UNITED STATES
PATENT AND TRADEMARK OFFICE

Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement	Docket No. PTO-P-2023-0048

COMMENT OF THE UNITED STATES
FEDERAL TRADE COMMISSION

I. Introduction

The purpose of the U.S. patent system is to foster innovation. It accomplishes this purpose by granting a limited period of exclusivity to qualifying inventions, which encourages their creation and then making the invention freely available to the public after that period has expired. Fostering innovation is also a key purpose of the federal antitrust laws. As discussed below, the United States Federal Trade Commission ("FTC" or "the Commission") has a mandate to enforce the antitrust laws to prevent anticompetitive conduct and unfair methods of competition, which may involve patents or patented products and includes the misuse or abuse of patents.

The FTC and the United States Patent and Trademark Office ("USPTO") share the common goals of promoting innovation and fair competition. Both agencies have long recognized that achieving these goals depends on cracking down on patent abuse. The patent system works most efficiently and effectively when the USPTO issues and maintains only properly granted and lawful patents. Improvidently granted patents or patents of improper breadth, however, can serve as a barrier to innovation and frustrate entry of new competitors in critical areas, including generic pharmaceuticals. As the FTC has previously noted, "Poor patent quality and legal standards and procedures that inadvertently may have anticompetitive effects can cause unwarranted market power and can unjustifiably increase costs."[1] In 2011, Congress enacted the America Invents Act ("AIA"), which created the Patent Trial and Appeal Board ("PTAB") and granted it authority to hear several types of administrative challenges to the validity of granted patents. Because invalid patents can improperly block competition—inflating costs and dampening new business entry and growth—access to timely review of patent validity is vital.

The USPTO issued a Federal Register Notice on April 19, 2024, requesting public comment on a notice of proposed rulemaking ("NPRM") proposing various modifications to the rules of practice for *inter partes* and post-grant review proceedings before the PTAB.[2] In this rulemaking, the USPTO seeks to better align PTAB practices with the USPTO's mission to promote and protect innovation and with the congressional intent behind the AIA: "to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs."[3] The Commission appreciates the USPTO's focus on improving patent quality and better aligning PTAB *inter partes* and post-grant review proceedings with the Congressional intent behind the AIA. The Commission further supports the

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[1] FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (Oct. 2003) at 5, http://www.ftc.gov/os/2003/10/innovationrpt.pdf [hereinafter 2003 report]; *see also* FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION (Mar. 2011) at 7, https://www.ftc.gov/sites/default/files/documents/reports/evolving-ip-marketplace-aligning-patent-notice-and-remedies-competition-report-federal-trade/110307patentreport.pdf [hereinafter 2011 report] (explaining that "poor quality patents can discourage innovation by creating uncertainty and raising costs").

[2] Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement, 89 Fed. Reg. 28693 (Apr. 19, 2024) [hereinafter NPRM].

[3] H.R. Rep. No. 112-98, pt. 1, at 40 (2011) (explaining that the AIA was "designed to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs"); S. Rep. No. 110-259, at 20 (2008) (predicting that the new post-grant review system "will give third parties a quick, inexpensive, and reliable alternative to district court litigation to resolve questions of patent validity").

USPTO's ongoing vigilance to ensure that the PTAB review process is not abused, including by the use of discretionary denials to impede meritorious challenges.

The NPRM includes a proposal specifically intended to support the FTC's and the Department of Justice's enforcement work regarding anticompetitive conduct related to patent settlements.[4] The Commission appreciates this opportunity to share its views related to USPTO's efforts to require the filing of all settlement agreements made in connection with the termination of an AIA proceeding and supports the proposal to require uniform disclosure of all such agreements. As discussed below, certain patent settlement agreements between pharmaceutical manufacturers can raise antitrust concerns where they include reverse payments that keep drug prices high by impeding competition from lower-cost generic drugs. The Commission looks forward to collaborating with the USPTO on this NPRM and on other areas at the intersection of antitrust law and intellectual property law, consistent with the policy set forth in the July 9, 2021, Executive Order on Promoting Competition in the American Economy.[5]

II. The FTC's Interest in the NPRM

For more than 25 years, the FTC has addressed the complementary role of intellectual property and competition in its policy and enforcement efforts.[6] Many of these policy efforts have considered issues relating to patent quality and competition.

In 2003, after a series of public workshops and consultations, the FTC issued a report, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy," (hereinafter 2003 FTC IP Report) that highlighted numerous concerns around the impact of patents that are likely invalid or contain claims that are overly broad—including how such patents serve to block competition and impede innovation.[7] For example, such patents may lead a competitor to forgo research and development in the areas that the patents improperly claim.[8] If the competitor instead chooses to pursue research and development in areas improperly covered by the patents without a patent license, it may face expensive and time-consuming litigation with the patent holder.[9] If the competitor instead chooses to negotiate a license to the questionable patents, the costs of follow-on innovation and commercial development increase due to unjustified royalties.[10]

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[4] NPRM, 89 Fed. Reg. at 28697.
[5] White House, Executive Order on Promoting Competition in the American Economy (July 9, 2021), available at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy.
[6] *See*, *e.g.*, U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (Apr. 6, 1995), https://www.justice.gov/sites/default/files/atr/legacy/2006/04/27/0558.pdf (revised Jan 12, 2017, https://www.ftc.gov/system/files/documents/public_statements/1049793/ip_guidelines_2017.pdf).
[7] 2003 FTC IP Report; U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION (Apr. 2007), https://www.ftc.gov/sites/default/files/documents/reports/antitrust-enforcement-and-intellectual-property-rights-promoting-innovation-and-competition-report.s.department-justice-and-federal-trade-commission/p040101promotinginnovationandcompetitionrpt0704.pdf.
[8] 2003 FTC IP Report at 5.
[9] *Id.* at 6.
[10] *Id*.

