



July 9, 2024

Kathi Vidal
Director
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Re: Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting (89 Fed. Reg. 40439)

Dear Director Vidal:

On May 10, 2024, the United States Patent and Trademark Office (USPTO) released a notice of proposed rulemaking regarding terminal disclaimers filed to obviate nonstatutory double patenting. In that same notice, the USPTO called for comments on the proposed rule. *See* Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, 89 Fed. Reg. 40439, 40439 (May 10, 2024).

DISH Network, L.L.C., Sonos, Inc., RingCentral Inc., NAGRA Kudelski Group, Capstan Therapeutic, Inc., and Nutcracker Therapeutics, Inc. submit this comment urging the USPTO *not* to adopt the proposed rule. By way of background, DISH Network, Sonos, RingCentral, and NAGRA Kudelski Group are public companies and technological leaders. They are, at various times, both plaintiffs and defendants in patent proceedings in district court and at the Patent Trial and Appeal Board. Capstan Therapeutics and Nutcracker Therapeutics are biotech startups developing cutting edge therapies. Thus, the interest of the undersigned companies is in creating and maintaining an efficient, predictable, and balanced patent system that fosters technological innovation.

I. The USPTO Should Withdraw the Proposed Rule.

The USPTO should withdraw the proposed rule for at least five reasons.

First, the proposed rule is contrary to law, subverts congressional intent, and will not survive a court challenge—especially in a post-*Chevron* world.

Second, there is no compelling evidence that the proposed rule solves an actual problem that companies face in the real world.

Third, the proposed rule will increase the costs of prosecution and the USPTO's backlog, while creating new opportunities for abuse in litigation and confusion for district courts.

Fourth, the proposed rule will have material negative consequences for startups and established innovators alike.

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Fifth, the negative consequences of the proposed rule are widespread as it applies across any patents, even patents from entirely different patent families, that are tied directly or indirectly by a terminal disclaimer.

We begin with a background discussion of how terminal disclaimers are used by companies like the undersigned and then discuss the illegality and negative impact of the proposed rule.

A. Background

Patentees regularly use terminal disclaimers as a prosecution expedient to obviate nonstatutory double-patenting rejections.

When a patent examiner rejects a patent application based on obviousness-type double patenting (OTDP), a patentee can obviate that rejection either by arguing that the claim or claims are “patentably distinct” from those of a related patent or by filing a terminal disclaimer. *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997). Often, the USPTO rejects only a subset of the claims, not all of them, for OTDP.

As the Federal Circuit has acknowledged, if the USPTO rejects a claim or claims for OTDP, companies regularly file terminal disclaimers as a prosecution expedient. *See, e.g., Quad Env't Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) (“[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.”).

This expedient is critically important. Patent prosecution is expensive, and the USPTO is often delayed—as can be seen from the amount of patent term adjustment (PTA) the USPTO routinely issues to patent owners. Indeed, of the 4.5 million patents filed on or after May 29, 2000 (when the statute providing PTA took effect), and issued since 2005, more than half have PTA and of the patents that have PTA, the average amount of PTA is more than 6 months.¹

As a result, the undersigned companies will sometimes file a terminal disclaimer to facilitate earlier issuance of a patent, instead of engaging in extensive back and forth with the USPTO on the merits of the rejection. In many cases there is not even a surrender of patent term—because the reference and examined patent are in the same patent family and have the same term—but only a requirement to maintain common ownership. Put differently, a patent applicant may believe that the USPTO’s

¹ Mark A. Lemley & Jason Reinecke, *Our More-than-Twenty-Year Patent Term* 1-2 (Stanford L. & Econ. Olin Working Paper No. 586, 2023); Dennis Crouch, *Prosecution Delays and Patent Term Adjustment on the Rise Again* (Nov. 13, 2022), <https://patentlyo.com/patent/2022/11/prosecution-delays-adjustment.html>.

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OTDP rejection can be overcome on the merits, but that it is not worth the resulting time, expense, and delay relative to filing a terminal disclaimer.

The proposed rule requires patentees filing terminal disclaimers to agree to tie the enforceability of one patent to the claims of others.

In the notice of proposed rulemaking, the USPTO proposes amending its rules of practice to require:

[T]erminal disclaimers filed to obviate nonstatutory double patenting to include an agreement by the disclaimant 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.

