THE BOSTON INTELLECTUAL PROPERTY LAW ASSOCIATION

July 9, 2024

Via Federal eRulemaking Portal: *www.regulations.gov*
Docket No. PTO-P-2024-0003

Attn: Katherine K. Vidal, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

Re: Notice of Proposed Rulemaking on Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting

Dear Honorable Director Vidal:

The Boston Intellectual Property Law Association ("BIPLA"), formerly the Boston Patent Law Association, wishes to thank the United States Patent and Trademark Office ("USPTO") for the opportunity to respond to the Notice of Proposed Rulemaking regarding terminal disclaimer ("TD") practice to obviate nonstatutory (a.k.a. obviousness-type) double patenting ("OTDP"). *See* 89 Fed. Reg. 40439 (May 10, 2024) ("the NPRM").

Established in 1924, the BIPLA is an association of more than 600 intellectual property ("IP") professionals, providing educational programs and a forum for the exchange of ideas and information concerning patent, trademark, copyright, and other intellectual property laws in the First Circuit, focusing on the greater Boston area. The membership of the BIPLA includes IP professionals working in all areas of science and technology, including pharmaceuticals, biotechnology, medical devices, chemistry, electrical engineering, mechanical engineering, and computer technologies. Members include in-house counsel, as well as attorneys in private practice and academia. The membership also includes IP professionals working in non-patent matters including trademark, copyright, and trade secrets. All are sensitive to developments in the law that affect American business.

The BIPLA submits these comments solely as its consensus view. It should be noted that, in many cases, issues of confidentiality and privilege constrain the public identification of specific clients and examples. Accordingly, the following comments may reflect the anecdotal experiences of the BIPLA's membership. They are not necessarily the views of any individual member, any firm, or any client.

The BIPLA appreciates efforts by the USPTO to engage its stakeholders regarding proposed changes to Patent Office practice. As an organization, we believe that the bargain laid out in the US patent laws, and grounded in the Constitution—the grant of a limited monopoly for useful, new, nonobvious inventions in exchange for their disclosure for the public benefit and use—is critical to incentivizing innovation across many sectors and strengthening the American economy and businesses of all sizes.

I. Overview of Response to NPRM

While the BIPLA is aligned with the USPTO's stated goal of promoting innovation and competition, the BIPLA respectfully submits that the proposals in the NPRM are overly broad and run contrary to statutory language and intent. Moreover, the proposed rule would exceed the USTPO's authority granted to it by Congress because it amounts to substantive rulemaking. Finally, while the NPRM appears to attempt to implement policy, which is the exclusive purview of Congress, the BIPLA encourages the USPTO to consider the far-reaching nature and impact of the proposed rule, and the substantial likelihood that its implementation would have an effect diametrically opposed to its indicated purpose.

II. The Proposed Rule Contravenes the Patent Statute and is Overly Broad

The NPRM in effect proposes a rule that can invalidate[1] the claims of a first patent based on a finding (or even an allegation, if followed by the filing of a statutory disclaimer) of invalidity of a single claim in a second patent, without substantive assessment of the validity of the claims of the first patent.

First, this rule violates the law on continuing applications, *i.e.*, that a continuing application "shall have the same effect" as to the disclosed subject matter as though filed on the date of the prior application, provided compliance with specified timing and disclosure requirements. *See* 35 U.S.C. § 120 (2012); *see also Tafas v. Dudas*, 541 F. Supp. 2d 805, 815 (E.D. Va. 2008). Allowing the invalidation of all of the claims in a continuation patent based on results for a single claim in a parent patent contravenes this provision.

Second, even beyond the context of continuing applications, the proposed rule violates numerous statutory provisions by allowing invalidation of all of the claims in a first patent based solely on a finding or allegation (if followed by a statutory disclaimer filed for any reason) of invalidity of any claim in a second patent, without a substantive determination of unpatentability of the claims in the first patent. For example, the Patent Act provides that "[a] person shall be entitled to a patent unless" the claimed invention lacks novelty or is obvious in view of the prior art. 35 U.S.C. §§ 102, 103; *see also Tafas*, 541 F. Supp. 2d at 817. Moreover, the Act prohibits the automatic invalidation of any claim based on the invalidation of a separate claim. 35 U.S.C. § 253(a) ("Whenever a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid."). Similarly, Section 282 of the Act provides that "[e]ach claim of a patent . . . shall be presumed valid independently of the validity of other claims." 35 U.S.C. § 282. In addition, the proposed rule would impermissibly eliminate statutory requirements on the allocation of burden for demonstrating invalidity of claims. *See Id.* ("The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity."). Allowing invalidation of claims without the statutorily required individual analysis under assigned burdens is contrary not

