

USPTO Disclaimer Rule Would Complicate Patent Prosecution

By **Marsha Rose Gillentine, Bree Vculek and John Covert** (July 3, 2024, 2:30 PM EDT)

On May 10, the U.S. Patent and Trademark Office published a notice of proposed rulemaking in the Federal Register that could dramatically affect patent prosecution, licensing and litigation.

The USPTO is responding to the current political environment to reduce drug costs by responding to circumstances where a patent owner with an approved drug is alleged to have built a patent thicket. Yet, the proposed rule applies not only in the Hatch-Waxman and Biologics Price Competition and Innovation Act context, but in all industries that have a long product development cycle or incorporate multiple patented inventions.[1]

The proposed rule applies to all patents and at all stages of product development.

In particular, the USPTO proposes requiring any terminal disclaimer to include a clause stipulating that a terminally disclaimed patent will be enforceable only if the patent is not and has never been tied directly or indirectly to a patent in which any claim has been finally held invalid as anticipated or obvious in a civil litigation or a USPTO proceeding.[2] This is in addition to the current requirements that a terminal disclaimer tie the expiration and ownership of patents.

According to the USPTO, the proposed rule "is intended to promote 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." [3]

The USPTO indicates that "[n]arrowing validity disputes in litigation to only one [patent tied to other patents by one or more terminal disclaimers to that patent] could result in more focused claim construction hearings, lower litigation costs, and faster resolution." [4] The USPTO said similarly only one patent would need to be challenged via post-grant challenge. [5]

The proposed rule does this at the expense of all patent owners by requiring the patent owner filing a terminal disclaimer to abandon her statutory presumption of validity under Title 35 of the U.S. Code, Section 282. [6] And, the proposed rule requires a patent owner filing a terminal disclaimer to give up her presumption under current law that filing a terminal disclaimer is not an admission of obviousness. [7] However, the USPTO provides no evidence in its Federal Register notice to support its



Marsha Rose Gillentine



Bree Vculek



John Covert

proposition that the rule will reduce prices for consumers.

This article attempts to demonstrate the implications of the proposed rule that prevents a patent owner from asserting a patent even though it is a nonobvious invention from a patent containing a single invalid claim simply because the two patents are "indirectly" tied via terminal disclaimer.

"Directly" vs. "Indirectly" Tied via Terminal Disclaimer

According to the USPTO, a patent is "directly" tied by a terminal disclaimer to "another patent when: (1) the terminal disclaimer is filed in the subject patent or application; and (2) the other patent, or the application that issued as the other patent, is the reference patent or application identified in the terminal disclaimer." [8] Therefore, only one terminal disclaimer is at issue when two patents are directly tied.

In contrast, an indirect tying by a terminal disclaimer occurs when there are two or more terminal disclaimers at issue. Specifically, according to the USPTO, a patent is "indirectly" tied by two terminal disclaimers to "another patent when: (1) a terminal disclaimer filed in the subject patent or application identifies an intermediate patent/application as the reference patent or application; and (2) a terminal disclaimer filed in the intermediate patent/application identifies the other patent."

The USPTO asserts that "[t]he tying by a terminal disclaimer is unidirectional and is effective only for the patent with the terminal disclaimer."

Example of Direct Tying

Example 1 provided in the Federal Register notice illustrates a direct tie to a terminal disclaimer of another patent. In this example, a "terminal disclaimer is filed in X [patent or application] identifying W [patent or application] as a reference patent or application" and is depicted as follows:

W ← X

The USPTO indicates that in this example, "if a claim of [W] is finally held unpatentable or invalid over prior art, [X] may not be enforced."

Examples of Indirect Tying

The USPTO provided Examples 2-5 in the Federal Register notice to illustrate an indirect tie to a terminal disclaimer of another patent.

Example 2 extends Example 1 where "a second terminal disclaimer is filed in Y [patent or application] identifying X [patent or application] as a reference patent." This situation is depicted as follows:

W ← X ← Y

According to the USPTO, "[Y] is tied directly to [X], and [X] is tied directly to [W]." Therefore, according to the USPTO, "if a claim of [W] is finally held unpatentable or invalid over prior art, and the terminal disclaimer in [Y] contains the proposed agreement, [Y] may not be enforced."

Example 3 extends Example 2 where "a third terminal disclaimer is filed in Z [patent or application]

identifying Y [patent or application] as a reference patent or application."

$W \leftarrow X \leftarrow Y \leftarrow Z$

In this situation, according to the USPTO, "all the tying relationships of example 2 remain." The USPTO also notes that in this example, "the three terminal disclaimers tie [Z] to [W]. As a result, if a claim of [W] is finally held unpatentable or invalid over prior art and if the terminal disclaimer filed in [Z] contains the proposed agreement, [Z] may not be enforced."

The USPTO also explains that

if a claim of [W] is finally held unpatentable or invalid over prior art, [Y] and [X] may not be enforced;
if a claim of [X] is finally held unpatentable or invalid over prior art, [Y] and [Z] is finally held unpatentable or invalid over prior art, [Z] may not be enforced.

Example 4 introduces complexities in which patents are directly and indirectly tied by terminal disclaimers. The example is represented as follows:

$W \leftrightarrow X \leftrightarrow Y$ and $W \leftrightarrow Y$

The USPTO indicates that in this example,

[W], [X], and [Y] are each directly tied to one another. In addition, they are each indirectly tied to one another. As a result, if a claim in any one of [W], [X], or [Y] is finally held unpatentable or invalid over prior art and if the terminal disclaimers filed in W, X, and Y contains the proposed agreement, the other two patents may not be enforced.

