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Comments of the Pharmaceutical Research and Manufacturers of America in Response to the USPTO's Notice of Proposed Rulemaking on Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting (Docket No. PTO-P-2024-0003)

July 9, 2024

I. Introduction

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments in response to the United States Patent and Trademark Office's (USPTO) Notice of Proposed Rulemaking on Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting (May 10, 2024)[1] (Notice).

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA's member companies have invested more than $1.2 trillion in the search for new treatments and cures, including an estimated $101 billion in 2022 alone.[2] The biopharmaceutical industry is committed to working every day to discover and develop new treatments for patients battling serious and life-threatening diseases such as cancer, heart disease, Alzheimer's, and many rare diseases.

New treatments and cures are made possible by the American system of intellectual property (IP) protections that give companies the certainty they need to make the long-term investments required to bring new medicines to patients as well as to improve them for additional benefit to patients after they secure FDA approval. Post-approval research and development (R&D) can lead to new or improved treatment options for patients that may enable better health, quality of life, or reduced treatment burdens improving treatment adherence and health outcomes. Patents are critical to incentivizing this important work and to ensure the full clinical benefits of medicines are realized.

Given the increasing cost of bringing a biopharmaceutical product to market and the increasing percentage of drug candidates that fail during clinical studies, IP protections are more important than ever to promote the investment in biopharmaceutical R&D. Strong and predictable IP protections in the United States are essential to the U.S.'s economic well-being, and these protections signal to other jurisdictions the critically important economic benefits of IP. The substantial investments related to biopharmaceutical R&D also fuel the U.S. economy. The biopharmaceutical industry supports nearly 5 million jobs and contributes $1.65 trillion in economic output when direct and indirect effects are considered.[3]

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[1] Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, 89 Fed. Reg. 40439 (Proposed May 10, 2024).

[2] PhRMA, *2023 PhRMA Annual Membership Survey (2023)*, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/PhRMA_membership-survey_single-page_70523_es_digital.pdf.

[3] TEConomy Partners, The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates, May 2024, https://www.teconomypartners.com/wp-content/uploads/2024/05/The-Econ-Impact-of-U.S.-Biopharma-Industry-2024-Report.pdf.

The USPTO is seeking public input regarding a proposed rule to modify terminal disclaimer practice to require that a terminal disclaimer:

> 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.[4]

This proposed rule, which appears to be premised on a misunderstanding of terminal disclaimers and the concept of so-called "patent thickets," would negatively impact incentives for innovation for PhRMA's member companies. This in turn could have negative implications for future life-saving and life-enhancing therapies for patients in need. The USPTO does not have the authority to promulgate such a rule for reasons discussed below. Thus, the proposed rule should not be promulgated.

II. Dispelling the Myths Surrounding Patent Thickets and Terminal Disclaimers in the Pharmaceutical Space

A. The USPTO Attempts to Sidestep the Comments it Received in Response to its October 4, 2022 Notice

The USPTO's proposed rule is a renewed attempt to implement misguided policy objectives articulated in the October 4, 2022 Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights.[5] That request for comments was, in turn, apparently driven largely by a June 8, 2022 letter from Senators Leahy, Cornyn, Blumenthal, Collins, Klobuchar, and Braun that alleged that "large numbers of patents that cover a single product or minor variations on a single product, commonly known as patent thickets . . . are primarily made up of continuation patents and can stifle competition."[6] The current Notice alleges that the "current state of the law exposes competitors attempting to enter the market to potentially high costs because they may have to defend against patents to obvious variants of a single invention despite the presence of terminal disclaimers,"[7] and the Notice also specifically

[4] 89 Fed. Reg. 40439.
[5] 87 Fed. Reg. 60130-60134.
[6] Letter from Sens. Leahy, Cornyn, Blumenthal, Collins, Klobuchar, and Braun to Kathi Vidal, at 1 (June 8, 2022); *see* 87 Fed. Reg. at 60131 (citing and quoting June 8, 2022 letter from Senators).
[7] 89 Fed. Reg. 40441.

referenced a comment suggesting that placing limits on terminal disclaimers would "lower drug prices for drugs that are no longer considered innovative."[8]

These unsubstantiated allegations about the U.S. patent system appear to be driving the USPTO's proposed changes to terminal disclaimers. Indeed, PhRMA voiced many of these concerns in prior comments, including "Comments of the Pharmaceutical Research and Manufacturers of America in Response to the USPTO's Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (Docket No. PTO-P-2022-025)" on February 1, 2023 as well as its Supplemental Comments for the same docket on February 28, 2023. The many comments submitted in response to the prior request for comments should, at a minimum, be incorporated by reference into the record for the current Notice, and the USPTO should address all comments here. PhRMA hereby expressly incorporates both submissions by reference in their entireties. Furthermore, PhRMA restates here the many inaccuracies regarding the purported concerns with terminal disclaimers.

B. Terminal Disclaimers Expedite Patent Prosecution and Promote Flexibility

As an initial matter, nonstatutory double patenting (NSDP)[9] is a judge made doctrine[10] that has been articulated to address two concerns. First, the NSDP doctrine is intended to prevent a patentee from obtaining an unjust time-wise extension of a patent for the same invention or an obvious modification of the invention claimed in another patent. Second, the doctrine is intended to prevent harassment by multiple assignees alleging infringement of the same inventions or obvious modifications of the inventions.[11] Terminal disclaimers function as a way to overcome an NSDP rejection or challenge through disclaiming the longer term of a patent such that the challenged patent would expire at the same time as the reference patent.[12] In addition, a terminal disclaimer will only serve to "obviate double patenting," if the two patents are commonly owned, which prevents separate infringement suits from different parties.[13] Terminal disclaimers thus serve as a "simple expedient" to overcome the concerns associated with NSDP.[14] Crucially, filing a terminal disclaimer does *not* impact any of the other requirements for patentability (i.e., being novel and non-obvious over the prior art), nor does it indicate that prior art exists that could impact patentability.

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[8] 89 Red. Reg. 40440.
[9] Nonstatutory double patenting is also known as nonstatutory obviousness-type double patenting, or OTDP.
[10] *See, e.g.*, *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1375 (Fed. Cir. 2018).
[11] *See, e.g.*, *In re Fallaux*, 564 F.3d 1313, 1318-1319 (Fed. Cir. 2009).
[12] *See, e.g.*, *SimpleAir*, 884 F.3d at 1167 ("And filing a terminal disclaimer may obviate an obviousness-type double patenting rejection, 37 C.F.R. § 1.321(c), as it did for the patents at issue, in exchange for limiting the patent term and alienability of the resulting continuation patent").
[13] *See, e.g.*, 37 C.F.R. § 1.321; *see also In re Van Ornum*, 686 F.3d 937, 945-946 (C.C.P.A. 1982) (recognizing that § 1.321 brings into effect a procedure already recognized by the court); *In re Hubbell*, 709 F.3d 1140, (Fed. Cir. 2013) ("As a general rule, a terminal disclaimer filed to overcome an obviousness-type double patenting rejection is effective only where the application and conflicting patent are commonly owned.").
[14] *See, e.g.*, *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) ("In legal principle, the filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection. It is improper to convert *this simple expedient of 'obviation'* into an admission or acquiescence or estoppel on the merits.") (emphasis added).

The proposed changes in the current Notice also would implicate important patent policy questions regarding the current flexibility afforded to prosecution. The USPTO should recognize that biopharmaceutical innovation is lengthy, complex, and unpredictable, and so flexibility in the patent application process is important. Under the current regime, the Patent Act encourages broad disclosure of inventive subject matter precisely because it permits a patent applicant to secure the full scope of patent protection that is supported by a patent application over time. In some instances, patent applicants may also choose to file a terminal disclaimer to obviate concerns associated with NSDP, which under the current rules, does not result in an invalidity finding of one claim automatically rendering all linked patents unenforceable. The USPTO's proposed change to terminal disclaimers, however, would change this flexibility. The U.S. patent system should be focused on incentivizing innovation and encouraging disclosure of inventive subject matter rather than on attempting to restrict flexibility and protection for inventions.

Finally, patents issued with terminal disclaimers face the *same* examination process and have the *same* statutory requirements for patentability as any other patent.[15] To the extent the USPTO or other stakeholders are concerned that such patents are issued without being subjected to the same scrutiny as other patents (on which no evidence has been put forward suggesting this is the case), the USPTO should look at improving the examination process, *not* weakening patent rights.

