Congress of the United States

Washington, DC 20515

April 26, 2023

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Dear Director Vidal:

We are writing to you about the U.S. Patent and Trademark Office's (USPTO's) efforts to hold pharmaceutical companies accountable for anti-competitive business practices.[1] Patients continue to suffer as prescription drug manufacturers jack up prices and rake in billions in profits.[2] We have previously sent letters requesting information and urging the USPTO to address the pharmaceutical industry's abuse of the patent system,[3] but we have yet to see the USPTO take substantial steps to exercise its existing administrative authorities to help lower drug prices, encourage competition, and increase innovation. We are writing again, with specific recommendations, to urge the USPTO to take immediate action and do everything in its power to hold prescription drug companies accountable for their greedy business practices, which have caused immense costs and immeasurable harm for patients across the country.

For decades, powerful pharmaceutical companies and other large corporate actors have repeatedly abused the patent system to stifle competition and prolong their market power, showing no regard for the harm done to patients through sustained high prices.[4] These firms have pursued excessive patents, using "evergreening" and "product hopping" strategies, filing "pay-for-delay" settlements, or creating patent "thickets" so they can extend their monopolies long after the first original patent expires.[5]

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[1] The Initiative for Medicines, Access & Knowledge, "Overpatented, Overpriced," September 2022, https://www.i-mak.org/wp-content/uploads/2023/01/Overpatented-Overpriced-2023-01-24.pdf.

[2] Patients for Affordable Drugs, "Ten Reasons Why We Need Lower Drug Prices Now," July 19, 2022, https://patientsforaffordabledrugs.org/2022/07/19/july-2022-price-hikes-report/.

[3] Letter from Senator Warren and Representative Jayapal to the U.S. Patent and Trademark Office, August 13, 2021, (On file with the Office of Senator Elizabeth Warren); Letter from Senator Warren and Representative Jayapal to the U.S. Patent and Trademark Office, December 5, 2022, https://www.warren.senate.gov/imo/media/doc/Warren-Jayapal%20Follow%20Up%20Letter%20to%20USPTO%20re%20Patent%20Abuse%20and%20Drug%20Pricing%20-%2012.5.22.pdf; Letter from Senators Warren and Sanders and Representatives Jayapal and Porter to the U.S. Patent and Trademark Office, February 23, 2023, https://www.warren.senate.gov/imo/media/doc/2023.02.22%20Letter%20to%20USPTO%20re%20Keytruda%20patent1.pdf.

[4] U.S. House Committee on Oversight and Reform, "Drug Pricing Investigation," Majority Staff, December 2021, https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf.

[5] BioPharma Dive, "A three-decade monopoly: How Amgen built a patent thicket around its top-selling drug," Jonathan Gardner, November 1, 2021, https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/; The New York Times, "How a Drug Company Made $114 Billion by Gaming the

While pharmaceutical companies have played essential roles in developing and producing life-saving drugs, they have used these tactics to maintain "sky-high drug prices [that] are not justified by the need to innovate."[6] In fact, the "largest drug companies spend more on payouts for investors and executives than on research and development" for new drugs, and many blockbuster drugs have relied on discoveries from federally-funded research supported by taxpayers.[7] At the same time, the USPTO appears to be incentivized to continue granting these excessive patents because of the revenue it collects from patent issuance fees.[8]

We support the USPTO's efforts to increase transparency,[9] examine the robustness and reliability of patents,[10] and collaborate with the U.S. Food and Drug Administration (FDA)[11] on these topics. But the pharmaceutical industry's continued abuse of the patent system, which has resulted in enormous corporate profits and inexcusable harms to patients, has demonstrated that more aggressive steps are needed. We recommend that the USPTO consider the following actions:

1. Revise the USPTO's practice of granting obvious patents. Under the USPTO's examination guidelines, a patent may not be claimed if the differences between the claimed invention and a prior one would have been obvious.[12] However, through a loophole called "obviousness-type double patenting," the USPTO allows a patent applicant to file additional and similar patents for their own invention as long as the patent owner agrees to file a "terminal disclaimer," which ensures that subsequent patents will expire on the same date as the initial patent.[13] But "this practice still allows the patent

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U.S. Patent System," Rebecca Robbins, January 28, 2023, https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html; Congressional Research Service, "Drug Prices: The Role of Patents and Regulatory Exclusivities," Kevin T. Richards, Kevin J. Hickey, and Erin H. Ward, February 10, 2021, https://crsreports.congress.gov/product/pdf/R/R46679.

