

**Comments from Public Citizen in Response to the U.S. Patent & Trademark Office’s Request for Comment on Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, No. PTO-P-2024-0003**

Public Citizen is a consumer advocacy organization with more than 500,000 members and supporters and a fifty-year history protecting the public’s interest before federal agencies, Congress, and the courts. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally. As such, we and our members have a strong interest in addressing how obvious and duplicative patents obtained by pharmaceutical companies unfairly deprive patients of more affordable generic or biosimilar alternatives.

We write to express our strong support for the proposed rule, which would change terminal disclaimer practices at the Patent & Trademark Office (PTO) to deter patent applicants from obtaining additional patent protection over the same invention. This will help eliminate unfair barriers to generic and biosimilar competition to branded medicines because, under the proposed rule, a potential competitor can avoid enforcement of duplicative patents.

**Background**

Currently, a patent applicant can submit a terminal disclaimer when they receive a rejection of a patent application on the basis of nonstatutory double patenting. In these circumstances, PTO has concluded at least one claim in the patent application is an obvious variant of a claim in a prior patent owned by the same applicant. If PTO granted this application, it would effectively grant additional patent protection for the same invention, which would violate a core principle of patent law. In response to this rejection, the patent applicant submits a terminal disclaimer that disclaims the period of patent protection that extends beyond the earlier patent. In theory, this is designed to ensure patent applicants cannot obtain extended protection on the same invention. But in reality, it allows companies to obtain duplicative protection over the same invention, even if they expire at the same time.

**Patent Thickets**

Terminal disclaimers can be used to obtain a dense web of interlocking claims covering the same invention. In the pharmaceutical sector, this terminal disclaimer practice contributes to the fraught phenomenon of patent thickets, which scholars and policymakers have extensively criticized as large masses of patents covering the same or similar subject matter and are very costly to challenge and overcome.<sup>1</sup> Rather than rely on the quality of their patents,

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<sup>1</sup> Press Release, Elizabeth Warren, Senate, Warren, Jayapal Call on Patent Office to Take Critical

pharmaceutical companies use the sheer number of patents accumulated on a drug to deter and delay generic and biosimilar competition.<sup>2</sup> The Department of Health and Human Services and the Food and Drug Administration also recognize the anticompetitive harms to patients that result from patent thickets.<sup>3</sup> The proposed rule by PTO is a commendable effort to rein in the proliferation of patent thickets that unjustly deprive patients of more affordable medicines by addressing the terminal disclaimer practice that enables, in part, patent thickets.

To illustrate the utility of the proposed rule, we can examine how it prevents past patent thicket abuses from unfolding again. Take, for example, adalimumab (marketed as Humira), the world's most lucrative biologic drug. From 2007 to 2021, Humira generated an immense \$122 billion in revenue.<sup>4</sup> While biosimilars launched in Europe in 2018, biosimilar entry in the United States was delayed until 2023 through settlement agreements between the branded and biosimilar manufacturers.<sup>5</sup> The patent thicket in the United States was key to depriving American patients of more affordable biosimilars until 2023. Experts found that 73 core patents had been granted for Humira in the United States.<sup>6</sup> In comparison, Europe had only granted 8 patents in the drug.<sup>7</sup> In the United States, 35 of the granted patents were asserted, on average, against manufacturers of biosimilar competitors to Humira, whereas **just three patents** were asserted, on average, in Europe against the biosimilar manufacturers.<sup>8</sup> That is, Humira's daunting mass of interlocking patents made challenging its exclusivity extremely difficult in the United States, delaying biosimilar access unlike in other countries.

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Steps to Lower Drug Prices and Fight Big Pharma's Patent Abuse (Apr. 27, 2023), <https://www.warren.senate.gov/oversight/letters/warren-jayapal-call-on-patent-office-to-takecritical-steps-to-lower-drug-prices-and-fight-big-pharmas-patent-abuse>; Michael A. Carrier & S. Sean Tu, *Why Pharmaceutical Patent Thickets Are Unique*, 32 TEX. INTELLECTUAL PROPERTY L. J. 79 (2022); Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars*, J.L & BIOSCIENCES 1 (2022).

<sup>2</sup> Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars*, J.L & BIOSCIENCES 1, 38 (2022).

<sup>3</sup> OFFICE OF THE SECRETARY FOR PLANNING & EVALUATION, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, COMPREHENSIVE PLAN FOR ADDRESSING HIGH DRUG PRICES: A REPORT IN RESPONSE TO THE EXECUTIVE ORDER ON COMPETITION IN THE AMERICAN ECONOMY (2021); Letter from Janet Woodcock, Acting Comm'r, U.S. Food & Drug Admin., to Andrew Hirshfeld, Dir., U.S. Pat. & Trademark Off. (Sept. 6, 2021), <https://www.fda.gov/media/152086/download>.

<sup>4</sup> Michael A. Carrier & S. Sean Tu, *Why Pharmaceutical Patent Thickets Are Unique*, 32 TEX. INTELLECTUAL PROPERTY L. J. 79, 88 (2022).