89 Fed. Reg. at 40439.

Under the proposed rule, to overcome an OTDP rejection via terminal disclaimer, a patentee would have to agree that the sought patent will be unenforceable if “any claim” in another patent tied (directly or indirectly) to it through terminal disclaimer is either (1) finally held unpatentable/invalid as anticipated/obvious by a federal court or the USPTO and all appeals have been exhausted, or (2) statutorily disclaimed after any challenge based on anticipation or obviousness has been made. *Id.* (emphasis added).

B. The proposed rule is contrary to blackletter law and congressional intent.

The proposed rule contradicts the Patent Act, Federal Circuit precedent, and congressional intent.

It is well-settled that patent validity is determined on a claim-by-claim basis. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) (“Of course, ... validity analysis must be performed on a claim-by-claim basis.”), *abrogated on other grounds by eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). Congress made clear that “that validity of each claim must be evaluated individually” and manifested that intent in the express terms of the Patent Act. *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 942 (Fed. Cir. 1992); *see* 35 U.S.C. § 282(a) (“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

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claims shall be presumed valid even though dependent upon an invalid claim.”); *see also* 35 U.S.C. § 253(a).

The proposed rule, however, contradicts this established law and Congress’s intent. It creates a domino-like scheme where a finding of invalidity based on either anticipation or obviousness as to *one* claim in one patent will render unenforceable *all* other claims in all patents tied to it (directly or indirectly). It flatly disregards the statutory presumption of validity.

Had Congress wanted to require that patentees agree to tie the enforceability of one patent to the validity of the claims of another to obtain disclaimer, it would have done so. But it did not—the only condition that Congress imposed on patent disclaimer is that “[a] patentee ... pay[] ... the fee required by law.” 35 U.S.C. § 253. And it emphasized that “[w]henever a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid.” *Id.* § 253(a). That the proposed rule technically does not invalidate the claims of patents that are directly or indirectly tied by a terminal disclaimer but “only” makes them unenforceable is a distinction without a difference. The value of the tied patents is unfairly destroyed.

The USPTO should acknowledge that neither it, nor any district court nor the Federal Circuit, could properly *impose* such a rule on patent owners without it being struck down. Just imagine a district court ruling that because one claim in a patent is anticipated by the prior art, every claim in every *other* patent in the family is unenforceable. Such a ruling would be lawless and overturned.

The illegality of the proposed rule is not, however, materially improved by the fact that the patent applicant must *agree* to it—both because the *rule itself* is contrary to the statutory scheme and because the applicant’s *agreement* is being obtained through coercion. *See Midwest Video Corp. v. FCC*, 571 F.2d 1025, 1052 (8th Cir. 1978) (setting aside “mandatory access rules [that] ... merely accomplish ... coercion ...”). Put simply, the proposed rulemaking gives patent applicants a Hobbesian choice—agree to make the enforceability of an entire patent family hinge on the validity of the *weakest* claim or wait an additional period (possibly years) for the patent to issue.

The proposed rule is substantive and outside the USPTO’s rulemaking authority.

The USPTO does not have authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before it. 35 U.S.C. § 2(b)(2); *see also Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (“[T]he broadest of the [USPTO’s] rulemaking powers ... does NOT grant the Commissioner the authority to issue substantive rules.”); *Tafas v. Dudas*, 511 F. Supp. 2d 652, 664 (E.D. Va. 2007) (same); *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 141 (D.D.C. 2008) (similar). The Federal Circuit has explained: “A rule is ‘substantive’ when it ‘effects a change in existing law or policy’ which ‘affects individuals rights and obligations.’” *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008) (cleaned up) (quoting *Animal Legal Def. Fund. v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991)); *see also Am. Hosp. Assoc. v.*



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Bowen, 834 F.2d 1037, 1045 (D.C. Cir. 1987) (“Substantive rules are ones which grant rights, impose obligations, or produce other significant effects on private interests, or which effect a change in existing law or policy.” (citations omitted)). Patent rights have long been recognized as individual property rights. *Kearns v. Gen. Motors Corp.*, 94 F.3d 1553, 1555 (Fed. Cir. 1996) (“By statutory and common law, each patent establishes an independent and distinct property right.”).

The proposed rule is plainly substantive as it changes what existing patent law requires to overcome OTDP rejections (which affects whether patents would or would not be granted) and forces patent owners to restrict their patent rights.

