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COMMENTS OF THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) TO THE USPTO'S MAY 10, 2024 PROPOSED RULEMAKING ON TERMINAL DISCLAIMER PRACTICE, 89 FED.REG. 40439, DOCKET NO. PTO-P-2024-0003

I. INTRODUCTION

On behalf of its member organizations, the Biotechnology Innovation Organization ("BIO") respectfully submits this Comment in response to the United States Patent and Trademark Office's (the "USPTO") May 10, 2024, Notice of Proposed Rulemaking regarding Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting. *See* 89 Fed. Reg. 40439 (May 10, 2024)(the "NPRM"). As explained below, BIO believes that the NPRM is unsupported by the factual record, lacks legal authority, lacks a policy justification, is inconsistent with statutory and case law, and would cause extensive harm to the patent system. Because the NPRM lacks any redeeming features, it should be withdrawn immediately.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members include virtually every major pharmaceutical developer in the United States including, by way of illustrative example, every developer of an FDA-approved COVID-19 vaccine in the United States (i.e., Pfizer, Johnson & Johnson, Moderna, and Novavax). BIO members range from startup companies developing their first commercial products to large pharmaceutical, agricultural, and biotechnological product manufacturing corporations. Importantly, BIO's innovators include stakeholders at every phase of the patenting process, including members who engage in patent prosecution, patent licensing, and patent assertion and challenges in civil litigation and before the USPTO.

At the outset, BIO is disappointed that the NPRM appears to build on misconceptions and unwarranted concerns BIO and other stakeholders addressed previously. For example, in our Comments in response to the USPTO's Request for Comments on USPTO-FDA Collaboration, 87 Fed. Reg. 67019 (Nov. 7, 2022) (Docket No. PTO-P-2022-0037-0054 and PTO-P-2022-0037-0082) (the "BIO USPTO-FDA Comments"), BIO explained that empirical data do not support allegations of "patent thickets" that seem to underly the current NPRM. To the contrary, as empirical data presented by BIO show, the current set of compromises that Congress reached in enacting the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act") and Biologics Price Competition and Innovation Act (the "BPCIA") are working efficiently and effectively to promote continued innovation in drug and biopharmaceutical industries while at the same time providing generic and biosimilar manufacturers incentives and mechanisms to enter the marketplace and provide competitively priced drugs. The NPRM would upset this delicate balance and grossly disfavor innovators by severely restricting their ability to protect their innovations with enforceable U.S. patent rights.

As reflected in the detailed comments provided below, BIO has many concerns about the NPRM, including the USPTO's motivation behind the proposed changes to terminal disclaimer practice and the absence of supporting analysis, the USPTO's lack of authority to implement the proposed changes which appear politically-driven and are certainly substantive in effect, and the far-reaching impact the proposed changes would have on the U.S. patent system, the innovation-based U.S. economy, U.S. international competitiveness, and the ability of companies to continue to invest the staggering resources required to research and develop new pharmaceutical products and other important innovations in biotechnology.

BIO is concerned by the convergence of USPTO policies that conform to well-rehearsed but unsubstantiated anti-patent narratives. As empirical data discussed below demonstrate, the USPTO has encouraged examiners to frequently deploy obviousness-type double patenting ("OTDP") rejections that require terminal disclaimers, and strenuously promoted OTDP invalidation theories in *In re Cellect LLC*, 81 F.4th 1216 (Fed. Cir. 2023) ("*Cellect*"). In the Federal Circuit decision in *Cellect*, the court explained that terminal disclaimers are the "solution" to the "problem" of OTDP. Cellect, 8 F.4th at 1221. Yet, the proposed changes to terminal disclaimer practice would effectively toss out "the solution" by rendering it untenably risky and thoroughly infeasible for patent owners.

II. EMPRICIAL DATA AND THE USPTO'S OWN STUDIES UNDERMINE ITS JUSTIFICATIONS FOR THE NPRM

As stated in the NPRM at 40439:

> This action is 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.

This statement is shocking in its elevation of the interests of "competitors"—even infringing ones—over validly granted U.S. patent rights. Why would the very agency that examines and grants patents propose to then render these same patents unenforceable so that competitors can avoid any consequences of infringing them? Despite affirming that "[the] proposed rule does not concern the validity of claims," the NPRM betrays the USPTO's manifest belief that terminally disclaimed patents cannot possibly be valid over any prior art that affects any claim in a "tied" upstream patent, but such a belief is irrational and does not withstand scrutiny.

BIO understands the impetus for the NPRM to stem from President Biden's Executive Order on "Promoting Competition in the American Economy," published at 86 Fed. Reg. 36987 (July 14, 2021), pursuant to which the USPTO sent a letter to FDA (available at https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf) that outlined specific USPTO initiatives, "most of which will strengthen our patent system for all technologies." Included in this list was an initiative to "[r]evisit obviousness-type double patenting

practice." *Id.* at 6. In its letter to the FDA, the USPTO raised the unsupported sentiment repeated in the NPRM:

> [M]ultiple patents directed to obvious variants of an invention could potentially deter competition if the number of patents is prohibitively expensive to challenge in post-grant proceedings before PTAB and in district court. And later issued patents to obvious variants may delay resolution of ongoing district court litigation thereby potentially delaying generic and biosimilar entry into the market.

BIO's comments submitted in 2023 in response to the USPTO's Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60130 (October 4, 2022) (the "Robustness and Reliability Notice") and the BIO USPTO-FDA Comments provided empirical data that should have dispelled these concerns. As explained in BIO's Comments, the average number of patents listed in the Orange Book for each new molecular entity (NME) is between 3-5 patents, and the average number of patents that are the subject of BPCIA litigation is around 12-15 (with a median of 5-7) patents – far from the "hundreds" of patents or "patent thickets" that are alleged to overwhelm putative competitors with avalanches of litigation. See BIO USPTO-FDA Comment at PTO-P-2022-0037-0082, p. 2-3. The average effective market life of a drug covered by patents from FDA approval to generic entry has over decades been stable at 12.5-13.5 years, which is far less than a 20-year statutory patent term and the "decades" of "evergreening" that are alleged to exist. (*See Id.,* at 3-4).

The BIO USPTO-FDA Comments also presented an analysis of all U.S. biosimilar products that have been subject to district court litigation, have received FDA approval, and for which a launch date is known. The data presented show that "when biosimilar approval-to-launch intervals are compared to the actual number of patents asserted against them in BPCIA litigation, it is clear that there is no … correlation [between number of litigated patents and the timing of biosimilar launch]." BIO Comment PTO-P-2022-0037-0054, at 3.

Not only did the USPTO fail to engage with extensive empirical data in its possession since at least its 2023 Requests for Comment. The USPTO also just published in June 2024 its very own study that reached the same conclusion. *See* USPTO Drug Patent and Exclusivity Study (2024) (available at: https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf). This USPTO study concluded that the number of patents on a given pharmaceutical product is not predictive of the timing of generic drug entry. Rather, the study concludes that "pharmaceutical market exclusivity … is influenced by a complex interplay of patent law and FDA statutes and regulations," as well as other factors. Thus, the USPTO's own study on this very issue completely fails to support the stated justification for the NPRM, and certainly does not justify the drastic changes to long-standing terminal disclaimer practice being proposed.

