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Submitted via Regulations.gov

Katherine K. Vidal
Under Secretary of Commerce for Intellectual Property
Director, United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

AUTM’s Comments on the USPTO’s Notice of Proposed Rulemaking re Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting (Docket No. PTO–P–2024–0003)

Dear Director Vidal:

Please accept AUTM’s comments on the USPTO’s Notice of Proposed Rulemaking (NPRM) re Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting (the “Proposed Rule”).

AUTM is the non-profit leader in efforts to educate, promote, and inspire professionals to support the further development and deployment of innovations arising from academic research. Our community is comprised of more than 3,000 members who work in more than 800 universities, research centers, hospitals, businesses, and government organizations around the globe.

AUTM’s membership has traditionally stemmed—and continues to draw primarily—from academic settings. AUTM members in such academic settings are focused on advancing early-stage inventions and other technologies to the marketplace, primarily through licensing and further development with partners (i.e., implementers). Between 2013 and 2022 (the most recent decade for which we have data), our skilled professionals filed over 160,000 patents for academic inventors and negotiated over 70,000 intellectual property license agreements on behalf of U.S. universities and academic research institutions. About 70% of these licenses are to start-ups and



small companies. It is estimated that the American economy has received nearly \$2 trillion in benefits from the technology transfer carried out by AUTM members over the past 30+ years.

AUTM members are at the very crossroads of innovation, taking early-stage inventions from the laboratory and helping to translate those inventions into new products and services through commercialization so that all Americans can benefit from them. Thus, we appreciate you considering AUTM's views on this important issue, as the patent system is critical to retaining America's position as the world leader in innovation and technology.

Summary of AUTM's Comments

AUTM joins former USPTO Directors, Deputy Directors, Commissioner of Patents¹ and Members of Congress² in recommending the immediate withdrawal of the Proposed Rule, which would render unenforceable entire patents if a single claim in a different patent is found to be invalid. The USPTO's stated goal underlying the Proposed Rule is to reduce costs for patent challengers by enabling such challengers to invalidate multiple patents by proving one claim within a linked portfolio is anticipated or obvious. This approach is both ill-advised and improper. It favors accused infringers and patent challengers over the patent owners, technology investors, and licensees who depend on the statutory presumption of patent validity to invent, protect, and deploy innovations.³ The USPTO's approach will only weaken the United States' innovation ecosystem, which was founded and relies heavily upon patent-incentivized investments.

Moreover, for the reasons discussed below, the Proposed Rule's attempt to limit statutorily authorized enforcement rights for a valid patent under the guise of a "voluntary agreement" with the patent owner overreaches the Office's statutory authority. Patent owners and licensees have long relied on terminal disclaimer (TD) practice to protect innovations that are new and nonobvious over the prior art, including improved products and methods that will benefit the public. Disrupting this well-established practice will wreak havoc on technology transfer by increasing uncertainty and decreasing the ability of universities to find licensees to help develop university-created technologies. If, as the USPTO represents, this disruption is necessary and will solve a real problem, which we strongly dispute,⁴ such changes should be made by Congress. The U.S. intellectual property system will be severely destabilized if every change in USPTO leadership carries a risk of sweeping changes to long-standing practices.

¹ Letter from former USPTO Directors (and others) to Director Vidal, May 28, 2024.

² Letter from Rep. Fitzgerald to Director Vidal, June 10, 2024 ("Fitzgerald Letter").

³ 35 U.S.C. § 282(a) states in part: "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; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim."

⁴ AUTM disputes both premises. The USPTO has neither shown that a problem exists nor that the Proposed Rule will correct it.

AUTM's Comments on Proposed Rule

1. The Proposed Rule wrongly perpetuates the obsolete judicially-created doctrine of nonstatutory double patenting (obviousness-type double patenting or OTDP)

The doctrine of obviousness-type double patenting (OTDP) originated years ago when patent terms were 17 years from the date of issue. Judges, who failed to appreciate the value of follow-on innovation, took it upon themselves to invalidate later-issued (and, therefore, later-expiring) patents whose subject matter they deemed “patentably indistinct” from a reference patent. In other words, instead of letting the market decide, they decided that potentially important follow-on inventions were, in fact, just the same invention. They took this action even when the invalidated patents passed muster under the statutory non-obviousness rules in effect at the time.

