Association for Accessible Medicines

Your Generics & Biosimilars Industry

February 7, 2019

The Honorable Lamar Alexander
United States Senate
Chairman, Committee on HELP
428 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Patty Murray
United States Senate
Committee on HELP
428 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Frank Pallone
United States House of Representatives
Chairman, Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Greg Walden
United States House of Representatives
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Alexander, Ranking Member Murray, Chairman Pallone, and Ranking Member Walden:

I am writing on behalf of the Association for Accessible Medicines (AAM) and its member companies, which deliver patient access to generic and biosimilar medicines accounting for 9 out of every 10 prescriptions in the United States. AAM strongly opposes the Hatch-Waxman Integrity Act of 2019 (S. 344/H.R. 990). The Hatch-Waxman Integrity Act, if enacted, would make it harder for generic and biosimilar drugs to bring price competition to patients seeking relief from skyrocketing brand name prescription drug prices. The legislation would weaken the quality of the patent system, limit the Constitutional rights of generic and biosimilar manufacturers, and provide special treatment to brand name pharmaceutical companies allowing them to charge patients higher drug prices for longer. Instead of considering such legislation that would decrease patient access to generic and biosimilar medicines, we strongly encourage Congress to advance policies that *increase* patient access to more affordable, FDA-approved generics and biosimilars and take meaningful action to lower prescription drug costs. AAM would be happy to work with you to advance legislation to eliminate pharmaceutical gamesmanship of the patent system and to preserve true innovation.

Balancing Innovation and Access

Manufacturers of generic and biosimilar medicines are proud to deliver safe, affordable and accessible treatments to patients and their families. Today, generic drugs account for 90% of prescriptions filled but only 23% of total spending on prescription drugs in the U.S.[1] When generic and biosimilar medicines are available to patients, competition reduces the cost of prescription drugs and drives savings for patients, taxpayers and the overall health care system. However, generic and biosimilar medicines face challenging barriers designed to hamper and delay competition. One of the most perverse challenges our industry faces is the gaming of the

[1]IQVIA, *2018 Generic Drug Access & Savings Report*, Association for Accessible Medicines, July 2018.

patent system to artificially extend a brand drug's monopoly well past the point lawmakers ever considered appropriate or necessary to incentivize innovation.

Innovative drug companies are strongly incentivized to develop new therapies. This is a critical piece of both the Drug Price Competition and Patent Term Restoration Act, commonly called Hatch-Waxman (P.L. 98-417) and the Biologics Price Competition and Innovation Act (BPCIA) (P.L. 115-52). In exchange for developing new and life-saving therapies, brand pharmaceutical companies are compensated in the form of generous patent rights and additional exclusivities. But these incentives are only a piece of these landmark laws.

Balancing the need for innovation, Hatch-Waxman and BPCIA also seek to ensure that patients will have access to more affordable versions of these medicines as soon as patents and exclusivities expire. When government-granted monopolies expire, competition — driven by the entrance of generic and biosimilar versions of these medicines — brings down the price of expensive brand-name drugs and ensures greater patient access to them. That balance, however, is in jeopardy. The Hatch-Waxman Integrity Act would imperil it even further.

Abuse of the Patent System

Brand pharmaceutical companies have enormous financial incentives to block market entry of generic or biosimilar versions of these medicines for as long as possible. For example, AbbVie Inc.'s rheumatoid arthritis drug Humira® is the world's best-selling prescription drug with over $18 billion in U.S. sales in 2017. Humira, approved in 2002, now takes in more revenue annually than all the National Football League's teams *combined*.