[6] U.S. House Committee on Oversight and Reform, "Drug Pricing Investigation," Majority Staff, December 2021, p. 3, https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf.

[7] *Id.*

[8] The Brookings Institution, The Hamilton Project, "Decreasing the Patent Office's Incentives to Grant Invalid Patents," Michael D. Frakes and Melissa F. Wasserman, December 2017, https://www.brookings.edu/wp-content/uploads/2017/12/es_121317_decreasing_patent_office_incentives_grant_invalid_patents.pdf.

[9] U.S. Patent and Trademark Office, "USPTO announced emphasis on transparency as it works to formalize Director review process," press release, April 22, 2022, https://www.uspto.gov/about-us/news-updates/uspto-announces-emphasis-transparency-it-works-formalize-director-review.

[10] Federal Register, "Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights," Patent and Trademark Office, February 14, 2023, https://www.federalregister.gov/documents/2023/02/14/2023-03119/request-for-comments-on-uspto-initiatives-to-ensure-the-robustness-and-reliability-of-patent-rights.

[11] U.S. Patent and Trademark Office, "USPTO – FDA Collaboration Initiatives," https://www.uspto.gov/initiatives/fda-collaboration.

[12] U.S. Patent and Trademark Office, "2141 Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 [R-07.2022]," https://www.uspto.gov/web/offices/pac/mpep/s2141.html; 35 U.S.C. § 103.

[13] Journal of Law and the Biosciences, "Biological patent thickets and delayed access to biosimilars, an American problem," Rachel Goode and Bernard Chao, 2022, p. 21, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9439849/pdf/lsac022.pdf.

owner to grow its family of patents" and create patent thickets.[14]

When pharmaceutical companies create patent thickets for a drug, they are no longer "relying on the quality of their patents to prevent market entry," but instead on "the sheer number of patents in the thicket."[15] And terminal disclaimers are rampant – over a third of drug patents listed in the FDA's Orange Book of approved drug patents include a terminal disclaimer, and over a half of drug patents that had an earlier-granted patent for the same product included a terminal disclaimer.[16] Pharmaceutical companies like AbbVie have taken advantage of this system to sue several would-be competitors for violating patents, reaching settlements that have delayed the market entry of biosimilars.[17] We agree with the USPTO's initiative to revisit the obviousness-type double patenting practice[18] and urge the agency to revise its practice of enabling patentees to obtain obvious patents. The USPTO should consider simply rejecting additional obvious patents filed by pharmaceutical companies, regardless of terminal disclaimers.[19]

2. Patents tied together by terminal disclaimers should all stand or fall together when challenged. Challenging a single patent in court can cost millions of dollars.[20] When there are hundreds of patents to navigate, challenging even low-quality patents "becomes prohibitive," while challenging every single patent becomes virtually impossible.[21] If USPTO has enabled pharmaceutical companies to assemble an excessive number of indistinct patents for a single drug by granting obviousness-type double patents, then it should require that all related patents that are chained together by a terminal disclaimer be invalidated if one patent in the chain is successfully challenged by a competing company.[22] This stipulation would help combat the patent thickets pharmaceutical companies have created that intimidate competitors from entering the market by making it "too costly and risky to do so."[23]

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[14] *Id.*

[15] *Id.* at p. 20.

[16] Nature Biotechnology, "Distinguishing and predicting drug patents," Colleen V. Chien, Nicholas Halkowski, and Jeffrey Kuhn, March 15, 2023, p. 318, https://www.nature.com/articles/s41587-023-01703-0.

[17] The New York Times, "How a Drug Company Made $114 Billion by Gaming the U.S. Patent System," Rebecca Robbins, January 28, 2023, https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html.

[18] Federal Register, "Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights," Patent and Trademark Office, February 14, 2023, https://www.federalregister.gov/documents/2023/02/14/2023-03119/request-for-comments-on-uspto-initiatives-to-ensure-the-robustness-and-reliability-of-patent-rights.

[19] Washington Law Review, "What Litigators Can Teach the Patent Office About Pharmaceutical Patents," S. Sean Tu and Mark A. Lemley, August 5, 2022, p. 1713, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3903513.

