Written Testimony of

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Thank you Chairman Terry, Ranking Member Schakowsky, and distinguished members of the subcommittee for the opportunity to testify at today's hearing on India.

My name is Roy Waldron, and I am Pfizer's Chief Intellectual Property (IP) Counsel. In that capacity, I am responsible for overseeing and protecting Pfizer's IP portfolio worldwide.

I would first like to express Pfizer's appreciation for the consistent efforts by the Energy and Commerce Committee to promote jobs, innovation and patient safety, including through the recent reauthorization of the Prescription Drug User Fee Act (PDUFA). PDUFA not only enhances our ability to provide faster access to new medicines to patients worldwide but it also enables the U.S. pharmaceutical industry to remain competitive in creating and delivering new cures to patients around the globe.

Recent decisions in India threaten to undermine our ability to innovate, create jobs and provide faster access to life-saving medicines. I testify today to highlight Pfizer's serious concerns about these decisions and urge the U.S. Congress and Administration to do all they can to make this issue a top priority in our bilateral relationship with India.

About Pfizer

Pfizer is a U.S.-based public company founded by two cousins in 1849 in New York and we are still headquartered there today. Pfizer's 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. We also collaborate with a wide variety of other stakeholders to support and expand access to reliable, high-quality healthcare around the world.

Pfizer employs more than 90,000 individuals worldwide, including over 30,000 people in the United States. We have a presence in most countries around the world and in all 50 States. Pfizer has 17 manufacturing sites across 11 states, including California, Michigan, North Carolina, and Tennessee.

Pfizer also has 34 R&D sites worldwide, 21 of which are in the United States, and R&D partnerships with 250 institutions. Last year alone, Pfizer spent nearly $8 billion on R&D, representing 14 percent of our revenues.

The Importance of Intellectual Property

Intellectual property is the engine that fuels the U.S. economy. According to a 2012 study by the U.S. Department of Commerce, IP-intensive industries directly and indirectly support 40 million U.S. jobs, drive over 60 percent of exports and pay on average 40 percent higher than other industries that do not rely on IP.[1]

The Pharmaceutical Research and Manufacturers of America member companies support more than four million jobs in the United States and invest over $35 billion annually in U.S. R&D, which represents 75 percent of worldwide R&D investments.[2] They also account for the single largest share of U.S. business R&D, representing nearly 20 percent of domestic R&D funded by U.S. business.[3] The path to a successful breakthrough cure is an arduous one. On average, it takes more than $1 billion and 10-15 years of research to develop a new medicine.[4] Only about one in 10,000 compounds that enter the drug discovery phase is ever approved by the U.S. Food and Drug Administration (FDA) and made available to patients.[5] And only two out of every 10 medicines will see a return on the investment spent on development. This lengthy research process is what leads to the development of life-saving and life-changing medicines.

Our R&D is ultimately protected by patents and other intellectual property, which provide the incentives necessary for further investments in the creation of new medicines. Effective IP laws and predictable and transparent enforcement of these laws are therefore essential to ensuring we have the resources to invest in researching and developing new treatments and cures for today's and tomorrow's diseases.

To put this into perspective, we file our patents in the very early stages of R&D, often a decade or more before the FDA review process begins. Thus, by the time we have submitted an application to the FDA, the patent life has already eroded by a meaningful extent. This significantly reduces the timeframe during which companies like Pfizer typically have to recoup our R&D investment of $1 billion before we lose the benefit of that investment. For the biopharmaceutical industry, IP protection enables our industry to continue to finance the research that advances the medicines available to patients around the world.

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[1] *See* Intellectual Property and the U.S. Economy: Industries in Focus (*available at* http://www.esa.doc.gov/Reports/intellectual-property-and-us-economy-industries-focus).
[2] Batelle Technology Partnership Practice, The U.S. Biopharmaceuticals Sector: Economic Contribution of the Nation (Columbus, OH: Batelle Memorial Institute, July 2011).
[3] National Science Board, 2012, "Science and Engineering Indicators 2012," Arlington VA: National Science Foundation (NSB 12-01).
[4] 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).
[5] Klees JE, Joines R., Occupational health issues in the pharmaceutical research and development process: Occup Med 1997; 12:5-27.

Opportunities for International Growth and India

With 95 percent of consumers living outside the United States, expansion to new markets is key to our ability to continue to grow, create jobs and identify new and innovative medicines. Pfizer's future growth and the jobs that come with that growth will depend on a level playing field in foreign markets.

India is a critical growth market for Pfizer. Pfizer has been operating in India for over 60 years. Our headquarters in India is in Mumbai; we have an R&D facility in Thane and a manufacturing facility in Goa.