<sup>5</sup> Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars*, J.L & BIOSCIENCES 1, 20 (2022); Jonathan Gardner, *Humira biosimilars arrive in the US, as Amgen launches first copycat to AbbVie's blockbuster drug*, BIOPHARMA DIVE (Jan. 31, 2023), <https://www.biopharmadive.com/news/humira-biosimilar-launch-amgen-abbvie-amjevita/641511/>.

<sup>6</sup> Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars*, J.L & BIOSCIENCES 1, 18-19 (2022).

<sup>7</sup> *Id.* at 19.

<sup>8</sup> *Id.* at 12.

A critical mechanism that allowed a patent thicket to be amassed on Humira is now the subject of this rulemaking: terminal disclaimers. Experts found that of the 73 patents granted in Humira, 59 of the patents were linked through terminal disclaimers and were obvious variants of other patents in the drug.<sup>9</sup> In sum, “80% of the U.S. Humira patents are not directed to new, non-obvious inventions,” and the terminal disclaimer practice was key to providing this sprawling web of duplicative protection over the drug.<sup>10</sup> In order to launch a biosimilar to Humira, a manufacturer would have had to win in challenging every duplicative claim that could apply to their product from this massive patent thicket that was asserted in an infringement suit. In contrast, the branded manufacturer had to prevail on just one claim to prevent their launch. The only alternatives for biosimilar manufacturers were to enter into settlement agreements delaying launches beyond the expiry of the core Humira patents or to forego entering the market until the related patents had expired.

The proposed rule helps even the playing field for generic and biosimilar manufacturers. Under the proposed regulation, when an applicant files a terminal disclaimer to address a rejection on the basis of nonstatutory double patenting, they must agree that the patent will be enforceable only if it has never been tied directly or indirectly to a patent with a claim that has been held invalid over prior art. The proposed rule would likely have deterred the patent thicket practices on Humira: had it been in effect, a biosimilar manufacturer would have needed to prevail on invalidating only the single weakest claim in a patent tied directly or indirectly to many other patents via the terminal disclaimer for **all of these latter patents** to be unenforceable. Large swathes of the Humira patent portfolio would have been vulnerable if the proposed rule were in place, which likely would have deterred the branded manufacturer from securing such duplicative patents in the first place. Thus, the rule would also advance patent quality by reducing incentives for obtaining vulnerable patent protection for indistinct inventions through the terminal disclaimer practice.

Additionally, the mere existence of a patent thicket may provide a chilling effect on generic and biosimilar competition. According to the Association of Accessible Medicines, potential competitors to a manufacturer of a branded drug or biologic that has amassed a patent thicket may not seek costly development projects if the patent thicket creates legal uncertainty and increases costs of litigation.<sup>11</sup>

In sum, the proposed rule will provide a critical tool for generic and biosimilar manufacturers to challenge patent thickets while also increasing the quality of patents by removing incentives for obtaining duplicative protection on drugs and helping reduce the chilling effect on generic and biosimilar development. U.S. patients will significantly benefit from the proposed rule, as generics and biosimilars will face fewer barriers to market entry, consequently providing Americans with more affordable alternatives to branded medicines earlier.

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<sup>9</sup> *Id.* at 18-19.

<sup>10</sup> *Id.*

<sup>11</sup> *Intellectual Property and Patent Reform*, ASS’N FOR ACCESSIBLE MEDS., <https://accessiblemeds.org/advocacy/intellectual-property-patent-reform> (last visited July 8, 2024).

As further evidence of how this proposed rule would help U.S. patients substantially, a staggering 1/3 of the patents in the Orange Book, which lists relevant patents covering approved small molecule drugs, have terminal disclaimers.<sup>12</sup> The patents listed in the Orange Book help manufacturers assess patent and regulatory barriers to approval of generics. Over time, the number of patents listed in the Orange Book has drastically increased: in 2000, a total of 186 patents were listed for new drugs, whereas in 2015, there were 323 patents listed.<sup>13</sup> With the proposed rule in place, manufacturers would not be as daunted by the increasing number of patents listed in the Orange Book that could bar generic entry. Instead, they could assess how many of the patents listed in the Orange Book are directly or indirectly linked to others via the terminal disclaimer and strategically challenge the single weakest claim that would clear many of the patent obstacles to generic entry.