[20] Biosimilars Council, "Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients," June 2019, https://www.biosimilarscouncil.org/wp-content/uploads/2019/06/Biosimilars-Council-White-Paper-Failure-to-Launch-June-2019.pdf; Landslide, "The Cost of Doubling Up: An Economic Assessment of Duplication in PTAB Proceedings and Patent Infringement Litigation," Anne S. Layn-Farrar, https://media.crai.com/sites/default/files/publications/The_Cost_of_Doubling_Up_An_Economic_Assessement_of_Duplication_in_PTAB_proceedings_Landslide_May_2018_Layne_Farrar.pdf.

[21] Journal of Law and the Biosciences, "Biological Patent Thickets and Delayed Access to Biosimilars, An American Problem," Rachel Goode and Bernard Chao, January 21, 2022, pp. 20-22, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4014760.

[22] *Id.*

3. Raise filing fees and limit the number and time period for continuation applications to discourage "obviousness-type double patents." The USPTO charges fees for its products and services, including a range of rates for patent filing, examination, maintenance, and post-issuance.[24] While we urge USPTO to revise its practice of issuing such patents altogether, it could also consider charging higher filing fees for applications covering obviousness-type double patents to discourage pharmaceutical companies from filing multiple indistinct patents and creating problematic patent thickets. The USPTO could further consider setting filing rates based on a tiered system, in which filing and maintenance fees would significantly increase following the tenth, fiftieth, or hundredth indistinct patent in a chain of related patents. These increased fees would discourage large firms from creating large thickets, especially out of weak patents.[25] In addition, the USPTO should limit the number and time period in which continuation patents may be filed. For example, applicants could be limited to submitting no more than two related patents, which must be filed within 12 months of the first related patent. Placing a time limit on applying for new claims could restrict abuses of continuation patents.[26]

4. Require applicants to disclose at the time of filing whether the drug compound covered by the patent application is in clinical trials. Despite pharmaceutical patents being some of the "most valuable patents in the world," about 25 percent of active patents in the FDA's Orange Book – the complete list of FDA-approved drugs and related patent and exclusivity information[27] – have been invalidated in court.[28] Past records of Orange Book patents processed through the USPTO suggest that, based on a product's clinical trial history, patent applicants know in advance when they are filing a valuable patent intended for the Orange Book.[29] The USPTO should rigorously examine such patents by requiring filers to disclose whether the patent application covers a drug product that is, or was, in FDA clinical trials, then accordingly assign more examiners and apply a more intensive examination.[30]

5. Reverse policies that have led to an increase in discretionary denials of petitions filed through the inter partes review (IPR) process. The IPR process is meant to serve as a

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[23] Congressional Research Service, "Drug Prices: The Role of Patents and Regulatory Exclusivities," Kevin T. Richards, Kevin J. Hickey, and Erin H. Ward, February 10, 2021, p. 50, https://crsreports.congress.gov/product/pdf/R/R46679.

[24] U.S. Patent and Trademark Office, "USPTO fee schedule," https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule.

[25] Washington Law Review, "What Litigators Can Teach the Patent Office About Pharmaceutical Patents," S. Sean Tu and Mark A. Lemley, August 5, 2022, pp. 1714-1715, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3903513.

[26] Boston University Law Review, "Ending Abuse of Patent Continuations," Mark A. Lemley and Kimberly A. Moore, 2004, https://law.stanford.edu/publications/ending-abuse-of-patent-continuations/.

[27] U.S. Food and Drug Administration, "Approved Drug Products with Therapeutic Evaluations | Orange Book," March 8, 2023, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

[28] Washington Law Review, "What Litigators Can Teach the Patent Office About Pharmaceutical Patents," S. Sean Tu and Mark A. Lemley, August 5, 2022, p. 1673, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3903513.

[29] *Id.* at p. 1674.

