

United States Senate
WASHINGTON, DC 20510

September 19, 2024

The Honorable Kathi Vidal
Director
U.S. Patent and Trademark Office
U.S. Department of Commerce
1401 Constitution Ave NW
Washington, D.C., 20230

Dear Director Vidal,

We write in strong support of the U.S. Patent and Trademark Office’s (USPTO) Notice of Proposed Rulemaking (NPRM), “Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting.” The proposed rule, released on May 10, 2024, would rein in the abuse of terminal disclaimers, ultimately fostering innovation and promoting competition.¹ We urge you to finalize this rule as soon as possible.

Patent seekers often rely on terminal disclaimers, which limit the exclusivity period of patents, to circumvent a potential rejection of a patent claim. Specifically, when a patent claim is at risk of being rejected because it is too similar to another patent held by the patent seeker, patent seekers may tie their second patent to the first through a terminal disclaimer. Instead of receiving a full exclusivity period, the second patent, now with a terminal disclaimer, will expire at the same time as the original patent. If a patent seeker agrees to this limited exclusivity period, USPTO agrees to not challenge the patent.

Pharmaceutical companies have relied on terminal disclaimers to build protective “patent thickets” around their most profitable drugs. By doing so, these companies increase the legal cost of bringing generic drugs to market—making it easier for companies to extend their market monopoly long after the drug should be considered novel. In turn, this delay keeps drug prices high for patients, burdening our health system and making it harder for people to access the care they need.

Restoring competition to the prescription drug market would provide American patients with much needed and overdue relief on the cost of prescription drugs—and USPTO’s NPRM is an important step towards this goal. The rule would require patent applicants filing terminal disclaimers to agree that their patent will be unenforceable if any claim in another patent tied to the original patent by a terminal disclaimer has been held unpatentable or invalid by a federal court or the USPTO. Challenging patents is extremely costly, and this rule would reduce incentives for filing numerous duplicative patents that are tied to each other by terminal disclaimers, which would reduce gamesmanship by patent holders and allow for more innovation in the market. USPTO should finalize this rule without delay.

¹ United States Patent and Trademark Office, *Proposed changes to terminal disclaimer practice to promote innovation and competition* (May 9, 2024) (online at <https://www.uspto.gov/about-us/news-updates/proposed-changes-terminal-disclaimer-practice-promote-innovation-and>).

To further bolster USPTO's efforts, Congress should also pass S. 3583, a bipartisan, bicameral bill that complements the proposed rule. S. 3583 would limit the number of patents with a common terminal disclaimer that a pharmaceutical company can assert in infringement litigation to one. As USPTO acknowledges in their NPRM, limiting the number of patents (with a common terminal disclaimer) a brand company can enforce will "streamline and expedite patent disputes, narrow validity issues, and provide greater certainty to competitors and to the public."² While our bill attempts to address patent thickets that have already been created, the proposed rule is equally as important, as it will prevent pharmaceutical companies from manipulating the use of terminal disclaimers to build future patent thickets. Together, by advancing our bill to address patent thickets and finalizing the proposed rule, we could provide tangible benefits to the patient community.

We thank you again for your continued commitment to creating a patent system that promotes innovation while addressing loopholes within the system that are being exploited by pharmaceutical companies for their profit. We strongly urge USPTO to finalize the proposed rule so that Americans can start to see the benefits of lower cost prescription drugs.

We thank you for your attention to this important matter.



Peter Welch
United States Senator



Mike Braun
United States Senator



Amy Klobuchar
United States Senator

² United States Patent and Trademark Office, *Proposed changes to terminal disclaimer practice to promote innovation and competition* (May 9, 2024) (online at <https://www.uspto.gov/about-us/news-updates/proposed-changes-terminal-disclaimer-practice-promote-innovation-and>).