



February 7, 2014

Docket No. USTR-2013-0040  
**PUBLIC DOCUMENT**

**SUBMITTED ELECTRONICALLY**

Ms. Susan F. Wilson  
Director for Intellectual Property and Innovation  
Office of the U.S. Trade Representative

**Re: Notice of Intent to Testify: 2014 Special 301 Review – Public Hearing**

Dear Ms. Wilson,

I write to request an opportunity to testify on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) at the public hearing before the Special 301 Subcommittee of the Trade Policy Staff Committee in the 2014 Special 301 Review, to be held on Monday, February 24, 2014. This request responds to the Federal Register notice, “2014 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing” (79 Fed. Reg. 420 (Jan. 3, 2014)). This notice is accompanied by an enclosed Hearing Statement.

Sincerely,

/s/ Jay Taylor

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**Hearing Statement of  
Pharmaceutical Research and Manufacturers of America (PhRMA)**

**before the  
Special 301 Subcommittee  
Trade Policy Staff Committee**

**Docket No. USTR-2013-0040  
February 24, 2014**

Thank you for the opportunity to speak today on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA is a nonprofit association that represents America's leading global pharmaceutical research and biotechnology companies which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA and our member companies strongly support the important work the Special 301 Subcommittee of the Trade Policy Staff Committee and its chair, the Office of the U.S. Trade Representative (USTR), are doing to identify countries that deny adequate and effective protection for intellectual property (IP) rights, and deny fair and equitable market access to U.S. companies and individuals who rely on IP protection.

Encouraging and fostering innovation and protecting the IP of U.S.-based innovative industries are critical to the future of the U.S. economy. IP is central to the 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, accounting for nearly 35 percent of U.S. GDP in 2010 or over \$5.1 trillion in economic output.<sup>1</sup> Robust IP rights have helped spark innovation and growth in countries – both developed and developing – throughout the world. As much as 40% of U.S. growth in the twentieth century was a result of innovations, according to Nobel laureate Robert Solow.<sup>2</sup>

PhRMA member companies are important economic drivers by generating high-quality, high-paying, and high-productivity jobs in the United States. Industry employment (direct, indirect, and induced) in 2011 totaled 3.4 million jobs, including direct employment of over 810,000 Americans.<sup>3</sup> The U.S. innovative biopharmaceutical industry exported over \$50 billion

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<sup>1</sup> 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 Jan. 30, 2014).

<sup>2</sup> See, e.g., Denison, E.F. (1962). "The Sources of Economic Growth in the United States and the Alternatives Before Us." Committee for Economic Development, Supplementary Paper Number 13; Solow, R.M. (1957). "Technological Change and the Aggregate Production Function." *Review of Economics and Statistics*, 39(3):312-23; Solow, R. M. (1956). "A Contribution to the Theory of Economic Growth." *Quarterly Journal of Economics*, 70:65-94.

<sup>3</sup> 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.

in biopharmaceuticals in 2012, making the sector the third largest U.S. exporter among R&D-intensive industries.<sup>4</sup>

Protecting the intellectual capital of the innovative biopharmaceutical industry in particular is vitally important for the continued medical breakthroughs that are saving the lives of patients all around the world. Patents and other IP protections are critical in securing the investment required to develop innovative medicines, which, in turn, will be the next generation of generic medicines. It seems obvious to say, but we would not have copies of medicines without those original discoveries. And we would not have those original discoveries but for the IP incentives necessary for the high-risk and resource-intensive investment into research and development.

The U.S. innovative biopharmaceutical industry provides substantial contributions to patient health. With nearly \$50 billion invested in R&D in 2012,<sup>5</sup> and having produced more than half the world's new molecules in the last decade, our members are world leaders in medical research.<sup>6</sup> With more medicines in development in the United States than in the rest of the world combined, the United States accounts for approximately 3,400 products in development in 2013, in large part due to IP protections and other strong incentives that foster the environment needed to support continued research and development investment.<sup>7</sup>

Medical research leads to advances in life-saving treatments for major diseases affecting patients around the world. The improved use of prescription medicines can result in better health outcomes also result in lower costs for other health care services (such as the 833,000 annual hospitalizations avoided through the use of recommended antihypertensive medication<sup>8</sup>), and increased worker productivity due to fewer medical complications, hospitalizations, and emergency room visits.