Example 5 purports to be an example of "two patents that are not indirectly tied by terminal disclaimers even though each has a terminal disclaimer identifying the same reference patent or application, due to the unidirectionality of tying by a terminal disclaimer." This example is represented as follows:

$X \rightarrow Y \leftarrow Z$

According to the USPTO,

[i]n this example, [X] and [Z] are both tied directly to [Y]. As a result, if a claim in [Y] is finally held unpatentable or invalid over prior art and if the proposed agreement is contained in the terminal disclaimers filed in X and Z, [X] and [Z] cannot be enforced.

But, according to the USPTO,

[Z] is not tied to [X], [X] is not tied to [Z], and [Y] is not tied to either [X] or [Z]. Thus, if a claim in [X] or [Z] is finally held unpatentable or invalid over prior art, there is no effect on whether the other two patents may be enforced.

The Proposed Rule Could Lead to Unenforceable, Valid Patent Claims

The examples in the Federal Register notice can be followed as a logic exercise. However, prosecution of patent applications and portfolios having multiple patent applications is much more complicated.

This could lead to an inability to enforce a patent with nonobvious claims simply because it is indirectly tied to a patent in which a single claim is found anticipated or obvious in view of the prior art. Below are a few examples of such situations.

Genus Claim Directly Tied to Species Claim Makes Species Claim Unenforceable

Under standard prosecution practice, a patent owner, especially a small company with a limited budget, could choose to prosecute claims to a genus followed by a continuation application directed to a species application. Depending upon the size of the genus of the first-granted patent, an examiner may make a rejection based on obviousness-type double patenting, causing the patent owner to file a terminal disclaimer over the first-granted patent.

If the patent owner files the terminal disclaimer in the species application, a defendant accused of infringing the species patent could file a post-grant procedure (e.g., inter partes review) challenging the validity of the claims to the first-grant genus that is directly tied to the species patent.

If a single claim of the genus patent is found to be anticipated or obvious in view of the prior art, then because the species patent is directly tied to the genus patent, the species patent will be unenforceable against an infringer even if it is patentable distinct from the genus patent.

Incongruously, under the proposed rule, narrower claims that are in the genus patent remain enforceable, while claims of any scope in the tied patent become unenforceable.

Species Claim Indirectly Tied to a Patent With Patentably Distinct Species Claim Becomes Unenforceable

A patentee may elect to pursue multiple applications directed to different species disclosed in a first patent application via a series of continuation applications. Such a situation could fall within Example 3 in the Federal Register notice:

W ← X ← Y ← Z ← A'

In this situation, a single species claimed in Patent Application A' is patentably indistinct from a single species claimed in Patent Z, and may result in an applicant filing a terminal disclaimer over Patent Z. Patent Z could include a claim that is patentably indistinct from a claim of Patent Y, and etc. along the priority chain.

However, in light of the species claimed, the claims of Patent A' could be patentably indistinct from that of Patent W. But under the proposed rule, if an accused infringer of one or more claims of Patent A' successfully challenges the patentability of a single claim of Patent W as being anticipated or obvious, Patent A' would be unenforceable simply because it is "indirectly" tied to Patent W even though the claim of Patent A' is a patentably distinct species of a claim of Patent W.

Conclusion

The USPTO proposed rulemaking requiring future terminal disclaimers to include a condition that the patent will not be enforceable if it is directly or indirectly tied to a patent in which a single claim has been found anticipated or obvious over the prior art will require significant — and expensive — changes to patent prosecution strategies.

As one example, applicants will need to carefully consider whether it is best to include claims that encompass all potential embodiments for examination to provoke a restriction requirement. However, in light of excess claim fees, this strategy may be economically unfeasible for certain applicants.

Additionally, today applicants commonly file a terminal disclaimer to overcome an examiner's rejection based on obviousness-type double patenting because it is the simplest and most economical strategy. But today, even before this proposed rule, it is in an applicants' best interest to spend the time and effort to traverse an obviousness-type double patenting rejection rather than filing a terminal disclaimer. If the proposed rule is implemented, additional rounds of arguments and/or appeals are likely to be required leading to increased prosecution costs and likely delay in grant of a patent.

Therefore, while the proposed rule may lead to streamlined litigation in the Hatch-Waxman and BPCIA context, it is very likely to lead to more complex and costly prosecution, and does so by forcing any patentee signing a terminal disclaimer to give up a portion of their statutory presumption of validity.

The proposed rulemaking is open to public comments until July 9.[9]

Marsha Rose Gillentine, Ph.D., is a director, Bree Vculek is a law clerk and John M. Covert is a director at Sterne Kessler Goldstein & Fox PLLC.

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[1] See <https://www.federalregister.gov/documents/2024/05/10/2024-10166/terminal-disclaimer-practice-to-obviate-nonstatutory-double-patenting>; Fed. Reg. 89, No. 92, 40439-49 (May 10, 2024).

[2] Fed. Reg. at 40440 (emphasis added).

[3] Id. at 40440.

[4] Id.

[5] Id.

[6] 35 U.S.C. § 282 ("Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.").

[7] *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (ed. Cir. 2007); *Quad Environmental Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (1991).

[8] Fed. Reg. at 40441.

[9] <https://www.regulations.gov/document/PTO-P-2024-0003-0001>.