



## American Intellectual Property Law Association

July 9, 2024

The Honorable Kathy K. Vidal  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
600 Dulany Street  
Alexandria, VA 22314  
*Via Federal Rulemaking Portal at <https://www.regulations.gov>*

**RE:           Comments on Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting (89 Fed. Reg. May 10, 2024; Notice) due July 9, 2024**

Dear Director Vidal:

The American Intellectual Property Law Association (“AIPLA”) is pleased to have the opportunity to reply to the notice of May 10, 2024, from the United States Patent and Trademark Office’s (“USPTO” or “Office”) Notice of Proposed Rule Making on terminal disclaimer practice to obviate nonstatutory double patenting (the “NPRM”).

AIPLA is a national bar association of approximately 7,000 members that include patent attorneys, patent agents, and other IP professionals engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property (“IP”). Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public’s interest in healthy competition, reasonable costs, and basic fairness.

The Office published the subject NPRM as part of the process for changing 37 C.F.R. §1.321 (the “Proposed Rule”), which relates to statutory disclaimers including terminal disclaimers (“TDs”). The NPRM cites 35 U.S.C. §2(b)(2)<sup>1</sup> for authorization of the change.<sup>2</sup> Through a series of significant proposed edits to the basic framework of TD practice, the Proposed Rule purports to promote competition by lowering the cost of challenging groups of patents tied by TDs. According to the NPRM, this will reduce barriers to market entry and lower costs for consumers, furthering the objectives of Executive Order 14036 on “Promoting Competition in the American Economy.”<sup>3</sup> In particular, the Office characterizes the Proposed Rule as specifying that the Office “will not issue a patent to a common owner or inventor with a claim

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<sup>1</sup> 35 U.S.C. §2(b)(2) states, in part, that the Office may establish regulations, not inconsistent with law, which—  
(A) shall govern the conduct of proceedings in the Office;  
(B) shall be made in accordance with section 553 of title 5;  
(C) shall facilitate and expedite the processing of patent applications . . . ;

<sup>2</sup> NPRM at 40448, col. 1.

<sup>3</sup> 86 FR 36987 (July 14, 2021). NPR at 40440, col. 1.

that conflicts with a claim of a second 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.”<sup>4</sup>

### **Brief Summary of AIPLA’s Comments**

For reasons set forth in detail below, AIPLA believes the Proposed Rule is impermissible and ill-advised as a matter of law and policy, and that it will not have the intended effect. AIPLA opposes the Proposed Rule for several reasons, including the following:

1. The policy reason underpinning the Proposed Rule is not supported by evidence and conflicts with current Office policy;
2. The Proposed Rule is beyond legal power or authority (i.e., *ultra vires*) and conflicts with 35 U.S.C. §§253 and 282;
3. The Proposed Rule is substantive in nature and the Office is therefore not authorized to make such changes, at least because Congress has not delegated substantive rulemaking authority to the Office;
4. The Proposed Rule is legally unsound at least because it is related to a judicial doctrine not a statute;<sup>5</sup>
5. The Proposed Rule is inconsistent with the principle of, e.g., 35 U.S.C. §282, which requires claim-by-claim analysis for patentability;
6. The language of the Proposed Rule is fatally ambiguous;
7. The Proposed Rule would unduly burden applicants and the Office.

### **AIPLA’s Detailed Comments**

#### **1. THE POLICY REASON UNDERPINNING THE PROPOSED RULE IS NOT SUPPORTED BY EVIDENCE AND IS IN CONFLICT WITH CURRENT USPTO POLICY.**

The policy reasons underlying the Proposed Rule lack evidentiary support or justification and, in some instances, are counter to existing USPTO policy. For example, the idea that reducing the enforceability of valid patent claims will increase competition, not only contradicts the evidence but also runs counter to the USPTO’s own positions, as stated in its current Strategic Plan:

The United States has become one of the most innovative and prosperous countries in the world in part because of our strong IP system, which helps drive job creation, economic development and prosperity, U.S. competitiveness, and national security. Our IP system is what helps to incentivize and protect the deep investment of time,

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<sup>4</sup> NPR at 40440.

