

Terminal Disclaimers of Patent Rights: Background and Issues for Congress

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[Terminal disclaimers](#) are a legal mechanism that allows a patent holder or applicant to relinquish part of a patent's term, so that the patent expires earlier than it would without the disclaimer. While terminal disclaimers are sometimes used to dedicate a patented invention to the public domain, they may also be used during patent prosecution, the administrative process through which an inventor applies for a patent before the U.S. Patent and Trademark Office (USPTO). In particular, current practice allows patent applicants to use terminal disclaimers to prevent a rejection of their patent application based on a judicially created doctrine called [obviousness-type double patenting](#). This practice means that if USPTO rejects a patent application based on obviousness-type double patenting, applicants can overcome that rejection—and potentially receive a patent on the invention claimed in the application—if they are willing to surrender part of any resulting patent's term through a terminal disclaimer.

Some stakeholders have [criticized](#) this use of terminal disclaimers, arguing that it may allow applicants to secure a “[thicket](#)” of multiple, overlapping patents on a single invention. This concern is often [raised](#) in the context of patents on drugs and biological products (biologics), which are sometimes protected by many patents, some of which may be linked together by terminal disclaimers. Other stakeholders [argue](#) that terminal disclaimers make patent prosecution more efficient, and that there is no evidence that terminal disclaimers harm innovation or economic competition.

On May 10, 2024, USPTO issued a [notice of proposed rulemaking](#) on terminal disclaimers. USPTO's proposed rule would have [required](#) patent applicants to agree that they will not enforce a patent tied to another patent by a terminal disclaimer, should that other patent have a claim invalidated on novelty or non-obviousness grounds by a court or USPTO. In other words, the proposed rule would have effectively tied the validity of a patent with a terminal disclaimer to the validity of the patent(s) underlying the initial obviousness-type double-patenting rejection. Following criticism from some stakeholders, USPTO formally [withdrew](#) its proposed terminal disclaimer rule on December 4, 2024.

This Legal Sidebar explains the current law and regulations on terminal disclaimers, USPTO's now-withdrawn proposed terminal disclaimer rule, and options for Congress.

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Double Patenting

[Double patenting](#) describes a situation in which an inventor improperly attempts to obtain more than one patent claiming either the same invention, or very similar inventions. Double-patenting doctrine was developed by the courts through a line of cases dating to 19th century [Supreme Court decisions](#).

Modern cases distinguish between two types of impermissible double patenting. The first type, sometimes called [statutory double patenting](#), derives from [Section 101](#) of the Patent Act of 1952, which provides that “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . may obtain *a patent* therefor” (emphasis added). Inventors thus cannot obtain a second patent claiming the same invention that they have already patented.

Because Section 101 only prohibits a second patent claiming an invention that is identical to an earlier patent, an applicant [could](#) “evade this statutory requirement by drafting claims that vary slightly from the earlier patent.” To address that concern, courts developed a second double-patenting prohibition, called *nonstatutory double patenting* or [obviousness-type double patenting](#) (OTDP). OTDP prohibits patent holders from acquiring a second patent on an invention that is an obvious variation on one of their earlier patents (i.e., different in only trivial or easily discovered ways). Under this doctrine, when a later patent’s claims are obvious in light of an earlier patent filed by the same inventor, the second patent is said to be not “[patentably distinct](#)” and is invalid for that reason.

The prohibition on statutory double patenting is absolute—if two patents claim the *same* invention, the second patent is invalid. A rejection based on OTDP, however, can be [overcome](#) during patent prosecution through a terminal disclaimer, as explained below.

Procedurally, a double patenting issue may arise in several ways. First, double patenting may result from two unrelated but commonly owned patents or patent applications that claim similar subject matter. Double patenting may also arise in the context of related patent applications, which USPTO calls “[continuing applications](#).” A continuing application [shares](#) at least one inventor and some or all of the technical disclosure contained in an earlier pending patent application. The Patent Act and USPTO provide for several types of continuing applications, including [continuations](#), [continuations-in-part](#), and [divisional applications](#). Under some circumstances, these later patent applications may “[claim priority](#)” to the earlier application—that is, the later application uses the earlier application’s filing date when determining the claimed invention’s novelty and nonobviousness. Colloquially, the earlier patent to which a continuing application claims priority is sometimes [called](#) the “parent” patent, and the continuing applications the “child” patents. Depending on the circumstances, child patents may [have](#) terminal disclaimers so that they expire at the same time as the parent patent.

