UNITED STATES
PATENT AND TRADEMARK OFFICE

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Initiatives to Ensure the Robustness and Reliability of Patent Rights	Docket No. PTO-P-2022-0025-0134

COMMENT OF THE ANTITRUST DIVISION OF
THE UNITED STATES DEPARTMENT OF JUSTICE

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I. INTRODUCTION

The Antitrust Division of the United States Department of Justice ("the Antitrust Division") appreciates this opportunity to share its views with the United States Patent and Trademark Office ("USPTO" or "the Office") on its Requests for Comments on "Initiatives to Ensure Robustness and Reliability of Patent Rights."[1] We understand that the USPTO is seeking comment on these current initiatives "to incentivize and protect new and nonobvious inventions while facilitating the broader dissemination of public knowledge," which will, in turn, "promote innovation and competition."[2] We commend USPTO's efforts to ensure that reliable, predictable, and quality patents continue to provide the public with confidence in the patent system and promote competition.

II. THE ANTITRUST DIVISION'S INTEREST

The Antitrust Division's mission is to promote competition through enforcement of the federal antitrust laws and by advocating for sound competition principles. The antitrust laws and intellectual property rights work in tandem to promote innovation. Innovation requires skill, effort, resources, and time. Patent rights reward investments with a fair return in exchange for the dissemination of new technical knowledge. At the same time, invalid patents in the marketplace do not yield these benefits and instead impede innovation. They can confer undue market power on their holders and create uncertainty, unnecessary costs, and litigation risks for firms seeking to compete on the merits and innovate. Thus, a well-functioning patent system should discourage patenting strategies that lead to invalid patents and provide appropriate incentives to compete to bring better products and services to market.

The Antitrust Division has supported the USPTO's past efforts to improve the patent system and enhance patent quality,[3] and increase access to patent legal services.[4] We submit these comments to address how improving Office practices can help to promote competition.

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[1] Request for Comments: Initiatives to Ensure the Robustness and Reliability of Patent Rights, 88 FR 9492 (Feb 14, 2023). *See also* Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 FR 60130 (Oct. 4, 2022). These initiatives include allowing more examining time into the patent examination system; giving patent examiners more training and resources; enhancing communication between patent examiners and the Patent Trial and Appeal Board (PTAB); applying greater scrutiny to continuation applications; reconsidering obviousness-type double patenting practice; and revisiting procedures for third-party input during the examination practice. *Id.*

[2] 87 FR 60130.

[3] Comments of the Antitrust Division of the U.S. Dep't of Justice at 7, In the Matter of Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims; and Changes to Practice for the Examination of Claims in Patent Applications, Docket Nos. 2005-P-066, 2005-P-067 (May 3, 2006); Comments of the Antitrust Division of the U.S. Dep't. of Justice and the U.S. Fed. Trade Comm'n., In the Matter of Notice of Roundtable on Proposed Requirements for Recordation of Real-Party-in-Interest Information Throughout Application Pendency and Patent Term, Docket No. PTO-P-2012-0047 (Feb. 1, 2013); Comments of the Antitrust Division of the U.S. Dep't. of Justice and the U.S. Fed. Trade Comm'n., In the Matter of Request for Comments on Enhancing Patent Quality, Docket No. PTO-P-2014-0043 (May 6, 2015).

[4] Comment of the Antitrust Division of the U.S. Dep't of Justice, In the Matter of Expanding Admission Criteria for Registration to Practice in Patent Cases Before the United States Patent and Trademark Office, Docket No. PTO-P-2022-0027 (Jan. 31, 2023).

III. THE PATENT PROSECUTION PROCESS SHOULD NOT FACILITATE PATENT STRATEGIES THAT UNNECESSARILY IMPEDE OR DELAY COMPETITION

The Antitrust Division supports the USPTO's efforts to revisit patent prosecution procedures, including continuation practice and obvious-type double patenting, which impacts patenting strategies in pharmaceutical markets as well as many technology-driven markets that are important to the U.S. economy.[5] Many commenters have offered specific proposals on ways to improve the USPTO's procedures with an eye toward mitigating anticompetitive patenting strategies that lead to "patent thickets," "evergreening" or facilitate "product hopping."[6] We defer to the USPTO on which specific changes will best serve the patent system, but we generally support reforms that deter such strategies. Competition benefits when the patent system rewards innovation while encouraging competitive entry as soon as inventions enter the public domain. Entry is particularly important in pharmaceutical markets, where competing generic versions of drugs can save consumers billions of dollars annually.[7]

Generic entry does more than save consumers money. Anticompetitive strategies that suppress or exclude competition from generic drugs deprive people of life-changing and even life-saving medicines.