<sup>5</sup> The Office admits to the nonstatutory nature of the Proposed Rule in the very text of the proposal that would change 37 C.F.R. §1.321(c) and (d) to *nonstatutory* double patenting rather than judicially created obviousness-type double patenting. NPR at 40441, col. 2. See also *Loper Bright v. Raimondo*, 603 U.S. \_\_\_\_ (2024).

money, resources, and collaboration needed to solve problems, deliver solutions, and enrich the lives of many Americans and others around the world.<sup>6</sup>

The NPRM is purportedly justified on the purely speculative view that current TD practice “could deter competition due to the prohibitive cost of challenging each patent separately in litigation or administrative proceedings.”<sup>7</sup> There is no objective basis on which to conclude that current TD practice results in anti-competitive behavior. The existing TD rule is over 40 years old, and the NPRM does not provide any evidence that expanding its scope is needed, appropriate, or will produce the intended result.

In AIPLA’s view, competition stimulates innovation, and patent protection works to protect the value of this innovation for a limited time. Competition and patents, including continuation applications and TD practice, are not inherently in conflict, as the NPRM suggests. Patent and competition laws “are complementary as both are aimed at encouraging innovation, industry, and competition.”<sup>8</sup> The Supreme Court has recognized the importance of competition and the patent system when it stated that “free competition” is “the baseline” on which “the patent system’s incentive to creative effort depends.” By limiting the duration of a patent, “[t]he Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’”<sup>9</sup>

AIPLA recognizes some possibility where the allowance and subsequent enforcement of a questionable patent claim could potentially increase costs necessary to challenge the claim’s validity, but the NPRM advocates a system that goes far beyond that scenario and would require non-enforcement of claims that may very well otherwise be valid and enforceable. As further discussed below, the Proposed Rule should also not be adopted because there is no evidence that it is needed and, as noted above, the policy itself is *contrary* to the USPTO’s current substantive position stated in its own strategic plan.

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<sup>6</sup> See [https://www.uspto.gov/sites/default/files/documents/USPTO\\_2022-2026\\_Strategic\\_Plan.pdf](https://www.uspto.gov/sites/default/files/documents/USPTO_2022-2026_Strategic_Plan.pdf).

<sup>7</sup> NPRM at 40439.

<sup>8</sup> *Atari Games Corp. v. Nintendo of Am.*, 897 F.2d 1572, 1576 (Fed. Cir.1990).

<sup>9</sup> See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (federal patent laws embody “a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.”). See also Federal Trade Commission Executive Summary of “To Promote Innovation: The Proper Balance Of Competition And Patent Law And Policy,” available at <https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrptsummary.pdf>. See also U.S. Const. art I, §8, ¶8.

## 2. THE PROPOSED RULE EXCEEDS AUTHORITY, IS IMPERMISSIBLY SUBSTANTIVE, CONFLICTS WITH JUDICIAL DOCTRINE, AND CONFLICTS WITH 35 U.S.C. §§ 253 AND 282

The NPRM proposes to add an additional requirement for TDs to include a statement that applicants would not enforce *any* claim in a patent subject to such a TD, even if only a single claim is found in conflict.<sup>10</sup> The NPRM also characterizes the proposed requirement as voluntary. This policy is not only ill-advised but is anathema to 35 U.S.C. §§253 and 282. For example, §282 states, in part, that “[E]ach claim of a patent . . . shall be presumed valid independently of the validity of other claims.” The Office’s assertion that a “lose-one claim, lose-all patents” TD penalty is a “voluntary” part of TD practice is disingenuous because the use of a TD to overcome a non-statutory double patenting rejection would *require* an averment that applicants not enforce claims that were not subject to such a rejection.

The Office provides no support in any statute or case law to justify why invalidity of just a single claim should result in the unenforceability of all other claims in the entire patent or even the patent family that includes patentably distinct inventions. In fact, the very statute authorizing disclaimers expressly forecloses this result. “Whenever a claim of a patent is invalid, *the remaining claims shall not thereby be rendered invalid.*” 35 U.S.C. §253(a) (emphasis added).

The language of the Proposed Rule would affect not only the terminal portion of a patent’s term under 35 U.S.C. §253(b), but would also force an applicant to agree that if any claim in the reference patent(s) recited in a TD is held unenforceable or statutorily disclaimed, all claims in the subject application in which the TD is filed would be unenforceable. This is inconsistent with 35 U.S.C. §253(a) on its face.