Another recently published USPTO study indicates the proposed rulemaking would render valid claims unenforceable. In particular, the USPTO also published in June 2024 an updated report on America Invents Act (AIA) proceedings involving challenges to Orange Book-listed and biologic patents, available at:

https://www.uspto.gov/sites/default/files/documents/orange_book_biologics_study_march2024.pdf. The study reports that institution rates for the study patents were lower than the average, meaning that the challenger did not even establish a reasonable likelihood of invalidating even one challenged claim of the patent. The study also reports that for Orange Book-listed patents, only 20% of proceedings resulted in all challenged claims being invalidated, while for the studied biologic patents only 25% of proceedings resulted in all challenged claims being invalidated. Considering the NPRM in light of these statistics underscores that the proposed change to terminal disclaimer practice not only "could potentially" but would definitely render valid claims unenforceable. This is an untenable and unjustified result.

The USPTO's vague concerns regarding the impact the number of related patents may have on the cost of district court litigation ignores realities of district court litigation and the wide discretion district court judges have to manage cases. The NPRM suggests that with the proposed rule, "in a litigation in which a patent owner is enforcing a patent along with several other patents … tied by one or more terminal disclaimers, a competitor could seek to have the court narrow any validity disputes to address only that patent." 89 Fed. Reg. at 40440. But district courts already have, and exercise, wide discretion to require parties to narrow the issues to be resolved, such as by identifying representative claims to be litigated. Although a generic company making a paragraph IV certification has to address all patents listed in the Orange Book in its notice letter to the patent owner, the USPTO has not cited any study that having to address multiple patents in a notice letter is "prohibitively expensive," especially where multiple patents are linked by a terminal disclaimer.

To the contrary, if patents linked by terminal disclaimers are really as indistinguishable as prevailing narratives propose, invalidity defenses are likely to involve the same cost drivers—the same prior art, the same experts, etc. —such that the incremental additional cost of litigating such patents is far from "prohibitive." Moreover, the BPCIA expressly leaves it to the parties to identify and negotiate the patents to be litigated, in the so-called "biosimilar patent dance". Even where the BLA holder initially identifies a substantial number of patents, only a fraction of these patents typically ends up in district court litigation where the issues invariably get narrowed even further as the case proceeds. In this regard, the NPRM ignores Federal Circuit precedent that provides an effective approach to address the case-specific effect of terminal disclaimers on related patents asserted in district court litigation, without the draconian results of the NPRM.

The NPRM also touts as a selling-point of the proposed rule that "a competitor could petition for an inter partes or post-grant review of just a single patent to which multiple patents are tied," and render the entire portfolio unenforceable by invalidating a single claim of the patent under § 102 or § 103. *See* 89 Fed. Reg. at 40440. The NPRM is inexplicably focused on the ability of "a challenger to seek the freedom to operate through the review of only one patent" even if the claims rendered unenforceable are valid under § 102 and § 103, and expresses no concern whatsoever for the potential evisceration of the patent owner's valid patent rights.

The NPRM also fails to recognize other reasons pharmaceutical patents may not be challenged in PTAB proceedings. For example, the first generic filer has an incentive to challenge Orange Book-listed patents in ANDA litigation, in order to qualify for its own market exclusivity period. With regard to biologics, relevant patents may be more vulnerable to challenge on written

description and/or enablement grounds that cannot be raised in an inter partes review proceeding, and biosimilar competitors may not be ready to challenge the patents during the time period permitted for post-grant review. Petitioners may also fear that an ultimately unsuccessful PTAB challenge might preclude them from asserting the same or alternative theories of invalidity in district court, under 35 U.S.C. § 315(e)(2). These reasons at least contribute to the relatively low percentage of pharmaceutical patents challenged in PTAB proceedings.

Overall, the NPRM provides no justification for its singular focus on competitor interests and the removal of impediments to their freedom-to-operate. As discussed in more detail below, and as the USPTO well-knows, by statute each claim of the same patent stands or falls independently. *See* 35 U.S.C. § 253. The USPTO has not shown that its proposal to require patent owners to give up this statutory protection is warranted. In practice, the changes proposed in the NPRM would mean that if only claim 7 of Patent A is invalidated under § 103, then claims 1-6 and 8-20 of Patent A remain valid and enforceable but claims 1-20 of Patent B would become unenforceable without even any discussion of their validity. Such results may not even meaningfully simplify the freedom-to-operate landscape for competitors, especially if innovators adapt to the NPRM by obtaining more claims per patent.

III. THE NPRM EXCEEDS THE USPTO'S RULEMAKING AUTHORITY

The NPRM would impose a new requirement for acceptance of a terminal disclaimer to obviate obviousness-type double patenting ("OTDP"), adding the requirement in clause (ii) below:

> [A] provision agreeing that the subject patent or any patent granted on the subject application shall be enforceable:
>
> > (i) Only for and during such period that the subject patent or any patent granted on the subject application is commonly owned with the reference patent or any patent granted on the reference application; and
> >
> > (ii) Only if the subject patent or any patent granted on the subject application 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) A claim has been finally held unpatentable or invalid under 35 U.S.C. 102 or 103 in a Federal court in a civil action or at the USPTO, and all appeal rights have been exhausted; or
> > >
> > > (B) A statutory disclaimer of a claim is filed after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made.

89 Fed. Reg. at 40449. As explained in the NPRM, "Under the proposed rule, the USPTO will not issue a patent … unless the terminal disclaimer includes an additional agreement that the

patent with the terminal disclaimer will not be enforced if any claim of the second patent is invalidated by prior art." 89 Fed. Reg. at 40439-40 (emphasis added). Thus, the NPRM's new condition on the issuance of patents amounts to a substantive rulemaking which the USPTO lacks authority to make.

The required conditioning of enforceability of the "subject patent" on the validity under § 102 and § 103 of every single claim in the "tied" patent (e.g., the reference patent of the OTDP rejection) is "substantive" because it limits the rights of the patent owner. *See Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008) ("A rule is substantive when it effects a change in existing law or policy which affects individual rights and obligations."); *see also Am. Hosp. Assoc. v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) ("Substantive rules are ones which grant rights, impose obligations, or produce other significant effects on private interests, or which effect a change in existing law or policy.").

The NPRM alleges that the changes "involve rules of agency practice and procedure, and/or interpretive rules, and do not require notice-and-comment rulemaking." 89 Fed. Reg. at 40445. The NPRM itself belies that characterization. As plainly stated in the NPRM, "The USPTO proposes to amend the rules of practice to add a new requirement for an acceptable terminal disclaimer that is filed to obviate (that is, overcome) nonstatutory double patenting." 89 Fed. Reg. at 40439 (emphasis added). The proposal is not one of practice or procedure, and is not "interpretative" of any existing statute, rule, or court decision. Rather, the NPRM is expressly policy-driven, in a misguided attempt to "prevent multiple patents directed to obvious variants of an invention from potentially deterring competition," based on an unsupported theory that "multiple patents tied by terminal disclaimers … could deter competition due to the prohibitive cost of challenging each patent separately in litigation or administrative proceedings." 89 Fed. Reg. at 40439 (emphasis added). Moreover, the NPRM expressly acknowledges opposing views received in public comments made in response to its Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60130 (October 4, 2022) (the "Robustness and Reliability Notice"). It is Congress, not the USPTO, who has authority to weigh competing interests and take actions that limit individual rights for policy reasons.

