

December 21, 2018

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

Re: Docket No. FTC-2018-0090: Hearing #4 On Competition
and Consumer Protection in the 21st Century

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) request for comments regarding "Hearing #4 On Competition and Consumer Protection in the 21st Century," held on October 23-24, 2018.¹ PhRMA 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.

PhRMA's comments focus on questions (1), and (3), as presented on the FTC website.²

- Question (1) asks: "Is there a role for the government in advancing or supporting innovation?"
- Question (3) asks: "How does modern economic analysis and empirical literature view the relationship between intellectual property and innovation, and the role of government in advancing and supporting innovation? Are there differences that depend on the type of intellectual property, and the protections offered for that intellectual property?"

We previously submitted comments addressing "[t]he role of intellectual property and competition policy in promoting innovation," and addressed specifically intellectual property protection relating to the biopharmaceutical industry. We believe those comments are responsive to question (2), which asks: "What is the importance of intellectual property – all forms – in advancing, protecting, and supporting innovation? Does it differ because of industry-specific or other market-based factors, or because of the form of intellectual property?" Accordingly, we attach them here as Appendix A.

PhRMA is committed to ensuring the continued health and competitive strength of a biomedical research and development (R&D) ecosystem that fosters innovation, incentivizes competition, and benefits U.S. consumers. Moreover, strong and predictable intellectual

¹ FTC Hearing #4: Competition and Consumer Protection in the 21st Century, <https://www.ftc.gov/news-events/events-calendar/2018/10/ftc-hearing-4-competition-consumer-protection-21st-century>.

² FTC Topics Open for Comment, <https://www.ftc.gov/policy/advocacy/public-comment-topics-process>.

property (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. 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.³

We believe the government can play an important role in fostering innovation by continuing to promote successful technology transfer between government and the private sector and taking steps to preserve and protect IP.

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

As explained in our previous comments (attached here as Appendix A), 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.⁴ 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.⁵ 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.⁶ As just one example, Alzheimer's disease research demonstrates the immense resources required for progress: a recent PhRMA analysis found that in the last two decades there were 146 unsuccessful medicines in clinical trials for Alzheimer's but only four new medicines were approved to treat the symptoms of the disease.⁷

The importance of IP incentives with respect to innovation are significant in the biopharmaceutical industry. In the last decade alone, the FDA has approved nearly 400 new medicines, including the first gene therapies to treat cancer and inherited blindness, a cure for many patients with hepatitis C, and the first drugs to treat primary progressive multiple

³ TEconomy Partners, *The Economic Impact of the US Biopharmaceutical Industry*. Columbus, OH: TEconomy Partners; November 2017.

⁴ 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.

⁵ See Getz KA, Campo RA. *New Benchmarks Characterizing Growth in Protocol Design Complexity*. *Therapeutic Innovation & Regulatory Science*. 2017.

⁶ 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.

⁷ PhRMA, "Researching Alzheimer's Medicines: Setbacks and Stepping Stones," September 2018, http://phrma-docs.phrma.org/files/dmfile/AlzheimersSetbacksSteppingStones_FINAL_digital.pdf.

sclerosis.⁸ With continued investments, our scientific understanding will continue to grow, creating new opportunities for profound advances against our most complex and costly diseases. Indeed, one study found that the discovery of a medicine that could delay the age of onset of Alzheimer's disease by five years could save \$83 billion in annual medical costs by 2030.⁹

Although some industry critics attempt to minimize the importance of continuous innovation in the biopharmaceutical industry, it is important to recognize that innovation does not stop with an initial FDA approval. 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 and improving patient outcomes.¹⁰ Advances in manufacturing processes can improve cost efficiencies and drug quality. Manufacturers justifiably seek to protect these innovations, while also disclosing these processes to the public, through patents. Such inventions should be afforded patent protection, just like any other patentable innovation or discovery.

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. The Government Can Play an Important Role in Supporting Biopharmaceutical Innovation

The U.S. biomedical R&D ecosystem is characterized by robust collaboration between the government, academia, biopharmaceutical companies, patient groups and others. Although the biopharmaceutical industry is increasingly investing in basic research, early discoveries and scientific insights resulting from federally-funded research can help fuel important medical advances.¹¹ As such, government and universities play an important yet complementary role to the private sector in the development of innovative new medicines.

As explained above, the process of developing a new medicine is fraught with risk and uncertainty, with only 12% of medicines that enter clinical trials ultimately approved by FDA. Simply achieving the milestone of beginning to test biomedical products in patients comes years after company researchers make an initial discovery or license promising research from an academic partner. The costs, risks, and frequent setbacks inherent in biopharmaceutical product

⁸ U.S. Food and Drug Administration, "Advancing Health Through Innovation, 2017 New Drug Therapy Approvals." January 2018, available at: <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM591976.pdf>.

