Comments from Public Citizen in Response to the U.S. Patent & Trademark Office's Request for Comment on 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

Public Citizen is a consumer advocacy organization with more than 500,000 members and supporters and a fifty-year history protecting the public's interest before federal agencies, Congress, and the courts. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally. As such, we and our members 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 helps combat inflated prescription drug prices in this country. Empirical research by Professor Charles Duan, a member of the Public Patent Advisory Committee, shows that IPRs leading to the cancellation of invalid pharmaceutical patents result in significant drug price reductions, generating financial savings and benefits to health and wellbeing.[1]

We write to express our strong support for 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 industry concerns. 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 as well as efforts to address the drug pricing crisis today. If implemented effectively, they have the potential to contribute to making medicine more affordable for people who need it.

In particular, we wish to emphasize our support for aspects of the proposal that:

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)).

[1] Charles Duan, *On the Appeal of Drug Patent Challenges*, 72 AM. U. L. REV. 1177, 1191-1207 (2023).

2. **Make a petition's merits the primary factor in the PTAB's decision to institute a proceeding.** (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)
4. **Require that a joint motion for termination of a proceeding, filed before or after institution, must be accompanied by any written settlement agreement,** which enhances transparency and oversight of unfair, anticompetitive practices in pre-institution settlement agreements. (See Proposed 37 CFR 42.74).

We commend the USPTO for the direction it has chosen in promulgating these regulations and look forward to engaging in the future on their implementation. Ensuring that PTAB proceedings remain accessible and effective supports innovation, competition, and public health. Thank you for your commitment to the patent system and your consideration of the public's interest.

Sincerely,
Public Citizen