Further, the Proposed Rule constitutes a “substantive rule” outside of the USPTO’s statutory authority because it impacts the scope of patent rights in one application based on validity determinations in another. The USPTO states that one of the goals of this proposal is “reducing the cost of separately challenging each patent in a group of multiple patents directed to indistinct variations of a single invention.” The USPTO’s approach, however, ignores that the claims in those multiple patents may be and likely are important to protect inventions, and are presumed valid and patentably distinct, one from the other.

The Proposed Rule lowers the bar for invalidating patents by only requiring invalidation of a single claim in a single reference patent to render a group of patents or patent claims unenforceable. Under 35 U.S.C. §282(a), however, each claim of a patent or application must stand or fall on its own merits, which requires the validity of each patent claim to be separately adjudged:

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims.<sup>11</sup>

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<sup>10</sup> See, e.g. proposed changes to 37 C.F.R. §§1.321(c) and (d).

<sup>11</sup> 35 U.S.C. §282(a).

The Proposed Rule also contradicts established case law under which each claim of a patent is its own independent invention; the fact that one claim is found invalid does not necessarily reflect on the validity of any other claim in the patent.<sup>12</sup> The Proposed Rule would ignore this bedrock principle and forces an applicant to “voluntarily” agree that all claims of a subject application (or patent) that is terminally disclaimed against another reference patent would be unenforceable if even a single claim of that other patent was found invalid or was disclaimed.

The Office asserts in the NPRM that the Proposed Rule will reduce applicant burden by switching from a claim-by-claim to a patent-by-patent analysis. This is unsupported and overly simplistic.<sup>13</sup> While it is possible this might reduce the Office’s efforts with respect to TD processing and/or examination, the ambiguous and challengeable nature of the Proposed Rule coupled with the uncertainty of the Proposed Rule itself and the potential impact of the continued expansion of obviousness-type double patenting case law make any such predictions illusory.

Section II.A. of the NPRM describes a confusing and unfounded assertion that the Proposed Rule will not impact the validity of the claims of the subject patent.

The proposed agreement would not affect the validity of the claims in the subject patent, or any patent granted on the subject application because it is a voluntary agreement by the patentee that the patent with the terminal disclaimer will be enforceable only under certain conditions and does not touch on the validity of the claims. The new requirement solves the current problem of requiring a competitor to invalidate multiple patents tied by terminal disclaimers in order to have the freedom to operate. To the extent an applicant believes claims are patentably distinct, they may either challenge the rejection or move those claims to an application in which a terminal disclaimer has not been, and will not be, filed.<sup>14</sup>

The assertion that the validity of the claims of the subject patent would not be affected by filing a TD in accordance with the Proposed Rule is disingenuous. The impact of the Proposed Rule is broader than just an admission that certain claims in the subject patent may be patentably indistinct from the reference patent(s). Under the proposed changes, *all* the claims in the subject patent would become unenforceable if a TD is filed even if only a single claim is rendered invalid in a reference patent. The patentee will be foreclosed from asserting the subject patent in litigation and arguing for the patentability of any claims in the subject patent for which a non-statutory double patenting rejection was not made during prosecution. This outcome most certainly impacts the validity of the claim of the subject patent.

Additionally, the Office lacks substantive rulemaking authority to execute policy outside of a narrow ability to interpret certain statutes. The Proposed Rule is clearly not interpreting a statute, nor does it reflect a required or called-for change in patent examination practice or

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<sup>12</sup> See, e.g., *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, finding there is no presumption that a child patent subject to a terminal disclaimer was patentably indistinct from its parent patents.

<sup>13</sup> See NPRM at section II.A.

<sup>14</sup> See NPRM at 40441.

procedure. Furthermore, the Office's reliance on Executive Order 14036 ("Promoting Competition in the American Economy"<sup>15</sup>) does not cure this defect.

