

**PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA
(PhRMA)
SPECIAL 301 SUBMISSION 2014**

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PhRMA 2014 SPECIAL 301
OVERVIEW

PhRMA 2014 SPECIAL 301 OVERVIEW

I. Importance of Special 301 and Effective Intellectual Property Protection

The Special 301 statute calls upon the Office of the United States Trade Representative (USTR) to address in its review foreign country practices that deny fair and equitable market access to U.S. persons that rely upon intellectual property (IP) protection. Encouraging and fostering innovation and protecting the IP of U.S.-based innovative industries is critical to the future of the U.S. economy. 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.

The TRIPS Agreement was a major achievement in strengthening the worldwide protection and enforcement of intellectual property rights by creating an international minimum standard, rather than an optimal level of protection for intellectual property rights. Under the TRIPS Agreement, intellectual property owners must be given rights promptly, must gain certain minimum assurances of the characteristics of the rights, and must have recourse to effective means for enforcing those rights. All of these obligations must be implemented in practice, as well as through laws and regulations. The Agreement was premised on the view that its obligations, if faithfully implemented by the diverse WTO Membership, would create the policy and legal framework necessary for innovation-based economic development of WTO Members by rewarding innovation with reliable rights-based systems and permitting the flow of its attendant commercial benefits. Because it concerns both the definition and enforcement of rights, the TRIPS Agreement is an important step toward effective protection of intellectual property globally.

A country cannot be said to adequately and effectively protect intellectual property rights within the meaning of the trade statutes if that country puts in place regulations that effectively nullify the value of the patent rights granted. A patent gives only the patent holder the right to sell its invention in a market, but that right can be undermined by government policies which either reduce the price down toward the marginal cost of production, or block the innovator's access to the market. When such schemes are in place, a patent holder loses the ability to gain a reasonable, market-based return on investment for the risks assumed in the course of innovation. Moreover, a country that utilizes such schemes is not adequately or effectively protecting intellectual property rights as defined in the applicable trade statutes. Accordingly, it is important that the Special 301 Report highlight those countries that engage in such policies that effectively deny, delay, or otherwise impede the rights of companies to benefit from their intellectual property.

Concerns outlined in this submission underscore the dangerous and detrimental nature of weak IP enforcement and market access barriers that undermine IP abroad. PhRMA welcomes the Administration's attention to these concerns and looks to the Administration and especially the USTR to effectively address these practices.

A. The U.S. Biopharmaceutical Sector, Jobs and Exports: Protecting and Growing America's Competitiveness and Developing the Next Generation of Medicines for the World's Patients

The research-based U.S. biopharmaceutical sector is an important contributor to U.S. economic growth. However, the sector is dependent on robust enforcement of international trade obligations to sustain and grow jobs and attract the research and development (R&D) investment needed to develop the new medicines that the United States and the world require to address our most complex and costly diseases. U.S. innovation and ingenuity represent our comparative advantage in the global trading arena, and will continue to be essential to America's future prosperity and growth. As American IP-intensive industries, including the research-based biopharmaceutical industry, continue to face daunting challenges in protecting their IP, it is essential that the U.S. Government address these challenges to ensure continued economic sustainability and growth, as well as to ensure that the United States remains a global leader in biotechnology.

Today, when policymakers talk about the jobs of the future, they talk about innovation and economic competitiveness. Innovation has, in the words of President Obama, traditionally made America the "engine of growth, and progress, and discovery for the entire world." Promoting and protecting these innovations through robust enforcement of international trade rules is increasingly important to the American economy, maintaining and growing America's comparative advantage in the global marketplace, and growing U.S. exports and jobs in the near and long term.

The United States has become a knowledge economy, with intellectual capital being the driver of American competitiveness, growth and prosperity. According to a 2011 study by economists Kevin Hassett and Robert Shapiro, patents, copyrights, and other economic ideas like general business methods accounted for one-half of the market value of all publicly-traded U.S. firms in 2011 – \$8.1 trillion to \$9.2 trillion or more than half of America's GDP at the time.¹ Intellectual property (IP)-intensive industries accounted for nearly 35 percent of U.S. GDP in 2010 or over \$5.1 trillion in economic output.² U.S. wages are higher in IP-intensive industries than in non-IP-intensive industries by about 60 percent. Capital spending per employee in U.S. IP-intensive industries is over twice that in other industries, and R&D spending per employee is almost 13 times that in non-IP-intensive sectors. IP-intensive industries in the U.S. export over three times the product value per employee than elsewhere in the economy, and 60 percent of all U.S. exports.³

The innovative biopharmaceutical industry is a good example of how intellectual capital contributes to the U.S. economy. The innovative biopharmaceutical industry is

¹ Hassett, K.A. and Shapiro, R. J., What Ideas Are Worth: The Value of Intellectual Capital And Intangible Assets in the American Economy (Sonecon, LLC), September 2011.

² U.S. Department of Commerce, Intellectual Property and the U.S. Economy: Industries in Focus, March 2012.

³ Pham, N.D., The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs, Wages and Exports (NDP Consulting), April 2010.

one of only two U.S. industries (the other being software) that hold intangible assets valued at \$800 billion or more. Those intangible assets account for over 90 percent of the biopharmaceutical industry's market value.⁴ In 2011, the biopharmaceutical sector supported \$789 billion in U.S. economic output, including direct and indirect effects.⁵ In 2012, the U.S. biopharmaceutical goods exports totaled almost \$51 billion,⁶ making the innovative biopharmaceutical sector the third largest exporter of R&D-intensive goods.⁷

PhRMA member companies are important drivers of high-quality, innovative job creation in the United States, investing more per employee in research and development than other manufacturing industries.⁸ Few industries are more competitive when it comes to providing high-quality, high-paying, and high-productivity jobs. Industry employment (direct, indirect, and induced) in 2011 totaled 3.4 million jobs, including direct employment of over 810,000 Americans.⁹ For all occupations involved in the biopharmaceutical sector, the average total compensation in 2011 per direct biopharmaceutical employee was more than twice the average compensation per U.S. worker in all other private sector industries.

According to data released in 2012 by the National Science Foundation, the U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business R&D, representing nearly 20 percent of all domestic R&D funded by U.S. businesses.¹⁰ Additionally, a recent study on "The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs, Wages, and Exports" found that R&D spending for the pharmaceutical industry had the fastest growth among IP-intensive sectors analyzed, increasing an average of 20.7 percent a year between 2000 and 2007.¹¹ With nearly \$50 billion invested in R&D in 2012,¹² and having produced more than half the world's new molecules in the last decade, the U.S. biopharmaceutical industry is the world leader in medical research.¹³ These figures highlight the pressing need to defend this sector's IP rights against infringement. 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

⁴ Hassett, K.A. and Shapiro, R. J. (2011).

⁵ Battelle Technology Partnership Practice, The Economic Impact of the U.S. Biopharmaceutical Industry. Battelle Memorial Institute, July 2013. Prepared for the Pharmaceutical Research and Manufacturers of America. (Battelle Report).