[1] While the proposals in the NPRM on their face implement voluntary declarations of patent enforceability (rather than validity), this is a distinction of form, but not substance–tying enforceability of one patent to a finding or allegation of invalidity in other patents nullifies any meaningful distinction.

only to each of these laws, but also the doctrine of OTDP itself, which has, since its creation, been based on a substantive determination of unpatentability. *See Odiorne v. Amesbury Nail Factory*, 18 F. Cas. 578 (C.C.D. Mass. 1819) ("[i]t cannot be" that a patentee can obtain two patents in sequence "substantially for the same invention[] and improvements"; "it would completely destroy the whole consideration derived by the public for the grant of the patent, *viz.* the right to use the invention at the expiration of the term") (J. Story); *McCreary v. Penn. Canal Co.*, 141 U.S. 467 (1891) (a second patent is void if it is "identical with… or only a colorable variation" of a first patent).

In addition, the NPRM itself makes clear the overbreadth of the proposed rule. In particular, Example 3 sets forth a situation in which the invalidation of a claim in a great-grandchild patent "Z" can result in the invalidation of all of the claims in the ultimate parent patent "W," without consideration of any substantive differences between the claims in the two matters or the fact that the intervening matters "X" and "Y" (whose claimed subject matter was presumably the basis for the required "linking" terminal disclaimers filed in those matters) may have been abandoned or have not yet issued.

$$W \leftarrow X \leftarrow Y \leftarrow Z$$

In other words, under the proposed rule, invalidation of a single claim in patent Z would result in invalidation of all of the claims of patent W, regardless of whether the invalidated claim in patent Z was, with respect to the claims of patent W:

(i) narrower;
(ii) broader;
(iii) of overlapping scope;
(iv) directed to related, but non-overlapping subject matter; or
(iv) directed to entirely unrelated subject matter.

Moreover, the impact would be the same even if the claims of patent W had been previously unsuccessfully challenged in post-grant or district court proceedings, effectively giving patent challengers unwarranted and immensely powerful multiple "bites at the apple."

The BIPLA respectfully submits that this overbreadth is at best difficult to rationalize, and at worst nonsensical–the type of "radical change[]" raised by five former USPTO Directors, Deputy Directors, and Patent Commissioner in their letter to you dated May 30, 2024 ("the May 30, 2024 Former USPTO Officials' Letter").

III. The NPRM Exceeds the Authority Granted to the USPTO by Congress

The BIPLA also respectfully submits that the proposals in the NPRM represent a *de facto* substantive change in law, effectively implementing a new ground for invalidating patents. Such substantive lawmaking is the exclusive purview of Congress, and not the USPTO. *See Tafas*, 541 F. Supp. 2d at 813. While the NPRM cites to a decision from the predecessor court to the Federal Circuit Court of Appeals, that decision is inapposite here. *See In re Van Ornum*, 686 F.2d 937 (C.C.P.A. 1982).

In particular, the court in *Van Ornum* codified a practice previously endorsed by the courts, and directly addressed one of the policy justifications underlying the judicially created doctrine of OTDP. *See id.* at 945, 947. In contrast, the NPRM contradicts extensive precedent from the Federal Circuit that TDs are procedural devices, and not admissions of obviousness. *See Simpleair, Inc. v. Google LLC*, 884 F.3d 1160, 1167 (Fed. Cir. 2018) ("our cases foreclose the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims."); *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007) ("A terminal disclaimer is simply not an admission that a later-filed invention is obvious."); *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 941 (Fed. Cir. 1992) (stating that "the critical premise" to appellant's argument that "by filing the terminal disclaimer, [patentee] admitted to obviousness-type double patenting) is wrong. The terminal disclaimer filed in [the target patent] did no more than give up the portion of the patent term beyond the expiration date of the [reference] patent. It did not concede double patenting with relation to any other patent."); *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) ("In legal principle, the 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. It is improper to convert this simple expedient of 'obviation' into an admission or acquiescence or estoppel on the merits."). As explained in the May 30, 2024 Former USPTO Officials' Letter, "[t]he proposed rules run counter to decades of patent practice, undermining long-settled expectations."