As mentioned, the Antitrust Division has supported proposed reforms that would improve patenting procedures and patent quality. We previously addressed the Office's proposed reforms to continuation practice, which allows a patent applicant to file additional and sometimes broader patent claims that benefit from an earlier filing date of a prior-filed application.[8] In 2006, the Antitrust Division acknowledged that "[t]here are legitimate reasons for filing continuations, e.g., to amend a claim in light of an examiner's evidence and arguments in order to more accurately describe the bounds of an invention, but some may use continuations to engage in strategic behavior."[9] We pointed to a "notorious example of strategic behavior," the case of Jerome

[5] *See, e.g.*, Comments of Garmin International, Inc., In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Jan. 31, 2023) (indicating harm to Garmin from five continuation applications in a patent family in which the owner "recycled the same "invention" again and again through the Patent Office").

[6] *See, e.g.*, Comments of Professor Bernard Chao, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Feb. 1, 2023); Comments of Patients for Affordable Drugs Now, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Jan. 31, 2023); Comments of the Campaign for Sustainable Rx Pricing at 3-9, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Jan. 31, 2023); Comments of the Biosimilars Forum, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Jan. 30, 2023).

[7] Ryan Conrad et al., *Estimating Cost Savings from New Generic Drug Approvals in 2018, 2019, and* 2020 (Food & Drug Admin. 2022) (indicating generic drugs approved in 2018 yielded an annual savings of $17.8 billion; savings from 2019 approvals amount to $24.8 billion; and savings from 2020 approvals were estimated at $10.7 billion).

[8] *See* USPTO, DEP'T. OF COMMERCE, Manual of Patent Examination Procedure (MPEP), Chapter 201.07-08.37, C.F.R. § 1.78.

[9] Comments of the Antitrust Division of the U.S. Dep't of Justice at 7, In the Matter of Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably

Lemelson, "whose continuation applications concerning machine vision and automatic identification bar code technology were maintained before the PTO for more than 38 years."[10] The strategic use of continuation applications can impede competition by expanding the scope of patent claims and capturing developments already in the marketplace;[11] improvements to the practice could alleviate this concern.

The use of continuation applications can help erect "patent thickets" around particular products,[12] but this is just one patenting strategy that can create uncertainty and raise costs for firms seeking to bring competing products to market. "Evergreening" is another strategy that makes entry difficult. It occurs when minor variations of a product are patented and introduced in order to extend a product's market exclusivity. The current record contains multiple comments discussing Abbvie's blockbuster drug Humira, which as one commenter points out, was the subject of 312 patent applications, 94 percent of which were filed after FDA approval.[13] This commenter reports that Abbvie's strategy of patenting variations and modifications to the delivery method had the practical effect of extending the term of Humira's exclusivity, earning it an additional $100 billion in sales with no competing generic product in the market.[14] Humira is far from the only blockbuster drug subject to evergreening strategies. Commenters also noted Merck's similar approach to its cancer drug Keytruda, which is covered by approximately 180 patents, most of which were applied for after the drug came to market.[15]

Patents on minor improvements can also facilitate "product hopping," which occurs when a drug manufacturer submits "an application to the FDA for approval of a 'new' product that is essentially the same as the original product, obtaining a patent for the related modification, and

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Indistinct Claims; and Changes to Practice for the Examination of Claims in Patent Applications, Docket Nos. 2005-P-066, 2005-P-067 (May 3, 2006).

[10] *Id.*

[11] High Tech Inventors Alliance (HTIA) Comment (Feb. 15, 2023) ("In a disproportionate number of such cases, these patents are continuations that are years removed from the initial patent in the family, and their claims appear to reflect how the market has evolved rather than anything that was actually invented and described in the specification."); *see also* Garmin, Inc. Comment (Jan. 31, 2022); Comments of Families USA, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Jan. 31, 2023); Comments of the Association for Accessible Medicines, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Feb. 1, 2023)

[12] *E.g.*, Patients for Affordable Drugs Now Comment (Jan. 31, 2023); Association for Accessible Medicines Comment (Feb. 1, 2023).

[13] Comments of Kaiser Permanente at 2, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Feb. 1, 2023) ("Kaiser Permanente Comments").

