In Response to Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (PTO-P-2022-0025)

February 1, 2023

Comments of

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Without a doubt, the costs of health care in the U.S. impose significant burdens on patients. The joint efforts by the Food and Drug Administration and the U.S. Patent and Trademark Office to address the cost of prescription drugs is laudable. Before making any of the proposed changes to the patent system, however, it is paramount that the PTO obtain reliable and thorough data. This data should include not only how often the alleged abuses of the patent system actually occur but also whether those practices do in fact deter or delay generic and biosimilar market entry. Furthermore, terms such as "unreasonable" or "undue" delay beg the question – against what baseline are they measured? Per the Congressional Budget Office, per capita spending on prescription drugs has decreased in the last fifteen years or so, even as use of prescription drugs has increased over time, largely because of the ability of generic and biosimilars manufacturers to enter the market.

And although more can undoubtedly be done to lower prescription drug prices further, equally as important is data on how any of the proposed changes to the patent system might affect not only the biopharmaceutical industry but also all other technologies that make use of the patent system. Allowing concerns about a narrow set of technologies to drive system-wide changes to the one-size-fits all patent system poses obvious dangers.

The following discussion identifies the various types of data that would be necessary for fully informed decision making with regard to alleged patent thickets, use of continuation applications, and obviousness-type double patenting and use of terminal disclaimers, particularly in the biopharmaceutical industry. Although brief and necessarily cursory, this discussion reveals the huge gaps in our understanding of biopharmaceutical patents and their impact and shows that we really ought not to leap to any conclusions at this point in time.

Patent Thickets: In their letter to the PTO, Senators Leahy et al. expressed their concern about so-called patent thickets, by which they appear to be referring to the idea that, by obtaining multiple patents

relating to the same drug substance, pharmaceutical companies can deter or delay access to generics and biosimilars. It is not at all clear that such "patent thickets" in fact exist in biopharma, much less that they actually serve to block generics or biosimilars. As a first matter, it is important to note that the term "patent thicket" has been used variously to describe an array of patenting patterns, including those in the cell phone industry, in which thousands of patents on cumulative and complementary technologies may need to be licensed from multiple patent holders.[1] One must therefore be careful in drawing inferences about the effect of biopharmaceutical patenting practices merely by referring to them as "patent thickets" and then analogizing them to what are clearly different patenting patterns in other industries.

It is not simply the number of patents, moreover, but also the scope of those patents that determines whether they can be used to exclude others. Determining whether or not a "patent thicket" exists therefore 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. It may very well be the case that the biopharma industry is relying more heavily on patent protections, including larger numbers of patents, to protect their investments, but to the extent any analysis could demonstrate a direct *causal* relationship between numbers of patents and delayed or deterred entry by follow-on therapeutics, such an analysis would have to control for several variables, including:

- *The number of patents per drug product (not per drug substance).* It is possible to have patents on both a drug substance and on the potentially wide variety of drug products into which that drug substance is incorporated. Generics and biosimilars are approved by the FDA as drug products, not as drug substances, however, so looking at all patents related to a drug substance may yield an overly large number compared to the patents a manufacturer would face in seeking FDA approval for a particular generic or biosimilar drug product.

- *The number of method-of-use patents related to a drug substance or product.* Both generic and biosimilar manufacturers frequently can avoid method-of-use patents by the expedient of labeling carveouts, otherwise known as "skinny labeling." Such patents do not block or even stay FDA approval of the generic or biosimilar.[2]

- *The actual clearance costs generics or biosimilars face in calculating likely infringement risk.* Compared to some other industries, clearance costs in biopharma are relatively low, not only because the overall numbers of patents are lower (e.g., as compared to the hundreds and thousands of patents that must be identified and assessed to determine freedom to operate in many areas of electronics and software), but also because of the notice patentees are required to give follow-ons, very early on before launching at risk, through Orange Book listings and even the BPCIA's "patent dance." Furthermore, if – as is often asserted – biopharma thickets

[1] *See* Edward J. Egan & David J. Teece, *Untangling the Patent Thicket Literature* (working paper 2015), at https://scholarship.rice.edu/handle/1911/92003.