C. Concerns Surrounding So-Called "Patent Thickets" are Unfounded

As discussed in Section II.A, the current Notice is a renewed attempt to implement misguided policy objectives reflected in the USPTO's October 4, 2022 Notice, which was partially motivated by a purported need to address so-called "patent thickets." But narratives about the quantity of patents and the families of patents comprising so-called "patent thickets" are driven by questionable data and misunderstandings about patent coverage. A newly issued patent does not extend the term of an old one. Ever since Congress passed the Uruguay Round Agreements Act of 1994,[16] which changed patent term from 17-year terms from time of grant, the core concerns surrounding continuing applications extending the life of a patent family have been obviated. Now, unless otherwise adjusted or extended as allowed by statute,[17] a patent's term expires 20 years from its "effective filing date," which, for a patent issuing from a continuation, continuation-in-part, or divisional application (*i.e.,* applications in the same family), is the filing date associated with the earliest-filed non-provisional application to which it claims priority.[18] Thus, absent those statutory exceptions, patents in the same family expire on the same date and do not extend the patent term. And a single patent covers only the subject matter set forth in its claims, and claims in different patents cannot be identical per statutory

[15] *See also* Drug Patent and Exclusivity Study, USPTO, 5 ("The USPTO grants patents on patent applications only after an examination to ensure that the claimed invention meets the statutory requirements for patentability."); *id.* at 5 n. 14 (recognizing the same statutory requirements apply for patents issued with terminal disclaimers).
[16] Public Law 103-465, 108 Stat. 4809 (1994).
[17] *See, e.g.*, 35 U.S.C. § 154(b) (Patent Term Adjustments); § 156 (Patent Term Extensions).
[18] 35 U.S.C. § 154; 35 U.S.C. § 100(i)(1); *see also* Drug Patent and Exclusivity Study, USPTO, 68-69 ("It is important to note that continuation patents, by statute, cannot extend the 20-year term of a parent (i.e., original) patent. The term of a continuation patent will expire at the same time the original patent will expire, except for any patent term adjustment or patent term extension of the continuation patent, if applicable.").

requirements.[19] Thus, multiple distinct inventions relating to a particular product may lead to multiple patents.

Despite the purported concerns raised, no evidence has been cited questioning the quality of the USPTO's examination process, including no evidence suggesting that patents with terminal disclaimers are more likely to be invalid when compared to patents that do not have terminal disclaimers, or that terminal disclaimers result in more expensive litigation or suppressed competition. Notably, letters from Senator Tillis, Ranking Member of the Senate Judiciary Committee Subcommittee on Intellectual Property, explained that "several of the main sources driving the narrative that patents are to blame for high drug prices do not appear to . . . be based on accurate facts and data from reliable, unbiased sources."[20] Indeed, despite the strong rhetoric, there is no sound evidence that excessive numbers of patents are being issued, litigated, or improperly stifling competition in the biopharmaceutical arena.

Indeed, the USPTO's recently published "Drug Patent and Exclusivity Study" demonstrates that the narratives regarding "patent thickets" and their alleged harm are incorrect and misleading.[21] For example, as the USPTO's study reported, "simply quantifying raw numbers of patents and exclusivities is an imprecise way to measure the intellectual property landscape of a drug product because not every patent or exclusivity has the same scope," and therefore, the "simple counts of patents can be *misleading* when every patent is counted equally, because *the number of patents does not provide a clear picture of the landscape* without a review of the scope of the claims in each patent."[22]

The USPTO's report further demonstrates that narratives about patent thickets have been built on seriously flawed data. For example, I-MAK has alleged that biopharmaceutical companies "maintain[] market control by exploiting an outdated patent system" and "secur[ing] hundreds of patents to block competition."[23] I-MAK's data are often cited by individuals in academia, witnesses at congressional hearings, and by policymakers. Yet I-MAK has also been repeatedly criticized for its lack of transparency in the underlying data and methodology as well as its flawed and inaccurate data and conclusions.[24] For example, in its methodology for counting "total patents" covering a product, I-MAK "includes not just patents, but also pending patent applications, and even fully abandoned patent applications."[25] Yet the USPTO's report expressly rejected this methodology, stating that "[a]bandoned applications do not result in

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[19] 35 U.S.C. § 101; *see also* *Drug Patent and Exclusivity Study*, USPTO, 69 ("Moreover, a patent applicant cannot be granted two patents for identical inventions.").
[20] Letter from Sen. Thom Tillis to Dr. Janet Woodcock and Mr. Drew Hirshfeld, at 1 (Jan. 31, 2022); Letter from Sen. Thom Tillis to Dr. Robert Califf and Mr. Drew Hirshfeld, at 1 (Jan. 31, 2022).
[21] *Drug Patent and Exclusivity Study*. The USPTO's study analyzed overlapping NDAs that were evaluated in the UC Hastings and I-MAK studies., discussed *supra*. *Drug Patent and Exclusivity Study*, USPTO, 11.
[22] *Drug Patent and Exclusivity Study*, USPTO, 57 (emphasis added).
[23] I-MAK, *Overpatented, Overpriced: Curbing patent abuse: Tackling the root of the drug pricing crisis*, at 10 (Sept. 2022).
[24] *See, e.g.*, Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents* (Jan. 2022); Letter from Sen. Thom Tillis to Dr. Janet Woodcock and Mr. Drew Hirshfeld (Jan. 31, 2022); Letter from Sen. Thom Tillis to Dr. Robert Califf and Mr. Drew Hirshfeld (Apr. 1, 2022).
[25] Letter from Sen. Thom Tillis to Dr. Robert Califf and Mr. Drew Hirshfeld, at 2 (Apr. 1, 2022). Unlike the I-MAK study, the USPTO's report does not include pending or abandoned patent applications.

granted patents, and thus, do not pose a barrier to competition" and pending patent applications "may never become patents," therefore, "*the total of all abandoned and pending applications is not a meaningful metric*."[26] Instead, the USPTO's report did not include pending or abandoned patent applications.[27]

The USPTO's report is just the most recent in a line of evidence demonstrating the flaws in I-MAK's data analysis. An article by Adam Mossoff states that "I-MAK's reported numbers of issued patents, patent applications, and exclusivity periods for drugs are infected with serious questions of reliability and accuracy," and he observes "repeated and vast discrepancies between I-MAK's numbers and the numbers found in official, publicly available governmental sources like the FDA's Orange Book and court opinions."[28] Professor Mossoff notes that I-MAK cites exclusivity expiry dates for medicines that extend far beyond actual generic entry for these medicines. I-MAK thus has inflated the purported number of patents covering biopharmaceutical products and has extended their predictions of loss of exclusivity dates beyond reality.[29]

Similarly, the reliability of conclusions drawn from the U.C. Hastings Evergreen Drug Patent Database (the "Hastings Database")[30] has also come into question. Scholars Erika Lietzan and Kristina Acri analyzed the accuracy of the Hastings Raw Dataset of expiry dates for patents and statutory exclusivities for drug products and identified significant deficiencies in the inferences drawn from it in the Hastings Database. Based on generic launch dates reflected in FDA's Paragraph IV Patent Certifications List, the authors demonstrated that the Hastings Database's "latest protection end date" listings do not accurately capture when generic drugs enter the market. Instead, based on the authors' dataset, many generic drugs were launched *before* the listed latest expiry date—in many cases, years earlier. Specifically, Lietzan and Acri found that "*generic competition launched on average eighty-four months (seven years) before the Hastings Database implies it would*."[31] They also found that, on average and based on a dataset of seventy-nine chemical entities, new chemical entities "experienced generic competition sixty-eight months (or more than five years) before the Hastings Database date."[32] Accordingly, the authors conclude that the "Hastings inference"— that until the last protection end date, the brand company may have limited generic competition and monopolized a drug

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[26] *Drug Patent and Exclusivity Study*, USPTO, 13 (emphasis added).
[27] *Id.*
[28] Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents*, at 5-6 (Jan. 2022).
[29] *See, e.g.*, *Statement of Corey Salsberg, Vice President and Global Head Intellectual Property Affairs for Novartis regarding "Listening Session on Joint USPTO-FDA Collaboration Initiatives,"* at 6 (Jan. 19 2022) (noting how I-MAK included "44 *abandoned* patent applications that never issued as patents, as well as a variety of patents that don't cover our drug."); *see also Comment – Adam Mossoff*, at 2-5 (raising "[q]uestions of [u]nreliability in I-MAK's [p]atent [d]ataset").
[30] *See* Evergreen Drug Patent Database.
[31] Erika Lietzan & Kristina Acri née Lybecker, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations*, 33 FORDHAM INTELL. PROP., MEDIA & ENT. L.J. 788, 788 (2023) (emphasis added).
[32] *Id.* at 789.

product—is invalid, and "that the 'latest protection end date' [in the Hastings Database] should not be used as a proxy for the likely generic entry date."[33]

And just as with the I-MAK study, the USPTO *expressly rejected* research methodologies used in the Hastings Database. The USPTO noted how that database "appear[s] to rely on patent 'use codes' corresponding to information provided by NDA holders to the FDA as a proxy for the scope of the patent."[34] But the USPTO "[did] not incorporate use codes" for its study, noting:

