Written Testimony of

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U.S.-INDIA TRADE RELATIONS: OPPORTUNITIES AND CHALLENGES

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Chairman Nunes, Ranking Member Rangel, and members of the subcommittee:

Thank you for the opportunity to testify here today. My name is Roy Waldron. I serve as Chief Intellectual Property Counsel at Pfizer Inc. In that capacity, I am responsible for managing and protecting Pfizer's intellectual property portfolio worldwide.

Pfizer is the largest biopharmaceutical company in the world and a U.S.-based public company. We were founded by two cousins in 1849 in New York and are still headquartered there today. Our mission is to apply science and our global resources to improve the health and well being of people's lives. We strive to set the standard for quality, safety, and value in the discovery, development and manufacture of medicines. And our portfolio includes biologics, small molecule medicines, vaccines, and some of the world's best-known consumer products.

We employ roughly 90,000 individuals worldwide, and 30,000 in the United States. And we have a presence in all 50 states, and have manufacturing facilities located in 11 states including California, New York, Wisconsin, and Massachusetts. We also have another 21 R&D facilities located in 10 states, including California and Connecticut.

Background

The biopharmaceutical sector supports over 4 million jobs in the United States. This is in part because it invests sizable amounts in R&D activities in the U.S. – over $35 billion annually.[1] The industry is also a significant U.S. exporter – exporting $46 billion in goods last year, making it the sixth largest exporting industry in the United States.[2]

With 95 percent of consumers outside the United States, companies look abroad for economic growth. Emerging markets are key to this approach and U.S. exports are fueled by the demand

[1] Batelle Technology Partnership Practice, The U.S. Biopharmaceuticals Sector: Economic Contribution of the Nation (Columbus, OH: Batelle Memorial Institute, July 2011).

[2] *See* http://dataweb.usitc.gov/, accessed April 17, 2012 (query run of U.S. domestic exports classified by 4-digit NAIC code 3254).

in these markets. The demand leads to jobs and revenues that support our R&D activities here at home that produce innovative discoveries to cure current and future diseases.

R&D is the lifeblood of Pfizer and the pharmaceutical industry. And it is the lifeblood that paves the way to producing new and innovative medicines to treat diseases for patients worldwide. Today, it takes on average more than $1 billion and 10-15 years to research and develop a new medicine.[3] Only about 1-in-10,000 compounds that enter the drug discovery phase is ever approved by the Food and Drug Administration (FDA) and made available to patients.[4] And the truth is that all of the value from our R&D is ultimately transformed into our intellectual property rights. Patents are one of the most important of these IP rights that support our existence.

It is important to remember; we file our patents in the very early stages of development, often a decade or more before the FDA review process begins. Therefore, by the time we have submitted an application to the FDA the patent life has already eroded by a meaningful extent. Thus, the timeframe during which biopharmaceutical companies like Pfizer typically have to recoup our R&D investment of $1 billion is significantly reduced before generic competition enters the market. However, the public health value of our investment continues for generations to come.

India is a critical growth market for Pfizer and for the pharmaceutical sector generally. Pfizer is committed to India and has been operating there for over 60 years. Our main office is located in Mumbai, but we also have manufacturing and R&D facilities in Thane, Goa, and Delhi. We employ about 5,000 in India and these jobs are estimated to support another 15,500 jobs in the

[3] JA DiMasi, and HG Grabowski. "The Cost of Biopharmaceutical R&D: Is Biotech Different?" Managerial and Decision Economics no. 28(2007): 469-79; PhRMA. "Drug Discovery and Development: Understanding the R&D Process." (Washington, DC: 2007).

[4] Klees JE, Joines R. Occupational health issues in the pharmaceutical research and development process: Occup Med 1997;12:5-27

Indian economy. Pfizer has conducted more than 250 clinical trials in India with 12,000 patients and 1,000 investigators.

Pfizer is a leader in India in terms of innovation and employee satisfaction, and has received awards and recognition through the years. For example, recently we won an award for being the best U.S. company operating in India in the manufacturing category. We were also recognized as one of the best companies to work for by Business Today magazine.

Pfizer also has a strong reputation for leveraging its resources to help those in need. In 2012, Pfizer promoted health literacy and disease awareness across 65 villages, and also partnered with the Spina Bifida Foundation to provide education grants and raise disease awareness among women.