In 1994, however, the passage of the Uruguay Round Agreements Act (URAA) should have removed most of these concerns when it changed the U.S. statutory patent term from 17 years from the date of issue to 20 years from earliest effective filing date. By limiting patent families (those with the same earliest effective filing date) to a single 20-year term, the URAA eliminated the ability of patent owners to obtain later-expiring patents for follow-on innovations. After the URAA, all patents in a family are effectively limited to the 20-year term of the first-filed patent, plus an occasional modest term extension due to regulatory delays (Patent Term Extension (PTE)) or delays at the U.S. Patent and Trademark Office (USPTO) (Patent Term Adjustment (PTA)). Thus, for post-URAA patents, the concern that led to the judicial creation of OTDP is largely non-existent as most patent families share a single 20-year term, and the patent families that do not share a single term have terms that vary by a few years at most.

Instead of limiting or eliminating the obsolete judicially-created doctrine of OTDP, recent Federal Circuit decisions have actually expanded it. No longer is OTDP used simply to address the concerns of some that later patents not be used to extend the patent term of a single invention. Instead, as discussed in more detail below, OTDP is being used as a vehicle to retroactively invalidate patents prosecuted in good faith.

The USPTO is also expanding OTDP by now proposing to render unenforceable patents prosecuted in good faith by radically augmenting the TD requirements. The new requirement is that the applicant filing the TD must agree “that the patent in which the terminal disclaimer is filed, or any patent granted on an application in which a terminal disclaimer is filed, will be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which: any claim has been finally held unpatentable or invalid as anticipated or obvious by a Federal court in

a civil action or by the USPTO, and all appeal rights have been exhausted; or a statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been made.”⁵ Essentially, this means that if a patentee has multiple patents tied together by terminal disclaimers, a competitor would only need to successfully invalidate *one claim* in *one* of those patents based on prior art in order to render *all* of the patents invalid.

The Federal Circuit’s recent *In re Collect* opinion is a chilling exemplar of the problems with current OTDP practice and the Proposed Rule. *Collect* held that the expiration date used for an OTDP analysis where a patent has received PTA is the expiration date after the addition of the PTA.⁶ Moreover, the panel did not merely limit the term of the challenged patents to the term of the (expired) patent in the family with the shortest term; the patents were each retroactively invalidated. The patent with the shortest term in the family had already expired, and the court reasoned that a retroactive terminal disclaimer could not be filed against a patent that had already expired.⁷

This case has been recaptioned *Collect v. Vidal* and is currently pending certiorari at the Supreme Court. Numerous amici have weighed in in support of certiorari seeking reversal of this troubling expansion of OTDP coupled with the loss of valuable PTA. Of particular concern at the moment is the fact that, under *Collect*, applicants would be motivated to file preemptive TDs to avoid the negative result the petitioner experienced there but, because of the Proposed Rule, filing such TDs would immediately put those patents at increased risk of being unenforceable due to the tying provisions in the Proposed Rule. Given the interest in this case and its connection to TDs, AUTM suggests that, at a minimum, the USPTO put a hold on the Proposed Rule until at least until such time as the Supreme Court denies certiorari.

2. The Proposed Rule unfairly favors alleged infringers and patent challengers over patent owners, investors, and licensees.

In a validity challenge, existing law requires that each patent be separately assessed on a claim-by-claim basis with each patent claim standing or falling on its own merits. Even in the same patent, “[e]ach claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of the other claims; dependent or

⁵ NPRM on “Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting,” 89 FR 40439 (May 10, 2024).

⁶ *In re Collect*, 81 F.4th 1216 (Fed. Cir. 2023).