> Not all Orange Book-listed patents have associated use codes—only those claiming a method of using the drug product—and use codes are not a replacement for a detailed analysis of a patent claim's scope. Moreover, newer methods of use protected by a patent may be carved out from generic drug product labels and thus may not necessarily prevent a generic launch for other uses for which patent protection has expired. For example, a generic version of MIRAPEX … was launched after expiration of the exclusivity under the FD&C Act without infringing later issued and non-expired method of use patents (directed to treating restless-leg syndrome).[35]

Finally, there are fewer patents in the biopharmaceutical industry than there are in many other industries. For example, between 2016 and 2021, the five companies with the most issued patents were all high tech companies, not biopharmaceutical companies.[36] Indeed, a summary of the top 300 organizations granted U.S. patents in 2023 demonstrates that the technology sector vastly outpaces the biopharmaceutical industry.[37] Indeed, there tend to be fewer patents per medicine than for many other marketed products, ranging from golf balls and golf clubs to cell phones to certain sneaker technology.[38] And as the USPTO itself points out, "multiple patents associated with a single marketed product are not unique to the pharmaceutical industry and are a common practice in many innovative industries, especially for complex products."[39] Regardless, a focus on the number of patents is also misguided. Patents allow an inventor to exclude others from making or using the claimed invention, but not all patents relating to a biopharmaceutical product actually prevent generic products from entering the market. For example, a generic manufacturer may decide to use a particular formulation or polymorphic form that is outside the

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[33] *Id.* at 845.
[34] *Drug Patent and Exclusivity Study*, USPTO, 61.
[35] *Id.* at 61-62 (footnotes omitted).
[36] *See* Prableen Bajpai, *Who Led the Patent Race in 2021?*, NASDAQ (Jan. 12, 2022).
[37] *See* Top 300 Organizations Granted U.S. Patents in 2023, 41st Annual Listing (Jan. 18, 2024).
[38] *See, e.g.*, Titleist Patent Marking (last visited July 8, 2024) (noting, for example, 24 patents covering the 2023 Pro V1 golf balls, 40 patents covering the 2021 Pro V1x golf balls, and 90 patents covering "irons" golf clubs); Building a Better Golf Ball, Popular Science (Nov. 24, 2008) (noting that a golf ball may contain as many as 70 separate inventions); TaylorMade Golf Patent Marking (listing over 100 patents for certain golf clubs); Apple-Samsung Case Shows Smartphones as Legal Magnet, New York Times (August 25, 2012) ("By one estimate, as many as 250,000 patents can be used to claim ownership of some technical or design element in a smartphone."); LG Patent Marking (last visited July 8, 2024) (listening hundreds of patents as covering LG's smartphones); Alison Noon, *Puma Must Face Nike's Flyknit Patent Infringement Claims*, Law360 (Oct. 10, 2018) ("Nike claimed to have acquired more than 300 utility patents to protect the knit-upper shoe trend it launched in 2012.").
[39] *Drug Patent and Exclusivity Study*, USPTO, 58.

scope of any patent claims.[40] And contrary to the suggestions of some commenters, terminal disclaimers do not facilitate "evergreening"—extending patent protection through what some view as non-patentable advances. Under the current regime, terminal disclaimers link the expiration date of two patents because the patentee has disclaimed part of the patent term that they may have otherwise been entitled to.[41]

All the above evidence demonstrates the fundamental flaws in the narrative that "patent thickets" deter innovation. Indeed, the USPTO's report intentionally analyzed similar samples as those analyzed in I-MAK reports and the Hastings Database.[42] In doing so, the USPTO expressly considered and rejected various methodologies used by those studies.[43] As even the USPTO itself has recently recognized these flaws, the USPTO should reconsider what "problems" this proposed rule is actually designed to solve, and whether those "problems" exist in the first place.

III. The USPTO Does Not Have Authority To Promulgate this Rule That Modifies Terminal Disclaimers To Obviate Nonstatutory Double Patenting

The USPTO lacks both statutory and constitutional authority to promulgate this proposed rule. This proposed rule is substantive and is far afield of the authority that anyone could expect Congress to have delegated to the USPTO. Furthermore, it conflicts with clear principles of patent law embedded in the Patent Act. The proposed rule also sets unconstitutional conditions on overcoming a nonstatutory double patenting rejection. Finally, even if the USPTO actually did have authority to promulgate the proposed rule, it would be doing so without any substantive guideposts from Congress in violation of the nondelegation doctrine.

A. Lack of Statutory Authority

1. The Proposed Rule is a Substantive Rule that the USPTO Lacks Authority to Promulgate

The USPTO's primary source of rulemaking authority is 35 U.S.C. § 2(b)(2), which provides that the USPTO "may established regulations, not inconsistent with law, which—(A) shall govern the conduct of proceedings in the Office…." Section 2(b)(2) only gives the USPTO authority to make procedural rules, not substantive rules.[44]

The USPTO has asserted that the rule is merely procedural because it is placing requirements on terminal disclaimers and is directed to "enforceability" rather than "validity."

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[40] *See, e.g.*, *Drug Patent and Exclusivity Study*, USPTO, 57-58 (reporting that a generic version of Mirapex® was launched after the FDA exclusivity period without infringing later issued and non-expired method of use patents); *id.* at 59 (observing that, "patent expiration dates, like the number of patents, may not be predictive of the timing of actual launch of competing products . . ., because not all listed patents may be infringed by a generic product.")
[41] This is particularly relevant in the case of patents from different families—here, the terminal disclaimer could result in a patent term that is years shorter than it might have otherwise been.
[42] *Drug Patent and Exclusivity Study*, USPTO, 15.
[43] *Id.* at 13, 61-62.
[44] *See Tafas v. Doll*, 559 F.3d 1345, 1352 (Fed. Cir. 2009), *reh'g en banc granted, opinion vacated*, 328 F. App'x 658 (Fed. Cir. 2009).

The USPTO further asserts that *In re Van Ornum*, 686 F.2d 937 (CCPA 1982) stands for the proposition that the USPTO can place any conditions on enforcement in terminal disclaimers. The USPTO's arguments are misguided.

i. The USPTO overreads the Van Ornum Case

First, the USPTO greatly overreads *In re Van Ornum*, 686 F.2d 937 (C.C.P.A. 1982). *Van Ornum* involved a scenario where the USPTO was merely implementing a settled nonstatutory double patenting principle of preventing harassment by multiple assignees. Furthermore, the USPTO in *Van Ornum* lifted terminal disclaimer language precisely from language that another case cited approvingly.[45] The court found "it desirable to tie both the termination and the ownership of the two patents together," and found the Office regulation to be valid for those reasons, *not* because the Office has some absolute authority to attach conditions on enforceability to terminal disclaimer.[46]

Here, the Office is coercing a single party with multiple patents into giving up rights to enforcement. The court in *Van Ornum* upheld the rule because it was aligned with fundamental principles behind nonstatutory double patenting rejections. Rules such as the one in *Van Ornum* that simply implement the current state of the law, either judicially or legislatively created, are generally acceptable.[47] The current Notice invents language that goes against the reasoning of multiple Federal Circuit cases,[48] and it even destroys the value to the public of terminal disclaimers, as expressly recognized in *Van Ornum*, because it "bring[s] such improvement inventions within the protection of the patent system."[49] The court in *Van Ornum* viewed

[45] *Id.* at 944-45 ("[W]e note that the language of paragraph (b) of the rule is precisely that used in the [In re] Griswold terminal disclaimer.").
[46] *In re Van Ornum*, 686 F.2d 937, 948 (C.C.P.A. 1982).
[47] *See Agilent Technologies, Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1375 (Fed. Cir. 2009) ("Judicial precedent is as binding on administrative agencies as are statutes."). As a further example, 37 C.F.R. § 1.321(c) as promulgated reflected this language approved of in *Van Ornum*, and it did not seek to go beyond the fundamental principles discussed in *Van Ornum*. 37 C.F.R. § 1.321(d) does extend those terminal disclaimer requirements to nonstatutory double patenting rejections based on art that was the "result of activities undertaken within the scope of a joint research agreement," but this regulation was promulgated directly as a result of statutory mandates from the Cooperative Research and Technology Enhancement (CREATE) Act of 2004 (Public Law 108–453, 118 Stat. 3596), which amended 35 U.S.C. § 103(c) to disqualify as prior art such references made as a result of joint research agreements. In each case, the USPTO was merely promulgating rules to reflect the current state of the law, either judicially or legislatively created, ***not*** using its rulemaking powers to change the state of the law.
[48] *See* Notice at 9-10 (citing *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167-68 (Fed. Cir. 2018) ("our cases foreclose the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims"); *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007) ("A terminal disclaimer is simply not an admission that a later-filed invention is obvious"); *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 941 (Fed. Cir. 1992) (filing a terminal disclaimer does "not concede double patenting with relation to any other patent"); *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) ("[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.")).
[49] 686 F.2d at 948 ("Certainly many, if not most, double patenting situations fall into the obviousness-type double patenting category and involve a modification of or improvement upon what an inventor or his assignee has already patented. The desire is to be able to bring such improvement inventions within the protection of the patent system, at the same time giving an incentive for their disclosure. For a long time the judge-made law of double patenting was a serious obstacle to doing so. Knowing this, the drafters of the 1952 Patent Act provided a possible remedy in the terminal disclaimer, 35 U.S.C. s 253.").

