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Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market
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Chair Durbin, Ranking Member Graham, and members of the Senate Judiciary Committee. Thank you for the invitation to testify before you today on the topic of competition in prescription drug markets. I have worked on this topic for several decades, both as the Elvin R. Latty Distinguished Professor at Duke Law School and during my recent service within the Executive Branch.¹ My research on these questions, some of which is discussed below, is funded by non-profit foundations and government agencies only.

The drug competition question has many different aspects, and my statement will address only a few of the relevant issues. I will focus on the ways in which biopharmaceutical patents of questionable validity create substantial challenges for competition. I will also identify narrowly tailored solutions to address the problem of questionable grants.

To be clear, I believe that the incentives provided by properly granted patents are very important for drug discovery and development. The patent incentive is particularly critical for small molecule drugs. Under the Hatch-Waxman statute, which governs competitive entry for small molecules, exclusivity over clinical trial data generated by the originator company lasts only 5 years. In contrast, under the Biologics Price Competition and Innovation Act, data exclusivity for large molecules lasts 12 years.²

While appropriately granted patents serve an important incentive role, poor-quality patents raise prices for consumers without promoting innovation. Unfortunately, we have substantial evidence that poor-quality patents are impeding competition. In what follows, I will review some of this evidence and discuss three surgical interventions for improving quality, competition, and innovation.

These are, first, greater coordination between the USPTO and FDA; second, limiting assertion of patents that are obvious variations of patents that have been determined to be invalid; and third, ensuring the continued vitality of the Patent Trial and Appeals Board.

Improving Patent Quality Through Interagency Coordination

I will begin with measures that can be taken to improve patent quality through greater coordination and information flow between the USPTO and the FDA. These measures should not be controversial. In fact, Congress has been quite eager to secure this coordination.

A number of Senators, including members of this Committee, have expressed concerns about applicant submissions and statements to the FDA that are highly relevant to patent validity but that are nonetheless never brought to the attention of the USPTO. These submissions can take the form of statements made to the FDA that are flatly inconsistent with statements made to the USPTO. For example, an applicant may provide a variety of evidence to the FDA to support its argument that a particular product is only a trivial variation of an already marketed product and therefore does not require additional testing prior to approval. Meanwhile, at the USPTO, the same applicant withholds this evidence and instead states that the product is truly nonobvious and therefore deserving of a patent. This was the scenario in *Belcher v. Hospira*,³ a 2021 case in which the behavior in question was so egregious that the Court of Appeals for

¹ In 2021, I served as Senior Advisor to the Office of the General Counsel at the Department of Commerce. In that capacity, I worked on President Biden's July 9, 2021 Executive Order on "Promoting Competition in the American Economy." My full CV is available at www.law.duke.edu/fac/rai.

² Notably, despite this 12-year exclusivity, originator biologics manufacturers not only assert many more patents in litigation than small molecule originators, but the filing of biologics patents appears to be timed so that a large percentage of these patents issue around the time the 12-year exclusivity is due to expire. Victor L. Van de Wiele et al., *The Characteristics of Patents Impacting Availability of Biosimilars*, 40 NATURE BIOTECHNOLOGY 22, 24 (2022).

³ 11 F.4th 1345 (Fed. Cir. 2021).

the Federal Circuit found that the Chief Science Officer for Belcher had committed the very serious patent law transgression of inequitable conduct and that the patent in question was therefore unenforceable.

Inequitable conduct is, however, very difficult to prove. Rightly so, as it seriously damages the reputation of an individual found guilty of such behavior. Findings of inequitable conduct require proof that an individual intended to mislead the USPTO with respect to information she knew to be material to patentability. The problem of incomplete information flow to the USPTO is, however, more systemic than occasional judicial findings of inequitable conduct would suggest.

For example, manufacturing process patents represent, by far, the largest category of patents asserted by originator biologics firms against would-be biosimilar competitors.⁴ My co-author Nicholson Price and I have shown that over 70% of these assertions involved patents with a priority filing date of more than one year after the branded product in question had been approved for marketing by the FDA.⁵ For such late-filed patents, longstanding Supreme Court case law makes it clear that the firm seeking the patent should make the USPTO aware of ways it is using manufacturing processes related to, or identical to, those it seeks to patent commercially, even if that commercial use is secret. The idea is straightforward – a firm that has been relying on secrecy for commercial advantage should not subsequently be able to extend its exclusivity further by securing a patent either on the same information or an obvious variation. The Supreme Court affirmed this line of case law as recently as the 2019 case of *Helsinn v. Teva*.⁶

In the case of originator biologics firms, the manufacturing process information that is secretly being used commercially is known to the FDA: FDA applicants must submit it as part of their approval process. However, the USPTO has not been aware of such prior commercial activity.