### **Serial Litigation**

Thus far, we have addressed our support for the proposed rule based on its utility for preventing and overcoming patent thickets, but we also note how the tool can limit anticompetitive serial litigation against generic manufacturers that is another consequence of these patent thickets. This stems, in part, from a practice called continuation patents.<sup>14</sup>

“Continuation patents are based on the same invention description and drawings as a previously filed application, and their disclosure is identical or nearly identical to a previous application. In fact, the defining characteristic of a continuation patent is that it cannot add new material, new illustrations, or new matter to the parent application [the application with the original disclosure of the invention].”<sup>15</sup> By relying on the same disclosure of an invention as the parent application, many of these continuation patents tease out additional patent claims that are obvious over the parent patent’s claims.<sup>16</sup> But to circumvent rejections based on obviousness-type double patenting, the applicant simply files a terminal disclaimer, which allows the obvious continuation patent to issue.<sup>17</sup> Applicants can also file multiple generations of continuations that all reference back to an original parent patent, and they can tailor claims in the later continuations to cover competing products as they come to market.<sup>18</sup> Thus, continuation patents can be critical to amassing patent thickets. For example, 79% of Humira’s

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<sup>12</sup> Press Release, Elizabeth Warren, Senate, Warren, Jayapal Call on Patent Office to Take Critical Steps to Lower Drug Prices and Fight Big Pharma’s Patent Abuse (Apr. 27, 2023), <https://www.warren.senate.gov/oversight/letters/warren-jayapal-call-on-patent-office-to-takecritical-steps-to-lower-drug-prices-and-fight-big-pharmas-patent-abuse>.

<sup>13</sup> Sean Tu, Aaron S. Kesselheim, Kathrine Wetherbee, & William B. Feldman, *Changes in the Number of Continuation Patents on Drugs Approved by the FDA*, 330 JAMA 469 (2023).

<sup>14</sup>Michael A. Carrier & S. Sean Tu, *Why Pharmaceutical Patent Thickets Are Unique*, 32 TEX. INTELLECTUAL PROPERTY L. J. 79, 89 (2022).

<sup>15</sup> *Id.* at 85.

<sup>16</sup> *Id.* at 85-86.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

patent portfolio were continuations.<sup>19</sup> Problematically, continuations allow branded manufacturers to engage in multiple waves of litigation against competitors.

For example, if a branded manufacturer fails to block generic competition in earlier lawsuits, it can use the information learned in this litigation to tweak claims in subsequent generations of continuations to cover the competing generic product. Using the terminal disclaimer, they can overcome obviousness-type double patenting rejections from prior patents in order for these continuations to issue and then initiate new waves of litigation against a generic. This serial litigation creates protracted uncertainty for generic manufacturers, can impose significant damages on these companies, and in some cases, can delay and deprive U.S. patients of more affordable alternatives to the branded medicines.

The proposed rule would limit such serial litigation because if subsequent generations of continuations are tied through a terminal disclaimer to a prior patent that has been invalidated over prior art, the continuations would no longer be enforceable and could no longer serve as the basis of new waves of litigation.

### **Addressing Loopholes**

We commend PTO for taking steps to close potential loopholes applicants could exploit to circumvent the impact of the proposed rule. PTO anticipated that if a parent patent was challenged for being invalid in light of prior art, an applicant might try to file a statutory disclaimer disclaiming any of the challenged claims in the parent patent to nullify the impact of the rule. That is, if the rule only tied enforceability of the patents with terminal disclaimers to validity of the parent patent's claim, the statutory disclaimer would preempt a decision on invalidity and allow applicants to circumvent the rule. Thus, we appreciate PTO's inclusion in the proposed rule that applicants must agree that patents with terminal disclaimers tying back to patents for which such statutory disclaimers have been filed will also be unenforceable.

We also highlight other loopholes applicants might try to exploit in order to circumvent the proposed rule and how PTO may address them. First, applicants may try to trigger a restriction requirement by PTO that would allow them to file divisional applications subject to a safe harbor against rejections for obviousness-type double patenting to expand duplicative patent rights on the same invention. A restriction requirement issues when a patent application tries to claim multiple inventions in a single patent, which requires an applicant to file divisional applications to cover the separate inventions. Without a safe harbor, though, the divisional applications would be obvious over the earlier patent application. This is the reason for the safe harbor against double patenting rejections for divisional applications. However, it is possible that manufacturers may increasingly resort to divisional applications which are immune to rejections on the basis of obviousness-type double patenting to try and maintain a sprawling web of duplicative patent rights on branded medicines after this rule is finalized.

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<sup>19</sup> *Id.* at 89.

Therefore, we advise PTO to monitor and take care in issuing restriction requirements as applicants may increasingly exploit divisional applications for maintaining duplicative protection over the same invention in response to the promulgated rule. PTO could also monitor how claims in divisional applications may be modified for anticompetitive purposes after the rule is finalized.

Lastly, we urge PTO to be skeptical of insubstantial ways patent applicants may try to recast indistinct claims as distinct to prevent double patenting rejections of later-filed patent applications after the rule is promulgated. Applicants may resort to different terminology or the incorporation of immaterial aspects of a written description to distinguish claims, and we advocate PTO guard against these attempts to circumvent the rule.

### **Conclusion**

We commend PTO for its rulemaking that will help curtail duplicative patenting and limit anticompetitive tactics by pharmaceutical corporations that deprive U.S. patients of more affordable generic and biosimilar alternatives. For this reason, we strongly support the proposed rule.

Sincerely,  
Public Citizen