UNITED STATES
PATENT AND TRADEMARK OFFICE

Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting	Docket No. PTO-P-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 charged with enforcing 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 USPTO share the common aims of fostering innovation and promoting fair competition. Both agencies have worked together over the years to align competition policy and the patent system to achieve these goals. They have recognized that achieving these goals depends on cracking down on abuse of the patent system. Such abuse can bar innovation and frustrate entry of new competitors into critical areas of the economy.

The Commission applauds the USPTO's ongoing work under the 2021 Executive Order on Promoting Competition in the American Economy[2] to bolster the robustness and reliability of patents while promoting innovation and competition.[3]

The Commission supports the USPTO's proposed rule to address the harmful exploitation of terminal disclaimers. A terminal disclaimer is a binding stipulation by a patent applicant that the patent's term will not extend beyond the term of another patent. Such terminal disclaimers are typically used by patent applicants to overcome the USPTO's rejection of patent claims that are essentially the same as those in an existing patent (a basis for claim rejection known as "nonstatutory double patenting" or "obviousness-type double patenting").[4]

While these terminal disclaimers ensure that the term of the new patent encumbered by the disclaimer will not extend beyond the term of the original patent, they also expedite the issuance of patents with duplicative claims, all of which must be overcome by potential market entrants. As a result, the strategic use of terminal disclaimers can facilitate the growth of patent thickets with multiple patents claiming essentially the same invention. As discussed below, the Commission has long been mindful of the potential anticompetitive effects of patent thickets and shares bipartisan Congressional concerns[5] that patent thickets erected by incumbents can delay and frustrate the entry of new biosimilars and generic drugs, increasing prescription drug costs and limiting patients' access to more affordable options. The use of terminal disclaimers linking similar patent claims can exacerbate the exclusionary impact of patent thickets by forcing potential market entrants to incur the high cost of challenging multiple duplicative patents.

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[1] Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting, 89 Fed. Reg. 40439 (May 10, 2024) [hereinafter NPRM].
[2] 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.
[3] Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60130 (Oct. 4, 2022).
[4] Manual of Patent Examining Procedure § 1490 (9th Ed. Rev. 07.2022) [hereinafter MPEP].
[5] Senators Patrick Leahy, John Cornyn, Richard Blumenthal, Susan Collins, Amy Klobuchar, Mike Braun, Letter to Kathy Vidal, Director of the U.S. Patent and Trademark Office (Jun. 8, 2022), https://www.collins.senate.gov/imo/media/doc/patent_letter.pdf.

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,[8] 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.[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 patents 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-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.
[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.

a patent license in areas covered by likely invalid or overbroad patents, it may face expensive and time-consuming litigation with the patent holder.[13]

Over the years, the FTC has explained how patent thickets can threaten to harm competition across a wide array of markets. Including overly broad or otherwise invalid patents in a patent thicket can reinforce and even magnify its exclusionary effects, raising costs to competitors, potential entrants, and ultimately, consumers.[14] The 2003 FTC Report described some of the problems associated with patent thickets and the incentives for defensive patenting strategies, such as the rise of incremental innovation in some industries and a pro-patent shift in the U.S. legal system.[15] The 2003 FTC Report detailed specific concerns in the semiconductor, computer hardware, and software industries.[16]

Recent concerns regarding patent thickets focus on their impact on competition in prescription drug markets, an area of significant enforcement focus for the Commission. The FTC has a long history of pursuing enforcement actions at the intersection of antitrust and intellectual property in prescription drug and other markets,[17] including litigation against anticompetitive "reverse-payment" patent settlements between pharmaceutical brand and generic firms,[18] sham patent litigation,[19] anticompetitive "loyalty programs" that impede generic entry,[20] and "product-hopping" schemes that preserve monopoly profits on a patented product by making modest reformulations that offer little or no therapeutic advantages to patients and deprive the public of the benefits of generic competition.[21]

The FTC also continues to scrutinize conduct by pharmaceutical manufacturers that may delay and deter entry of lower-cost generic competitors, including improper listing of patents in the FDA's Orange Book.[22] In March, the Commission filed a brief as *amicus curiae* in a private