⁷ *Id.* at 1231.

multiple dependent claims shall be presumed valid even though dependent upon an invalid claim.”⁸

Through the Proposed Rule, the USPTO seeks to limit enforceability of a patent in which no claim has been found invalid solely because the patent is tied to a separate patent with a single invalidated claim. The USPTO argues that this “death by association” is necessary to lower the costs of challenging groups of patents so that competitors can “focus on addressing the validity of the claims of a single patent.”⁹ Notably, the USPTO does not cite evidence that challengers are foregoing credible challenges to issued patent claims because of costs.¹⁰ But even if there was some need to decrease costs for patent challengers, this is not a problem that falls within the USPTO’s duties. The USPTO’s primary role is issuing patents for inventions that are found to meet the statutory requirements. Although the USPTO may “advise the president of the United States” on issues regarding “patent enforcement,” it is not the role of the USPTO to prioritize the rights of patent challengers over the rights of patent owners and licensees.¹¹

The Proposed Rule will unnecessarily prolong prosecution, which is directly contrary to the USPTO’s long-standing goal of compact prosecution. Patent applicants will now have to carefully assess whether a TD should be filed and will be more likely to argue against these rejections, which will require both patent applicants and the USPTO to spend more time and resources.

AUTM disagrees with the USPTO’s premise that reducing challengers’ legal fees outweighs the need to preserve the predictability and stability of the U.S. patent system and protect patent owner and licensee rights. Here, the USPTO’s “solution” to help alleged infringers and patent challengers will devalue all patents that involve a TD and will create a special category of patent claims that are more easily invalidated and thus more attractive to patent challengers.

In other words, the Proposed Rule will reduce the reliability of the issued patent. This reduced reliability is tantamount to throwing sand in the gears of the highly productive and economically

⁸ 35 U.S.C. § 282(a).

⁹ NPRM on “Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting,” 89 FR 40439-49, 40440 (May 10, 2024).

¹⁰ AUTM agrees that “[t]he proposal seeks to solve a problem that does not exist. At a minimum, the USPTO has made no showing that the terminal disclaimer and continuations practice is harming the American economy or that the new rules would improve matters if adopted.” Fitzgerald Letter.

¹¹ See <https://www.uspto.gov/about-us> (“The United States Patent and Trademark Office (USPTO) is the federal agency for granting U.S. patents and registering trademarks. In doing this, the USPTO fulfills the mandate of Article I, Section 8, Clause 8, of the Constitution that the legislative branch ‘promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.’ ... The USPTO advises the president of the United States, the secretary of commerce, and U.S. government agencies on intellectual property (IP) policy, protection, and enforcement....”).

beneficial technology transfer machine. Universities and the under-resourced start-ups and small businesses that most often license their technologies will find it more difficult to consummate a licensing transaction—potentially allowing promising new technologies to waste away on the shelf for the benefit of no one. No rational investor would choose a project where his or her return is so much in doubt because they cannot rely on their patents to prevent copycat products from immediately entering the marketplace. As such this proposed “solution” is far too disproportionate in view of the USPTO’s alleged “problem.”

3. The Proposed Rule is contrary to public interest and will ultimately deter market introduction of new technologies.

Fundamental research (often university-driven) is the bedrock for future products and economic growth. Breakthrough scientific discoveries are not made in a vacuum; incremental research progress, and the means to protect it, are necessary steppingstones to achieve applied research and viable innovations. Entrepreneurial partners and investors advance innovations through further development, scale up, testing, and regulatory approvals to ultimately achieve commercialized products and services for the marketplace. Our patent laws and infrastructure are designed to support this national innovation ecosystem because the long run return is the “well-being of the United States economy; United States workers; our communities; and our national security.”¹²

By discouraging the filing of continuation applications on incremental and patentable research innovations, the Proposed Rule will force researchers to choose between (i) on the one hand, delaying peer review and journal submissions until all reasonable permutations and improvements to an invention are completed, potentially to the detriment of faculty and graduate student advancement; or (ii) on the other hand, publishing research progress while foregoing patent protection on later results. The latter choice eliminates opportunities for private investment, development, and market introduction of new products based on such results, even if such results are functionally superior to the claims within the original/parent application. As a result, improved products and services that would benefit the public will not be commercially developed.

