Your Generics and Biosimilars Industry

Statement for the Record
The Association for Accessible Medicines
"A Prescription for Change:
Cracking Down on Anticompetitive Conduct in Prescription Drug Markets"
July 13, 2021

Thank you Chairwoman Klobuchar, Ranking Member Lee and members, of the Senate Judiciary's Subcommittee on Antitrust for holding this important hearing and for the opportunity to submit this written statement on behalf 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. Our members provide approximately 52,000 jobs at nearly 150 facilities and manufacture more than 60 billion doses of generic medicines in the United States every year.[1] AAM's core mission is to improve lives by advancing timely access to affordable generic and biosimilar medications.

Over the years, AAM has worked extensively with the Senate Judiciary Committee to ensure that the patent system is appropriately balanced and that antitrust law is properly used to police truly anticompetitive behavior. We are especially grateful for this Committee's work on addressing anticompetitive gaming of the regulatory system and in passing the bipartisan Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. Thank you Chairwoman Klobuchar, Ranking Member Lee, and Senator Leahy for your leadership in making the CREATES Act a reality. The law is responsible for meaningful progress accelerating patient access to more affordable generic medicines.[2]

We are pleased that the Antitrust Subcommittee is holding today's hearing and shining a spotlight on the anticompetitive tactics used by some brand name pharmaceutical companies to delay patient access to generic and biosimilar medicines well beyond the periods that Congress intended. In this submission, we propose six areas for reform:

- preserving procompetitive, pro-patient patent settlement agreements;
- ensuring that "skinny labeling" remains a viable FDA pathway for generic and biosimilar manufacturers to bring lower-cost medicines to market as quickly as possible;
- preventing monopolistic behavior by powerful purchasing organizations;
- prohibiting rebate traps and other anticompetitive mechanisms that deter coverage of and access to lower-cost medicines;
- prohibiting false and misleading statements about the safety and efficacy of biosimilars; and
- strengthening *inter partes* review ("IPR") to encourage competition while preserving true innovation.

We discuss each of these proposals in greater detail below.

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[1] AAM, "Securing Our Access & Savings: 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report," September 2020.

[2] FDA, "Office of Generic Drugs 2020 Annual Report," February 2021. Available at: https://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2020-annual-report.

I. Preserving Procompetitive Settlement Agreements

We urge the Subcommittee to focus its attention on the areas where the patent system is out of balance and systematically undermined competition. Some proposals that have been introduced in Congress are concerning because they would actually serve to ***reduce*** opportunities for competition in this critical area.

The first step is to do no harm. Generic medicines come to market only after the brand-name drug company has an opportunity to litigate any patents that it may have. Under the Hatch-Waxman Amendments of 1984, if the brand-name drug company wins, the generic will be kept off the market until after the last patent expires.[3] A generic developer that litigates all the way through trial and appeal, only to end up with that outcome, is actually in a worse position than if it had never challenged the patent in the first place. Facing uncertainty about the outcome and the possible launch date, a generic developer expends significant resources in both litigation and launch preparations without realizing any revenue.

In the vast majority of cases and particularly since the Supreme Court's decision in *FTC v. Actavis*, settlement of Hatch-Waxman litigation enables competition and benefits the public in a very tangible way: it can allow patients to access more affordable generic alternatives considerably sooner than the patents would otherwise allow. At least one analysis has found that patent settlements led to generic entry, on average, ***81 months*** before patent expiry.[4] This option is becoming all the more important as brand-name pharmaceutical companies amass larger and larger patent portfolios on each product. If ***every*** patent had to be litigated all the way to final judgment—with no possibility of settlement—that would create a barrier to entry and deter generic manufacturers from even trying to launch a competing product before the patent expires.

