Association for Accessible Medicines

Your Generics & Biosimilars Industry

Testimony of

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Before the

Subcommittee on Consumer Protection and Commerce

of the House Committee on Energy and Commerce

"Profits Over Consumers:

Exposing How Pharmaceutical Companies Game the System"

September 19, 2019

Chairwoman Schakowsky, Ranking Member Rodgers, and Members of the Subcommittee:

Thank you for holding this important hearing, which could have great consequences on this Committee's critical work to lower drug prices and increase pharmaceutical price competition for America's patients. My name is Jeff Francer, and I am the general counsel of the Association for Accessible Medicines ("AAM"). AAM is the nation's leading trade association for manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines. Today, generic and biosimilar medicines comprise 90% of prescriptions in the United States at only 22% of total drug spending.[1] As of 2016, AAM's members provided more than 36,000 jobs at nearly 150 facilities and manufactured more than 61 billion doses of generic medicines in the United States every year. Our core mission is to improve lives by advancing timely access to more affordable generic and biosimilar medications.

I. INTRODUCTION

Increasing competition in the prescription drug market—especially with the introduction of more affordable generic and biosimilar medicines—has been the only meaningful way to deliver savings at the pharmacy counter for patients. Generic medicines play an integral role in health care and enhance patient access to life-saving treatments. Indeed, generic manufacturers have delivered savings of nearly $2 trillion—including $293 billion in 2018—to patients and the health care system in the last decade.[2]

Biosimilar medicines represent another critical step forward in reducing high drug prices. Biosimilars are safe, effective and lower-priced versions of costly brand-name biologics. By the year 2025, over 70 percent of drug approvals are expected to be biological products.[3] Experts estimate that FDA-approved biosimilars could save more than $54 billion over the next 10 years.[4] In doing so, biosimilars will enable greater access to lifesaving cures for an estimated 1.2 million patients.[5]

However, the sustainability of a competitive generic market and the availability of generic medicines for patients is in jeopardy. Current market realities and anticompetitive tactics—combined with misguided policies—threaten the long-term stability of the generics and biosimilars markets. As AAM outlined in a February 2018 whitepaper, "Ensuring the Future of Accessible Medicines in the U.S.," generic and biosimilar manufacturers are facing an increasing set of challenges to getting new competitive and

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[1] AAM, *2019 Generic Drug and Biosimilar Access Report in the U.S.*, April 2019.

[2] *Id.*

[3] U.S. Pharmacist, *Biosimilars: Current Approvals and Pipeline Agents*, October 2016.

[4] RAND, *Biosimilars Cost Savings in the United States*, October 2017.

[5] The Biosimilars Council, *Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines*, August 2017.

more affordable medicines to market and to ensuring patient access to generic medicines on the market continues without interruption.[6]

One of the greatest barriers to increased prescription drug competition is abuse of the U.S. patent system. Increasingly, brand-name drug companies are building patent "thickets" around their drugs, not just for the original innovative research, but for much smaller changes that may not be deserving of decades-long monopolies. In some instances, brand-name drug companies are attempting to accumulate patents not because they are innovative, but rather to increase litigation and development costs for potential generic and biosimilar competitors. This problem significantly impairs competition and, not surprisingly, increases costs—patent thickets have cost patients and payers approximately $7.6 billion in lost savings since 2015.[7]

Generic and biosimilar competition can also be delayed by another practice known as "product hopping." Product hopping occurs when a brand-name drug company seeks to switch patients to a new version of a drug just before the original product becomes subject to generic competition. In many cases, the switch is forced on patients because the brand-name drug company stops selling the original product—a so-called "hard switch." The main goal of such switches is not to improve patient health. Instead, these switches are designed to extend monopoly pricing, delay generic competition, and limit patient access to more affordable generic and biosimilar medicines.

Several cases illustrate the potential anticompetitive and anti-patient effects of product hopping. For example, in the case of Namenda®, the brand-name drug company planned to force Alzheimer's patients to switch to its new extended-release (ER) formulation by withdrawing its immediate-release (IR) formulation from the market.[8] The company knew that even if lower-cost IR generics were approved later, physicians would be highly reluctant to switch these vulnerable patients back to an IR formulation once they were stable on an ER formulation. The brand-name drug company's documents confirm as much: as the company conceded at the time, "if we do the hard switch and . . . convert patients and caregivers to once-a-day therapy versus twice a day, ***it's very difficult for the generics to then reverse-commute back***."[9]

The product hop in Suboxone® was equally harmful. There, the brand-name drug company sought to switch patients to a newly-formulated version by making allegedly false claims that it was safer than the older version and could better prevent accidental poisoning by children.[10] This case is particularly egregious because it not only involves

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[6] AAM, *Ensuring the Future of Accessible Medicines in the U.S.: Avoiding Shortages & Ensuring Competition for America's Patients*, February 2018.

