In Response to Notice of Proposed Rulemaking on Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting

(PTO-P-2024-0003)

July 9, 2024

Response of

Emily Michiko Morris
David L. Brennan Endowed Chair and Associate Professor
The University of Akron School of Law
emichikomorris@uakron.edu

Mark F. Schultz
Goodyear Tire & Rubber Company Endowed Chair in Intellectual Property Law
Director, Intellectual Property & Technology Law Center
The University of Akron School of Law
mschultz@uakron.edu

Joshua Kresh
Interim Executive Director
Center for Intellectual Property x Innovation Policy (C-IP2)
George Mason University, Antonin Scalia Law School
jkresh@gmu.edu

We thank you for this opportunity to comment on and express our opposition to the PTO's proposed changes to terminal disclaimers and their use to overcome obviousness-type double patenting objections. The PTO's rather unusual proposal is troubling in its design and is neither necessary nor likely to be effective.

The PTO's Proposal Contravenes Basic Patent Policy

For the first time in U.S. patent law history, the PTO is proposing a rule that would effectively nullify issued patents not based on their invalidity or unenforceability but rather solely on the concern that there are too many of them. Despite couching this proposal as addressing obviousness-type double patenting (ODP) and terminal disclaimers, the PTO repeatedly concedes that this proposal is not about patent validity. And although the PTO also couches it as a matter of enforceability, this proposal just as clearly is not about misconduct, reliance, or any of the other equitable concerns that underly existing patent unenforceability doctrines. Instead, this proposal by its own terms is clearly about the number of patents covering an invention.

The number of patents on a particular technology cannot possibly be a valid basis on which to deem a patent either invalid or unenforceable. Taken to its extremes, this logic could justify any number of measures to eliminate patents simply because of concerns that there are too many of them, regardless of their validity. For example, the guilt-by-association logic in the PTO's proposal means that patents connected by one or more terminal disclaimers would all fall together even if no common issue of invalidity ties the patents together. This would be equivalent to saying that, if one independent claim in a patent is found invalid, all dependent claims arising from that independent claim necessarily must also be invalidated – regardless of the grounds on which the independent claim was found invalid and regardless of the fact

that dependent claims are inevitably narrower in scope and therefore more likely to be found valid than independent claims – simply because one or more of the dependent claims were obvious variations on the independent claim.

Moreover, despite the PTO's stated desire to avoid increasing costs and delays or placing greater burdens on applicants, the current proposal would do just that. The PTO justifies its proposal in part by comparing it to a rule requiring an applicant to stipulate that filing a terminal disclaimer is an admission of obviousness, which would have increased litigation and administrative costs. Requiring instead that an applicant stipulate that filing a terminal disclaimer is an admission of unenforceability would increase litigation and administrative costs even more, however. Because the consequences of a stipulation of unenforceability are so much more severe than a stipulation of obviousness, applicants are much more likely to mount prolonged arguments against any objections of obviousness-type double patenting.

Under the PTO's proposal, applicants also are more likely to compensate by increasing the number of claims they include in their original applications in order to avoid continuations or subsequent applications that might lead to terminal disclaimers. Indeed, the PTO suggests that this would be an alternative to filing terminal disclaimers under its proposal. For technologies that involve long development timelines, many iterations of prototypes, and extensive testing, it is difficult to capture an invention in a single patent application, especially at the beginning of such development cycles.[1] For example, the biopharmaceutical industry relies on continuations because of the long clinical trials required and the inability to foresee which particular embodiment of a drug will eventually meet the standards for FDA approval. Biopharma companies cannot invest in clinical trials without some patent protection already in hand, however, and so they seek broad initial patent protections at the beginning of the development cycle and then return to the PTO to seek further refined and tailored claims as testing continues. Thus, because the long time periods involved make it impossible to include these narrower claims within the parent patent, biopharma instead relies on continuations of the parent to shore up protection. Unlike the more considered, selective, and experience-based claims that might have been filed in later continuations and applications, however, the claims included in original applications under the PTO's proposal are likely to be much more numerous, speculative, and scattershot. This in turn would also increase prosecution costs and burdens, as well as increasing the likelihood of litigation, as would the longer, more claim-heavy patents that would result.[2]

In effect, the PTO's proposal is simply a penalty for anyone who uses a terminal disclaimer to overcome an ODP objection. This penalty is most likely to fall on applicants who do not have the wherewithal or the time to contest ODP objections, including small entities and historically disadvantaged applicants such as women and minorities.