The Supreme Court's 2013 decision in *FTC v. Actavis* significantly changed the landscape for how patent settlement litigation is resolved.[5] Settlement agreements with "large, unjustified reverse payments" were determined to be potentially anticompetitive when combined with a market entry date well-beyond patent expiry. AAM supports the Supreme Court's decision in *Actavis*. However, recent legislative proposals go beyond the Supreme Court's decision in *Actavis* and would substantially alter a generic developer's ability to accelerate patient access to more affordable medicines and further tips the playing field to the advantage of brand-name pharmaceutical companies.

Current proposals before Congress do not simply target so called "pay-for-delay" patent settlement agreements. Many patent settlements—a potential universe of more than 200 agreements between brands and generic companies—would potentially be impacted. By deeming virtually all settlements presumptively anticompetitive, those proposals—if enacted—would severely chill the ability of generic and biosimilar developers to obtain a settlement and disincentivize their ability to challenge patents in

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[3] 35 U.S.C. § 271(e)(4)(A).

[4] Patent Docs, IMS Study Shows Pro-Competitive Effects of Reverse Payment Settlement Agreements in ANDA Litigation, July 2013.

[5] 570 U.S. 136 (2013).

the first place. The legislative proposals go well beyond the Supreme Court's opinion that "traditional settlement considerations, such as avoided litigation costs," do not pose the same risks as a "pay-for-delay" payment.

As the FTC has stated, "the number of settlements potentially involving "pay for delay" decreased significantly in the wake of the Actavis decision." FTC's data confirms this point —potential "pay-for-delay" deals dropped from 33 in FY2012 to 5 in FY2015 and just one in 2016.[6] The data are even more compelling in 2020: according to the FTC, the most recent report shows "a continued decline in use of the types of reverse-payment agreements that are most likely to harm consumers."[7]

In other words, the vast majority, if not all, patent litigation settlements that occur today benefit patients. Patent settlement agreements, as a result of the Supreme Court's decision in *Actavis*, ensure early generic and biosimilar competition before the patents have all expired. Patent settlement agreements provide generic developers with certainty about the generic entry date, which allows manufacturers to fulfill the promise of early entry ***on*** that date. As the Subcommittee takes action on the topic of today's hearing it should not ***undermine*** one of the ways in which our current system enables generic drug and biosimilar competition to expensive brand-name drugs.

II. Ensuring That Skinny Labeling Remains a Viable Practice

As part of the 1984 Hatch-Waxman Amendments, Congress made the policy judgment that generic manufacturers should be able to bring lower-cost alternatives to market even if the brand-name drug manufacturer still holds patents on select methods of using a drug. This practice, known as "skinny labeling," allows a generic manufacturer to avoid patent infringement by "carving out" patented uses from its label and entering the market with its generic labeled for non-patented uses. The benefits for patients and payers are tangible—since 1984, patients and payers have saved billions of dollars by obtaining generic versions of expensive drugs for unpatented uses. Skinny labels have proven particularly important for generic competitors of blockbuster brand-name drugs where patent owners frequently seek to extend their monopolies by obtaining seriatim method-of-use patents. And they are even more important in the biologics context—brands frequently obtain many indications for diseases such as cancer, and a patent on any one such indication should not preclude competition on unpatented indications.

The "skinny labeling" pathway, however, has been called into question as a result of the recent *GSK v. Teva* case.[8] In *GSK v. Teva*, the Federal Circuit affirmed a $234 million verdict for patent infringement, including during a period of time that Teva completely carved out the patented method of use from its label. The Federal Circuit relied on the fact that Teva truthfully and accurately described its generic product as "therapeutically equivalent" to the brand-name product. Although the decision has since

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[6] FTC, "Overview of Agreements Filed in FY2017," December 2020. Available at https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf

[7] https://www.ftc.gov/news-events/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent

[8] 976 F.3d 1347 (Fed. Cir. 2020).

been vacated and is pending rehearing, it has sowed significant confusion in the industry and led to additional litigation. Indeed, at least five cases have since been filed where brand-name pharmaceutical companies have asserted patent infringement based on a carved-out label.[9]