[30] *Id.*; U.S. Patent and Trademark Office, "USPTO – FDA Collaboration Initiatives," https://www.uspto.gov/initiatives/fda-collaboration.

quick and less expensive alternative to challenging patents than litigation. In the past, the IPR process has successfully challenged the validity of drug patents for prostate cancer,[31] diabetes,[32] and opioid addiction,[33] paving the way for generics to enter the market and lower drug prices. However, the Patent Trial and Appeal Board's decision in *Apple, Inc. v. Fintiv, Inc*. established a precedent for agency policies that has led to an alarming rise in discretionary denials of IPR petitions.[34] This harmful precedent has diminished an effective tool for challenging the validity of pharmaceutical patents primarily designed to extend the manufacturer's monopoly on a drug.[35] We are alarmed that the USPTO is now seeking to formally amend the rules of practice for IPR and codify this existing precedent through an Advance Notice of Proposed Rulemaking.[36] We urge the USPTO not to finalize this rule and to instead strengthen and protect the IPR system by formally rolling back agency policies that have led to an increase in discretionary denials.

6. Establish an office dedicated to building public transparency, serving the public interest, and strengthening interagency communication. Accessing basic information about patents such as expiration dates, owners, licensing, and application statuses is difficult if not impossible for members of the public and even experts, limiting public knowledge and accountability of the U.S. patent system.[37] The USPTO can ensure it is serving the public interest by creating an independent office dedicated to improving public understanding and engagement with the patent system.[38] The office should be tasked with supporting transparent communication with public agencies, public interest groups, and entities with interests in patents.[39] With this avenue for communication in place, the USPTO can also strengthen its ongoing collaborations with the FDA.[40]

Thank you for your attention and engagement on this is important issue. We appreciate that USPTO has requested comments on several of these recommendations[41] in its efforts to strengthen the robustness and reliability of patents, and we welcome further discussion and

[31] Fierce Pharma, "J&J's blockbuster Zytiga falls to patent challenges, boosting threat of 2018 generics," Eric Sagonowsky, January 28, 2018, https://www.fiercepharma.com/legal/j-j-s-zytiga-falls-to-patent-challenge-opening-possibility-2018-generic-competition.

[32] Goodwin, "PTAB Issues Final Written Decisions Finding Most Claims of Sanofi's Lantus Patents Invalid," Big Molecule Watch, June 3, 2020, https://www.bigmoleculewatch.com/2020/06/03/ptab-issues-final-written-decisions-finding-most-claims-of-sanofis-lantus-patents-invalid/.

[33] BioPharma Dive, "Indivior loses patent battle for Suboxone Film," Randi Hernandez, March 23, 2018, https://www.biopharmadive.com/news/indivior-loses-patent-battle-for-suboxone-film/519868/.

[34] Bloomberg Law, "Apple's 'Fintiv' Challenge Ups Pressure for Patent Review Rules," Kelcee Griffis, March 16, 2023, https://news.bloomberglaw.com/ip-law/apples-fintiv-challenge-ups-pressure-for-patent-review-rules.

[35] The Commonwealth Fund, "Policymakers' Attention Turns to Drug Patents in the Debate on Prices," Kristi Martin, October 7, 2021, https://www.commonwealthfund.org/blog/2021/policymakers-attention-turns-drug-patents-debate-prices.

[36] Federal Register, "Changes Under Consideration to Discretionary Institution Practices, Petition Word-Count Limits, and Settlement Practices for America Invents Act Trial Proceedings Before the Patent Trial and Appeal Board," Patent and Trademark Office, April 21, 2023, https://www.federalregister.gov/documents/2023/04/21/2023-08239/changes-under-consideration-to-discretionary-institution-practices-petition-word-count-limits-and.

[37] *Id.*

[38] Emory Law Journal, "The Inequalities of Innovation," Colleen V. Chien, October 11, 2022, pp. 74-75, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3157983.

[39] *Id.* at 74-77.

[40] *Id.*

collaboration to address these anti-competitive practices, protect the integrity of the patent system, and lower drug prices for all Americans.

Sincerely,

Elizabeth Warren
United States Senator

Pramila Jayapal
Member of Congress

[41] Federal Register, "Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights," Patent and Trademark Office, February 14, 2023, https://www.federalregister.gov/documents/2023/02/14/2023-03119/request-for-comments-on-uspto-initiatives-to-ensure-the-robustness-and-reliability-of-patent-rights; Federal Register, "Changes Under Consideration to Discretionary Institution Practices, Petition Word-Count Limits, and Settlement Practices for America Invents Act Trial Proceedings Before the Patent Trial and Appeal Board," Patent and Trademark Office, April 21, 2023, https://www.federalregister.gov/documents/2023/04/21/2023-08239/changes-under-consideration-to-discretionary-institution-practices-petition-word-count-limits-and.