The proposed rule substantively modifies the judicially-created doctrine of OTDP. As the Federal Circuit has explained repeatedly, the OTDP doctrine is driven by a purpose to avoid improper “timewise extension of the patent right.” *In re Kaplan*, 789 F.2d 1574, 1579 (Fed. Cir. 1986). Current terminal disclaimer practice plainly serves this purpose, and the Federal Circuit has repeatedly affirmed that current terminal disclaimer practice is sufficient to overcome OTDP rejections. *Supra* 2. The proposed rule, however, does not further the purpose underlying the OTDP doctrine, and it materially alters the terminal disclaimer remedy. Under the proposed rule, if one claim in a reference patent is invalidated or statutorily disclaimed, then the claims in a terminally disclaimed patent are automatically unenforceable, regardless of their underlying merits. That is wholly removed from the underlying purpose of barring impermissible timewise patent extensions, and the proposed rule directly impacts the conditions governing whether a patentee is entitled to a patent and how patents can be invalidated. This is especially concerning here, where, as explained above, the proposed substantive rule does not comport with patent law. *See* 89 Fed. Reg. at 40441 (citing *In re Van Ornum*, 686 F.2d 937, 945 (C.C.P.A. 1982) for support that the proposed rule is within the USPTO’s authority); *but see Tafas*, 511 F. Supp. 2d at 664 (reliance on *Van Ornum* “is helpful to the PTO only if this Court disagrees with [the] contention that [the proposed rule is] inconsistent with the Patent Act.”).

Put simply, the proposed rule is contrary to the Patent Act and unlikely to be upheld. It will not get *Chevron* deference. *Loper Bright Enters. v. Raimondo*, 603 U.S. ---, 2024 WL 3208360, at *22 (June 28, 2024). And courts will see it for what it is—an attempt by an administrative agency to remake the statutory scheme that Congress enacted.

C. The proposed rule is counterproductive.

The proposed rule is directed to a problem that does not exist.

In the notice of proposed rulemaking, the USPTO claims that current terminal disclaimer practice “deter[s] competition due to the prohibitive cost of challenging each patent separately in litigation or administrative proceedings.” 89 Fed. Reg. at 40439. According to the USPTO, “[t]he proposed rule is intended to promote competition by lowering the costs of challenging groups of patents tied

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by terminal disclaimers, resulting in reduced barriers to market entry and lower costs for consumers” by “[n]arrowing validity disputes in litigation to only one ... patent,” purportedly leading to “focused claim construction hearings, lower litigation costs, and faster resolution.” *Id.* at 40440.

The motivation underlying the proposed rule targets a non-existent problem. The USPTO states that “multiple patents tied by terminal disclaimers that are directed to obvious variants of an invention” are deterring competition and unnecessarily driving up litigation costs. *Id.* at 40439.

The undersigned companies believe this is error.

First, the USPTO has cited no empirical evidence regarding the number or percent of cases that involve (i) groups of related patents, or (ii) patents with family members that have been fully adjudicated in other cases against other defendants. The undersigned believe that the number of cases that fall into either one of those categories is small.

Second, most courts and judges that see a significant volume of patent cases (e.g., Delaware, Northern California, Northern Illinois, Eastern Texas) have rules that limit the number of claims a plaintiff can assert.² Whether a plaintiff asserts, e.g., 10 claims from one patent or 10 claims spread out across multiple patents that share the *same* specification and *same* priority date or across patent families makes little to no practical difference. And even if it were slightly more work to litigate the latter—in most multi-patent cases that the undersigned have been involved in (both as plaintiffs and as defendants), plaintiffs often seek to diversify their litigation risk by allocating the allowed number of claims across patents from different families.

Third, the USPTO’s statement about the nature of the problem it is trying to solve *assumes* that the patents that are tied to one another by terminal disclaimers are *actually* unenforceable and that the problem is, really, how to get to that (ultimate) end point in an efficient manner. But there is *no* empirical evidence to support that proposition and no persuasive reason to think that it is true. *See Midwest Video*, 571 F.2d at 1062 (“It is not readily apparent that the present rules were based on a clear administrative record that shows existence of a problem justifying intrusion on [individual] rights ...”). If the USPTO believes the evidence will support its position, it should, at

² For example, in 2022, Chief Judge Connolly issued a form scheduling order for Hatch-Waxman cases assigned to him. This order requires plaintiffs to narrow asserted claims *from the outset*: “Unless otherwise agreed to by the parties, Plaintiff(s) may assert no more than ten claims of any one patent and no more than 32 claims in total against any one Defendant.” Scheduling Order for Hatch-Waxman Patent Infringement Cases (D. Del. Apr. 26, 2022) (accessible at <https://tinyurl.com/yh6bh7cb>); *see, e.g.*, N.D. Ill. Pat. R. 2.2 (describing initial infringement contentions) (“A party claiming patent infringement must serve ... an identification of no more than 25 claims of each patent in suit ... but no more than 50 claims total ...”); N.D. Ill. Pat. R. 3.1 (describing final infringement contentions) (“[E]ach party claiming patent infringement must serve ... a list identifying no more than 10 claims per patent and no more than 20 claims overall that the party is asserting ...”).

