PUBLICCITIZEN

1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

Public Citizen is a nonprofit consumer advocacy organization with 500,000 members and supporters. Public Citizen's Access to Medicines Program works with partners worldwide to improve health outcomes and make medicines affordable and available for all through tools in policy and law. We are submitting these comments in opposition to the U.S. Patent and Trademark Office ("USPTO") proceeding with proposed rulemaking that would codify practices which harm consumers by allowing low-quality, erroneously granted patents to remain place.

People in the United States pay the highest drug prices in the world.[1] These exorbitant prices are harming people's health and threatening families' economic security, with to three-in-ten Americans reporting not taking their medicine as prescribed due to cost.[2] Americans' hardship has made lowering drug prices one of their top demands for policymakers, regardless of political affiliation.[3]

High drug prices are rooted in laws which provide patent and other legal monopolies.[4] While these government-granted monopolies were intended by policymakers to provide incentive for new medical inventions, far too often they instead reward corporations with highly paid legal teams by inappropriately extending monopoly periods, which in turn stifles price-lowering generic and biosimilar competition, hurting the very patients policymakers intend for these rules to help.

The U.S. Patent and Trademark Office ("USPTO") should not proceed with rulemaking that would make discretionary denial of petitions by the Patent Trial and Appeal Board ("PTAB") for IPR more common. Denying valid petitions can deprive Americans of the essential price reductions that come with generic and biosimilar competition and instead, delay entry of generic competition. On average, generic competition on small molecule drugs save Americans 79% over the pre-competition price. Robust competition often delivers even deeper price reductions.[5]

---

[1] https://www.citizen.org/article/pharma-101-a-primer/

[2] https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/

[3] https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2020/02/Politico-HSPH-Priorities-Poll-report-021020.pdf

[4] https://www.citizen.org/article/pharma-101-a-primer/

[5] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices

Any delay in the introduction of generic and biosimilar competition can have significant economic impact on patients and payors. Instead of proceeding with the proposed rulemaking, Public Citizen urges the PTO to re-prioritize patent quality and restore the IPR system to its proper focus, which is resolving the problems of erroneously-granted patents, which raise drug prices and make medicines unaffordable.