[7] Biosimilars Council, *Failure to Launch,* June 2019.

[8] *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).

[9] *Id.* at 656 (emphasis added).

[10] *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665 (E.D. Pa. 2014).

allegedly false claims regarding pediatric safety, but also because it delayed competition for a drug intended to treat opioid addiction in the middle of one of the worst health epidemics in U.S. history.

The impact of product hopping on generic and biosimilar competition can be significant. *First*, product hopping impairs automatic substitution, which is "the only cost-efficient means of competing available to generic manufacturers."[11] Indeed, under many state laws, a generic drug can only be automatically substituted for a brand-name drug at the pharmacy counter if it is "therapeutically equivalent" to the brand. By changing the dosage form or strength of the branded drug, however, brand-name drug companies can ensure that generic versions of the original brand-name product will not be "therapeutically equivalent" and therefore not substitutable.[12] *Second*, because the new version typically will be protected by new patents, it will be protected from generic competition for years to come. By moving the goal posts every few years through product hopping, brand-name drug companies can potentially delay meaningful competition.

AAM supports legislation to curb anticompetitive brand tactics. However, any solution should be carefully calibrated to ensure it is not overbroad. AAM is supportive of innovation and recognizes that some changes to existing pharmaceutical products can result in substantial health benefits. Thus, it will be important for Congress to consider how to distinguish between "product hopping" that is anticompetitive from legitimate medical improvements.

In addition, the Committee should consider further legislative changes to strengthen competition in the pharmaceutical marketplace, including legislative changes to help eliminate anticompetitive patent thickets, including:

- Ensuring a date certain for generic and biosimilar competition;
- Accelerating the biosimilar "patent dance";
- Harmonizing Hatch-Waxman with the America Invents Act ("AIA");
- Requiring more timely FDA action on biosimilar labeling changes seeking to add a "carved out" indication or other condition of use; and
- Ensuring that new generic and biosimilar competition is available to patients through preferred formulary placement.

These suggested legislative changes are discussed more fully in AAM's comments below.

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[11] *Actavis*, 787 F.3d at 655-56.

[12] *Orange Book Preface: Approved Drug Products with Therapeutic Equivalence Evaluations*, 36th edition, Center for Drug Evaluation & Research, FDA, June 2016.

II. OVERVIEW: HOW PRODUCT HOPPING IMPAIRS GENERIC COMPETITION

A. Product Hopping Generally

Product hopping is a tactic used by some brand-name drug companies that takes advantage of the special rules governing approval and use of generic drugs. It occurs when a brand-name drug company reformulates a medicine—typically when its patents and exclusivity are about to expire—and then seeks to switch patients from the original to the reformulated medicine.[13] The purpose is to move the bulk of the business from an older product that is about to face generic competition to a reformulated product that has additional patent protection and thus will not face generic competition for years. And the result is that patients end up paying higher prices because of the lack of any meaningful competition for the new medicine. Indeed, the district court in Namenda® estimated that "consumers would pay almost $300 million more and third-party payors would pay almost $1.4 billion more" if the Namenda® product hop had been successful.[14]

Product reformulations can take many forms. In some cases, the brand-name drug company makes a relatively simple change to the product's dosage form such as switching from a tablet to a capsule. For example, the sponsors of Prozac®, an antidepressant, and Tricor®, a cholesterol treatment, switched from capsule to tablet dosage forms.[15] In other cases, the brand-name company may slightly modify the active ingredient, as was done with the heartburn medicine Nexium®, or combine two previously approved active ingredients into a single product, as was done with the migraine treatment Treximet®.[16]

The method by which brand-name drug companies accomplish the switch also can take many forms, although they are typically categorized into "hard" versus "soft" switches. A "hard switch" occurs when the brand-name drug company withdraws the original product from the market so that patients have no choice but to switch to the newer, reformulated drug.[17] A "soft switch" occurs when the brand-name drug company does not withdraw the original product from the market but takes other aggressive steps to encourage patients to switch to the new product, such as marketing only the new product, increasing the price of the original product, or imposing burdensome distribution requirements on the original product.[18]

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[13] Michael A. Carrier and Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 171-72, 2016.

