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RE: Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, Docket No. PTO-P-2024-0003, 89 FR 40439 (May 10, 2024)

TREASURER

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Dear Director Vidal:

The Interests of the Association and its Members

SECRETARY

Cheryl Wang
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The New York Intellectual Property Law Association (NYIPLA) is a one-hundred-and-two-year-old professional association whose interests and practices lie in the area of patent, trademark, copyright, and other intellectual property (IP) law. Traditionally, the NYIPLA has been one of the largest regional IP bar associations in the United States. The NYIPLA's members include a diverse array of attorneys specializing in patent law, including in-house counsel for businesses that own, enforce, and challenge patents, as well as attorneys in private practice who prepare and prosecute patents and represent entities in various proceedings before the U.S. Patent and Trademark Office (USPTO), the federal courts, and various arbitral fora.

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Many of the NYIPLA's member attorneys prosecute patents through the USPTO on behalf of patent applicants. Many of the NYIPLA's member attorneys also actively participate in patent litigation, representing both patent owners and accused infringers. The NYIPLA's members also frequently engage in patent licensing matters on behalf of both licensors and licensees. The entities served by the NYIPLA's members include inventors, entrepreneurs, venture capitalists, businesses, universities, research institutions, and industry and trade associations.

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General Principles

NYIPLA supports a stable and efficient patent system that promotes innovation through the issuance of valid and enforceable patents.

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The use of terminal disclaimers has long been established as an administrative procedural tool by which patent applicants may obviate rejections based on the judicially created doctrine of obviousness-type double patenting ("OTDP"). Terminal disclaimers have been used by applicants as a tool to expedite prosecution before the USPTO, avoiding the need to substantively address an OTDP rejection.

Under current rules, a terminal disclaimer filed to overcome an OTDP rejection requires agreement by the applicant that any resulting patent:

- Will only be enforceable as long as it is commonly owned with the other patent(s) or application(s) identified in the terminal disclaimer; and
- Will have a term that does not extend beyond the term of the patent or application forming the basis for the OTDP rejection.

The USPTO now seeks to add a further requirement to both 37 CFR 1.321 (c) and (d): that terminal disclaimers filed to obviate OTDP rejections include an agreement by the disclaimant that the patent in which the terminal disclaimer is filed will be enforceable only if it has never been associated through terminal disclaimer(s) with a patent: (a) in which any claim has been finally held unpatentable or invalid over prior art; or (b) for which a statutory disclaimer of a claim has been filed after any challenge based on anticipation or obviousness of that claim has been made.¹

This proposed rule represents a major, substantive change to prosecution and enforcement practice. It would undermine expectations long-held by patent owners and accused infringers alike. This proposed change would have widespread impact. In 2024 alone, more than 18% of granted patents included a terminal disclaimer.²

The NYIPLA does not endorse the adoption, through proposed rule-making, of such a significant change to established patent practice.

Specific Comments

Subject to the above overarching principles, NYIPLA makes the following specific comments on the Proposed Rule.

1. The Proposed Rule runs counter to long-settled principles of law:

It is a bedrock principle of U.S. patent law that “[e]ach claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims.”³ Consequently, the validity of a patent must be determined on a claim-by-claim basis. It is further established law that “[t]he burden of establishing invalidity of a patent or any claim thereof” rests on the party asserting such invalidity.⁴

Even in the context of OTDP, Federal Circuit precedent requires a claim-to-claim comparison of a challenged claim against a reference claim, for purposes of determining whether the reference claim renders obvious or anticipates the challenged claim.⁵ Indeed, 35 U.S.C. §253(a), the statutory provision for disclaimers begins with “[w]henever a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid.” Consequently, OTDP-based rejections entered during patent prosecution—and OTDP-based invalidity findings following litigation—are routinely drawn to well fewer than all claims in an application or patent.

Such OTDP challenges may be obviated by the procedural tool of terminal disclaimer. But it is well established that filing a terminal disclaimer is not an admission regarding the patentability or validity of the claims against which a double-patenting challenge is raised,

¹ Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting (PTO-P-2024-0003-0001) (“Proposed Rule”).

² See Dennis Crouch, Terminal Disclaimers: A Growing Concern in Patent Practice, Patently-O (May 10, 2024), <https://patentlyo.com/patent/2024/05/terminal-disclaimers-practice.html>.

³ 35 U.S.C. §282(a).

⁴ *Id.*

⁵ See, e.g., *UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313, 1323 (Fed. Cir. 2018).

let alone an admission with respect to the other (non-challenged) claims in the patent or application.⁶

The Proposed Rule turns each of these principles on their head by rendering unenforceable all claims of a terminally disclaimed patent when a single claim of the reference patent is statutorily disclaimed or found invalid—and by reaching this outcome without any substantive analysis of the claims of the terminally disclaimed patent. This result is incompatible with settled principles of patent law and prosecution practice.

2. The Proposed Rule disincentivizes statutory disclaimer:

Statutory disclaimer is a mechanism by which a patentee can dedicate the subject matter of a given patent claim to the public. Statutory disclaimer can be used, for example, when a patentee decides not to enforce a particular claim in light of challenger-asserted prior art that was previously unknown to the patentee. Under the Proposed Rule, however, the relinquishment through statutory disclaimer of a challenged claim in one patent would result in the loss of enforcement right over all claims in all patents that are directly or indirectly linked to the challenged patent by terminal disclaimer. This would create a perverse incentive for a patentee in this situation to litigate the patent with the individual patent challenger, rather than disclaiming—and dedicating to the public—the subject matter of the challenged claim.