On this point, BIO notes that in recent years, legislation has been proposed in Congress that purports to address the alleged problem of so-called patent-thickets. Indeed, in January 2024 Sen. Welch (D-VT) introduced S. 3583 "to address patent thickets." The proposed bill would limit NDA holders or BLA holders asserting their patents in ANDA litigation or BPCIA litigation to one patent from a group of patents linked by terminal disclaimer(s). *See* S. 3583, 118th Cong. (2023-2024) (available at https://www.congress.gov/bill/118th-congress/senate-bill/3583/text). While existing legislative proposals suffer from many problems, the fact that Congress is taking on this issue underscores that doing so is not in the USPTO's purview.

A. *Van Ornum* Shows The USPTO Lacks Authority For The NPRM

The NPRM cites *In re Van Ornum*, 686 F.2d 937 (C.C.P.A. 1982), as allegedly supporting its authority to impose this new requirement on terminal disclaimers, but the USPTO's reliance on *Van Ornum* is misplaced for a number of reasons. Indeed, contrary to the USPTO's reliance on

Van Ornum, the decision underscores that the proposed changes to terminal disclaimer practice are contrary to law and beyond the USPTO's authority.

Both the reasoning and the context of the *Van Ornum* decision are very different from what the USPTO now proposes. At issue in *Van Ornum* was the validity of 37 C.F.R. § 1.321(b) ("Rule 321(b)"), which requires a terminal disclaimer filed to obviate an OTDP rejection to "include a provision that any patent granted on that application shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the rejection."[1] In upholding the validity of that rule, the court noted that the rule—which had been implemented in 1971—required the same language that had been endorsed by the C.C.P.A. in *In re Griswold*, 365 F.2d 834 (C.C.P.A. 1966). *See Van Ornum,* 686 F.2d at 944-45. Indeed, the court noted that the USPTO proposed this rule in 1970, having been prompted by the *Griswold* decision, which was cited in the corresponding notice of proposed rulemaking. *Id*. at 945.

Contrary to the USPTO's characterization, *Van Ornum* did not hold that the USPTO has unrestricted rulemaking authority to require terminal disclaimers to include language placing conditions on enforcement.

i. *Van Ornum* Recognizes That Terminal Disclaimer Conditions on Enforceability Are Substantive

At the outset, BIO emphasizes that the C.C.P.A. in *Van Ornum* acknowledged that the condition on enforceability embodied in Rule 321(b) was substantive, stating plainly at 686 F.2d 945: "True, the rule is substantive in that it relates to a condition under which a patent will be granted which otherwise would have to be denied for double patenting." The court nevertheless upheld the rule because it was "consistent with statutory and case law," *Id*., but that is not the case for the current NPRM.

ii. Rule 321(b) Followed Caselaw and Existing USPTO Practice

As noted above, fundamental to the decision in *Van Ornum* was that fact that Rule 321(b) essentially "enacted" existing case law, which is not the situation here. In its decision in *Van Ornum*, the C.C.P.A. actually takes credit for the use of non-alienation agreements to address the concern that double patenting might permit potential harassment by multiple assignees, which it had highlighted in its 1966 *Griswold* decision. In *Griswold*, the C.C.P.A. characterized the non-alienation agreement in the terminal disclaimers before it as "ingenious":

> The above language includes an imaginative solution to one of the more theoretical objections to double patenting, split ownership of two patents and potential harassment.

In re Griswold, 365 F.2d 834, 840 n.5 (C.C.P.A. 1966). As noted in *Van Ornum*, following *Griswold*, the USPTO established non-alienation agreements "as an administrative practice" in early 1968, in a Commissioner's Notice published at 848 O.G. 1 (Feb. 14, 1968). Thus, by the

[1] The CCPA refers to this requirement as a "non-alienation" agreement; we also refer to it herein as a "common ownership" requirement.

time Rule 321(b) had been proposed, its condition on enforceability had been supported by the C.C.P.A. and had been an ongoing practice for several years. Accordingly, the NPRM for Rule 321(b) was able to accurately state that the language of the proposed condition "is substantially the form which met with the approval of the Court of Customs and Patent Appeals in footnote 5 of *In re Griswold*." *Van Ornum*, 686 F.2d at 945 (quoting Notice of Proposed Rule Making, 35 Fed. Reg. 20012 (Dec. 24, 1970)). The USPTO can cite no such authority for the current NRPM.

Another distinguishing circumstance of *Van Ornum* is that by the time Van Ornum challenged Rule 321(b) in 1982, it had been implemented for over a decade without controversy, and with the endorsement of the bar. Thus, by the time the C.C.P.A. was asked to review the validity of Rule 321(b), including a non-alienation agreement in a terminal disclaimer had been an accepted and established practice for about 15 years. In sharp contrast, the current NPRM proposes an upheaval to longstanding terminal disclaimer practice.

Thus, a fundamental difference between Rule 321(b) at issue in *Van Ornum* and the current NPRM is that the non-alienation agreement of Rule 321(b) was first endorsed by the appellate court and then implemented by the USPTO, and already accepted by the patent user community. But the Court of Appeals for the Federal Circuit has not prompted, suggested, or endorsed what the NPRM proposes. Rather, as discussed in more detail below, the effects of the NPRM are contrary to Federal Circuit precedent. Thus, in direct contrast to Rule 321(b), this NPRM does not implement recent case law, is not supported by any existing statute or case law, and if promulgated is likely to be challenged in court by members of the patent user community.

iii. Unlike Rule 321(b), the NPRM is Not Justified or Supported by Any Fundamental OTDP Principles

Another fundamental difference between Rule 321(b) and the currently proposed changes to terminal disclaimer practice is that Rule 321(b) was consistent with and supported by fundamental principles of OTDP, whereas the NPRM instead undermines policies behind OTDP and current terminal disclaimer practice.

Perhaps the first case to approve the use of a terminal disclaimer to overcome OTDP was *In re Robeson*, 331 F.2d 610 (C.C.P.A. 1964). In that case, the CPPA noted the statutory basis for terminal disclaimers had been enacted as part of the 1952 Patent Act (e.g., 35 U.S.C. § 253), and stated at 331 F.2d 614:

> Where, as here, the claimed subject matter is an obvious modification of what has already been claimed, a second patent is contrary to one of the fundamental principles underlying the patent system, namely, that when the right to exclude granted by a patent expires at the end of the patent term, the public shall be free to use the invention as well as obvious modifications thereof or obvious improvements thereon. Thus, to grant a second patent for an obvious variation deprives the public of those rights. If, however, the second patent expires simultaneously with the first, the right to fully utilize the patented discovery at the expiration date remains unimpaired. Thus the terminal disclaimer here precludes any extension of monopoly.