[2] Despite the Federal Circuit's recent decision in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc*., 7 F.4th 1320, 1338 (Fed. Cir. 2021), in which it seemed to limit the protective effects of a Section viii carveout, courts interpreting this case have largely limited its holding to its facts. *See, e.g.*, *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc*., 578 F. Supp. 3d 642, 647 (D. Del. 2022); ThermoLife Int'l, LLC v. Hi-Tech Pharms., Inc., No. 1:15-CV-00892-ELR, 2022 WL 17905552, at *9 (N.D. Ga. May 17, 2022); *Genentech, Inc. v. Sandoz, Inc.*, 592 F. Supp. 3d 355, 367 (D. Del.), appeal dismissed, No. 2022-1595, 2022 WL 2165992 (Fed. Cir. June 16, 2022), and aff'd, 55 F.4th 1368 (Fed. Cir. 2022). The *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc*. decision itself is still pending certiorari by the U.S. Supreme Court.

arise because of continuation patent applications and/or obviousness-type double patenting (ODP), clearance costs may be nominal where common theories of noninfringement and/or invalidity apply to an entire patent family.

- *The number of patents and the number of claims per patent actually litigated in patent infringement suits against generics or biosimilars.* Although reference drug manufacturers may initially assert large numbers of patents, litigation often leads parties to narrow their focus to just a limited set of patents and a limited set of claims (a point closely related to the overall clearance costs incurred due to alleged biopharma thickets).

- *The litigation costs per patent.* This datum may in turn depend on the composition of an alleged biopharma patent thicket. Again, if biopharma thickets arise because of continuations and/or ODP, litigation costs could be significantly lower where common theories of noninfringement and/or invalidity apply to an entire patent family.[3]

- *The number of patents within the alleged thickets that are invalid.* Implicit in many discussions of alleged biopharma thickets is the idea that some percentage of the patents included are invalid and that, by virtue of their numbers, they are more costly to eliminate through *inter partes* or post-grant review or even through litigation. This perception that thickets block generic or biosimilars through patent volume rather than through patent quality that is not borne out by the data, however. Pharmaceutical patents overall are half as likely to be invalidated as all other patents, despite the fact that so-called secondary patents comprise the vast majority of those whose validity is challenged.[4]

- *Ownership of the patents within an alleged thicket.* If ownership is dispersed, the alleged thicket may arise for technological rather than strategic reasons.

- *The effective patent life, rather than the nominal patent life, of drug products.* Many critics of biopharmaceutical patenting point to the nominal patent life of drugs – the time from a drug's approval through to the drug's latest expiring patent – but given that many of a drug's patents may be on methods of use, polymorphs, formulations, or other aspects of a drug that a generic or biosimilar does not need to copy for marketing approval, nominal patent life is not a meaningful concept. Instead, the effective patent life of a drug product – the time from the drug product's approval through to generic or biosimilar entry or expiration of any patents whose scope would block such entry – is a much more meaningful.

Some commentators contend that the U.S. compares unfavorably to other countries in terms of patenting patterns and generic or biosimilar market entry, but such differences require much more detailed analysis to be meaningful. To draw a direct causal relationship between any differences in patent numbers

[3] 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 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/.

[4] S. Sean Tu & Mark A. Lemley, *What Litigations Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. L. REV. 1673, 1690-92 (2022).

and any differences in generic or biosimilar market entry, any comparative analysis also would have to control for all relevant inter-jurisdictional differences such as:

- *Differences in allowable patent scope* – for example, any differences between the EU's "unity of invention" standard and the U.S.'s "independent and distinct" standard in terms of how many inventions can be included in a single patent;

- *Differences in patentability* – for example, the recent (albeit short-lived) application of the "promise doctrine" in Canada;

- *Differences in the substance and clarity of regulatory approval standards for generics or biosimilars*, which may affect the time required to complete the approval process;

- *Differences in the rates in which biopharma companies litigate to enforce their patents*;[5] and

- *Differences in drug pricing and price controls, market size, regulatory costs, standards of substitutability, or other factors*, which may affect the value of additional investments in patent protection or enforcement.

Finally, it is appropriate to remember the big picture. Every year, the innovative commercial biopharma industry delivers new treatments that improve and save patients' lives. The U.S. is a leader in biopharma innovation, which brings great benefits to the U.S. economy. While some might imagine an ideal world where biopharma is not a commercial industry, in the world as it is, life-saving innovation and economic leadership is the product of a private sector industry that relies on the U.S. patent system to secure its investments.

