USPIRG.org
Info@USPIRG.org

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

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RE: Docket No. PTO-P-2022-0025, USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights

Director Vidal:

On behalf of the U.S. PIRG (Public Interest Research Group) and our state affiliates, I am submitting comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights, published October 4, 2022 in the Federal Register.[1]

U.S. PIRG is a nonprofit advocate for the public interest. We speak out for a healthier, safer world which includes promoting policies that support the delivery of the high value healthcare we deserve. To succeed in this goal, we must address skyrocketing health care costs, including the cost of prescription drugs. We have a long history advocating for policies that create strong, competitive health care markets that work to keep prices in check.

We are particularly concerned about barriers to entry of generic and biosimilar medications. Pharmaceutical competition plays an important role in reining in the cost of prescription drugs. With even just one generic alternative, prices for that drug go down by as much as 40%.[2]

[1] Federal Register, 87 FR 60130 *accessed on* Feb 27, 2023 at https://www.federalregister.gov/documents/2022/10/04/2022-21481/request-for-comments-on-uspto-initiatives-to-ensure-the-robustness-and-reliability-of-patent-rights
[2] FDA, Generic Competition and Drug Prices, Dec. 2019, *accessed on* Feb 27, 2023 at https://www.fda.gov/media/133509/download, p. 2

The U.S. Patent and Trademark Office (PTO) has a public duty to strike a balance that encourages ground-breaking innovation by approving patent applications on new treatments and cures while withholding approval from applications on old or obvious treatments that unnecessarily hinder or delay competition from generic and biosimilar drugs. President Biden's executive order to end anti-competitive practices specifically called for greater availability of generic and biosimilar drugs in the marketplace to provide low-cost options for the people who need them.[3]

We applaud the PTO for its desire to encourage innovation and price-lowering competition from generic and biosimilar drugs through this Request for Comments (RFC). We support many of the proposed opportunities outlined in the RFC to improve patent examination and approval processes to best reach that balance of supporting medical advances and ensuring generic drugs and biosimilars reach pharmacy shelves.

Patent approvals impact drug prices.

Prescription drug prices, particularly for those medications without competition, continue to rise, 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 prescription drugs to live full lives and to treat their illnesses and medical conditions.[4] And yet 1 in 4 people struggle to pay for their medications.[5] 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.[6] Some choose not to fill a prescription (19%) and about one in 10 cut their pills in half or skip a dose.[7] Because drug costs make up about 20% of health insurance premiums, when drug prices rise, so do the costs of our premiums.[8] Generic drugs and biosimilars must be able to enter

[3] The White House, Executive Order on Promoting Competition in the American Economy, July 9, 2021 *accessed on* Feb 28, 2023 *at* https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/

[4] Emily Ihara, "Prescription Drugs", Georgetown University Health Policy Institute, *accessed on* Feb 28, 2023 *at* https://hpi.georgetown.edu/rxdrugs/#:~:text=More%20than%20131%20million%20people,United%20States%20%E2%80%94%20use%20prescription%20drugs

[5] 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 on* Feb 28, 2023 *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/

[6] See note 5.

[7] See note 5.

[8] AHIP, "Your Health Care Dollar: Vast Majority of Premium Pays for Prescription Drugs and Medical Care", Americas Health Insurance Plans, September 6, 2022, *accessed on* Feb 28, 2023 *at* https://www.ahip.org/news/press-releases/your-health-care-dollar-vast-majority-of-premium-pays-for-prescription-drugs-and-medical-care

the market to bring about the competition necessary to drive down drug prices. But patents that wrongly confer or extend rights to exclusive market access block generic and biosimilar competition, inappropriately keeping prices high for consumers, plans and our government health programs.

Robust patents are quality patents.

