

Comments of Innovation Alliance in Response to the USPTO's Notice of Proposed Rulemaking on Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting Docket No. PTO-P-2024-0003

July 9, 2024

The Innovation Alliance¹ appreciates the opportunity to submit these comments in response to the Notice of Proposed Rulemaking (NPRM) issued by the U.S. Patent and Trademark Office ("USPTO" or "Office") regarding terminal disclaimer practice to obviate nonstatutory double patenting.²

The Innovation Alliance is a coalition of research and development-based technology companies representing innovators, patent owners, and stakeholders from a diverse range of industries that believes in the critical importance of maintaining a strong patent system that supports innovative enterprises of all sizes. The Innovation Alliance is committed to strengthening the U.S. patent system to promote innovation, economic growth, and job creation, and we support legislation and policies that help to achieve those goals.

We appreciate the USPTO's desire to promote innovation and competition and share this goal. But the proposed rule would have the opposite effect. It would require patent applicants seeking to overcome a nonstatutory double patenting rejection to "agree[]" that an entire patent will become unenforceable if a single patent claim in a different patent is held unpatentable or invalid.³ This "agreement" would cast away the statutory guarantee 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."⁴ And applicants would be required to enter into this "agreement" to obtain a patent to which they are entitled, except for a rejection on a "nonstatutory" basis.⁵ This would be so despite the statutory requirement that, "if on . . . examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor."⁶ The proposed rule is therefore inconsistent with established patent statutory and caselaw, costly and impractical for the Office to administer, and exceeds the USPTO's rulemaking authority.

The proposed rule weakens U.S. patent rights at a time when foreign competitors in China, Europe, and elsewhere are investing in critical and emerging technologies and adopting policies that threaten U.S. global technology leadership. The United States should not further weaken its own competitive advantage in the face of these challenges. The USPTO should withdraw the proposed rule.

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I. Background

The Innovation Alliance opposes requiring applicants seeking to overcome a nonstatutory double patenting rejection to file a terminal disclaimer limiting their ability to enforce their patents if any claim in another patent is held unpatentable or invalid and urges the Office not to adopt the proposed rule.

¹ https://innovationalliance.net/.

² 89 FR 40439.

³ *Id.* at 40449.

⁴ 35 U.S.C. § 282(a); see also 35 U.S.C. § 253(a) ("Whenever a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid.").

⁵⁵ 89 FR at 40449.

⁶ 35 U.S.C. § 131.

As the NPRM notes,⁷ the Office previously requested comments on a proposal that "the USPTO limit or change non-statutory double patenting practice, including requiring applicants seeking patents on obvious variations to prior claims to stipulate that the claims are not patentably distinct from the previously considered claims as a condition of filing a terminal disclaimer to obviate the rejection."⁸ In other words, the Office was considering requiring applicants faced with a nonstatutory double patenting rejection of a claim to agree that the later-filed claim is not patentably distinct from an earlier-filed claim identified by the examiner. Commenters, including the Innovation Alliance, opposed that proposal, citing *SimpleAir, Inc. v. Google LLC*⁹ and other cases, stating that the proposal "would contradict the settled law."¹⁰

Even after receiving and considering those comments, the Office now proposes *expanding* the agreement it would require from applicants faced with the same rejection, requiring them to agree not to enforce *any* claim in a later patent if *any* claim in an earlier patent is held unpatentable or invalid. The expanded proposal is highly problematic and suffers the same defects raised in relation to the earlier proposal—and more. While there is no Federal Circuit case directly on point, that is not so because it is a more defensible proposal. Instead, it is because such a surrender of patent rights has never before been considered, much less required, in the context of nonstatutory double patenting. It should not be required now.

As a practical matter, the proposed rule would penalize inventors for seeking to ensure their patents are of the highest quality. In one common example, an application filed overseas as a counterpart to a U.S. patent may result in later-discovered prior art, because the foreign search was conducted after the U.S. patent was issued. If the U.S. patent family is still open, the applicant would be expected to file a continuation application with amended claims. Although the continuation claims may be found patentable over the later-discovered art, the U.S. patent examiner may, correctly or incorrectly, reject the new claims in the continuation application based on nonstatutory double patenting.

If the applicant follows the typical, current procedure and files a terminal disclaimer to overcome the double patenting rejection, the higher quality claims of the continuation will be unenforceable under the proposed rule if any claim of the U.S. parent application is found invalid. Despite doing everything right by taking the steps necessary to get a higher quality patent, the applicant winds up paying a severe price under the new rule—a significant weakening of their valid patent rights.

