

Frank Cullen, Executive Director Andrei Iancu, Co-Chair David Kappos, Co-Chair Judge Paul Michel (Ret.), Board Member Judge Kathleen O'Malley (Ret.), Board Member

July 9, 2024

#### Via Electronic Submission

The Honorable Katherine 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

### Re: Docket No. PTO-P-2024-0003, Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting

Dear Director Vidal,

The Council for Innovation Promotion (C4IP) welcomes the opportunity to submit comments in response to the notice of proposed rulemaking issued on May 10, 2024, setting forth new requirements that a patent applicant must fulfill in order to file terminal disclaimer for overcoming an obviousness-type double patenting rejection (Docket No. PTO-P-2024-0003).

C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. Founded and chaired by former directors of the U.S. Patent and Trademark Office from previous Democratic and Republican administrations, whose board also includes two retired judges from the Court of Appeals for the Federal Circuit, our nonprofit organization hopes to be a valued partner to those considering policies impacting America's intellectual property system.

C4IP has deep concerns about the current proposal and urges the Office to withdraw it.

As a matter of policy, the proposal will discourage innovators from seeking patent protection via a dramatic and unwarranted change to a routine part of patent prosecution. Costs will increase for both obtaining patents and enforcing them. Applicants will seek to avoid filing terminal disclaimers with this new "poison pill" stipulation. Accused infringers will take advantage of this proposal to attack competitors' portfolios or pressure them into low-value settlements. Investors will be less interested in backing such patents or patent families that could colorably be attacked on this basis. Trade secrets will look ever more promising for those who have that option — a tradeoff that has a big price tag for the public



in the form of knowledge kept out of the public sphere. The Office points to no evidence that this rule is needed, effectively just assuming that it would have the preferred effect of promoting competition. The truth is that it will actually weaken American innovation and competitiveness.

As a legal matter, C4IP believes this proposal exceeds the scope of the Office's rulemaking authority. Even with clear authority to propose rules of this sort, the Office would be foreclosed from promulgating these in particular, as they would contravene both statute and precedent. The proposal will undoubtedly be challenged in the courts. This fight will significantly prolong the harmful impact of this proposal, even if it is ultimately struck down.

In sum, C4IP views this proposal as a negative for U.S. inventors and innovation more generally. It will draw investment away from resource-intensive U.S. research and development, including in vital areas such as quantum computing, energy, and personalized medicine. All of this would be predicated upon an unproven need to more easily invalidate patents already issued by the Office.

We address our concerns in more detail below.

### I. This Proposal Will Inject Significant New Uncertainty into Patents, Harming Inventors, Deterring Investment, and Slowing Innovation

The proposed rules would render entire patents unenforceable if they are tied to another patent by a terminal disclaimer (TD) and even only a single claim in that other patent is found invalid. This proposal is disproportionate in the extreme and will have ripple effects throughout the patent system that ultimately hurt inventors and innovation.

### A. The NPRM will lead to a slower, costlier patent prosecution process for inventors that will negatively impact patent value and startup success

### 1. The proposed rules will frontload prosecution costs

Applicants will be incentivized to avoid filing terminal disclaimers that require this new "poison pill" stipulation. To this end, applicants will be incentivized to include claims directed to all conceivable aspects of their invention in the initial application. This will frontload examination costs for both the Office and the applicant, who will encounter the Office's excess claims fees in addition to greater attorney costs. This higher cost will come before inventors have a clear sense of the commercial value of their inventions and whether they are worth this



cost. Many will not be able to afford these higher upfront costs and will likely choose either to have a patent that covers only part of what they invent or no patent at all.

#### 2. The NPRM will slow the prosecution process

In addition to monetary costs, this proposal will cost time. Examining larger initial claims sets takes longer and will contribute to the already-growing application pendency backlog. If (despite efforts to avoid it) an applicant faces an obviousness-type double-patenting (ODP) rejection, he or she will fight it rather than file a TD. In addition to both the examiner and applicant needing to spend more time on a claim-by-claim analysis of an ODP rejection — a formality that is often short-circuited under the present system — the applicant is likely to pursue an appeal of the examiner's ODP rejection, if it is maintained, to the Patent Trial and Appeal Board (PTAB), another time-consuming process.