We urge the PTO to reaffirm its definition of a robust patent as one that is correctly issued in compliance with patent law.[9] Patents are intended to benefit the public by providing a description of the claimed innovation that others can use and build upon after the patent expires. In return, patent owners are granted exclusive rights for 20 years from the date the PTO grants their patent application. [10] But the exponential rise of patent applications and approvals[11] appears to have done as much, if not, more harm than good given how difficult it is for generic and biosimilar drug competitors to challenge patents and/or enter the market after patents on a drug's primary ingredient expire. To take advantage of monopoly pricing that patents make possible, pharmaceutical companies have focused their efforts on building up portfolios of patents on trivial features or obvious variations of their existing patented drugs: between 2005 and 2015, 78% of drugs associated with new patents were for drugs that were already on the market. [12]

When companies wrap their original patents with follow-on patents, they create a thicket of protection designed to ward off competition. Generics have the right to challenge patents and when they do, they will about 73% of the time.[13] But the cases can take years and are expensive ($2.5 - $3.5 million dollars).[14] With costs that high, competitors can be deterred from even attempting to challenge the patent thicket. And that means fewer generic and biosimilar competitors will take on the effort it takes to come to market. It also means that the patent system is failing to encourage both innovation and competition.

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[9] USPTO, Quality Metrics, *accessed on* Feb 28, 2023 *at* https://www.uspto.gov/patents/quality-metrics
[10] FDA, Frequently Asked Questions on Patents and Exclusivity, *accessed on* Feb 22, 2023 at https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#:~:text=2.-,How%20long%20is%20a%20patent%20term%3F,the%20duration%20of%20a%20patent
[11] U.S. Patent and Trademark Office, U.S. Patent Statistics Chart, Calendar Years 1963 - 2020, *accessed on* Feb 24, 2023 at https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm
[12] Robin Feldman, May your drug price be evergreen, Journal of Law and the Biosciences, December 7, 2018, *accessed on* Feb 24, 2023 *at* https://pubmed.ncbi.nlm.nih.gov/31143456/
[13] Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration, July 2002 *accessed on* Feb 27, 2023 at https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf
[14] "Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds, Bloomberg Law, Sept 10, 2019 *accessed on* Feb 24, 2023 at https://news.bloomberglaw.com/ip-law/costs-soar-for-trade-secrets-pharma-patent-suits-survey-finds

We agree with your goal expressed in this request for comments that we must "ensure that our system, as a whole, does not unnecessarily delay generic and biosimilar competition, which provide cost savings to Americans when they purchase pharmaceutical products."[15] To achieve this goal, we urge the PTO to provide greater scrutiny of patent applications, particularly for applications concerning drugs which already are covered b y at least one patent or are already on the market. It is time to reform the system to better promote scientific advancement *for the benefit of the public.*

The PTO should implement strategies that focus more on the robustness and quality of patent examination and put less emphasis on swift review.

One key element of the PTO's mission is to provide high quality and timely examination of patent and trademark applications.[16] Each year over 600,000 patent applications[17] are filed for review by the 8,000 examiners at the Patent Office.[18] The sheer volume of applications put patent examiners under pressure to serve their so-called "customers" - the patent applicants - by working quickly. Internal PTO recognition and reward systems add to the emphasis on *swiftly* moving patent applications through the examination process. A 2016 PTO presentation indicated 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%).[19] Rewarding speed has a natural consequence: examiners spend an average of 19 hours examining an application.[20]

This emphasis on swift reviews is likely working against the PTO's mission to ensure high quality examination of applications.[21] The seminal study by Michael D. Frakes and Melissa F. Wasserman showed that the increased cost ($600M/year) of giving patent examiners

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[15] See note 1.
[16] Our Mission, "US Patent and Trademark Office", US Department of Commerce, *accessed on* Feb 28, 2023 *at* https://www.commerce.gov/bureaus-and-offices/uspto#:~:text=The%20mission%20of%20the%20U.S.,(IP)%20policy%2C%20and%20delivering
[17] "US Patent Statistics Chart Calendar Years 1963-2020", US Patent and Trademark Office, Patent Technology Monitoring Team, *accessed on* Feb 28, 2023 *at* t https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm
[18] "Attend 2022 Patent Examiner Virtual Open House", US Patent and Trademark Office, March 1, 2022, *accessed on* Feb 28, 2023 *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
[19] US Patent and Trademark Office, "Examination Time and the Production System", *accessed on* Feb 28, 2023 *at* https://www.uspto.gov/sites/default/files/Examination%20Time%20and%20the%20Production%20System.pdf
[20] 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
[21] See Note 16.

