



December 1, 2025

The Honorable John A. Squires
U.S. Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

SUBJECT: DOCKET NUMBER PTO-P-2025-0025

Dear Director Squires,

Thank you for the opportunity to provide comments to the U.S. Patent and Trademark Office (USPTO) on the following proposed rule:

- *Revision to Rules of Practice before the Patent Trial and Appeal Board, No. PTO-P-2025-0025*

Arnold Ventures is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. As a philanthropy, we do not accept funding from industry or have a financial stake in policy outcomes. Our work within the health care sector is driven by the recognition that the system costs too much and fails to adequately care for the people it serves. Our work spans a range of issues including commercial-sector prices, provider payment incentives, prescription drug prices, clinical trials, Medicare sustainability, and Medicaid.

We thank you for the opportunity to provide comments. We have a strong interest in preserving and strengthening the accessibility and effectiveness of the inter partes review (IPR) process, which is used for challenging invalid patents at the Patent and Trial Appeal Board (PTAB). The PTAB plays a critical role mitigating the harmful effects of invalid patents, including those in the pharmaceutical sector.

Evidence shows that the PTAB's capacity to cancel wrongly granted patents and to decide whether a patent claim is valid are critical to bringing more competition to the pharmaceutical market, which in turn lowers drug prices and improves patient access. Empirical research shows that IPRs leading to the cancellation of invalid pharmaceutical patents result in significant drug price reductions, some as large as 97%.¹

Arnold Ventures does not support the proposed rule and urges the USPTO to withdraw it. The proposed rule would severely limit the use of IPRs in the pharmaceutical sector, which would make the pharmaceutical market much less competitive. The IPR process is a critical congressional check on patent quality that is important to promote competition and innovation. **If adopted, the rule would extend brand name pharmaceutical company monopolies and lead to higher prices for patients, employers, and taxpayers.** This is in direct conflict with the administration's priority to deliver lower drug prices to American patients by accelerating competition,² particularly its recent efforts to bring more competition to the US biosimilar market.³

In 82% of IPR cases involving patents older than six years, at least one claim was found invalid.⁴ These are patents that should never have been granted. The PTAB's judges are catching critical mistakes that district courts often miss. This would be drastically curtailed if the proposed rule were finalized. Currently, the IPR process also allows generic and biosimilar manufacturers to resolve invalid patent claims earlier (before the case can be brought to a district court), helping to make the patent challenge process more efficient. But the incentives to challenge patents using the IPR process would be greatly undermined by the proposed rule.

Thank you for your consideration of our comments. Please contact Mark E. Miller, Ph.D. Executive Vice President of Health Care at Arnold Ventures at mmiller@arnoldventures.org or Andrea Noda, MPP, Vice President of Health Care at anoda@arnoldventures.org with any questions.



Sincerely,

Andrea Noda
Vice President of Health Care

¹Duan, Charles, On the Appeal of Drug Patent Challenges, 2 AM. U. L. REV. 1177, 1203–04 (2023), available at: <https://ssrn.com/abstract=4406404> or <http://dx.doi.org/10.2139/ssrn.4406404>.

²[Lowering Drug Prices by Once Again Putting Americans First – The White House](#)

³[FDA Moves to Accelerate Biosimilar Development and Lower Drug Costs | HHS.gov](#)

⁴Alex 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>.