⁶ PhRMA analysis of data from United States International Trade Administration (ITA), TradeStats Express: State Export Data.

⁷ Industry R&D data from National Science Board of the National Science Foundation, "Science and Engineering Indicators 2012," 2012; industry export data from PhRMA analysis of data from U.S. ITA, TradeStats Express: National Export Data; software publishers data from the International Intellectual Property Alliance.

⁸ Pham, N.D. (2010).

⁹ Battelle Report.

¹⁰ Science and Engineering Indicators 2012, National Science Foundation, Division of Science Resource Statistics. 2012.

¹¹ Pham, N.D. (2010).

¹² Pharmaceutical Research and Manufacturers of America. "PhRMA Annual Membership Survey." 1981–2013.

¹³ 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.

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.¹⁴

The research and development conducted by the innovative U.S. biopharmaceutical industry leads directly to patients living longer, healthier, and more productive lives. These companies discover advances in life-saving treatment for major diseases like the treatments that lowered cancer death rates by 15.5% between 2000 and 2011.¹⁵ Better use of prescription medicines can 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), and increased worker productivity due to fewer medical complications, hospitalizations, and emergency room visits.¹⁶ In fact, treating patients with high blood pressure in accordance with clinical guidelines would result in health system savings alone of \$15.6 billion a year.¹⁷

Because the benefits from the biopharmaceutical sector are so robust, it is critical that failures to provide IP protections to innovative medicines around the world are addressed through the Special 301 and other U.S. Government initiatives. Enforcement must be a fundamental priority to support the U.S. economy and provide the incentive for continued innovation which leads to new medicines and improved health of Americans and patients globally.

B. Failure to Protect IP Harms the U.S. Economy

Protecting the IP of U.S.-based innovative industries is critical to the future of our economy. A number of studies have found that patents and other IP protections are significantly more important to biopharmaceutical firms in “appropriating the benefits from innovation compared with other high tech industries.”¹⁸ This is due in large part to the research-intensive nature of this sector, which contributes to high research and development costs. In knowledge-based sectors, such as the biopharmaceutical sector, intangible assets are often more valuable than tangible assets. This sector is reliant on the ability to raise capital to support the substantial investments in research and development needed to develop today’s treatments and tomorrow’s cures.

When IP is infringed, biopharmaceutical companies are often unable to recoup their research and development investments, reducing the capital available to reinvest in more research and development. IP rights and their enforcement assure inventors and companies that their investments in time, money, and human capital will be protected if they are successful, and that they will have the opportunity to earn a return

¹⁴ Adis Insight, “R&D Insight Database” (February 2013).

¹⁵ U.S. Department of Health and Human Services (HHS), Center for Disease Control (CDC), National Center for Health Statistics (NCHS), Health, United States, 2011 With Special Features on Socioeconomic Status and Health. Hyattsville, MD: HHS (2012).

¹⁶ D.M. Cutler, et al., The Value of Antihypertensive Drugs: A Perspective on Medical Innovation. *Health Affairs* 26(1): 97–110 (2007).

¹⁷ D.M. Cutler (2007).

¹⁸ See, e.g., Grabowski, H., Patents, innovation, and access to new medicines, *J Int'l Economic Law* 2002:849-860.

on investment. A clear legal framework provides the certainty, security, and predictability necessary for this sector's sustainability and growth. A lack of commitment to protect IP will impair future research and development investment, and discourage the capital investments that are so critical to developing new technologies that not only help patients, but create new jobs. Given the dominant role of intellectual capital in the U.S. economy, the failure to adequately protect IP poses serious economic harm.

C. Providing Innovative Solutions to Healthcare Access in the Developing World

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 are actively engaged in helping to solve the health problems of the developing world, and America's biopharmaceutical companies are one 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 well as other materials and labor.¹⁹

IP drives innovation, without which patients would not have access to new medicines. 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."²⁰ 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.²¹ These companies are among the largest funders of the research and development necessary to cure neglected and major diseases of the developing world, including malaria, tuberculosis, sleeping sickness and dengue fever. Specifically, 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.²² In fact, as of the end of 2013, America's innovative biopharmaceutical companies are developing close to 400 new medicines for infectious diseases, including viral, bacterial, fungal, and parasitic infections such as the most common and difficult-to-treat form of hepatitis C, a form of drug-resistant malaria, a form of drug-resistant MRSA, and a novel treatment for smallpox.²³ Without these efforts, which are threatened when IP protections are eroded and the incentives for innovating new medicines are

¹⁹ IFPMA Survey, validated by LSE Health and Social Care at the London School of Economics and Political Science.

²⁰ Remarks by Bill Gates at the World Economic Forum, Gates Foundation Press Conference (January 29, 2010).

²¹ See www.globalhealthprogress.org.

²² Moran, M. et al., "Neglected Disease Research and Development: A Five Year Review," Policy Cures, (2012).

²³ 2013 Medicines in Development – Infectious Diseases Report, Pharmaceutical Research and Manufacturers of America (December 2013).

undermined, access to effective, sustainable healthcare for the developing world's patients would be impossible.

II. Protecting IP Rights in Foreign Markets

In order to facilitate the protection of the rights of U.S. businesses in foreign markets, PhRMA recommends that USTR:

1. Reduce the number of U.S. trading partners that fail to enforce IP rights and use ongoing and future trade negotiations to secure robust IP protections;
2. Assist countries to fully implement and urge enforcement of their international IP obligations;
3. Advocate at international organizations to defend and strengthen IP rights; and
4. Engage on foreign government price controls and cost containment measures that undermine IP and impede market access.

A. Reduce the Number of U.S. Trading Partners that Fail to Enforce IP Rights

It is vital for innovative U.S. industries, and in particular the research-based biopharmaceutical sector, that the U.S. Government ensure that our trading partners comply with international obligations to protect and enforce IP rights, including patents, trademarks, and regulatory data protection. As the most innovative economy in the world, the United States has the most to lose from weak global IP regimes in foreign markets. A lack of commitment to protect U.S. IP around the world will encourage further IP infringement – thereby impairing U.S. exports and companies that choose to compete in foreign markets, hurting U.S. industries' competitiveness by undermining future research and development investment, and discouraging the venture capital investments that are so critical to developing new technologies that not only help patients, but create new jobs for millions of Americans.

The United States must therefore monitor and enforce trading partner compliance with international trade rules and other agreements relating to the protection of intellectual property. These include bilateral and regional free trade agreements (FTAs) and multilateral agreements including the World Trade Organization (WTO) Agreements on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), Trade-Related Investment Measures (TRIMS Agreement) and Technical Barriers to Trade (TBT Agreement), as well as the General Agreement on Tariffs and Trade 1994 (GATT 1994). In addition, adherence to modern IP-treaties, such as the Patent Cooperation Treaty, which creates a global IP infrastructure, is very important. These agreements were thoughtfully crafted to create a global framework for intellectual property protection. The United States must seek to ensure that other parties are as committed as it is to complying with agreed-upon rules.