To prevent competition, AbbVie adopted a novel legal strategy, petitioning for and acquiring approximately 100 additional patents on the drug.[2] While its initial patent expired in 2016, AbbVie extended its monopoly to 2034 by applying for dozens more patents shortly before the first expired. Those patents, if left unchallenged, would provide *32 years* of monopoly protection from when the drug was first launched.[3] In combination with its aggressive patent strategy, AbbVie continues to take annual price increases of nearly 10 percent, driving the price to more than $38,000 per patient (after rebates), making this treatment inaccessible to many Americans, while burdening the health care system.[4]

To be clear, these patents are intended to delay competition and are not designed to protect novel or true innovation. One has already been thrown out. The U.S. Patent and Trademark Office (PTO) found, through *Inter Partes* Review (IPR), that AbbVie's claimed "novel" use of the drug had already been well known and published in a medical journal prior to AbbVie's patent

[2] Koons, Cynthia, "This Shield of Patents Protects the World's Best-Selling Drug," Bloomberg Businessweek, September 7, 2017, https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug.

[3] Ibid.

[4] Danny Hakim, "Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher," New York Times, January 6, 2018, https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html.

application.[5] Yet in order to break AbbVie's monopoly, companies must engage in time-intensive, expensive patent litigation, thus allowing the drug company to continue to profit – from patients and government payers – as a result of its anti-competitive tactics designed to extend its monopoly.

The case of Humira is, unfortunately, not an outlier. It is common practice and part of an increasing trend across the pharmaceutical industry. A recent study examined every drug patent for those products marketed between 2005 and 2015. The study determined that 78 percent of new patents issued in this period were awarded to drugs that had already been on the market.[6] The study found further that more than 70 percent of the 100 best-selling drugs extended their monopoly protections beyond the duration of the initially-granted patent.[7] These legal maneuvers were designed – often explicitly – to delay the time when generic or biosimilar versions of these medicines could reach patients. Meanwhile, prices continue to rise and access to affordable medicines is further jeopardized.

IPR Compliments Hatch-Waxman & BPCIA and Congress Intended for Both to Exist

Claims that PTO's authority to reexamine patents somehow amounts to "double jeopardy" or "two bites at the apple" because of Hatch-Waxman or BPCIA litigation simply is not true. "Second look" review procedures like IPR have existed at PTO since at least 1980, well before the 1984 enactment of Hatch-Waxman. In fact, the Leahy-Smith America Invents Act (AIA) overwhelmingly passed the House and Senate – 304 to 117 and 89-9 respectively – with the full support of the brand pharmaceutical industry.[8]

AIA created IPR to ensure PTO maintained its ability to take a second look at whether an otherwise granted patent is in fact valid. Congress has consistently maintained this ability to remedy mistakes and avoid the tremendous costs to consumers and taxpayers that stem from improperly granted patents. Last year the U.S. Supreme Court ruled in *Oil States v. Greene's Energy* that IPR proceedings are Constitutionally permissible and do not violate the rights of property owners. The Court ruled,

> *Inter partes* review involves the same basic matter as the grant of a patent. It is 'a second look at an earlier . . . grant,' and it involves the same interests as the original grant…Patents remain 'subject to [the Board's] authority' to cancel

[5] Matthew Bultman, *PTAB Invalidates Humira Patent In Coherus Challenge*, Law360 (May 17, 2017), *available at* https://www.law360.com/articles/925184/ptab-invalidates-humira-patent-in-coherus-challenge .

[6] Koons, Cynthia, "Most New Drug Patents Are for Old Remedies, Research Shows," Bloomberg, November 1, 2017, https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows.

[7] *Ibid.*

[8] PhRMA, Statement on Patent Reform – 2011, https://www.phrma.org/press-release/phrma-statement-on-patent-reform-2011

> outside of an Article III court, and this Court has recognized that franchises can be qualified in this manner.[9]

The IPR authority was and remains necessary because PTO frequently makes mistakes and issues invalid patents. Many of those mistakes are on account of heavy workloads for patent examiners: on average, a patent examiner spends only 19 hours reviewing a patent's validity. In 2016, fewer than 9,000 patent examiners were tasked with reviewing more than 650,000 patent applications. IPR has fairly and effectively improved patent quality across all industries by ensuring PTO has a mechanism to catch errors and invalidate a patent that never should have been granted in the first place.