Pfizer employs about 5,000 individuals in India, and these jobs are estimated to support another 15,500 jobs in the Indian economy. Over the last two decades, Pfizer has conducted more than 250 clinical trials in India involving almost 12,000 patients. Pfizer currently has almost 70 clinical trials in various stages ongoing in India with more than 1,200 participants.

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

Pfizer strives to positively impact the health of people around the world. Our work in India is a prime example of how we seek to meet this goal. In 2012, for example, Pfizer promoted health literacy and disease awareness across 65 villages. We also partnered with the Spina Bifida Foundation to provide education grants and raise disease awareness among women in India.

Pfizer also offers patient access programs in India, which provide medically-eligible patients with treatment options based on socio-economic criteria. For example, 62% of patients with a particular cancer are treated with our drug Sutent and of those, 80% receive a complete or partial subsidy. Pfizer 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.

The Problem: India's Hostile Innovation and Investment Environment

Over the past year, the pharmaceutical industry has seen a rapid deterioration of the business environment in India. Since early 2012, India's policies and actions have undermined patent rights for at least 9 innovative medicines. Many of these medicines have received patent protection in most countries across the world, suggesting that India is an outlier in recognizing and enforcing patent rights. This is not only creating significant uncertainty in the market but it also undermines our ability to compete fairly in India, and our willingness to invest there.

Pfizer's story: Sutent

Sutent was first developed in the United States. The approval of Sutent in the U.S. in 2006 marked the first time that the FDA approved a new oncology product for two indications

simultaneously, gastrointestinal stromal tumors and advanced kidney cancer. The treatment has helped extend survival for this terminal illness beyond any previous treatment tested to date.

Pfizer's recent experience in India demonstrates a flagrant disregard of patent rights. In the last year, Pfizer has struggled to defend its patent for the compound sunitinib, the active ingredient in Sutent, against efforts to revoke it. The patent has now been revoked twice under questionable legal theories and is currently back in force pending new proceedings before the Indian Patent Office, an administrative body of the Ministry of Commerce and Trade. Each of the earlier revocations was reversed when Pfizer showed that its rights to a fair hearing and due process had been denied.

During the back and forth of the revocation proceedings, one generic manufacturer (NATCO) launched its product in the Indian market. As a result, the market is now flooded with about two years' worth of supply from this manufacturer. In order for there to be effective patent protection, the system of IP enforcement ought to include mechanisms to recall infringing goods from the market.

Other examples

I would also like to highlight a few additional examples to illustrate the significant challenges our industry is facing in India.

In another recent erosion of IP rights, India denied a patent under Section 3(d) of its Patents Act for Gleevec, Novartis' anticancer therapy that has been patented in 40 other countries around the world. In that case, the Indian Supreme Court interpreted an "enhanced efficacy" requirement for patentability in a way that led to denial of the patent. This decision is inconsistent with India's obligations under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Also, in 2012, India granted its first compulsory license for Bayer's kidney cancer medicine, Nexavar, allowing for the generic manufacture of this medicine. Often, 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 are generally seeking to use the technology at a much-reduced cost. In some cases, 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 sought to justify its 2012 compulsory license, in part, on the basis of "failure to work the patent" because the product was being imported rather than manufactured locally. While compulsory licensing should only be used in certain extraordinary circumstances, the local manufacturing requirement initially used to justify the compulsory license was clearly inconsistent with India's international obligations. The standard for "working the patent" remains unclear.

Moreover, media reports have indicated that the Government of India is exploring its ability to issue additional compulsory licenses for the manufacture of other patented medicines, particularly three additional cancer drugs. This establishes a dangerous precedent not only in India but also to others who look to India as an economic leader.

One of the challenges with India's patent law is that it is riddled with pitfalls for the pharmaceutical patent owner —and some provisions have to date been interpreted to the detriment of innovators. For example, Section 8 of the Indian Patents Act, a provision with vaguely-worded requirements on reporting of activity in other patent offices around the world, could be used to render patents invalid if applied in an expansive and exacting manner as has been threatened. This is of growing concern and ought to be carefully watched.

The above decisions and actions illustrate the erosion of the patent system in India and create disincentives to conduct further research to identify new life-prolonging and life-saving therapies in the future. A patent is only meaningful, if the rights holder can count on the right being enforced in a predictable and transparent manner. The current protectionist industrial policies are inconsistent with India's commitment to the global trading system and the laws that govern it.

The Economic and Public Health Impact of India's Decisions

The impacts of India's decisions are significant.

First, they are a significant blow to the IP system that drives U.S. growth and innovation worldwide. In the case of our sector, India's actions undermine the incentives needed for pharmaceutical companies to make investments required in developing new medicines. The chilling effect in global R&D investment as a result of India's intellectual property policies could have a direct impact on jobs and investment in the U.S., given that the U.S. is the largest recipient of spending on global R&D. Moreover, it could mean less investment in new treatments for diseases that plague our population.