⁹ Alzheimer's Association, "Changing the Trajectory of Alzheimer's Disease: A National Imperative," 2015, available at: <https://www.alz.org/media/Documents/changing-the-trajectory-r.pdf>. Accessed December 2018.

¹⁰ See., e.g., U.S. FDA. "FDA approves new injectable drug to treat schizophrenia." 06 Oct 2015. <https://web.archive.org/web/20180125101515/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465801.htm> . (Announcing approval of a new injectable treatment for schizophrenia allowing for less frequent dosing than previous formulations with the potential to increase patient compliance.)

¹¹ Mervis, J. (2017, March 9). Data Check: U.S. government share of basic research funding falls below 50%. *Science*. Retrieved From: www.sciencemag.org/news/2017/03/data-check-us-government-share-basic-research-funding-falls-below-50.

development are borne by private industry and their investors.¹² It is not realistic to expect that NIH, or any combination of federal agencies, could invest a comparable amount of time, expertise, and financial resources.

Technology transfer from the public to the private sector is the mechanism by which promising discoveries may be translated into meaningful treatments for patients. Beyond the important role of facilitating commercialization, technology transfer also plays an important role in creating jobs and growing the economy. Without an efficient technology transfer system, many promising scientific discoveries would languish as there would be little incentive for the private sector to invest the additional time and resources needed to advance these discoveries.

The United States has a strong system of federal technology transfer laws, namely the Bayh-Dole Act and the Stevenson-Wydler Act. Collectively, these statutes establish the rules and economic expectations within which business, government and academia interact to commercialize federally-funded inventions and benefit U.S. consumers.

A. *The Bayh-Dole Act*

Passed with strong bipartisan support in 1980, the Amendments to the Patent and Trademark Act, commonly referred to as “the Bayh-Dole Act,” created the uniform framework for technology transfer of federally-sponsored research to the private sector for development and commercialization. The Bayh-Dole Act allows universities and other nonprofit and for-profit institutions that receive federal government support through grants and contracts to retain title to patents covering inventions arising from federally-funded research. Such institutions may then license these inventions to partners who subsequently invest substantial resources to translate such discoveries into commercial products. As such, the Bayh-Dole Act creates a viable route by which new insights from universities and other institutions can be transferred to start-ups or more established firms for commercial development.

Bayh-Dole helped establish a culture of entrepreneurship in America's universities and research institutes by creating a well-defined path for ownership and development rights for university researchers and spin-offs.^{13,14} As a 2012 Congressional Research Service report stated, “one of the major factors in the reported success of the Bayh-Dole Act is the *certainty it conveys concerning ownership of intellectual property*.”¹⁵ In addition, as the Director of the United

¹² For examples of setbacks in cancer research and Alzheimer's Disease, please see: “Researching Cancer Medicines: Setbacks and Stepping Stones” (June 2015), <http://phrma-docs.phrma.org/sites/default/files/pdf/2014-cancer-setbacks-report.pdf>; “Alzheimer's Medicines: Setbacks and Stepping Stones (July 2015), <http://phrma-docs.phrma.org/sites/default/files/pdf/alzheimers-setbacks-and-stepping-stones.pdf>.

¹³ President's Council of Advisors on Science and Technology (PCAST), Report to the President -- Transformation and Opportunity: The Future of the U.S. Research Enterprise. November 2012. Available at: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast_future_research_enterprise_20121130.pdf.

¹⁴ D'Este P, Perkmann M. Why do academics engage with industry? The entrepreneurial university and individual motivations. *J Technol Transf.* 2011;36(3):316–39.

¹⁵ Schacht, W. The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology. Congressional Research Service Report 7-5700 (Dec 3 2012). Available at: <https://www.fas.org/sgp/crs/misc/RL32076.pdf>.

States Patent and Trademark Office (USPTO) recently noted, "when patent owners and the public have confidence in the patent grant, inventors are encouraged to invent. Investments are made. Companies are created and grown. Jobs are created and science and technology advance."¹⁶ Collectively, clear IP ownership by the grantee along with the certainty of exclusive licensing terms established under Bayh-Dole have helped foster licensing of technology resulting from federal funding for use by private sector entities to advance biomedical research.