Further, in order to tackle these and other trade barriers, and to ensure that U.S. sectors such as the biopharmaceutical industry face a level export playing field, the U.S. Government should continue to focus on monitoring and enforcing trading partner compliance with international trade rules, including under bilateral and regional free trade agreements (FTAs) in place and currently being negotiated, and multilateral agreements such as through the WTO. These agreements were thoughtfully crafted to protect U.S. IP, exports and jobs, and the United States must ensure that other parties are as committed as we are to complying with agreed-upon international rules.

These efforts must be closely coordinated with U.S. Government agencies tasked with negotiating and enforcing U.S. international trade agreements, including the Office of the United States Trade Representative, the Department of Commerce, the Department of State, the United States Patent and Trademark Office, and the Intellectual Property Enforcement Coordinator.

B. Assist Countries to Fully Implement and Enforce Their IP Obligations

With respect to innovative biopharmaceuticals, here are some key areas where IP has the greatest significance:

Patent System: Patents play a crucial role in fostering inventions. The incentives of the patent system for innovation are of particular importance to biopharmaceutical inventions. Recognizing the importance of patent protection, the TRIPS Agreement requires WTO Members, as a general rule, to make patents available for inventions in all fields of technology. (TRIPS includes an exception for least developed countries, which includes many African countries.²⁴) Developing countries have increasingly put patent systems in place, but with mixed results.

Scope of Patentable Subject Matter – Especially troubling is the recent phenomenon in some countries to undermine IP protections by applying unduly narrow standards of patentability either at the time of the patent application or after the fact in legal disputes concerning the validity of the patent through several mechanisms. For example:

- India has not only narrowed the scope of patentable subject matter in a manner specific to pharmaceutical patents through amendment of its patent law, but has also revoked commercially significant pharmaceutical patents after grant using “hindsight” analyses to claim lack of inventiveness.
- Argentina released new patent examination guidelines in 2012 (currently being considered for codification into law) that specifically prohibit certain types of pharmaceutical patents and add additional patentability criteria for pharmaceutical and agrochemical patents only beyond the requirements of novelty, inventiveness, and utility as set forth in the TRIPS Agreement.

²⁴ See Extension of the Transition Period Under Article 66.1 for Least-Developed Country Members, WTO Document IP/C/40 (Nov. 30, 2005) and Doha Declaration on the TRIPS Agreement and Public Health, WTO Document WT/MIN(01)/DEC/2 (Nov. 20, 2001), at paragraph 7.

- The Canadian judiciary has created a heightened standard for patentable utility that has so far been applied only in pharmaceutical patent cases.
- In an amendment to Brazil's patent law, the health regulatory authority has been given authority to review pharmaceutical patent applications that may present a "health risk." That review is given equal weight to the patent office's review, thereby creating an additional hurdle for pharmaceutical patent applications. Moreover, legislation that similarly grants the health regulator authority over patentability determinations has been proposed in countries like Argentina and Colombia.

WTO Members must make patents available and patent rights enjoyable for inventions in all fields of technology, with limited specified exceptions. In addition, this must be done without discrimination based on the place of invention, field of technology, or whether products are imported or locally produced. Restrictions on the scope of patent eligible subject matter undermine the patenting of important biopharmaceutical inventions, are inconsistent with international standards set forth in the TRIPS Agreement, and, perhaps more importantly, prevent U.S. businesses from realizing the potential of valuable inventions in these markets.

Key trading partners with behavior of concern related to scope of patentability include: Argentina, Australia, Brazil, Canada, China, Colombia, Costa Rica, Ecuador, Finland, India, Peru, Thailand, Vietnam and Venezuela.

Compulsory Licensing – Once an inventor obtains a patent, it must have certainty that unauthorized uses will be prevented in order to appropriately license or exploit the invention and recoup its investment. However, several U.S. trading partners have implemented policies that undermine the ability of U.S. businesses to enforce patent rights. While TRIPS does outline a procedure for compulsory licensing in exceptional situations, industrial policy is not one of these circumstances. Several countries either have on the books or are actively considering laws or policies that would provide for compulsory licenses (or perhaps even revocation of a patent) if there is no local manufacture of a patented product. For example, India's Intellectual Property Appellate Board affirmed in 2013 the first-ever issuance of a compulsory license (CL) for an anti-cancer patented pharmaceutical product based, in part, on a finding that products must be manufactured in India to satisfy India's "working requirement." This finding is contrary to India's TRIPS commitments (as well as its broader WTO obligations), and distorts what was intended as a public health exception into an industrial policy by using a CL as a pretext to support India's local generic manufacturing industry. It also is clearly prejudicial to U.S. businesses operating in foreign markets, attempting to manufacture in the United States and to supply these markets through exports.

Regulatory Data Protection – In addition to discovering and patenting new medicines, biopharmaceutical companies expend tremendous effort and resources conducting clinical research that generates data establishing the

safety and efficacy of biopharmaceutical inventions, which regulatory authorities require for marketing approval. The TRIPS Agreement requires that such data be protected against “unfair commercial use.” This is generally implemented by prohibiting third parties from using the data to support their own marketing approval applications without authorization from the innovator for a defined period of time (commonly referred to as data protection, data exclusivity, or regulatory data protection). This permits the originator to recoup its significant investment in generating the proprietary data and the up-front costs for a product launch. This protection is even more important in many countries where patents may not yet be available for biopharmaceutical products or, more commonly, where effective means of enforcing patents may not be available. In these countries, data protection may provide one of the few incentives for regionally-specific innovation and may provide an important incentive to launch new innovative products in the country.

PhRMA is deeply concerned about the failure of almost all the developing countries on which we report to implement their TRIPS Article 39.3 obligation to prevent unfair commercial use of undisclosed test data. Even the European Union, one of the United States’ strongest partners in providing robust IP protections, is proposing through the European Medicines Agency a policy of unrestricted access to and publication of clinical trial data that will substantially harm patient privacy, the integrity of the regulatory system, and incentives for pharmaceutical research and development. PhRMA member companies believe it is now time to refocus government efforts on core commercial priorities, and that U.S. commercial interests would be best served by a strong, high-level and consistent commitment to full implementation of TRIPS, including those provisions concerning protection of undisclosed data.

Key trading partners with behavior of concern related to the implementation and enforcement of regulatory data protection include: Algeria, Argentina, Australia, Brazil, Canada, Chile, China, Costa Rica, Dominican Republic, Ecuador, Egypt, El Salvador, Honduras, India, Malaysia, Mexico, Morocco, Nicaragua, Peru, the Philippines, Russia, Taiwan, Thailand, Tunisia, Turkey, Vietnam and Venezuela.