IV. The USPTO Should Consider the Unintended Consequences of the Proposed Rule

The stated purpose of the NPRM is simplification of patent disputes–"[n]arrowing validity disputes in litigation to only one [] patent could result in more focused claim construction hearings, lower litigation costs, and faster resolution." 89 Fed. Reg. at 40440. First, as discussed in detail below, while allowing the invalidation of a claim for OTDP without a substantive showing of obviousness may potentially reduce litigation costs, it is substantially likely to increase the cost and effort for applicants to secure claims in the first place (or even prevent them from obtaining those claims at all). This is effectively a cost-shifting measure–a matter of policy that should be left to Congress, and not an administrative agency like the USPTO. In addition, Federal district courts already have at their disposal (and routinely implement) various mechanisms to manage patent litigation. *See, e.g.*, 28 U.S.C. § 2071; *In re Katz Interactive Call Processing Patent Litigation*, 639 F.3d 1303 (Fed. Cir. 2011).

But even setting aside the inappropriateness of the USPTO using rulemaking to affect patent policy, the USPTO appears to have not thoroughly considered the actual impacts this Rule would have. As explained in more detail below, the BIPLA is concerned that the outcome of this rulemaking would be contrary to what appears to be its intended purpose, and, indeed, the very rationale set out for the protection of IP in the Constitution.

1. Context May Illuminate the Intent of the NRPM

The BIPLA believes that recent action from both the executive and legislative branches may provide informative context for the NPRM that sheds light on its intended purpose. The NPRM itself makes reference to President Biden's July 9, 2021 Executive Order 14036 on ''Promoting Competition in the American Economy,'' stating that the NPRM "is intended to promote competition by lowering the cost of challenging groups of patents tied by terminal disclaimers, resulting in reduced barriers to market entry and lower costs for consumers." 89 Fed. Reg. 40440.

While the NPRM does not mention prescription drug pricing, this was a clear focus of not only the Executive Order, but also subsequent correspondence and action from the USPTO, the Federal Food and Drug Administration ("FDA") and members of Congress. *See* September 10, 2021 letter from Acting FDA Commissioner Janet Woodcock to Acting Under Secretary of Commerce for IP and USPTO Director Andrew Hirshfeld, *available at* https://www.uspto.gov/sites/default/files/documents/EO14036-FDALettertoPTO.pdf (last visited Jul. 8, 2024) ("September 10, 2021 Letter from Woodcock to Hirshfeld"); June 8, 2022 letter from United States Senators Patrick Leahy, Richard Blumental, Amy Klobuchar, John Cornyn, Susan M. Collins, and Mike Braun to Director Vidal, *available at* https://www.collins.senate.gov/imo/media/doc/patent_letter.pdf (last visited Jul. 8, 2024) ("June 8, 2022 Letter From Six U.S. Senators"); July 6, 2022 letter from Director Vidal to FDA Commissioner of Food and Drugs Robert M. Califf, *available at* https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf (last visited Jul. 8, 2024) ("July 6, 2022 Letter from Vidal to Califf"); January 19, 2023 Joint USPTO-FDA Public Listening Session on Collaboration Initiatives, *summary available at* https://www.uspto.gov/about-us/events/joint-uspto-fda-public-listening-session-collaboration-initiatives (last visited Jul. 8, 2024).

Notably, this activity repeatedly mentioned "patent thickets" allegedly held by "drug companies," and suggested implementing restrictions on continuing application practice and rules around TDs to attempt to enhance competition and enable access to lower-cost drugs. Indeed, these letters explicitly target the filing of continuing applications by life sciences companies as a purported problem, and raise the possibility that the filing of a TD could be considered an admission of obviousness, causing these patents to "stand and fall together." *See* September 10, 2021 Letter from Woodcock to Hirshfeld, pg. 3; June 8, 2022 Letter From Six U.S. Senators, pg. 2; July 6, 2022 Letter from Vidal to Califf, pg. 6.

While the BIPLA does not agree with the assumptions underlying the views expressed in these letters and other actions, particularly to the extent that they are not well-supported by validated data, this history provides important context that suggests that the intent of the NPRM was to target continuing applications related to drug and biologics patents filed by large life sciences companies, with the goal being to lower prescription drug prices. However, the USPTO's own recent research[2] demonstrates the weakness of the underlying premises. *See* USPTO Drug Patent and Exclusivity Study Report, June 12, 2024, *available at* https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf (last visited Jul. 8, 2024) (hereinafter the "2024 USPTO Report" or "Report"). For example, the 2024 USPTO Report seems to caution against blindly targeting so-called "patent thickets" because "simply quantifying raw numbers of patents and exclusivities is an imprecise way to measure the intellectual property landscape of a drug product because not every patent or exclusivity has the same scope." *Id.* at 57. Indeed, the USPTO's analysis found that "[f]or several products studied, generics were launched before the expiration of all applicable Orange Book-listed patent and exclusivity time periods for that product," such that "a higher number of patents may not necessarily delay a generic launch." *Id.* at 58, 59. The Report accordingly cautions that "pharmaceutical market exclusivity from the time of NDA approval to the launch of a first generic competitor is influenced by a complex interplay of patent law and FDA statutes and regulations," and "the timing of the entry of generic products is not