In addition, questionable patents can contribute to patent thickets, which are large numbers of patents obtained after the initial round of patents covering an innovative active ingredient.[11] After describing a number of concerns that flow from improperly granted patent claims, the 2003 FTC IP Report detailed concerns about the inadequate options for challenging questionable patents, and ultimately recommended that Congress create an administrative procedure for post-grant patent review that allows for meaningful challenges to patent validity short of federal court litigation.[12] In the years following the 2011 enactment of the AIA, the FTC has supported prior USPTO efforts to improve patent quality by explaining how a well-functioning patent system can help incentivize new entry into markets, innovation, and competition.[13] Earlier this year, the FTC submitted a comment in connection with the draft interagency guidance framework for considering the exercise of march-in rights, noting that patent thickets may frustrate government efforts to use march-in rights to provide affordable public access to drugs.[14]

The FTC also has a long history of pursuing enforcement actions at the intersection of antitrust and intellectual property, to address the misuse and abuse of patents in ways that undermine fair competition.[15] The Commission has enforced U.S. antitrust laws to prevent anticompetitive "reverse-payment" patent settlements between pharmaceutical brand and generic firms, which can arise when parties settle patent disputes with the patentee paying its would-be competitor to drop the challenge and stay off the market. These agreements are known as "reverse-payment" settlements because "a party with no claim for damages … walks away with money simply so it will stay away from the patentee's market."[16] In *FTC v. Actavis*, the Supreme Court held that reverse-payment agreements create a "risk of significant anticompetitive effects."[17] The potential anticompetitive harm from this type of agreement is that the payment "prevent[s] the risk of competition" and may allow the parties to "maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market."[18]

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[11] *Id.* at 7.
[12] *Id.* at 7-8.
[13] U.S. Dep't of Justice Antitrust Division & Fed. Trade Comm'n, Comment on Proposed Requirements for Recordation of Real-Party-in-Interest Information Throughout Application Pendency and Patent Term (Feb. 1, 2013) at 4, https://www.ftc.gov/sites/default/files/documents/advocacy_documents/proposed-requirements-recordation-real-party-interest-information-throughout-application-pendency.pto-p-2012-0047-patent-and-trademark-office/130201pto-rpi-comment.pdf; U.S. Dep't of Justice & Fed. Trade Comm'n, Comment on Enhancing Patent Quality (May 6, 2015) at 3, https://www.ftc.gov/system/files/documents/advocacy_documents/comment-united-states-federal-trade-commission-united-states-department-justice-united-states/150507ptocomment.pdf.
[14] Comment of the United States Federal Trade Commission (Feb. 6, 2024), Comment No. 2023-008-0821, National Institute of Standards and Technology, Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, FR Doc No. 2023-26930.
[15] *See,e.g.,* Overview of FTC Actions in Pharmaceutical Products and Distribution (April 2024), Overview of FTC Actions in Pharmaceutical Products and Distribution, available at https://www.ftc.gov/system/files/ftc_gov/pdf/Overview-Pharma.pdf.
[16] *FTC v. Actavis, Inc.*, 570 U.S. 136, 152 (2013).
[17] *Id.* at 158-59.
[18] *Id.* at 157.

Congress took steps to enhance the FTC's ability to detect potentially anticompetitive patent settlement agreements by passing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), which requires pharmaceutical companies to file patent settlements and related agreements with the FTC and the Department of Justice.[19] Congress recognized that "pacts between big pharmaceutical firms and makers of generic versions of brand-name drugs that are intended to keep lower-cost drugs off the market" posed a potential threat to competition.[20] In 2018, Congress expanded this filing requirement to include certain patent settlement agreements involving biologics and biosimilar applicants.[21]

The Commission has also taken aim against patent holders engaged in other unfair methods of competition, including sham patent litigation,[22] anticompetitive "loyalty programs" that impede generic entry,[23] and "product hopping" schemes that preserve monopoly profits on a patented product by making modest reformulations that offer little or no therapeutic advantages and deprive the public of the benefits of generic competition.[24] The FTC continues to scrutinize patentholder conduct that can delay and deter entry of lower-cost generic competitors, including pharmaceutical companies' improper listing of patents in the FDA's Orange Book.[25]

III. The NPRM Settlement Proposal Would Enhance the FTC's Ability to Monitor Anticompetitive Conduct Related to Patent Settlements