terminal disclaimers as simply helping to create "a situation … which is tantamount for all practical purposes to having all the claims in one patent."[50] Yet this proposed rule does the opposite—it treats claims differently when spread across multiple patents. And as discussed herein, the proposed rule undercuts statutory mandates.[51] In addition, Federal Circuit caselaw has made it clear that filing a "terminal disclaimer is simply not an admission that a later-filed invention is obvious."[52] Instead, "the filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection."[53]

ii. <u>The USPTO's Textual Change from Validity to Enforceability is a Meaningless Form Over Function Argument, Where the Substance is the Same</u>

Second, the USPTO relies far too much on a "form over function" argument regarding "enforceability" versus "validity" in asserting that this proposed rule is merely procedural and does not conflict with statutes or caselaw. Agencies have previously sought to sidestep statutory limitations by "mislabeling their substantive pronouncements," but, as the Supreme Court recently rearticulated, "courts have long looked to the *contents* of the agency's action, not the agency's self-serving *label*," when assessing an agency action.[54] As discussed above, the proposed rulemaking would make sweeping changes to the nature of nonstatutory double patenting law and is in substantive conflict with Federal Circuit caselaw. For example, caselaw makes clear that the filing of a terminal disclaimer does not function as an admission regarding the patentability of any claims, nor is it a concession regarding the validity (or enforceability) of any other patent.[55] Indeed, the very suggestion that a terminal disclaimer somehow has estoppel or claim preclusion effect was squarely rejected in *SimpleAir, Inc. v. Google LLC*.[56] There, the Federal Circuit stated that its "cases foreclose the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims."[57] Regardless of

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[50] *Id.*
[51] *See, e.g.*, § III.A.3.
[52] *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007).
[53] *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991).
[54] *Azar v. Allina Health Services*, 587 U.S. 566, 575 (2019) (finding that an agency's rule was substantive and required notice-and-comment rulemaking despite the agency's label to the contrary and noting that courts look at the contents of the agency's action) (emphasis in original); *see also Guardian Fed. Sav. & Loan Assn. v. Federal Sav. & Loan Ins. Corp.*, 589 F.2d 658, 666–667 (CADC 1978) (if "a so-called policy statement is in purpose or likely effect ... a binding rule of substantive law," it "will be taken for what it is") (quoted by *Azar*, 587 U.S. at 575).
[55] *See, e.g.*, *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167-68 (Fed. Cir. 2018) ("our cases foreclose the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims"); *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007) ("A terminal disclaimer is simply not an admission that a later-filed invention is obvious"); *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 941 (Fed. Cir. 1992) (filing a terminal disclaimer does "not concede double patenting with relation to any other patent"); *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) ("[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.").
[56] 884 F.3d at 1167 ("We disagree with Google that filing a terminal disclaimer settles the issue of claim preclusion here")
[57] *Id.*

the USPTO's label or characterization, the purpose and likely effect of the rule is to create "a binding rule of substantive law," and it should "be taken for what it is."[58]

2. Congress Did Not Intend to Grant the USPTO This Authority[59]

The Supreme Court has recognized that there are "cases in which the 'history and the breadth of the authority that [the agency] has asserted,' and the 'economic and political significance' of that assertion, provide a 'reason to hesitate before concluding that Congress' meant to confer such authority."[60] Under this doctrine, courts "presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies."[61] Even if an assertion of regulatory authority has "a colorable textual basis," courts recognize that "[e]xtraordinary grants of regulatory authority are rarely accomplished through modest words, vague terms, or subtle devices, … [n]or does Congress typically use oblique or elliptical language to empower an agency to make a radical or fundamental change to a statutory scheme."[62]

Here, as noted earlier in Section III.A.1, the USPTO's primary source of rulemaking authority is 35 U.S.C. § 2(b)(2), which provides that the USPTO "may establish regulations, not inconsistent with law, which—(A) shall govern the conduct of proceedings in the Office…." Under § 2(b)(2) the USPTO only has authority to make procedural rules, not substantive rules.[63]

In contrast to this limited procedural rulemaking, the USPTO is asserting authority to fundamentally change the law on terminal disclaimers, nonstatutory double patenting, and the presumption that patents are valid and must be invalidated on a claim-by-claim basis. The result of such rulemaking would shift how patent litigation proceeds in district courts and drastically shift the incentives of the patent system for applicants throughout the country.[64] Congress does not, and agencies may not, "hide elephants in mouseholes,"[65] and Congress could not have intended to grant the USPTO such sweeping authority via the comparatively innocuous provision

[58] *Guardian Fed. Sav. & Loan Assn.*, 589 F.2d at 666-67.
[59] "After the Supreme Court's overruling of *Chevron* deference in *Loper Bright Enterprises v. Raimondo*, (Slip Op.) (2024), agencies no longer receive deference to their interpretation of their enabling statutes, regardless of whether the major questions doctrine or any other doctrine applies. And even before *Loper*, the Federal Circuit had stated that the USPTO does not receive *Chevron* deference when acting under § 2. *Merck v. Co., Inc. v. Kessler*, 80 F.3d 1543, 1549-50 (1996). Thus, the USPTO's interpretation is only one factor that is "depend[ant] upon the thoroughness evidence in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944); *Loper*, (Slip Op.) at 10; *Merck*, 80 F.3d at 1550. As discussed herein, the extensive substantive impact of this proposed rule in contrast to the modest grant of authority in § 2(b)(2), as well as the substantive conflict between the proposed rule and multiple statutes, informs that the USPTO's grant of authority is not so far-reaching.
[60] *West Virginia v. EPA*, 597 U.S. 697, 721 (2022) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159-60 (2000).
[61] *West Virginia*, 597 U.S. at 723 (internal quotations omitted).
[62] *West Virginia*, 597 U.S. at 722-23 (internal quotations and citations omitted).
[63] *See Tafas v. Doll*, 559 F.3d 1345, 1352 (Fed. Cir. 2009), *reh'g en banc granted, opinion vacated*, 328 F. App'x 658 (Fed. Cir. 2009).
[64] *See infra* Section IV.
[65] *Brown & Williamson Tobacco Corp.*, 529 U.S. at 910; *West Virginia*, 597 U.S. at 746 (Gorsuch, J., concurring).

of making rules that "shall govern the conduct of proceedings in the Office."[66] This proposed rule thus should not be promulgated for at least this reason.

3. USPTO Disregards Statutory Provisions of the Patent Act

The USPTO's rulemaking is in substantive conflict with multiple core statutory provisions of the patent act, and it should not be promulgated for this reason.

35 U.S.C. § 282 states, "[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*."[67] Section 282 makes clear that the presumption of validity is on a claim-by-claim basis, not a patent-by-patent basis. The USPTO's proposal to determine enforceability of one patent with a terminal disclaimer based on the *invalidity of one claim of a different patent* would undermine § 282.

"Unenforceability" is not functionally different from invalidity here.[68] Patents only have value to a patent holder to the extent they can be enforced. Rendering all claims of one patent unenforceable because of what happened to one claim of a different patent, against which NSDP may not even have been raised, effectively nullifies § 282's mandate of presumption of validity for each patent and each claim of a patent.

This proposed rule further undermines the law of anticipation and obviousness. The underlying premise of the "stand and fall together" proposals are that, if a first patent is anticipated or obvious over prior art, a second patent that is anticipated or obvious over the first patent would necessarily also be anticipated or obvious over the same prior art. But this is not how the law of NSDP works. As an initial matter, terminal disclaimers filed to, e.g., expedite prosecution, do not mean any claim of the terminally disclaimed patent is in fact anticipated by or obvious over any claim of the reference patent. The Federal Circuit has made this clear.[69] Furthermore, even only a single claim that is patentably indistinct from a single claim in another patent can trigger an NSDP rejection and require a terminal disclaimer. Yet because a terminal disclaimer applies to the *entire* patent, not to specific claims, the rule in the Notice could render the entire patent unenforceable if any claim in a patent that it is tied to is found to be invalid as anticipated or obvious. This result is in direct conflict with the fundamental rule that anticipation and obviousness must be determined on a claim-by-claim basis. The USPTO's suggestion that an applicant can just move claims to other patent applications does not resolve this conflict. An

[66] 35 U.S.C. § 2(b)(2).
[67] Emphasis added.
[68] As the USPTO admitted, the proposed rule will effectively operate to allow a competitor to "seek to have the court narrow any validity disputes to address only [one] patent." 89 Fed. Reg. 40440. The proposed rule deprives a patent owner's ability to address invalidity attacks on a claim-by-claim basis under § 282.
[69] *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167-68 (Fed. Cir. 2018) ("our cases foreclose the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims"); *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007) ("A terminal disclaimer is simply not an admission that a later-filed invention is obvious"); *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 941 (Fed. Cir. 1992) (filing a terminal disclaimer does "not concede double patenting with relation to any other patent"); *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) ("[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.").

applicant should not need to surrender the flexibility in how to pursue claims. Nor should an applicant need to incur further costs when the underlying unenforceability rationale is inconsistent with the statute's presumption of validity and requirement for a claim-by-claim invalidity determination.

