The USPTO Proposes a Radical Change to Terminal Disclaimer Practice: You Have an Opportunity to Comment

On May 10, 2024, the United States Patent and Trademark Office (USPTO) issued a **notice of proposed rulemaking** that, if enacted, would tie the enforceability of every claim of a patent subject to a terminal disclaimer to the validity of any claim of the reference patent. In other words, if any claim of the reference patent were found to be invalid for lack of novelty or for obviousness, then the subject patent would be unenforceable **in its entirety**. This proposed rule is a significant departure from current U.S. standards which evaluate the validity of challenged claims on an individual basis.

The USPTO is accepting comments on the proposed rule until July 9, 2024. Comments may be made at **www.regulations.gov/commenton/PTO-P-2024-0003-0001**. As of June 28, 2024, 88 comments have been submitted.

Background

35 U.S.C. § 101 states that:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

This section has been interpreted as meaning that an inventor is only entitled to patent an invention once. If an applicant were to attempt to patent the same invention twice, the claims would be rejected for statutory double patenting under 35 U.S.C. § 101.

U.S. courts created the concept of obviousness-type double patenting (also called non-statutory double patenting). See e.g., In re Longi, 759 F.2d 887, 893 (Fed. Cir. 1985). This judicially-created doctrine holds that an inventor may not obtain a patent on an obvious variant of an issued (or co-pending) claim (the cited patent or co-pending application is known as a reference patent or application) as doing so could result in an unlawful extension of patent protection for an invention.

An obviousness-type double patenting rejection may be overcome by (1) successfully arguing that the pending claims are not obvious variants of the claims of a reference patent/application, or (2) the filing a terminal disclaimer meeting the requirements of 37 C.F.R. 1.321(c). A terminal disclaimer *disclaims* any patent term of the subject patent that extends beyond the term of the reference patent/application. Noteworthy, terminal disclaimers include an agreement by the patentee that the subject patent is only enforceable for and during such period that it is owned by the same party (or parties) that owns the reference patent (with the presence of a Joint Research Agreement impacting this provision).

Current Proposal

The proposed rule released by the USPTO would add an additional requirement to the use of a terminal disclaimer. Under the proposed rule the applicant would need to agree that:

the patent in which the 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: [a] **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 [b] a statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been made.* (emphasis added)

Per the USPTO,

[t]his 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.

The USPTO states that the proposed rule is designed to "further the objectives of Executive Order 14036 on "Promoting Competition in the American Economy," 86 FR 36987 (July 14, 2021)." In that Executive Order, President Biden noted that "patent and other laws have been misused to inhibit or delay—for years and even decades—competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs." The proposed rule on terminal disclaimers specifically notes that "multiple patents tied by terminal disclaimers that are directed to obvious variants of an invention could deter competition due to the prohibitive cost of challenging each patent separately in litigation or administrative proceedings."

Form FDA 483 Response Best Practices Announced by the FDA

In Draft Guidance published this week by the U.S. Food and Drug Administration (FDA), **Guidance for Industry – Processes and Practices Applicable to Bioresearch Monitoring Inspections**, the Agency provides some wisdom on best practices for

responding to Form FDA 483s, albeit in the context of its Bioresearch Monitoring (BIMO) program inspections, but very much translatable to *any* Form FDA 483 response. FDA notes the following best practices:

> A response should demonstrate the establishment's acknowledgment and understanding of FDA's observations. It should also demonstrate the establishment's commitment to address the observations, including a commitment from senior leadership.
>
> Responses should be well-organized and structured to:
>
> - Address each observation separately
> - Note whether the establishment agree(s) or disagree(s), and why
> - Provide both corrective and preventive actions and timelines for completion
> - Provide both completed and planned actions and related timelines
> - Provide a method of verifying or monitoring the effectiveness of the actions
> - Submit documentation (e.g., training, Standard Operating Procedures (SOPs), corrective action plans, records, etc.)

Importantly, FDA also states that timely Form FDA 483 responses that include "appropriate corrective and preventive actions could impact FDA's determination of the need for subsequent Agency action." FDA encourages responses within 15 business days after the end of an inspection and, helpfully, notes that any responses received within that window "will be considered before further Agency action or decision." Interested stakeholders may submit comments **here** on FDA's Draft Guidance until August 5, 2024.

*Please contact **Julie Tibbets** or any member of our **Life Sciences Regulatory & Compliance practice** with questions on FDA's Draft Guidance or on responding to Form FDA 483s.*