The potential anticompetitive consequences—and harm to patients—from the *GSK* case are significant. Skinny labels ensure "that one patented use will not foreclose marketing a generic drug for other unpatented ones."[10] Absent a strong skinny labeling practice, brand-name pharmaceutical companies will be able to use a single method of treatment patent to foreclose ***all*** competition from generic and biosimilar medicines. The Department of Justice has recognized the potential deleterious impact of diminished skinny labeling—as it stated to the Supreme Court, this is part of a trend where "brand-name manufacturers [have] exploit[ed] certain features of the original Hatch-Waxman scheme to prevent or delay FDA approval of generic competitors."[11]

We would be happy to work with the Subcommittee to develop legislative solutions that ensure that skinny labeling remains a viable practice and that brand-name manufacturers cannot abuse the patent system to forestall generic and biosimilar competition.

III. Preventing Monopolistic Behavior by Powerful Purchasing Organizations

Increasing consolidation in the supply chain is certainly another key threat to sustainable generic markets. Compared to the fragmented generic drug market, consolidation in the wholesale market and contractual arrangements between pharmacy chains and wholesalers have left generic manufacturers with only a small number of purchasers. The result is a market where three purchasers account for more than 90 percent of all wholesale revenue.[12]

As these purchasing consortia move more and more toward single-source contracts for generic drugs, it creates a dynamic where it is possible that no more than three generic manufacturers may be able to successfully market any given product. This dynamic risks future competitive success in the generic market as generic drug manufacturers may be forced to maximize economies of scale and consolidate. It is clear the significant benefits for patients of reliable access to affordable generic medicines are at risk. Notwithstanding the economic principle that more suppliers of a good or service creates lower prices for consumers, it is unclear that the new imbalance between 200 generic competitors and a handful of purchasers is sustainable.

Accordingly, this Subcommittee should be vigilant concerning the potential anticompetitive effects that may result from increasingly powerful purchasing consortia. This buyer consolidation poses a number of dangers, including smaller companies being locked out of the marketplace and critical drug

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[9] https://news.bloomberglaw.com/health-law-and-business/teva-drug-label-case-spurs-fresh-litigation-as-judges-weigh-redo

[10] Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 416 (2012).

[11] Brief of the United States, Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 416 (2012).

[12] Fein, Adam J. Fein. The 2016-2017 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors, September 2016.

shortages. Excessive consolidation of power among the purchasing consortia also presents the risk of exerting undue market power over generic suppliers, driving wholesale prices below marginal costs and reducing output. In turn, this may lead to manufacturers exiting the market, reduction of output, ceasing production of unprofitable drugs, and shortages. Such consolidation also poses a danger of elevating costs to patients and payers. In short, the ever-increasing market power of large purchasers may lead to higher prices for patients.

IV. Prohibiting Anticompetitive Rebate Traps

The use of anticompetitive "rebate traps" by brand-name pharmaceutical companies has been well-documented. In these cases, brand-name companies threaten to remove rebates that they provide to payers unless the biosimilar is effectively excluded from the market. Some pharmaceutical companies may go so far as to threaten the rebates on a basket of products in the event that the contracted entity utilizes a biosimilar in place of the reference product.[13]

While a biosimilar is entering at a significant discount from the brand-name product, the "rebate trap" forces the health plan to choose to block biosimilar use or pay the full price for the brand-name product. At that point, it becomes economically infeasible for a payer to cover a biosimilar with the loss of significant rebate dollars from the brand-name company. Despite the biosimilar costing patients and Medicare less, the payer is financially incentivized to exclude the biosimilar and continue to use the brand biologic given the uncertainty of biosimilar uptake and the certainty of the brand-name biologic pulling its rebate.

These anticompetitive rebate traps have harmed patients and payers. They should be precluded, and AAM would be happy to work with the Subcommittee to develop solutions.