[14] *Actavis*, 787 F.3d at 661.

[15] *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006).

[16] *Walgreen Co. v. AstraZeneca Pharmaceuticals*, 534 F. Supp. 2d 146 (D.D.C. 2008).

[17] Carrier, *supra* note 13, at 168.

[18] *Id*.

Although brand-name drug companies often argue that these types of changes are made to improve the product and benefit patients, the changes are sometimes intended to sidestep meaningful generic competition just before it occurs. In this way, brand-name companies may take advantage of the unique regulatory regime governing the approval and use of generic drug products. Specifically, under the Hatch-Waxman Act, a generic drug may be approved if it is the "same" as a brand-name product in terms of, among other things, active ingredient, dosage form, route of administration, strength, and labeling, and if it is bioequivalent to the brand-name product—*i.e.*, performs the same way in the body.[19] A generic that meets these rigorous approval requirements is deemed to be "therapeutically equivalent" to the brand. Under many state laws, a "therapeutically equivalent" generic drug can be substituted for the brand at the pharmacy counter.[20] This generic drug substitution, in fact, is the primary way generic drugs compete against brand-name drugs and result in significant savings to patients and the healthcare system.

Product hopping, however, flips this engine of competition on its head. By making minor changes to the original brand-name drug—such as switching from a tablet to a capsule—the brand-name drug company can ensure that a generic version of the original product will not be "therapeutically equivalent" to the reformulated product. By switching the market to the reformulated product right before FDA approves a generic of the original product, the brand-name drug company can ensure that generic uptake will be minimal. A few examples of how this tactic is used in practice may be helpful to explain to the Committee just how pernicious and anticompetitive this strategy can be.

B. Examples of Product Hopping

1. Namenda®

Namenda® was an extremely successful, immediate-release (IR) treatment for moderate-to-severe Alzheimer's disease. When the drug neared the end of its patent protection, however, the sponsor sought to avoid this patent cliff by introducing a new, extended-release version called Namenda® XR in 2013 and working aggressively to switch patients from Namenda® IR to Namenda® XR.[21] To accomplish this switch, the sponsor stopped actively marketing Namenda® IR, aggressively promoted Namenda® XR to healthcare providers and patients, and offered deep discounts for Namenda® XR to make it considerably less expensive than Namenda® IR.[22] These "soft switch" tactics, however, did not work. Indeed, the brand-name drug company's internal projections

[19] *Id*. at 173-74.

[20] *See id*. at 186-87.

[21] *Actavis*, 787 F.3d at 638, 642.

[22] *Id*. at 648.

"estimated that only 30% of Namenda IR users would voluntarily switch" to Namenda® XR before generic entry.[23]

In light of these data, the brand-name drug company moved to a "hard switch" in 2014, announcing that they would withdraw Namenda® IR from the market and urging healthcare providers to "discuss switching to Namenda® XR" with their patients.[24] Such a hard-switch would convert "80 to 100% of IR patients to XR prior to generic entry," meaning that there would be "few to no prescriptions" left for which generics would be eligible to compete.[25] The brand-name drug company also requested that the Centers for Medicare and Medicaid Services ("CMS") remove Namenda® IR from the Medicare formulary so that Medicare health plans would no longer cover it.[26]

The brand-name drug company's contemporaneous statements made clear that the purpose of the reformulation was to make it "very difficult" for generic competition. Indeed, the company's own internal documents confirmed as much:

- "We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity."

- "[W]hat we're trying to do is make a cliff disappear and rather have a long—a prolonged decline. And we believe that by potentially doing a forced switch, we will hold on to a large share of our base users."

- "[I]f we do the hard switch and we convert patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back."[27]

Ultimately, the State of New York filed suit to prevent the hard switch, which resulted in an injunction prohibiting the brand-name drug company from withdrawing Namenda® IR from the marketplace. That injunction was affirmed by the Second Circuit.[28]

2. Suboxone®

Another troubling example of "product hopping" involves Suboxone®, a well-known

[23] *Id.*

[24] *Id*.

[25] *Id.* at 655.