Terminal Disclaimers

Statutory and Regulatory Basis

Patent law first provided for terminal disclaimers via statute in 1952. [Section 253](#) of the Patent Act provides that “any patentee or applicant may disclaim or dedicate to the public the entire term, *or any terminal part of the term*, of the patent granted or to be granted” (emphasis added). An [influential legislative history](#) of the Patent Act of 1952 explained that proponents of the terminal disclaimer provision thought it might be used “in combatting a defense of double patenting, to permit the patentee to cut back the term of a later issued patent so as to expire at the same time as the earlier issued patent and thus eliminate any charge of extension of monopoly.”

37 C.F.R. § 1.321 sets forth the current procedures for making terminal disclaimers. Subsection (c) permits the use of terminal disclaimers to “obviate” (i.e., avoid) OTDP rejections during patent prosecution. Thus, if a USPTO patent examiner initially rejects the proposed claims in a patent application based on OTDP, the applicant has a choice. He can either (1) contest the OTDP rejection on its merits (e.g., by arguing that the second patent is patentably distinct, or by proposing different claims), or (2) avoid the OTDP issue entirely via a terminal disclaimer. The second path sidesteps a fight with USPTO on the substance of whether the second patent’s claims are indeed obvious in light of the first patent, at the cost of a shortened term for the second patent.

To make a terminal disclaimer, the patent applicant [must](#) state the portion of the patent term disclaimed, pay a fee, and provide that any resulting patent will be enforceable only while it is commonly owned with the earlier patent on which the OTDP rejection was based. The common ownership condition is designed to ensure that patents tied together by a terminal disclaimer remain owned by the same entity. If ownership of one of the patents is transferred without the other, then the terminally disclaimed patent becomes unenforceable under USPTO’s rules.

Historical Development

The use of terminal disclaimers to overcome challenges to patent validity based on OTDP derives from case law following the enactment of the Patent Act of 1952. In a series of cases in the 1960s, the U.S. Court of Customs and Patent Appeals (CCPA) [held](#) that a terminal disclaimer could be [used](#) to obviate an OTDP problem. In these decisions, CCPA [reasoned](#) that OTDP was “grounded in public policy and primarily intended to prevent prolongation of monopoly”—that is, to prevent the patent holder from extending his patent term through a later-issued patent on essentially the same invention. (At the time, a later-issued patent would always expire after an earlier-issued patent.) The CCPA reasoned that a terminal disclaimer of any “excess” patent term in the later-issued patent—so that both patents expire [at the same time](#)—“foreclosed the possibility of such an extension” of the patent monopoly. The CCPA thus concluded that a “terminal disclaimer [that] causes two patents to expire together” was “[tantamount for all practical purposes to having all the claims in one patent](#).” The effect of the disclaimer, then, is to treat the claims in the second patent application as if they were in the first application for OTDP purposes, so long as the applicant agrees that both patents will expire at the same time.

The U.S. Court of Appeals for the Federal Circuit, shortly after [its creation by Congress in 1982](#), adopted the decisions of the CCPA as [binding precedent](#) for the new court. Thus, CCPA holdings on OTDP from the 1960s are still cited in [contemporary cases](#), which continue to adhere to the rule that a terminal disclaimer obviates an OTDP rejection.

Recent Executive and Administrative Developments

On July 9, 2021, then-President Biden issued an executive order titled “[Promoting Competition in the American Economy](#).” Among other things, the order directed the Commissioner of the U.S. Food and Drug Administration (FDA) to [communicate](#) with USPTO about whether the patent system may “unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law.” (Like any other invention, new drugs and biologics may be protected by patents, which [may](#) deter or delay market entry of generic and biosimilar versions of those products.)

In 2021 and 2022, FDA and USPTO exchanged a [series of letters](#) on this topic and announced several initiatives “to ensure that the U.S. patent system properly and adequately protects innovation and is not used to unjustifiably delay . . . more affordable versions of pharmaceuticals into the hands of Americans who need them.” Among the concerns raised by FDA in its [letters](#) was the use of continuing patents to “create ‘patent thickets’ by obtaining multiple patents on different aspects of the same product.” USPTO

responded that it may “[r]evisit obviousness-type double patenting practice,” noting that “[a]lthough a terminal disclaimer ensures that the later patent will remain commonly owned with and have the same patent term as the earlier patent, multiple patents directed to obvious variants of an invention could potentially deter competition if the number of patents is prohibitively expensive to challenge.”

On October 24, 2022, USPTO issued a formal [Request for Comments](#) (RFC) on the initiatives outlined in its letter to FDA, including its proposal to revisit its regulations on OTDP and terminal disclaimers. As relevant here, USPTO sought comment on [whether](#) to “limit or change” its OTDP practice. For example, the RFC [proposed](#) “requiring applicants to stipulate that the claims are not patentably distinct from the previously considered claims as a condition of filing a terminal disclaimer,” or treating the terminal disclaimer as an admission of obviousness so that a family of patents tied by terminal disclaimers would “stand and fall together.” USPTO received more than [200 comments](#) from stakeholders and the public.

