UNITED STATES
PATENT AND TRADEMARK OFFICE

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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

FTC Comment
June 18, 2024

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 pa

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*.

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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

[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.*.

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