B. The Stevenson-Wydler Act

The Stevenson-Wydler Technology Innovation Act, also passed in 1980, plays a complementary role to Bayh-Dole by facilitating technology transfer from federal laboratories to the private sector. This legislation required that federal laboratories actively pursue and participate in technology transfer activities. Today, there are many federal laboratories across the country generating important federally-funded research that can have a direct benefit for the public, or serve as a promising source of technology transfer for subsequent development and commercialization.

Accordingly, the government has an important role to play, not only in funding important early stage, basic research but in administering these statutes and ensuring that the robust system of technology transfer in the United States operates optimally, driving continued innovation.

III. Strong and Predictable IP Helps Foster Innovation

Strong and predictable IP protections are essential to innovation across different sectors of the U.S. economy, but are particularly important in R&D-heavy industries like biopharmaceuticals. A study by Boston University economist Iain Cockburn and Genia Long of Analysis Group found that patents are more important to incentivizing R&D in biopharmaceuticals compared to other industries. The study also found that patents are more important to fostering biopharmaceutical R&D investment than other forms of IP (i.e., copyrights and trademarks) and other strategic business assets (i.e., lead time).¹⁷ A separate study surveying senior biopharmaceutical executives found that ensuring a strong, predictable system of IP protections was one of the most critical factors in driving continued R&D investment in the biopharmaceutical industry.¹⁸ To ensure the U.S. retains its global leadership in the biopharmaceutical industry, it is critical to maintain robust IP protections.

The literature also shows that IP rights help ignite innovation across industries, not just in the biopharmaceutical industry. In one study focused on whether patents help startups grow, economists from New York University and Harvard Business School found that patent approvals

¹⁶ Andrei Iancu, Director of U.S. Patent and Trademark Office, comments at NIST symposium presentation April 19, 2018. Available at: <https://www.nist.gov/tpo/return-investment-roi-initiative/unleashing-american-innovation-symposium>.

¹⁷ Iain Cockburn & Genia Long (2015) The importance of patents to innovation: updated cross-industry comparisons with biopharmaceuticals, Expert Opinion on Therapeutic Patents, 25:7, 739-742, DOI: 10.1517/13543776.2015.1040762

¹⁸ Battelle Technology Partnership Practice, The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It, Apr. 2014, at 21, <http://phrma-docs.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf>.

were associated with increased sales and job creation.¹⁹ The researchers also demonstrated that patent approvals improved the ability of startups to innovate. Specifically, startups whose patent applications were approved saw a 49 percent increase in the number of subsequent patents obtained. A successful patent application also more than doubled the probability that a startup would subsequently go public. This is further supported by a 2017 study where economics professor Dr. Kristina Acri looked at existing evidence to assess the impact of IP on a host of economic indicators, ultimately concluding that “patents are strongly correlated with increased innovation, knowledge diffusion, and economic development and growth.”²⁰

Finally, other researchers have sought to quantify the value of intellectual capital, to better understand the impact on the U.S. economy. In a 2011 report, economists Kevin Hassett and Robert Shapiro examined the value of intellectual capital and intangible assets of 24 industries, ranging from pharmaceutical and biotechnology to software and energy.²¹ The report found that intellectual capital had grown three times faster than the overall economy from 2005 – 2011, increasing by 45 percent compared to a 16 percent growth in nominal GDP. Moreover, the study found that intangible assets accounted for nearly 80 percent of the market value of publicly-held companies, suggesting that intangible assets are becoming increasingly important in determining the market value of U.S. firms. Given the important economic role of intellectual capital, the authors conclude by making the case for governments to pursue and prioritize policies which “secure property rights for such capital, in order to maintain the incentives to develop new intellectual capital.”

IV. Conclusion

PhRMA appreciates the opportunity to comment and address the relationship between intellectual property and innovation and the role of the government in supporting new advances. In the research-based biopharmaceutical industry, IP rights are critical to fostering innovation, ensuring continued R&D, and facilitating the successful transfer of technology. To that end, the government can play an important role by ensuring that IP rights are preserved and protected.

Sincerely,

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

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

¹⁹ Farre-Mensa J., Hegde D., and Ljungqvist A., (2016) “The Bright Side of Patents.” NBER Working Paper No. 21959. Available at: <https://www.nber.org/papers/w21959.pdf>.

²⁰ Acri, Kristina. *Economic Growth and Prosperity Stem From Effective Intellectual Property Rights*. 24 Geo. Mason L. Rev. 865 (2017).

²¹ K.A. Hassett and R.J. Shapiro, “What Ideas Are Worth: The Value of Intellectual Capital and Intangible Assets in the American Economy,” Sonecon, LLC, September 2011.

Appendix A

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

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

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 infringement¹³ 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.

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 goals²⁰ 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

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/
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_____/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>