

USPTO proposed rulemaking on terminal disclaimers | IP Frontiers

■ CHRISTINA E. BRULE [SPECIAL TO THE DAILY RECORD](#)

The United States Patent and Trademark Office (USPTO) published a notice of proposed rulemaking on May 10, 2024 for a rule that would affect terminal disclaimer practice to obviate (overcome) non-statutory double patenting.



Christina E. Brule

BACKGROUND

Non-statutory double patenting, or obviousness-type double patenting (ODP), is a judicially created doctrine (e.g., there is no statutory authority) made to serve public policy interests by preventing the unjustified or improper timewise extension of the right to exclude granted by a patent (see MPEP §804(II)(B)). Under ODP, the claims of an application may be rejected if they are not patentably distinct from the claims of a patent; where the application and patent are commonly owned. That is, if the claims of the application are either anticipated by or would have been obvious over the claims of the patent, the office may reject them.

Generally, the path of least resistance to overcome an ODP rejection is to file a terminal disclaimer. A terminal disclaimer limits the term of

any patent granted on the application to the term of the commonly owned patent which formed the basis for the rejection. Thus, any patent term adjustment (PTA) accrued during prosecution of the application is forfeited and the resulting patent will expire no later than the earlier patent.

THE PROPOSED RULE

The proposed rule would add the following new requirement for filing terminal disclaimers: “[T]he disclaimant must agree that the patent in which the terminal disclaimer is filed, or any patent granted on an application in which a terminal disclaimer is filed, 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 in which: 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 a statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been made.”

The USPTO states: “This action is being taken to prevent multiple patents directed to obvious variants of an invention from potentially deterring

competition and to promote innovation and competition by allowing a competitor to avoid enforcement of patents tied by one or more terminal disclaimers to another patent having a claim finally held unpatentable or invalid over prior art.” In other words, the proposed rule is meant to prevent a scenario where multiple suits are brought against an accused infringer by different assignees of patents claiming patentably indistinct variations of the same invention.

The proposed rule would be prospective only because previously filed terminal disclaimers would not include the new language regarding the agreement of unenforceability. However, such patents with terminal disclaimers filed before implementation of the rule could still form part of an indirect link. For example, if a terminal disclaimer is filed in an application over patent A, and a terminal disclaimer had been filed in patent A over an earlier patent B, then an invalidity finding under sections 102 or 103 of any claim in patent B would render any patent granted on the application unenforceable via an indirect link (and patent A would not be affected by the new rule).

Comments regarding the proposed rule closed earlier this month, on

July 9, 2024, and a total of 351 comments were received. Following are a few notable excerpts:

Intellectual Property Owners Association: “Section 253(a) states that ‘[w]henver a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid.’ This requirement also appears in 35 U.S.C. §§ 282(a) and 288. The proposed rule contradicts these statutes by eliminating the requirement that validity, and, accordingly, enforceability of the claims be determined on a claim-by-claim basis.

“Section 288 evinces the statutory intent to prevent the invalidity of one claim from infecting the enforceability of a patent’s other claims. But under the proposed rule, the invalidity of one claim would preclude the enforceability of another. The USPTO’s statutory authority does not permit imposing such new substantive limits regarding the filing and processing of terminal disclaimers, particularly those that impact a patent owner’s rights by reducing the term of a validly granted patent contrary to Congressional intent.”

Amgen: “The proposed rule vitiates the right to pursue continuation applications as provided by the Patent Statute. Section 120 of the Patent Statute expressly grants applicants the right to file continuation applications to secure multiple patents that protect all aspects of the invention described in the original patent application. Under the statute, continuation applications are entitled to the same priority date as the original application if they meet certain criteria. This statutory provision grants applicants the right to file continuations without imposing specific numerical limits. The USPTO, as an administra-

tive agency, cannot contravene or add substantive restrictions to these statutory rights without explicit legislative authorization.”

Patients for Affordable Drugs: “The use of terminal disclaimers enables drug manufacturers to create dense networks of non-innovative patents that artificially extend monopolies, prevent generic competition from entering the market, and keep prices high for patients. The ‘terminal disclaimer’ allows the patent holder of the brand name drug to obtain additional duplicative patents, even though the new patent claims are obvious and not innovative. Further, applying for additional patents right at the end of exclusivity periods can extend a pharmaceutical manufacturer’s monopoly period decades past the expiration of the primary drug patent.”

Pharmaceutical Research and Manufacturers of America (PhRMA): “A newly issued patent does not extend the term of an old one. Ever since Congress passed the Uruguay Round Agreements Act of 1994,16 which changed patent term from 17-year terms from time of grant, the core concerns surrounding continuing applications extending the life of a patent family have been obviated. Now, unless otherwise adjusted or extended as allowed by statute, a patent’s term expires 20 years from its ‘effective filing date,’ which, for a patent issuing from a continuation, continuation-in-part, or divisional application (i.e., applications in the same family), is the filing date associated with the earliest-filed non-provisional application to which it claims priority. Thus, absent those statutory exceptions, patents in the same family expire on the same date and do not extend the patent term. And a single

patent covers only the subject matter set forth in its claims, and claims in different patents cannot be identical per statutory requirements. Thus, multiple distinct inventions relating to a particular product may lead to multiple patents.”

CLOSING

Several entities supporting the proposed rule argue that so-called “patent thickets” (a) deter competition, in part due to prohibitive costs of litigating each patent, (b) delay entry into the market of generic medicines, and (c) result in drug pricing that makes essential drugs unaffordable.

On the other hand, entities against the proposed rule largely argue that (i) the USPTO lacks authority for such a rule, (ii) the rule would invade the province of the courts and Congress, (iii) the rule would vitiate the presumption of validity on a claim-by-claim basis, and (iv) continuations do not deter competition or delay entry of generics.

The full text of the notice of proposed rulemaking can be found at the Federal Register (<https://www.federalregister.gov/documents/2024/05/10/2024-10166/terminal-disclaimer-practice-to-obviate-nonstatutory-double-patenting>) and all document comments can be found at Regulations.gov (<https://www.regulations.gov/document/PTO-P-2024-0003-0001/comment>).

Christina E. Brule, Ph.D., Esq. is an associate attorney in the Albany Office of Heslin Rothenberg Farley & Mesiti P.C. Her experience includes patent preparation and prosecution, trademark preparation and prosecution, copyright, and general IP counseling. She can be reached at (518) 452-5600 or Christina.Brule@hrfmlaw.com.