The Notice directly states a further fundamental incompatibility when giving its examples: impacted patents may be tied indirectly by terminal disclaimers (patent Y has a terminal disclaimer over patent X, which has a terminal disclaimer over patent W, but patent Y has no terminal disclaimer over patent W).[70] Yet the USPTO would render *both* patents Y and X unenforceable due to invalidity of patent W even though no disclaimer has been made between patents Y and W, let alone any actual determination that one is obvious in view of the other. For example, under this proposed rule if a broad claim in one patent is held invalid as anticipated or obvious, then another patent composed entirely of narrow claims with limitations that are not found in the prior art is unenforceable simply because of an indirect terminal disclaimer link.

In addition to § 282, this proposed rule is also in conflict with other statutory provisions. The proposed rule further conflicts with 35 U.S.C. § 253(a), which states that "[w]henever a claim of a patent is invalid the remaining claims *shall not thereby be rendered invalid*."[71] Yet under this proposed rule, if a single claim of one patent is found invalid, then all claims of *an entirely different patent* are rendered forever unenforceable. Sections 253 and 282 reflect a broader principle that claims must each stand or fall on their own merits, not together, and this proposed rule ignores that principle.

B. Lack of Constitutional Authority

1. The Proposed Rule Violates the Unconstitutional Conditions Doctrine

The USPTO is the gatekeeper to a core property right that is enshrined in the Constitution.[72] Although government actors may place certain conditions on awarding such property rights based on legitimate state interests, there must be an "essential nexus" between that interest and the condition, and there must also be a "rough proportionality" between the condition and the withheld benefit.[73] The conditions articulated in the proposed rule lack both such requirements.

To start, applicants that have fulfilled all other statutory requirements of the Patent Act have a legally cognizable property interest in a patent proceeding to grant. Intangible rights such as patents and trade secrets have long-been regarded as property interests protected by the Fifth Amendment's Takings Clause.[74] Indeed, the USPTO itself has endorsed the applicability of the

[70] *See* 89 Fed. Reg. 40443.
[71] Emphasis added.
[72] U.S. Const. Art. I, § 8, Cl. 8.
[73] *Nollan v. California Coastal Comm'n*, 483 U.S. 825 (1987); *Dolan v. City of Tigard*, 512 U.S. 374 (1994).
[74] *See Consolidated Fruit Jar Co v. Wright,* 94 U.S. 92 (1976) ("[A] patent for an invention is as much property as a patent for land. The right rests of the same foundation and is surrounded and protected by the same sanctions."); *Patlex Corp v. Mossinghof*, 758 F.2d 594 (Fed. Cir. 1985) ("[I]t is beyond reasonable debate that patents are property.").

Fifth Amendment to patents.[75] This property interest is not limited to issued patents, but it extends to the interest in a patent application proceeding to grant when the applicant has fulfilled all other statutory requirements of the Patent Act. Specifically, 35 U.S.C § 102(a) states that "[a] person *shall be entitled to a patent* unless" certain statutory bars are met.[76] If the applicant has overcome all bars to grant such as anticipation, obviousness, unpatentable subject matter, or lack of § 112 support, then § 102 is clear that the applicant is "entitled" to a patent.

Notably, the art that is subject to nonstatutory double patenting rejections *is not statutory prior art* under § 102(b)(2)(C). For example, 35 U.S.C. § 102(b)(2)(C) states, "[a] disclosure *shall not be prior art* to a claimed invention under subsection (a)(2) if … (C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person."[77] Yet, in the context of NSDP, a reference may be an NSDP reference *only if* the reference patent and challenged claim share the same inventive entity, a common joint inventor, a common application, or a common owner/assignee.[78] Thus, if the only hurdle standing between the applicant and her statutorily entitled patent is the nonstatutory double patenting rejection, then the conditions the USPTO places on filing a terminal disclaimer must meet the essential nexus/rough proportionality test.

There is no essential nexus between any legitimate USPTO interest and the conditions of the proposed rule. The USPTO asserts the vague interests of preventing obvious variants of patents "from potentially deterring competition," while also promoting "innovation and competition by allowing a competitor to avoid enforcement of patents" tied by terminal disclaimers.[79] As discussed below, these interests are not at all served by the proposed rule, and are in fact thwarted by the proposed rule, and thus lack an essential nexus.

As discussed above in § II.A.1.i, in *In re Van Ornum*,[80] a case in which the CCPA upheld the USPTO placing enforceability requirements on terminal disclaimers, the conditions placed by the USPTO were in accordance with and furthered a core principle of nonstatutory double patenting: preventing harassment by multiple assignees. The court found "it desirable to tie both the termination and the ownership of the two patents together," and found the Office regulation to be valid for those reasons.[81] In contrast, the proposed rule here stretches far beyond either of the two core principles of nonstatutory double patenting rejections: preventing harassment by multiple assignees and preventing unwarranted extension of patent term.

The condition in the proposed rule also lacks a rough proportionality with any potential negative impact of granting a patent. To start, as discussed herein, there is no reliable evidence that patents with terminal disclaimer relationships "deter competition" or hinder innovation as

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[75] *See e.g.*, *Celgene Corporation v. Peter* 931 F.3d 1342 (Fed. Cir. 2019): "The PTO does not dispute that a valid patent is private property for the purposes of the Takings Clause. See Intervenor's Br. 43 ("A patent holder has a property interest in a valid patent"); Oral Argument ("We don't dispute that a valid patent is property for the purposes of the Takings Clause.").
[76] Emphasis added.
[77] Emphasis added.
[78] *See, e.g.*, MPEP 804.
[79] 89 Fed. Reg. 40439.
[80] 686 F.2d 937 (CCPA 1982).
[81] *In re Van Ornum*, 686 F.2d 937, 948 (C.C.P.A. 1982).

suggested by the USPTO, and there is not a negative impact the USPTO should be seeking to curb. As discussed above, even the USPTO has now questioned the connections between so-called "patent thickets" involving terminally disclaimed patents and effects on competition.[82] But even to the extent there is any impact, the proposed solution—rendering an entire patent unenforceable if even one claim is found invalid in a patent that has a terminal disclaimer relationship, and without conducting any claim-by-claim analysis—is wildly out of scope.

The proposed rule and the rationale behind it have no nexus with the purposes of nonstatutory double patenting rejections and terminal disclaimers, and even if there was such a nexus, the condition is not proportional to the purported problem to be solved. Thus, this proposed rule violates the unconstitutional conditions doctrine, and should not be promulgated for at least this reason.

2. The Proposed Rule Violates the Nondelegation Doctrine

As discussed above, the USPTO lacks statutory authority to promulgate the proposed rule. However, to the extent the USPTO does have such authority, this authority violates the nondelegation doctrine. The Constitution does not vest in both the executive branch and Congress overlapping authority to create substantive patent law. U.S. Const. art 1, § 8, cl. 8. In order for legislative action to not be "a forbidden delegation of legislative power," Congress must "lay down by legislative act an intelligible principle to which the person or body authorized to exercise the delegated authority is directed to conform."[83] Specifically, Congress must have "made clear to the delegee the general policy he must pursue and the boundaries of his authority."[84] The Federal Circuit has held that rulemaking authority must have "substantive guideposts and procedural requirements that must be observed" by the body exercising the delegated authority.[85]

Here, Congress has not articulated any policy or standard to confine the USPTO's discretion in using terminal disclaimers to affect new policies. Congress has provided certain guideposts on the statutory implications of disclaimers in, e.g., 35 U.S.C. § 253 (such as stating that the invalidity of one claim does not impact the validity of other claims). Congress also provided substantive guideposts in the CREATE Act of 2004,[86] which amended 35 U.S.C. § 103(c) to disqualify as prior art such references made as a result of joint research agreements, and the USPTO acted within those guideposts when it promulgated 37 C.F.R. § 1.321(d).[87] And of course Congress has provided substantive guideposts in § 2(b)(2), which limits the USPTO to promulgating procedural rules.[88] But Congress has not provided any substantive guideposts for using terminal disclaimer provisions to effect other policy changes that substantively change