Effective Patent Enforcement – To ensure adequate and effective protection of IP rights for the research-based pharmaceutical industry, mechanisms are needed which prevent marketing or grant of marketing approval for patent infringing products, and such mechanisms are lacking in key markets such as China, India, and the EU. Providing for dispute resolution on patent infringement before the product in question is allowed to enter that market is an important tool. Postponing marketing approval for any generic product known by regulatory entities to be covered by a patent until expiration of the patent or the resolution of legitimate patent disputes (often referred to as linkage) is important. Such a mechanism provides a “procedural gate” or safeguard, because it ensures that drug regulatory entities do not inadvertently contribute to infringement of patent rights granted by another government entity by granting marketing rights to a

competitor of the innovative company. Legal mechanisms that allow for early resolution of patent disputes before an infringing product is launched on the market avoid the unnecessary costs and time of litigating damages claims in patent litigation and increase market predictability.

Key trading partners with inadequate implementation of mechanisms for the early resolution of IP disputes and marketing approvals include: Algeria, Argentina, Australia, Canada, Chile, China, Colombia, Dominican Republic, Egypt, El Salvador, the European Union, India, Korea, Malaysia, Mexico, Peru, the Philippines, Russia, Taiwan, Thailand, Turkey and Vietnam.

Patent Term Adjustment and Restoration – Finally, a prerequisite for ensuring that a patent holder can enjoy the commercial benefits of its IP rights to the fullest extent possible is a patent office in each market that grants patents on eligible inventions within a reasonable period of time, and a regulatory approval authority that grants timely marketing approval. However, in some countries (including most developing countries and even developed countries like Canada), there are unreasonable patent or marketing approval backlogs that raise uncertainty as to whether an invention will be protected in a meaningful way at all in that market. These backlogs seriously erode the patent term enjoyed for these inventions because patent terms are calculated from the date a patent application is filed and, unlike in the United States, there is no mechanism to extend the patent term to offset any of the delays caused by one or both of the respective patent office or marketing approval backlogs.

Key trading partners with concerning patent backlogs and marketing approval delays include: Argentina, Brazil, Canada, Chile, Costa Rica, Dominican Republic, Malaysia, New Zealand, Thailand, Turkey, and Vietnam.

Preferential Trade Policies That Limit U.S. Companies' Abilities to Compete Globally and Undermine IP: PhRMA represents a full spectrum of biopharmaceutical companies, ranging from large, global companies to smaller companies, all of which make valuable contributions to U.S. economic health and growth. A key focus of U.S. trade policy should be to promote a level playing field globally in order for U.S. companies to fairly compete and enter new markets. Unfortunately, a number of countries are increasingly implementing policies that are preferential to domestic companies and which unfairly inhibit or prevent U.S. companies from entering or expanding in markets outside of the United States. Many of these policies appear to violate international treaties, e.g., the TRIPS, TRIMs and TBT Agreements, and GATT. Addressing these discriminatory policies should be a key priority of U.S. Government engagement.

Local Manufacturing Requirements as Conditions for Market Entry – While a number of countries provide tax and other incentives for companies to conduct R&D and manufacturing in their countries, several countries are seeking to grow their own economies by discriminating against foreign manufacturers. For

example, in 2013 Russia's Industry and Trade Ministry proposed a decree stipulating that only Russian and Belarusian drugs would be allowed to participate in government procurement tenders, if two or more local manufacturers are registered in the market in this product category. Moreover, in 2013 a new law on public procurement (typically referred to as "Law on the Federal Contract System") was passed that allows for discriminatory procurement practices by giving the government a right to enforce a ban on foreign goods in public procurement tenders (Article 14. National regime in public procurement). Such practices would clearly harm patient interests and unfairly discriminate against the innovative medicines produced by U.S. and multinational companies.

Requirements to Establish Local Manufacturing or Transfer IP – In some countries, local manufacturing requirements may be coupled with other policies that limit fair access to foreign markets. In Indonesia, for example, a government decree that came into effect in November 2010, set unreasonable conditions for market entry. Only companies meeting Indonesian licensing requirements are allowed to obtain marketing approval for their products. In order to obtain licensure, companies must either establish a factory in Indonesia or transfer sensitive intellectual property to a local Indonesian company. Licensing requirements generally are intended to ensure that companies meet globally recognized good manufacturing and good distribution practices. Indonesia's decree, however, uses licensing requirements as a way to severely limit market access. Furthermore, under new Argentine regulations, importers must submit a Prior Import Statement (PIS) before placing an order to import goods. However, there are no criteria established as to the grounds for approval/rejection. An unofficial policy as reported by some PhRMA member companies is a requirement to balance their own foreign trade account (*i.e.*, for every dollar that they import, they must have one dollar worth of exports).

De Facto Bans on Imports – Other countries have policies that in essence prevent market entry. Turkey, for example, does not recognize the internationally accepted certification of good manufacturing practices (GMP) from other countries unless they have mutual recognition agreements (MRAs) on inspections with Turkey (neither the United States nor the European Union has such an MRA). In part due to the small number of Turkish inspectors available to review facilities worldwide, the policy will serve as a *de facto* ban on imports. The Turkish Government has publicly stated that the purpose of this policy is to promote local Turkish pharmaceutical companies at the disadvantage of foreign companies. This measure likely conflicts with GATT Article III as it discriminates in favor of domestic producers, as well as GATT Article XI due to the fact that it effectively bans imports.

C. Advocate at International Organizations to Defend and Strengthen IP Rights

Any effort to promote the ability of U.S. businesses to protect intellectual property in world markets must also take into account activities at international organizations such as the United Nations (UN) system, including the World Intellectual Property Organization (WIPO) and World Health Organization (WHO), as well as the WTO. Certain U.S. trading partners take active positions on IP issues within international fora that seek to diminish IP protection and widen the berth for potential infringement of innovative companies' rights. The United States must remain vigilant in these organizations, work with like-minded countries in countering these positions, and continue to advocate for robust IP protection and due enforcement in the face of mounting attempts to diminish these rights. Moreover, the U.S. Government should continue to promote activities that support the increased harmonization of patent and other intellectual property laws, and the adoption of standards at the international level to eliminate barriers to protecting intellectual property. In addition, continued advocacy and refinement of existing systems, such as the Patent Cooperation Treaty, that facilitate the ability of companies to obtain patents in multiple jurisdictions should continue to be pursued.

D. Engage on Foreign Government Price Controls and Cost Containment Measures that Undermine IP and Impede Market Access

The Special 301 statute calls for designation of countries with policies that undermine IP and impede market access. This is reinforced by section 301(d)(3)(F)(ii) of the Trade Act of 1974, as amended, which "includes restrictions on market access related to the use, exploitation, or enjoyment of commercial benefits derived from exercising intellectual property rights"

Because of the United States' preeminence in the life-sciences sector, foreign cost containment measures create market access barriers that pose a significant threat to the U.S.-based biopharmaceutical industry, and in turn the U.S. economy. More specifically, these policies have the ability to dramatically impact the industry's ability to gain market access to and compete in new and existing markets thereby harming the ability to sustain and create exports, maintain and develop jobs, stimulate future innovation, and more.