With life-saving innovation and U.S. economic leadership at stake, the burden of proof should be on those who wish to change the system. We need further study before any substantive changes should be implemented or even contemplated, especially since much of the data needed to meet that burden is difficult to gather.

Continuations: The letter from Senators Leahy et al., as well as a number of empirical studies, suggest that there are patent thickets in biopharma because of the number of patents issuing from continuation applications. In addition to the concerns raised above about the alleged thickets, however, the proposed changes to the administration of continuation applications raise particular concerns. One concern is the lack of data on what exact role continuations play in alleged thickets (other than merely contributing to the overall number of patents) and whether they warrant imposing heightened examination requirements on continuation applications or limits on their use. A second concern is the harm to innovation that any changes to continuations would have on biopharma and other industries that typically have long development cycles.

With regard to the first issue, the lack of data regarding harm, it is not clear why continuation patents are more problematic than other types of patents. Continuations (as distinguished from continuations-in-part) share the same specification, the same expiration date, and the same ownership. If descriptions by various critics of continuation patents in biopharma are accurate, they also tend to narrow in scope from

[5] For example, biosimilars in the UK and Canada are apparently less likely to face patent infringement suits than biosimilars in the U.S. Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem*, 9 J. L. & BIOSCIENCES 1, 13 (2022). This could reflect the smaller numbers of biopharma patents in the UK or Canada, but it could also reflect rational decisions not to invest in litigation in less profitable markets.

parent to child to grandchild and so on.[6] Patent families arising from continuations are in this way similar to a single, large patent with many tapering claims – it is just that in the case of continuation families, those claims are spread across multiple, smaller patents with fewer claims.[7] The specific differences that continuations entail, of course, are first the number of patents involved and second the fact that the issuance of the patents are spread over time, but the significance of these differences is not at all apparent.

To determine whether continuation patents result in actual harm, there is much more work to be done than simply relying on the implications of the label of "thicket." For example, the following questions should be addressed:

- What percentage of the alleged patent thickets do continuation patents represent versus other types of patents, such as patents on new formulations, methods of use, and so on? If continuations comprise only a small part of biopharma thickets, changing continuation practices would do little to ameliorate thickets.

- Does having the same patent coverage spread over time across multiple patents with fewer claims significantly affect clearance costs? Does evaluating claims from multiple patents with identical specifications cost significantly more than evaluating multiple claims from the same patent?

- Similarly, does spreading patent coverage over time across multiple patents significantly affect litigation costs (including duration of litigation)? Are the costs of litigating patents originating from a common disclosure any more burdensome than litigating claims arising from a common disclosure?[8]

- Do claims in continuation patents differ in nature and scope in ways that make them more prone to invalidity than claims in patents that do not belong to continuation families?

- To the extent that continuation patents issue later in time than their parent patents, do they pose issues of public notice? For example, given that biopharma continuation patents have both common disclosures with and narrower scope than their parents, do continuations nevertheless cause uncertainty or surprise? Where in the biopharma lifecycle do continuations typically issue – before or after generics or biosimilars prepare for regulatory approval? If issued mostly before attempted follow-on entry, continuations can hardly cause surprise.

- Likewise, what kinds of patents are most likely to be subject to continuations – primary composition of matter patents or later incremental innovation patents? Where do continuation patents fall in a drug's lifecycle and what is the effective patent life of most continuations? If continuations tend to issue earlier in a drug's lifecycle, they may have little capacity to block generic or biosimilar market entry.

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[6] *See* 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).

[7] Indeed, some have suggested that claims allowed through continuations should be added to the parent patent rather than issued in a separate child patent. *See, e.g.*, Tu & Lemley, *supra* note 4, at 1714-15.

[8] In fact, Tu & Lemley document that continuations tend to rise or fall as a group due to common invalidity or non-infringement arguments. Tu & Lemley, *supra* note 4, at 1699-1700.

- To what extent could concerns about continuations – or ODP patents – be ameliorated by allowing petitioners to challenge multiple patents in single proceeding if related through a common specification or terminal disclaimers if based on common arguments and evidence of invalidity?