[26] *Id*.

[27] *Id.* at 657-58.

[28] *Id.* at 663.

treatment for opioid addiction. Suboxone® was originally approved in 2002 in a sublingual tablet dosage form. After its exclusivity expired, the brand-name drug company received approval for a new version of Suboxone® in a sublingual film dosage form. This new version had patent protection extending until 2023.[29]

Once FDA approved the film version of Suboxone®, the brand-name drug company initiated an aggressive switch campaign to avoid impending generic competition, which included raising the price of the original tablet formulation even though the film formulation was more expensive to manufacture and package.[30] Moreover, the brand-name drug company made promotional claims that the new film version was safer because it carried a lower risk of accidental pediatric poisoning. The sponsor even went so far as to announce that would be withdrawing the original tablet formulation from the market because of these pediatric safety concerns and did so six months later.

These safety claims appear to have been false. Indeed, the risks to children may actually have been ***higher*** for the new film version of Suboxone® than the original tablet formulation.[31] As a result of these allegedly false marketing claims, which were intended to further the sponsor's "product hopping" strategy, the sponsor has now been indicted by the Department of Justice for, among other things, mail fraud, wire fraud, health care fraud, and conspiracy. As the grand jury found, the brand-name drug company's "fraudulent scheme lasted for years and hindered patients' health care providers', and health care benefit programs' accurate assessment regarding opioid-addiction treatment in order to increase the company's profits."[32]

3. Tricor®

Finally, the Tricor® case shows how brand-name drug companies can engage in multiple product hops. There, the brand-name drug company originally obtained approval of Tricor®, a cholesterol-lowering drug, in a capsule dosage form.[33] While generic drug approvals were blocked by exclusivity, the brand-name drug company sought and obtained approval of a new tablet dosage form in slightly different strengths. After approval, the company engaged in a variety of hard switch tactics, including:

- stopping all sales of Tricor® capsules;
- buying back existing inventory of those capsules from pharmacies; and

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[29] *Suboxone*, 64 F. Supp. 3d at 674-75.

[30] *Id*. at 674.

[31] *Id*.

[32] *United States v. Indivior Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.)*, Case No. 1:19-cr-00016, Dkt. No. 3 (W.D. Va. 2019).

[33] *Abbott*, 432 F. Supp. 2d at 415-16.

- changing the National Drug Data File ("NDDF") code to "obsolete." [34]

As a result of these tactics, generic substitution was no longer possible because the generic capsules were not therapeutically equivalent to the new Tricor® tablets.[35]

Unsurprisingly, the brand-name drug company engaged in another round of product hopping later in Tricor®'s lifecycle. The brand-name drug company sought and obtained approval of slightly different strengths (145 mg and 48 mg instead of 160 mg and 54 mg), removed the prior strengths from the market, and once again changed the NDDF codes to obsolete.[36] Ultimately, the brand-name drug company apparently settled the product hopping claims for $184 million.[37]

C. Negative Implications of Product Hopping

These examples illustrate the potential anticompetitive problems created by product hopping. *First*, product hopping can eliminate automatic generic substitution. This is because even minor modifications to a medicine—such as changing from a capsule to a tablet—can affect substitutability. Brand-name drug companies know that a generic tablet cannot be automatically substituted for a capsule even if both products behave the same way in the body. Thus, they introduce new products just before the old product faces generic competition. This breaks the "therapeutic equivalence" link that allows for automatic generic substitution. As a result, a generic version of the original product cannot be automatically substituted at the pharmacy counter for the new product, therefore perpetuating the brand-name drug company's monopoly and its monopoly pricing.

This lack of automatic substitution affects patients. Notably, generics made up only 2% of unit sales after the maker of Tricor® engaged in multiple product hops, including hard switch techniques.[38] Even when a brand-name drug company does not engage in a hard switch, generic entry remains difficult. Indeed, generics only compromised about 25% of unit sales after the brand-name drug company made a soft switch from Prilosec®

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[34] *Id*. at 416.

[35] *Id*. at 414.

[36] *Id*. at 418.

[37] Nicole Callan, *Antitrust Liability for "Product Hopping": A Look at Recent Decisions*, ABA Section of Antitrust Law, 2015.