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[13] 2003 FTC Report at 6.
[14] 2003 FTC Report at 7.
[15] 2003 FTC Report, Chap. 2 at 25-27.
[16] 2003 FTC Report, Chap. 3 at 34-43, 51-56.
[17] *See* Overview of FTC Actions in Pharmaceutical Products and Distribution (Apr. 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/Overview-Pharma.pdf.
[18] *FTC v. Actavis, Inc.*, 570 U.S. 136, 152 (2013).
[19] Complaint, *FTC 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.
[20] Amended Complaint, *FTC 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.
[21] Joint Motion for Entry of Stipulated Order for Permanent Injunction and Equitable Monetary Relief and Dismissal, *FTC 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; Joint Motion for Entry of Stipulated Order for Permanent Injunction and Equitable Monetary Relief and Dismissal, *FTC 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.
[22] 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

action between two pharmaceutical companies arguing that improper Orange Book listings can harm drug competition and constitute a violation of the Sherman Act;[23] the district court agreed, refusing to dismiss the generic competitor's antitrust claims and ordering the branded manufacturer to delist its improper listings.[24] The problem of patent thickets has been associated with Orange Book-listed patents. Recent scholarship has found that approximately 90 percent of litigated Orange Book patents are follow-on patents not directed to new chemical entities, and that such patents rely heavily on terminal disclaimers to avoid obviousness-type double patenting rejections during the examination process.[25]

Earlier this year, the FTC submitted a comment to the National Institute of Standards and Technology in connection with the draft interagency guidance framework for considering the exercise of march-in rights (hereinafter "FTC NIST Comment"), which included a description of the harmful impact that patent thickets can have on the market entry of generic drugs and biosimilars.[26] The comment noted the drastic increase in the number of drug patents issued in recent decades, observing that present-day blockbuster biologic drug Humira is covered by more than 130 patents. The FTC NIST Comment also noted that patent thickets in the biotechnology sector often include large numbers of "secondary patents," *i.e.*, patents that are obtained after the first patent to claim the active drug ingredient. Such secondary patents tend to be more frequently invalidated but can still potentially delay generic or biosimilar competition,[27] and dense patent thickets can discourage investment in innovative activity.[28] The FTC NIST Comment encouraged the USPTO to address the problem of patent thickets, including potentially revisiting the use of "terminal disclaimers, which can impede entry of cheaper generic and biosimilar drugs."[29] The Commission commends USPTO's efforts to address this important issue.

Patents in the Orange Book (Sept. 14, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.

[23] FTC Brief as Amicus Curiae, *Teva Branded Pharma. Prods. R&D, Inc. v. Amneal Pharma of NY, LLC*, No. 2:23-cv-20964 (D. N.J. filed Mar. 22, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/ftc_brief_as_amicus_curiae_teva_amneal.pdf.

[24] *Teva Branded Pharma. Prods. R&D, Inc. v. Amneal Pharma of NY, LLC*, No. 2:23-cv-20964 at 9 (D. N.J. Jun. 10, 2024).

[25] *See* S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. U. L. REV. 1673, 1691, 1704 (Aug. 11, 2021), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3903513.

[26] 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, https://www.ftc.gov/system/files/ftc_gov/pdf/2024.02.06March-InRightsComment.pdf.

[27] Michael A. Carrier & S. Sean Tu, *Why Pharmaceutical Patent Thickets Are Unique*, TEXAS INTELLECTUAL PROP. L. J. (Aug. 1, 2023), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4571486.

[28] *See* Alex Brill & Christy Robinson, *How Patent Thickets Constrain the US Biosimilars Market and Domestic Manufacturing*, Matrix Global Advisors (May 2021), https://getmga.com/wp-content/uploads/2022/04/PatentThickets_May2021_FINAL.pdf .

[29] 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 at 16, https://www.ftc.gov/system/files/ftc_gov/pdf/2024.02.06March-InRightsComment.pdf.

