adults living in the United States are living with at least one chronic condition, and over 20% are living with multiple conditions.¹ Many of the medications our community relies on are financially inaccessible due to the lack of an affordable generic

alternative. According to a report released by KFF, three in ten U.S. adults reported that they have not taken their medications as prescribed at some point this past year because of their high price.²

However, when the PTAB cancels invalid pharmaceutical patents, patients gain immediate access to affordable medications. For example, IPR-driven price reductions have led to cardiovascular medications falling 97% in price, cancer drugs dropping 80-98%, and treatments for opioid addiction becoming 50% more affordable.³ IPR has allowed millions of our community members to access medications that were previously out of reach due to bad patents.

Under the proposed rules, many of these life-saving determinations of unpatentability would never have occurred. Even in cases where a PTAB decision of unpatentability is later challenged in district court, district court judges heavily rely on the technical expertise of the PTAB when making decisions, extensively utilizing the record and technical materials provided by the PTAB, or just issuing a summary affirmance without an opinion.⁴ In fact, district courts rarely reverse the decisions made by the PTAB, further emphasizing the importance of protecting access to this administrative tribunal.⁵ The devastating consequences of restricting public access to the PTAB will lead to an entire generation of young adults having to choose between creating a successful future for themselves and our nation or accessing the medication they need for survival.

Increasing Patent Quality Is Imperative

The USPTO claims these restrictions promote “reliable” patents; however, the evidence shows the real problem is that the USPTO grants too many low-quality patents in the first place. USPTO’s own records show that in IPR cases involving patents older than six years, 82% had at least one claim found invalid.⁶ These are patents that should never have been granted, and the PTAB’s judges often possess better expertise in biochemistry and pharmaceuticals to review these patents compared to district court judges.⁷ Invalid patents don’t become valid simply because they are old; they continue blocking competition, raising prices, and harming patients. Rather than restricting this quality control mechanism, the USPTO should focus on improving examination quality.

Protecting Fairness in USPTO

When a low-quality pharmaceutical patent is granted, that single patent can be used to target a large number of entities seeking to create generics, blocking access to these affordable options for young adult patients. Due to the large number of entities facing litigation by a single low-quality pharmaceutical patent, it would only be fair to provide all interested parties with the power to challenge its patentability under the PTAB. Under the proposed rule’s provision to instill a “one and done” denial framework [Section 42.108(e)], if the one early challenger fails to

bring a strong case against the patentability of the patent, all other interested parties are prevented from challenging the patent, even if they have a strong case against its patentability. While the proposed rule added an “extraordinary circumstances” exception [Section 42.108(g)], this exception is very limited in scope and unfairly excludes situations of new evidence or prior error. In essence, this would provide additional protection to patent holders outside of what Congress intended under the AIA and foster further delays to generic entry for patients. We ask the USPTO to withdraw this proposed rule and protect the ability of third parties to challenge a previously reviewed patent in the PTAB.

Protecting the Public’s Ability to Access the PTAB

IPR provides the public with a meaningful opportunity to challenge the validity of invalid pharmaceutical patents before the PTAB. IPR is a critical conduit for the public to participate in the patent system, which directly influences patient health and quality of life. Weak pharmaceutical patents, such as marginal or minor changes to an existing medication, stifle innovation and prevent more affordable generics and biosimilars from entering the market. If pharmaceutical companies are permitted to continually file unnecessary patents to extend their monopolies without the public maintaining the ability to bring these bad patents to IPR, **many young adult patients will continue to face the reality of unaffordable prescription drug prices.** Maintaining a strong, accessible IPR process is essential to ensuring that the young adult patients have access to affordable medications.

Respectfully,

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1. Watson KB, Carlson SA, Loustalot F, et al. Chronic Conditions Among Adults Aged 18–34 Years — United States, 2019. *MMWR Morb Mortal Wkly Rep* 2022;71:964–970. DOI: <http://dx.doi.org/10.15585/mmwr.mm7130a3>.
2. Difficulty Paying for Prescription Drugs Among U.S. Adults — United States, 2024. KFF Health Tracking Poll. 2024. <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-prescription-drug-costs/>.
3. Charles Duan, On the Appeal of Drug Patent Challenges, 72 *Am. U. L. Rev.* 1177 (2023), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4406404.
4. *See id.*
5. *See id.*
6. Alex Moss, When Truth Speaks: Challenging the USPTO's "Settled Expectations" Rule, Public Interest Patent Law Institute (Oct. 20, 2025), <https://www.piplius.org/news/when-truth-speaks-challenging-the-usptos-settled-expectations-rule>.
7. *See supra* note 3.