[38] Transcript of Record at 534-35, Teva Pharm. USA, Inc. v. Abbott Labs., 580 F. Supp. 2d 345 (D. Del. 2008); Carrier, *supra* note 13, at 217.

to Nexium®.[39] Had generic entry not been impeded by these product hops, generics would have likely captured approximately 85% of the market.[40]

Second, product hopping can delay innovation. Significantly, the makers of Tricor® delayed seeking a new indication until after the reformulated product had been introduced, even though "[t]he data necessary to get the new indication was available much earlier."[41] Likewise, with Neurotonin®, the brand-name drug company admitted that a "principal reason [for not seeking FDA approval [for new indications] was that it wanted to reserve them for a later promotional campaign for its reformulated product."[42] And, in Namenda®, the brand-name drug company delayed introducing Namenda® XR until the eve of generic competition—even though it had actually received approval three years earlier.[43]

Third, product hopping—in combination with other anticompetitive techniques—can substantially delay generic approvals. Indeed, in Suboxone®, generic approvals on the original tablet formulation were delayed for months after the brand-name drug company used citizen petitions to augment its product hopping scheme.[44] The pendency of the citizen petitions allowed the brand-name drug company to delay generic approval and, in the meantime, "convert the vast majority of Suboxone sales from the tablet to the film."[45]

III. OVERVIEW: HOW PATENT THICKETS HARM PATIENTS

As discussed above, product hopping can have significant consequences for manufacturers, patients, and taxpayers. Perhaps the greatest long-term obstacle to increased prescription drug competition, however, is patent abuse by some brand-name drug companies. While AAM's member companies strongly support innovation, patent abuse is preventing them from delivering more affordable generic and biosimilar medicines to patients.[46]

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[39] Carrier, *supra* note 13, at 217.

[40] *Id.*

[41] *Id.* at 202.

[42] *Id.*

[43] *Id.*

[44] End Payors' Second Am. Compl. at 4, *In re: Suboxone Antitrust Litig.*, MDL No. 2:13-md-2445 (E.D. Pa. 2015).

[45] *Id.* at 5.

[46] AAM, *Ensuring the Future of Accessible Medicines in the U.S. – Ensuring Competition for America's Patients*, February 2018.

Recent research confirms the extent of the problem and the increased costs borne by patients. Increasingly, brand-name drug companies are building impenetrable thickets of patents around their drugs. Indeed, at least 78 percent of the new patents in FDA's Orange Book are associated with ***existing*** drugs on the market.[47] And more than 70 percent of the roughly 100 best-selling drugs have had their patent protection "extended at least once, with almost 50% having [their patent protection] extended more than once."[48]

The problem has only become more severe and pervasive. Indeed, the Institute for Medicines, Access, and Knowledge ("I-MAK") recently examined the top 12 brand-name drugs on the market and found that a total of 848 patents (71 per drug) shield these medicines from generic and biosimilar competition for an average of 38 years.[49] A few examples from the report demonstrate how patent thickets stifle competition and raise prescription drug prices:

- The world's top-selling brand-name drug, Humira® is now protected by more than 130 patents,[50] and It has become a more lucrative franchise than ***the entire National Football League***.[51] Perhaps unsurprisingly, the price of Humira® has increased 144 percent since 2012.[52]

- One of the most prescribed cancer treatments, Revlimid®, is now protected by a patent thicket consisting of 96 patents that may provide for as much as 40 years of monopoly protection.[53] The price of Revlimid® has increased 79 percent since 2012.[54]

- Diabetes patients who rely on the insulin treatment, Lantus®, may not see a generic or biosimilar alternative for 37 years because of the 49 patents that have been issued.[55] The price of Lantus® has increased 114 percent since 2012.[56]

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[47] Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J. L. & Biosciences 590, December 2018.

[48] *Id.* at 597.

[49] I-MAK, *Overpatented, Overpriced*, August 2018.

[50] *Id.*

[51] Anna Rose Welch, *AbbVie's Humira Can Tackle the NFL – But Can It Handle Biosimilars*, Outsourced Pharma, February 2015.

[52] I-MAK, *Overpatented, Overpriced*, August 2018.

[53] *Id.*

[54] *Id.*

[55] *Id.*

[56] *Id.*

As these examples show, many brand-name drug companies are accumulating more and more non-innovative patents that are designed to increase litigation and development costs for potential generic and biosimilar competitors. Patients and taxpayers ultimately pay the price for these tactics—without effective generic and biosimilar competition, patients will continue to pay bloated monopoly pricing. Addressing patent abuse must be a top priority for Congress to effectively reduce prescription drug prices.

