



July 9, 2024

Honorable Katherine Vidal
Under-Secretary of Commerce for Intellectual Property and
Director of the U.S. Patent and Trademark Office
U.S. Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Re: “Request for Comments on Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting,” 89 FR 40439, May 10, 2024 – Docket No. PTO-P-2024-0003.

USIJ Response to USPTO Request for Comments re Terminal Disclaimers

The Alliance of U.S. Startups and Inventors for Jobs (“USIJ”) responds herein to “Request for Comments on Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting” (“RFC” or “proposed rule”), published May 10, 2024 as 89 FR 40439 – Docket No. PTO-P-2024-0003.¹ USIJ **strongly opposes** the proposed rule, which will have a devastating impact on entrepreneurs, inventors, startups and small companies that comprise the most important part of the innovation ecosystem of this nation. The practical impact of the proposed rule, when combined with the first-to-file requirement adopted by Congress in 2011, will be to eliminate use of congressionally authorized terminal disclaimers for all but the simplest of inventions, and will alter fundamentally whatever role patents still play in promoting the investment of time and resources by entrepreneurs and investors in commercializing new technologies. The proposed rule represents either an inexcusable misunderstanding or a complete indifference to how invention actually occurs in the real world. The innovation process is almost always iterative, nonlinear

¹ USIJ is a coalition of 23 companies – startups, entrepreneurs, inventors and investors – all of which depend on stable and reliable patent protection as a foundational prerequisite for making long term investments of capital and time commitments to high-risk businesses developing new technologies. USIJ was formed in 2012 and is committed to promoting a strong intellectual property system that supports innovation, investment, and breakthrough technologies that change our world. Our mission is to ensure that this system continues to thrive for the benefit of American startups and inventors, and most importantly, American leadership in science and technology. USIJ collaborates with several other associations that are similarly concerned with the declining availability of U.S. patents essential to protect our country’s most important inventions that will define the future of technology.

and unpredictable, and a viable patent system must also allow for – indeed must **encourage** – this type of incremental innovation for which terminal disclaimers are absolutely essential in many cases. The legal arguments relied upon to support adoption of the proposed rule are based on a misreading of Title 35 and the Administrative Procedures Act. The purported factual justification for the proposed rule is based on theories and beliefs that are unsupported by any data or evidence and are flatly contradicted by USPTO’s own reports.

Numerous scholars, venture capital investors, business leaders and government officials – including the current Director of the USPTO, Kathi Vidal – have acknowledged the signal contribution to groundbreaking innovation attributable to startups and small companies, and have recognized the importance of trustworthy and reliable patents as a foundation for making long-term commitments of capital and human resources needed for developing disruptive new technologies.² Despite this recognition, however, there have been many decisions made within our federal government – Congress, the judiciary and the executive branch – whose combined effect over the last fifteen years or so have weakened the U.S. patent system to the point of irrelevance for an increasing number of investors and entrepreneurs. The decline of reliability and enforceability of properly issued patents has been accompanied by a growing recognition by entrepreneurs, inventors and their investors that intellectual property rights needed to support long-term, high-risk are no longer available in the U.S., which in turn has caused many of these individuals and entities to shift their investments and focus away from developing strategically critical technologies, either to lower risk opportunities that are less dependent on reliable patents, or to other countries where their R&D effort is less vulnerable to theft by large, entrenched incumbents.³ The proposed rule will accelerate that trend. Indeed, it is difficult to envision a greater threat to the integrity and reliability of issued patents than a rule that would allow an invalidity ruling as to a single claim in one part of large family of patents to destroy much or all of the entire family. The foreseeable consequences of the proposed rule are staggering, particularly for the

² *E.g.*, “Drug Patent and Exclusivity Study,” published June 12, 2024 by the U.S. Patent and Trademark Office (“PTO Study”), pp. 2, 7, 16, etc. This Study was conducted in response to a request from Senator Tillis of North Carolina asking the USPTO to determine the accuracy of some of the information from drug pricing “activists” regarding the role of patents in limiting competition in the marketing of drugs. The Study is discussed in a report from the U.S. Chamber of Commerce entitled “Debunking Myths: USPTO’s Report on Life Science Patents,” <https://www.uschamber.com/intellectual-property/debunking-myths-usptos-report-on-life-science-patents>.