For science to progress, researchers must share their findings rapidly through scientific publications. For the general public to enjoy the fruits of innovation, the investments necessary to cultivate them hinge upon the time-limited, legal exclusivity to inventions secured by our patent system. Consistent with our commitment to the progress of science, our country’s

¹² EO 14104 on “Federal Research and Development in Support of Domestic Manufacturing and United States Jobs,” 88 FR 51203-08, 51203 (July 28, 2023).

innovation policy infrastructure promotes federal funding for early-stage research and rewards patent-driven investments as necessary components of strengthening U.S. competitiveness.¹³

As evidenced by the Proposed Rule, however, the USPTO seems to be willingly moving in the opposite direction. The Proposed Rule will do nothing but hamper the ability of universities to obtain patent protection for early-stage technologies and properly maintain them throughout the course of their developmental lifecycle due to the increased complexity of patent prosecution associated with the Proposed Rule and, relatedly, the increased costs associated with the recent fee changes. Should the Proposed Rule go into effect, the relatively simple process of using a TD to obviate OTDP rejections will be replaced with more complex and costly prosecution tactics, including claim amendments, provoking restriction requirements, and vigorously attempting to traverse any and all OTDP rejections.

When basic research leads to patentable early-stage technologies, it is difficult—usually impossible—for the researchers to predict the most effective and publicly beneficial applications of their inventions (i.e., the ultimate products and services). Rather, the researchers continue their work, and as they make improvements, they collaborate with patent practitioners and technology transfer professionals to protect the improvements they make and to find and work with industry partners to test the potential applications of the new research and develop products for the most promising applications. The new products for the most promising applications are covered by continuation patents and may appear to cover only obvious variants of the base technology. Those final incremental improvements, however, are often the difference between blockbuster products and ones that are utterly unsuccessful in the marketplace. Moreover, it is not possible to know when the patent applications covering such innovations will be discovered or issue as patents.¹⁴ The new continuation fee structure penalizes later found inventions by progressively and dramatically increasing the filing fees on later filed continuation applications.

By devaluing any later-issued patents that include a TD, the Proposed Rule disrupts this process and removes incentives for developing the most promising (but now less valuable) patented technologies. Notably, this will not harm the well-established and well-funded companies whose products benefit from first-mover advantage and substantial marketing capabilities. Thus, the Proposed Rule disproportionately harms universities and the under-resourced start-ups and small businesses that most often license university technologies.

¹³ *Id.*

¹⁴ We also note that the Proposed Rule will treat claims with different effective filing dates in different patents as if they have the same filing date. For example, claim Y may be invalidated by intervening prior art because it has a later effective filing date than claim Z. Under the Proposed Rule, an invalidated claim Y would render unenforceable all claims in a later patent to which it is tied via a TD even if the prior art that invalidated claim Y is not prior art to the now-unenforceable claims.

As a result, and despite claims to the contrary, the Proposed Rule will hinder market entry, rather than remove barriers.¹⁵ It will also harm the public through diminished consumer choice and higher prices due reduced competition.

For example, if a university-owned patent portfolio that includes terminally-disclaimed patents is licensed exclusively to two companies with each company licensing a different field of use (e.g., exclusivity for human use for Licensee A and exclusivity for veterinary use for Licensee B), a competitor of Licensee A can kill the patents upon which Licensee B relies. Importantly, this is true even though the competitor is not challenging Licensee B's patents and has no interest in using—and no intention to use—the technology for veterinary applications. This creates a situation where Licensee B cannot reasonably rely on the enforceability of the issued patents in the veterinary field and thus has little incentive to develop the federally-funded innovation underlying those patents. Without the incentive, the new products and services never come to fruition.