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a minimum, perform a rigorous study—for example, by going through all the patent decisions in the *Lex Machina* database and determining both how many and what percent of patents that *would have been rendered unenforceable* by the proposed rule have actually been found invalid when challenged in court. Unless the number is high in absolute terms and as a percentage, the USPTO will have confirmed that its proposed rule is trying to solve a problem that either does not exist or is not material. Indeed, filing a terminal disclaimer already ensures that the patent does not have more term than the patent it is tied to and can be enforced only as long as the patents are commonly owned. It is just not a tool to unfairly kill patents *en masse* as now proposed.

The proposed rule will increase the costs to companies and the burden on the USPTO.

When faced with an OTDP rejection under the proposed rule, “[t]o 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.” 89 Fed. Reg. at 40441. This will create several problems.

First, the undersigned believe that in many cases, applicants will no longer file a terminal disclaimer as the right to have the validity of each claim determined on its own is too important to relinquish. In a substantial number of cases (and likely a majority), patent owners will choose to fight an OTDP rejection on the merits rather than file a terminal disclaimer. Given the pervasiveness of continuation practice³ and of OTDP rejections for one or more claims of a patent application, the rule is likely to increase materially the expense to patent applicants, the USPTO’s workload, and delays in patent issuance. The *fact* is that a *majority* of patents are currently issuing with PTA solely due to USPTO delays because the USPTO is not succeeding in examining patents in an expeditious manner.

Second, by discouraging the filing of terminal disclaimers, the proposed rule *contravenes* recognized public policy. As the Federal Circuit has stated: “[T]he use of a terminal disclaimer in overcoming a nonstatutory double patenting rejection is in the public interest because it encourages the disclosure of additional developments, the earlier filing of applications, and the earlier expiration of patents whereby the inventions covered become freely available to the public.” *In re Berg*, 140 F.3d 1428, 1436 (Fed. Cir. 1998) (quoting MPEP § 804.02). The USPTO cannot dispute that, by placing new burdens on terminal disclaimers, it will *discourage* their use. Thus, even if the proposed rule did advance some other public interest (and as noted above, there is no evidence to support the assertion that it does), it is at odds with fundamental public policy.

³ For example, in 2018, continuing applications “comprised 20% of the almost 600,000 utility patent ... filings at the USPTO.” Cesare Righi, Davide Cannito & Theodor Vladasel, *Continuing patent applications at the USPTO*, 52 RSCH. POL’Y 1, 1 (2023).

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Third, the proposed rule will create mischief in litigation. Consider, for example, a plaintiff who sues a defendant on a patent that is subject to terminal disclaimer under the proposed rule. An enterprising defendant will, as a matter of course, find a related patent with the *broadest* claim and file an *inter partes* review (IPR) proceeding attacking it. Why? Because if that one claim is invalidated, the defendant effectively wins the lawsuit—*all* the claims of the terminally disclaimed patent at issue in the lawsuit would be rendered unenforceable. As a result, to file an IPR, a defendant no longer has to find prior art invalidating the claims it is *actually* accused of infringing. Instead, the defendant just needs to find prior art for *a* claim somewhere in the chain of patents that are directly or indirectly tied together by a terminal disclaimer. And because there is no standing requirement for IPR proceedings, the claim the defendant attacks need not even be one it is (or ever would be) accused of infringing. Meanwhile, the plaintiff will not even be able to abrogate such an IPR by disclaiming the challenged claim—because, under the proposed rule, such a disclaimer has the *same* downstream effects as a finding of invalidity. The proposed rule therefore has the perverse outcome of encouraging unnecessary and undesired patent litigation and driving up costs for patent owners.