India's recent decisions regarding the pharmaceutical industry also represent a further erosion of the overall IP environment in India, which should be of concern to other IP-reliant industries. India's disregard for intellectual property protection and enforcement is not limited to the pharmaceutical industry. In fact, a cross-sectoral IP Index published by the U.S. Chamber of Commerce's Global IP Center last year ranked India last of 11 countries in IP protection and enforcement across a variety of sectors.[6]

Second, India's recent IP decisions discriminate against U.S. companies and hinder our ability to compete on a level playing field in India. At the same time as India is rolling back protections for U.S. innovators, Indian pharmaceutical companies enjoy unfettered access to the U.S. market and have grown their U.S. sales dramatically. For example, three of India's major pharmaceutical companies generated approximately 50 percent of their revenue from sales in the

[6] *See* Measuring Momentum, the GIPC International IP Index (*available at* http://www.theglobalipcenter.com/measuring-momentum-the-gipc-international-ip-index/).

United States.[7] American companies should be afforded no less protections than their Indian competitors.

Third, India's short-sighted approach will do more harm than good for its own patients, innovators, and economic development. If India continues to erode IP rights and enact protectionist policies, the result could be significantly reduced foreign investment in India as well as delays in getting Indian patients access to the newest medicines. Moreover, such policies also promote an environment for India's own pharmaceutical companies, that is hostile to the development of innovative medicines, including for diseases that are especially prevalent in India and its region, such as tuberculosis, diarrheal disease and water-borne illnesses.

And fourth, these decisions threaten to establish a dangerous precedent for other countries seeking to promote their own protectionist industrial policies. India is often seen as a leader amongst emerging economies and its governments to set the right tone to promote innovation—including indigenous innovation in India If we are to avoid permanent harm to our ability to innovate new life saving and enhancing inventions, it is essential that we take all necessary measures to avoid a contagion effect.

A Call to Action

The international IP system is being challenged on a number of fronts. Recently, a high level Commission, co-chaired by Dennis C. Blair and Jon M. Huntsman, Jr., released a report on the theft of U.S. Intellectual Property. In that report, the Commission predicts that as companies mature in emerging markets over the long term, these markets "will develop adequate legal regimes to protect the intellectual property of international companies as well as domestic companies." At the same time, the Commission wisely cautions that "[t]he United States cannot afford to wait for that process… and needs to take action in the near term to protect its own interests."[8]

India's protectionist and discriminatory policies, which exploit U.S. IP to benefit its own industry, require an equally bold response. This is vital to not only promote the incentives to deliver new cures and medicines around the globe but also to protect our overall IP-based system and the job creation that this system supports.

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[7] *See, e.g.*, Press Release, "Dr. Reddy's Q1 FY13 Financial Results," July 19, 2012 (*available at* http://www.drreddys.com/media/popups/q1fy13_results_19jul2012.html); Press Release, "Sun Pharma reports a strong quarter," August 10, 2012 (*available at* http://www.sunpharma.com/images/finance/FY13%20Q1%20Press%20Release%20Financials.pdf); Press Release, "Q1 FY13," August 10, 2012 (*available at* http://www.wockhardt.com/pdf/QUARTERLY-REPORT-(Q1)-f12ee.pdf).

[8] *See* The IP Commission Report (*available at* http://www.ipcommission.org/).

We recommend that the following steps be taken:

1) The U.S. Congress and Administration should work to elevate India IP issues to the highest levels of all U.S.-India bilateral dialogues to seek resolution to these concerns.

2) The U.S. government should raise concerns in every available bilateral and multilateral forum to send a strong signal to the Indian Government and to other governments that such actions will not be taken lightly.

3) We urge the U.S. government to explore all available diplomatic, trade, policy and legal tools and seek to engage like-minded partners such as the European Union, to address India's protectionist policies and ensure equal treatment for U.S. and Indian companies.

4) The U.S. must continue to demonstrate strong leadership in promoting effective and enforceable IP rules of the highest standard around the world, including in the Trans-Pacific Partnership (TPP) and the Trans-Atlantic Trade and Investment Partnership (TTIP).

Conclusion

Pfizer is in the business of creating high quality medicines and making these medicines available to patients as quickly as possible. To achieve this goal, effective, predictable and enforceable intellectual property protections are essential. India's recent actions threaten to undermine our ability to innovate and save and improve lives. It is important that we view these actions for what they are: protectionist policies to benefit India's own domestic industry. We appreciate the focus you have provided on this issue today and look forward to working with Members of this Committee and other stakeholders to identify and implement solutions that will benefit innovators and patients in the U.S., India and worldwide.