Regarding advancement of a policy agenda to promote competition as a rationale for the proposed changes, the USPTO states that the NPRM is designed to "strike[s] a balance between incentivizing innovation in the first instance while providing more certainty to competitors and the public." The NPRM asserts that in response to "public feedback" the Proposed Rule would add a third condition to TDs for the stated goal of "reducing the cost of separately challenging each patent in a group of multiple patents directed to indistinct variations of a single invention." The NPRM does not cite any specific public feedback to support its position.<sup>16</sup>

The Proposed Rule is contrary to existing law, exceeds the Office's rulemaking authority, and would constitute a significant and negative shift in patent policy. AIPLA has concerns that the underlying motivation for the rules package includes inaccurate narratives regarding patenting practices in certain technology sectors. These inaccurate narratives are leading to policy proposals, including the current one, that will have adverse impacts across all technology sectors. Various sectors utilize TDs in the process of protecting their innovations. In one report, data indicated that increase in use of TDs spanned various diverse types of entities, suggesting the NPRM's widespread impact that would affect "a broad swath of the innovation ecosystem".<sup>17</sup>

The Office also cites *In re Van Ornum*, 686 F.2d 937 (C.C.P.A. 1982) for its rulemaking authority for the instant rule. *In re Van Ornum* provides no such authority to the Office. This decision addressed the 1982 version of 37 C.F.R. §1.321. Then, the C.C.P.A. found that Rule 1.321 was within the Office's authority because it was merely interpretive of 35 U.S.C. §253, which is directed to statutory disclaimers, not patent enforcement.

Here, however, the NPRM lays out substantive changes addressing TD practice for double patenting rejections by first altering the language of the Rule from being related to "obviousness-type double patenting" to being related to "nonstatutory double patenting." This change in wording highlights the Office's acknowledgement in the NPRM that there is no statute being interpreted or implemented. Here, the Office, in calling the Proposed Rule as addressing nonstatutory double patenting, acknowledges the lack of statutory basis for the proposal. Further, the NPRM fails to provide any insight into the scope of nonstatutory double patenting versus obviousness-type double patenting currently recited in 37 C.F.R. §§1.321(c) and (d).

In addition, the Supreme Court recently clarified in *Loper v. Raimondo* that governmental rulemaking requires some antecedent statutory authority, or clarification of some statutory ambiguity.<sup>18</sup> In light of the Supreme Court's decision in *Loper*, even agency interpretations are limited. While the Office relies upon *In re Van Ornum* for their instant rulemaking effort, following *Loper* the Office should look to Judge Baldwin's dissent in *In re Van Ornum* instead because that is more consistent with Supreme Court's *Loper* decision. Judge Baldwin

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<sup>15</sup> NPRM at 40440, col. 1.

<sup>16</sup> NPRM at 40439.

<sup>17</sup> See, "Terminal Disclaimers: A Growing Concern in Patent Practice", May 10, 2024, by Dennis Crouch.

<sup>18</sup> *Loper Bright Enterprises v. Raimondo*, 603 U. S. \_\_\_\_ (2024).

unequivocally denies the Office's authority for issuing even the currently present rule 37 C.F.R. §1.321. Judge Baldwin, in his dissent, states:

Appellants challenge the validity of Rule 321(b) arguing that it is contrary to law in that it goes beyond the rulemaking authority of the Commissioner of Patents and Trademarks (Commissioner) and it extends the Commissioner's authority to govern post-patent issuance conduct of patentees. These arguments are persuasive. . . . The Commissioner has exceeded his authority by attempting to govern by regulation the acts of patentees and the enforceability of patents.<sup>19</sup>

Simply put, the Proposed Rule – to affect enforceability and extend to claims that are not in conflict with those already issued – floats untethered to anything but the changing tides of public policy.

Based on the above:

1. The Proposed Rule lacks any antecedent bases in statute or judicial doctrine to justify the use of the limited rulemaking authority provided under 35 U.S.C. §2(b).
2. The Proposed Rule is substantive in nature because it would force an applicant to disclaim statutory rights.
3. The Proposed Rule is impermissible because the Office lacks substantive rulemaking authority.
4. The 1982 CCPA findings in *In re Van Ornum* are insufficient to remedy points 1-3, above.

### **3. THE PROPOSED RULE IS FATALLY AMBIGUOUS**

The Proposed Rule would require an applicant to eschew enforceability of otherwise patentable claims unless the subject patent was “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...”<sup>20</sup>

The NPRM at pages 40442 and 40443 attempts to define direct and indirect tying between patents and applications. Such language used in the Proposed Rule is untethered to any statutory, regulatory, or case law language or authority. The Proposed Rule is inherently ambiguous as there is no basis in the law from which to understand the words, interpret them or estimate their legal significance.

