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950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

August 20, 2018

Federal Trade Commission
400 7th St. SW
Washington, DC 200024

Re: Docket No. FTC-2018-0048: Competition and Consumer Protection in the 21st Century Hearings, Project Number P181201

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide comments in response to the Federal Trade Commission's (FTC's or Commission's) notice of hearing and request for comments on its upcoming hearings intended to examine 21st Century business practices, technologies, and developments and consider whether "adjustments to competition and consumer protection law, enforcement priorities, and policies" are required to reflect these changes.[1] PhRMA appreciates the opportunity to focus on topic (8) in the Federal Register notice, addressing "[t]he role of intellectual property and competition policy in promoting innovation."[2] As provided in the comments below, intellectual property (IP) is the lifeblood of innovation, particularly in the biopharmaceutical industry.[3] IP incentivizes innovation and fosters competition. Existing IP statutory schemes specific to biopharmaceuticals have helped facilitate both innovation and increased competition through additional brand competition as well as competition resulting from generic and biosimilar entry. Given the critical role of IP in promoting innovation, we encourage FTC to continue using its existing tools and authorities to address anticompetitive behavior, while ensuring that IP is protected so that the United States can continue to be a global leader in biopharmaceutical research and development (R&D).[4] Moreover, strong and predictable IP protections in the United States are essential to the United States' economic well-being, and signal to other jurisdictions the critically important economic benefits of IP. As the notice also references the opportunity to bring attention to potential distortions in the marketplace that may impact competition and FTC enforcement priorities and policy, we have included in our comments a brief discussion of market distortions in the distribution and payment system for prescription medicines, which we urge the FTC to monitor.

[1] 83 Fed. Reg. 38307 (Aug. 6, 2018).
[2] *See id*. at 38309.
[3] As the Congressional Budget Office has stated, "[t]he pharmaceutical industry is one of the most research-intensive industries in the United States. Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm." *See* CBO, *Research and Development in the Pharmaceutical Industry* (Oct. 2006).
[4] We applaud the FTC for holding hearings on how the Commission can foster competition. *See*, *e.g.*, FTC, Public Hearing, Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics (Nov. 8, 2017).

PhRMA is a voluntary, nonprofit association that represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $71.4 billion in 2017 alone.

I. Intellectual Property is the Bedrock of Innovation in the Biopharmaceutical Industry

IP protections are the lifeblood of innovation in biopharmaceuticals. They are critical incentives for innovation, given the unique attributes of the biopharmaceutical R&D process, which is lengthy, costly, and uncertain. It takes, on average, 10 to 15 years and $2.6 billion to develop one new medicine.[5] Protocol design for clinical trials has increased in complexity, which has contributed to growing R&D costs and challenges related to patient enrollment and retention.[6] Manufacturing processes, particularly for biologics, have contributed to the growing complexities of drug development. IP protections, including both patents and statutory exclusivity protections, are key to supporting continued future biopharmaceutical innovation in the long term, including by compensating for the costly failures inherent in the biopharmaceutical R&D process. They are based on the concept of providing exclusive marketing periods for a set period of time as an incentive to support the substantial R&D efforts required for discovering and developing new and improved medicines. These incentives are particularly critical given the need to account for the many potential drug candidates that do not make it through the R&D and U.S. Food and Drug Administration (FDA) approval processes—only 12% of investigational medicines reaching clinical trials are ultimately approved.[7]

The benefits of these intellectual property incentives with respect to innovation are significant in the biopharmaceutical industry. In the last decade alone, the FDA has approved more than 400 new medicines, including the first medicine to treat the underlying cause of cystic fibrosis, the first vaccine to prevent cervical cancer, and the first therapeutic vaccine to treat prostate cancer.[8] With continued investments, our scientific understanding will continue to grow, creating new opportunities for profound advances against our most complex and costly diseases. As just one example, the discovery of a medicine that could delay the age of onset of Alzheimer's disease by five years would mean 1.6 million fewer Americans would have Alzheimer's, and this in turn could save $100 billion in annual medical costs by 2030.[9]

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[5] DiMasi JA, Grabowski HG, Hansen RW. Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. Journal of Health Economics. 2016; 47:20-33.
[6] See Getz KA, Campo RA. New Benchmarks Characterizing Growth in Protocol Design Complexity. Therapeutic Innovation & Regulatory Science. 2017.
[7] DiMasi JA, Grabowski HG, Hansen RW. Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. Journal of Health Economics. 2016; 47:20-33.
[8] U.S. Food and Drug Administration, "New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products of 2013," Silver Spring, MD: FDA, 26 December 2013, available at: www.fda.gov/drugs/developmentapprovalprocess/druginnovation/default.htm#aria.
[9] Alzheimer's Association, "Changing the Trajectory of Alzheimer's Disease: A National Imperative," May 2010.