Challenging Investment Climate in India

India's large population, significant unmet medical needs, and growing middle class all contribute to its great potential, but unfortunately the business environment for innovative industries has deteriorated significantly in recent history. India has taken steps that call into question the sustainability of foreign investment and the ability of American companies to compete fairly. In fact, the Global Intellectual Property Center's International Intellectual Property Index, ranked India dead last in terms of overall protection of intellectual property.

Despite being a member of the World Trade Organization, and an important global trading partner, India has systematically failed to interpret and apply its intellectual property laws in a manner consistent with recognized global standards. We have seen a growing trend of anti-IP developments in India, and this is creating significant uncertainty in the market and negatively impacting our industry and Pfizer.

Experience accumulated after India began granting product patents in 2005, shows it has routinely flouted trade rules to bolster the Indian generic industry at the expense of innovators.

At the same time, Indian pharmaceutical companies have grown their U.S. sales dramatically. Three of India's major pharmaceutical companies, for instance, (Dr. Reddy's Laboratories,[5] Sun Pharma[6] and Wockhardt[7]) generated between 42 – 56 percent of their global generic sales in the United States. As one of those companies explained, "The company's U.S. and EU operations have been the major contributor in its growth and the momentum continued in this quarter as they contributed to 71 per cent of consolidated revenues."[8] This is an issue of basic equity.

The Government of India has essentially created a protectionist regime that harms U.S. job creators. The harm is evident in pharmaceuticals where the United States has welcomed Indian generic companies while India is closing its borders to U.S. innovators. Correcting India's protectionist intellectual property regime will require firm leadership by the United States in international organizations and in India.

I. Unwarranted Denial of Intellectual Property Rights

In September of last year, India revoked Pfizer's patent for a cancer medicine, Sutent. The approval of Sutent in 2006 had marked the first time that the FDA approved a new oncology product for two indications simultaneously, gastrointestinal stromal tumors (GIST) and advanced kidney cancer. This drug was first developed by a small U.S. biotechnology company in California. The patent for sunitinib, which is the active compound in Sutent, was granted in many countries around the world, including India. The Indian patent had been in effect for five years prior to its revocation. Its counterparts have never been revoked in any of the 90 countries where it currently enjoys protection, including the United States, Europe, and Japan.

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[5] Press Release, "Dr. Reddy's Q1 FY13 Financial Results," July 19, 2012: http://www.drreddys.com/media/popups/q1fy13_results_19jul2012.html.

[6] Press Release, "Sun Pharma reports a strong quarter," August 10, 2012: http://www.sunpharma.com/images/finance/FY13%20Q1%20Press%20Release%20Financials.pdf.

[7] Press Release, "Q1 FY13," August 10, 2012: http://www.wockhardt.com/pdf/QUARTERLY-REPORT-(Q1)-f12ee.pdf.

[8] http://articles.economictimes.indiatimes.com/2012-08-06/news/33065615_1_wockhardt-q1-wockhardt-today-net-profit.

The revocation will allow Indian generic companies to manufacture and sell generic copies of Sutent long before the patent is set to expire. This constitutes a fundamental breakdown of an incentive-based IP system.

To ensure Sutent is available to patients who need it, Pfizer developed a patient access program in India. Pfizer's program provides medically eligible patients treatment options based on socio-economic criteria. 62% of patients with the disease are treated with Sutent and 80% of these patients receive a complete or partial subsidy. But the program doesn't stop there. It also offers education on managing the disease and medicine, counseling for patients and their families, and in some cases, patients receive nutritional support as well.

Glivec™ is another important anticancer therapy for which intellectual property rights have been denied. The patent was denied under section 3(d) of the Indian Patents Act, which contains a discriminatory provision concerning the inventions of the biopharmaceutical industry. The provision requires certain types of inventions to show "enhanced efficacy", which limits substantially the ability to obtain a patent. Not only is this term unclear, but it goes far beyond the specific requirements of patents under the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement including novelty, inventive step, industrial applicability, and sufficient disclosure for carrying out the invention. Moreover, by discriminating against a particular field of technology, section 3(d) may be inconsistent with provisions of TRIPS, which sets one standard for all patents and does not allow different patent requirements for different industries. Using this prohibition, India has refused a patent to Glivec™ despite patent protection for this product that exists in nearly every other country of the world.

India also provides for a pre-grant procedure in Article 25(1) of the Indian Patents Act. In most countries, applications for patents are examined *ex parte* and published at some point before they are granted. India, however, allows interested parties to "oppose" the grant of the patent after publication, but before the date established for the grant of the patent. Given that the

term of patent protection is measured from the date of first filing, these delays erode the effective life of the patent. If not properly policed, these pre-grant oppositions are opportunities for abuse. India also does not provide for adjustment of patent terms to compensate for delays in patent processing.

