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**Before the U.S. International Trade Commission
Investigation No. 332-550
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Thank you for the opportunity to speak today on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) in support of the important work the International Trade Commission is doing to examine progress made by the Indian government to address the industrial trade and investment policies identified in the Commission's first report.

PhRMA is a nonprofit association that represents America's leading global biopharmaceutical research companies which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. In addition to being a key trading partner for the United States, India is an important market for our member companies and many of our members have a long history of serving Indian patients. The election in May 2014 of the Bharatiya Janata Party (BJP), led to victory by now-Prime Minister Modi, was cause for optimism among PhRMA's member companies. The BJP Manifesto included a focus on establishing "an Intellectual Property Rights Regime which maximizes the incentive for generation and protection of intellectual property for all type of inventors" with the goal of "encourag[ing] and incentiviz[ing] private sector investments – both domestic and foreign, in science and technology and in high-end research aimed towards innovation."¹ The innovative biopharmaceutical industry's pursuit of secure intellectual property (IP) protections, consistently enforced, aligns with Prime Minister Modi's goals of bringing growth to India through research, innovation, and manufacturing. The Modi Government has also emphasized predictable decision-making, implementation of political commitments, transparency, and good governance – all factors that are consistent with a rules-based government open to dialogue and problem-solving in partnership with stakeholders.

PhRMA and its member companies are encouraged by the ongoing efforts of the U.S. Government to seek high-level engagement with the Modi Government on intellectual property, including the reestablishment of the Trade Policy Forum, the Special 301 Out-of-Cycle Review, and President Obama's emphasis on a predictable IP regime during his visit with Prime Minister Modi and business leaders in January. In particular, the commitment to an ongoing technical work plan as part of the High-Level IPR Working Group offers opportunities to secure concrete commitments that demonstrate India's genuine intention of fostering innovation and improving patient access to new medicines. Further, India's draft National IPR Policy, issued in December 2014, recognizes the tremendous economic and socio-cultural benefits that a strong IP regime can bring to India through economic growth, employment, and a vibrant R&D environment. PhRMA also acknowledges the measured and cautious approach taken by the Government in

¹ Bharatiya Janata Party Election Manifesto 2014, available at http://www.bjp.org/images/pdf_2014/full_manifesto_english_07.04.2014.pdf (last visited Apr. 23, 2015).

responding to recent requests for compulsory licenses² and the successes some companies have had in enforcing their patents in India at the preliminary injunction stage.

However, despite these potentially positive signs and sustained industry engagement, PhRMA and its member companies remain negatively impacted by India's barriers to U.S. trade and investment, including its failure to respect IP rights. There remains significant unpredictability in IP protection and enforcement in India as no progress has been made in terms of meaningful policy change to address the challenges faced by the innovative biopharmaceutical industry in India or in tackling the true barriers to patient access to new medicines. On the contrary, four new examples of negative IP decisions in India have been added to the list of roughly twenty products that have had their patent rights undermined in India over the last few years.

States in India continue to be able to grant marketing authorization to generic versions of a medicine four years after the original product was first approved, regardless of the patent status of the original medicine. As a result, companies are forced to seek redress in India's court system, an exercise that is fraught with delays and unpredictability. For example, it took two years for a preliminary injunction to be granted against infringing versions of Merck's diabetes drug, but five days later, the Indian Supreme Court stayed the injunction until it hears the appeal.³ As a result, the infringing product remains on the Indian market.

Pharmaceutical patents, which have been granted in dozens of other countries, continue to be revoked in India using "hindsight" analyses made during post-grant oppositions and pre-grant oppositions citing a lack of inventiveness. In December 2014, the Indian Patent Office revoked the patent for Abbvie's Humira® citing lack of an inventive step and insufficiency of description, despite having granted a patent to Humira in 2009.⁴ The order revoking the patent coincided with the launch of the generic version of Humira by another Indian company.⁵

And patent applications for innovative medicines continue to be denied on the impermissible basis that the applicant has failed to demonstrate that their new form of a known substance has "enhanced efficacy" under Section 3(d) of the Indian Patents Act. In March 2015, Boehringer Ingelheim's patent on Spiriva®, which was granted in 2013, was revoked in part

² See Live Mint, "DIPP seeks details on blood cancer drug for issuance of CL," Oct. 19, 2014, available at: http://www.livemint.com/Industry/zC10tFm18dmz4E6pyGyjm/DIPP-seeks-details-on-blood-cancer-drug-for-issuance-of-CL.html?utm_source=copy (last visited Apr. 23, 2015).

³ Live Mint, "SC stays Delhi HC order restraining Glenmark from making anti-diabetes drug," Mar. 25, 2015, available at: <http://www.livemint.com/Companies/H0TjAmE0SMQaQQ3IEqfebP/SC-stays-Delhi-HC-order-restraining-Glenmark-from-making-ant.html> (last visited Apr. 23, 2015).