Innovation in the biopharmaceutical industry does not stop with an initial FDA approval. Indeed, post-approval innovations, including new uses in different disease states, different dosage forms, and novel delivery systems are critical in expanding treatment options for patients. Advances in manufacturing processes can improve cost efficiencies and drug quality. These innovations similarly require R&D incentivized by IP protections. As just one example, a new injectable treatment for schizophrenia has allowed for less frequent dosing than previous formulations with the potential to increase patient compliance. The long-acting formulation allows the medicine to remain within a therapeutic range for an extended period, helping patients better manage their disease symptoms.[10]

Predictable and consistent IP protections have been the keystone to a range of valuable treatment advances for patients. Future innovation likewise will depend on robust, clear, and predictable intellectual property protection.

II. Intellectual Property Fosters Competition

IP serves as an incentive for competitors to develop new and improved medicines to compete with existing medicines on both price and clinical effects. These innovations provide consumers with increased access and treatment options and result in increased competition in the marketplace. Innovative biopharmaceutical companies frequently compete against each other to launch a "first-in-class" product and this drive to be first often results in multiple brand competitors entering the market in a short time span. As an example, in less than a year after market entry of the first in a new class of hepatitis C treatments there were multiple competitors on the market that competed on both price and clinical effects. The resulting competition was so fierce that in 2015, Pharmacy Benefit Manager (PBM) Express Scripts, announced that new hepatitis C treatments had become less expensive in the United States than in other western countries as a result of its aggressive negotiation.[11]

IP protections and competition are by and large a product of the market economy. IP is designed to, and does, foster both innovation and competition. Patents give innovator companies a degree of certainty that their idea is protected—fostering innovation—while at the same time, the specifics of the invention are published so others can learn from it and use it as the foundation for future invention and discovery—promoting competition. This public disclosure of inventions spreads knowledge and encourages others (i.e., competitors) to invent around existing patents and find new and different ways to solve a problem and develop competing products.

The substantial investments related to biopharmaceutical R&D also fuel the U.S. economy. The IP-intensive biopharmaceutical industry supports a total of more than 4.7 million jobs across the U.S. economy and contributes $1.3 trillion in economic output when direct and indirect effects are considered.[12]

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[10] U.S. FDA. "FDA approves new injectable drug to treat schizophrenia." 06 Oct 2015. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465801.htm.

[11] LaMattina J. For Hepatitis C Drugs, U.S, Prices Are Cheaper Than in Europe. Forbes. December 4, 2015. http://www.forbes.com/sites/johnlamattina/2015/12/04/for-hepatitis-c-drugs-u-s-prices-are-cheaper-than-in-europe/#7ced43f564bb.

[12] TEConomy Partners, The Economic Impact of the US Biopharmaceutical Industry. Columbus, OH: TEConomy Partners; November 2017.

PhRMA encourages FTC to consider the procompetitive benefits and economic impacts of IP as it assesses comments to this docket.

III. The Hatch-Waxman Amendments and the Biologics Price Competition and Innovation Act Carefully, and Successfully, Balance Innovation and Competition

Recognizing the need to provide a regulatory approval pathway that fosters competition through the market entry of generic and biosimilar medicines, while also maintaining incentives for innovation, Congress has enacted two statutory frameworks that simultaneously reward innovation and establish streamlined regulatory approval pathways for generic or biosimilar products. These statutory schemes, the Hatch-Waxman Amendments (Hatch-Waxman) and the Biologics Price Competition and Innovation Act (BPCIA), have been successful in both fostering innovation and creating robust generic and growing biosimilar markets.

Hatch-Waxman was enacted in response to a landscape in which innovator companies were losing substantial effective patent life during clinical development and the FDA review and approval process, and generic companies did not have an abbreviated pathway for approval of generic copies after IP protections expired. Hatch-Waxman created a framework that allowed generics to develop products during the period of innovator patent protection without liability for patent infringement[13] and seek FDA approval to market products immediately upon patent expiration, or even prior to patent expiration if they successfully challenge patents through the litigation framework created by Hatch-Waxman. Given the nature of the framework created, patent litigation is a natural part of the generic pathway, as are settlements of such litigation.