III. The NPRM's Proposed Changes to Terminal Disclaimer Practice Would Reduce Market Entry Barriers and Incentives for Using Terminal Disclaimers to Build Patent Thickets

As discussed in the NPRM, patent owners often file applications to pursue multiple patents with claims that vary in only minor ways from each other. The USPTO rejects claims in a patent application that are duplicative of claims included in other patents or patent applications of the same patent applicant.[30] Such rejections address the problem of obviousness-type double patenting (also known as nonstatutory double patenting) between patents or patent applications that are commonly owned or owned by parties under a joint research agreement. Nonstatutory double patenting is a judicially created doctrine that rejects claims in patent applications that are essentially the same as those in a prior patent.[31] However, under current practice, a patent applicant can overcome a USPTO rejection for nonstatutory double patenting by filing a "terminal disclaimer."[32] The terminal disclaimer is a binding stipulation by the patent applicant that the patent's term will not extend beyond the term of the original patent.

The proposed rule would add a new requirement for terminal disclaimers made to overcome a nonstatutory double patenting rejection. Under the proposed rule, such terminal disclaimers would have to include a provision that the patent would be enforceable only if it has not been tied by a terminal disclaimer (to obviate nonstatutory double patenting) to another patent containing any claim that has been finally held unpatentable or invalid by a federal court or the USPTO, and for which all appeal rights have been exhausted.[33]

The Commission agrees with the USPTO that patents directed to obvious variants of an invention can stifle competition despite the use of terminal disclaimers.[34] Currently, terminal disclaimers prevent patent holders from using follow-on patents claiming inventions already covered under existing patents or applications to improperly extend the term of their market exclusivity. But patents tied by terminal disclaimers can still be used by applicants to impose significant costs on potential competitors. As noted in the NPRM, under the current rules, potential entrants, confronting overlapping claims in different patents linked by a terminal disclaimer, must challenge both claims separately. Competitors seeking to enter the market may be forced to defend against multiple patent infringement claims based on obvious variants of a single invention, which can impose high costs on potential entrants.[35] It is estimated that the

[30] NPRM, 89 Fed. Reg. at 40439; MPEP § 804(II)(B) ("A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. *In re Goodman,* 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)").
[31] S. Sean Tu, *Patenting Fast and Slow: Examiner Rejections and Applicant Traversals to Nonprior Art Rejections*, 2021 MICH. ST. L. REV. 411 441 (2021), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3546944; See also MPEP § 804(II)(B) ("A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s).").
[32] 37 CFR § 1.321.
[33] NPRM, 89 Fed. Reg. at 40441.
[34] NPRM, 89 Fed. Reg. at 40439.
[35] NPRM, 89 Fed. Reg. at 40441.

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.

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[36] Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem*, 9 J. L. & BIOSCIENCES 1, 19 (2022), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9439849/.

[37] *See* S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. U. L. REV. 1673, 1704, n. 107 (Aug. 11, 2021), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3903513 ("If patentees are attempting to quickly create a patent thicket, then speedy prosecution is critical. If the technology has significant overlap with prior patents, then overcoming the rejection by simply filing a terminal disclaimer is the most reasonable response for a patentee who wants a large number of patents to create a fence.").

[38] S. Sean Tu et al., Biologic Patent Thickets and Terminal Disclaimers, JAMA (Dec. 14, 2023), *available at* https://jamanetwork.com/journals/jama/article-abstract/2813272.

[39] Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem*, 9 J. L. & BIOSCIENCES 1, 19 (2022), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9439849/.

[40] *See* NPRM, 89 Fed. Reg. at 40444.

The Commission believes the proposed rule will reform terminal disclaimer practice in a manner that reduces gamesmanship by patent holders, as well as the number, size, and impact of patent thickets. Intellectual property policy that promotes competition and market entry will foster vibrant markets that promote innovation and lower prices for businesses and consumers. The Commission appreciates the USPTO's commitment to preventing abuse of the patent system and promoting fair competition and innovation in the American economy. We look forward to continuing to participate in the USPTO's efforts to advance our agencies' shared goals.