In *Robeson*, the C.C.P.A. drew a distinction between "same invention" type double patenting that cannot be overcome with a terminal disclaimer, an OTDP that can:

> We conclude that on the facts here, the only real objection to granting appellant's application is an extension of the monopoly. The terminal disclaimer, which Congress has expressly provided, removes any danger of such result.

Robeson, 331 F.2d at 615. As explained in *Van Ornum*, *Griswold* addressed the other "objection" to OTDP that *Robeson* did not give much weight, i.e., potential harassment by multiple assignees. Thus, the common ownership requirement embodied in the non-alienation agreement followed naturally from the earlier common term requirement.

Van Ornum highlights important public policy interests that support the grant of terminally disclaimed patents—interests the NPRM has lost sight of. For example, the C.C.P.A. in *Van Ornum* explains that terminal disclaimer practice is "in the public interest because it encouraged the disclosure of additional developments, the earlier filing of applications, and the earlier expiration of patents whereby the inventions covered became freely available to the public." *Van Ornum*, 686 F.2d at 947 (citing *In re Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967)).[2]

As *Van Ornum* reminds, current terminal disclaimer practice evolved via the C.C.P.A., and strikes a balance between protecting the public from unjustified time-wise extensions of the right to exclude on the one hand, and benefiting the public by encouraging inventors to pursue patent applications that will make a "considerable disclosure of technology" on the other. *See Braithwaite*, 379 F.2d at 601. Indeed, the C.C.P.A. in *Van Ornum* expressly addressed this balance:

> Certainly many, if not most, double patenting situations fall into the obviousness-type double patenting category and involve a modification of or improvement upon what an inventor or his assignee has already patented. The desire is to be able to bring such improvement inventions within the protection of the patent system, at the same time giving an incentive for their disclosure. For a long time the judge-made law of double patenting was a serious obstacle to doing so. Knowing this, the drafters of the 1952 Patent Act provided a possible remedy in the terminal disclaimer, 35 U.S.C. § 253. *See* P.J. Federico, *Commentary on the New Patent Act,* 35 USCA p. 49 (1954). That provision is merely permissive and it was left to the courts to work out its application on a case-by-case basis. This court in the first *Braithwaite* case […], speaking of such inventions and the granting of a second patent upon the filing of a terminal disclaimer making the two patents expire together, said:

[2] Although the application at issue in *Braithwaite* was a continuation-in-part application, similar incentives pertain to current terminal disclaimer practice as between continuing applications. For example, current terminal disclaimer practice incentives inventors to fully describe various embodiments, combinations, and subcombinations in a single application, which results in early disclosure of all subject matter even if claims to various aspects are pursued in sequential applications. Under the NPRM, inventors may be discouraged from filing such fulsome applications, and instead may disclose only the subject matter they expect to be able to claim in a single patent.

> When a terminal disclaimer causes two patents to expire together[,] a situation is created which is tantamount for all practical purposes to having all the claims in one patent.
>
> Obviously, that thought contemplates common ownership of the two patents, which remains common throughout the life of the patents.
>
> *Van Ornum*, 686 F.3d at 948 (emphasis added, internal citations omitted).

The NPRM completely and inexplicably ignores this balance and ignores the public benefit of including modifications and improvements in the *quid pro quo* of the patent system, which incentivizes their disclosure to the public. Indeed, the NPRM ignores the fact that incentivizing and facilitating the grant of terminally disclaimed patents is as much an objective of terminal disclaimer practice as protecting the public from an unjustified timewise extensions of the right to exclude and potential harassment by multiple assignees. In cases like *Robeson, Griswold*, and *Braithwaite* the C.C.P.A. endorsed terminal disclaimers that would permit the grant of a terminally disclaimed patent "as if having all the claims in one patent." *Van Ornum*, 686 F.3d at 948 (quoting *Braithwaite* case, 379 F.2d at 601), and removed "serious obstacles" that would prevent benefits associated with the terminally disclaimed patents from accruing to the public. Not so the NPRM.

Unlike the non-alienation agreement of Rule 321(b) that was consistent with longstanding principles of OTDP and terminal disclaimer practice, the NPRM's unenforceability proposal does not have any logical connection to OTDP, but instead undermines policies behind OTDP and current terminal disclaimer practice. The NPRM would discourage inventors from filing comprehensive patent applications, and disincentivize disclosure of improvements and follow-on developments that might raise OTDP issues, pushing such inventions away from the patent system. The NPRM would penalize patent owners willing to accept the balance embodied in current terminal disclaimer practice and surrender patent term and alienability of their patents, by foisting on them an irrational condition on enforceability. The NPRM would complicate the patent examination process and increase costs for applicants and the USPTO. In short, the NPRM would run counter to everything terminal disclaimers are meant to achieve.

The only policy justification offered by the USPTO is that competitors may find it burdensome and expensive to challenge multiple patents tied by terminal disclaimers. Yet this justification has nothing to do with principles of OTDP or historic terminal disclaimer practice. After all, challenging multiple patents that are not tied by terminal disclaimers is also burdensome and expensive, and likely significantly more so. At bottom, the NPRM does not even reflect an attempt to improve the practices or policies underlying the doctrine of OTDP; rather, the USPTO's policy justification collapses into a general and unsupported objection that "too many patents" may "potentially deter competition." *See, e.g.,* 89 Fed. Reg. at 40439. As such, it is not supported by *Van Ornum*.

B. The Substantive Effect of the NPRM is at Odds with Van Ornum and Contrary to 35 U.S.C. § 253

Not only is the NPRM unsupported by *Van Ornum*, it also runs directly counter to principles of OTDP underlying that decision.

As discussed in *Robeson* and *Van Ornum*, the doctrine of double patenting stems from "the rule that there should be only one patent for one invention." *Van Ornum,* 686 F.2d at 946 (citing *Miller v. Eagle*, 151 U.S. 186 (1894)). As explained in *Van Ornum* and *Braithwaite* case, current terminal disclaimer practice in effect treats the tied patent as if it were in a single patent with the reference patent. *See Van Ornum*, 686 F.3d at 948 (quoting *Braithwaite* case, 379 F.2d at 601). The NPRM would violate this principle by conditioning enforceability of the tied patent on the validity of all claims of the reference patent. No provision of statute or case law conditions enforceability of one patent claim on the validity of other claims in the same patent.

Indeed, in this way, the effect of the NPRM would be directly at odds with 35 U.S.C. § 253, which provides that "[w]henever a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid." The NPRM would not only violate the requirement to treat claims of the same patent independently but would go further by effectively making claims of different patents fall together. The NPRM also would be inconsistent with Federal Circuit precedent to the effect that filing a terminal disclaimer does not amount to an admission of obviousness of the subject patent. *See, e.g.*, *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167-1168 (Fed. Cir. 2018).