Foreign governments are increasingly employing a range of strategies to control prices and contain costs related to biopharmaceuticals. Based on a recent 2012 analysis, approximately 53 countries proposed or implemented cost containment measures impacting the biopharmaceutical sector.²⁵ In fact, the biopharmaceutical sector is unique in that it faces onerous price controls and other related measures in the vast majority of the sector's export markets, and in many of these markets the government is the sole pharmaceutical purchaser.

²⁵ Ross Consulting, analysis for PhRMA, August 2012.

According to a recent study conducted for the Office of Health Economics in London by Garau et al., lower prices mean less income for pharmaceutical companies, ultimately translating into less investment in innovation. The report further notes that lower prices will have a negative impact on incentives for R&D and will ultimately reduce and delay the availability of innovative products in certain countries.²⁶ These conclusions corroborate findings from a 2004 U.S. Department of Commerce Report that concluded price control policies can limit competition in some markets and require national health systems to forego the benefits of certain innovations in reducing health care costs dramatically impacting the U.S. biopharmaceutical industry's ability to enter and compete in new markets as well as its ability to compete in existing markets.

In addition to price controls, the biopharmaceutical sector has witnessed a surge in a number of cost containment measures, which in some cases have disproportionately targeted our sector. Such measures often have significant ripple effects in many markets. For example, *ad hoc* price cuts implemented in one country can directly and indirectly impact the price of medicines in many other markets due to international reference pricing where a government considers the price of a medicine across a set (or "basket") of countries to determine the price of medicine in its own country. This can create a downward spiral in terms of prices for medicines, and may result in product shortages for medicines patients need. For example, according to a recent report, in 2011 the modeled impact of a hypothetical 10 percent price drop in Greece would have cost industry \$390 million in Greece but \$1 billion in Europe (i.e., 2.5 times more) and \$2.8 billion worldwide (i.e., 7.0 times more)²⁷ if all countries re-referencing Greek prices through formal and informal links are included.²⁸

PhRMA members recognize the significant fiscal challenges that foreign governments face and seeks to be a partner in finding solutions; however, some governments have proposed or implemented cost containment measures 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.

Examples of key cost containment measures include *ad hoc* government price cuts, international and therapeutic reference pricing, mandatory rebates, and many others. Such measures can delay or reduce the availability of new medicines and can contribute to an unpredictable business environment in foreign markets for U.S. companies. Moreover, governments are increasingly engaging in product evaluation

²⁶ Garau, M., Towse, A. and Danzon, P. (2011) *Pharmaceutical pricing in Europe: Is differential pricing a win-win solution?* Occasional Paper 11/01. London: Office of Health Economics.

²⁷ Estimates are assumed to be upper bound as the analysis made several assumptions including that both formal and informal reference baskets were current; the inclusion of second round effects (i.e., the impact of the country that references Greece), so implicitly assumes two rounds of updating; all countries have a comparable products on the market that can be referenced to the Greek product; and simplification of the impact by determining the average changes based on the number of countries in the reference price rules.

²⁸ Charles River Associates. International Reference Pricing: Relationship Mapping, Re-Referencing, and Economic Spillover Impact. April, 2011.

methods like health technology assessment as a barrier to market access and a cost containment tool.

Ad Hoc Government Price Cuts – *Ad hoc* price cuts include arbitrary measures employed by some countries to meet short-term budgetary demands without considering longer-term implications to innovation and other critical factors. For example, over the last few years, Turkey has ratcheted up the mandatory social security discount from 11 percent in 2009 to 41 percent at the end of 2011. These price cuts have not been revoked even though Turkey’s pharmaceutical spend in 2012 came in significantly under budget.

International Reference Pricing (IRP) – IRP is a cost containment mechanism whereby a government considers the price of a medicine in other countries to establish the price in its own country. The reference price for a medicine is calculated by considering the price of the same medicine across a set (or “basket”) of countries using one of several possible methodologies. While historically used as an informal reference mechanism to double check assumptions and to provide additional input to the price setting process, over time IRP has become a highly damaging ‘runaway train’ with ever-more countries adopting and applying it as a rigid cost containment mechanism designed to achieve lowest price.

While the ability of governments to ultimately achieve cost containment through IRP is limited for numerous reasons,²⁹ mounting evidence points to the damaging nature of the policy including a 2010 study by Kanavos et al. which concluded that “by using [IRP], countries can import low price levels and generate rapid savings – however, at the risk of non-availability or delayed market entry of the respective product;³⁰ ”and another study by the European Commission concluding that IRP “allows for price arbitrage and is a deterrent to producers [to conduct business in those areas].”³¹

If IRP is to be used by a country, its methodology must be balanced and “the application of IRP should be objective and transparent, in order to provide opportunities for assessing its effects, make decision-makers accountable, reduce uncertainty for the pharmaceutical industry, and diminish the risk of discrimination and corruption.”³² Nevertheless, certain countries are in egregious

²⁹ European Commission Report: Cost-Containment Policies in Public Pharmaceutical Spending in the EU (Sept. 2012).

³⁰ Kanavos P, Vandros S, Habicht J, de Joncheere K. Review of the Estonian Pharmaceutical Sector: Towards the Development of a National Medicines Policy, available at <http://www.euro.who.int/en/where-we-work/member-states/estonia/publications3/review-of-the-estonian-pharmaceutical-sector-towards-the-development-of-a-national-medicines-policy> (last visited Feb. 7, 2014).

³¹ European Commission Report: Cost-Containment Policies in Public Pharmaceutical Spending in the EU (Sept. 2012).

³² WHO/HAI Project on Medicine Prices and Availability (Working Paper 1: External Reference Pricing). May 2011.

violation of such principles leading to a downward spiral in the prices for medicines with damaging results for PhRMA members.

Therapeutic Reference Pricing (TRP) – TRP is a cost containment mechanism whereby a group of medicines within a country is ultimately designated as a unique cluster of pharmacological-therapeutic equivalents and a maximum reimbursement limit (or reference price) for that cluster is set. TRP assumes that all products used to treat the same condition are interchangeable, without evidence. Treating medicines as if they are identical can harm patients, erode the benefits of patent protection, impede competition, and inhibit future innovation. For example, in Korea, pharmaceuticals with therapeutically and pharmacologically comparable active ingredients (including both innovative and generic medicines) are clustered, and the lowest priced medicine in the group is used to set a product's price. In addition to the price cuts previously mentioned, the resulting prices significantly undervalue the cost of developing innovative medicines included in such therapeutic reference groups. Similarly, Finland engages in a similar practice by linking the reimbursement price paid for patented products to the lowest priced generic medicine in the same therapeutic class.