twice the time to review applications was easily offset by savings in reduced patent litigation costs ($900M/year).[22]

It's time to shift the balance away from an overemphasis on serving patent applicant "customers" by reviewing applications too swiftly. We urge a return to your mission's directive to serve the public by allowing patent examiners to spend more time reviewing applications so that patent examination results in approvals of only robust quality patent applications.

Return to mission by developing processes and mechanisms to recognize the public impacted by patent examiner decisions.

The PTO's daily work is highly technical and defined by statute. And the nature of patent examiners' work - reading and analyzing technical applications - can obscure the impact that patents have in the daily lives of the people in the United States. As a public agency, the PTO has a duty to work for the public good. More should be done to hear and consider how decisions on individual patent applications impact the real stakeholders in the patent system - the American public.

We urge the PTO to improve opportunities for public input in the following ways:

1. Increase patient engagement. Many health care decisions are made with little or no consumer and patient input. This is particularly true when it comes to the complex process for evaluating patents on medical treatments. Even though patent examinations processes are technical and can require specialized knowledge, the patient and consumer voice is still valuable and essential. When decision makers lose touch with the end-user, in this case, the patient and consumer community, decisions sometimes unwittingly put the needs and interests of the consumer last. Patent examiners hear directly from patent applicants and their representatives; they should hear from people who depend on access to medicine in heavily patented fields, too.
2. Develop an easy-to-use public database with relevant information from both the PTO and the FDA to allow academic and other public researchers to find and evaluate new and pending patents and their related drugs. Researchers need reliable and more easily obtainable information to analyze and study FDA and USPTO applications and final determinations. Although the Orange and Purple Books share some information, a more robust database would be helpful to inform the public. This kind of database would enable the public to provide more useful

[22] See Note 20.

input to the PTO, and empower us to develop more effective solutions to anticompetitive practices which keep generic and biosimilar drugs off the market. Publicly available patent information should include information identifying all related patents and patent applications, including continuation applications while they are pending. This information should also be easily searchable so that members of the public can search for words in the text of the patent applications and other pertinent records, such as requests for continued examination (RCEs), and Office Actions describing examiner determinations. Disclosure of information about related FDA applications and determination decisions would also be useful for academic and public analysis.

Responses to specific questions in the request for comments:

Q1. Expansion of searches for "Prior Art":

As the PTO and the U.S. Food and Drug Administration (FDA) explore greater collaboration, we urge you to expand searches for prior art to include drug company assertions and disclosures made to the FDA in order to identify material information not otherwise available, including conflicting statements by pharmaceutical applicants. These conflicting messages may underlie attempts at obtaining patents that lack novelty or obtaining market approval for drugs without essential safety and efficacy testing. over-patenting drugs. Closer examination should be given to applications when the drug company tells the PTO "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 like* this other drug that you already approved." Greater collaboration and deeper scrutiny are necessary to identify, address and deter drug companies from engaging in this kind of double-speak. Patent examiners should have the benefit of improved FDA-PTO collaboration efforts to flag applications which correspond to substantially similar drugs. Once flagged, PTO examiners should work with the FDA to share information provided by applicants that could inform the search for prior art. Examiners should also be given additional time and authority to review those applications for inaccuracies or outright fraudulent and deceptive claims.

Q2. Claim Support

Patent applicants should be required to provide greater clarity about the support for their claimed inventions and to document this support in the prosecution history record. Patents are intended to provide a clear picture of the innovation that the public can use and build upon. Broad stroke or evasive descriptions go against this requirement for patent allowance. The PTO should demand clearer, specific descriptions to allow patent challengers to understand exactly what is and is not protected. The public and competitors will then be better able to assess a patent's scope, develop non-infringing innovations of

their own, and, if necessary, challenge the patent's validity. Additionally, clearer claim support will assist the patent examiner, making their evaluations of written description and enablement as well as prior art searches easier and less time-consuming.