V. Prohibiting Biosimilar Misinformation

As the Biden Administration recently highlighted,[14] intentional misinformation disseminated by brand-name manufacturers serves as one of the largest barriers to biosimilar uptake. This misinformation is intended to sow doubt among patients and prescribers regarding biosimilars' safety and efficacy, as well as construct regulatory, policy and legal roadblocks to competition.

By way of example, a brand-name biologic manufacturer recently stated that "even with the most advanced technologies, scientists can't make exact copies of biologics. That's why they're called biosimilars – they are very similar, but not identical, to the original medicines….[g]iven that biosimilars follow an abbreviated regulatory pathway in the United States, they usually receive approval based on less comprehensive data sets compared to the original medicines."[15] This explicit disparagement ignores the rigorous scientific standards used by FDA to evaluate biosimilars and goes so far as to

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[13] Goldman, A. (2018, June 7). Walgreen and Kroger sue Johnson & Johnson over Remicade, Allege Antitrust Violation. Retrieved from https://www.keionline.org/28114

[14] Executive Order on Promoting Competition in the American Economy, July 9, 2021.

[15] Genentech. "Similar, Not the Same; The Road Ahead for Biosimilars." https://www.gene.com/stories/similar-not-the-same-the-road-ahead-for-biosimilars?topic=oncology

exclude the fact that biosimilars must be "highly similar to their reference products" as defined by Congress.[16] Such disparagement takes advantage of stakeholder—especially patient—unfamiliarity with biologic medicines including biosimilars, and the important role these medicines play in addressing serious or life-threatening conditions for patients.

To that end, AAM urges the Subcommittee to take steps to prohibit false, misleading, or otherwise deceptive statements about biosimilar products and their safety or effectiveness.

VI. Strengthening *Inter Partes* Review

This Committee has pride of authorship over one of the most important mechanisms for ensuring patent quality: inter partes review (IPR) and the other post-grant review procedures that allow the Patent Office to reconsider the mistaken grant of patents that never should have issued. As a strong majority of the Supreme Court held in upholding the Judiciary Committee's bi-partisan work, IPR "protects 'the public's paramount interest in seeing that patent monopolies are kept within their legitimate scope.'"[17]

The examination process is not by itself sufficient to serve that "paramount" public interest. The process is one-sided and limited, and provides no meaningful opportunity for interested third parties to participate. Significantly, the examiner must accomplish a number of distinct tasks during the examination process—all of which must be completed in a mere ***19 hours***.[18]

In particular, the examiner must consider whether the claimed invention satisfies all of the provisions that Congress has included into the Patent Act, including whether the claimed invention is new and not obvious. Novelty and non-obviousness are measured against the prior art—but much of the prior art that comes before the examiner is submitted by the applicant. And the examiner's ability to search for additional prior art—much less to apply its teachings to the application—is highly constrained. That dearth of information is magnified by the Patent Office's "count" system—a system set up to reward productivity, not care.[19]

Litigation in federal district court is not an adequate forum by itself to weed out invalid patents. District court cases are slow-moving and costly. The parties generally litigate infringement as well as the invalidity of the patents. That means months or even years of fact and expert discovery. Significantly,

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[16] 42 U.S.C. 262

[17] Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1374 (2018) (citation omitted).

[18] Michael D. Frakes & Melissa F. Wasserman, Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data, Nat'l Bureau of Econ. Research Working Paper 20337, at 7 (July 2014), http://www.nber.org/papers/w20337.pdf.

[19] Eric Blatt & Lian Huang, USPTO Incentive Policies Influence Patentability Decisions, available at https://www.law360.com/ articles/1052622/uspto-incentive-policies-influence-patentability-decisions.

the District of Delaware and the District of the New Jersey—two of the most popular forums for Hatch-Waxman litigation—have a median time to trial of 731 and 795 days, respectively.[20]

That is why Congress adopted legislation allowing the Patent Office to fix its own mistakes with the benefit of more time and more information. IPR allows interested parties to supply the Patent Office with important pieces of prior art that the examiner may have missed during examination. It allows invalidity issues to go before experts from within the Patent Office, rather than lay jurors or generalist federal trial judges. It also allows certain grounds of invalidity to be tested in a speedy, time-limited, and streamlined proceeding without the distraction of other issues such as infringement. And it allows a patent owner's arguments to be tested through cross-examination and the submissions of opposing experts in a way that examination does not allow.

