PATIENTS FOR AFFORDABLE DRUGS™

November 21, 2025

The Honorable John A. Squires
United States Department of Commerce Under Secretary for Intellectual Property
United States Patent and Trademark Office (USPTO) Director
600 Dulany Street, Alexandria, VA 22314

RE: Rules of Practice before the Patent Trial and Appeal Board (PTO-P-2025-0025)

Dear Under-Secretary of Commerce and USPTO Director Squires:

Patients For Affordable Drugs (P4AD) appreciates the opportunity to offer comments in support of the request for comment entitled "Rules of Practice before the Patent Trial and Appeal Board.") On behalf of patients across all 50 States struggling to afford their medication, we strongly oppose the proposed changes to the Patent Trial and Appeal Board (PTAB) outlined in the notice of proposed rulemaking.

P4AD is the only national patient organization focused exclusively on system-changing policies to lower prescription drug prices. We are bipartisan and independent, and do not accept funding from any organizations that profit from the development or distribution of prescription drugs.

When prescription drug prices are too high, Americans face challenges affording other expenses, such as food and housing. As the Trump Administration has acknowledged, the United States is experiencing an affordability crisis. One in three Americans is struggling to afford the medications they're prescribed. Older Americans are particularly vulnerable and are more likely to skip doses or forgo prescription refills due to cost, at more than double the rate in other countries.[1] In 2022, about one in five adults ages 65 and older either skipped, delayed, or rationed their prescribed medicines due to cost.[2]

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[1](2024, December 5). *Healthcare Affordability for Older Adults: How the U.S. Compares to Other Countries*. The Commonwealth Fund. https://www.commonwealthfund.org/publications/issue-briefs/2024/dec/health-care-affordability-older-adults-how-us-compares-other-countries

[2](2023, May 18). *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*. Journal of the American Medical Association. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012

When a drug company makes a truly innovative discovery, it should be rewarded with a patent and receive a fair return for risk and investment. The patent system is designed to facilitate these rewards for innovation so that drug companies are incentivized to pursue true clinical breakthroughs and inventions that bring meaningful benefits to patients. The entry of generic and biosimilar competition leads to lower costs for patients, and a single generic can lower the cost of a prescription drug by 30%, and the entry of six or more generics can lower prices by nearly 85%.[3] However, drug companies frequently abuse the patent system to extend their monopolies and delay the entry of generic and biosimilar competition, leading to higher drug prices for patients.

The PTAB is an Essential Tool to Lower Drug Prices for Americans

The America Invents Act (AIA) outlined a framework for the PTAB that allows for more efficient, accessible, and affordable challenges to invalid patents. Prior to the creation of the PTAB, invalidating unlawful patents cost millions of dollars in district courts, harmed many communities, and led to patients, patient advocacy organizations, and researchers often lacking standing. The PTAB and Inter Partes Review (IPR) created a much-needed pathway for curbing Big Pharma's patent abuse and bringing lower-cost generic and biosimilars to market. Instead of gutting one of the best pathways for overturning unlawful patents, the administration should focus on increasing patent quality and ending Big Pharma's abuse of the patent system.

Patent Abuse Delays Competition and Harms Patients

Patent-protected brand-name drugs make up only 8% of prescriptions but account for 84% of drug spending.[4] Drug companies abuse the U.S. patent system to maintain their monopolies and keep prices high for patients for as long as possible. Patents and patent litigation are the biggest impediments to getting biosimilars onto the market.

When the PTAB cancels invalid pharmaceutical patents, it opens the door for patients to access more affordable medications right away. Studies tracking price changes after IPR challenges show just how powerful the impact can be, with cardiovascular medications falling 97% in price, cancer drugs dropping 80-98%, and treatments for opioid addiction becoming 50% more affordable.[5] These aren't abstract numbers—they represent millions of patients who can afford medications that were previously out of reach. Under the proposed rules, many of

[3] (2022, March 17). *The Generic Drug Approval Process.* FDA https://www.fda.gov/drugs/cder-conversations/generic-drug-approval-process

[4] (2023, April 19). *The Cost of Prescription Drug Abuse*. Public Interest Research Group https://pirg.org/resources/the-cost-of-prescription-drug-patent-abuse/

[5] 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.

these life-saving reviews would never have been instituted, as these cases involved patents that had evaded meaningful scrutiny in district court. Under the proposed rules, generic companies would have to either wait for patent protection on a drug to expire or pay millions of dollars in district courts to challenge a drug's patents in order to bring a generic to market. The PTAB offers a more affordable option for patent litigation, costing on average a few hundred thousand dollars as opposed to the millions of dollars that district court cases cost on average.[6] PTAB judges also have the technical subject matter expertise needed to accurately assess complicated biotech patent cases that district courts lack.

USPTO's own data show that in IPR cases involving patents older than six years—that is to say, the same patents these rules would block from IPR—82% had at least one claim found to be invalid.[7] These are patents that should have never been granted in the first place and are potentially blocking access to lifesaving, affordable generics and biosimilars for patients. Already, drug companies are extending their exclusivity periods multiple times, sometimes expanding their exclusivities by 15 or even 20 years.[8] Patients like 77-year-old Sue in Kentucky can't afford to wait for unlawful patents to expire. Sue was prescribed Humira for her autoimmune condition, but was forced to stop filling her prescription because she was unable to afford the $8,000 co-pay on her fixed income. Abbvie filed over 250 patents on Humira and artificially extended its monopoly for over 20 years, making over $100 billion in revenue at the expense of American lives.[9]

On behalf of patients across all 50 states, we urge the proposed rules to be withdrawn. Just this week, a new study showed that nearly half of US adults are worried they won't be able to afford health care in the coming year, while four in five Americans (80%) support changes to patent laws to address drug pricing.[10] Americans want and need action to hold the industry accountable and reform the patent system, not a handout to the pharmaceutical industry. We

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[6] (2013, August) *2013 Report of the Economic Survey*, AIPLA. https://www.aipla.org/detail/journal-issue/2013-report-of-the-economic-survey

[7] 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.

[8] (2023, November 16). *Patents and regulatory exclusivities on FDA-approved insulin products: A longitudinal database study, 1986–2019*. PLOS Medicine https://www.fda.gov/drugs/cder-conversations/generic-drug-approval-process

[9] (2023, January 28). *How a Drug Company Made $114 Billion by Gaming the U.S. Patent System*, The New York Times. https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html

[10] (2025, November 17). *How Do Americans Experience Healthcare in Their State?* Gallup. https://news.gallup.com/poll/698042/americans-experience-healthcare-state.aspx

respectfully request that the proposed rules be withdrawn in their entirety. Patients' lives hang in the balance.

Sincerely,

Merith Basey MSc
Executive Director
Patients For Affordable Drugs