### 3. Routine prosecution practices will be disrupted by this NPRM

There are numerous other reasons why applicants may need to seek continuations, which may lead to the filing of a TD, that would be imperiled by the Office's proposal. For example, if applicants find new prior art during the course of prosecution, they will have to disclose it and may need to seek claims of the same scope in a continuation to verify that those claims have been examined in light of all prior art of which applicants are aware. Applicants trying to do the right thing will be rewarded with patents of significantly lesser value.

#### 4. A slower, costlier prosecution will hurt startups

Research has shown that timely issuance of a patent can make a critical difference to startups, leading to increased employment and the ability to attract venture capital funding, among other benefits.<sup>2</sup> The Office's proposal directly undermines an inventor's ability to get this initial patent in a reasonable amount of time, with foreseeable negative consequences for startups.

### B. Accused infringers will have a new tool for gaming the system with this NPRM

Accused infringers will take advantage of this proposal to strategically attack competitors' portfolios or pressure them into low-value settlements. Rather than challenge a strong,

<sup>[1]</sup> See Quad Env't Techs. Corp. v. Union Sanitary Dist., 946 F.2d 870, 873 (Fed. Cir. 1991) ("Voluntary limitation of the term of the later-issued patent is a convenient response to an obvious-type double patenting rejection, when the statutory requirement of common ownership is met.").

<sup>[2]</sup> Laurent Belsie, Prompt Patent Approval Spurs Startup Growth, The Digest, National Bureau of Economic Research (2016), available at <a href="https://www.nber.org/digest/apr16/prompt-patent-approval-spurs-startup-growth">https://www.nber.org/digest/apr16/prompt-patent-approval-spurs-startup-growth</a>.



meritorious claim head-on, a competitor will look to see if there is a TD and, if so, will survey that patent for any potentially invalid claim. Under the Office's proposal, the accused infringer would have the option of taking that other patent to the PTAB with its lower standard of proof, invalidating that single claim, and thereby wiping out the claim it was actually targeting. This shortcut gives a significant and unfair advantage to accused infringers.

Even where a patent owner has diligently avoided filing a TD at the urging of the Office, an accused infringer may allege that they needed to do so. Such allegations, already made in patent cases, will undoubtedly be alleged more often with the procedural benefits the Office now proposes.

### C. This NPRM will devalue patents as an asset class, deterring investors

Investors will have to factor in this draconian hook for rendering an entire family of patents unenforceable. Investors consider putting their money into ventures with patents precisely because patents offer an assurance of stability in an inherently risky investment environment. But this proposal would significantly impact the stability that patent families provide. As this stability is eroded, so too will be the willingness of investors to rationalize securing an investment on the basis of patents.

At the very least, investors will have to perform even more detailed due diligence on not just whether there are any patents with TDs, but also whether there are any patents susceptible to ODP invalidity arguments and how many patent claims would be affected. This will increase transaction costs for obtaining investment and increase the likelihood that the investment will not be made at all.

### D. Under this NPRM, inventors will be incentivized to keep knowledge to themselves with trade secret protection

As patent prosecution becomes more expensive and complicated, trade secret protection will become an even more attractive option for innovators who can use it. Many cannot — those in industries requiring regulatory approval often cannot, nor can inventors of products that are readily reverse-engineered.

But even for those to whom trade secret protection is available, this option comes at a high price for society. Trade secrets are a valuable and important source of protection of intellectual property in their own right, but by their nature, they do not dedicate an inventor's newfound knowledge to the public. A patent's required public disclosure means



that new knowledge is readily and quickly disclosed to all through the patent. This disclosure enables the inventor to freely engage in public discourse and collaborations without losing his or her rights and sets the stage for new developments based on the patent's teachings.

Trade secrets, by definition, are effective only as long as the public knows nothing. Trade secrets also tend to favor already dominant market incumbents, who can literally develop a storehouse of knowledge available only to those on the inside. Collectively, this means innovation overall is likely to be slowed, and certain innovations independently developed several times over. This would be both a loss of society-wide benefits from faster innovation and a waste of resources on needless re-discovery.

### II. The Office Has Not Demonstrated a Need for this Proposed Rulemaking

For such a stark change in practice with such adverse consequences, the Office has provided no evidence that it is needed. The Office cites to no data about how many ODP rejections it normally issues, the frequency with which such rejections are traversed as compared to obviated with a TD, or how often these rejections are currently appealed.