⁴ Business Standard, "Patent Office sets aside earlier order granting patent to Abbott's Humira," Jan. 6, 2015, available at: http://www.business-standard.com/article/companies/patent-office-sets-aside-earlier-order-granting-patent-to-abbott-s-humira-115010600580_1.html (last visited Apr. 23, 2015).

⁵ Business Today, "Glenmark wins patent row but says has no plans to launch product," Jan. 9, 2015, available at: <http://businesstoday.intoday.in/story/glenmark-wins-patent-row-against-abbott/1/214410.html> (last visited Apr. 23, 2015).

because it failed to demonstrate therapeutic efficacy under the requirements of Section 3(d).⁶ And in June 2014, Abraxis' Abraxane® was denied a patent because it could not meet the requirements of Section 3(d), despite having been approved in the U.S. under the FDA's priority review program which prioritizes applications for medicines which offer significant improvements in terms of their safety or efficacy.⁷

Other examples of India's inconsistent approach to implementation of a strong IP regime include the lack of protection provided for clinical test and other data that innovative pharmaceutical manufacturers are required to submit during the marketing approval process. In addition, India's model Bilateral Investment Treaty text, released in March, excludes intellectual property from its definition of investment.⁸ Finally, the appeal decision upholding the Nexavar® compulsory license determined the "working" clause in the Indian patent law should be decided on a "case to case basis" and that the "patentee must show why it could not be locally manufactured," thus putting the onus on the patent holder and further adding to the unpredictability.⁹ Despite the Indian Government's desire to attract increased R&D investment to India, such language does little to reassure potential investors that the technology and IP they bring to India will be protected. Weak IP protection directly discourages such R&D. These shortcomings help explain why India attracts less than three per cent of global pharmaceutical R&D spending.¹⁰ Further, the effect of India's anti-innovation policies can be felt in other countries where those policies are being emulated at a rapid pace, undermining growth and innovation in the United States' strongest and most promising industries, and ultimately harming consumers and patients around the world.

Intellectual property rights are vitally important to the innovative biopharmaceutical industry for the continued medical breakthroughs that are saving the lives of patients all around the world. With more medicines in development in the United States than in the rest of the world combined, the United States was home to approximately 4,000 products in development in 2015, in large part due to the fact that it provides the environment and incentives needed to support continued research and development investment, including a strong IP framework.¹¹ IP is also central to productivity, growth, and the competitiveness of U.S. companies in the global market. IP-intensive industries contribute to greater and more sustainable long-term economic growth,

⁶ Live Mint, "Germany's Boehringer loses India patent on lung drug to Cipla," Mar. 10, 2015, available at: http://www.livemint.com/Home-Page/pRPcnwkK5WU31rGElqad9L/Germanys-Boehringer-loses-India-patent-on-lung-drug-to-Cipla.html?utm_source=copy (last visited Apr. 23, 2015).

⁷ FDA Approves Abraxane for late-stage pancreatic cancer, Sep. 6, 2013, available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367442.htm> (last visited Apr. 23, 2015).

⁸ Model Text for the Indian Bilateral Investment Treaty available at https://mygov.in/sites/default/files/master_image/Model%20Text%20for%20the%20Indian%20Bilateral%20Investment%20Treaty.pdf (last visited Apr. 23, 2015).

⁹ Intellectual Property Appellate Board, Bayer Corporation vs. Union of India, The Controller of Patents, and Natco Pharma Limited, OA/35/2012/PT/MUM, Mar. 4, 2013, available at: <http://www.ipabindia.in/Pdfs/Order-45-2013.pdf> (last visited Apr. 23, 2015).

¹⁰ Batelle Institute, 2014 Global R&D Funding Forecast, R&D Magazine (Dec. 2013).

¹¹ *Analysis of Adis data as of Feb. 10, 2015, on medicines in development by phase and under regulatory review.*

accounting for nearly 35 percent of U.S. GDP in 2010 or over \$5.1 trillion in economic output.¹² In fact, the U.S. innovative biopharmaceutical industry supported 3.4 million U.S. jobs in 2011¹³ and exported over \$54 billion in biopharmaceuticals in 2014, placing the sector among the top-five of the largest U.S. exporters of R&D-intensive products.¹⁴

India's unfair trade actions also have consequences within India. In fact, a leader of an Indian pharmaceutical company recently stated that "the country has lost nearly \$10 billion worth of investment by not respecting IP norms," but rather the negative IP decisions have done "more harm to [its] image than actually helped patients...."¹⁵ It is well established that developing countries gain from high-quality and high-quantity technology transfers associated with foreign direct investment. Such investment brings with it new technologies, higher productivity and wages, and spillovers to other firms that spur modernization. International businesses also bring R&D to countries that provide supportive IP environments, including R&D that is aimed at unmet local needs. Medical research leads to advances in life-saving treatment for major diseases affecting patients around the world like the treatments that lowered cancer death rates by 15.5% between 2000 and 2011.¹⁶