³ Even after just a year in operation, the Unified Patent Court in Europe is attracting more and more American companies to protect their IP in Europe, a development that does not bode well for the continued success of the U.S. patent system. *E.g.*, <https://www.finnegan.com/en/insights/articles/the-unified-patent-court-what-we-learned-in-year-1.html>; see also, “The Importance of an Effective and Reliable Patent System to Investment in Critical Technologies,” a 2020 report from Professor Mark Schultz, Goodyear Tire & Rubber Company Endowed Chair in Intellectual Property Law and Director, Intellectual Property and Technology Law Program at the University of Akron. https://static1.squarespace.com/static/5746149f86db43995675b6bb/t/5f2829980ddf0c536e7132a4/1596467617939/USIJ+Full+Report_Final_2020.pdf

entrepreneurial and investor communities that must make decisions to commit time and capital years in advance of commercialization, if it ever happens, of an invention.

The inability even to speculate, let alone articulate, all of the potential situations in which the proposed rule will have devastating consequences becomes particularly evident from some of the supporting discussion for the proposed rule, which is all but incomprehensible. The discussion found at pages 89 FR 40441 – 40444, including particularly how finders of fact will determine whether two patents are “tied,” either “directly” or “indirectly” to one another, will itself be a nightmare for judges to attempt to unravel.⁴ The proposed rule contemplates that **an entire patent or group of patents** tied to the parent by disclaimers would become unenforceable, not merely a claim that is being asserted. This is arbitrary in the extreme as well as punitive, given that many of the claims thus rendered unenforceable might not be subject to a double patenting rejection at all. For a startup wishing to develop and commercialize a new and unproven technology over a period of years, the proposed rule will make it nearly impossible to raise the tens to hundreds of millions of dollars required to bring an invention to commercialization.

The USPTO Does Not Have the Authority to Promulgate the Proposed Rule. Section 253 of Title 35 provides two points of relevance here: First, § 253(a) provides that the issue of claim validity in a patent must be addressed individually, *i.e.*, the invalidation of one claim does not invalidate the others. Second, § 253(b) provides that a patent applicant or owner is entitled to disclaim the terminal portion of the grant prior to expiration of the patent, the so-called “terminal disclaimer” that allows a patent owner give up a portion of its authorized temporal scope in order and allow it to expire simultaneously with a related patent that is commonly owned by the same inventor or group of inventors. This provision was enacted by Congress to allow patent owners to overcome a rejection from patent examiners (and later the judiciary) that claims in a later filed patent were “obvious” in light of one or more claims in an earlier patent – so called “obviousness type double patenting” (“OTDP”). This basis for a rejection had no foundation in the statute but was created on the theory that when the first patent expired, the claimed subject matter and all obvious variations on it should pass into the public domain. By taking advantage of a terminal disclaimer, the patent owner is able to let both patents expire at the same time and thus avoid whatever problems might otherwise arise from their co-existence.

The proposed rule seeks to avoid the statutory prohibition in § 253(a) by referring to invalidity as “unenforceability.” This is little but sleight-of-hand as if no one would see the essential identity of the two. Whatever they choose to call it, the effect is the same – one day the inventor owns a patent it can

⁴ Under the operative portion of the proposed rule, the PTO will “require that a terminal disclaimer filed to obviate nonstatutory double patenting include an agreement by the disclaimant that the **subject patent** or any patent granted on the subject application shall 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: (1) any claim has been finally held unpatentable or invalid under 35 U.S.C. 102 ... or 103 ... or (2) a statutory disclaimer of a claim is filed after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made.”

use to deter infringement; the next day that is no longer the case. That transaction has a substantive impact on the property rights of the patent owner, which the USPTO has no power to carry out.