Also, the Office's attempt to define a regulatory term by descriptive discussion in an NPRM is untenable. Because these are new terms, used in a new way, the Proposed Rule is tantamount to legislation, which is impermissible. No amount of discussion in a Federal Register Notice can cure this vagueness. For this reason alone, the NPRM should be withdrawn.

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<sup>19</sup> *In re Van Ornum* at 14, emphasis added.

<sup>20</sup> Proposed Rule at 37 C.F.R. §§1.321(c)(3)(ii) and (d)(3)(ii).

## 5. SUGGESTED WORK-AROUNDS WOULD BE UNTENABLE, EXPENSIVE, AND FURTHER BURDEN THE OFFICE AND APPLICANT

The NPRM provides a list of alternative ways to address obviousness-type double patenting including, (1) combining the conflicting claims into a single application, (2) canceling or amending conflicting claims, (3) arguing that rejected claims in the application are patentably distinct from the claims of the reference patent or application, (4) filing a reissue application of the patent whose claims formed the basis of the nonstatutory double patenting, or (5) an applicant may separate the patentably distinct claims into another application.

Each of these alternatives is already available to applicants. None offers a solution that is beneficial to the Office or to the applicant. To be sure, the first three options are routinely practiced by some practitioners today; however, each is an incomplete solution. For example, valuable claims are sometimes only identified *after* an initial application has issued as a patent, and filing a reissue application limits the scope of subject matter that can possibly be recaptured. Furthermore, a spike in reissue patent application filings would only result in an increased burden on the Office.

The suggestion that any rejected claim may be somehow separated into another patent application, if followed to its logical conclusion, would *increase* the number of patent applications filed through the continuation process. When different subsets of claims are subject to different obviousness-type double patenting rejections, separating claims into different applications based on the nuance of each obviousness-type double patenting rejection could *exponentially* increase the number of continuation applications filed.<sup>21</sup> This alone would also increase costs for applicants and the Office. There will be many applicants facing a profound conundrum – they will not be able to afford the costs of such a multiple claim or patent approach, the costs associated with protracted arguments about obviousness-type double patenting, or costs in one or more appeals, etc. For applicants, filing more patent applications is simply unduly burdensome.<sup>22</sup>

The proposed change would also force patent applicants to make important decisions *prematurely* in prosecution. This would increase the burden on the applicant, especially small and medium-sized entities with limited resources, at a very early stage (i.e., early in a patented product's life cycle). Furthermore, being forced to file patent applications earlier or develop complex claim strategies will unnecessarily complicate and time compress filing and litigation strategies, and increase upfront costs.

Also, patent application pendency would only increase under the Proposed Rule for reasons outlined above. Instead, today applicants provide a TD to compact and simplify prosecution, enabling them to focus on more important legal issues, such as eligibility, novelty, and obviousness.

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<sup>21</sup> Claim interpretation alone could become enigmatic, considering the differences between USPTO interpretation versus a court's interpretation of claims and claim language interrelatedness.

<sup>22</sup> When considered together with the proposed fee increases (see USPTO Setting and Adjusting Patent Fees During Fiscal Year 2025 (89 Fed. Reg. 23226, April 3, 2024) the combined effect could dramatically reduce innovation, patenting, and imbalance competition.



In sum, the alternatives offered in the Notice are either (a) already utilized by practitioners to avoid filing a TD or (b) options that would cut severely against the Office's stated goals.

## 6. ADDITIONAL CONCERNS

AIPLA notes that it is unclear whether the Proposed Rule would have retroactive effect, thereby substantially affecting patentees' existing rights. Clarification is required.

### *NPRM §IV.A. Administrative Procedures Act (APA)*

For the reasons already set forth, AIPLA disagrees with the proposition that the Proposed Rule “involve[s] rules of agency practice and procedure, and/or interpretive rules, and do[es] not require notice-and-comment rulemaking.”<sup>23</sup> The Proposed Rule is substantive in nature and beyond the scope of at least 35 U.S.C. §2(b). For this reason alone, the NPRM should be withdrawn.