More acutely, HIV/AIDS is perhaps the best example of the incredible progress that has been made in combatting infectious diseases in recent decades. The discovery and development of new treatments have turned HIV infection from a death sentence into a chronic disease. In the U.S. alone, death rates have fallen more than 80 percent since 1995 as a result of the development and introduction of multiple drugs used in innovative combinations, known as highly active antiretroviral therapy (HAART).<sup>9</sup> As of December 2013, there are 394 medicines in development for infectious diseases that plague many developing countries for which new treatments are needed, including a medicine for the most common and difficult-to-treat form of

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<sup>4</sup> U.S. International Trade Commission, Trade DataWeb, accessed July 12, 2013, available at <http://dataweb.usitc.gov/> (query run of U.S. domestic exports classified by 4-digit NAIC code 3254).

<sup>5</sup> Pharmaceutical Research and Manufacturers of America. "PhRMA Annual Membership Survey." 1981–2013.

<sup>6</sup> Battelle Technology Partnership Practice. Growth Platform for Economies Around the World. Battelle Memorial Institute (May 2012). Prepared for the Pharmaceutical Research and Manufacturers of America.

<sup>7</sup> Adis Insight, "R&D Insight Database" (February 2013).

<sup>8</sup> D.M. Cutler, et al. "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation." *Health Affairs* 2007; 26(1): 97–110.

<sup>9</sup> Medicines in Development, "Infectious Diseases 2013," Presented by the Pharmaceutical Research and Manufacturer of America, available at <http://www.phrma.org/sites/default/files/pdf/MedsInDevInfectiousDiseases2013.pdf> (last visited Feb. 6, 2014).

hepatitis C that inhibits the enzyme essential for viral replication; an anti-malarial drug that has shown activity against a form of malaria that is resistant to current treatments; and a novel treatment that works by blocking the ability of the smallpox virus to spread to other cells, thus preventing it from causing disease.<sup>10</sup> Research-based biopharmaceutical companies are also hard at work developing innovative treatments for chronic diseases, such as the 73 medicines in the pipeline for Alzheimer's.<sup>11</sup> Since 1980, life expectancy for cancer patients has increased by about three years, and 83 percent of those gains are attributable to new treatments.<sup>12</sup>

These figures highlight the pressing need to defend this sector's IP rights against infringement and appropriation. The path from basic research to new medicines is extremely complex, requiring high-cost risk taking and fraught with setbacks. Quite simply, IP rights make these efforts possible.

Unfortunately, many of our trading partners do not respect the value of innovative medicines as demonstrated through limitations on the availability of pharmaceutical patents in places like India with Section 3(d) of its Patents Act, or even Canada, with its patent utility doctrine. Other barriers include unfair or impermissible compulsory licensing rules, lack of adequate regulatory data protection, lack of effective patent enforcement mechanisms, and patent or marketing approval delays that erode the effective patent term for pharmaceutical products and for which innovators are rarely compensated. Patents play a crucial role in fostering new discoveries and creating the right incentives for the high-risk and resource-intensive commitment to the development of new medicines. A strong IP system is a fundamental component of an innovation-supportive environment, not only in the U.S., but in all markets where our member companies participate.

In addition to the IP system, other foreign government policies and practices such as government price controls and cost containment measures also impede market access for cutting-edge drugs. Foreign cost containment measures create market access barriers that pose a significant threat to the U.S. economy because of the United States' preeminence in the life-sciences sector. Global impacts on the U.S. research-based biopharmaceutical industry's ability to sustain and create exports, maintain and develop jobs, and stimulate future innovation can be felt here at home. Some governments have proposed or implemented cost containment measures – such as ad hoc government price cuts, international and therapeutic reference pricing, and mandatory rebates – without a predictable, transparent, and consultative processes. Such cost containment policies typically put short-term government objectives ahead of long-term strategies that would ensure continued R&D into medicines that patients need most.

Other countries promote preferential trade policies, including local manufacturing requirements, forced technology transfer, and *de facto* bans on imports, which are intended to

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<sup>10</sup> Id.

<sup>11</sup> Medicines in Development, "Alzheimer's Disease 2013," Prepared by the Pharmaceutical Research and Manufacturer of America, available at <http://www.phrma.org/sites/default/files/Alzheimer%27s%202013.pdf> (last visited Feb. 6, 2014).