The PTO Has Not Shown That Its Proposal Is Either Necessary or Likely to be Effective

The PTO's proposal does not give specific examples or data to support its assertion that multiple patents tied by terminal disclaimers could "deter competition" due to the cost of challenging each patent separately. The proposal echoes many of the criticisms of the pharmaceutical industry and its alleged practice of acquiring multiple patents on the same drugs, suggesting that the proposal is driven in large part by concerns about pharmaceutical patents.[3] The PTO's reference to responses submitted for an earlier Request for

---

[1] *See* Amy R. Motomura, *Innovation and Own Prior Art*, 72 HASTINGS L.J. 565, 571-75 (2021).

[2] Although the PTO also suggests that applicants can use patent reissue to add later formulated claims to their original patents, applicants may be wary of doing so, given that reissue requires that patentees file a statement that the applicant believes the original patent to be wholly or partly inoperative or invalid. 37 CFR 1.175; MPEP 1414.

[3] *E.g.*, S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. U.L. REV. 1673, 1690 (2022); Michael A. Carrier & S. Sean Tu, *Why Pharmaceutical Patent Thickets Are*

Comments (87 FR 60130), on proposed initiatives designed to ensure that the patent system does not "unjustifiably delay generic drug and biosimilar competition," also indicate that the PTO's current proposal also is motivated by concerns about pharmaceuticals. There is no evidence that the mere number of patents on a particular therapeutic has any effect on whether and when a generic drug or biosimilar is able to enter the market, however. And even if such pharmaceutical patent thickets were deterring follow-on therapeutics, the PTO's proposal would be much less effective than existing law in addressing patents obtained through continuations and the use of terminal disclaimers.

Before making such a drastic change to the patent system as the PTO now proposes, it is paramount that the PTO obtain reliable and thorough data on not only how often the alleged terminal disclaimer-based patent thickets actually occur but also whether they do in fact deter or delay generic and biosimilar market entry. It is not simply the number of patents but also the scope of those patents that determines their power to exclude others. Determining whether or not a "patent thicket" exists involves more than merely averaging numbers of biopharmaceutical patents or aggregating their patent terms and then drawing inferences therefrom. Instead, any meaningful analysis of potential biopharma patent thickets must focus on the actual effects such patents have on when generics or biosimilars can enter the market. Critics who point to alleged biopharmaceutical patent thickets have shown no evidence of a causal relationship between the number of patents on a drug and whether and when follow-on therapeutics are able to enter the market.

In fact, there is much evidence to the contrary. The PTO itself in a recent study conducted in collaboration with the FDA on twenty-five top selling new drugs in 2017 demonstrated that "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."[4] A similar but more extensive study by Morris & Kresh also show that, among the more than one hundred small-molecule drugs that were listed as top revenue earners in 2012, the number of patents per drug had no significant correlation with follow-on therapeutic entry dates.[5] And despite the fact that the biopharmaceutical industry is alleged to have made increasing use of continuations, studies have repeatedly shown that average effective patent life – the time between reference list drug market entry and generic market entry – has remained the same or decreased.[6]

The PTO nonetheless asserts in its proposal – again, without supporting data – that allowing multiple patents on multiple variations of an invention would place an undue burden on infringement defendants by requiring them to challenge each patent individually. According to the PTO, this would complicate claim construction hearings, raise litigation costs, and delay resolution. This is not necessarily or even often the case, however, even in complex patent litigation.[7]

Unique, 32 TEXAS INTELL. PROP. L.J. (forthcoming 2024); Comment of Tu, S. Sean, in response to Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments (posted Jan. 18, 2023).

[4] *Drug Patent and Exclusivity Study*, USPTO, at chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf (2024).