Importantly, the impact of the proposed rule is not limited to any particular industry. The proposal will affect inventors engaged in long-term research and development in critical and emerging technologies like wireless communications, advanced semiconductors, artificial intelligence, cloud computing, and countless others that hold multiple related patents on complex technologies, slowing or chilling innovation industries key to U.S. global competitiveness.

II. The Proposed Rule Conflicts With Established Patent Law

The proposed terminal disclaimer rule contradicts the Patent Act. As the name of the rule— "Terminal Disclaimer Practice to Obviate *Nonstatutory* Double Patenting"—itself indicates, there is no basis in the patent statute for the terminal disclaimer rule or the concept of double patenting. Thus, the proposed

⁷ 89 FR at 40440.

⁸ *Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights,* 87 FR 60130, 60134 (Oct. 4, 2022)) (RFC).

⁹ 884 F.3d 1160 (Fed. Cir. 2018).

¹⁰ 89 FR at 40440; Comments of Innovation Alliance in Response to the USPTO's Request for Comments Regarding USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights (Docket No. PTO-P-2022-0025), *available at* <u>https://www.regulations.gov/comment/PTO-P-2022-0025-0120</u>.

rule would require a patent holder to disclaim all claims in a patent if any claim in a *different* patent is held unpatentable or invalid. This approach directly conflicts with the Patent Act, which provides 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."¹¹ Likewise, "[w]henever a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid."¹² Thus, by statute, claims in even a single patent do not stand or fall together. They certainly do not stand or fall with claims in a different patent. The proposed rule would require patent owners to relinquish their statutory right to have their patent claims evaluated independently.

The proposed disclaimer would also be inconsistent with case law. The Federal Circuit has "foreclose[d] the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims."¹³ In spite of this controlling authority, the Office now would not require such an admission from patent applicants. Instead, it would go further, requiring the patent applicant to agree *not to enforce* those resulting claims if *any* individual claim in the earlier patent—even a claim that was not the basis for the double patenting rejection—is held unpatentable or invalid.

Rather than requiring the patent applicant to admit that the rejection is proper, the proposed rule would require the patent applicant to surrender the enforceability of all its patent claims even where the rejection is irrelevant to the rejection. But that, too, would conflict with caselaw, as the Federal Circuit has held that "the invalidity of [one claim] because of double patenting, even if true, does not necessarily require the invalidation of [other claims]."¹⁴ The proposed rule thus ignores the Federal Circuit's limitations on the scope and effect of terminal disclaimers, while requiring patent applicants to relinquish even more patent rights.

Requiring patent owners to agree to tie unrelated claims of different patents together in the proposed way also raises serious questions of fairness and due process. Double patenting rejections are made on a claim-by-claim basis, so often not all claims in a patent subject to a terminal disclaimer are subject to the rejection. And the patent over which the disclaimer is made may have claims that are not the reason for the double patenting rejection. Thus, if one claim in the first patent is determined to be invalid or unpatentable, there should be no reason to infer that all the claims in the later patent—including those that were not subject to the double patenting rejection.

There are also situations where the patentee may have little incentive to defend a particular patent claim (*e.g.*, if the claim does not cover any competitor's product but is nevertheless challenged). But the proposed terminal disclaimer would preclude the patent owner from asserting any another claim in the later patent, even though it has not yet had a full and fair opportunity to defend its claims in that patent that are commercially significant. Requiring such a terminal disclaimer would be inconsistent with the due process protections to which patent owners are entitled.¹⁵

¹¹ 35 U.S.C. § 282(a).

¹² 35 U.S.C. § 253(a).

 ¹³ SimpleAir, 884 F.3d at 1167–68; see also Quad Envtl. Techs. Corp. v. Union Sanitary Dist., 946 F.2d 870, 874 (Fed. Cir. 1991) ("[T]he filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection.").
¹⁴ Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 942 (Fed. Cir. 1992).

¹⁵ See Blonder-Tongue Labs. v. University of Illinois Found., 1402 U.S. 313, 328 (1971) ("[Some litigants] have never had a chance to present their evidence and arguments on the claim. Due process prohibits estopping them despite one or more existing adjudications of the identical issue which stand squarely against their position."); see also Allen v. *McCurry*, 449 U.S. 90, 95 (1980) ("But one general limitation the Court has repeatedly recognized is that the concept of collateral estoppel cannot apply when the party against whom the earlier decision is asserted did not have a 'full and fair opportunity' to litigate that issue in the earlier case.").