NYIPLA does not endorse a rule that disincentivizes an inventor from dedicating the subject matter of a patent claim to the public, where statutory disclaimer is appropriate.

3. The Proposed Rule undermines long-standing expectations:

Continuation practice is codified in 35 U.S.C. §120 and 37 CFR § 1.53(b). Continuation applications allow inventors to refine and strengthen claims in their original patent applications, clarifying aspects of their inventions based on the original disclosure, and protecting commercial embodiments without losing the original priority date. This longstanding framework has provided stability and predictability in the U.S. patent system.

The Proposed Rule threatens to discourage or eliminate the use of continuation applications. If the Proposed Rule is enacted, pending continuation applications could, during ongoing prosecution, suddenly lose the protections that the inventors have regularly relied upon when filing. This would be a major and substantive change that would disrupt established patent practice.

The change wrought by the Proposed Rule would be particularly draconian in light of the recent holding in *In re Collect*, which, if not reversed by the Supreme Court, **increases** the need for patentees to file terminal disclaimers.⁷ In *Collect*, the Federal Circuit held that a patent that has received patent term adjustment (PTA) under 35 U.S.C. §154 to compensate for delays by the USPTO may be held invalid for OTDP over its own family member(s). At the same time, the court recognized that use of terminal disclaimers has been the long-established remedy for OTDP.⁸

The Proposed Rule forces the patentee into a Hobbesian choice: forfeit its later-expiring patent to OTDP, or “cure” the OTDP problem by terminally disclaiming the extra term of the challenged patent resulting from USPTO delays—only to create another problem: unenforceability of all claims if just one reference patent claim is invalidated or statutorily

⁶ *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) (a terminal disclaimer “simply serves the statutory function of removing the rejection of double-patenting rejection, raises neither presumption nor estoppel on merits of the rejection.”).

⁷ *In re Collect, LLC*, 81 F.4th 1216, 1229 (Fed. Cir. 2023).

⁸ *Id.* at 1228-1229.

disclaimed. Put differently, the Proposed Rule puts patentees in an untenable position, where following Federal Circuit guidance will potentially render their patents unenforceable in the event of invalidation or statutory disclaimer of a single claim in a reference patent.

To the extent that the Proposed Rule is intended as a deterrent from pursuing new continuation applications altogether, this would have a chilling effect on innovation by limiting a statutorily authorized practice that enhances flexibility and efficiency of patent prosecution. Such a change would risk destabilizing a well-established part of the U.S. Patent System, which could in turn deter investment in research and development, discourage entrepreneurial efforts, and stifle U.S. competition in the global sphere.

The NYIPLA does not endorse a rule that undermines the long-settled expectations for stakeholders in the patent law system.

4. The Proposed Rule is vulnerable to legal challenge:

The Proposed Rule represents a significant departure from current patent practices, and would fundamentally alter existing rights and obligations of patent holders and applicants. Some commentators on the Proposed Rule have already noted that such substantive rulemaking exceeds the authority traditionally vested in the USPTO.⁹

The NYIPLA does not endorse the proposed adoption, through rulemaking, of a such substantive change to U.S. patent practice.

5. The Proposed Rule will increase prosecution costs and burden:

The Proposed Rule will increase patent prosecution costs overall. To avoid the significant penalties that the Proposed Rule would attach to terminal disclaimers, patent applicants will be required to fight every double patenting rejection to resolution. This will significantly raise the cost of obtaining patents. These increased prosecution costs will disproportionately impact under-resourced innovators. The monetary impact of this rule should not be understated. USPTO data show that the use of terminal disclaimers has been steadily increasing in recent years.¹⁰ A rule that makes the use of terminal disclaimers strategically prohibitive will create barriers to obtaining patents and force innovators, including individual inventors, to expend more resources in prosecuting their patents.

Additionally, the Proposed Rule will encourage patent applicants to file and prosecute single applications containing groups of claims that they otherwise would have included in continuation applications, in the hopes of drawing restriction requirement(s) that trigger the safe harbor of 35 U.S.C. § 121. Thus, insofar as the Proposed Rule is intended to decrease the number of claims filed on related subject matter, the Rule is unlikely to be successful in achieving that goal. Prosecution of such large applications containing several groups of claims drawn to related inventions will impose additional cost and time burdens for examiners and applicants alike.

Further, the Proposed Rule would significantly diminish the enforcement value of any patent that is terminally disclaimed after drawing an OTDP rejection, regardless of the merits of that rejection.

The NYIPLA does not endorse a rule that will significantly increase the costs and burden of obtaining patents, while diminishing their enforcement value.

⁹ See, e.g., May 28, 2024, Letter from former USPTO officials to Director Vidal RE: Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting (89 FR 40439); see also *Tafas v. Dudas*, 511 F. Supp. 2d 652, 663 (E.D. Va. 2007).

¹⁰ See *supra*, n.2.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Patrice P. Jean". The signature is fluid and cursive, with a long horizontal stroke at the end.

Patrice P. Jean, President
New York Intellectual Property Law Association