

# Now & Next

## Intellectual Property Alert

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### **USPTO changes course on controversial proposed rule for terminal disclaimers**

By Ion C. Moraru, PhD and Benjamin R. Holt

Patent owners relieved by USPTO proposed rule withdrawal.



#### **What's the impact?**

- Patent owners may continue to use terminal disclaimers as a strategy to overcome non-statutory double patenting rejections.
- Patent owners must continue to exercise caution in using terminal disclaimers.

On May 10, 2024, the United States Patent and Trademark Office (USPTO) issued a [proposed rule](#) that would have added a new requirement for terminal disclaimers used to obviate non-statutory ("obviousness-type") double patenting rejections. The USPTO [withdrew](#) this proposed rule, however, on December 4, 2024, after receiving more than 300 comments.

Obviousness-type double patenting is a judicially created doctrine preventing improper extension of patent rights by obtaining a second patent for an invention not patentably distinct from one in a first patent. To obviate an obviousness-type double patenting rejection, patentees commonly file a terminal disclaimer in accordance with [37 CFR 1.321\(c\) or \(d\)](#) to disclaim the term in the second patent extending beyond the term of the first patent, if any, along with certain

other requirements. Put simply, a terminal disclaimer synchronizes the expiration of the second patent with that of the first patent.

## Proposed terminal disclaimer rule

The proposed rule would have imposed an additional requirement for a patentee filing a terminal disclaimer: an agreement that the granted patent (or any other patent granted on the subject application) will only be enforceable if the patent is not tied and has never been tied directly or indirectly through one or more terminal disclaimers to a patent in which any claim has been finally held unpatentable or invalid over prior art by a federal court or the USPTO. The proposed rule would have been prospective and only affected terminal disclaimers filed after the rule's effective date. Also, similar to current practice, the proposed rule would have been unidirectional and only encumbered a granted patent subject to the terminal disclaimer, not any prior patents listed in the disclaimer.

According to the [USPTO](#), the proposed rule was intended to promote innovation and competition, reduce costs, expedite patent disputes, narrow validity issues, and provide greater certainty to competitors. But many observed that certain parties would have been favored, such as patent infringers. This is because, under the proposed rule, a patent challenger would only need to show **one** invalid or unpatentable claim of a patent to render unenforceable **all** claims of **all** other patents tied to that patent via terminal disclaimer(s). The proposed rule would also have affected certain patentees and industries more than others, such as pharmaceutical companies that often protect drug products with large portfolios of related patents involving terminal disclaimers.

## USPTO withdraws proposed rule

The USPTO recently announced withdrawal of the proposed rule, stating that it "has decided not to move forward with the proposed rule at this time." Weighing comments provided by the public, the USPTO cited resource constraints in its decision. Among those commenting against the rule, many argued that it would:

- / Significantly raise cost and time of prosecution;
- / Disproportionately affect those with limited resources;
- / Raise the risk of terminal disclaimer practice;
- / Discourage use of continuation applications;
- / Increase examiner workload through increased restriction practice;
- / Encourage appeals impacting docket workload and pendency at the PTAB;
- / Shift the balance of power to patent challengers;
- / Render patents unenforceable without challenging claims;

- / Reduce portfolio value to the weakest claim; and
- / Contradict patenting principles, statutes, and Federal Circuit precedent.

## Terminal disclaimers going forward

Withdrawal of the proposed rule maintains the status quo on terminal disclaimers. But even absent the proposed rule change, patent owners and litigants must still continue to navigate with care the existing framework for terminal disclaimers and double patenting, including understanding the nuances of double patenting challenges and the requirements and implications of terminal disclaimers.

For example, even under the existing framework, obviousness-type double patenting issues continue to arise in litigation, including a Federal Circuit decision earlier this year.<sup>1</sup> And while a terminal disclaimer may overcome a double patenting rejection and lead to faster allowance, the resulting reduced patent term may impact the amount of damages a patentee can obtain in litigation. Also, while an obviousness-type double patenting rejection may pertain to a single claim in a patent application, the terminal disclaimer cuts short the term of the entire patent. Further, a terminal disclaimer that identifies the wrong application or patent can have severe consequences and may be difficult, if not impossible, to correct. In fact, even a small typographical error may lead to unenforceability of a patent.<sup>2</sup> Therefore, patent owners and litigants should tread carefully.

## Future USPTO proposals

The withdrawal of the proposed terminal disclaimer rule does not preclude the possibility of future rule changes regarding terminal disclaimers or other aspects of patent practice. This situation underscores the importance of staying informed of ongoing discussions and future rulemaking from the USPTO. Patent owners and litigants should keep updated on such developments and how they may impact patent practice and strategy, including the [USPTO's new fees](#) coming in 2025.

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<sup>1</sup> [Allergan USA, Inc. v. MSN Labs. Priv. Ltd.](#), 111 F.4th 1358 (Fed. Cir. 2024).

<sup>2</sup> [SIPCO, LLC v. Jasco Prods. Co. LLC](#), No. CIV-19-709-PRW, 2024 WL 2754047 (W.D. Okla. May 29, 2024).

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