[2] The 2024 USPTO Report is based on the USPTO's own analysis (conducted with the assistance of the FDA) of "a representative sample of 25 New Drug Applications (NDAs) (representing 13 distinct active ingredients) listed in the FDA's Orange Book between 2005-2018 that were also considered by these data sources using available public data points." 2024 USPTO Report, at 1. The BIPLA encourages the USPTO to continue its efforts to support its actions based on publicly available and validated data, transparently presenting its methodologies.

fully reflected by a computation of patents and exclusivities and competition could be affected by other factors." *Id.* at 59.

Furthermore, the BIPLA wishes to express its concern, and request that the USPTO seriously consider, that the proposed rule would have an impact far beyond patents related to drugs, the life sciences sector, and large companies. Indeed, in addition to those groups of innovators, substantial negative consequences would be felt on patents related to software and electronics, in the high tech industry,[3] and by small businesses and solo inventors, who are least equipped to bear the attendant high costs of the NPRM's proposed implementation.

Indeed, the BIPLA's consensus view is that the likely impact of the NPRM would be not only to hamper competition, but also to decrease public disclosure of inventions, and thereby stifle innovation.

2. Negative Impact Across Technology Areas

The BIPLA membership has numerous specific concerns about the proposed rule with respect to companies operating in a variety of technology areas. For example, BIPLA members work with dozens of companies in the computer software and electronics area that make extensive use of continuation-in-part applications and TDs to obtain foundational IP enabling them to attract the investment necessary for survival. As another example, companies in life sciences and non-life sciences spaces commonly pursue initial patents to "platform"-type technology, and then file later applications directed to "species"-type innovations. For those companies, under current practice, filing a TD is straightforward and efficient, because they are not seeking to extend the term of protection or obtain multiple patents directed to different aspects of the same product, but instead to obtain more specific protection for the products they develop and later determine are commercially viable.

Under the proposed rule, these practices would be substantially deterred. For example, companies would be faced with the difficult decision of moving towards including all relevant claims in a single, initial application (whether to obtain grant of those claims directly or provoke restriction requirements leading to divisional applications potentially subject to the 35 U.S.C. § 121 OTDP safe harbor), or potentially having to substantively argue against (and, if necessary, appeal) OTDP rejections because the negative consequences of filing a TD would simply be too great, potentially risking the validity of a broad array of patents covering many products. In either case, not only would the cost of patent prosecution be substantially increased, but the timeline for achieving issued patent claims would be significantly extended. Both outcomes would present significant harm to these companies–early issued patents are an enormously important basis for both initial and continued investment that companies of all sizes need to survive in today's difficult economic environment. Additionally, delayed issuance of patents is of no particular benefit to competitors attempting to understand and assess the risks of entering a particular space before significant investment and launching of products. In the end, companies would have less resources and support for innovation, and might decide against seeking patent protection at all, thus reducing innovation, competition, and disclosure of information.

[3] The USPTO appears to be aware of the potential impact of this rule across technology areas. 2024 USPTO Report, at 58 ("With respect to multiple patents that cover a single product, multiple patents associated with a single marketed product are not unique to the pharmaceutical industry and are a common practice in many innovative industries, especially for complex products.").

There is also a mismatch between the apparent focus of the NPRM and the temporal aspect of patent term that is important to many companies. Specifically, while the NPRM appears to focus on potential abuses at the terminal portion of patent term, the most valuable term for many companies is the short term (*e.g.*, the next five years), and not, for example, a Patent Term Adjustment period falling 20 years after the earliest effective filing date. But the impact of the NPRM would be felt equally (or perhaps even disproportionately) for companies valuing primarily the early portion of the statutory patent term.

3. Negative Impact On Small Players

Across technology areas, key competition and innovation comes from smaller players, who are already under pressure from the current system because of the high cost of securing meaningful patent protection for their products and services. For many early companies, issued patents can be the most valuable assets they possess, and the primary basis for investment or acquisition. And yet the impact of the NPRM would be disproportionately felt by those smaller players (who can scarcely afford increased prosecution costs).