### *NPRM §IV.B. Regulatory Flexibility Act (RFA)*

AIPLA questions the assumptions underpinning the Office's conclusion that the Proposed Rule will not have “a significant economic impact on a substantial number of small entities.” There is no reasoning for the estimate by the Office that only about 20% of small entity owners would not file a TD with the agreement contained in the Proposed Rule. If for the reasons already explained, most small entity owners elect to challenge and appeal obviousness-type double patenting rejections instead of filing a TD under the Proposed Rule, the assertion that the proposed changes would not create an economic impact of more than \$100 million for small entities is not reasonable. Furthermore, the estimates used by the Office only consider the cost of one additional response to an Office action and fail to account for the costs of protracted examination or appeals to the PTAB and/or the Federal Circuit. Even if only a portion of such small entity applicants were forced to pursue such appeals, the costs will quickly surpass the \$100 million threshold. Exceeding this threshold invokes additional rulemaking requirements, as set forth in the Administrative Procedures Act<sup>24</sup> and as set forth by Executive Order 13422.

### *NPRM §IV.J. Executive Order 12630 (Taking of Private Property)*

AIPLA questions the Office's conclusory assertion that the Proposed Rule will not affect a taking of private property. “[P]atents shall have the attributes of personal property.”<sup>25</sup> By requiring a “voluntary” agreement to forego such personal property rights to file a TD, the Proposed Rule on its face creates a potential for the taking of private property.

### *NPRM §IV.K. Congressional Review Act (CRA)*

For the reasons discussed above with respect to the RFA, AIPLA disputes the assertion in this section that the Proposed Rule will not exceed the \$100 million threshold of annual effect on the economy. Even if the Proposed Rule were not *ultra vires* and outside the scope of the

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<sup>23</sup> 89 Fed. Reg. 40445.

<sup>24</sup> See, e.g., 5 U.S.C. §553.

<sup>25</sup> 35 U.S.C. §261.

rulemaking authority of the Office, the Proposed Rule would constitute a “major rule” as defined in 5 U.S.C. §804(2).

*Need for Public Comment*

The NPRM asserts in §IV.A. that the Proposed Rulemaking does not require the notice-and-comment provisions of the Administrative Procedures Act (5 U.S.C. §553 *et seq.*). In particular, the NPRM states:

The changes proposed by this rulemaking involve rules of agency practice and procedure, and/or interpretive rules, and do not require notice-and-comment rulemaking. Nevertheless, the USPTO is publishing this Proposed Rule for comment to seek the benefit of the public’s views on the Office’s proposed regulatory changes.

Here, the Office seems to be, on the one-hand, asking for public input and, on the other, suggesting that they are not bound to consider such input as required, e.g., under 5 U.S.C. §553.

The NPRM, however, fails to provide any basis for this conclusion. For example, the NPRM fails to identify any existing law that is allegedly clarified by the NPRM, let alone show that the NPRM interprets that law. Therefore, the NPRM *prima facie* fails to show that the Proposed Rule is interpretive. As explained in more detail above, the NPRM itself contradicts the Office’s conclusion that the Proposed Rule is merely procedural in that the proposed change would only alter the way Applicants present themselves to the USPTO, i.e., that to obviate a double patenting rejection, an applicant must file a document called a TD in a particular manner.

Further, the NPRM cites Executive Order 14036 (EO) as authority to substantively alter what is required for filing a TD to overcome a double patenting rejection.<sup>26</sup> An EO includes, *inter alia*, policy guidance given to executive agencies. EOs do not carry any imprimatur of law as they are issued by the President. The Constitution expressly grants Congress alone the power to make laws, not the Executive. Reliance on an EO as authority for substantive rulemaking is well outside the constraints of the Administrative Procedures Act.

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<sup>26</sup> NPRM at 40440.

## **Conclusion**

AIPLA appreciates the opportunity to comment on the NPRM regarding changes to terminal disclaimer practice. For reasons set forth above, AIPLA believes the Proposed Rule is ill-conceived, exceeds the Office's authority, and should be withdrawn.

Thank you.

A handwritten signature in cursive script that reads "Ann M. Mueting". The signature is written in dark ink and is positioned above the typed name and title.

Ann M. Mueting

President

American Intellectual Property Law Association