The regulatory power of the USPTO is set forth in 35 U.S.C. § 2(b), which allows the USPTO to adopt regulations that are “not inconsistent” with the law, and then sets forth specific categories of regulation that are permitted, all of a procedural nature. Notably missing is any suggestion that the USPTO has authority to create rules or regulations that affect the substantive rights of patent applicants and patent owner, other than to administer the patent statute as it is written. *See, e.g., Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-1550 (Fed. Cir. 1996), a case in which the USPTO attempted to adjudicate the rights of a patent owner under the Hatch-Waxman Act (35 U.S.C. § 156). In rejecting the ruling by the USPTO, the Federal Circuit held that the agency was without power to adopt rules or regulations with substantive impact. The Court stated that “The broadest of the PTO’s rulemaking powers ... authorizes the [agency] to promulgate regulations directed only to ‘the conduct of proceedings in the [PTO]’; it does not grant ... the authority to issue substantive rules.”

To the extent that USPTO argues the proposed rule is a logical interpretation of the meaning of 35 U.S.C. § 253, it can point to nothing from the legislative history of Section 253 or the statutory language itself suggesting that Congress intended to allow the imposition of further requirements on disclaimers. Indeed, any such interpretation that USPTO may apply today will be subject to de novo review before an Article III court, because such an interpretation is “exclusively a judicial function.” *Loper Bright Enters. v. Raimondo*, 603 U. S. ____ (2024) (overruling *Chevron* deference and reinvigorating 5 U.S.C. § 706, which requires courts to “hold unlawful and set aside agency action, findings, and conclusions found to be ... not in accordance with the law.”). The proposed rule clearly falls into that category.

Reliable, Enforceable Patents Are the Backbone of Our Nation’s Leadership in Technology. Before addressing the specifics of the proposed rule, we emphasize the critical importance of patents to entrepreneurs, inventors and their investors that throughout our history have been disproportionately responsible for the majority of significant “breakthrough” inventions that have allowed the U.S. to dominate the “progress of science and the useful arts,” as specifically called out in Article I, Section 8, Clause 8 of the U.S. Constitution. It is important to bear in mind the economic reality and importance of what is meant by the term, “useful arts.” Scientific research and experimentation have been ubiquitous throughout history, not just in this nation but the entire world. What has made America unique is our creative ability to translate scientific learning into new products and services, which no other nation has ever matched. For more than 200 years, patents provided one of the fundamental driving forces for our industrial policy, precisely because reliable and enforceable patents established a fertile climate to encourage risk taking and long-term investments in the implementation of new ideas and the creation of new products. The proposed rule set forth in the RFC will further limit the use of U.S. patents by entrepreneurs and investor in favor of other forms of protection. Worth noting is that more and more technology today is being protected by trade secrets, which are contractual rights existing under both federal law and laws of most states. This is not a trend the USPTO should be encouraging, given that

one of the key attributes of the patent system is the dissemination of scientific knowledge and knowhow so that others can build on it.⁵

The Proposed Rule Is Calculated to Inflict Wanton Damage on Patent Owners. The proposed rule reflects pressure on the USPTO to control drug prices by further neutering the U.S. patent system for all users of the system. The rationale for the rule is said to promote competition:

“This action is being taken to prevent multiple patents directed to obvious variants of an invention from *potentially deterring competition* and to promote innovation and competition by allowing a competitor to avoid enforcement of patents tied by one or more terminal disclaimers to another patent having a claim finally held unpatentable or invalid over prior art.” (89 FR 40439, p. 40439.)