<sup>12</sup> E. Sun, et al. "The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology, and End Results (SEER) Database." *Journal of Clinical Oncology* 2008; 26:15S (May 20 Supplement): Abstract 6616.

grow domestic industries by undermining opportunities for foreign or local innovation. U.S. innovative biopharmaceutical companies are merely seeking a level playing field, and this should be a key focus of U.S. trade policy. 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 also continues to speak out against the scourge of counterfeit medicines, which affect the health and safety of patient worldwide. According to the World Health Organization and Institute of Medicine, counterfeiting is greatest in areas where the relevant regulatory and enforcement systems are less developed. For example, estimates indicate that between 10 to 30 percent of medicines sold in developing markets are believed to be counterfeit.<sup>13</sup> Testing reported in 2012 found one-third of anti-malarial medicines in sub-Saharan Africa and South East Asia lacked active ingredients.<sup>14</sup> By contrast, counterfeiting is estimated to affect less than one percent of medicines sold in industrialized economies with developed regulatory and enforcement systems.<sup>15</sup> This is why U.S. Government engagement on strengthening regulatory and enforcement systems – in addition to enhanced customs controls and information sharing – around the globe is so critical.

PhRMA and its member companies are actively engaged in seeking productive dialogue with foreign governments where we have these IP and market access concerns. The Special 301 review process is an important opportunity to identify where progress has been made and where it has not, and to request that the U.S. Government provide increased bilateral attention and monitoring to several issues in a number of countries. The details of PhRMA's requests are outlined in its public submission.

It is important that the incentives of the IP system promoting research investment be maintained because there can be no access to medicines that are not discovered. PhRMA member companies have been and continue to be partners with key stakeholders, including governments, in solving global health problems. Research-based biopharmaceutical companies and global health leaders are currently involved in more than 340 initiatives with more than 600 partners to help shape sustainable solutions that improve the health of all people.<sup>16</sup> Our companies are some of the largest contributors of funding for development of innovative cures for diseases affecting developing regions in Latin America, Asia, and Africa. In the last decade, biopharmaceutical companies provided over \$9.2 billion in direct assistance to healthcare for the developing world, including donations of medicines, vaccines, diagnostics, and equipment, as

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<sup>13</sup> The World Health Organization, IMPACT, at [www.who.org](http://www.who.org) (2008).

<sup>14</sup> Guarvika, M.L.N., et al., Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa, *The Lancet Infectious Diseases*, 12(6):488 – 496 (June 2012).

<sup>15</sup> IOM, *Countering the Problem of Falsified and Substandard Drugs*, February 2013. and World Health Organization Fact Sheet No. 275, *Medicines: spurious/false-labelled/ falsified/counterfeit (SFFC) medicines* (May 2012), available at <http://www.who.int/mediacentre/factsheets/fs275/en/> (last visited Feb. 7, 2014).

<sup>16</sup> See [www.globalhealthprogress.org](http://www.globalhealthprogress.org).

well as other materials and labor.<sup>17</sup> Without these efforts, which are threatened when IP protections are eroded and the incentives for innovating new medicines are undermined, access to effective, sustainable healthcare for the developing world's patients would be impossible.

IP drives the future of medicine. As stated by Bill Gates at the 2010 World Economic Forum, "the key reason that we're making progress against these diseases is that there's been an incentive for drug companies to invent, and they've invented great drugs."<sup>18</sup> Innovative biopharmaceutical companies invested more than \$525 million into new cures and treatments for neglected diseases in 2011 alone – making them the third largest funder in the world, ahead of all countries but the United States.<sup>19</sup> These efforts are threatened when IP protections are eroded and the incentives for innovating new medicines are undermined. We stand ready to support USTR, this Subcommittee, and the entire U.S. Government in seeking adequate and effective protection of U.S. IP rights abroad to ensure that patients around the world have access to the state-of-the-art medicines our member companies develop and manufacture.

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<sup>17</sup> IFPMA Survey, validated by LSE Health and Social Care at the London School of Economics and Political Science.

<sup>18</sup> Remarks by Bill Gates at the World Economic Forum, Gates Foundation Press Conference (January 29, 2010).

<sup>19</sup> Moran, M. et al., "Neglected Disease Research and Development: A Five Year Review," Policy Cures, (2012).