The same concern was expressed in the May 30, 2024 Former USPTO Officials' Letter, which stated that "[t]he proposal will increase the number of challenges to double patenting rejections and reduce the use of terminal disclaimers. This will, in turn, significantly increase the cost of obtaining patents and the hurdles in enforcing patents. This will disproportionately impact independent inventors, start-ups and small businesses, and other under-resourced innovators."

In particular, the effect of the NPRM on patent prosecution timelines and costs could be lethal for these smaller players. A common current practice for such entities is to file an initial application based on what is most important at the time, often prioritizing prosecution of claims to a single embodiment based on limited funds. The crucial importance of early-issued patents discussed above is especially important for these players–securing funding and investment based on these first patents in the short term is truly an existential requirement, as they attract critical investment, allowing later filings in either continuing, continuation-in-part, or new applications to more specifically claim commercially valuable refinements identified during the development process.

It is necessary for the USPTO to understand and account for the fact that the development of an invention does not stop with application filing, or even with the issuance of a first counterpart in a family. It is common for an applicant to obtain early patents directed to subject matter that later turns out not to be commercially valuable, but that continued development of the disclosed subject matter over the lifetime of a disclosure (often funded with proceeds attracted by those initial patent grants) reveals later embodiments covered by the original disclosure that have more commercial potential. Importantly, the identification of commercially valuable embodiments covered by a patent application's disclosure is something that can only be determined over time, based not only on technological development, but also commercial considerations like conversations with investors, partners and potential partners, identification of markets and sub-markets, and addressing regulatory considerations.

However, if the NPRM were implemented, in order to preserve their ability to obtain claims to those later-identified commercially valuable embodiments, small players would be pushed to avoid filing TDs (or even filing continuing applications at all) because of the risk that a single claim in a commercially irrelevant early patent could be invalidated, wiping out important protection for commercially successful products or services across an

entire family of related patents. Put another way, under the NPRM, filing a TD could risk the whole value of the company. If a patentee realizes that its initial patent claims an invention that is not commercially viable, but additional disclosure in the application (or even additional disclosure to be filed in a new application) could be directed to viable subject matter, prosecuting that subject matter in another application presents an enormous risk.

In addition, as indicated above, under the NPRM, patent applicants would be incentivized to present many claims in a single application to avoid the need for TDs, substantially increasing costs not only by way of excess claims fees, but also due to extended prosecution because of the potential need to argue the claims separately. Patent applicants may also incur additional expense associated with extensions of time as they try to determine, over time, the most commercially valuable embodiments needing protection in the patent they eventually hope to secure.

The natural result of these impacts would be increased argument in patent prosecution, more Requests for Continued Examination ("RCEs") (for which the USPTO has proposed increasing fees, *see* 89 Fed. Reg. 23226, 23247 (Apr. 3, 2024)), more appeals to the Patent Trial and Appeal Board, and generally increased burdens for patent prosecution costs at a time when resources are already scarce. Moreover, rising cost burden and delayed timeline for acquiring issued claims will result in reduced investment in these companies. The very real impact here would be a death knell for many solo inventors, early stage companies, and small businesses, which are often (and correctly) referred to as "the lifeblood of the U.S. economy."

4. Negative Impact on the USPTO

The BIPLA also recommends that the USPTO consider the impact of the NPRM on its own personnel. As discussed above, the NPRM would disincentivize TDs, instead prompting applicants to argue, file RCEs, appeal rejections, add claims to applications (rather than filing multiple continuing applications over the course of years), and file more divisional applications. All of these practices would result in substantial additional burden on the USPTO and its examining corps, as prosecution is more likely to be extended through RCEs and appeals, and demands on examiners will be increased as claim numbers and the number of divisional applications increase. In fact, in applications with large numbers of claims, examiners will be incentivized to issue restriction requirements to help manage their own time budgets for examining new applications. And applicants will be forced to pay exorbitant, non-refundable excess claims fees, only to cancel claims once a restriction requirement is received.

In addition, while double patenting rejections are already presently part of the patent examination process, these rejections do not necessarily apply to all of the claims in an application. As a result, under current practice, there may be incentives for applicants to simply cancel claims subject to OTDP rejections to allow the issuance of some subject matter, with the cancelled claims being presented in a continuing application. But under the NPRM, this incentive would be eliminated, because the impact of simply filing a continuing application represents a risk to not only the parent patent, but any patent or application in the family that is linked by a terminal disclaimer. This would lead to extended prosecution and reduced final disposition of matters, making it even harder for examiners to manage their dockets.