Several times, the Office states that the proposal will help competitors invalidate patents, but this does no more than state the obvious — patents are, by design, a grant of exclusivity intended to benefit and incentivize the inventor, so making them easier to invalidate will always make it easier for those who did not spend the time and money to develop the invention to enter the market with competing products. The Office's proposal to make it easier to eliminate all claims of a patent containing a TD is a proper benefit to competitors only if the follow-on patents have some defect of their own; otherwise, it is an undeserved windfall.

Besides rhetoric, the Office cites to no evidence that harm to competitors is caused by current TD practice. The Office speculates that this change will help competitors to lower the cost of challenging patents. But infringement lawsuits already whittle down allegations into representative patents and patent claims as trial approaches. Other legal doctrines (in addition to the existing encumbrances imposed by TDs) prevent multiple lawsuits on the same legal claims. The limitations on PTAB to a single patent are by congressional design, as discussed further below. The Office also understates the degree to which a negative PTAB decision on the claims of one patent affects the enforceability of similar claims in another patent.



#### III. The Office's Proposal Is Contrary to Law

### A. The Office cannot issue this proposal because it exceeds the Office's authority and conflicts with established law

### 1. The Office lacks authority to issue this NPRM

It is well established that the Office lacks "substantive" rulemaking authority with respect to regulating patent prosecution.<sup>3</sup> In simple terms, the Office can alter its procedures but cannot affect a party's substantial rights.<sup>4</sup> By limiting (in fact, eliminating) the enforceability of a patent it has issued, the USPTO's proposed rule crosses the line by taking away the rights it duly issued to a private party without further process based on an invalidity challenge to a different patent. The Office's attempt to frame this change as an "agreement" by the patent applicant — and thus more of a procedural rule — is unavailing. The Office's proposal is simply a new requirement for filing a terminal disclaimer, one not required by statute and one that has a clear impact on the worth of issued rights.<sup>5</sup>

### 2. This NPRM would effectively overrule statutes and case law

Even if the Office had clear authority to issue a rulemaking affecting substantive rights, it would not have the authority to rewrite statutes or binding law.<sup>6</sup> The Office's proposal does just this by mandating the unenforceability of all the claims in a patent, despite the fact that several statutes require invalidity be determined on a claim-by-claim basis.<sup>7</sup> The Office's proposal would also purport to overturn binding Federal Circuit precedent, which has made clear that TDs do not have the impact that the Office would now make them have — an admission of obviousness of follow-on patents.<sup>8</sup> While the Office tries to avoid this conflict

 $<sup>[3] \ \ 35 \</sup> U.S.C. \ \S \ 2(b)(2)(A); Merck \ \& \ Co. \ v. \ Kessler, \ 80 \ F.3d \ 1543, \ 1549-1550 \ (Fed. \ Cir. \ 1996).$ 

<sup>[4]</sup> Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979) (a "touchstone" of whether a rule is substantive is whether it "affect[s] individual rights and obligations."); Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 927 (Fed. Cir. 1991) ("A rule is 'substantive' when it 'effects a change in existing law or policy' which 'affects individual rights and obligations.").

<sup>[5]</sup> Cf. Chamber of Commerce of the United States v. U.S. Dep't of Labor, 174 F.3d 206, 210 (D.C. Cir. 1999) ("[T]he voluntary form of the rule is but a veil for the threat it obscures.").

<sup>[6]</sup> SAS Inst., Inc. v. Iancu, 584 U.S. 357, 363 (2018).

<sup>[7] 35</sup> U.S.C. §§ 253, 282.

<sup>[8]</sup> SimpleAir, Inc. v. Google LLC, 884 F.3d 1160, 1167-68 (Fed. Cir. 2018); Motionless Keyboard Co. v. Microsoft Corp., 486 F.3d 1376, 1385 (Fed. Cir. 2007) ("A terminal disclaimer simply is not an admission that a later-filed invention is obvious."); Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 941 (Fed. Cir. 1992); Quad Env't Techs. Corp., 946 F.2d at 874 ("[T]he filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection. It is improper to convert this simple expedient of 'obviation' into an admission or acquiescence or estoppel on the merits.").



by stating that its proposal does not require an admission of obviousness,<sup>9</sup> its impact is the same.<sup>10</sup> This elevation of form over substance does not change what the Office is proposing.