The NPRM suggests these principles are not violated because the NPRM requires a condition on enforceability rather than a stipulation of invalidity, but to any thinking person those semantics are a distinction without a difference. What value is a "valid" patent that cannot be enforced? The USPTO obviously determined it did not have authority to require applicants "to stipulate that the claims are not patentably distinct from the … [reference] claims as a condition of filing a terminal disclaimer," since it is no longer pursuing that proposal of the Robustness and Reliability Notice. How then can it have authority to require applicants to stipulate to unenforceability instead? What rights remain in a patent if it no longer embodies a right to exclude?

Overall, there has been no change in the law that would require or justify the significant departure from longstanding, established terminal disclaimer practice proposed in the NPRM. Thus, the NPRM is invalid *ab initio* as beyond the USPTO's limited rulemaking authority.

IV. THE NPRM WOULD UNDERMINE THE VALUE OF U.S. PATENTS

The USPTO's press release announcing the NPRM (available at https://www.uspto.gov/about-us/news-updates/proposed-changes-terminal-disclaimer-practice-promote-innovation-and) quotes Under Secretary Vidal as stating, "We must remain steadfast in incentivizing and protecting the investments in innovation that drive U.S. leadership, while

recognizing that surgical changes can create efficiencies that reduce costs and promote competition." Yet, the NPRM proposes far more than a "surgical change" to terminal disclaimer practice. The NPRM would undermine the value of any patent with a terminal disclaimer, because the enforceability of that patent would not rest only on its own merits, but on the validity under § 102 and § 103 of every claim in every patent linked by a terminal disclaimer.

BIO believes the USPTO has grossly underappreciated the sweeping impact the NPRM would have on all U.S. patents, and has failed to grapple with the fact that the NPRM would undermine the value of U.S. patents, and discourage innovators from seeking U.S. patents on improvement inventions and follow-on technologies, even though such patents incentivize investment in research and development and support important innovations, as well as promote further innovation by publication of the improvements.

A. OTDP Is Applied More Broadly Than The NPRM Supposes

Throughout the NPRM and related commentary, the USPTO refers to patents tied by a terminal disclaimer as "patents with claims that vary in only minor ways from each other," but the USPTO's guidance to examiners on OTDP practice does not limit OTDP to claims that "vary in only minor ways." Rather, MPEP § 804 advises that an OTDP rejection based on an obviousness rationale is "analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. § 103 except the disclosure of the reference patent is not considered prior art." MPEP § 804 (II)(B)(3). Thus, the MPEP advises examiners to apply the *Graham* factors and instructs examiners to rely of secondary references where needed, as long as they qualify as prior art. *Id.* In practice, examiners raise OTDP rejections that rely on multiple secondary references to support the obviousness rationale. When even a single secondary reference is required, it is likely the claims vary in more than minor ways.

The NPRM also ignores OTDP that can arise when the strict requirements of 35 U.S.C. § 121 are not met, and claims directed to originally restricted and non-elected subject matter face OTDP rejections over claims an examiner previously identified as patentably distinct. Such scenarios can arise when a restriction requirement is issued between method of use claims and product claims, such as if the method claims are elected first, the first continuing application pursues additional method claims, and the product claims are pursued in an application outside the safe harbor of § 121. Similar scenarios may arise between combination and subcombination claims, when OTDP arises between claims previously identified as patentably distinct. In these and many other common OTDP scenarios, as the USPTO surely knows, it is disingenuous to assume the claims "vary in only minor ways."

The NPRM acknowledges that OTDP is not limited to continuing applications that stem from the same priority application and share the same priority date, but does not go far enough when it only additionally mentions patent applications voluntarily filed on the same day. *See* 89 Fed. Reg. at 40439. As set forth in MPEP § 804, OTDP can arise between any applications/patents with at least one common inventor or one common owner, regardless of relative filing dates. This means improvement patents can face OTDP issues over platform technology and, depending on the relative time course of examination, platform patents can face OTDP issues over later-filed improvement patents. For example, genus claims with an earlier

patent term filing date could face OTDP rejections over later-filed species claims. In reality, whenever an inventor or patent owner files a second patent application in the same technology area, there may be a risk of OTDP.

The NPRM does not discuss how many patents are granted with terminal disclaimers, but in a recent blog article, Dennis Crouch reported that more than 18% of patents granted in 2023 had a terminal disclaimer, amounting to almost 60,000 utility patents. *See* D. Crouch, Terminal Disclaimers: A Growing Concern in Patent Practice, PATENTLY-O (May 10, 2024), (available at https://patentlyo.com/patent/2024/05/terminal-disclaimers-practice.html. The reported data from 2006-2023 show a steady increase from 9% in 2006 to about 15% in 2021, followed by a drop in 2022 and a jump to more than 18% in 2023. Professor Crouch attributes these trends to "a growing complexity in patent portfolios and an increasing emphasis on non-statutory double patenting at the USPTO." In a more recent article Professor Crouch additionally identified an estimated 425,000 patents that do not carry a terminal disclaimer, but which are at risk of an OTDP attack due to differences in patent term adjustment due to differing terms of one more patent family members. (see: https://patentlyo.com/patent/2024/07/unveiling-potential-adjustment.html#more-40836).

These data are helpful to understanding the potential impact of the NPRM, but only scratch the surface of identifying the universe of possibly impacted patents. This is because the data do not show how many patents were tied together by a given terminal disclaimer. While each terminal disclaimer represents at least one patent being tied to at least one other, a given terminal disclaimer may directly tie multiple patents, and indirectly tie multiple others. Thus, interpreting the data as indicating that 20% of patents could be impacted by the NPRM likely would grossly understate the effect of the proposed rule. As Professor Crouch's article notes:

> The data also indicate that this trend spans a diverse set of entities—from large tech corporations to small startups and individual inventors. This diversity suggests that the implications of both the rising trend of terminal disclaimers and the proposed regulatory changes are widespread, affecting a broad swath of the innovation ecosystem.

BIO is concerned the USPTO shows no sign of having considered the widespread effects the NPRM would have.

B. OTDP Arises On A Claim-By-Claim Basis But The NPRM Links All Tied Patents

The draconian impact of the NPRM is evident when it is understood that OTDP arises on a claim-by-claim basis, but the NPRM would condition enforceability of an entire patent on the validity of all claims of the tied reference patent. Under the NPRM, if OTDP was based only on claim 7 of the tied reference patent and only claim 13 was invalidated, all claims of the subject patent would be unenforceable.

Additionally, the NPRM's inclusion of "indirectly" tied patents guarantees that patentably distinct claims will be rendered unenforceable. The NPRM explains "indirectly" tied patents at 89 Fed. Reg. 40442:

The subject patent or any patent granted on the subject application is tied indirectly by two terminal disclaimers to another patent when: (1) a terminal disclaimer filed in the subject patent or application identifies an intermediate patent/application as the reference patent or application; and (2) a terminal disclaimer filed in the intermediate patent/application identifies the other patent, or the application that issued as the other patent, as the reference patent or application.

