

USPTO Proposes Rule Adding Conditions of Enforceability to Patents Tied to Terminal Disclaimers

On Friday, May 10, 2024, the USPTO issued a notice of proposed rulemaking in the [Federal Register](#) directed at amending the rules of practice to add a requirement for terminal disclaimers filed to overcome rejections for nonstatutory double patenting. In the summary of the rule, the USPTO notes that the proposed change would require terminal disclaimers filed to include an agreement by the disclaimant that any patent related to the terminal disclaimer (including the patent in which the terminal disclaimer is filed and any disclaimed patent) will be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting rejections in which:

1. any claim has been finally held unpatentable or invalid as anticipated or obvious by a Federal court in a civil action or by the USPTO, and all appeal rights have been exhausted; or
2. a statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been made.

The USPTO asserts that the action is being taken to prevent multiple patents directed to obvious variants of an invention from potentially deterring competition. Comments regarding the proposed rule must be received by July 9, 2024, in order to ensure consideration.

While patent challengers may welcome this new rule, patent owners should be wary. If implemented, the new rule would greatly affect filing and prosecution strategies for applicants who tend to file many continuation applications. Essentially, the proposed rule provides that if a patent claim tied directly or indirectly to a terminal disclaimer is determined to be invalid, then any patent directly or indirectly linked to that patent claim via a terminal disclaimer is rendered unenforceable. Accordingly, one successful invalidity challenge to a single patent claim could potentially render an entire patent estate – or a large portion thereof – unenforceable under the proposed rule.

Nonstatutory Double Patenting

Nonstatutory double patenting (also called obviousness-type double patenting) is a judicially-created doctrine that was created to prevent patentees from prolonging patent term by prohibiting claims filed in a second patent that are not patentably distinct from claims filed in a first patent. For example, a second patent claiming “A composition comprising 95% A and 5% B” may be rejected for nonstatutory double patenting in view of the first patent claiming “A composition

comprising A and B.” Although the second patent may be more specific, an Examiner may argue that the claims of the second patent would be obvious in view of the claims of the first patent since both claims are directed to compositions comprising A and B.

So what is a patent applicant to do when the claims of the second patent are rejected? There are three options. The first is to amend the claims in the second patent such that they are patentably distinct from those of the first patent, for example, “A composition comprising 95% A and 5% C.” The first patent’s claim does not include the element C, and so a nonstatutory double patenting rejection is improper. However, applicants may not prefer this route, since it substantially changes the scope of the invention they were attempting to claim in the second patent.

The second option is to simply argue that the claims of the second patent *are* patentably distinct from the claims of the first patent. Back to our composition comprising 95% A and 5% B, perhaps there is a reason why it would not be obvious to include such a high ratio of element A in the composition as compared to element B which would not be obvious to the skilled artisan. Even if true, the patentee may not want to argue how the scope of the second patent’s claims differs from the scope of the first patent’s claims. These arguments could potentially be used against the patentee in future litigation to construe the scope of the claims in an unfavorable way.

This brings us to the third (and historically, the most favorable) option – filing a terminal disclaimer.

Terminal Disclaimers

A terminal disclaimer, as provided in 35 U.S.C. § 253(b) and 37 C.F.R. § 1.321, allows a patent applicant to “disclaim or dedicate to the public the entire term, or any terminal part of the term, of a patent to be granted” such that the term of the disclaimed patent does not extend beyond the term of the patent that gave rise to the nonstatutory double patenting rejection. In effect, the terminal disclaimer causes both the first patent and the second patent to expire when the first patent would have otherwise expired, thereby preventing the patentee from prolonging their patent term as intended by the nonstatutory double patenting doctrine.

Although the example provided here includes only two patents, many patentees file several patent applications directed to a single product or a single line of products which may be terminally disclaimed. This “patent thicket” helps to deter potential infringers.

Terminal disclaimers currently include a requirement that the disclaimed patent and the subject patent(s) must be commonly owned by the same entity; otherwise, the disclaimed patent and the subject patent(s) are unenforceable.

The USPTO’s New Rule

The rule proposed by the USPTO adds an additional requirement to the terminal disclaimer that would affect the enforceability of the disclaimed and subject patents after a challenge under 35 U.S.C. § 102 or § 103. If any claim is determined to be unpatentable or invalid under § 102 for anticipation or under § 103 for obviousness by a Federal Court in a civil action or by the USPTO and all appeal rights have been exhausted, then every other claim that is directly or indirectly tied to the invalidated claim by a terminal disclaimer is deemed unenforceable. Additionally, a statutory disclaimer filed after any challenge under § 102 or § 103 would also render all other claims in any directly or indirectly tied patent unenforceable.

Importantly, the proposed rule also applies to any patents directly tied to a terminal disclaimer or indirectly tied by two or more terminal disclaimers. The tying is unidirectional and the rule provides examples illustrating when patents are tied and subject to the rule.

In the simplest example, two patents are directly tied. As illustrated in the proposed rule, a terminal disclaimer filed in X patent or application identifying W patent or application as a reference patent, then X is directly tied to W. No such terminal disclaimer was filed in W. This is illustrated by the diagram: $W \leftarrow X$. This tying is unidirectional, meaning that W is not tied to X. Thus if a claim in W is held to be invalid over prior art, then X becomes unenforceable. But, if a claim in X is held to be invalid over prior art, W may still be enforced.

Indirect tying occurs when (1) a terminal disclaimer filed in the subject patent or application identifies an intermediate patent/application as a reference patent or application; and (2) a terminal disclaimer filed in the intermediate patent/application identifies the other patent, or the application that issued as the other patent, as the reference patent or application. Thus, any patent in the chain of terminal disclaimers will be subject to unenforceability under the proposed rule. Going back to the previous example, the rule provides the following diagram: $W \leftarrow X \leftarrow Y$, where X is now an intermediate patent that is tied to W, but not tied to Y. Accordingly, if a claim in X is held invalid over prior art, Y may not be enforced, but W may be enforced.

In another example, a terminal disclaimer is filed in X identifying W as a reference patent. Then, a second terminal disclaimer is filed in W identifying X as a reference patent. This is represented by the diagram: $X \leftrightarrow W$. Here, X and W are directly tied to each other; accordingly, any claim held invalid over the prior art in either X or W renders the other patent unenforceable.

It will be appreciated that the larger a patent estate becomes and the more terminal disclaimers that are filed, the more complex these relationships become. If the rule is implemented, understanding these relationships will be vital to identifying weak points in patent families, where a potential challenger could invalidate a single claim to automatically render several others unenforceable.

If you have questions or concerns about this proposed rule, please contact your Polsinelli attorney for guidance.