Furthermore, it would be helpful to have more information on how use of continuations reflects the long development cycles in biopharma and how its patenting strategies might change if continuations were limited or given heightened review. In explaining their reliance on continuations, for example, biopharma cites the very long development times in the industry and the inability to foresee which particular embodiment of a drug candidate will eventually prove to be not only effective but also safe enough for FDA approval. After inventing new drug candidates, determining which embodiment of the drug will be safe and effective enough for FDA approval can take years of testing. Biopharma companies are notoriously reluctant to invest in clinical trials without some patent protection already in hand, however, and so they must seek patent protection before knowing what form the ultimately marketable drug will take. Biopharma companies will then return to the PTO to seek further refined and tailored claims as testing zeroes in on the particular embodiment that is most likely to gain FDA approval. 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.

Given this justification, it would therefore be helpful to know:

- When in a drug's life cycle continuations typically occur – before regulatory approval, while clinical trials or other testing is ongoing?

- Does the narrowed scope of biopharma continuation patents reflect increasingly narrowed focus on particular embodiments?

- How likely are later generation continuation patents to withstand invalidity challenges as compared to earlier generation patents within the same family?

- Relatedly, to what extent does the increase in biopharma continuation patents correlate with heightened use of the written description and enablement requirements to reject or invalidate genus claims?

In other words, if continuations are indeed a reflection of the comparatively long and unpredictable nature of drug development, changing or limiting use of continuations could have profound effects on biopharma.

Obviousness-Type Double Patenting and Terminal Disclaimers: Another particular type of patent of concern in the letter from Sens. Leahy et al. involves so-called obviousness-type double patenting ("ODP") and terminal disclaimers. These concerns depend on two assumptions, however: first, that patent thickets in biopharma truly are a problem, and second, that ODP and terminal disclaimers contribute significantly to that those thickets.

As noted above, whether patent thickets, however the term is defined, actually exist in biopharma is a question for which we do not have enough data yet, and much the same can be said about any role ODP and terminal disclaimers might have in any such thickets. Because terminal disclaimers ensure that ODP claims expire at the same time as the prior art patents over which they are obvious, the resulting patent families are somewhat akin to one large patent with many claims, albeit perhaps with additional disclosures

in the later issued ODP patent. In this way ODP patents also resemble continuations and presumably are relied on for many of the same reasons. Thus, before eliminating use of terminal disclosures – and thereby effectively eliminating ODP claims - it would therefore be useful to know more about what role, if any, they might play in alleged biopharma thickets. At a very minimum, it would be good to have standard information such as how often ODP patents are issued in biopharma, what percentage of alleged biopharma patent thickets they constitute, and how they affect clearance and litigation costs as compared to non-ODP patents.

And even if terminal disclaimers were not eliminated but instead were used to create estoppel, that change would have to be prospective and affect only patents that have not yet been issued. To do otherwise would be unfair to patentees who filed terminal disclaimers in reliance on the current rule that a terminal disclaimer is simply a procedural device, not a substantive admission of obviousness. Likewise, any rule stating that ODP families rise and fall together – that if the prior art patent is invalidated the later ODP patent also is invalidated – would have to be prospective in effect only. Again, under current law, terminal disclaimers do not estop later arguments that ODP patents are patentably distinct, and even if they did, such estoppel would apply only to the relationship between the prior art patent and the ODP patent, not that between the ODP patent and any prior art used to invalidate the prior art patent. (For example, even if the prior art patent were invalidated as obvious over particular prior art references, the ODP patent would not necessarily also be obvious over those references). This logic applies *a fortiori* to cases in which the prior art patent is invalidated for lack of written description or enablement. Moreover, giving terminal disclosures an estoppel effect would likely prolong prosecution by forcing applicants to argue against obviousness, and, if the applicant were successful, the resulting patent would no longer be subject to early expiration.

Concluding Remarks: Although re-examining the patent system and looking for how to create greater efficiencies is always a good idea, such re-examination should be done carefully and with as much supporting data as possible. At the very least, determining whether problems do in fact exist and what the size of those problems might be is an absolute necessity before making any changes to the patent system. The PTO also should think prospectively, moreover, and consider carefully the effect of any changes not only on the biopharmaceutical industry but on other industries and technologies as well.