Now more than ever, IPR is a critical tool to ensure that pharmaceutical patents are truly innovative. Brand-name drugs are protected by increasingly larger and larger patent estates. As this Committee is aware, Humira®—the bestselling drug in the United States—is the subject of more than a hundred patents and makes more money annually than all of the NFL teams combined. And many other brand-name pharmaceutical companies are following suit and developing enormous portfolios around their top-selling drugs. The effect of this trend is that litigation by generic and biosimilar drug developers to challenge some of these patents is often prohibitively expensive and risky.

IPR was designed to streamline and simplify this process, and it has indisputably worked. Indeed, many generic and biosimilar manufacturers have used IPR proceedings to successfully launch their alternatives, providing patients with earlier access to more affordable medications. For example, generic pharmaceutical companies successfully defeated the claims of a patent covering the drug Zytiga®, allowing for the launch of generic versions of the drug to treat prostate cancer.[21] As a result of this successful IPR, patients saved an average 81% on this life-saving medicine due to the availability of generic Zytiga®.[22] Over the course of four IPRs, generic pharmaceutical companies also invalidated all challenged claims of several patents covering OxyContin® in response to infringement allegations asserting over a dozen patents.[23] And through a series of IPRs, numerous other drug patents have been invalidated—in whole or in part—through IPR, including patents for Lantus®, Herceptin®, Rituxan®, Avastin®, and Neulasta®.[24]

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[20] Pharmaceutical Patent Litigation Increases Nearly 30 Percent in 2017: Lex Machina Releases Fourth Hatch-Waxman/ANDA Litigation Report, available at https://lexmachina.com/media/press/lex-machina-releases-fourth-hatch-waxman-anda-litigation-report/.

[21] *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063 (Fed. Cir. 2019) (affirming IPR decisions)

[22] *See* AAM, Let's strengthen IPR to accelerate patient access and lower prescription drug prices.

[23] *See Amneal Pharmaceuticals, LLC v. Purdue Pharma, L.P. et al.*, Case Nos. IPR2016-01412, (Feb. 8, 2018), IPR2016-01413, (Jan. 17, 2018), IPR2016-01027, (Nov. 8, 2017), and IPR2016-01028, (Nov. 8, 2017).

[24] *See* AAM, Statement for the Record, Senate Judiciary Committee Hearing on the "Support Technology and Research for Our Nation's Growth and Economic Resilience Patents Act of 2019 ('STRONGER')," at 2-3 (Sept. 11, 2019).

Despite these tangible benefits for patients and payers, IPR has been steadily undermined over the past several years. In particular, the PTO has implemented rules that make it prohibitively difficult and risky for a generic or biosimilar manufacturer to file—much less succeed—in an IPR. The PTO has also given patent owners multiple bites at the apple in changing their claims throughout the proceeding—a practice that fundamentally disincentivizes IPR filings.

We would be happy to work with the Subcommittee to strengthen and restore IPR so that it promotes competition while protecting true innovation.

Conclusion

Patient access to biosimilar and generic medicines has never been more critical. High launch prices on new brand biologics and annual price increases on existing brand-name drugs, combined with an increasing trend of anti-competitive tactics designed to delay or prevent competition from more affordable biosimilars and generics, are pushing access to medicines out of reach for too many patients. We appreciate the Subcommittee's attention to these issues and for the opportunity to provide our views and recommendations on how best to ensure sustainable patient access to more affordable prescription medicines. We look forward to working with you to build on the success of the CREATES Act and continue to advance solutions that meaningfully reduce the cost of prescription drugs for America's patients.