IV. POTENTIAL LEGISLATIVE SOLUTIONS

A. Product Hopping

AAM supports legislative solutions to address anticompetitive brand-name drug company gamesmanship tactics such as product hopping. AAM cautions, however, that the Committee should be careful to ensure that any legislative solutions are narrowly tailored. AAM recognizes the value of true innovation and does not believe that improvements to existing products that provide real value and health benefits to patients should be discouraged.

Instead, legislative solutions could focus on increasing scrutiny of the types of product hopping strategies that provide few, if any, benefits to patients and instead are intended primarily to avoid legitimate generic competition. Those strategies may include:

- Deleting NDDF codes;
- Destroying or buying back existing inventory;
- Increasing the price for the original drug without a legitimate business justification for doing so; or
- Withdrawing the original drug from the market for reasons unrelated to safety.

AAM would be happy to work with the Committee to formulate appropriate legislative strategies to address anticompetitive product hopping.

B. Ensuring a Date Certain for Generic and Biosimilar Competition

The high cost of prescription drugs is an immediate problem, and we urge the Committee to consider longer-term solutions as well. We suggest that the Committee focus on solutions to patent thickets, which now represent the most significant impediment to biosimilar competition.

One option to consider would be to provide biosimilar applicants with a date certain for market entry. During consideration of the Biologics Price Competition and Innovation Act (“BPCIA”), Eli Lilly expressly proposed this concept: if regulatory exclusivity were granted for a long enough period, Lilly would be willing to give up its ability to use its

patents to keep biosimilars off the market longer.[57] Yet in the final BPCIA, brand-name drug companies received 12 years of exclusivity—almost as long as the 14 years Lilly proposed, and much longer than any other form of exclusivity on the books—but gave up ***none*** of their ability to stave off competition through patents.

AAM recognizes the value of true innovation and wants to see the owners of properly issued patents receive compensation for the use of their invention. But in the context of today's patent thickets, each patent potentially becomes a weapon far out of proportion to the innovation it embodies. Each patent can be used to keep biosimilar competition off the market, either through a court order enforcing the patent through an injunction or by a company-crippling award of lost profits for the entire biologic franchise. The patent laws do not have to give such disproportionate power to incremental advancements in knowledge—say, to the 132nd patent in the thicket covering a single product, even assuming the other 131 are valid.

After a suitable monopoly period, Congress could choose to refocus any remaining patents on providing compensation to the inventor, perhaps through royalties, rather than by blocking competition. Working out the details of such a system would involve work and discussion by both the Committee and stakeholders. But if the Committee wants to have a lasting impact on the high prices that the current patent environment makes possible, it is time to begin such a discussion.

C. Accelerating the Biosimilar Patent Dance

We also suggest that the Committee consider ways to accelerate the BPCIA patent dance and therefore expedite patient access to more affordable biosimilar medicines. Under the current law, the BPCIA patent dance—which initiates the patent litigation process for biosimilars—cannot be commenced until after a biosimilar application has been accepted for review by FDA.[58] This means that a biosimilar company must wait years to test patents that may be invalid. As the Federal Circuit has recognized, this type of delay is inefficient and harms consumers. Indeed, "the public is best served by getting invalid patents declared invalid as early as possible."[59]

Consistent with this strong policy, we propose a 1-2 year acceleration of the BPCIA patent dance. At the biosimilar manufacturer's option, it could start the patent dance after a Type 3 Biosimilar User Fee Amendment ("BsUFA") meeting with FDA. Importantly, a Type 3 BsUFA meeting does not occur until a biosimilar applicant submits a "comprehensive data package," including "[f]ull study reports for a clinical study or clinical

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[57] John Wilkerson, *Lilly Proposed Forfeiting Biologics Patents if Exclusivity Sufficient*, Inside Health Policy, December 2008.

[58] 42 U.S.C. § 262(l)(2).

[59] *Hallco Mfg. Co. v. Foster*, 256 F.3d 1290, 1297 (Fed. Cir. 2001).

studies."[60] Exchanging this "comprehensive data package" as part of the accelerated dance would help ensure that brand-name drug companies have sufficient information to meaningfully ascertain infringement claims and timely commence patent litigation. It also ensures that any subsequent patent litigation is sufficiently ripe and justiciable.