Q4. Preventing unauthorized over-patenting

Generic and biosimilar drugs are blocked from coming to market when pharmaceutical companies abuse the patent system. When patents claim truly novel inventions, they contribute new information and advances to the public, but applications lacking novelty contribute nothing while depriving the public of access to information that would otherwise be available for free. Drug companies that obtain large numbers of low quality patents to create patent-thickets impede access to entire fields of innovation and deter validity challenges. Companies that use evergreening as a patent tactic obtain low quality patents that prolong their monopolies after the original patent on a drug's primary ingredient or method of use expires. These abuses of patent law allow brand drug companies to keep prices high with no fear of market competitors. As the PTO points out in the Federal Register notice, "multiple patents directed to obvious variants of an invention could potentially deter competition if the number of patents is prohibitively expensive to challenge in post-grant proceedings before PTAB and in district court."[23]

The PTO should conduct more stringent review of patent applications that cover 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, other scientific information provided to the FDA by drug companies, and the FDA's analyses of drug company submissions. Patent examiners should be provided with extra support from FDA experts knowledgeable with that class of 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 PTO must reject patent applications that do not satisfy the Patent Acts's requirements and should provide especially rigorous scrutiny of applications, that, if granted, would contribute to patent thickets and advance other tactics that unduly prevent or postpone generic and biosimilar competition. It's time to put an end to patents that allow companies

[23] Federal Register, 87 FR 60130 *accessed on* Feb 22, 2023 at https://www.federalregister.gov/d/2022-21481/p-19

to block competition and maintain monopoly pricing without any novel advance that could justify such restriction on innovation, competition and access to medicine.

PIRG supports and encourages the PTO to move forward on the proposals outlined in your letter[24], specifically:

- Increasing examiner time for patent application review, for the reasons mentioned above.
- Improve training of patent examiners, which can be done through greater collaboration with FDA experts and improved interactions with the public. Regular information sharing and joint training could improve a collaborative approach to examinations. Training should also include enforcement powers of each agency and information sharing about "bad actors" and "bad practices" could alert each agency to know which applications should receive greater scrutiny. Recognizing that pharmaceutical business practices and strategies regularly employ tactics that unfairly manipulate the patent and drug application systems to hinder generic competition and/or endanger public health, a coordinated approach to enforcement can leverage the limited resources of each agency to ensure regulatory and statutory compliance by pharmaceutical companies. And as medicines, therapies and delivery mechanisms get more complex, patent examiners need support from FDA colleagues and input from the public and patient communities in understanding whether the application materials describe a truly new invention or a tweak on an existing patent.
- Institute more rigorous and time-intensive scrutiny for certain types of applications that are especially likely to claim obvious variations of available medical treatments already protected by active or expired patents.

Conclusion

When drug patents are inappropriately granted, it unnecessarily extends market exclusivity for the patent-holder and unjustifiably precludes innovation. The PTO's policies and procedures must be changed to prevent pharmaceutical companies from piling up low-quality patents that create barriers to competition and allow brand name drug companies to keep charging more for their medicines. The American public needs more timely access to lower cost life-saving generic and biosimilar medicines. Improved patent examination processes mean fewer patent thickets, less need for expensive patent litigation to challenge weak or overbroad patents and a return to an emphasis on high quality patent approvals. The public benefit will be measurable: more generic drug

[24] U.S. PTO letter to the Food and Drug Administration, dated July 6, 2022, *accessed on* February 24, 2023 at https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf

competitors will make it to market sooner and patients, insured families and our government health plans will benefit from the resulting price competition. These benefits in turn will strengthen the public's confidence in the patent system and respect for the quality of granted patents.

Thank you for your review of our comments.

Sincerely,

Patricia Kelmar
Senior Director, Health Care Campaigns
pkelmar@pirg.org