As discussed in the NPRM, the PTAB currently requires all parties that settle their case after an AIA proceeding has been instituted to file the settlement agreement and any collateral agreements with the PTAB before the proceeding will be terminated. The statute provides for filed settlement agreements to be made available to federal government agencies on written request.[26] The proposed rule would, among other things, clarify that parties must file with the

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[19] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 §§ 1111-1118, 117 Stat. 2461-64 (codified at 21 U.S.C. § 355 note).
[20] S. Rep. No. 107-167 at 4 (2002).
[21] Patient Right to Know Drug Prices Act, Pub. L. No. 115-263, 132 Stat. 3672 (2018).
[22] Complaint, *Fed. Trade Comm'n v. AbbVie Inc.*, No. 2:14-cv-05151 (E.D. Pa. filed Sept. 26, 2014), https://www.ftc.gov/system/files/documents/cases/140908abbviecmpt1.pdf.
[23] Amended Complaint, *Fed. Trade Comm'n v. Syngenta Corp.*, No. 1:22-cv-00828 (M.D.N.C. filed Dec. 23, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/amended_complaint_public_redacted.pdf.
[24] Joint Motion for Entry of Stipulated Order for Permanent Injunction and Equitable Monetary Relief and Dismissal, *Fed. Trade Comm'n v. Indivior, Inc.*, No. 1:20-cv-00036 (W.D. Va. filed Jul. 24, 2020), ECF No. 3, https://www.ftc.gov/system/files/documents/cases/jt_mtn.pdf; Joint Motion for Entry of Stipulated Order for Permanent Injunction and Equitable Monetary Relief and Dismissal, *Fed. Trade Comm'n v. Reckitt Benckiser Group PLC*, No. 1:19-cv-00028 (W.D. Va. filed Jul. 11, 2019), ECF No. 2, https://www.ftc.gov/system/files/documents/cases/reckitt_joint_motion_for_stipulated_order_7-11-19.pdf.
[25] FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book (Nov. 7, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book; FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs (Apr. 30, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma; *see also* Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book (Sept. 14, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf
[26] 35 U.S.C. § 317(b).

USPTO all *pre-institution* settlement agreements, including any collateral agreements, similar to what is required for post-institution settlement agreements.[27]

The potential for patent settlement agreements to violate antitrust laws is well-established.[28] This concern extends to patent disputes that are settled at any point in the PTAB review process, including those that are finalized prior to the commencement of a PTAB proceeding. Extension of disclosure requirements to any settlement regardless of timing or effective date would support the FTC's ability to identify and investigate potentially unlawful settlements in the pharmaceutical context and more broadly. While the FTC receives certain patent settlement agreements pursuant to the MMA, the USPTO's proposed rule applies to a broader set of patent settlement agreements related to pharmaceuticals as well as those in other industries, which would be beneficial to the FTC's ability to enforce the antitrust laws and prevent unfair methods of competition.

The Commission agrees that the proposed changes would enhance the government's ability to monitor and curb potentially harmful and unlawful pre-institution settlement agreements, including through potential antitrust enforcement actions. According to the NPRM, since FY2020, pre-institution settlements have made up over half of all settlements in AIA proceedings. Given the significant percentage of settlements that are currently not required to be disclosed but nonetheless may carry the same antitrust risks, the Commission believes the proposed rule will support efforts to detect and investigate potentially anticompetitive conduct related to settlement agreements.

Moreover, the Commission supports the proposed rule because it closes a loophole that may otherwise allow parties to circumvent disclosure requirements. As the NPRM describes, parties are currently able to avoid disclosure of settlements by filing a motion to dismiss or withdraw their petition before institution of proceedings.[29] The institution of proceedings is solely within the discretion of the parties, and the current scheme encourages settlements prior to the institution of proceedings for those looking to avoid the consequences of disclosure. Extending the disclosure requirement to settlements regardless of when they are signed is consistent with the intent of Congress to require disclosure of settlements that arise out of proceedings before the USPTO.

IV. Conclusion

The U.S. patent system, bolstered by the AIA and the implementation of robust post-grant proceedings, is foundational to encouraging the innovation and technological advances that fuel our economy. However, abuse of the patent system can block rivals, impede new business formation and growth, inflate costs, and harm the public. The Commission appreciates the USPTO's commitment to preventing patent abuse and ensuring that post-grant proceedings serve

[27] NPRM, 89 Fed. Reg. at 28697.
[28] *See, e.g.*, *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); *Impax Labs., Inc. v. FTC*, 994 F.3d 484 (5th Cir. 2021); *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017); *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015); *In re AndroGel Antitrust Litig. (No. II)*, No. 1:09-cv-955-TWT, 2018 WL 2984873 (N.D. Ga. June 14, 2018).
[29] NPRM, 89 Fed. Reg. at 28697.

as an efficient and fully accessible alternative to lengthy and expensive district court patent litigation. The Commission supports the inclusion of a provision in the PTAB rules of practice that would require the filing of all settlement agreements. We look forward to continuing to participate in the USPTO's efforts to advance our agencies' shared goals of promoting innovation and fair competition.