Such scenarios are illustrated in examples 2 and 3 at 89 Fed. Reg. 40443:

Example 2: W ← X ← Y

Example 3: W ← X ← Y ← Z

In example 2, a terminal disclaimer is filed in X over W, and a terminal disclaimer is filed in Y over X. Y is said to be indirectly tied to W. In example 3, a terminal disclaimer is filed in X over W, a terminal disclaimer is filed in Y over X, and a terminal disclaimer is filed in Z over Y. Y and Z are said to be indirectly tied to W. Yet, if Y and Z are not terminally disclaimed over W, even if X is terminally disclaimed over W, the claims of Y and Z should be patentably distinct from the claims of W. If not, Y and Z should require terminal disclaimers over W to avoid OTDP over W. Thus, these scenarios demonstrate that invalidation of one claim could result in patentably distinct claims being unenforceable.

Taking the NPRM's inter partes review scenario as an example, a competitor could petition for inter partes review of a single claim of a tied reference patent and render the entire portfolio unenforceable by invalidating that single claim under § 102 or § 103, even if the ground of invalidity would not apply to the claims of the other patents. Even more egregiously, a competitor could be unsuccessful in invalidating a claim in a subject patent, and then proceed to try to invalidate a claim in the reference patent, and if that attempt fails, move on to another "upstream" patent to which that reference patent is tied until there are no more patents to challenge. In this way, the NPRM would allow competitors to circumvent the estoppel provisions of 35 U.S.C. § 315(e)(1) as well as the timing limitations of 35 U.S.C. § 315(b) in ways never contemplated by Congress.

The NPRM suggests that patent owners could mitigate these risks by taking steps to "move patentably distinct claims to an application in which a terminal disclaimer will not be filed." 89 Fed. Reg. at 40441. But this advice only addresses scenarios where only some claims of the subject application are rejected. It does not address scenarios where only some claims of the reference patent are relied upon in the OTDP rejection. Once granted, the claims of a patent cannot be readily divided into separate patents. This advice also does not address indirectly tied patents. In example 2 and example 3 above, we can assume the claims of Y and Z are patentably distinct from the claims of W, but that would not be sufficient to spare them from unenforceability if any claim of W is invalidated under § 102 or § 103. Such an outcome is illogical and unsupported by any valid rationale.

C. The NPRM Leaves No Practical Way to Avoid the Poison of a Single Invalid Claim

The examples provided in the NPRM make clear that it is the USPTO's intention that a single invalid claim in a tied reference patent would render unenforceable all claims of all patents directly or indirectly tied to that reference patent by terminal disclaimers. Thus, a single anticipated or obvious claim of a reference patent could act as a "poison pill" and render unenforceable all claims of all patents directly or indirectly tied to that reference patent by terminal disclaimers.

At 89 Fed. Reg. 40444, the NPRM outlines four options for addressing OTDP rejections, but only one applies to OTDP raised by a granted patent:

> (4) 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.

This suggestion highlights the perverse nature of the NPRM—the best way to protect enforceability of a claim from potential invalidity of claim of a different patent is to consolidate all claims in a single patent.

This suggestion also glosses over the statutory requirements for a valid reissue application, the two-year limitation on broadening reissue applications, and the substantive limitations on the claims that can be pursued. For example, the recapture rule could prevent using a reissue application to pursue claim scope that was surrendered during original prosecution; thus, a reissue application may not be an option for pursuing original claim scope that was amended during prosecution of the granted patent. Also, reissue applications generally cannot be used to pursue subject matter that was non-elected pursuant to a restriction requirement made during prosecution of the granted patent; thus, reissue may not be an option for avoiding the effects of the NPRM on a "divisional" application that is outside the OTDP safe harbor of § 121.

Another option evident from the NPRM is to file a statutory disclaimer of the invalid claim before any challenge of that claim has been made under § 102 or § 103. *Cf.* 89 Fed. Reg. at 40442. Although the NPRM emphasizes at 89 Fed. Reg. at 40442 that "the proposed agreement [conditioning enforceability] cannot be avoided by filing a statutory disclaimer of a claim under 35 U.S.C. § 253(a) after any challenge based on 35 U.S.C. §§ 102 or 103 to that claim has been made," it does not explain or discuss what would constitute a "challenge" in this context. Would an allegation of invalidity in a notice letter pursuant to a Paragraph IV certification be sufficient? A petition for inter partes review even if not instituted? A request for *ex parte* reexamination?

Taken as a whole, the NPRM makes clear that unless the patent owner prospectively identifies and statutorily disclaims all claims of a reference patent vulnerable to challenge under § 102 or § 103, there will be no way to protect even valid claims in tied patents from the poison pill. This is a draconian result that is not justified by the principles of OTDP or any other legal doctrine.

D. The NPRM Gives Competitors Unjustified Power to Eviscerate Patent Families

BIO is particularly troubled by the power the NPRM gives competitors to eviscerate entire patent families tied by terminal disclaimer(s), based on invalidity of a single claim.

As expressly acknowledged in the NPRM, the proposed rule would "enable[e] a challenger to seek the freedom to operate through the review of only one patent." 89 Fed. Reg. at 40440. Although the NPRM refers to freedom to operate relative to "patents claiming obvious variants of a single invention," OTDP is applied much more broadly, and terminal disclaimers may directly or indirectly tie patents with at least some patentably distinct claims. In at least those scenarios, the NPRM would render unenforceable patentably distinct claims. The USPTO has not and cannot justify a rule that would give competitors freedom to operate with respect to a claim that is patentably distinct from a claim invalidated under § 102 or § 103. The NPRM's complete disregard for patent owner rights in such scenarios is appalling.

The sweeping reach and effect of the NPRM outlined above gives competitors unjustified power to eliminate the right to exclude associated with entire patent families tied by terminal disclaimer(s), based on invalidity of a single claim. Returning to the NPRM's inter partes review scenario, a competitor could challenge a single claim of a patent the owner has no intention of enforcing, and thereby render unenforceable all claims directly or indirectly tied to that patent by a terminal disclaimer, even if the invalidated claim would not be infringed, would not be asserted by the patentee, and even if the ground of invalidity would not apply to the claims of the subject patents. Given that claims of a later-filed patent can be cited as an OTDP reference against claims of an earlier-filed application or patent, a scenario could arise where the prior art used to invalidate a claim of the reference patent under § 102 or § 103 does not even qualify as prior art to the claims of the other patents. That is an absurd outcome that cannot be justified by the vague concerns for competitors expressed in the NPRM.

The expansive power the NPRM gives to competitors must not be underestimated. Take a BCPIA scenario as an example, and assume the BLA holder seeks to litigate ten patents (a median number in the data reported in BIO's USPTO-FDA Comment), each having 20 claims, out of which 7 patents are tied directly or indirectly by terminal disclaimers. Under the NPRM, in order to establish freedom to operate relative to all seven patents, the competitor need only invalidate one of the 140 claims under § 102 or § 103 and need not even invalidate a claim that could be asserted against its biosimilar product.

BIO also believes the NPRM would perversely encourage serial PTAB proceedings. For example, a putative competitor, concerned about Patent C tied to Patent A and Patent B by a terminal disclaimer, could strategically challenge a claim in Patent A, and thereby hope to secure unenforceability of Patent C. If invalidation of a claim in Patent A is unsuccessful, the competitor could next try to challenge a claim in Patent B, etc. The USPTO shows itself concerned about gamesmanship by patent applicants, but the NPRM would provide opportunities for gamesmanship by competitors unlike anything that's been seen since the PTAB came into existence.