Mandatory Rebates – Rebates are measures whereby payers achieve a lower real purchase cost than what they would have incurred at list price level. In rebate systems, a price reduction is negotiated with the payer while maintaining the official list price of a product. *Ad hoc* mandatory rebates can negatively impact a company's ability to plan ahead, and contribute to creating a highly unpredictable business environment. For example, in March 2010, the German Ministry of Health unexpectedly called for a "temporary" increase of the mandatory rebate from 6 to 16 percent on non-reference priced medicines. This policy has been implemented since August 2010 and a three year moratorium was put in place through the end of 2013. (Notably the anticipated budget shortfall that was cited to justify the temporary increase of the rebate never materialized. Although the Government has finally issued proposals to reduce the mandatory rebate to 7 percent, these proposals plan to maintain the price moratorium.) Similarly, on August 20, 2011, Spain imposed a mandatory 15 percent rebate on all medicines sold in Spain for ten or more years.

In addition to the more common mechanisms highlighted, numerous additional egregious policies are in play or are under active consideration which hinder market access. For example, India's Department of Pharmaceuticals (DoP) Committee on Price Negotiation is considering several new measures including whether the price negotiation of a patented medicine should be linked with its marketing approval. Moreover, the DoP notified and is in the process of implementing the Drug Price Control Order (DPCO) 2013 which sets ceiling prices for essential medicines by taking the simple average of all drugs with a market share of 1% or more by volume. Price controls will not substantially improve access to medicines in India, because lack of access is more a function of insufficient healthcare financing systems and inadequate healthcare

facilities;³³ even medicines and vaccines which are offered free of charge often do not reach the patients who need these medicines.³⁴ In another example, Colombia continues to layer numerous government pricing and reimbursement control policies on top of one another including one that expands price controls to the private market by applying maximum price provisions based on egregious calculation methods.

Governments are also increasingly using product evaluation methods like health technology assessment (HTA) as a barrier to market access and cost containment tool. HTA is a field of scientific research to inform policy and clinical decision-making around the introduction and diffusion of health technologies. PhRMA believes that research into the clinical benefits of products and the appropriate use of health technology assessments can be valuable in informing treatment decisions between doctors and patients. However, the recent, rapid emergence of HTA systems across the globe has raised great concern among PhRMA's member companies as a growing number of countries adopt health technology assessments as a cost containment tool. Many of these systems serve as "gate keepers" that restrict access to the reimbursed market and thereby undermine patient access to the most effective and often life-saving medicines. For example, approval for reimbursement in Mexico includes a complex system that requires the submission of a pharmacoeconomic evidence for inclusion in the national formulary. Initial data suggests that only approximately one-third of products obtain a positive approval, with an average time to decision of over one year, which prolongs access for patients to innovative treatments.³⁵ We are also troubled by countries that rely on health technology assessments from another country/system without conducting any sort of analysis to determine if the assessment makes sense for the local context. For these reasons, HTA systems can be a significant market access barrier to U.S. companies' ability to introduce innovative medicines to new markets.

Further, new medicines can also face various types of system and process-related delays which both prevents timely availability to patients and reduces the remaining patent life of original brands, thereby eroding commercial sales potential before generic competition begins. For example, although legislation requires the Turkish Ministry of Health to assess and authorize the registration of medicinal products within 210 days, the average regulatory approval period exceeded 1000 days, with an average of 934 days in 2012.³⁶ In another instance, China's Ministry of Human Resources and Social Security (MoHRSS) has been severely delayed in updating its National Reimbursement Drug List (NRDL). Having only undertaken two substantive

³³ "A Study of Healthcare Accessibility," Dr. DY Patil Medical College, Pune, India, prepared for India Health Progress, Mar. 2011. Wagstaff, Adam, "Health System Innovation in India Part I: India's health system challenges," available at <http://blogs.worldbank.org/developmenttalk/health-system-innovation-in-india-part-i-india-s-health-system-challenges> (last visited Feb. 7, 2014).

³⁴ "India Turns to Mobile Phones in Bid to Improve Vaccination Rate," India Real Time/Wall Street Journal (Aug. 4, 2011); Patra, Nilanjan, "When Will They Ever Learn?: The Great Indian Experience of Universal Immunisation Programme" (Dec. 2009), available at http://www.isid.ac.in/~pu/conference/dec_09_conf/Papers/NilanjanPatra.pdf (last visited Feb. 7, 2014).

³⁵ AMIIF 2011 Report.

³⁶ AIFD Situation Assessment Survey of CTD Applications (Dec. 2012).

updates in ten years (2004 and 2009), market access of new (and existing) medicine has been severely restricted.

In light of these concerns, PhRMA calls on USTR to engage with foreign governments to address key government price controls and cost containment measures that undermine IP and impede market access. PhRMA believes that the U.S. government can play a critical role in addressing discriminatory government price controls and cost containment measures, and highlighting the global benefits for patients that could result from a reduction in key trade barriers related to government price controls and cost containment policies.

E. Ensuring Transparency and Due Process in the Development and Implementation of Regulatory Approval Systems and Pricing and Reimbursement Processes

As noted above, the biopharmaceutical industry is unique in that most foreign governments, as sole or primary healthcare providers, impose burdensome price controls and regulations on the sector. As a result, market access for pharmaceuticals is not only dependent on manufacturers meeting strict regulatory approval standards, but also in obtaining positive government pricing and reimbursement determinations. It is imperative, therefore, that regulatory procedures and decisions regarding the approval and reimbursement of medicines are governed by transparent and verifiable rules guided by science-based decision making. There should be meaningful opportunities for input from manufacturers and other stakeholders to health authorities and other regulatory agencies and a right of appeal to an independent, objective court or administrative body. In particular, proposed laws, regulations and procedures concerning how medicines are approved, priced and reimbursed should be:

- Promptly published or otherwise made available to enable interested parties to become acquainted with them.
- Published prior to adoption in a single official journal of national circulation, with an explanation of the underlying purpose of the regulation. In addition, interested parties (including trading partners) should be provided a reasonable opportunity to comment on the proposed measures. Those comments and any revisions to the proposed regulation should be addressed in writing at the time that the agency adopts its final regulations. Finally, there should be reasonable time between publication of the final measures and their effective date so that the affected parties can adjust their systems to reflect the new regulatory environment.

In turn, specific regulatory determinations or pricing and reimbursement decisions should be:

- Based on fair, reasonable, consistent and non-discriminatory procedures, rules and criteria that are fully disclosed to applicants.

- Completed within a reasonable, specified time. In some countries there are no deadlines for making decisions on whether to approve new medicines. In others, deadlines exist, but are regularly not met. These delays impede market access, deplete the patent term, and are detrimental to patients waiting for life-saving medicines.
- Conducted so that they afford applicants timely and meaningful opportunities to provide comments at relevant points in the decision-making process.
- Supported by written reports which explain the rationale for the decision and include citations to any expert opinions or academic studies relied upon in making the determination.
- Subject to an independent review process.

In short, it is essential that decisions whether to approve and/or reimburse a new medicine are made in a reasonable, objective and impartial manner.