The underlying premise of this statement is that allowing competitors to copy patented inventions is beneficial competition, a premise that contradicts the very purpose of the patent system, which is to grant to inventors the “exclusive” right to their inventions and discoveries. What conceivable public benefit can accrue from an arbitrary and punitive rule that strips inventors of their patent rights for simply exercising their statutory rights to disclaim a portion of their patent life? A better way to promote competition would be to encourage competitors to avoid the patented technology and come up with their own invention or design around.

Furthermore, there is no factual support for the statement. It assumes that a patent owner will sue an infringer on one patent, and then after losing sue again challenging the same product on a different patent that is an obvious variation of the claim on which it just lost. This hypothetical proposition is unsupported by examples and is oblivious to the reality and actual structure of most patent litigation, which is normally relates to a specific product or group of products alleged to infringe. It is common for a product to infringe several patents at the same time and many lawsuits involve the assertion of multiple patents because this is most efficient way to establish the owner’s patents against an infringing product. The cost of patent litigation is already prohibitive for most companies, so that the hypothetical litigation strategy envisioned by the proposed rule would make patent enforcement by startups and small enterprises nearly impossible. To whatever extent an accused infringer might fret over the possibility of being sued on some obvious variation of the claims on which it has already prevailed, the defense opportunities for declaratory relief and PTAB challenges provide ample tools to address such a problem. Moreover, many patent disputes are resolved by the parties entering into a portfolio license or by the infringer designing around or developing its own new invention, alternatives that in the long run are far more beneficial for the public than the affirmative promotion of copying other people’s work and investments.

⁵ E.g., PTO Study (see fn. 2), p.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.”)

The recent USPTO Study (see fn. _), conducted in view of the Administration’s policy to promote access to affordable drugs in accordance with Executive Order 14036, analyzes the impact of patents on generic entry into the market for thirteen of the bestselling and most profitable patented drugs. The report, in 107 pages, makes 16 references to terminal disclaimers all of which are simply benign statements of how these mechanisms have worked well for decades to obviate disputes over whether earlier issued patents give rise to obviousness grounds for invalidity of follow on and related patents. The Study also contains 50 references to the words “competitive” or “competition,” not a single one of which refers in any way to “terminal disclaimers.” Simply put, the PTO Study demonstrates that there is no substance behind the PTO’s latest move to limit the role of the U.S. patent system. To the contrary, a fair reading of the PTO Study is that patents are doing exactly what they are intended to – incentivize companies and inventors to create new drugs and with appropriate safeguards for a robust generic drug industry to provide competition when the patents expire.

The proposed rule also will strengthen the hand of infringers to harass patent owners by challenging a single claim in a patent with a terminal disclaimer in the PTAB or in court, thus placing at risk the entire family except the original parent patent (often the only one without a terminal disclaimer). Patent owners can expect to be confronted with outrageous demands for unfair settlements which can be exacted simply with the threat of a challenge to all related patents. Accused infringers will request stays while their other challenges work their way to conclusion. In short, the opportunities for abuse of this capability are both numerous and powerful.

The Proposed Rule Seeks to Eliminate Patent Families That Are Essential to Protect Modern

Technology. A fundamental problem with the proposed rule is that it will severely limit the ability of companies and inventors to obtain proper patent coverage for their inventions. Many inventions today, if not most, are complex assemblies of multiple new technologies, or follow-on improvements of earlier designs, thus making inevitable the creation of patent families designed to protect all of the subparts of an invention and its improvements.⁶ Especially in light of the “first to file” rule that forms a key part of the Leahy-Smith America Invents Act, 35 U.S.C. § 102(a), it is imperative for companies developing new technologies to get their patent applications on file as soon as their inventions are sufficiently developed to be ready for patenting, even though not fully reduced to practice, thus requiring additional invention that may be separately patentable to be ready for market.⁷ Although publication of the first application

⁶ Examples abound, but perhaps the late Ray Dolby illustrates the point as well as any other. Mr. Dolby spent years thinking about how to remove the high frequency hiss from a music recording but was told by many knowledgeable people that it was simply impossible. Setting out on a path of his own, and with a high risk of failure, Dolby finally managed to create a noise reduction system that worked well enough to license to recording companies and others. Dolby’s first patents on this system issued in the mid-1990s, but the development of improvements on the subparts continues to this day, and Dolby Laboratories has been issued nearly 3500 patents as of today. Without enforceable and reliable patents to protect years of work from the copyists that emerge once such an invention is proven to be economically feasible, the incentive to undertake such work in the first instance is severely curtailed or lost entirely.