At bottom, the rationale for an accelerated patent dance is simple: an earlier start to the patent dance means that patent litigation ends earlier. And a more-timely conclusion to patent litigation ultimately expedites biosimilar market entry and patient access to more affordable alternatives. We are happy to work with the Committee to help develop this solution.

D. Harmonizing Hatch-Waxman with the AIA

We also suggest harmonizing Hatch-Waxman with the AIA. Presently, a thirty-month stay of approval may only be terminated by a district court decision.[61] It cannot be terminated by a Patent Trial and Appeal Board ("PTAB") final written decision—even if that decision invalidates all claims of all patents that created the thirty-month stay. That creates a potentially inequitable scenario: the PTO's invalidation of all brand-name drug patents will still not lead to generic competition. To address this, we suggest updating the Hatch-Waxman Act by including provisions that would terminate a thirty-month stay based on a PTAB final written decision on all relevant patents and claims.

E. Biosimilar Carve-Ins

We also encourage the Committee to expand its efforts to speed biosimilar competition by addressing another significant barrier to biosimilar market entry: FDA's treatment of biosimilar labeling "carve-ins."

One way that biosimilar manufacturers navigate patent thickets is to "carve-out" patented indications or uses from their labeling and gain initial approval with "skinny labeling." But biosimilar manufacturers may need to eventually carve those indications back in after they address patents through litigation or settlement. This "carve-in" process is critical for the success of biosimilars, as each carved-out use limits the potential market and savings for consumers.

Significantly, there is not an efficient process for adding uses back into the labeling of biosimilars once patent issues have been addressed. The FDA currently treats such applications as "Supplements with Clinical Data" under BsUFA and reviews them on a full 10-month clock. This protracted review period is inappropriate. It severely undermines the ability of biosimilar manufacturers to bring their products to market, costing consumers millions of dollars and hurting the industry for years to come.

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[60] FDA Draft Guidance, *Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products*, June 2018.

[61] 21 U.S.C. § 355(c)(3)(C); 21 U.S.C. § 355(j)(5)(B)(iii).

In January 2019, former FDA Commissioner Scott Gottlieb, M.D., said that FDA was "going to be putting out policy this year to explain how to carve back in indications … We're working on defining an efficient way to do that."[62] We suggest that the Committee encourage FDA to follow through on its commitment and reduce the review time for these specific type of supplements to no longer than 90 days. This policy will go a long way toward creating a healthy biosimilars market, improving consumer choice, and saving the healthcare system billions of dollars.

F. Preferred Formulary Placement

New generic competitors are particularly important to ensuring future prescription drug savings. That is why the FDA prioritizes its review of first generic competitors to a brand-name drug. Although the FDA has been approving generic drug applications at a record-setting pace, brand-name drug companies have pioneered the use of exclusionary rebates to block new generic or biosimilar competition.

As a result, new generic competitors are increasingly unavailable to patients because they are blocked by exclusionary brand drug rebate agreements or placed on formulary tiers with inappropriately high cost sharing. For instance, a recent analysis found that Medicare drug plans are increasingly shifting generic drugs from tiers with lower copayments for patients to brand tiers with higher copayments and coinsurance.[63] This means that seniors do not benefit from lower prices and lower out-of-pocket costs, and taxpayers continue to pay for high-priced brand-name drugs.

Policymakers can take immediate steps to ensure that patients receive the full benefit of lower-cost generic and biosimilar medicines by:

1. Ensuring Medicare Part D plans cover new, lower-priced generic products at launch;

2. Providing for placement of generic drugs on tiers designated as generic and separate from brand tiers; and

3. Creating a separate specialty drug tier to allow for formulary differentiation among specialty brands versus specialty generics and biosimilars.

These policies would support greater patient access to lower-cost generics and would immediately reduce seniors' out-of-pocket costs by more than $4 billion.[64] Ensuring such policies would help put an end to some brand-name drug company schemes that

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[62] Gottlieb, Scott, M.D., Keynote Address to the J.P. Morgan Healthcare Conference, January 2019.

[63] Avalere Health, *Effect of Potential Policy Change to Part D Generic Tiering on Patient Cost Sharing and Part D Plan Costs*, February 2019.

[64] *Id.*

undermine pharmaceutical competition and would generate immediate savings for America's patients and taxpayers.

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Thank you again for the opportunity to testify on this important issue. I look forward to answering your questions.