Along these same lines, the proposed changes to terminal disclaimer practice would upset the delicate balance achieved by the Hatch-Waxman Act by offering competitors an end-run around valid patents awarded patent term extension under 35 U.S.C. § 156(a). By the intended operation of the proposed changes to terminal disclaimer practice, if a PTE-awarded patent is directly or indirectly tied to a reference patent by a terminal disclaimer, a competitor could render the PTE-awarded patent unenforceable simply by invalidating a single claim of the reference patent under § 102 or § 103, even if the ground of invalidity did not pertain to the PTE-awarded patent. Such a result would be inconsistent with and unjust under the Hatch-Waxman Act, and would deny patent owners their side of the bargain by eliminating validly-accrued patent term and more. Notably, agricultural and industrial biotech patents would be similarly impacted despite not being eligible for PTE under § 156(a).

E. The NPRM Would Have Perverse Effects On Patent Portfolio Valuation

The NPRM fails to acknowledge or address the effect the proposed changes to terminal disclaimer practice would have on patent portfolio valuation. Currently, patent portfolios may be valued based on the collective value of the constituent patents. Under the NPRM, valuations may have to include a discount to account for the risk one or more claims of one or more reference patents tied to others by terminal disclaimer(s) could be invalidated under § 102 or § 103, and thereby render all patents tied to that patent unenforceable.

In this regard, it should be understood that these concerns would not be limited to patents granted with a terminal disclaimer, but would include patents that might have unidentified OTDP issues (i.e., patents owned by the same entity or having a common inventor and directed to generally the same subject matter). This is because an OTDP issue could be identified post-grant that would be obviated by a terminal disclaimer.

The NPRM also could discourage innovators from pursuing “second” patents in a given patent family, or even from pursuing patents on improvements and follow-on technology that might raise OTDP issues. While this would serve the NPRM’s goal of facilitating freedom to operate for competitors, it would mean that innovators would obtain fewer patent rights than they are entitled to under the Patent Act. For example, innovators may forego patent protection on initially unclaimed embodiments that could raise OTDP issues for a granted patent. (While the USPTO would not be able to require a terminal disclaimer to be filed in the granted patent, the patent owner may need to file a terminal disclaimer to obviate OTDP issues that could arise in litigation or *ex parte* reexamination.) Again, BIO questions the USPTO’s motivation in promulgating a rule that would incentivize innovators to forego patent protection and undermine investment in innovative technologies.

V. THE NPRM WOULD DRIVE UP EXAMINATION COSTS

BIO is concerned the USPTO has failed to appreciate the impact the proposed changes to terminal disclaimer practice would have on examination, and believes the economic impact analysis understates the costs to small business concerns and others.

A. The NPRM Would Turn OTDP Rejections Into High Stakes Issues

It should be evident that the proposed changes to terminal disclaimer practice would make OTDP rejections high stakes issues that would leave many applicants with no option but to challenge them wherever possible. Under current practice - especially where a terminal disclaimer will not impact patent term anyway - applicants often file terminal disclaimers to avoid cost and complication during examination, even if they do not believe the claims are not patentably distinct. If the proposed rule changes are implemented, applicants will be much more likely to challenge OTDP rejections tooth-and-nail, leading to more *ex parte* appeals and district court litigation against the USPTO challenging OTDP rejections.

As noted above, data reported by Prof. Crouch indicate that about 18% of patents granted in 2023 had a terminal disclaimer. In its economic impact analysis, the NPRM estimates that about 20% of small entity applicants faced with an OTDP rejection would try to avoid filing a terminal disclaimer by arguing against the rejection or amending the claims, but the NPRM does not explain how it arrived at that figure. *See* 89 Fed. Reg. at 40446. If the proposed changes to terminal disclaimer practice are implemented, BIO expects its members (which include many small business concerns) would scrutinize OTDP rejections and challenge them whenever there was a basis for doing so, including pursuing *ex parte* appeals and district court litigation against the USPTO when warranted.

B. The Alternative Strategies Suggested in the NPRM Would Increase Costs

The NPRM outlines several options applicants could pursue to avoid having to file a terminal disclaimer to obviate an OTDP rejection. As presented at 89 Fed. Reg. 40444, these include:

> (1) combining the conflicting claims into a single application,
>
> (2) 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,
>
> (3) arguing that rejected claims in the application are patentably distinct from the claims of the reference patent or application, or
>
> (4) 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.

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.

Many of these options are impractical, and may not even be possible for a given application or operate to overcome a given OTDP rejection. For example, options (1) and (2) and the final alternative would not be options if the OTDP rejection is based on a granted patent, and option (4) may not be an option depending on the subject matter being pursued. Additionally, any of these options could significantly complicate examination, and many would incur significant USPTO fees in addition to attorney fees for determining and implementing the proposed strategies.

The NPRM also overstates the ease with which a terminal disclaimer can be withdrawn, and its guidance on the impact of a terminal disclaimer filed in an abandoned application is directly contrary to current MPEP guidance. The NPRM states repeatedly that a terminal disclaimer can be withdrawn before the subject application grants, such as if the claims are amended in a manner that avoids OTDP. *See* 89 Fed. Reg. 40444. As noted in the NPRM, that requires filing a petition under 37 CFR § 1.182, as explained in MPEP § 1490(VIII). However, the cited section of the MPEP only indicates that "nullification of an erroneously filed recorded terminal disclaimer" can be sought by a petition "[u]nder appropriate circumstances, consistent with the orderly administration of the examination process." But in contrast to the optimistic tone of the NPRM, the MPEP states that petitions seeking to reopen the question of the propriety of the double patenting rejection that prompted the filing of the terminal disclaimer "have not been favorably considered." MPEP § 1490(VII).

Instead, the MPEP counsels "filing of a continuing application … while abandoning the application in which the terminal disclaimer has been filed." Importantly, according to the NPRM, abandoning an application in which a terminal disclaimer has been filed would not nullify the effect of the proposed rule changes if the terminal disclaimer indirectly linked another patent or application to the reference patent, as explained below.

Returning to examples 2 of the NPRM (W ← X ← Y), the NPRM states that the terminal disclaimer filed in Y over reference application X indirectly links Y to W even if application X is abandoned. *See* 89 Fed. Reg. 40443. Thus, according to the NPRM, even if application X is abandoned to avoid the effect of the terminal disclaimer filed in Y over X (as counseled by MPEP § 1490(VIII)), invalidation of any claim in W under § 102 or § 103 still would render all claims of Y unenforceable. Indeed, according to the NPRM, the only way to avoid the indirect effect on Y of the terminal disclaimer tying X to W would be to successfully withdraw that terminal disclaimer before Y grants as a patent. (Presumably, another option would be to withdraw the terminal disclaimer filed in Y tying Y to X, but the NPRM does not propose this approach.)