Since 2012, 7,686 IPR petitions have been filed. This number is dwarfed by the more than 2.5 million currently enforceable patents. And claims that the IPR process is a "death sentence" for innovators is simply over wrought hyperbole. In 2017, PTO released data showing that only 11% of IPRs deal with pharmaceutical patents. Of those patents, the PTO's second look found that 36% were invalid and 39% were valid.[10] Patents that do not represent innovation and are deemed "obvious" do not warrant government-granted monopolies that keep drug prices high for patients and taxpayers. The benefits patients reap when invalid patents are removed and more affordable generic and biosimilar medicines can enter the market far outweigh some of the exaggerated claims made about the IPR process (e.g., "patent death squad").

We also note that generic and biosimilar manufacturers do not currently have a choice between using IPR versus traditional Hatch-Waxman or BPCIA litigation. This is because generic and biosimilar manufacturers are generally the defendants in patent litigation. In Hatch-Waxman, the choice resides with the brand pharmaceutical companies who decide whether to sue, where to sue, and when to sue. Moreover, should a generic or biosimilar manufacture attempt and fail to invalidate a patent in an IPR, it can be barred from making the same invalidity arguments in Hatch-Waxman litigation. For these reasons – and others – Congress intended these twin mechanisms for ensuring pharmaceutical patent validity to exist jointly. As recently as 2015, Congress reaffirmed that pharmaceuticals should not be carved out from the IPR process.

Hatch-Waxman Integrity Act Singles Out Generic & Biosimilar Developers and is Unconstitutional

The Hatch-Waxman Integrity Act prohibits *only* generic or biosimilar developers from asking PTO to initiate an IPR. Therefore, everyone *except* generic and biosimilar developers would be able to request IPR review of pharmaceutical patents. This result makes no sense and appears to violate the industry's First Amendment rights to petition the government. Generic and biosimilar manufacturers require tools to combat innovative legal strategies that are meant to avoid competition, unfairly maintain brand monopolies and keep drug prices high for patients

[9] Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 584 U.S. ____ (2018), available at https://www.supremecourt.gov/opinions/17pdf/16-712_87ad.pdf.

[10] U.S. Patent and Trademark Office, "Patent Trial and Appeal Board Statistics, March 31, 2017, Slide Presentation, https://www.uspto.gov/sites/default/files/documents/AIA%20Statistics_March2017.pdf.

and taxpayers. The Hatch-Waxman Integrity Act would remove one such tool available to them: the PTO's IPR process.

While proponents of the Hatch-Waxman Integrity Act may claim that the bill would simply require a generic or biosimilar company to choose where they would litigate the validity of a patent – either in district court or at the PTO – the bill contains no such choice. The Hatch-Waxman Integrity Act would require manufacturers of generic and biosimilar medicines, as a condition of applying for FDA approval, to certify they will not file IPR petitions challenging the validity of a drug patent. Simply put, if generic and biosimilar manufacturers choose to continue operating their businesses – which necessarily rely on FDA approval – they must voluntarily surrender their right to use a tool available to every other sector of the economy. Such discrimination against the manufacturers of generic drugs and biosimilars flies in the face of bipartisan goals to enhance generic and biosimilar competition to lower prescription drug prices.

Furthermore, by prohibiting the makers of generic and biosimilar medicines from taking advantage of the IPR process, the Hatch-Waxman Integrity Act will increase gamesmanship and the filing of invalid drug patents. Brand pharmaceutical companies have every incentive to hide prior art from the PTO during patent examination. By depriving PTO of this information, non-innovative patents can be issued. Prohibiting our members from raising questions about the validity of a patent would restrict competition and encourage brand name drug companies to maintain artificially high drug prices.

Members of Congress Should Increase, Not Decrease, Patient Access to Generics and Biosimilars

Americans continue to rank the rising cost of prescription drugs as a top public policy concern. Instead of supporting legislation that further insulates drug companies' monopoly profits, Congress should pass laws that reduce regulatory burdens, increase competition in prescription drug markets, and speed the availability of generic and biosimilar medicines. On behalf of our members, I encourage you to join us in opposing this misguided legislation.

Sincerely,

Chester "Chip" Davis, Jr.
President & CEO