III. The Proposed Rule Would Increase Costs and Complicate Prosecution

Not only does the proposed rule conflict with the patent statute and case law, it is also bad policy, increasing the cost and complexity of prosecution for a significant number of patents examined by the Office, including for small entities and individual inventors. Today, nearly 20% of patents issue with terminal disclaimers.¹⁶ They cover a wide range of technologies and "span[] a diverse set of entities—from large tech corporations to small startups and individual inventors," suggesting that the proposed rule would have implications that "are widespread, affecting a broad swath of the innovation ecosystem."¹⁷ Even the NPRM recognizes the substantial effects the proposed rule would have on small entities, noting that, "[o]f the 175,500 Office actions issued to small entities, approximately 14%, or approximately 24,570, contain at least one nonstatutory double patenting rejection."¹⁸

Terminal disclaimers involve a tradeoff of patent rights in exchange for speedier prosecution. Requiring the enforceability of patents subject to terminal disclaimers to turn on the unpatentability or invalidity of just one claim in another patent would likely force patent applicants to contest, and obligate the Office to defend, the merits of these nonstatutory double patenting rejections far more frequently than they do today. This would increase prosecution costs, cause unnecessary prosecution delays, make patent examination more complex and difficult, waste valuable USPTO resources, increase the likelihood of litigation, and potentially lead to lower-quality patents. And these negative effects would fall disproportionately on independent inventor and small entity patent applicants.

Under current practice, filing a terminal disclaimer frequently has little downside. Thus, patent applicants often will file a terminal disclaimer when faced with a nonstatutory double patenting rejection, even if they think the rejection is improper. Under current law, doing so removes the rejection without negative consequences with respect to validity of the patent, and typically with little to no other cost to the applicant.¹⁹ Thus, filing a terminal disclaimer in current practice can be the most efficient way to overcome a nonstatutory double patenting rejection, regardless of its propriety. This is particularly true for small entity and independent patent applicants, who are least able to incur the expense of challenging such a rejection.

Forcing patent applicants to surrender valuable rights to enforce their patents in terminal disclaimers would cause that behavior to change, resulting in significant effects on prosecution practice. The change in behavior would increase costs on both applicants and the Office, extend the duration and burden of examination, and otherwise disrupt the existing examination practice. Simply put, not all nonstatutory double patenting rejections are proper, so they would be challenged more frequently if applicants were required to file the proposed terminal disclaimer to overcome them. The unknown risk to the patent applicant of surrendering valuable patent enforcement rights would increase uncertainty, incentivizing patent applicants to challenge nonstatutory double patenting rejections if there is even a small likelihood of prevailing, to avoid that unknown risk. More such challenges would be more burdensome for both applicants and the Office, both in terms of time and money. They also would lead to patent term adjustments when challenges to double patenting rejections are successful, thus increasing patent term rather than limiting it.

¹⁶ See <u>https://patentlyo.com/patent/2024/05/terminal-disclaimers-practice.html</u>. The data show that approximately 18% of patents issued in 2023 and thus far in 2024 have had terminal disclaimers, as have more than 10% of patents issued each year since 2009.

¹⁷ Id.

¹⁸ 89 FR at 40446.

¹⁹ See Quad Envtl. Techs. Corp., 946 F.2d at 874 ("[T]he filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting and raises neither presumption nor estoppel on the merits of the rejection.").

The proposed rule would unnecessarily remove terminal disclaimers as an effective tool in patent prosecution. Doing so would have easily foreseeable negative consequences. Without the ability to rely on terminal disclaimers, applicants would be forced to attempt to claim all possible subject matter within the parent application at the time of filing and during prosecution. This would add significant cost, increase the complexity of examination, and slow down the examination process. There would also likely be an increase in post-allowance RCEs to add desired claims to the parent application. Additionally, applicants would be incentivized to attempt to add claims to provoke a divisional application to eliminate the need to file a terminal disclaimer. Moreover, the proposed rule would encourage patent applicants to file a large number of claims in a single patent application, which would make patent examination more complex and difficult, potentially leading to low-quality patents and longer patent terms.

Removing terminal disclaimers as an effective tool during patent prosecution would discourage filings of continuation applications, as well as render them less effective tools. Continuation applications are critical to the effectiveness and robustness of the U.S. patent system. Restrictions on continuation practice would frustrate the quid pro quo principle of patent disclosure, encourage gamesmanship and unscrupulous copying, and compromise overall patent quality.

Under current practice, the effect of filing a terminal disclaimer in a continuation application against a parent or grandparent application is frequently minimal. As a result, many applicants choose not to oppose nonstatutory double patenting rejections, even if they think the rejections are substantively improper. Rather than incurring the cost of opposing an improper rejection, applicants often elect simply to file a terminal disclaimer to obviate the rejection. Requiring such applicants to make the more burdensome terminal disclaimer in the proposed rule would change this calculus, leading more applicants to oppose nonstatutory double patenting rejections, increasing the burdens on both the applicants and the Office.