5. Negative Impact on Disclosure and Innovation

The BIPLA membership is also concerned that the NPRM may discourage disclosure and the innovation that comes from making inventions publicly available. In particular, because applicants will understand that prosecution costs are likely to be very high and frontloaded, and later filings to more specific embodiments may not be feasible (or may risk a broad swath of the company's important IP protection), applicants may limit their disclosure of innovations in patent applications and file fewer applications. For example, they might direct patent filings to only broader concepts, leaving more specific disclosures to be protected as trade secrets. This indeed would be a natural reaction, particularly given the potential for indefinite protection of trade secrets under both state and federal law. Unfortunately, this incentive runs directly counter to the very purpose of patent laws as set forth in the Constitution – to promote the progress of science and useful arts.

6. Existing Mechanisms and Incentives Already Address the Policy Concerns Addressed by the NPRM

The USPTO should also consider how existing mechanisms and incentives already address the concerns purportedly addressed by the NPRM. For example, TDs already function to eliminate time-wise extensions of patent term, the main policy concern expressed in the case law that established the OTDP doctrine. *See In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013). In fact, the 2024 USPTO Report states that "[w]hen multiple patent applications are filed by the same patentee to novel but obvious variations of related inventions, the doctrine of non-statutory double patenting prevents patents on these inventions from issuing with a different patent expiration date. Accordingly, the patents tied by terminal disclaimers will have the same patent term . . ." *Id.* at 59. In addition, Applicants are already strongly incentivized to file TDs, rather than argue OTDP rejections, to streamline prosecution. But rather than encouraging TDs, the NPRM would discourage applicants from pursuing that path. In addition, on top of existing OTDP doctrine, estoppel, including both common law estoppel and estoppel set forth in 37 C.F.R. § 42.73(d)(3)(i), already limits patent owners from obtaining patent claims that are not patentably distinct from a finally refused or canceled claim.

Given this context, the BIPLA respectfully submits that the NPRM proposes an overbroad solution in search of a nonexistent problem.

V. The Implied Justifications for the NPRM Are Flawed

Finally, the BIPLA respectfully submits that the proposed rule is supported by two implicit justifications that are fundamentally unsound. First, the proposed rule appears to presume that an applicant has agreed to file a TD because it is in agreement with the examiner that the target claims are patentably indistinct from the reference claims. However, as discussed in Section III, *supra*, TDs are procedural devices, and not admissions of obviousness. TDs instead function to secure the applicant's agreement to disclaim "the terminal part of the statutory term of any patent granted on the [target] application which would extend beyond the expiration date of the full statutory term" of the reference patent. *See* USPTO Manual of Patent Examining Procedure § 1490; USPTO Forms PTO/AIA/25, PTO/AIA/26. In practice, applicants often acquiesce to the filing of a TD in response to an OTDP rejection solely in order to advance prosecution, secure a patent, and avoid getting bogged down in a debate about whether or not they agree with the examiner's position. There may be external factors, such as building company value in the near term, securing funding, avoiding further expenditures, and/or the

marketability of the success that cause a company to take this approach–but these factors have nothing to do with the merits of the rejection.

Second, the proposed rule assumes that invalidation of the broadest claim of one patent among a family of patents linked by TDs necessarily means that all of the narrower claims in all of the linked patents would also be invalidated by the same prior art. However, this is not necessarily the case. The difference between the broad claim and the prior art plus the difference between the broad claim and the narrower claim could result in an overall difference in the narrower claim that is patentably distinct over the prior art. This difference could be even greater if the applicant merely acquiesced to filing the TD, *e.g.*, for external reasons, rather than arguing the double patenting rejection. As discussed in more detail in Section II, *supra*, the validity of each claim must be substantively assessed independent of separate claims.

The BIPLA respectfully submits that these flawed justifications further undermine the implied rationale for the proposed rule.

VI. Conclusion

The BIPLA strongly suggests that the USPTO reconsider, withdraw, or substantially revise the NPRM. In particular, if the USPTO considers a revised rule, it should do so with another NPRM, rather than a final rule, to allow sufficient time and opportunity for further review, evaluation, and comment from stakeholders, including the BIPLA.

The BIPLA appreciates the opportunity to respond to this request, and looks forward to the opportunity to further engage with the USPTO on this issue.

Thank you in advance for your consideration of these comments.

Sincerely,
Boston Intellectual Property Law Association

By: _____

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