II. Abuse of Compulsory Licensing Provisions

Compulsory licenses are intended for use in extraordinary situations of extreme urgency or other national emergency to meet the legitimate needs of the public. Often, however, compulsory licenses may be used by competitors as a means to obtain authorization to use or transfer technology developed by others without having to pay the substantial costs associated with developing and testing the product. These copiers want to obtain a free ride or use the technology at a much-reduced cost. Also, compulsory licenses are inappropriately viewed by some governments as part of their industrial policy to establish domestic production or to reduce government expenditures for medicines.

India issued a compulsory license for a cancer medicine patented by an innovative pharmaceutical company last March and the Indian government has sought to justify the compulsory license, in part, on the basis that the product was imported rather than manufactured locally. That industrial policy basis for a compulsory license must be repudiated as it plainly contravenes established international obligations.

Moreover, recent media reports indicate that the Government of India has started the process of issuing compulsory licenses for the manufacture of three additional cancer drugs. Unlike the compulsory license issued under Section 84 of the Patent Act against Nexavar™, these compulsory licenses would fall under Section 92 of the Act—the public emergency provision that can be issued directly from the Indian Administration without a notice and comment period to the industry.

The generic industry in India has paid attention to all of these developments. We believe that Indian generic companies now see any innovative product as fair game for compulsory license. If left alone, this trend will destroy the market for innovative pharmaceuticals in India.

III. Ignoring Obligations to Prevent Unfair Commercial Use of Data to Grant Generic Marketing Approval

Regulatory data protection is required by the TRIPS Agreement and India was required to prevent unfair commercial use of pharmaceutical regulatory data through the grant of generic marketing approval based on the innovator's data by January 1, 2000. They still have not done so.

IV. Ineffective Patent Enforcement

Indian law permits state regulatory authorities to grant marketing approval for generic versions of medicines four years after the product was first marketed. They are not required to verify or consider the remaining term of relevant patents. Because infringers can obtain marketing approval from the government, patent holders are forced to seek redress in India's court system after approval of the generic – a form of recourse that is not effective in practice.

Conclusion

The issuance of unwarranted compulsory licenses, the unfair revocation of valid patents, and the denial of patentability of inventions in India are critical areas of concern in our industry. As a company, and an industry, we are more than willing to discuss viable solutions to increase access to quality medicines with the Indian government. However, these recent actions by India threaten economic growth in the United States and our industry generally, and Indian patient's access to innovative and high-quality medicines.

These measures further weaken the competitiveness of the U.S. innovative pharmaceutical sector in India. And since many other countries look to India as a leader and an example, India's

actions reverberate far beyond its borders. We have seen several countries adopt policies similar to India's, which are leading to a worldwide deteriorating trend on intellectual property.

These actions diminish our market share abroad, which hinders U.S. exports, and ultimately harms U.S. jobs. These intellectual property violations also jeopardize our U.S. R&D activities and advances in public health, as the revenues of today are funding the research necessary to develop new and innovative medicines of the future. It is for this reason that the U.S. government has a significant interest in protecting the intellectual property of U.S. companies abroad.

Pfizer and other U.S.-based innovative pharmaceutical companies are working actively to resolve these problems and appreciate the assistance and support of Congress and the Administration. We are grateful for your attention and engagement on this issue. And, we hope that you will continue to prioritize this matter and work together to address these challenges.

Specifically, I'd like to highlight four recommendations:

- The U.S. government should increase the frequency of talks with the Indian Government, and continue to raise concerns directly with such officials.

- The U.S. government should raise concerns at every available bilateral and multilateral fora to send a strong signal to the Indian Government and to other governments that such actions are not condoned by the U.S government.

- The U.S. government should review all available policy tools in light of India's deteriorating intellectual property environment.

- The U.S. government should pursue a robust trade agenda that includes strong intellectual property protections that build on the Korea-U.S. Free Trade Agreement and U.S. law, including robust provisions in the Trans-Pacific Partnership Agreement (TPP).

Strong IP provisions in U.S. trade agreements will demonstrate to countries like India that the U.S. is firmly committed to protecting intellectual property.

Thank you holding this hearing today and for your interest in obtaining more information on the opportunities and challenges facing Pfizer and other U.S. companies doing business in India.