The added cost and time that would result from eliminating terminal disclaimers as an effective tool, along with likely other unforeseen issues that would arise, outweigh any perceived benefit. These increased burdens likely would fall hardest on small, solo, and economically-disadvantaged inventors, who are the least able to bear them. The Office should withdraw the rule and continue the existing practice for deploying terminal disclaimers to address nonstatutory double patenting.

IV. The Proposed Rule Exceeds the Office's Rulemaking Authority

The proposed rule would likely be challenged as a substantive rule that the Office has no power to make.²⁰ Although the proposed rule would facially involve an agreement by patent applicants not to enforce their patents under certain circumstances, those applicants would be required to enter into the agreement in order to obtain patents to which they are entitled under the law, except for a nonstatutory basis that is premised on multiplicity of patents, not patentability. This would "effect[] a change in existing law or policy which affects individual rights and obligations."²¹ The proposed rule would therefore be a substantive rule, and the Office is not authorized to promulgate substantive rules.²²

A similar limitation on continuation applications has been found unlawful. *See Tafas v. Dudas*, 541 F.Supp.2d 805 (E.D. Va. 2008), *vacated in part by Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009), *rehearing en banc granted and opinion vacated by Tafas v. Doll*, 328 F. App'x 658 (Fed. Cir. 2009). The rule at issue in *Tafas* would have permitted an applicant to file as a matter of right two continuation applications after the initial application, but any subsequent continuation applications could only be filed

²⁰ See Merck & Co. v. Kessler, 80 F.3d 1543, 1550 (Fed. Cir. 1996) ("Congress has not vested the Commissioner with any general substantive rulemaking power.").

²¹ Cooper Techs. Co. v. Dudas, 536 F.3d 1330, 1336 (Fed. Cir. 2008) (cleaned up).

²² See id. ("35 U.S.C. § 2(b)(2) does not authorize the Patent Office to issue substantive rules.").

with a petition to show cause. The court in *Tafas* found that this limitation was an impermissible substantive rule. *See id.* at 814-15. The proposed rule here would be akin to the impermissible limitation in *Tafas* and thus likely would be challenged as a substantive rule that the Office lacks the power to promulgate. Moreover, it would be even less defensible under *Loper Bright Enterprises v. Raimondo*, after which courts no longer defer to even "permissible" agency interpretations of statutes.²³

The Office does not have statutory authority to restrict or modify the use of terminal disclaimers to overcome nonstatutory double patenting. The obviousness-type double patenting doctrine and its remedy—the terminal disclaimer—were created by the courts as part of federal common law.²⁴ Unlike the courts, the Office does not have the power to create or modify common-law principles or remedies. Instead, "the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes."²⁵

The Office does not have authority to restrict or modify either the nonstatutory double patenting doctrine or its judicially-created remedy, and *Van Ornum* does not hold otherwise. *Van Ornum* upheld a USPTO regulation that set forth a requirement for terminal disclaimers that was "precisely that used in" a disclaimer that the Court of Customs and Patent Appeals had called "ingenious" and "an imaginative solution to one of the more theoretical objections to double patenting [identified in case law], split ownership of two patents and potential harassment."²⁶ Thus, the regulation there simply promulgated a rule that was not only "not inconsistent with law,"²⁷ it was expressly credited by the courts as an important "solution" to a problem in the judicially-created doctrine of nonstatutory double patenting.²⁸ That is not the case here, where the Office instead seeks to promulgate a rule that is inconsistent with both the statute and Federal Circuit case law, as explained above. *Van Ornum* does not support the Office's proposal.

V. Conclusion

The Innovation Alliance shares the goals of promoting innovation and competition set forth in the NPRM. But the proposed rule would not advance those goals. Instead, it would impose substantial burdens on both the Office and patent applicants, especially small and independent inventors who are least able to bear those burdens. It would also conflict with both the statute and Federal Circuit authority, leading to likely challenges to the proposed rule as both improper and beyond the Office's authority. The Office should withdraw the proposed rule.

²³ No. 22-451, slip op. at 1 (U.S. June 28, 2024).

²⁴ See Milwaukee v. Illinois, 451 U.S. 304, 313 (1981) ("We have always recognized that federal common law is subject to the paramount authority of Congress. It is resorted to in absence of an applicable Act of Congress, and because the Court is compelled to consider federal questions which cannot be answered from federal statutes alone.") (cleaned up).

²⁵ Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979).

²⁶ Id. at 945 (quoting In re Griswold, 365 F.2d 834, 840 n.5 (C.C.P.A. 1966)).

²⁷ *Id.* (quoting 35 U.S.C. 6(a) (1976); now codified in 35 U.S.C. § 2(b)(2)).

²⁸ Id.