[5] Emily Michiko Morris & Joshua Kresh, *Pharmaceutical "Nominal Patent Life" Versus "Effective Patent Life," Revisited*, at https://cip2.gmu.edu/2024/05/20/pharmaceutical-nominal-patent-life-versus-effective-patent-life-revisited/ (May 20, 2024).

[6] *See, e.g.*, Henry G. Grabowski et al., *Continuing Trends in U.S. brand-Name and Generic Drug Competition*, 24 J. MED. ECON. 908, 916 (2021); C. Scott Hemphill & Bhaven M. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 330 (2012).

[7] In fact, even if large patent numbers significantly raise litigation costs in biopharma, at least one commentator suggests that this alone would not deter generic or biosimilar market entry. Because generics and perhaps also

Although each claim must be afforded its own presumption of validity and individual evaluation, courts have developed means of making that evaluation less onerous. For example, when multiple claims relate to common subject matter, courts often can apply collateral estoppel, even to unlitigated claims. Depending on the aspect of a claim that makes it susceptible to invalidation, claims from related patents can rise and fall together on the same grounds.[8] Related claims often use the same terms or refer to the same claim elements and thus resolution of the validity of one claim may give rise to issue preclusion on the validity of another, even in subsequent lawsuits.[9] Although suit on multiple patents may require a court to compare and contrast claims, collateral estoppel often can be used to avoid repetitious arguments. And even when patents do not share claim language or elements, courts routinely require litigants to narrow their arguments and to whittle them down to a small number of exemplary claims. Thus, courts already have existing means for reducing the burdens of multi-patent litigation that – unlike the PTO's proposal – allow for due process and claim-by-claim analysis.

There is also no evidence that so-called patent thickets deter potential competitors from using PTAB proceedings to establish freedom to operate. As the PTO and others note, PTAB proceedings can be brought against only one patent at a time. Even if this fact by itself were sufficient to justify the drastic change that the PTO has proposed, there are reasons to doubt that it actually hinders competitors. As a first matter, those who challenge biopharmaceutical patents such as those on small-molecule drugs do not typically opt for PTAB proceedings, as litigation in court provides benefits such as an automatic preliminary injunction and a period of exclusivity as the only generic(s) on the market. Second, outside of biopharmaceuticals data shows that most PTAB proceedings overlap with and are often duplicative of federal court litigation.[10] Defendants often bring patent challenges before the PTAB after first being sued in court, thus using PTAB proceedings not as a costs-saving means to clear themselves of potential infringement liability but more as leverage in court.[11] Third, successful invalidation of one patent in a PTAB proceeding is likely to make patentees hesitant to assert related patents that are vulnerable on the same grounds – indeed, this is likely why defendants named in lawsuits find it beneficial to go to the PTAB, even if for only one patent.

Conclusion

Because of the rather unusual and likely harmful nature of the PTO's proposal to change the effect of terminal disclaimers, the burden of justifying the proposal ought to be on the PTO. Nullifying patents regardless of their validity would significantly undermine confidence in patents and impair the functioning of the patent system. Neither the PTO nor anyone else has shown that the patent "thickets" arising from the use of terminal disclaimers are in fact deterring competition, nor have they shown that such a drastic change in the patent system would be either necessary or effective in addressing such thickets. We therefore object to the PTO's proposal.

---

biosimilars "are in the litigation business," their business plans fully anticipate having to litigate large number of patents. Zachary Silbersher, *The Hudson Institute Memo Draws the Wrong Conclusion from Discrepancies in I-MAK's Data*, IPWatchdog (Mar. 23, 2022), at https://ipwatchdog.com/2022/03/23/hudson-institute-memo-draws-wrong-conclusions-discrepancies-maks-data/id=147816/.

[8] John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 252 (1998); Comment of Tu, S. Sean, in response to Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments (posted Jan. 18, 2023).

[9] *Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013); *Aspex Eyewear, Inc. v. Zenni Optical Inc.*, 713 F.3d 1377, 1381 (Fed. Cir. 2013).

[10] Saurabh Vishnubhakat, *Patent Inconsistency*, 97 Ind. L.J. 59, 70–74 (2022).

[11] Saurabh Vishnubhakat et al., *Strategic Decision Making*, 31 BERKELEY TECH. L.J. 45, 69, 73-74 (2016).