[82] *See supra* Section II.C.
[83] *Mistretta v. United States*, 448 U.S. 361, 372 (1989) (citing *J.W. Hampton Jr & Co v. United States*, 276 U.S. 394, 406 (1928)).
[84] *Gundy v. United States*, 588 U.S. 128, 146 (2019).
[85] *Terran ex. rel. Terran v. Secretary of Health and Human Services*, 195 F.3d 1302, 1314 (Fed. Cir. 1999).
[86] Public Law 108–453, 118 Stat. 3596 (2004).
[87] 37 C.F.R. § 1.321(d) extends terminal disclaimer requirements to nonstatutory double patenting rejections based on art that was the "result of activities undertaken within the scope of a joint research agreement," which was promulgated in view of statutory mandates from the CREATE Act of 2004.
[88] *See Tafas v. Doll*, 559 F.3d 1345, 1352 (Fed. Cir. 2009), *reh'g en banc granted, opinion vacated*, 328 F. App'x 658 (Fed. Cir. 2009).

patent rights, as the USPTO is doing here.[89] To require terminal disclaimer agreements that change substantive patent rights is not merely "filling up the details" of patent policy already established by Congress. And it does not amount to merely acting in a manner prescribed by Congress upon the establishment of conditional facts by the USPTO. Instead, this is a clear exercise of legislative power vested solely in the legislature, which cannot be delegated to the USPTO.

IV. Policy Considerations and Unintended Consequences

The proposed rule would starkly change the decision-making process for an applicant or patentee on whether to file a terminal disclaimer. Indeed, as the examples in the Notice make clear, there could be sweeping ramifications to the value of patents that are tied (directly or indirectly) with a patent that has had a claim invalidated on §§ 102 or 103 grounds, leading patent applicants to seek to avoid terminal disclaimers. Thus, the proposed changes to terminal disclaimer practice would likely result in less efficient prosecution, including longer prosecution times, applicants disclosing less information about their inventions in patent applications, and a perverse outcome when applicants receive patent term adjustments based on the delay solely caused by the USPTO.

A. Unintended Consequences of Challenges Arising From the Proposed Rule

1. Longer Patent Prosecution

i. More Disputes at the USPTO

Given the potential loss of rights by filing a terminal disclaimer under the proposed rule, applicants may be more likely to submit extensive arguments and file appeals to overcome NSDP rejections in order to avoid filing a terminal disclaimer.[90] This would require that the examiner provide a detailed basis for any NSDP rejection and the applicant to respond with a detailed explanation disputing the NSDP rejection, with increased potential for repeated rejections and appeals. This would further increase the already significant burden on examiners and the USPTO. Thus, the proposed change would result in longer prosecution times and more involvement from both the applicant and the examiner.

ii. Increased Claims and Increased Costs for Applicants

The proposed changes would likely lead to patent applications with more claims that in turn would be more costly for applicants. Under current practice, patent applicants can manage patent prosecution in accordance with their own goals, finances, and understanding of the

[89] *See Terran*, 195 F.3d at 1314.

[90] Given the harsh consequences of filing a terminal disclaimer under the proposed rule, applicants would be greatly incentivized to fight even if the USPTO's separate proposed rule increasing fees for terminal disclaimers is adopted (with the smallest fee for filings before any nonstatutory double patenting rejections and increased fees for fighting the rejection). *See* Setting and Adjusting Patent Fees During Fiscal Year 2025, 89 Fed. Reg. 23226 (Proposed April 3, 2024). And to the extent applicants are coerced into acquiescing to the rejection and ceding patent rights in view of the increased fees, this further demonstrates how the conditions imposed by the USPTO would be unconstitutional. *See supra* Section III.B.1.

marketplace. For example, some may initially file smaller, narrower claim sets and then later seek to obtain protection for the full scope of their inventive disclosure, while others may initially file broader claims and later seek narrower claims, and still others may file larger claim sets up front. However, under the proposed changes, applicants may seek to avoid having to file a terminal disclaimer via filing more claims in the original application, thus undermining their freedom to pursue different claim scope over time. Instead, strategically the applicants may feel forced to seek patent protection for every iteration of what the applicant invented.

Filing more claims in initial applications would result in a more complicated and drawn-out prosecution process as well as increasing costs through excess claim fees and increased patent attorney time. Indeed, the effect of the proposed terminal disclaimer changes in combination with the USPTO's proposed fee amendments that double excess claim fees would put pressure on the applicant from all sides and ultimately incentivizes applicants to seek fewer patents with fewer claims, which is the opposite of what the USPTO should be promoting. Indeed, the USPTO has previously attempted to limit the number of patents an applicant obtains in a rule placing harsh restrictions on continuation applications, but the Federal Circuit rejected that rule as inconsistent with the statutory protections on continuation practice from 35 U.S.C. § 120 in *Tafas v. Doll*.[91] This proposed rule is also concerning for its effects on limiting an applicant's freedom to pursue follow-on applications. The district court in *Tafas v. Dudas*[92] permanently enjoined the USPTO from implementing a rule placing substantive limits on continuation practice.[93] The proposed rules limit an applicant's rights in patents that are continuations linked by a terminal disclaimer, which appears to be inconsistent with the decisions in *Tafas v. Doll* and *Tafas v. Dudas*.

Finally, such practices would unduly punish smaller companies and universities, which make up an important part of the biotech community and U.S. research ecosystem. Many significant discoveries relevant to the development of new products come from academic institutions and smaller labs. These smaller groups often do not have the financial resources to frontload prosecution costs and pursue more prolonged prosecution and appeals, especially considering the striking proposed fee increases, and this rule would place significant burdens on such applicants.

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[91] 559 F.3d 1345, 1360 (Fed. Cir. 2009), *vacated*, 328 F. App'x 658 (Fed. Cir. 2009). The Federal Circuit took this case *en banc*, which vacated its panel decision. However, because the USPTO withdrew its proposed rule change prior to the Federal Circuit issuing its *en banc* decision, the full Federal Circuit never addressed this issue. The now-vacated panel decision still provides guidance as to why the USPTO would lack the ability to substantively change continuation practice.

The remaining non-vacated decision on the matter is the Eastern District of Virginia's decision. *See Tafas v. Dudas*, 541 F. Supp.2d 805 (E.D. Va. 2008). There the District Court found that the USPTO could not engage in substantive rulemaking that limited the number of continuation applications an applicant could file. *Id.* at 811.

[92] 541 F. Supp.2d 805 (E.D. Va. 2008).

[93] *Tafas v. Dudas*, Case 1:07-cv-00846-JCC-TRJ, Docket entry No. 276 (E.D. Va. April 1, 2008).

2. Incentivizes Narrower Patent Disclosures

Under the current system, an applicant is encouraged to provide fulsome disclosures of what they have discovered and invented. This is consistent with the quid pro quo of the patent system, which incentivizes disclosure to the public to advance technology, and in exchange provides the inventors with the right to exclude others for a limited time under the patent.[94] The USPTO recognizes the importance of these disclosures:

> The patent system promotes innovation and open competition by granting rights to patent owners to exclude others from making, using, offering to sell, selling and importing the patented invention into the United States for a limited time in exchange *for publicly disclosing the invention*. *These public disclosures serve as the foundation upon which further research and innovation is made*.[95]

In light of broad disclosures, applicants often file continuation applications to subsequently claim different aspects of what they invented from the initial disclosure without adding new information. Given the loss of rights an applicant risks when facing an NSDP rejection based on the similarity of claims in different patents (or patent applications), an applicant may elect to only disclose the information necessary to pursue a single set of claims (so as to avoid any NSDP rejections in the future). This would thus incentivize disclosing less information to the public, which could hinder further research and innovation. As a separate, but related, unintended consequence, applicants may start to avoid patent protection and instead try to pursue trade secret protection. This also disincentivizes innovation in any area that could feasibly be argued to be "patentably indistinct" from prior innovations.

3. Implications of *In re Cellect* and Terminal Disclaimers in the Context of PTA

Recent caselaw developments have created even more perverse consequences under the USPTO's proposed rule. Now, patent term adjustment (PTA), which under the statute compensates patentees for delay during prosecution by adjusting patent term, can give rise to NSDP. Thus, the USPTO's proposed changes could foist terminal disclaimers onto applicants based solely on the delay of the USPTO.

By way of background, under *In re Cellect* the difference in expiration of two patents based on a patent term adjustment could be the basis for NSDP.[96] Patent term adjustments are the result of delay during prosecution caused by the USPTO, not the applicant. Therefore, whether a patent receives a patent term adjustment is based on the conduct of the USPTO and is outside the control (and conduct) of the patent applicant.

