UNITED STATES
PATENT AND TRADEMARK OFFICE

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Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting	Docket No. PTOP-2024-0003

COMMENT OF THE UNITED STATES
FEDERAL TRADE COMMISSION

I. Introduction

The United States Federal Trade Commission ("FTC" or "the Commission") welcomes the opportunity to share its views on the United States Patent and Trademark Office's ("USPTO") notice of proposed rulemaking on "Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting."[1] The Commission is

The FTC supports the USPTO's efforts to prevent "multiple patents directed to obvious variants of an invention from potentially deterring competition."[6] The Commission looks forward to collaborating with the USPTO on this NPRM and on other areas at the intersection of competition policy and intellectual property law.

II. The FTC's Interest in the NPRM

The FTC, in both its policy and enforcement work, has long appreciated the impact that intellectual property rights have on competition and innovation. A well-functioning patent system can help incentivize innovation and competition, while facilitating new entry into markets. In the years following the 2011 enactment of the *America Invents Act*,[7] the FTC supported USPTO efforts to improve patent quality, most recently in a comment related to the rules of practice for *inter partes* and post-grant review proceedings before the Patent Trial and Appeal Board.[8][9]

In 2003, 2007, and again in 2011, the FTC, following multiple public workshops and consultations, published lengthy reports discussing the intersection of intellectual property and competition.[10] The 2003 report "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy" (hereinafter "2003 FTC Report") in particular explored the proper balance between patent exclusivity and competition, highlighting numerous ways in which invalid or overly broad patents can discourage follow-on innovation, undermine competition, and raise prices through unnecessary licensing and litigation.[11] For example, such patents may lead a competitor to forgo research and development related to the subject matter that the patent improperly claim.[12] If the competitor chooses to risk pursuing research and development without

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[6] NPRM, 89 Fed. Reg. at 40439.
[7] PUB. L. NO. 112-29, 125 STAT. 284 (2011) (amending sections of 35 U.S.C.).
[8] 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-p2012-0047-patent-and-trademark-office/130201ptorpi-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.
[9] Fed. Trade Comm'n, Comment on 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 (Jun. 18, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/FTC-Comment-to-PTO-6-18-24-final.pdf.
[10] Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (Oct. 2003) at 8, http://www.ftc.gov/os/2003/10/innovationrpt.pdf (hereinafter 2003 FTC 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; Fed. Trade Comm'n, The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition (Mar. 2011), https://www.ftc.gov/sites/default/files/documents/reports/evolving-ip-marketplace-aligning-patent-notice-and-remedies-competition-report-federal-trade/110307patentreport.pdf.
[11] 2003 FTC Report at 1-8.
[12] 2003 FTC Report at 5.

average cost to challenge a patent in *inter partes* review or post-grant review is $774,000, and litigating a patent case in federal court can cost considerably more.[36]

Under the current rules, incumbent firms can use terminal disclaimers to help create and enlarge patent thickets that insulate them from competition. For instance, a patent holder can rely on terminal disclaimers to overcome a nonstatutory double patenting rejection from the USPTO and quickly add more patents that fence off an existing technology from rivals behind a patent thicket.[37] A recent study of biologic patent thickets found that of the 271 biologic patents involved in litigation, nearly half contained terminal disclaimers. The study also found that the filing of such patents with terminal disclaimers spiked near the end of the FDA-granted exclusivity period for the branded biologic, suggesting to the authors that biologic firms could be using terminal disclaimers to strengthen barriers to biosimilar entry.[38] Another example of how terminal disclaimers can facilitate the growth of patent thickets is found with AbbVie's blockbuster biologic drug Humira: a recent study found that approximately 80 percent of the patents in the Humira portfolio were duplicative and linked to other patents via terminal disclaimers.[39]

Certain aspects of the proposed rule would directly address these problems. Under the proposal, a potential competitor could operate freely in the market without needing to invalidate multiple patents tied together by terminal disclaimers because invalidating the original claim referenced in one or more terminal disclaimers would render unenforceable the later-filed patents with the terminal disclaimers. The proposed requirement that the disclaimant condition the enforceability of its patent on the patentability and validity of the claims in the original patent to which it is tied would ensure that patent claims tied together by terminal disclaimers would stand or fall together. Accordingly, the proposed rule would reduce the costs now incurred by actual or potential entrants challenging weak patents or defending against assertions of patent claims that are obvious variants of a single invention. In addition, the rule would also reduce incentives for market incumbents to file numerous duplicative patents tied to each other by terminal disclaimers, while leaving in place a range of alternatives for patent owners and applicants to deal with nonstatutory double patenting rejections,[40] which should help reduce the scope, prevalence, and exclusionary impact of patent thickets.

[36] Rachel Goode & Bernard Chao,