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Kathi Vidal,JD, Director
U.S. Patent and Trademark Office
Alexandria, VA 22314

Robert M. Califf, MD, Commissioner
U.S. Food and Drug Administration
Silver Spring, MD 20993

January 17, 2022

Re: Docket No. PTO-P-2022-0037

Director Vidal and Commissioner Califf:

On behalf of U.S. PIRG, the Public Interest Research Group, and our 24 state affiliates, I am submitting these comments in response to the request by the Food and Drug Administration (FDA) and the Patent and Trademark Office (USPTO) for public input on areas for USPTO-FDA collaboration and engagement.

PIRG is a nonprofit, nonpartisan consumer advocacy organization with a 50 year history of speaking out for a healthier, safer world which includes promoting policies that support the delivery of the high value healthcare we deserve. As part of our campaign to address skyrocketing health care prices, we advocate for solutions to the reasons drug prices are so high and increase every year. We support efforts to create strong, competitive health care markets that work to keep prices in check. Generic and biosimilar drugs play an important role in reining in the cost of prescription drugs. They provide therapeutically equivalent alternatives for doctors to prescribe and for consumers to access at their pharmacies under state generic drug substitution laws.

In more recent years, PIRG has focused our attention on the barriers to market entry of generic and biosimilar medications as one key reason drug prices are so high. The FDA and the USPTO are important to removing these barriers. We appreciate your decision to prioritize a more collaborative bi-agency approach as you review and approve new medications coming to market and the patents that relate to those drugs.

The impact of high prescription drug prices.

The prices of prescription drugs are skyrocketing, driving up the cost of health care for patients, insured families and our state and federal health programs. Two-thirds of U.S. adults rely on

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prescription drugs to live full lives and to treat illnesses and medical conditions.[1] And yet 1 in 4 people struggle to pay for their medications.[2] When people can't fit drugs in their monthly budgets, they make decisions that impact their health. Almost a third of all adults report not taking their medicines as prescribed at some point in the past year because of the cost.[3] Some choose not to fill a prescription (19%) and about one in 10 cut their pills in half or skip a dose.[4] Because drug costs make up about 20% of our insurance premiums, when drug prices go up, so do our premiums.[5]

Competition by generic and biosimilar drugs bring savings.

People in America pay two to three times more than those in other countries for the same medications.[6] Why? We aren't spending more because we use more prescription drugs. It's simply that the prices for our medications are higher. The best way to bring down prices is to allow competitors to come to market. When generics are introduced into the marketplace, even brand name drugs drop their prices. Savings in recent years from new generic drug approvals are dramatic.[7] Generic drug approvals in 2018 yielded annual savings of over $17.8 billion; in 2019 generic approvals resulted in $24.8 billion in savings, and new generics approved in 2020 showed another $10.7 billion in savings. That's the power of a competitive marketplace. But why do we still have so many brand name drugs with no generic or biosimilar equivalent? One reason is the misuse of patents by pharmaceutical companies.

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[1] Emily Ihara, "Prescription Drugs", Georgetown University Health Policy Institute, accessed at https://hpi.georgetown.edu/rxdrugs/#:~:text=More%20than%20131%20million%20people,United%20States%20%E2%80%94%20use%20prescription%20drugs

[2] Ashley Kirzinger et al., "Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say it's Difficult To Afford Their Medicines, Including Larger Shares Among Those With Health Issues, With Low Incomes and Nearing Medicare Ages", KFF, March 1, 2019, accessed at https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/

[3] See note 2.

[4] See note 2.

[5] AHIP, "Your Health Care Dollar: Vast Majority of Premium Pays for Prescription Drugs and Medical Care", Americas Health Insurance Plans, September 6, 2022, accessed at https://www.ahip.org/news/press-releases/your-health-care-dollar-vast-majority-of-premium-pays-for-prescription-drugs-and-medical-care

[6] Robert Preidt, "Compared to Other Countries, Americans Pay Much More for Prescription Drugs", US News, January 29, 2021, accessed at https://www.usnews.com/news/health-news/articles/2021-01-29/compared-to-other-countries-americans-pay-much-more-for-prescription-drugs

[7] 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

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Abuse of the patent system blocks market competition.

Certainly, drug companies are bringing innovative, life-saving medications to market. But unfortunately recently drug makers are spending significant time and money obtaining new patents on medications already on the pharmacy shelves. This abuse of the patent system works to block generics and biosimilars from competing with the therapeutically-equivalent brand name drugs. And without competition, the brand name drugs can keep their prices high.

