

I'm Patricia Kelmar, Senior Director for U.S. PIRG, the Public Interest Research Group, a consumer advocacy organization. The U.S. spends far more on prescription drugs than other countries, not because we use more drugs, but because we pay higher prices. High prices impact our personal budgets, increase our health insurance premiums and put greater strain on important taxpayer-funded health programs like Medicare and Medicaid. The Patent Office plays a key role in whether or not patients have access to lower cost medications in the marketplace. We support proposed fee schedule changes that will give the PTO resources to improve scrutiny of patent applications submitted by the pharmaceutical industry. And I'll draw your attention to one change that will negatively impact the public's ability to challenge weak patents.

While brand-name drugs make up only 8% of prescriptions, they account for 84% of all U.S. drug spending.¹ But when generics and biosimilars enter the market, the competition drives down prices. Savings are dramatic—\$10-20 billion annually.² That's the power of a competitive marketplace. Unfortunately recent misuse of patents by pharmaceutical companies is undermining price competition. The Patent Office is the first agency in the drug approval process that can make a huge difference on whether lower cost alternatives are ever offered to patients.

Part of the PTO's mission is to provide high quality and timely examination of patent applications.³ The sheer volume of applications (600,000 a year⁴) puts the 8,000 patent examiners⁵ under time pressure, resulting in an average of only 19 hours examining each application.⁶

Studies by the Inspector General and General Accounting Office both show that examiners need more resources and time. We agree. They need time to uncover patent applications that are filed in an attempt to

¹ IQVIA Institute for Human Data Science, *The Use of Medicines in the U.S. 2022*, April, 2022, 39, <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022> accessed on April 2, 2023.

² Ryan Conrad PhD et al., "Estimating Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020", US Food and Drug Administration, August 2022, accessed at <https://www.fda.gov/media/161540/download>

³ Our Mission, "US Patent and Trademark Office", US Department of Commerce, accessed at [https://www.commerce.gov/bureaus-and-offices/uspto#:~:text=The%20mission%20of%20the%20U.S.,\(IP\)%20policy%2C%20and%20delivering](https://www.commerce.gov/bureaus-and-offices/uspto#:~:text=The%20mission%20of%20the%20U.S.,(IP)%20policy%2C%20and%20delivering)

⁴ "US Patent Statistics Chart Calendar Years 1963-2020", US Patent and Trademark Office, Patent Technology Monitoring Team, accessed at https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm

⁵ "Attend 2022 Patent Examiner Virtual Open House", US Patent and Trademark Office, March 1, 2022, accessed at <https://www.uspto.gov/about-us/events/attend-2022-patent-examiner-virtual-recruitment-open-house#:~:text=patent%20examiner%20vacancies,-The%20USPTO%20employs%20over%208%2C000%20patent%20examiners%2C%20and%20we%27re,a%20patent%20can%20be%20granted.>

⁶ Michael D. Frakes & Melissa F. Wasserman, "Is the time allocated to review patent applications inducing examiners to grant invalid patents?: Evidence from micro-level application data", NBER Working Paper Series, July 2014, accessed at https://www.nber.org/system/files/working_papers/w20337/w20337.pdf#page=9

build a portfolio of questionably weak patents. This well-documented business strategy, known as "patent thickening", is employed by drug companies to effectively deter or prevent generic and biosimilar competition.

Amassing excessive numbers of "secondary" patents on a single drug keeps competition at bay.⁷ It is a lengthy and expensive process to invalidate an approved patent. Better to fund more examiner time to ensure weak patents are never approved, rather than hoping litigation will right any wrongs.⁸

I'll submit written details relating to these three comments:

1. **We support the new proposed fees related to continuing applications, and urge you to consider raising the proposed amounts.** Continuing applications are often used to build patent thickets, by patenting post FDA-approval changes to formulations, delivery mechanisms or additional methods of use. **Of** the top 10 selling drugs, 66% of patent applications were filed **after** the Food and Drug Administration (FDA) approved the drug.⁹ The PTO deserves to be fully compensated for the detailed work to uncover attempts by applicants to build patent thickets through continuing applications.
2. **We oppose the fee increases for inter partes review (IPR), the only avenue for the public to challenge weak patents.** Because the public cannot prove standing in a federal district court, to challenge weak patents, IPR is our only option. When IPR fees were lower, public interest groups like EFF, I-MAK, and Consumer Watchdog petitioned for review. The previous administration's increases put IPR proceedings financially out of reach for public interest groups, and these additional proposed increases of more than \$10,000 will shut out the public interest definitively. Under the proposed IPR fees, it would cost us almost \$52,000 just to ask for review and get to the institution phase. That's an insurmountable sum for most nonprofits. And that doesn't even include the money we would need to raise to hire attorneys, pay for experts, and all of the other costs associated with an IPR case. Please consider lowering or even waiving IPR fees for low-resourced public entities.
3. **Finally, we need more information to fully evaluate the proposed fee schedule** such as an explanation of how the costs per unit were derived and cost amounts for the unquantified tasks in the schedule. Fees should be aligned to support agency functions that utilize the most resources.

In conclusion, we support fee increases to fund excellence in patent examination, while preserving other agency resources for examiner training and enforcement activity. And please, lower or eliminate IPR fees so consumers and patients will not be financially blocked from using their rights to challenge weak patents.

Thanks very much!

⁷ Aaron Kesselheim, Commonwealth Fund, *Strategies that Delay Market Entry of Generic Drugs*, September 8, 2017, <https://www.commonwealthfund.org/publications/journal-article/2017/sep/strategies-delay-market-entry-generic-drugs>

⁸ Charles Duan, *On the Appeal of Drug Patent Challenges*, American University Law Review, March 31, 2023, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4406404

⁹ I-MAK, *Overpatented, Overpriced Curbing patent abuse: Tackling the root of the drug pricing crisis*, September, 2022, p.3, <https://www.i-mak.org/wp-content/uploads/2023/01/Overpatented-Overpriced-2023-01-24.pdf>.