Global research-based pharmaceutical companies remain concerned about patients' access to medicines and are committed to working with the Government of India and other stakeholders to provide sustainable access to medicines and healthcare overall. Patient access to medicines is impossible without innovation. Policies that stymie clinical research and innovation are not likely to expand access to health care and, in most cases, may even limit the availability of innovative medicines to Indian patients. In fact, recent analysis shows that half of all new medicines launched worldwide between 2000 and 2009 faced a launch delay of five years or more in India.¹⁷ Still, medicines themselves are but one component of access to health care. While India has a highly qualified workforce, it still has an insufficient number of qualified healthcare personnel (particularly in rural areas), inadequate and poorly equipped healthcare

¹² Intellectual Property and the U.S. Economy: Industries in Focus, U.S. Department of Commerce (Mar. 2012), available at <http://www.esa.doc.gov/sites/default/files/reports/documents/ipandtheuseconomyindustriesinfocus.pdf> (last visited Apr. 23, 2015).

¹³ Battelle Technology Partnership Practice, *The Economic Impact of the U.S. Biopharmaceutical Industry* (July 2013). Battelle Memorial Institute. Prepared for the Pharmaceutical Research and Manufacturers of America.

¹⁴ PhRMA analysis of data from U.S. Department of Commerce, International Trade Administration. "TradeStats Express™: National Trade Data." Export.gov.

¹⁵ Hindu Business Line, "Compulsory Licensing hit India's image: Hetero Pharma," Mar. 31, 2015, available at: http://articles.economicstimes.indiatimes.com/2015-03-31/news/60682269_1_sofosbuvir-swine-flu-drug-kidney-cancer-drug-sorafenib (last visited Apr. 23, 2015).

¹⁶ U.S. Department of Health and Human Services (HHS), CDC, National Center for Health Statistics (NCHS). "Health, United States, 2011 With Special Features on Socioeconomic Status and Health." Hyattsville, MD: HHS, 2012; K.D. Kochanek, et al. "Deaths: Final Data for 2009." *National Vital Statistics Reports* 2011; 60(3): 32. Hyattsville, MD: NCHS, available at www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr60_03.pdf (last visited Apr. 23, 2015); D.L. Hoyert and J. Xu. "Deaths: Preliminary Data for 2011." *National Vital Statistics Reports* 2012; 61(6): 28. Hyattsville, MD: NCHS, available at www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_06.pdf (last visited Apr. 23, 2015).

¹⁷ Ernst R. Berndt and Iain M. Cockburn. *The Hidden Cost of Low Prices: Limited Access to New Drugs in India.* *Health Affairs*, 33, no.9 (2014): 1567-1575.

facilities, and most importantly, lacks a comprehensive system of healthcare financing.¹⁸ However, India has thousands of manufacturers of pharmaceuticals who operate in a very competitive environment, and as a result, India has some of the lowest prices of medicines in the world.¹⁹ Despite a robust domestic industry, essential medicines are still not easily accessible; for example, essential medicines may only be available at government pharmacies 20 percent of the time.²⁰

India should, therefore, take a more holistic approach when it comes to healthcare, favoring an innovative environment that supports R&D while, at the same time, addressing the challenges posed by access to healthcare in India. Pro-innovation policies and increased access to medicines are not mutually exclusive; to the contrary, they should go hand-in-hand to the benefit of patients. Seeking solutions for India's health care needs at the expense of innovation and IPR is not the way forward. Weak IP protections will not resolve the broad challenges in health care funding, infrastructure, and distribution that perpetuate access barriers. Instead, promotion of a favorable policy and regulatory environment that contributes to fostering investment and clinical research will, in turn, advance the development of innovative medicines for Indian patients.

Despite our member companies' best efforts to engage in a productive dialogue with the Indian Government about the critical link between innovation and patient health, the innovative biopharmaceutical industry continues to face significant challenges in that market. More work is needed to improve confidence and reliability in India's IP policy environment. The United States has an important interest in seeing India change course on IP policies. As a matter of fairness, it is imperative that the United States demand of all its trading partners the same commitment to open markets and a rules-based trading system that the United States has demonstrated. Moreover, in the midst of a robust trade agenda, it has never been more important for the United States to signal this message to current and future trade partners. Our industry, the U.S. economy, and the future of innovation cannot afford to let India continue on this path that discourages new opportunities, new knowledge, and new medicines in India and around the world.

¹⁸ "Health Systems Financing: The Path to Universal Coverage," *The World Health Report*, World Health Organization, 2010.

¹⁹ Analysis based on IMS MIDAS Data.

²⁰ "Health workforce, infrastructure, essential medicines", World Health Statistics 2013, The World Health Organization.