4. Framing a prohibition on patent enforcement as a “voluntary agreement by the patent owner” does not salvage the Proposed Rule.

The rights of a patent owner cannot be limited through administrative rulemaking. In response to the earlier USPTO Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 FR 60130 (October 4, 2022), commentors correctly noted that the USPTO lacks statutory authority to make substantive rules. Accordingly, the USPTO withdrew previous suggestions to limit terminal disclaimers (TDs). The withdrawn rules would have required (1) a stipulation that the claims in TD-linked applications/patents are not patentably distinct, or (2) an agreement by the disclaimant that filing a terminal disclaimer is an admission of obviousness.¹⁶ In this third attempt, the USPTO distinguishes its prior approach by stating that the Proposed Rule “does not concern 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....”¹⁷

There are two obvious concerns with this approach. First, it is simply not true that the validity of the claims in the subject patent is untarnished. The fact that a challenge to the reference patent

¹⁵ NPRM, 89 FR 40440 (The proposed rule 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.).

¹⁶ Federal Circuit precedent has established that a terminal disclaimer does not constitute an admission that the claims of the disclaimed patent are obvious. *See, e.g., Quad Env'tl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991).

¹⁷ NPRM, 89 FR 40441.

can render the claims in the subject patent unenforceable clearly tarnishes the subject patent, even if the claims are valid at that moment. A valid but unenforceable patent is just a stack of paper memorializing a regrettable investment.

Second, and more concerning, is the observation that the Proposed Rule requires an applicant to “voluntarily” surrender property rights (the right to enforce a valid patent) as part of an “agreement” during the patent prosecution process because the government wants to lower the costs for accused infringers in their attempts to invalidate patents. Considering the consequences of failing to “agree” (maintenance of an OTDP rejection), applicants’ compliance with the Proposed Rule cannot reasonably be seen as voluntary.

In this sense, the Proposed Rule is to the 14th Amendment as *NRA v. Vullo*¹⁸ is to the 1st Amendment. In *NRA v. Vullo*, the U.S. Supreme Court grappled with government regulators using indirect pressure to limit protected speech. In the Court’s opinion, Justice Sotomayor stated, “Government officials cannot attempt to coerce private parties in order to punish or suppress views that the government disfavors.”¹⁹ During a discussion around the definition of “coercion” in oral arguments, Justice Alito described how to determine whether government action “goes too far along that line,” stating, “All [the NRA] need[s] to do is show that the desire to suppress speech was a motivating factor. They don’t have to prove that regulatory action would have been taken...”²⁰ Here, then, the desire to lower costs for patent challengers is enough to meet the threshold for unacceptable government coercion.

5. The demise of the *Chevron* doctrine further undermines the Proposed Rule

The demise of *Chevron* further weakens the predicate for the Proposed Rule. Since the USPTO’s interpretation of substantive patent law issues has never enjoyed *Chevron* deference, the demise of the doctrine makes it even more improper for the USPTO to start issuing rules that seek to change substantive patent law.

As the Supreme Court complained in its decision overruling *Chevron*, the doctrine “allows agencies to change course even when Congress has given them no power to do so” which “fosters unwarranted instability in the law,” and leaves “an eternal fog of uncertainty” as the result.²¹ These adverse sequelae of those unwarranted changes are compounded when the agency action in question is directed to urban legend or bogeymen.

¹⁸ *National Rifle Association of America v. Vullo*, 602 U.S. ____ (2024).

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Loper Bright Enterprises et al. v. Raimondo, Secretary of Commerce, et al.*, 603 US ____ (2024).

Here, for example, the Proposed Rule is driven by the Administration’s stated desire to eliminate so-called “patent thickets”.²² However, not everyone is convinced that patent thickets are a problem in need of a solution. As Judge Easterbrook inquired in his August 2022 opinion in the Humira patent thicket-based antitrust case, “... what’s wrong with having lots of patents? If AbbVie made 132 inventions, why can’t it hold 132 patents?”²³

Assuming arguendo that “patent thickets” (i.e., too many patents) are indeed such a massive problem, they are an issue for Congress to address—not the USPTO—for two reasons.