Responding to Congressional and White House interest in the question, the USPTO has recently issued guidance stating that applicants have a duty of disclosure and reasonable inquiry with respect to information disclosed to other agencies.⁷ In fact, this guidance specifically instructs examiners that they can inquire about secret commercial use of manufacturing processes disclosed to the FDA.

The USPTO's guidance is certainly helpful. But placing the burden on examiners and applicants means that enforcement must generally occur primarily through doctrines like inequitable conduct. As noted earlier, inequitable conduct is very difficult to prove. Moreover, fault-finding in costly federal court litigation many years after the questionable patent has been issued is not the best approach to the information flow issue. The problem is a system-level problem, and it deserves a system-level solution.

The system-level solution is straightforward. The Executive Branch has the relevant information. It is simply siloed – an all-too familiar problem for government agencies. One reason information sometimes remains siloed is agencies' acute awareness of the need to maintain trade secrecy. This is where a Congressional push would be very useful. As Senator Durbin's proposed Patent Interagency Coordination and Improvement Act (co-sponsored by Senators Tillis, Grassley, Coons, and Welch) recognizes, information flow from the FDA to the USPTO can be managed in a manner that is perfectly consistent with trade secrecy.

⁴ S. Sean Tu, Rachel Goode, and William B. Feldman, *Biologics Patent Thickets and Terminal Disclaimers*, 331 JAMA 355 (2024).

⁵ Arti K. Rai and W. Nicholson Price II, *An Administrative Fix for Manufacturing Process Patent Thickets*, 39 NATURE BIOTECHNOLOGY 20 (2021).

⁶ 586 U.S. 123 (2019).

⁷ USPTO, *Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue*, and for Proceedings Before the Patent Trial and Appeal Board, 87 Fed. Reg. 45764 (2022).

Under this proposed Act, or similar legislation, information about the manufacturing process for a given biologic that the FDA had on hand at the time of the originator biologic's approval for marketing could be made available in a trade-secret-protected fashion to the USPTO. The USPTO could then use the information to ensure that any subsequent manufacturing process patent granted to the originator was valid because it was novel and nonobvious over the prior commercial use. Additionally, potential biosimilar competitors could then be confident that any issued patent with a priority date later than one year after marketing had not been used to make the biologic at launch and thus did not need to be infringed to make a biosimilar.

As Senator Durbin's proposed legislation recognizes, interagency coordination could also involve assistance in the other direction – from the USPTO to the FDA. Specifically, the USPTO could assist the FDA in determining whether small molecule patents that originator firms proposed for listing on the Orange Book legitimately belong on the Orange Book. In work with Jorge Contreras, I have argued that this sort of *ex ante* procedure would be quite similar to what administrators of patent pools have utilized to address the problem of over-declaration of patents in the standard-setting arena.⁸

Terminal Disclaimers and Obviousness-Type Double Patenting

Another mechanism for substantially improving competition without deterring genuine innovation relates to terminal disclaimers. Unlike late-filed manufacturing process patents of the sort discussed in the prior section, groups of patents linked by terminal disclaimers don't result in additional patent term. However, such patents add to the overall thicket of patents with which a challenger must contend.

Terminal disclaimers are stipulations that the application on which a given applicant is seeking a patent will expire at the same time as an earlier patent owned by the applicant. Although terminal disclaimers can be filed for a number of different reasons, the reason that is most problematic for purposes of unduly thwarting biopharmaceutical competition arises when terminal disclaimers are used to overcome obviousness-type double patenting rejections. In this context, the patent examiner has determined that the follow-on application is obvious given the applicant's prior patent. Rather than fighting the rejection, the applicant chooses to file a terminal disclaimer.

Disclaimers filed to overcome obviousness-type double patenting rejections indicate an applicant's uncertainty about the patent application's strength over the prior patent. Under current Federal Circuit case law,⁹ however, invalidation of the prior patent does not automatically invalidate the follow-on patent. As a consequence, challengers must invalidate patents linked by terminal disclaimers individually. That can be a very expensive undertaking.

Data on the number of terminal disclaimers involved in biologics patenting suggest the scope of the challenge. One study that examined biologics patents asserted in litigation against biosimilars between 2010 and April 2023 found that 48% of these patents contained terminal disclaimers.¹⁰

A USPTO notice of proposed rulemaking issued on May 10, 2024 attempts to address this issue.¹¹ It states that the agency is considering requiring a statement from patent applicants that file terminal disclaimers to overcome obviousness-type double patenting rejections that they will not seek to enforce

⁸ Jorge L. Contreras and Arti K. Rai, *Orange Book Over-Declaration of Pharmaceutical Patents: the Advantages of Ex Ante Over Ex Post Review*, HEALTH AFFAIRS FOREFRONT, December 13, 2023.