## 3. This NPRM conflicts with the statutes governing PTAB post-grant proceedings

The proposed rule would also undermine the congressional limits placed on the PTAB. The Leahy-Smith America Invents Act provided accused infringers a greater opportunity to participate in challenges to a patent before the Office, but in so doing, attempted to craft a balance between competing interests. To this end, the authorizing statutes only allow a petitioner to challenge one patent at a time, on a claim-by-claim basis.<sup>11</sup> The Office's proposal would effectively expand the PTAB's decision to reach any patents tied by a TD in addition to the patent before it. The PTAB's decision would invalidate the entirety of any such patent family, even though the statutes only allow it to decide on the patentability of each patent claim before it.<sup>12</sup> This entire proposal is thus in direct conflict with the PTAB post-grant statutes, a conflict the USPTO does not even address. Nor does the USPTO cite to any part of those post-grant challenge statutes as a source of rulemaking authority that would supposedly authorize such a rulemaking.<sup>13</sup>

### B. The Van Ornum case cannot support this proposed rulemaking

The Office relies primarily on *In re Van Ornum* to assert that it can issue these rules under 35 U.S.C. § 2(b)(2)(A). *Van Ornum* affirmed an earlier rule promulgated by the Office requiring a patent applicant to stipulate, with the filing of a TD, that the patent would be commonly owned in addition to the already-existing requirement of being term-limited.<sup>14</sup>

1. Van Ornum approved a rule directly affecting application processing before the Office, putting it within the Office's procedural rulemaking power, unlike the NPRM here

<sup>[9]</sup> TD NPRM, *supra* note 1, at 40441 ("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.").

<sup>[10]</sup> See Chamber of Commerce, 174 F.3d at 212.

<sup>[11] 35</sup> U.S.C. §§ 311(b) ("Scope") (a petitioner may request cancellation of "1 or more claims of a patent") (emphasis added), 321(b) (same).

<sup>[12]</sup> See 35 U.S.C. §§ 318(a), 328(a).

<sup>[13]</sup> TD NPRM, *supra* note 1, at 40448 (citing to only 2(b)(2)).

<sup>[14] 686</sup> F.2d 937 (CCPA 1982) (the ruling considered the Office's authority when the relevant, virtually identical, statutory language was codified at 35 U.S.C. § 6(a)).



Although *Van Ornum* upheld the Office's authority to issue an expansion of TD stipulations to include common ownership, that case does not provide an expansive enough interpretation of the Office's rulemaking authority to permit the instant NPRM. The *Van Ornum* court interpreted the broadest of the USPTO's rulemaking authorities to allow the Office to issue procedural rules that had some substantive impact. But in *Van Ornum*, the Office was still regulating conduct that came before it, as the facts of that case demonstrate. There, the applicants were not able to obviate the ODP rejection because they could not represent that they would maintain common ownership, having already assigned the patent forming the basis of the ODP rejection to a different entity. Here, in contrast, the condition that the Office seeks to impose with this rulemaking — whether a patent can be asserted in federal court — is not capable of coming before the Office. In other words, the Office seeks to require the applicant to agree to a condition otherwise wholly outside the Office's control. That condition directly impacts the substantive rights of the patent owner. *Van Ornum* cannot support the NPRM.

### 3. In *Van Ornum*, the substantive impact of the Office's rule was also consistent with earlier court statements; the opposite is true for this NPRM

As for the substantive impact that the common ownership rule had outside the Office, the *Van Ornum* court concluded that this extra-office impact was justified based on an earlier C.C.P.A. case. In that case, *In re Braithwaite*, the court stated that "[w]hen 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." The *Van Ornum* court reasoned that the Office's common ownership provision was consistent with the *Braithwaite* court's pronouncement that a TD causes two patents to become functionally one. Thus, the rule's requirement of common ownership throughout the life of a patent was implicit in the *Braithwaite* court's holding rather than a creation of the Office's. In contrast here, the Office's proposed rule does not give effect to previous statements of its reviewing court; as discussed earlier, it contravenes holdings from the Federal Circuit.

The Office's proposal even contravenes what the *Braithwaite* court actually said. Here, the Office does not propose to treat all claims in the issued patent with a TD and the original

<sup>[15]</sup> Id. at 945.

<sup>[16]</sup> *Id.* at 944. And accordingly, the controversy the *Van Ornum* court addressed was not an APA-type of facial challenge, but instead a dispute arising out of a rule that had already been in force at the Office for about a decade. *Id.* at 945.

<sup>[17]</sup> Id. at 948 (quoting In re Braithwaite, 379 F.2d 594, 601 (CCPA 1967) (alterations in original omitted)).