[14] *Id.*

[15] Comments of Adam Mossoff at 2, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Feb. 1, 2023) (*citing* Rebecca Robbins, *How a Drug Company Made $114 Billion by Gaming the U.S. Patent System*, N.Y. TIMES (Jan. 28, 2023), https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html); Association for Accessible Medicines Comment at 3 (Feb. 1, 2023) (*citing* same).

effectuating a switch to the new product . . ."[16] When a brand encourages doctors to prescribe the modified version of a drug or removes the original product from the market, this product switch lessens the impact of generic competition because, under generic substitution laws, pharmacies cannot substitute the generic versions of the original drug for the modified drug.[17] Thus, product hopping "forc[es] generic manufacturers to start over in developing a generic version of a [modified] brand-name product."[18] Product hopping can raise prices and harm consumers and the practice has been challenged under antitrust and unfair competition laws.[19] It is also the subject of legislative reform.[20]

Finally, as the USPTO observes, obviousness-type double patenting also can delay entry.[21] Current USPTO rules permit obviousness-type double patenting, where "a patent owner tries to secure a patent for an obvious variation of the innovation covered by another of their own patents," on the condition that the applicant file a "terminal disclaimer" indicating that the subsequent patent will expire at the same time as the original patent over the same invention.[22] Although this practice can be procompetitive in cases where it creates incentives to further innovation, it also creates competitive risks. As one commenter put it, "[t]erminal disclaimers permit applicants to file patents for obvious variations to claims contained in prior granted patents so long as the expiration dates match, but this practice could lead to large, duplicative patent thickets that are burdensome for litigants to challenge while contributing little to innovation."[23] The record indicates that the United States is the only country that allows the use of terminal disclaimers in its patent system.[24]

Director Vidal has stated that the USPTO "must make sure our [patent] system as a whole does not unnecessarily delay generic, biosimilar, and more affordable version of those drugs into

[16] Comments of Pharmaceutical Care Management Association at 2, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Jan. 31, 2022) Comments at 2; *see also* Kaiser Permanente Comments at 2.
[17] *See* Michael A. Carrier and Steve D. Shadowen, Product Hopping: A New Framework, 92 NOTRE DAME L. REV. 167, 175-76 (2016) (discussing product hopping and its effect on generic drug substitution laws).
[18] Kaiser Permanente Comments at 2; *see also* Campaign for Sustainable Rx Pricing Comment at 3-9 (Jan. 31, 2023); Comments of the Pharmaceutical Care Management Association, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Jan. 31, 2023).
[19] *See, e.g., New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2nd Cir. 2015); Press Release, FED TRADE COMM'N, FTC Returns Nearly $60 Million to Those Suffering from Opioid Addiction Who Were Allegedly Overcharged in Suboxone Film Scheme, (May 10, 2021) (involving a product hopping scheme in which Reckitt had initially sold Suboxone in tablet form, but as generic manufacturers prepared to enter and compete with Reckitt, the company and its former subsidiary Invidor introduced a film version and attempted to steer the market toward the film and away from the legacy tablet product by misrepresenting that the film product was safer than the tablet); *see generally* Carrier & Shadowen, Product Hopping, *supra* note 17 (providing background and examining judicial analysis of product hopping).
[20] Affordable Prescriptions for Patients Act of 2023, S. 150, 118th Cong. § 2 (2023); *see also Executive Business Meeting Before the Comm. on the Judiciary*, 118th Cong. (2023).
[21] 87 FR 60130; *See also* Letter from Katherine K. Vidal to Dr. Robert Califf, MD In the Matter of USPTO Initiatives Regarding Drug Pricing at 6 (July 6, 2022) ("USPTO Letter").
[22] *See also* USPTO Letter at 6 (July 6, 2022).
[23] PMCA Comments at 4 (Jan. 31, 2022).
[24] Campaign for Sustainable Rx Pricing Comment at 4 (Jan. 31, 2023).

the hands of Americans who need them."[25] The Antitrust Division is hopeful that USPTO's efforts to revisit Office practices can help to alleviate unnecessary barriers to entry in pharmaceutical and other markets where patenting strategies that can impede competition are prevalent.

IV. IMPROVING THE ACCURACY OF PATENT EXAMINATIONS FACILITATES A WELL-FUNCTIONING PATENT SYSTEM THAT CAN PROMOTE COMPETITION

The Antitrust Division supports improving the accuracy of patent examinations. The reforms under consideration would, among other improvements, extend the time for examining patent applications and broaden the resources and information available to examiners, including requiring patent applicants to identify additional support for claims of novelty and non-obviousness during patent prosecution.[26] All of these reforms go toward providing examiners with more time and information to conduct a more thorough review of patent applications, which could lead to higher quality patents.