Congressional oversight hearings uncovered evidence that pharmaceutical companies use strategies to suppress competition and maintain monopoly pricing.[8] These new business practices, like product hopping, patent thickets and evergreening, are part of a corporate strategy that is intended to drive up company and shareholder profits without needing to invest in research and development for new treatments and medications. A 2021 House Oversight Committee report found that "[d]rug companies abuse the patent system and FDA market exclusivities to suppress competition."[9] Their investigation identified more than 600 patents for the 12 drugs they reviewed, and found their monopoly periods could be extended to a combined total of nearly 300 years. Extending monopoly-pricing keeps prices high which drives up the prices for patients, for insured families in their annual premiums, and for taxpayers funding our state and federal health programs.

Patents play an important role in spurring innovation and opening up discoveries that others can benefit from. But the monopoly-pricing granted by a patent isn't meant to last forever. Our American economic model is premised on a free and competitive market system. Patents are supposed to expire so competitors can enter the market to offer lower-cost generic or biosimilar drugs. And although a wrongly-granted patent can be challenged in federal courts , these challenges are complex and can take years before a decision is handed down. And drug patent litigation is expensive. The median cost of a drug patent lawsuit under the Hatch-Waxman Act rose to $3.5 million in 2019 from $3 million in 2015.[10] Even if the generic competitor does win and is allowed to sell their alternative, it still means we have waited those extra years of litigation

[8] "Chairwoman Maloney Releases Comprehensive Staff Report Culminating the Committee's Sweeping Drug Pricing Investigation", Committee on Oversight and Accountability Democrats, December 10, 2021, accessed at https://oversightdemocrats.house.gov/news/press-releases/chairwoman-maloney-releases-comprehensive-staff-report-culminating-the-committee

[9] See note 8.

[10] These numbers reflect cases with $10-$25 million at risk and include pre- and post-trial costs. Malathi Nayak, "Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds", Bloomberg Law, September 10, 2019, accessed at https://news.bloomberglaw.com/ip-law/costs-soar-for-trade-secrets-pharma-patent-suits-survey-finds

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before enjoying the benefits of price competition. The Patent Trial and Appeal Board[11] offers a swifter and less expensive way to challenge patents and should be utilized more effectively to challenge patents. But the public good is better served when all cost and delay of patent challenges are entirely avoided because the patent examination was conducted thoroughly in the first place.

Recommendations

We commend the agencies' desire to improve their collaboration and efforts to address high drug prices. We urge you to consider the following recommendations to meet this goal.

1. **Less emphasis on swift review and more emphasis on quality review.** One key element of the PTO's mission is to provide high quality and timely examination of patent and trademark applications.[12] Each year over 600,000 patent applications[13] are filed for review by the 8,000 examiners at the Patent Office.[14] The sheer volume of applications put patent examiners under pressure to serve their "clients" - the patent applicants - by working quickly. Based on information found on a 2016 PTO presentation, 55% of a patent examiner's performance appraisal is based on productivity (number of office actions in a set period of time - 35%) and docket management (completing those actions within the expected timeframe - 20%).[15] Examiners spend an average of 19 hours examining an application.[16] This emphasis on swift reviews is likely working against the PTO's mission to also provide *high quality* examination of applications.[17] The seminal study by Michael D. Frakes and Melissa F. Wasserman showed that the increased cost

[11] Janet Gongola, "The Patent Trial and Appeal Board: Who are they and What do they do?", US Patent and Trademark Office, Summer 2019, accessed at https://www.uspto.gov/learning-and-resources/newsletter/inventors-eye/patent-trial-and-appeal-board-who-are-they-and-what#
[12] 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
[13] "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
[14] "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.
[15] US Patent and Trademark Office, "Examination Time and the Production System", accessed at https://www.uspto.gov/sites/default/files/Examination%20Time%20and%20the%20Production%20System.pdf
[16] 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
[17] See Note 12.

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($600M/year) of giving patent examiners twice the time to review applications was easily offset by savings in reduced patent litigation costs ($900M/year).[18] We understand that you are considering adding more examiner time for patent application review. We strongly encourage you to make this change. It's time to shift the balance away from an overemphasis on serving patent applicant "clients" by reviewing applications too swiftly. We urge a return to your mission's directive to serve the public by allowing more examination time to utilize the following recommended information sharing and collaborative work between the two agencies. High quality examination of drug patent applications means fewer patent thickets, less expensive patent litigation challenging weak or overbroad patents and a return to an emphasis on high quality patent approvals. The public benefit will be measurable: more generic drug competitors will make it to market sooner and patients, insured families and our government health plans will benefit from the resulting price competition.