<sup>[18]</sup> Van Ornum, 686 F.2d at 948 ("Obviously, that thought [in Braithwaite] contemplates common ownership of the two patents, which remains common throughout the life of the patents.").



patent as "one patent." Instead, the patent with the TD is a second-class patent whose claims all rise or fall based on one claim of the original patent, rather than each claim on its own merits, as would be the case if the claims were all in one patent. This is true even if the invalidated claim in the original patent is broad and one or more claims of the patent with the TD are completely different — narrower, for example, or directed to another part of the invention.

The comparison between the proposed rule at issue here and the rule approved in *Van Ornum* ultimately shows that, with this proposed rulemaking, the Office is attempting to go too far, stretching this precedent past its breaking point.

# IV. The NPRM and the Office's Recent Fee Proposals Combine to Illegally Undermine Continuation Practice and Should Be Withdrawn as a Matter of Good Governance

This NPRM, combined with the recent proposed fee increases on TDs and new fees on filing continuations, squarely takes aim at the viability of continuations practice more generally.<sup>19</sup> The Office's attempt to make pursuing continuations both more costly and procedurally perilous tilts the playing field decidedly against the usage of these prosecution practices, both of which are authorized by statute.<sup>20</sup> Past attempts to limit continuations practice have been found legally wanting.<sup>21</sup> Attempts to do the same using different mechanisms will appropriately and predictably face similar headwinds. At the very least, the Office is headed into a legal gray area and one that will cast a large shadow over patent prosecution for the foreseeable future as legal battles play out.

Gambling this way with the propriety of Office procedures is gambling with the patent system's overall effectiveness and potentially with the Office's ability to keep its authority over fee setting, which is due to expire soon.<sup>22</sup> Changes of this magnitude are meant to come from Congress, not the Office, and not in this backhanded way.

 $[19] \ \ USPTO, \textit{Setting and Adjusting Patent Fees During Fiscal Year 2025}, 89\ FR\ 23226\ (2024), \ \underline{https://www.federalregister.gov/documents/2024/04/03/2024-06250/setting-and-adjusting-patent-fees-during-fiscal-year-2025}; \ USPTO, \textit{Table of Patent Fees-Current, Proposed and Unit Cost (NPRM)}, \ \underline{https://www.uspto.gov/sites/default/files/documents/Patent-Fees-Current-Proposed-Unit-Cost-NPRM-2024.xlsx}.$ 

[20] 35 U.S.C. §§ 120, 253.

<sup>[21]</sup> Tafas v. Dudas, 541 F. Supp. 2d 805, 815 (E.D. Va. 2008) (holding that the Office lacked authority to issue a rule with the effect of limiting continuations under 35 U.S.C. § 120); aff'd in relevant part, Tafas v. Doll, 559 F.3d 1345, 1360 (Fed. Cir. 2009), vacated by Tafas v. Doll, 328 Fed. Appx. 658 (Fed. Cir. 2009) (granting rehearing en banc); Tafas v. Kappos, 586 F.3d 1369 (Fed. Cir. 2009) (dismissing the en banc appeal as moot but denying the motion to vacate the district court decision).

<sup>[22]</sup> The SUCCESS Act, Pub. L. 115-273, § 4 (2018) (new expiration date set at Sept. 16, 2026).



The Office can, and often does, play a valuable role in bringing about major changes to the patent system, such as by conducting detailed studies of the need and impact of potentially major changes, together with moderating extensive public discourse in an attempt to build consensus. This is good governance at its best. The changes in this NPRM, in contrast, were preceded by no Office studies, analyses, or public consultation — at least nothing meaningful in relation to the magnitude of the proposed changes. As a result, the proposal itself is disruptive and unproductive, given the lack of notice and lack of need. To salvage what is left of good governance, the best way to move forward would be to start over and to start that by withdrawing this proposal.

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There are a litany of policy and legal reasons that counsel against the adoption of the Office's proposal. To address a speculative problem, the Office contemplates changes certain to do real harm to innovators. The changes proposed here will make patents a less stable vehicle for investment, hurting innovators' ability to obtain funding and, more generally, impacting long-term research and development, collaboration, and trade. The proposal sends a signal that America is not serious about investing in its innovation future. It will also become more difficult to stop other countries from stealing the ideas of our innovators if we greenlight it at home.

We urge the Office to withdraw this proposal.

C4IP again thanks the USPTO for the opportunity to comment on this NPRM and would be pleased to provide any further input that may be requested.

Sincerely,

Frank Cullen

**Executive Director** 

Council for Innovation Promotion (C4IP)