Hatch-Waxman has fostered competition through the timely entry of generic drugs. For example:

- As FDA officials have recognized, 90% of all prescriptions in the United States are filled with generic products.[14]
- For brand medicines facing generic entry in 2013-2014, generics captured an average of 93% of the market (by volume) within a year of entry.[15]
- This competitive dynamic is expected to continue in the years ahead.[16]
- The patent challenge procedures of Hatch-Waxman are robust. Multiple generic applicants typically challenge listed patents as soon as they are statutorily able to do so.

These numbers on their face demonstrate just how successful the Hatch-Waxman framework has been for incentivizing innovation and appropriately protecting innovation, yet ultimately providing increased access to generic drugs.

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[13] See 35 U.S.C. 271(e)(1).
[14] IMS Institute for Healthcare Informatics, Medicines Use and Spending in the U.S. A Review of 2017 and Outlook to 2022 (Apr. 2018).
[15] Grabowski H, Long G, Mortimer R, and Boyo A. Updated Trends in US Brand-Name and Generic Drug Competition. J Med Economics. 2016;19(9):836-844.
[16] QuintilesIMS Institute, Outlook for Global Medicines Through 2021: Balancing Cost and Value (Dec. 2016).

While the BPCIA is less than a decade old, and biosimilar development is significantly more complex and expensive than generic drug development, the benefits of the BPCIA on innovation and competition are already being seen. For instance:

- FDA has approved 12 biosimilars, including 8 since 2017.
- One study has estimated that biosimilars could save between $24 and $150 billion between 2017 and 2026.[17]

Although the biosimilar market is growing slower than some had predicted, and not all approved biosimilar products have launched yet, it is important to reiterate that the BPCIA framework is still in its infancy and the biologic pharmaceuticals it addresses are extremely complex products that are in many ways more difficult to develop and produce compared to small molecule pharmaceuticals. Yet these challenges are being addressed by the growing biosimilar industry. As more biosimilars are approved and reach the market and as the biosimilar market matures, biosimilars will likely become an increasingly important part of the pharmaceutical ecosystem. Like Hatch-Waxman, the BPCIA strikes a careful balance between innovation and competition.

IP fosters both innovation and competition, and these dual purposes can be enhanced with carefully crafted statutory schemes. Hatch-Waxman and the BPCIA are two such schemes, with Hatch-Waxman creating today's robust generic marketplace and the BPCIA well on its way to increasing competition from biosimilars in the biologics marketplace. As the BPCIA created market continues to evolve during its early years, it is important not to craft prematurely policies and legislation that could jeopardize biopharmaceutical innovation.

IV. FTC Should Play an Active Part in Informing Global Understanding of Intellectual Property, Competition Policy and Innovation

The FTC should actively inform and shape global understanding of the role that intellectual property plays in incentivizing innovation and fostering competition. Such engagement – particularly among countries that are not members of the Organization for Economic Cooperation and Development or that do not participate in the International Competition Network – is more critical now than ever, given the dramatic proliferation of national competition authorities and the damaging approaches some of these authorities are taking to antitrust matters involving IP held by American businesses across a wide range of industries.

In 1990, there were just 16 jurisdictions with a competition authority. Today, there are more than 120.[18] Some of these authorities have proposed or adopted approaches that fundamentally misconstrue the relationship between IP, competition policy and innovation – approaches that suggest almost any exercise of the temporary rights a patent confers is

[17] *See* Mulcahy *et al.*, Biosimilar Cost Savings in the United States (2017), https://www.rand.org/content/dam/rand/pubs/perspectives/PE200/PE264/RAND_PE264.pdf.
[18] Organization for Economic Cooperation and Development (OECD), Challenges of International Cooperation in Competition Law Enforcement, 2014. Available at http://www.oecd.org/daf/competition/Challenges-Competition-Internat-Coop-2014.pdf.

necessarily anticompetitive.[19] In some cases, these approaches appear designed to achieve discriminatory industrial policy goals[20] or to justify compulsory licensing of patents.[21] Even in relatively smaller markets, competition decisions can have a significant impact – particularly if enforcement and remedial obligations are applied extraterritorially.

The FTC can help support and sustain innovation by working with other national authorities to promote fair, transparent and impartial antitrust procedures, to foster a shared understanding of the symbiotic nature of IP and competition policy and to encourage greater appreciation for international comity and the benefits that IP provides.