III. Address Counterfeiting of Medicines, Which Threaten Health and Safety of Patients World Wide

It is critical that the United States engage on the issue of counterfeit medicines – counterfeiting is first and foremost a crime against patients. As Hassett and Shapiro note: “[w]hile traffic in other counterfeit markets causes substantial economic harm, especially for an idea-based economy like the United States, counterfeit medicines often cause injuries and death as well economic damage.”³⁷ By deliberately and deceitfully attempting to pass themselves off as something that they are not, namely, genuine approved medicines, counterfeit medicines pose a global public health risk that leads, *inter alia*, to resistance to treatment, illness, disability and even death. Counterfeit medicines are manufactured, marketed and distributed with the deliberate intent to deceive patients and healthcare providers as to the source or nature of the product. As a result, these products threaten the health and safety of consumers throughout the world.

Currently, the trade in counterfeit medicines is estimated at \$75B.³⁸ According to the World Health Organization and Institute of Medicine (IOM), counterfeiting is greatest in areas where the relevant regulatory and enforcement systems are less developed. For example, recent estimates indicate that between 10 to 30 percent of medicines sold in developing markets are believed to be counterfeit.³⁹ Testing reported last year in the *Lancet* found one-third of anti-malarial medicines in sub-Saharan Africa and South East Asia lacked active ingredients.⁴⁰ A 2009 International Policy Network study also found

³⁷ *Id.*

³⁸ Mackey, Tim K. et al., *Dangerous Doses: Fighting Fraud in the Global Medical Supply Chain*, Foreignaffairs.com (May 14, 2012), available at: <http://www.foreignaffairs.com/articles/137634/tim-k-mackey-bryan-a-liang-and-thomas-t-kubic/dangerous-doses> (last visited Feb. 7, 2014).

³⁹ The World Health Organization, IMPACT, at www.who.org (2008).

⁴⁰ 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).

that fake tuberculosis and malaria drugs kill 700,000 people a year in developing countries.⁴¹ By contrast, counterfeiting is estimated to affect less than 1% of medicines sold in industrialized economies with developed regulatory and enforcement systems.⁴²

Although the prevalence of counterfeit medicines appears to be greatest in developing and least-developed markets, the counterfeit supply chain has no geographic boundaries. A recent report by the IOM stated that “unscrupulous manufacturers and criminal cartels take advantage of the comparatively weak drug regulatory systems in these countries, knowing that the regulators are poorly equipped for surveillance or enforcement.”⁴³ In China, India and other developing countries with drug manufacturing capabilities, lax oversight not only leads to domestic sales of counterfeits, but also to significant exports of counterfeits.⁴⁴ This problem can be exacerbated by the ease with which counterfeiters can offer fake medicines to consumers world-wide over the Internet. As the IOM notes: “[B]ecause the internet facilitates easy international sales, online drug stores have spread the problem of falsified and substandard drugs....”⁴⁵

While most countries recognize counterfeit medicines as a threat to the public health and safety, many lack the comprehensive framework of laws and controls necessary to safeguard the drug supply chain against counterfeit sales and exports. In countries like China, India, Russia, Brazil and Mexico (i.e., markets where pharmaceutical counterfeiting is believed to be a growing threat), several common deficiencies contribute to the growing prevalence of pharmaceutical counterfeiting in worldwide markets. Weak enforcement due to inadequate remedies, penalties, resources and commitment is the most significant problem, and one that undermines the effectiveness of all relevant laws, including prohibitions against trademark counterfeiting, as well as drug regulatory controls.

To combat the global proliferation of counterfeit medicines and active pharmaceutical ingredients (APIs), PhRMA supports strengthening efforts with U.S. trading partners to adopt and implement a comprehensive regulatory and enforcement framework that: (i) subjects drug counterfeiting activity to effective administrative and criminal remedies and deterrent penalties; (ii) adequately regulates and controls each link in the legitimate supply chain; (iii) trains, empowers and directs drug regulators, law enforcement authorities and customs to take effective and coordinated action, including against exports and online activity; and (iv) educates all stakeholders about the inherent dangers of counterfeit medicines. In addition, to enhance and harmonize the legal framework required to combat counterfeits globally, the U.S. government should explore

⁴¹ Harris, J., et al., Keeping It Real, Health Issues, International Policy Network (May 2009).

⁴² IOM, Countering the Problem of Falsified and Substandard Drugs, February 2013. and World Health Organization Fact Sheet No. 275, Medicines: spurious/falsely-labelled/ falsified/counterfeit (SFFC) medicines, (May 2012), available at <http://www.who.int/mediacentre/factsheets/fs275/en/> (last visited Feb. 7, 2014).

⁴³ IOM, Countering the Problem of Falsified and Substandard Drugs (Feb. 2013).

⁴⁴ Pharmaceutical Security Institute analysis.

⁴⁵ IOM, Countering the Problem of Falsified and Substandard Drugs (Feb. 2013).

supporting the development and adoption of an international convention to criminalize and combat counterfeit medical products, such as The Medicrime Convention.⁴⁶

There is also a need to increase customs controls and information-sharing in a world where counterfeit shipments follow ever-more convoluted itineraries, including stops at free trade zones. Coordinated enforcement operations focused on counterfeit medicines should continue to be a focused priority, including the U.S. Customs and Border Protection (CBP)-led cooperation with APEC and Operation Pangea. These provide critical public awareness as well as building cooperative relationships with individual countries and increasing their commitment to the issue. Future operations should seek to enhance coordination to tackle the illegal online pharmacy operations, going beyond Operation Pangea, and focusing on investigations and arrests of major actors behind the international networks.

In addition, more international cooperation is required among G8 countries to implement the 2012 commitments to share best practices and tackle illegal online pharmacies. The commitments were critical, but should now translate into concrete bilateral or multilateral cooperation. The U.S. government should continue to support enhanced cooperation on counterfeit pharmaceuticals in key multi-lateral fora, including G8, G20, and APEC.

IV. Country Designation Index

A. Priority Foreign Country or Section 306 Monitoring

PhRMA recommends that India and Turkey be designated as Priority Foreign Countries in USTR's Special 301 report for 2014. PhRMA also recommends that the People's Republic of China continue under Section 306 Monitoring. The detailed information presented in the country-specific sections below demonstrates that these countries have in place the most harmful acts, policies, and practices, which, in turn, have the greatest adverse impact on the U.S. innovative biopharmaceutical industry. PhRMA urges USTR to take resolute action to remedy these violations, including the consideration of WTO dispute settlement, as necessary.

B. Priority Watch List

PhRMA believes that 14 trading partners should be included in the 2014 Priority Watch List. PhRMA urges USTR to take bilateral (and multilateral as appropriate) action to remedy these significant concerns regarding IP protections and enforcement.

⁴⁶ Medicrime Convention: Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health: The Council of Europe, available at <http://www.coe.int/t/DGHL/StandardSetting/MediCrime/Medicrime-version%20bilingue.pdf> (last visited Feb. 7, 2014).