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[94] *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 150-151(1989) ("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.").
[95] *Drug Patent and Exclusivity Study*, USPTO, 7 (emphasis added).
[96] *In re Cellect*, 81 F.4th 1216, 1229 (Fed. Cir. 2023).

An applicant that has already lost patent term due to delay at the USPTO would now be compensated for that loss with PTA, but such compensation would come with new NSDP and terminal disclaimer strings. Once an NSDP challenge is raised in a litigation,[97] two options a patent applicant may have available would be to: (1) file a terminal disclaimer to overcome the NSDP challenge, give up the patent term adjustment (i.e., the adjusted patent term that is the result of the USPTO's delay), and subject the patent to enforcement challenges; or (2) have the claim of the patent that received a patent term adjustment be at risk of invalidation based on NSDP. The second option would require the applicant to forego patent protection notwithstanding the allowability of the claim but-for the claim having been issued without delay at the USPTO.

Thus, this proposed rule provides perverse incentives for the USPTO to further its policy goals by delaying prosecution to generate PTA. Generating PTA would subject a patent applicant to additional burdens of analyzing new patents for potential double-patenting issues and potentially force a patent applicant to file a terminal disclaimer and thus weaken its patent portfolio by tying the fate of its claims across multiple patents. Under the USPTO's proposed rule, filing a terminal disclaimer—because of the USPTO's delay in prosecution—would then link the patent that had received the PTA with the patent it is terminally disclaimed over (and potentially other patents in that linkage) such that all of the claims would "rise and fall together" with respect to anticipation or obviousness. This linkage would only be the result of the USPTO's delay, regardless of any applicant action or inaction. This is precisely the opposite of Congress's intent when establishing PTA, which was to encourage timely prosecution at the USPTO.[98]

B. Articulated Benefits of the Proposed Rule are Flawed

1. The Proposed Rule Does Not Promote Innovation, but Instead Weakens Patent Rights and Increases Costs

Weakening patent rights deters innovation. It undermines the ability of applicants to recoup costs for innovation. And it certainly does not promote innovation of competitors seeking to avoid patents—this rule makes it easier to copy disclosures from innovators. As the USPTO has made clear, the patent system plays a "critical role in incentivizing and protecting the investments essential for bringing life-saving and life-altering drugs to market, while not unnecessarily delaying getting generic, biosimilar, and more affordable versions of those drugs into the hands of Americans who need them"; thus the USPTO "is working to ensure that patent

[97] Another issue with the proposed rule is that it applies when "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. 40439. This language is insufficiently precise about what constitutes a "challenge": for example, whether this applies only to petitions and counterclaims of invalidity or something less formal.

[98] *See, e.g.*, 35 U.S.C. § 154(b)(1)(A)(iv) ("term of the patent *shall* be extended 1 day for each day" of USPTO delay) (emphasis added); American Inventors Protection Act of 1999, H.R. Rep. No. 106-287, Part 1, at 50 (1999) ("Thus, no patent applicant diligently seeking to obtain a patent will receive a term of less than the 17 years as provided under the pre-GATT standard") (footnote omitted); *see also Wyeth v. Kappos*, 591 F.3d 1364, 1366-1367 (Fed. Cir. 2010) (the 1999 American Inventors Protection Act "promised patent applicants a full patent term adjustment for any delay during prosecution caused by the PTO").

rights are *robust and reliable*, and comply with the requirements for patentability."[99] Here, the USPTO's proposed rule change is counter to the goal of ensuring that patent rights are robust and reliable.

Indeed, as discussed above in Section IV.A.2, the disclosures in patents serve as the foundation upon which additional research and innovation is based. [100] This is especially true in the pharmaceutical space, where it is well recognized that patent protection helps drive innovation. Indeed, the rationale behind the Hatch-Waxman Act recognized the importance of patents and how the Act helped the public to "receive[] the best of both worlds—cheaper drugs today and better drugs tomorrow."[101] Indeed, Senator Hatch noted that the restored patent term that was part of the Act would "restore to our domestic drug companies some of the incentive for innovation," and "[t]hat incentive will produce both the investment and commitment to resea[r]ch and development that will again place the United States in unquestioned leadership in the field. And it will generate an increase in the number of important new drugs, among the most vital causes for this century's dramatic increase in quantity of life."[102] As was true in 1984, patent protection helps spur innovation. For example, the USPTO recently recognized that "the prospect of patent protection and exclusivity can motivate innovators to invest in the development of novel products and new treatment options for patients."[103]

In addition, weakening patent rights disrupts the quid-pro-quo of the patent system, where applicants invest in and disclose innovations to the public and obtain a term of exclusivity as a result. The USPTO assumes that weakening patent rights will motivate patent holders to instead make and disclose even more entirely new innovations. However, there is no support for this assumption, and the recent USPTO study suggests that the "patent system" has a "critical role in incentivizing and protecting the investments essential for bringing life-saving and life-altering drugs to market."[104] Instead, weakening patent rights will reduce the incentives to make and disclose such innovations in the first place, especially when a company would be unable to protect all aspects of their innovative disclosures. As a result, companies may instead be incentivized to withhold disclosures in favor of relying on trade secret protection.

This could be especially acute for pharmaceutical companies, such as when pursuing new uses for existing products, identifying the most potent species within a family of compounds, or improving upon formulations or dosing regimens that could result in increased patient

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[99] *Drug Patent and Exclusivity Study*, USPTO, 2 (emphasis added).
[100] *Drug Patent and Exclusivity Study*, USPTO, 7.
[101] Senator Hatch remarks, S. 2926, 130 Cong. Rec. 23627, 23764 (August 10, 1984).
[102] *Id.*
[103] *Drug Patent and Exclusivity Study*, USPTO, 7; *id.* (Patents also embody and incentivize investment in research, development, and clinical trials by innovator pharmaceutical and biotech companies.").
[104] *See, e.g.*, *id.* at 2; *id.* at 7 ("Patents also embody and incentivize investment in research, development, and clinical trials by innovator pharmaceutical and biotech companies. Innovator companies bear the expense and risk of developing life-saving drug products and, under the U.S. statutory framework, are granted patents protecting those inventions for a limited period of time."); *id.* at 66 ("In the cycle of innovation, inventors build upon the knowledge and advancements of those that came before them. The patent system helps accelerate this cycle through disclosure of these innovations and in incentivizing research and development. Using the patent system to protect these later innovations that build upon earlier patented inventions is a common business practice in many, if not all, industries.").

compliance and quality of life.[105] Such improvements have real-world benefits to patients: doctors and patients understand the critical importance of reducing the number of doses, reducing pill size or improving patient adherence. Reducing incentives for such improvements is not in the best interest of patients.[106]

2. The Proposed Rule Encourages Challengers to Game the System

Separately, the proposed rule would create a troubling incentive for a would-be infringer to target patent portfolios that are linked (directly or indirectly) by terminal disclaimers. Under the proposed rule, if patents, A, B, C, D, and E are all linked by terminal disclaims, then if a single claim in patent A is found invalid as anticipated or obvious, then each of the claims in patents B, C, D and E will be found unenforceable regardless of how different the claims may be to the one previously invalidated. This is true even if the invalidated claim in patent A was not related to the NSDP assertion that resulted in filing a terminal disclaimer in the first place. Thus, the would-be infringer only needs to win on one claim to eliminate the value across an entire portfolio of patents, and the consequence may be that truly innovative claims on important technology are *never invalidated* but are deemed unenforceable and become little more than an office ornament. And notably, this result is entirely one-sided: the burden on accused infringers is reduced because a finding of invalidity in a single claim can render all of the claims in all of the linked patents unenforceable, but the burden on patent owners is unchanged because they must still prove each asserted claim is valid and infringed. This may even lead to an absurd scenario where a claim is found valid, infringed, yet unenforceable because of what happened to an entirely different claim in a different patent.

Furthermore, this proposed rule would provide an incentive for petitioners or accused infringers to challenge not simply one patent as the USPTO suggests, but *every* patent linked by terminal disclaimers, including patents that were never asserted. Because a finding of invalidity to a single claim could potentially render multiple patents linked by a terminal disclaimer unenforceable, a challenger could effectively avoid liability from claims that are otherwise valid and infringed by challenging entirely different claims. And the lack of any reciprocal risk to the accused infringer in the proposed rule further encourages the accused infringers to game the system.

This is particularly troubling because the prior art that invalidated a claim in patent A may not invalidate the rest of the claims, and there are even situations where that art is not prior art under the statute to the rest of the claims. For example, a prior art species may render

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[105] *See, e.g.*, *Drug Patent and Exclusivity Study*, USPTO, 5 ("[C]ompanies may file patent applications for changes to drugs that they intend to evaluate as a means to address patient compliance or side effect issues, to improve administration of the drug (e.g., via new dosage forms or routes of administration), or to expand the use of the active ingredient for treatment of additional diseases and conditions. Some improvements, if patented, may be economically significant yet have lower research and development costs than the original invention."); *id.* at 69 ("In the pharmaceutical or biotechnology area, a new patent may be granted on innovations . . . These changes could make an existing drug significantly safer and/or more effective" or include "new uses for existing drugs," which "has become one of the key ways to search for effective treatments of a variety of diseases, from AIDS to heart disease to multiple sclerosis.").

