June 18, 2024

Director Kathi Vidal
U.S. Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Subject: Docket number PTO-P-2023-0048
Filed electronically at https://www.regulations.gov

Dear Director Vidal,

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

- *Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement, No. PTO-P-2023-0048*

Arnold Ventures is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. We work to develop evidence to drive reform across a range of issues including health care, education, and criminal justice. Our work within the healthcare sector is driven by the recognition that the system costs too much and often fails to adequately care for the people it serves.

We have a strong interest in preserving and strengthening the accessibility and effectiveness of proceedings for challenging invalid patents at the Patent and Trial Appeal Board (PTAB). The PTAB plays a critical role in the public’s ability to mitigate the harmful effects of invalid patents, particularly in the pharmaceutical sector.

Evidence shows that the PTAB’s capacity to cancel wrongly granted patents is critical to bringing more competition to the pharmaceutical market, which in turn lowers drug prices and improves patient access. Empirical research shows that inter partes reviews leading to the cancellation of invalid pharmaceutical patents result in significant drug price reductions, some as large as 97%.¹

Arnold Ventures strongly supports the proposed regulations. These regulations represent a significant step towards a system that more fairly balances the public’s interest in eliminating invalid patents and their owners’ interests in preserving them. By keeping the PTAB’s focus on the merits of a petition when deciding institution, these regulations align with Congress’s intent when it created these proceedings. If implemented effectively, they can facilitate meaningful improvements to the accessibility and affordability of prescription drugs.

Specifically, we support the following outlined in the proposed rule:

1. **Preserve the ability of “any person” to file a petition for review, as provided by the America Invents Act.** (See 35 U.S.C. § 311(a)).
2. **Make a petition’s merits the primary factor in the PTAB’s decision to institute it.** (See Proposed 37 CFR § 42.108).
3. **Define serial petitions** as petitions that challenge at least some of the same claims (instead of the same patent) as a previous challenge by the same patent owner (instead of any entity). (See Proposed 37 CFR § 42.2)

We commend the USPTO for working to ensure that PTAB proceedings remain accessible and effective, which is vital for innovation, competition, and public health. 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