January 30, 2014

Ms. Lisa Barton  
Acting Secretary  
U.S. International Trade Commission  
500 E Street, SW  
Washington, D.C. 20436

Re: Pre-Hearing Statement, Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy, Investigation No. 332-543

Dear Acting Secretary Barton,

Please find enclosed the pre-hearing statement of the Pharmaceutical Research and Manufacturers of America in the above-referenced investigation.

Respectfully submitted,

/s/ Rod Hunter

Rod Hunter
Statement of Rod Hunter  
Senior Vice President, Pharmaceutical Research and Manufacturers of America (PhRMA)  
Before the U.S. International Trade Commission  
Investigation No. 332-543  
February 13, 2014  

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 ITC is doing to examine India’s discriminatory trade policies and evaluate the effects of those barriers on the U.S. economy and U.S. jobs.

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. Many of PhRMA’s member companies are directly impacted by India’s barriers to U.S. trade and investment, including its failure to respect intellectual property (IP) rights. Other members feel the effect of India’s anti-innovation policies in other countries where those policies are being emulated at a rapid pace. In all cases, India is setting a global precedent that has the potential to undermine growth and innovation in the United States’ strongest and most promising industries, ultimately harming consumers around the world.

IP is 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, accounting for nearly 35 percent of U.S. GDP in 2010 or over $5.1 trillion in economic output.¹ 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.²

India’s IP environment does not value innovation. In May 2013, President Pranab Mukherjee pointed out in his National Technology Day speech, “India’s innovation bottom line is not very encouraging.”³ He observed that the U.S. and China receive 12 times as many patent applications as India. The example of the pharmaceutical sector demonstrates the problems with India’s policies.

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Over the past two years, at least fifteen products have had their patent rights undermined in India, with products often facing multiple challenges. India has issued a compulsory license under Section 84 of its Patents Act based, among other grounds, on the failure to demonstrate why the product had not been manufactured locally. This provision raises concerns regarding India’s obligations on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and highlights India’s ulterior motive to promote domestic industry and force localization of capital. India continues to threaten additional compulsory licenses under this provision and under the special provisions of Section 92 and Section 66 of India’s Patents Act.

The unfair and discriminatory patentability standard under Section 3(d) of India’s Patents Act sets up a hurdle to obtaining a pharmaceutical patent in India. With limited exceptions, TRIPS requires that an invention that is new, involves an inventive step, and is capable of industrial application, be entitled to patent protection. Section 3(d) additionally requires a showing of “enhanced efficacy.” Moreover, this additional condition appears to be applied only to pharmaceuticals, and thus discriminates against a particular field of technology. Under this provision, salts, esters, ethers, polymorphs, and other derivatives of known substances are presumed to be the same substance as the original chemical and thus not patentable, unless it can be shown that they differ significantly in properties with regard to efficacy. Section 3(d) also undermines incentives for innovation by preventing patentability for improvements which do not relate to efficacy, for example an invention relating to the improved safety of a product.

Other examples of India’s IP rules designed to stifle innovation include abusive pre-grant opposition proceedings, the lack of protection provided for clinical test and other data that innovative pharmaceutical manufacturers are required to submit during the marketing approval process, lax patent enforcement for patented pharmaceutical products when a generic product seeks marketing approval during the patent term, and unnecessarily burdensome patent application requirements. These are just a few of the examples that paint a bleak picture of patent protection in India – a barren environment that regularly produces unjustifiable patent revocations, denials, and infringement.

The Government of India has created a protectionist regime that harms U.S. job creators. The harm is evident in our industry, where the U.S. has welcomed Indian companies while India is closing its borders to U.S. innovators. Indian pharmaceutical manufacturers enjoy unfettered access to the U.S. market. Approximately 40% of all FDA marketing approvals for generic medicines in 2013 were for Indian products. One of India’s major generic pharmaceutical companies, Wockhardt, has reported generating 52% of sales revenue from the U.S. in the 2012-2013 financial year. Another, Sun Pharma, publicly stated in December 2013 that 70% of Sun’s sales come from the U.S. alone. Dr. Reddy’s Laboratories reported a 76% increase in net profits

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for the quarter ending September 30, 2013 due to “high margin launches in the US market.”
And the Government of India is benefitting from the implementation of this industrial policy – it collects more taxes on pharmaceutical products than it spends on medicines.

Many of India’s policies target the U.S. innovative biopharmaceutical industry, which also happens to provide substantial value to the U.S. economy. With nearly $50 billion invested in R&D in 2012, and having produced more than half the world’s new molecules in the last decade, our members are world leaders in medical research. PhRMA represents a full spectrum of biopharmaceutical companies, ranging from large, global companies to smaller companies, all of which make valuable contributions to the health of patients and the economy. In fact, the U.S. innovative biopharmaceutical industry supported 3.4 million U.S. jobs in 2011 and exported over $50 billion in biopharmaceuticals in 2012, making the sector the third largest U.S. exporter among R&D-intensive industries. While the Indian Government seeks to grow its domestic generic pharmaceutical industry by undermining innovation (local and foreign), U.S. innovative biopharmaceutical companies are merely seeking a level playing field.

The innovative biopharmaceutical industry is not alone in this desire. The impacts of India’s trade barriers are being felt across IP-intensive and manufacturing industries. Local content requirements for the information and communications technology and clean energy industries, inadequate copyright protections for the music and film industries, overly burdensome regulatory restrictions on the foreign financial institutions, and unfair capital investment requirements in the retail sector all demonstrate India’s unwillingness to be a true partner with the United States in opening markets and expanding opportunities for growth.

India’s unfair trade actions also have consequences within India. 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-

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8 Broad analysis for 2011 indicates total annual Government expenditure on drugs in India around $1.15B in comparison to the $1.22B it receives in taxation of pharmaceuticals. Includes domestic tax (VAT and excise duty) and import taxes; based on broad analysis of 2011 data representative at national level; state level data not investigated. Source: Indian Department of Pharmaceuticals Annual Report 2012; High Level Expert Group (HLEG) Report on Universal Healthcare Coverage for India 2011, Instituted by Planning Commission of India.

But weak IP protection directly discourages such R&D. The design of India’s IP laws to disfavor innovators and protect generic drugmakers has compromised the integrity of an innovative economy to the short-term benefit of the owners of local generic companies. These shortcomings help explain why India attracts less than three per cent of global R&D spending.\footnote{Batelle Institute, 2014 Global R&D Funding Forecast, R&D Magazine (Dec. 2013).}

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. This includes making significant investments in the R&D of new medicines that will address significant unmet healthcare needs in Indian patients. Additionally, many innovative companies have developed patient access programs that help to ensure their medicines are accessible to patients who need assistance. In a poignant example, India denied Novartis’ patent on Glivec under Section 3(d) even though Novartis provided free access for 95% of the Glivec patients in India.\footnote{“Novartis Loses Glivec Patent Battle in India,” Wall Street Journal (Apr. 1, 2013), available at http://online.wsj.com/news/articles/SB10001424127887323296504578395672582230106 (last visited Jan. 30, 2014).}

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 barriers in that market. The United States has an important interest in seeing India change course on IP and other unfair trade policies. As of November 2013, India was the United States’ 11th largest trading partner.\footnote{U.S. Census Bureau, http://www.census.gov/foreign-trade/statistics/highlights/top/top1311yr.html (last visited Jan. 24, 2014).} 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.