First, from a substantive perspective, issued patents manifest property rights of the kind the United States government was instituted to secure and, in the United States, Congress has the exclusive power to secure them.²⁴ As Representative Scott Fitzgerald of Wisconsin stated in his recent letter to Director Vidal:²⁵ “Depriving a patent owner of its rights in two patents based on the complete challenge to only a single claim in one of those patents in the manner proposed would appear to clearly violate an inventor's due process rights.” This statement suggests that the courts must be involved in any deprivation or revocation of patent rights.

Second, from a procedural perspective, the USPTO remains under a permanent injunction put in place by the district court judge in *Tafas v. Dudas*²⁶ and ultimately upheld by the Federal Circuit²⁷ against implementing any rules involving continuation practice. In fact, the judge in *Tafas* relied on earlier Federal Circuit precedent stating that the USPTO lacks any substantive rule making authority.²⁸ Ironically, the USPTO conceded the same earlier in the *Tafas* litigation.²⁹

Representative Fitzgerald also makes this point in his letter.³⁰ There, he reiterates the fact that the USPTO is not authorized to promulgate substantive rules. He notes that the Proposed Rule, however, would alter applicants’ substantive rights under 35 U.S.C. Sections 102 and 103 by making valid and issued claims in a subject patent unenforceable based on successful challenges to a reference patent’s claims. Put another way, the USPTO’s attempt to use a judge-made doctrine to strip away statutorily authorized patent enforcement rights is a substantive change in

²² In the USPTO Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 FR 60130 (October 4, 2022), the USPTO cited concerns that multiple patents directed to obvious variants of an invention would deter competition if the number of patents is prohibitively expensive to challenge.

²³ *Mayor and City Council of Baltimore, et al. v. AbbVie et al.*, No. 20-2402 (7th Cir. 2022).

²⁴ U.S. Constitution, Art. I, Sec. 8, Cl. 8.

²⁵ Fitzgerald Letter.

²⁶ *Tafas v. Dudas*, 541 F. Supp. 2d 805 (E.D. Va. 2008).

²⁷ *Tafas v. Kappos*, 586 F.3d 1369 (Fed. Cir. 2009).

²⁸ *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996). See also *Animal Legal Def. Fund. v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991).

²⁹ Defs.’ Opp. to Pls.’ Mot. for TRO and Prelim. Inj., Dkt. No. 46 in 1:07cv1008, 21-23.

³⁰ See Fitzgerald Letter.

the law that, per the U.S. Constitution, requires Congressional review and approval. Congress has not given the USPTO the authority to implement such a change.

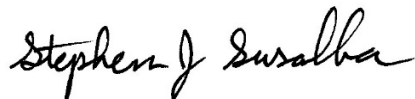
Moreover, the change put forth by the agency is such an abrupt and radical departure from established continuation/TD practice that it flies in the face of the *Tafas* permanent injunction and the point the Supreme Court recently stressed in overruling *Chevron*, namely, that the courts are responsible for ensuring that the law "develop[s] in a principled and intelligible fashion."³¹

Thus, the recent decision overruling *Chevron* clearly demonstrates that the Proposed Rule is the wrong approach, for the wrong reason, at exactly the wrong time for our patent system and our country.

Conclusion

In sum and for the reasons articulated herein, AUTM urges the USPTO to immediately withdraw the Proposed Rule. We appreciate the opportunity to provide comments on this NPRM, and we look forward to continued productive dialog on this and other matters critical for American innovation.

Sincerely,

A handwritten signature in black ink that reads "Stephen J. Susalka". The signature is written in a cursive, flowing style.

Stephen J. Susalka, Ph.D.
Chief Executive Officer

³¹ *Loper Bright*, citing *Vasquez v. Hillery*, 474 U.S. 254, 265 (1986).