V. Reforming the Distribution and Payment System for Prescription Medicines Could Address Market Distortions and Benefit Patients

Over time, the distribution and payment system for prescription medicines has resulted in market distortions that negatively impact patients. As the health care marketplace continues to evolve, we urge the FTC to monitor potential reforms in federal health care programs and their implications for patients and to support more PBM accountability in the commercial market where appropriate. Today's prescription drug distribution and payment system is characterized by a complex web of financial transactions and proprietary contracts and has evolved over time with changes in drug benefits as well as changes in the size, role, and structure of PBMs. Over the past decade, the PBM industry has undergone significant horizontal and vertical consolidation, leaving the sector with just three large participants – Express Scripts, CVS Health, and OptumRx – that cover more than 70 percent of the marketplace. Greater concentration in the PBM sector has led to increased bargaining power, which has provided PBMs with substantial ability to manage utilization and enabled them to negotiate increasingly large rebates in exchange for preferential formulary placement.[22]

While the current system has helped to control overall spending, it has also created incentives for PBMs to favor medicines that carry higher rebates,[23] thus leading to an environment in which list prices are rising rapidly even as net prices have held steady.[24] Since PBM compensation – including the portion of the rebate retained by the PBM as well as the

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[19] See, for example, Malaysia Competition Commission (MyCC), The MyCC Guidelines on Intellectual Property Rights and Competition Law, April 2018.
[20] U.S. Chamber of Commerce, International Competition Policy Expert Group: Report and Recommendations, March 2017. Available at https://www.uschamber.com/sites/default/files/icpeg_recommendations_and_report.pdf.
[21] World Trade Organization Council for Trade-Related Aspects of Intellectual Property Rights, Intellectual Property and the Public Interest: Promoting Public Health through Competition Law and Policy, Communication from China and South Africa, May 2018. Available at https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=246136,245570,245531,245522,245408,245411,245425,245357,245352,245316&CurrentCatalogueIdIndex=5&FullTextHash=.
[22] Berkeley Research Group, The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders. January 2017. Available at: http://www.thinkbrg.com/newsroom-publications-vandervelde-blalock-phrma.html
[23] Hoey DB. Rebates to pharmacy benefit managers are a hidden contributor to high drug prices. November 2016. Available at: https://www.statnews.com/2016/11/28/rebates-pharmacy-benefit-managers-contribute-high-drug-prices/
[24] IQVIA. Understanding the Drivers of Drug Expenditure in the U.S. September 2017.

administrative fees they charge their clients – is often calculated as a percentage of a medicine's list price, PBMs may be incentivized to establish formularies that favor medicines with high list prices and large rebates over lower cost medicines.[25] Meanwhile, the savings generated by these rebates do not always directly make their way to patients facing high cost-sharing for their medicines, who are required to pay deductibles and coinsurance based on list prices. Addressing these market distortions and enacting reforms to change the supply chain incentives that favor high list prices would therefore have positive consequences for both patients and payers.

As discussed in more detail in our recent comments on HHS' Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,[26] as a first step, we support reforms that (1) ensure that patients benefit from rebates at the point of sale; and (2) move to a system that either prohibits or discourages entities in the supply chain from retaining compensation based on a percentage of the list price of a medicine. All participants in the drug supply chain can and should be paid based on the value they provide. However, it does not make sense that their compensation is always, or even in most cases, proportional to a medicine's list price. We encourage the FTC to monitor and support other potential reforms, including increased PBM reporting requirements, which would provide additional opportunities to improve accountability and could help drive market-based approaches to greater efficiency and better alignment of PBM incentives with payer interests.

VI. Conclusion

PhRMA appreciates the opportunity to comment and address the role of IP and competition policy in promoting innovation. Strong and predictable IP protections are essential to innovation, particularly in R&D-heavy industries like biopharmaceuticals. Intellectual property promotes competition, and well-crafted policies like the Hatch-Waxman Amendments and the BPCIA simultaneously further both innovation and competition. Where there are anti-competitive behaviors, the FTC has existing enforcement tools to address these issues. We also urge the FTC to monitor and engage on policy proposals to increase PBM accountability in the commercial market to address market distortions and other reforms to the distribution and payment system.

Sincerely,

/s/
Anne McDonald Pritchett, PhD
Senior Vice President, Policy and Research

/s/
David E. Korn
Vice President, Intellectual Property and Law

[25] Hoey DB. Rebates to pharmacy benefit managers are a hidden contributor to high drug prices. November 2016.
[26] https://www.phrma.org/public-communication/rfi-comments-on-hhs-blueprint-to-lower-drug-prices-and-reduce-out-of-pocket-costs