USPTO’s Withdrawn Terminal Disclaimer Rule

USPTO’s May 2024 [notice of proposed rulemaking](#) (NPRM) would have amended terminal disclaimer practice in a different way than envisioned in the RFC. The NPRM [noted](#) that some commenters argued that requiring an applicant to stipulate that a terminally disclaimed patent’s claims are not patentably distinct conflicted with case law. For example, the Federal Circuit held in *SimpleAir, Inc. v. Google LLC* (Fed. Cir. 2018) that a terminal disclaimer does *not* operate as an admission regarding the obviousness of the resulting patent’s claims. At least arguably, then, the RFC’s proposals were outside of USPTO’s [regulatory authority](#). Instead of a stipulation about patent validity, USPTO’s proposed rule would have [imposed](#) a “condition upon enforcement” of the disclaimed patent when a terminal disclaimer is used. USPTO cited *In re Van Ornum* (CCPA 1982) in support of its regulatory authority.

The NPRM’s now-withdrawn rule would have required that an applicant using a terminal disclaimer to overcome OTDP [to agree](#) that the enforceability of any disclaimed patent depends on the validity of the patent tied to the disclaimed patent through a terminal disclaimer (the original patent). In particular, if any claim of the original patent is held unpatentable or invalid on certain grounds by a final decision of a federal court or by USPTO (for example, through an [inter partes review](#)), then the disclaimed patent could not have been [enforced](#) under the withdrawn rule. The same rule would have also applied when a disclaimed patent is tied indirectly to another patent [through](#) “multiple intermediate patents/applications.”

USPTO’s NPRM posited that the withdrawn rule on terminal disclaimers [would have](#) “promote[d] competition by lowering the cost of challenging groups of patents tied by terminal disclaimers, resulting in reduced barriers to market entry and lower costs for consumers.” Proponents of USPTO’s withdrawn rule on terminal disclaimers [argued](#) that it would have helped eliminate patent “[thickets](#)” and improved patent quality. A 2023 [letter](#) from two Members of Congress supported this notion, urging USPTO to adopt a rule where patents tied together by terminal disclaimers “stand or fall together.”

Opponents of the proposed rule urged USPTO not to adopt it for several reasons. As noted above, some [doubted](#) that USPTO has regulatory authority to promulgate a “[substantive](#)” rule imposing conditions on patent enforceability. Other commentators noted that the rule would have [departed](#) from the usual patent law principle that each patent claim’s validity is assessed independently, as it would have rendered unenforceable *all* the claims of a disclaimed patent if even *one* claim of the original patent was invalidated. (Section 282 of the Patent Act explicitly [provides](#) that “[e]ach claim of a patent . . . shall be presumed valid independently of the validity of other claims.”) In support of this view, five former Directors or Deputy Directors of USPTO wrote [a letter](#) urging the agency to withdraw the rule. Along with the concerns above, these former USPTO leaders [argued](#) that the proposed rule would have increased the costs of patent prosecution for applicants and USPTO, because applicants would avoid using terminal disclaimers and instead contest OTDP rejections on their merits.

The comment period for the NPRM [closed](#) on July 9, 2024. USPTO received nearly [350 comments](#) on the proposed rule. While [strong views](#) about the proposed rule were expressed from all sides, one partial [survey](#) of the comments received found that most commentors opposed USPTO's proposal.

Several months later, USPTO formally announced that it had [withdrawn](#) the terminal disclaimer rule. While USPTO [cited](#) “resource constraints,” commentators [noted](#) that USPTO's proposed terminal disclaimer rule was “polarizing” and drew strong objections from some stakeholders.

Considerations for Congress

Ultimately, the existence and scope of terminal disclaimers derives from an act of Congress: [Section 253](#) of the Patent Act. Congress therefore may consider a range of options in exercising its oversight over USPTO and its lawmaking function with respect to terminal disclaimers.

For example, Congress could enact statutory amendments that eliminate terminal disclaimers, clarify the situations in which they be used, limit USPTO's authority to impose conditions on their use, or deny funding to USPTO for activities related to terminal disclaimers. For example, bills introduced in the 118th Congress, [S. 3583](#) and [H.R. 6986](#), proposed to limit the number of patents that may be asserted in certain patent litigation involving drugs and biologics to one patent from any given “patent group.” The bill defined a patent group to include all terminally disclaimed patents that reference a given patent. Like USPTO's withdrawn rule, this proposal would thus have “tied together” terminally disclaimed patents to the original patents they reference, albeit in a more limited way.

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