⁷ In *Pfaff v. Wells Electronics*, 525 U.S. 55 (1998), the Supreme Court held that an invention could be “on sale” even though it was not fully reduced to practice if it was sufficiently defined to write a proper patent

and any claims that may issue on such may be prior art in a general sense to later filed patents, a terminal disclaimer in the follow-on product removes both as potential prior art by providing that any later filed patents will expire at the same time as the parent.

One subtext underlying the proposed rule is that “one patent per product” is enough, and anything more than that creates too much complexity for competitors to deal with. This “patent thicket” argument is debunked in the PTO Study, which notes at page 67 with respect to pharmaceuticals:

“[A] known active pharmaceutical ingredient with a new extended-release formulation that reduces the necessary dose frequency may be shown in clinical trials to benefit a patient by, among other things, simplifying dosing regimens and improving adherence to the prescribed drug, and a new use of an old drug may be shown in clinical trials to provide a new, effective treatment for a disease.

“[Such] improvements, when deemed patentable, are entitled to patent protection, which is limited in scope to the patentable improvement. Importantly, once the original patent expires, the public may use the technology covered by the expired patent. Patents on the improvements only prevent the public from using the *new technology* until the *new* patents expire. ... multiple patents on similar inventions (*i.e.*, patentably indistinct inventions) are statutorily permitted so long as a terminal disclaimer is filed to ensure that the patents remain commonly owned and have the same original expiration date. The patent on the invention that is not patentably distinct cannot extend the duration of exclusivity of the other patents.” (Emphasis in the Study).

The Proposed Rule Will Be Especially Problematic for Startups and Young Companies Developing New Technologies. There are many reasons why all inventors and patent owners need terminal disclaimers, but startups and young companies have some particular needs in this regard. The first-to-file imperative is especially important when multiple groups of inventors are racing to find a workable solution to a technological problem, making it prudent to file an application as soon as an invention is ready for patenting and without regard to whether it is fully reduced to practice.⁸ Further, many new technologies are developed under license agreements between university and startups that permit professors to publish their scientific work before the invention is ready to market. The university scientists, of course, want to enhance their academic credentials even though the licensee startups might prefer to wait until the technology is further developed. Further still, almost all startups are constrained by inadequate funding from filing large numbers of patent applications on their inventions at the outset, preferring an omnibus disclosure of a number of inventions (to preserve the filing date), but following up months or even years later with specific patents covering specific parts of their inventions. Even after a product is ready for market or placed on sale, many companies continue to

application. This decision makes it imperative, in a “first to file” world, for inventors to describe their work in patent applications even though additional work is needed which may become the subject of later filed applications.

⁸ See fn. 7.

develop and improve their technology and are entitled to patent coverage, even though the claims may be narrower than those in the original patent. In all of these situation, terminal disclaimers become an essential part of the total program for protecting new inventions. Indeed, it is not uncommon that the most important inventions in a patent family are later ones developed with a greater understanding of the technology, the prior art, the market potential, and a number of other factors that take time to become apparent. Under the proposed rule, it would be these later filed claims that are most likely to contain terminal disclaimers and thus the one most vulnerable to being wiped out arbitrarily and without provocation of any kind.

We respectfully submit that this is no way to run a patent system with the purported objectives of ours. USIJ objects strongly to the adoption of the proposed rule.

Respectfully submitted,

/s/ Robert P. Taylor

Robert P. Taylor
USIJ General Counsel