As we have noted "when issued patents provide certainty regarding their validity and the scope of their claims, they function most like property rights that facilitate market transactions benefiting competition."[27] By contrast, as noted above, invalid patents do not serve this purpose and they often lead to litigation that can unnecessarily delay entry and robust competition. Commenters have pointed out that sales and public uses by the patent applicant frequently are not disclosed to the USPTO and as a result, many patents are later found invalid on this basis.[28] Indeed, commenters have expressed broad support for efforts to enhance the sources of prior art available to patent examiners.[29] They also have suggested that changes could improve disclosure and access to prior art, which would better inform patent examinations.[30]

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[25] USPTO Letter at 1 (July 6, 2022).
[26] 87 FR 60130.
[27] Comments of the U.S. Fed. Trade Comm'n and the U.S. Dep't of Justice, In the Matter of Request for Comments on Enhancing Patent Quality, Docket No: PTO-P-2014-0043 (May 6, 2015).
[28] *See, e.g.*, Comments of Jonathan S. Masur and Lisa Larrimore Ouellete, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Jan. 27, 2023) (noting scholarship that "sales and public uses were the basis for nearly *half* of district court decisions holding patents invalid for lack of novelty from 2011 to 2017. Of these findings, 27% were due to the *activities of the patent owner*, meaning that the patent owner placed the invention on sale or in public use before the relevant priority date and thus should have disclosed the prior art to the USPTO.")
[29] *See, e.g.*, Comments of the American Bar Association Intellectual Property Law Section at 2, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Jan. 26, 2023); Comments of the High Tech Inventors Alliance at 3, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Feb. 15, 2023); Comments of the Intellectual Property Owners Association at 2, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Feb. 1, 2023); Comments of Brad Pederson at 1-2, In the Matter of Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025 (Jan. 30, 2023).
[30] *See, e.g.*, Masur and Ouellette Comment at 8 (Jan. 27, 2023) (proposing several approaches to increase the breadth of prior art available to patent examiners, including "(a) asking inventors to certify whether they are aware of any real-world use or sale of the claimed invention at the time of filing, (b) improving prior art databases available to

While we again defer to the USPTO's expertise in choosing which proposals will improve the examination process, the Antitrust Division agrees that providing additional resources and access to information, including the use of automated tools and third-party submissions of prior art,[31] along with more time to consider applications, could improve the examination process and make invalid claims less likely to issue. These improvements could also deter firms from engaging in the patenting strategies discussed above and using the patent prosecution process as a means to acquire or maintain market power that unnecessarily prevents competition.

In addition, the Antitrust Division supports the USPTO's efforts to leverage technical know-how and information that exists in peer agencies, including the Food and Drug Administration (FDA) and others, and applauds the collaborative initiatives that are already underway.[32] Collaboration with the FDA is especially important in the pharmaceutical industry. Firms bringing new drugs to market often navigate the regulatory processes for FDA and USPTO concurrently, and make representations to both agencies that are not always consistent.[33] We note that misrepresentations to the USPTO can form the basis of antitrust liability,[34] but even inconsistent statements to the agencies can undermine patent quality and unnecessarily delay entry. More generally, because the FDA approval process interacts with the PTO's process, the two agencies should work together to prevent regulatory manipulation that is inconsistent with both agencies' goals. Patent thickets and product hopping are particularly problematic in the pharmaceutical industry because firms can exploit regulatory arbitrage between the patenting rules and the drug approval process.

Beyond critical collaboration with the FDA, other regulatory agencies, such as United States Department of Agriculture (USDA) and others, whose work touches many areas of the economy, have deep knowledge and data that can enhance the patent examination process, and the Antitrust Division encourages the USPTO to seek other opportunities to expand access to resources for examiners. Improving examinations with a more rigorous and informed process will not only benefit the patent system but also help to ensure that competition is not harmed by the assertion of poor-quality patents.

V. CONCLUSION

For the reasons above, the Antitrust Division commends the USPTO for considering improvements to Office practice that could have a positive impact on competition. We appreciate

examiners to include real-world prior art, and (c) engaging with counterpart agencies, particularly the FDA with respect to pharmaceutical patents.")

[31] 87 FR 60131.

[32] Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments, 87 FR 67019 (Nov. 7, 2022). *See also* Interagency Patent Coordination and Improvement Act of 2023, S. 79, 118th Cong. (2023) (establishing of an interagency task force between USPTO and FDA).

[33] John R. Thomas, Remarks of Professor John R. Thomas In the Matter of Listening Session on Joint USPTO-FDA Collaboration Initiatives, Docket. No. PTO-P-2022-0037 (Jan. 19, 2023) (observing during a recent USPTO listening session, "[t]he tension between the two sorts of advocacy [before the USPTO and FDA] is clear: Patent attorneys commonly assert a product is novel and nonobvious, while food and drug lawyers assure the government that a product is safe and effective because it has been done before. Adding to the difficulty of keeping a story straight is that pharmaceutical firms ordinarily employ different counsel before the two agencies.")

[34] *Walker Process Equipment, Inc. v. Food Machinery and Chemical Corp.*, 382 U.S. 172 (1965).

this opportunity to offer comments in support of USPTO's careful stewardship of the patent system, and would invite further opportunities to collaborate on competition issues at the intersection of patent policy and antitrust law. We look forward to continuing participation as the Office addresses these important issues.

Respectfully Submitted,

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