[106] *See supra* n. 105.

obvious a genus claim, but that would not render obvious a separate, distinct species claim that is claimed in a separate application. Notably, this proposed rule is not limited to families, meaning that prior art could invalidate a later-filed patent and then rule unenforceable an earlier-filed patent for which the reference would not even be prior art.[107]

3. The Proposed Rule Does Not Lower Costs to Challenge Patents

The USPTO suggests that the proposed terminal disclaimer would result in a lower cost to patent challenges. The USPTO does not point to any studies or data to support this claim, but instead seems to be relying on the enforceability linking, which as discussed above violates the Patent Act and is fundamentally unfair and is unconstitutional.[108] The USPTO's suggestion also reflects a misunderstanding of district court litigations and post-grant challenges, and PhRMA is not aware of any data that suggests litigation costs are greater if a party is challenging multiple terminally disclaimed patents versus challenging fewer, but more complex patents (as could be incentivized by this proposed rule).[109] And district court litigation already naturally narrows validity disputes, and courts frequently limit the number of asserted claims and promote narrowing throughout the litigation.

For example, the District of Delaware previously released a Hatch-Waxman scheduling order limiting the patent holder to asserting "no more than ten claims of any one patent and no more than 32 claims in total against any one Defendant."[110] Similarly, the Eastern District of Texas's local rules provide a model scheduling order setting out requirements for narrowing asserted claims through the course of the case.[111] Regardless, even without court-mandated restrictions, the simple fact of how trials work is that plaintiffs have limited time to present their cases and will frequently narrow asserted claims, or the parties may agree on certain representative claims.

Indeed, Congress has already enacted efficient, targeted litigation systems through the enactment of the Hatch-Waxman Act and the BPCIA. The Hatch-Waxman Act was passed decades ago following significant debate and consideration from all stakeholders, and it was carefully crafted to balance incentives for innovation and generic competition. The BPCIA was likewise passed following significant consideration and balancing of interests, and it was crafted to account for the specific issues related to biologics and biosimilars. This proposed rule does not evince a similar carefully crafted balance and instead threatens to disrupt multiple statutory schemes.

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[107] By way of example, if Patent A had a priority date of January 1, 2000 and received a year 1 PTA, such that it expired January 1, 2021, and Patent B had a priority date of June 1, 2000 such that it would expire on June 1, 2020, if Patent A is terminally disclaimed over Patent B, then, under the proposed changes by the USPTO, if Patent B is found invalid based on prior art from March 1, 2000, Patent A would not be enforceable even though the reference that invalidated Patent B would not be prior art to Patent A.
[108] *See* §§ III.A, III.B, and IV.B.2.
[109] As previously discussed in Section IV.B.2, the proposed rule incentivizes defendants to challenge multiple, tied but unasserted patents to increase their likelihood of success.
[110] https://www.ded.uscourts.gov/sites/ded/files/chambers/Scheduling%20Order%20for%20Hatch-Waxman%20Patent%20Infringement%20Cases.pdf.
[111] https://www.txed.uscourts.gov/sites/default/files/forms/ModelPatentOrder.pdf.

The USPTO also overestimates the costs of post-grant challenges to petitioners. Petitioners do have to challenge multiple patents in separate petitions, but if the claims truly cover very similar subject matter, the cost of doing so with patents linked by terminal disclaimers is greatly reduced compared to filing challenges to completely unrelated patents. For example, in these cases, the art should be the same and the same experts should be applying the same invalidity analysis, which are the activities that drive the majority of the cost. And if there are substantive differences between the claims in various patents such that the petitioner cannot use the same art or arguments, which drives up costs for preparing multiple petitions, this underscores why validity is evaluated on a claim-by-claim basis. Separately, estoppel-based arguments would have the potential to limit and streamline issues. Moreover, post-grant proceedings frequently occur in the context of a litigation, where courts frequently adopt narrowing requirements, such that claims have already been narrowed by the time a post-grant proceeding is filed.[112]

4. The USPTO's Alternatives to Filing a Terminal Disclaimer Were Not Adequately Considered

The USTPO provides four methods by which a patentee could "avoid filing a terminal disclaimer."[113] These methods include: (1) combining the conflicting claims into a single application; (2) canceling or amending the conflicting claims; (3) arguing the rejection; or (4) filing a reissue of the reference patent to add the conflicting claims from the application, provided that the added claims do not introduce new matter into the reissue application.[114] But the USPTO's notice does not evaluate the cost or feasibility of these options.

As an initial matter, options 2 and 3 amount to either foregoing claims that are subject to NSDP or confirming that the claims are, on the merits, not actually subject to NSDP. Furthermore, if an applicant argues against the rejection, the Notice did not address the cost and time required for additional rounds of prosecution and appeals at the USPTO. Meanwhile, neither option 1 nor option 4 is fully addressed by the Notice and they are not even discussed when evaluating the cost to small businesses. For instance, the Notice does not address the cost and time delay of a reissue application. Nor does it address the time limits of broadening reissue applications and the challenge that a claim can arguably be subject to nonstatutory double patenting, but still be broader or introduce new matter. Similarly, the Notice also does not address the expense and burden of filing all claims that might one day be rejected for nonstatutory double patenting in a single application, or moving all other claims into a continuation application so that claims that were not rejected are not tied. This is especially

[112] *See, e.g.*, *supra* n. 110 (narrowing in Delaware Hatch-Waxman cases) and n. 111 (narrowing claims in Eastern District of Texas cases).
[113] 89 Fed. Reg. at 40444.
[114] *Id.* The USPTO also notes that one may avoid tying of the patents by withdrawing a recorded terminal disclaimer before the subject application is issued in a patent. 89 Fed. Reg. at 40441-42. Of course, such a withdrawal entails significant expense to the applicant, and it would be applicable in very limited circumstances such as mistakenly filing a terminal disclaimer. And regardless, any NSDP rejection would need to be substantively overcome. *See* M.P.E.P. 1490 (VIII)(A).

relevant in view of the proposed increased fees for continuations and for additional claims, as noted above.

Moreover, to the extent the USPTO claims to be encouraging applicants to either address nonstatutory double patenting rejections on the merits, combine claims with patentably indistinct scope into one application, or cancel claims and pursue them in a new application, this flies in the face of the USPTO's recent Notice of Proposed Rulemaking proposing increased fees for (1) fighting terminal disclaimers on the merits (and even incentivizing filing a terminal disclaimer before any nonstatutory double patenting rejection), (2) having "too many" claims in one application, and (3) having "too many" continuation applications.[115] The USPTO should explain how these options are viable in view of such increased fees disincentivizing such practices.

V. Conclusion

For at least the reasons presented in these comments, PhRMA believes that these proposed rules on changing requirements for filing terminal disclaimers should not be promulgated. Further, PhRMA echoes the call from prior USPTO Directors, Deputy Directors, and Patent Commissioners[116] and urges the USPTO to withdraw this proposal.

PhRMA appreciates the opportunity to comment on the USPTO's proposed rules on changing requirements for filing terminal disclaimers. PhRMA welcomes continued dialogue on its concerns over the areas discussed in these comments and the consequences of the USPTO adopting these proposed rules.

Respectfully submitted,

/s/	/s/
David E. Korn Vice President, IP and Law	John E. Nappi Assistant General Counsel, Law

[115] Setting and Adjusting Patent Fees During Fiscal Year 2025, 89 Fed. Reg. 23226 (Proposed April 3, 2024). In that Notice of Proposed Rulemaking, USPTO also asserted that the increased excess claim fee is particularly necessary to promote compact prosecution and counter an expected increase in excess claims resulting from raising the fee for continuing applications, evincing a desire to disincentivize something the USPTO is expressly providing as an option here. *Id.* at 23241.

[116] Letter from Drew Hirschfeld, Andrei Iancu, David Kappos, Laura Peter, and Russell Slifer to Katherine K. Vidal (May 28, 2024), at 2 ("At a time when America is losing its technological edge to China and other nations and needs to maximize its creative output in order to compete in artificial intelligence, 5/6G, quantum, energy, biotechnology, and so much more, the USPTO's NPRM destabilizes the patent system and advances anti-innovation policies. The terminal disclaimer and continuations proposal creates uncertainty every day that it remains under consideration, disrupting the innovation economy even if the rules are ultimately not adopted. The USPTO should withdraw this proposed rules package immediately and work to restore stability and predictability in the American patent system.").