2. **More stringent review of patent applications for prescription drugs already on the market.** Patent applicants should clearly disclose when a new application (including a continuation application) claims aspects of or improvements to an existing drug already on the market. These applications should be flagged and assigned to more experienced examiners who should be given additional time to review them. Patent examiners should have access to a wider array of information for prior art searches, not just the USPTO's patent database. This should include information available in the Orange Book, Purple Book, and other scientific information provided to the FDA by drug companies. Patent examiners should be provided with extra support from FDA experts knowledgeable with that approved drug so they can assist the patent examiner in understanding whether the new patent meets the tests for subject matter eligibility, usefulness, nonobvious and novelty. The goal is to avoid approving patents filed for the purpose of creating patent thickets and other tactics that prevent or postpone generic competition. It's time to put an end to patents that allow monopoly pricing without any substantial change to the medication or its efficacy.
3. **Mutual sharing of assertions and disclosures between agencies to identify conflicting statements by pharmaceutical applicants.** We encourage you to establish a system for sharing applicant information and claims on changes to existing drugs to enhance coordination that helps the agencies find conflicting messages which might underlie attempts at over-patenting drugs. Closer examination should be given to applications when the drug company tells the patent office "We deserve a patent - this is a *brand-new* innovation in treatment" at the same time claiming to the FDA "Our drug is safe - it's *just*

[18] See Note 16.

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like this other drug that you already approved." It's our understanding that these conflicting messages aren't always uncovered. Greater oversight is necessary to challenge drug companies for this kind of double-speak. The agencies should flag applications to the USPTO and FDA which correspond to substantially similar drugs, share information provided by applicants (especially regarding clinical test results and the necessity of clinical testing), and spend more time reviewing those applications for inaccuracies or outright fraudulent and deceptive claims.

4. **Development of an easy-to-use public database with relevant information from each agency to research new and pending patents and their related drugs.** Regulatory officials and academic researchers need reliable information to analyze and study FDA and USPTO applications and final determinations, such as granted patents. Although the Orange and Purple Books share some information, a more robust database could be helpful to inform potential solutions to tactics which keep drug competitors off the market. Publicly available patent information should not be limited to the initial "parent" patent, but also include other pertinent information, including continuation applications, requests for continued examination (RCEs), and examiner determinations. Disclosure of similar information used in FDA application decisions would also be useful for academic and public analysis.
5. **Collaborative auditing, inspection and enforcement of drug applications.** Regular information sharing and joint training on enforcement tools could improve a collaborative approach to auditing, inspections and enforcement actions. Recognizing that pharmaceutical business practices and strategies regularly employ tactics that unfairly manipulate the patent and drug application systems to hinder generic competition, a coordinated approach to enforcement can leverage the limited resources of each agency to ensure regulatory and statutory compliance by pharmaceutical companies.
6. **Increased patient engagement.** Today's listening session represents a very important first step toward improving patient and consumer input with the FDA and the USPTO. Many health care policy solutions are proposed, analyzed and decided with little or no consumer and patient input - particularly when the issues at stake are as complex as patent and drug approval processes. But even though these issues are dense and can require specialized knowledge, the patient and consumer voice is still an essential part of the discussion. When policymakers lose touch with the end-user, in this case, the patient and consumer community, the details of policy decisions sometimes unwittingly or even in some cases purposefully put the needs and interests of the consumer last. As a public interest advocate, I often walk into meetings with less technical knowledge than most others in the room. But I can still add value by bringing the broader perspective of the

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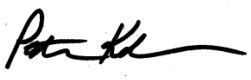
insured individuals paying for their health care or the individual perspective of a patient seeking and using health care products and services. We may not be able to tackle the deeper technical or legal challenges, but we can offer valuable insight on the impact of your decisions. And with a little extra coaching and training from the agencies, patients and consumers can grow greater knowledge that will help us be even more valuable resources for your work. As an example, I've served on the Patient and Consumer Engagement Advisory Committee with the National Quality Forum, NQF. NQF is charged with developing health care quality measures often used by the Centers for Medicare and Medicaid Services when making payments decisions and for public health star quality ratings. It's highly technical work but through this Advisory Committee, we've been collaborating with NQF's leadership to recruit more patient and consumer representatives to participate in evaluating new proposed quality measures. And we've been offering training to help these individuals to be more effective when participating in the evaluations of new quality measures. I'd be happy to share this patient engagement model with leadership at the FDA and USPTO. Working together, we can develop low-resourced but highly effective ways to improve public engagement with your agencies.

In conclusion, PIRG looks forward to working with the FDA and USPTO on these ideas and others that will put an end to patent thickets and other schemes that work to keep drug prices too high. President Biden's executive order to end anti-competitive practices specifically called for greater support for generic and biosimilar drugs in the marketplace to provide low-cost options for the people who need them.[19] With the support of the President and the combined existing powers your agencies hold, you can break down barriers that block generics from reaching pharmacy shelves. With even just one generic alternative, you can bring prices for that drug down by as much as 40%.[20] Working together, we know we can make a difference on the high cost of prescription drugs.

Respectfully submitted,



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[19] The White House, Executive Order on Promoting Competition in the American Economy, July 9, 2021. Accessed https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/

[20] FDA, Generic Competition and Drug Prices, Accessed at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices