

Proposed Terminal Disclaimers Rule Harms Colleges, Startups

By **Marsha Rose Gillentine, Bree Vculek and Eric Steffe** (July 15, 2024, 4:33 PM EDT)

On May 10, the U.S. Patent and Trademark Office published a notice of proposed rulemaking in the Federal Register proposing an additional requirement for an acceptable terminal disclaimer filed in response to an obviousness-type double patenting rejection.

This would mean including 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.[1]

This is in addition to the current requirements that a terminal disclaimer tie the expiration and ownership of patents.[2]

Set against the backdrop of the current political environment to reduce drug costs, the USPTO's proposed rule manifests an attempt to make it more difficult for the pharmaceutical industry to build so-called patent thickets.

Yet, the proposed rule applies to all patents, in all industries and at all stages of product development, and therefore has implications reaching far beyond patent thickets.

The USPTO provides no evidence in its Federal Register notice to support its proposition that the rule will reduce prices for consumers. And the USPTO's proposed remedies for avoiding the harshness of the proposed rule will be unworkable in many situations that are routinely encountered by universities and startup companies. In particular, the USPTO suggests:

- Combining the conflicting claims into a single application;
- Canceling or amending any conflicting claims in the application or in the other application containing the conflicting claims that formed the basis of the nonstatutory double patenting;
- Arguing that rejected claims in the application are patentably distinct from the claims of the reference patent or application; or



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- Filing a reissue application of the patent whose claims formed the basis of the nonstatutory double patenting in order to add canceled conflicting claims from the application into the reissue application, provided that the added claims do not introduce new matter into the reissue application.[3]

The USPTO also indicates that, alternatively, "an applicant may separate the patentably distinct claims into another application and file a terminal disclaimer with the proposed agreement in the application with the indistinct claims." [4]

However, these purported remedies incorrectly imply that all relevant embodiments of an invention are developed simultaneously such that they can be included in a single filing and that only one entity controls the prosecution of an entire portfolio of related inventions. This is often not the situation, especially for universities and startup companies.

Additionally, the USPTO ignores the limits on filing reissue applications — reissue claims must be for the same general invention, cannot recapture canceled subject matter, and there is a time limit for filing a broadening reissue application.[5]

The present article details, from a practical perspective, a few of the negative implications the proposed rule would have on universities and startup companies if implemented.

The proposed rule will penalize universities and startup companies for continuing research.

Universities and startup companies often have cutting-edge ideas and establish experimentally that some technology has significant real-world promise.

However, such initial inventions, as groundbreaking as they may be, typically require significant further development and financial investment prior to commercialization. Therefore, universities and startup companies must publish to raise public interest, present their discoveries to potential investors to raise capital, and collaborate with larger companies with expertise in product development that universities and startup companies typically lack.

Clearly, universities and startup companies would be foolish not to file a patent application prior to such disclosures. However, given the nature of product development — e.g., drug development — additional patent applications are necessary to cover the technology as it progresses.

For example, during drug development, extensive additional experimentation is required before identifying and selecting a lead compound or biological construct, and determining ways to deliver the compound or construct so that it is both safe and efficacious. Thus, "combining the conflicting claims into a single application" is simply not feasible in the majority of situations involving product development, especially drug development.

Further, having to reach outside one's own institution or company to marshal the resources or expertise necessary to further develop inventions significantly increases the likelihood that later-filed applications will be jointly owned with another company.

When other entities become involved, prosecution control of an entire portfolio by a single entity becomes less likely, which of course, renders the solution of "combining the conflicting claims into a single application" even less feasible.

Additionally, as discussed above, the USPTO proposes requiring any filed 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.[6]

Because a genus claim is typically easier to invalidate as anticipated or obvious in view of the prior art, a patent with narrower claims solely directed to the commercial embodiment could be unenforceable simply because the applicant had to file a terminal disclaimer over an earlier-granted genus patent having a single claim that is invalidated later in an administrative or judicial proceeding.

Therefore, due to the necessity of filing patent applications early prior to contacting outside entities for funds and resources, universities and startup companies are particularly ill-suited to follow the USPTO's guidance in the Federal Register.

"Fields of use" licenses giving patent prosecution control to different entities are incompatible with the proposed rules.

Universities seek to license university-owned technology to private industry.

Oftentimes, universities exclusively license inventions to more than one company based on different fields of use. Each exclusive licensee typically gains the right to control prosecution of the various applications directed to the different inventions related to its licensed field of use.

However, due to confidentiality concerns and because another licensee might be a competitor, other than to exchange cited references to comply with the duty to disclose requirements when practicing before the USPTO, companies will not act in concert with respect to their prosecution efforts.

Therefore, claims of two applications licensed to different companies may overlap leading to obviousness-type double patenting rejections in one or both applications where there is an overlapping owner or inventor. No company will want to file a terminal disclaimer over a patent or application over which the company has no control.

This scenario would raise huge risks for each licensee that will be faced with the possibility that another licensee will overreach and prosecute claims of questionable validity.

The proposed rule may also reduce the value of a university's intellectual property if it becomes more difficult to license the same patent portfolio to multiple entities, causing otherwise interested would-be licensees to go elsewhere and seek alternative technologies to investigate. This problem is not just theoretical, as many universities file patent applications directed to platform technologies that are applicable for many different uses.

Limiting the number of companies that can license the patent portfolio could also result in fewer inventions being commercialized, potentially harming not only the universities, but also the public.

Conclusion

To be clear, our focus on universities and startup companies is not intended to imply that the USPTO's proposed rule is workable for large companies.

Obviously, filing patent applications as early as possible and at each stage of technological development, which leads to inevitable obviousness-type double patenting rejections, is a strategic necessity for most companies regardless of size under the first-inventor-to-file system in the U.S.

And it goes without saying that implementing a system where picture claims to a commercial product can be invalidated "by proxy" due to being tied, directly or indirectly, to a genus claim in another patent may devalue intellectual property and cause significant uncertainty in various industries.

But the USPTO's 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 also significantly negatively affect universities and startup companies.

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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.

[3] Id.

[4] Id.

[5] Manual of Patent Examining Procedure, § 1412.

[6] Fed. Reg. at 40440.