This guidance in the NPRM represents another significant change in current terminal disclaimer practice that the USPTO has not justified. The USPTO is simultaneously conditioning significant consequences on a terminal disclaimer while making it difficult to avoid the effects of a terminal disclaimer filed in an application intended to be abandoned. Moreover, the USPTO has not explained why indirect tying (as illustrated in example 2 between Y and W) should be so difficult to undo. As discussed above, the fact that Y does not require a terminal disclaimer over W indicates that the claims of Y are patentably distinct from the claims of W. Thus, making it difficult to extricate Y from potential invalidity of a claim of W seems punitive.

C. The Economic Impact Analysis Is Incomplete and Inaccurate

The economic impact analysis set forth in the NPRM is incomplete and inaccurate in several respects. For example, the NPRM does not account for prosecution strategies applicants may pursue in order to reduce the likelihood of receiving an OTDP rejection, such as pursuing more claims in a given application, which would increase both the applicant's costs and the USPTO's examination burden.

With regard to the estimated costs of addressing OTDP rejections, the economic impact analysis estimates that about 50% of the responses filed in small entity applications to avoid filing a terminal disclaimer (e.g., by arguing against the OTDP rejection or amending the claims) would not be successful, but the NPRM again does not explain how it arrived at that figure. *See* 89 Fed. Reg. at 40446. While the NPRM accounts for estimated attorney fees for one additional response to try to avoid filing a terminal disclaimer, it does not account for the possibility that more applicants would appeal OTDP rejections, and so does not account for attorney fees or USPTO fees associated with an *ex parte* appeal. Nor does the economic impact analysis account for the possibility that applicants would pursue the other options suggested for avoiding a terminal disclaimer discussed above. As noted above, many of the options would incur significant USPTO fees in addition to attorney fees for determining and implementing the proposed strategies, none of which are accounted for in the economic impact analysis.

It also is surprising that the economic impact analysis does not take into account the proposed changes to the terminal disclaimer fee schedule set forth in the pending Fee-Setting NPRM. As shown in the table below, under the proposed fee changes, the fee for filing a terminal disclaimer would increase throughout the course of prosecution, from $200 if filed before an OTDP rejection is made to $800 if filed after a final rejection (e.g., after an unsuccessful attempt to avoid filing a terminal disclaimer), and even higher if filed on or after a notice of appeal. *See* Notice of Proposed Rulemaking for Setting and Adjusting Patent Fees during Fiscal Year 2025 89 Fed. Reg. 23226, 23248 (April 3, 2024) (the "2025 Fee-Setting NPRM").

TABLE 14—TERMINAL DISCLAIMER FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Terminal disclaimer, filed prior to the first action on the merits.	Undiscounted	$170	$200	$30	18	n/a
Terminal disclaimer, filed prior to a final action or allowance.	Undiscounted	170	500	330	194	n/a
Terminal disclaimer, filed after final or allowance	Undiscounted ...	170	800	630	371	n/a
Terminal disclaimer, filed on or after a notice of appeal.	Undiscounted ...	170	1,100	930	547	n/a
Terminal disclaimer, filed in a patented case or in an application for reissue.	Undiscounted ...	170	1,400	1,230	724	n/a

The economic impact analysis fails to take into account the higher terminal disclaimer fee applicants would have to pay if they try to avoid filing a terminal disclaimer but subsequently file one, e.g., after the OTDP rejection is maintained in a final Office action.

In this way, the present NPRM is inconsistent with the proposed changes to the terminal disclaimer fee schedule. As outlined above, the new fee schedule would penalize applicants who do not file a terminal disclaimer before an OTDP rejection even has been made, and further penalize applicants who try to avoid filing a terminal disclaimer. Yet, under the proposed changes to terminal disclaimer practice of the present NPRM, filing a terminal disclaimer would be a weighty decision that would not be taken lightly, and voluntarily filing a terminal disclaimer could be a risky undertaking unless the need for a terminal disclaimer was certain.

The NPRM also estimates some applicants will enjoy savings by not filing a terminal disclaimer (because of the associated fee), but the justification for this calculation is hard to follow. The USPTO starts with an estimate of 175,500 Office actions issued in small entity applications per fiscal year, assumes 24,570 (14%) of those would have an OTDP rejection, and 20% of those (4,914) would not be addressed by a terminal disclaimer. The USPTO estimates that 50% of the attempts to avoid filing a terminal disclaimer by arguing against the rejection or amending the claims will be unsuccessful, *i.e.*, that attempts in 2,457 applications will be unsuccessful. That should mean a terminal disclaimer would be avoided in 2,457 applications (i.e., in the other 50% of applications), but the USPTO calculates savings for all 4.914 applications. The only way that could occur is if the applications that were unsuccessful in avoiding the OTDP rejection are abandoned. Thus, by the USPTO's own economic impact analysis, the NPRM would result in abandonment of 2,457 small entity applications in its sample fiscal year, which could represent valid patent rights that would not be granted or available to support investment and economic activity. BIO again questions the USPTO's motivation for promulgating a rule that would have such a negative impact on the grant of U.S. patents.

D. The NPRM Would Disparately Impact Small/Emerging Companies and Universities

As outlined above, BIO believes the economic impact analysis provided in the NPRM understates the likely impact on small entities, including small/emerging companies and universities. Such entities have limited budgets and often must spread out their patent costs, and so cannot afford to pursue all claim scope in a single application or pursue the other costly strategies for avoiding a terminal disclaimer suggested in the NPRM. These entities may be more likely to file a terminal disclaimer for short-term budgetary reasons, even if the OTDP rejection could be challenged, and even if doing might undermine the value of their patent portfolios.

E. The NPRM Could Undermine USPTO Operations

If the NPRM has its intended effect, it could result in fewer patent applications being filed, which would result in a loss of revenue for the USPTO. BIO notes that the 2025 Fee-Setting NPRM does not take into account the possible impact of the present NPRM on USPTO workload or revenue. While the USPTO would enjoy cost savings from not having to process or examine applications that are not filed, the examination costs for applications tied by terminal disclaimers are likely to be lower than for other applications (because, for example, the examiner may already

be familiar with the technology and prior art). Thus, by forgoing filing, search, examination, issue, and maintenance fees for applications that could be examined efficiently, the USPTO may be undermining its own operating cost estimates.

Further, neither the present NPRM nor the 2025 Fee-Setting NPRM take into account the increased burden on the examining corps and the PTAB that will be associated with the increased challenge of OTDP rejections, which could result in more Office actions per application and a greater number of *ex parte* appeals. The USPTO is already struggling with a historically high backlog of unexamined applications. The proposed changes to terminal disclaimer practice could further exacerbate the backlog by increasing the resources required to examine applications with OTDP rejections.

VI. Conclusion

As explained above, BIO believes the proposal laid out in the NPRM suffers from too many fundamental flaws to be salvageable by amending or modifying it. BIO regrets that the USPTO made no apparent effort to engage with the extensive factual record that was developed during last year's "robust and reliable patents" and FDA-PTO "collaboration" RFCs. BIO is interested in, and ready to, work with the USPTO on common-sense solutions for enhancing patent quality to the highest attainable standards, but the NPRM is not one of them.

For all the foregoing reasons, BIO urges the USPTO to withdraw this NPRM.

Respectfully submitted,

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