⁹ *Simple Air v. Google*, 884 F.3d 1160 (Fed. Cir. 2018).

¹⁰ S. Sean Tu, Rachel Goode, and William B. Feldman, *Biologics Patent Thickets and Terminal Disclaimers*, 331 JAMA 355 (2024).

¹¹ USPTO, Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, 89 Fed. Reg. 40439 (2024).

patents encumbered by terminal disclaimers if the patents to which they are linked have been invalidated. I believe that the proposed rule is a good idea as a policy matter and is an appropriate exercise of the agency's rulemaking authority.

That said, the patent statute does not clearly define the scope of the agency's rulemaking authority over initial examination. Instead, the statute refers to rules that "govern the conduct of proceedings in the Office."¹² The Court of Appeals for the Federal Circuit has sometimes interpreted this language to hold that the agency's rulemaking authority over initial examination is narrowly "procedural."¹³ For this reason, a finalized rule is vulnerable to litigation arguing that the rule exceeds the scope of the agency's rulemaking authority.

A very useful revision to the patent statute would expand the scope of the agency's rulemaking authority over initial examination. For example, a revision could conform the initial examination language to that used to describe the agency's rulemaking authority over the PTAB. In the PTAB context, the Supreme Court has held that the relevant statutory language, which references "governance"¹⁴ generally, is not limited to very narrow matters. This sort of revision would allow the USPTO to adjust nimbly to ground-level realities, including gaming tactics, in a variety of different contexts.

Alternatively, Congress could simply revise the patent statute to state that patents encumbered by terminal disclaimers made to overcome obviousness-type double patenting rejections over a prior patent are unenforceable or invalid if the prior patent is held invalid.

Robust Review of Biopharmaceutical Patents at the Patent Trial and Appeals Board

Third, it is important to preserve robust review of biopharmaceutical patents at the Patent Trial and Appeals Board (PTAB). In the America Invents Act of 2011, Congress created the PTAB to serve as more efficient and accurate mechanism than district courts for correcting inevitable USPTO errors.

Particularly in the case of biologics, where large numbers of patents cover a single molecule, PTAB challenges have played an important role in addressing patents that block competition. According to one study that looked at use of the PTAB through June 2021, 102 biologics patents covering 34 FDA-approved molecules had been challenged at the PTAB.¹⁵ This number was substantially greater than the 9 FDA-approved drugs that had, by June 2021, faced patent challenges in district courts. Because challenges at the PTAB do not have a standing requirement, competitors don't have to wait until they are ready to launch before challenging erroneously granted patents.

It's also important to note that the PTAB's highly professional judges, who are specifically required by statute to be trained in both science and law, carefully evaluate challenges. In the period through June 2021, the PTAB granted review on only 43 of the 102, or 43%, of the challenged patents.¹⁶ Moreover, of those 43 patents, it found only 24 patents to be invalid on all challenged claims.

¹² 35 U.S.C. 2(b)(2)(A).

¹³ *Cooper Technologies Co. v. Dudas*, 536 F.3d 1330, 1335 (Fed. Cir. 2008).

¹⁴ *Cuozzo v. Lee*, 579 U.S. 261 (2016).

¹⁵ Victor T. Van de Wiele, Aaron S. Kesselheim, and S. Sean Tu, *Biologics Patent Challenges Under the America Invents Act*, 42 NATURE BIOTECHNOLOGY 374 (2024).

¹⁶ *Id.*

Not surprisingly, studies have repeatedly shown that the PTAB's affirmance rate at the Federal Circuit exceeds that of district courts.¹⁷ And in the case of biopharmaceutical patents in particular, the PTAB may, if anything, be too cautious. One study on small molecules found that while the PTAB's decisions are overwhelmingly affirmed by the Federal Circuit, it is more likely to be reversed on decisions finding *patentability* than decisions finding *unpatentability*.¹⁸

Robust expert review by the PTAB is a key pillar of a high-quality patent ecosystem and should be preserved.

¹⁷ Matthew G. Sipe, *Experts, Generalists, Laypeople – and The Federal Circuit*, 52 HARVARD J.L. & TECH. 576 (2019).

¹⁸ Charles Duan, *On the Appeal of Drug Patent Challenges*, 72 AMERICAN UNIVERSITY LAW REVIEW 374 (2023).