Indeed, the notice of proposed rulemaking identifies this exact scenario as resulting from the proposed rule. *See* 89 Fed. Reg. at 40440. As the USPTO described, “a competitor could petition for an [IPR] of just a single patent to which multiple patents are tied by ... terminal disclaimers with the proposed agreement.” *Id.* In doing so, “[t]he outcome of the ... challenge to the claims in the selected patent” would determine “the enforceability of the multiple patents tied to that selected patent.” *Id.*; *see also id.* at 40443 (Examples 2, 3). This is, respectfully, exactly the kind of gamesmanship and abuse of process that the USPTO should be trying to discourage—not promote.

Fourth, the proposed rule will create confusion and difficulty for courts. Imagine, for example, that a patent with a terminal disclaimer (under the proposed rule) *and* a related patent are asserted together in the same lawsuit. At trial, the jury determines that (i) one claim from the related patent is obvious in light of the prior art, and (ii) all other claims of that patent, and all claims of the terminally disclaimed patent, are *not invalid*. Under the proposed rulemaking, the claims of the terminally disclaimed patent are *unenforceable* based on a demonstrably incorrect assumption—i.e., that any one claim of the related patent is a good indication of the validity of *all* the claims of the terminally disclaimed patent. It goes without saying that there is enormous inequity in this situation—and it creates a difficult position for the district court judge and the Federal Circuit on appeal—who will *have to* disregard the jury’s verdict of validity. It also badly wastes judicial resources and jury time.

D. The proposed rule will harm innovation.

The proposed rule will negatively impact startups and established companies.

Nearly 20% of the patents issued in 2023—almost 60,000 patents—included terminal disclaimers. Dennis Crouch, *Terminal Disclaimers: A Growing Concern in Patent Practice*, PatentlyO (May 10, 2024), <https://tinyurl.com/mu84cvdt>. These patents were issued across the board to different types of inventors, from large companies to small startups to even individuals. *Id.* The effect of the proposed rule, therefore, will be far-reaching and widespread. Startups, academic institutions, and individual inventors are especially vulnerable to the consequences of the proposed rule. There is no question that patents play a critical role for startups. Often, patents are necessary to secure venture capital funding, exit strategies, and, of course, to protect what is being researched and developed. *See, e.g.*, Stuart J. H. Graham & Ted Sichelman, *Why do Start-ups Patent?*, 23 BERK. TECH. L.J. 1063 (2008); *Startups with patents and trade marks are 10 times more successful in securing funding, new study finds*, European Patent Office (Oct. 17, 2023), <https://tinyurl.com/myw47727>; Annamaria Conti et al., *Patents as Signals for Startup Financing*, 61 J. OF INDUS. ECONS. 592 (2013). Startups, academic institutions, and individuals, however, will struggle to adapt to the increased patent prosecution costs and delays associated with the proposed rule. *See supra* 7.

Larger companies will also suffer as a result of the proposed rule, particularly those that often engage in continuation practice. For example, high tech companies depend on continuation practice as they reduce embodiments of their technology to actual practice in commercial form. Continuation applications allow technology companies to disclose their discoveries as much as possible as early as possible, with the assurance that subsequent applications can provide protection for what is later actually reduced to practice and commercialized based on the original disclosure. A patent specification, for instance, may broadly disclose a new technology and numerous potential applications. The first patent application may claim one use of the technology, but subsequent continuation applications, filed with terminal disclaimers tying them to the first, may claim uses disclosed in the original disclosure that were later developed. Healthcare companies similarly make use of continuation applications as they develop and conduct clinical trials of life-saving treatments disclosed in an original disclosure. The proposed rule would obliterate this practice—which is authorized by law, *see* 35 U.S.C. § 120—and drastically alter research and development.



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For each and all these reasons, the proposed rule should be withdrawn.

Sincerely,

Clement Seth Roberts
ORRICK, HERRINGTON & SUTCLIFFE LLP
405 Howard Street
San Francisco, CA 94105
(415) 773-5700

Alyssa Caridis
ORRICK, HERRINGTON & SUTCLIFFE LLP
333 South Grand Avenue, Ste. 2700
Los Angeles, CA 90071
(213) 629-2020

Irena Royzman, Ph.D.
ORRICK, HERRINGTON & SUTCLIFFE LLP
51 West 52nd Street
New York, NY 10019
(202) 506-3518

Samantha Leff
ORRICK, HERRINGTON & SUTCLIFFE LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
(202) 339-8400

*Counsel for DISH Network, L.L.C., Sonos, Inc., RingCentral Inc.,
NAGRA Kudelski Group, Capstan Therapeutic, Inc., and
Nutcracker Therapeutics, Inc.*