C. Watch List

The PhRMA submission identifies 24 countries which should be included on the Special 301 Watch List in 2014. These are countries whose specific issues of IP protection and enforcement concern will require continued or enhanced monitoring by USTR. In this context, public diplomacy is critical. In many cases, we understand the political barriers to legal reforms need to be addressed to provide rule-of-law protections such as fair and equal enforcement of pharmaceutical patents. Successful implementation will require a commitment from the U.S. Government to promote full adherence to the WTO TRIPS Agreement.

PRIORITY FOREIGN
COUNTRY

INDIA

PhRMA and its member companies acknowledge the challenges India faces in extending healthcare access to its large and growing population. Our members are concerned about patients' access to medicines and are committed to working with the Government of India to provide sustainable access to medicines and healthcare overall. This includes making significant investments in the research and development of new medicines that will address significant unmet healthcare needs in Indian patients. Sustainable solutions to India's healthcare concerns should be found through programs that prioritize healthcare financing, infrastructure, availability, human resource needs, and environmental and societal factors to achieve the goal of widespread access.

We remain concerned, however, about public policy issues that affect our member companies, as well as the broader healthcare industry in India. Specifically, India has implemented a number of negative policies that are designed to benefit India's business community at the expense of foreign innovators, including inadequate intellectual property (IP) protection and enforcement. These policies are not likely to expand access and, in most cases, may even limit the availability of innovative medicines produced by both domestically owned companies and PhRMA member companies because they create an environment that does not recognize the value of innovation. Further, there have been a number of negative policies that create market access barriers, including proposed further implementation of price controls, high import duties, and strict clinical trials regulations. We welcome the opportunity to work with the Indian Government in designing an equitable approach and implementing a system that is appropriate to India and balances the need to support innovation while enhancing access.

Key Issues of Concern:

- **Patent protection:** Over the past two years, the Indian Patent Controller and the Indian judiciary have issued several intellectual property decisions that undermine the rights of innovative biopharmaceutical companies. India's legal and regulatory systems pose procedural and substantive barriers at every step of the process, ranging from the impermissible hurdles to patentability posed by Section 3(d) of the India's patents act, to the threat of compulsory licensing on specious grounds, to pre-grant and post-grant opposition proceedings. Not only is this a concern in the Indian market, but also in other emerging markets that may see India as a model to be emulated. Since early 2012, at least fifteen products have had their patent rights undermined in India. In addition, the Government of India is considering issuance of compulsory licenses (CLs) through a Ministry of Health Committee on the grounds of national emergency; extreme urgency, and public non-commercial use.
- **Lack of regulatory data protection:** The Indian Regulatory Authority relies on test data submitted by originators to another country when granting marketing approval to follow-on pharmaceutical products. This indirect reliance results in unfair commercial use prohibited by the World Trade Organization (WTO)

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and discourages the development of new medicines that could meet unmet medical needs.

- **Government price controls:** The Department of Pharmaceuticals (DoP) has proposed an international reference pricing scheme with a purchasing power parity adjustment for government procured patented medicines and those patented medicines provided through health insurance. This proposal would create an unviable government pricing framework and business environment for medicines whose price levels in India are already low in comparison to other countries. The Drug Price Control Order (DPCO) 2013 includes a provision discriminating against foreign products by exempting indigenous research and development.
- **Clinical trials:** New clinical trials were halted after the Indian Ministry of Health and Family Welfare adopted rules that require broader compensation for participants who claim to have been injured due to a clinical trial. Most recently, the Drug Controller General of India (DCGI) ordered that, in addition to obtaining written informed consent, audio-visual recording of the consent of each subject is mandatory in a clinical trial and effective immediately. Such uncertainty in the regulatory process for clinical trials threatens the overall clinical research environment in India, as well as the availability of new treatments and vaccines for Indian patents.

The innovative biopharmaceutical industry greatly appreciates the efforts to address these concerns at the highest levels of the U.S. Government over the past two years. Notwithstanding these efforts, there has not been any substantive improvement in India's patent laws and policies, and the situation is in fact deteriorating. The compounding effect of the policies and practices summarized above is to "deny adequate and effective intellectual property rights" and to "deny fair and equitable market access" to the IP-intensive, research-based U.S. biopharmaceutical industry.⁴⁷

Moreover, despite the U.S. Government's and the business community's sustained work to raise concerns about the impact of these policies on the innovative biopharmaceutical industry's products, research, and intellectual capital, the Indian Government has been unwilling to engage on these issues and make progress toward a reasonable solution.⁴⁸ For example, India has been listed on the U.S. Trade Representative Special 301 Priority Watch List – requiring increased bilateral attention – every year since the first Special 301 Report in 1989 (except for three years when India was designated as a Priority Foreign Country). The U.S. Chamber of Commerce's Global Intellectual Property Center placed India last out of 25 countries included in its 2014 International IP Index, well behind Ukraine, which was designated as a Priority

⁴⁷ See 19 U.S.C. § 2242(b)(1)(A).

⁴⁸ See 19 U.S.C. § 2242(b)(1)(B).

Foreign Country in USTR's 2013 Special 301 Report.⁴⁹ Yet India continues to embrace these damaging policies, especially its IP rules, by publicly highlighting them as models for other emerging economies while touting the flourishing Indian generic medicines industry and other industries that have benefited from India's industrial policies.

For these reasons, PhRMA requests that India be designated a **Priority Foreign Country** in the 2014 Special 301 Report, so that the U.S. Government can further investigate the IP and market access barriers confronted by U.S. businesses in India and constructively engage with the Indian Government on how to quickly and effectively resolve these problems.

Intellectual Property Protections

Narrow Standards for Patentability

TRIPS requires that an invention which is new, involves an inventive step, and is capable of industrial application, be entitled to patent protection. Section 3(d) of the Indian Patents Act as amended by the Patents (Amendment) Act 2005 adds an impermissible hurdle to this by adding a fourth substantive criteria of "enhanced efficacy" to the TRIPS requirements. Moreover, this additional hurdle appears to be applied only to pharmaceuticals. 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.

Additional requirements for patentability beyond that the invention be new, involve an inventive step and capable of industrial application, are inconsistent with the TRIPS Agreement. Article 27 of the TRIPS Agreement provides a non-extendable list of the types of subject matter that can be excluded from patent coverage, and this list does not include "new forms of known substances lacking enhanced efficacy," as excluded by Section 3(d) of the Indian law. Therefore, Section 3(d) is inconsistent with the framework provided by the TRIPS Agreement. Moreover, Section 3(d) represents an additional hurdle for patents on inventions specifically relating to chemical compounds and, therefore, the Indian law is in conflict with the non-discrimination principle also provided by TRIPS Article 27. From a policy perspective, Section 3(d) 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 the overly narrow standards for patentability in India are the recent patent revocations using "hindsight" analyses made during post-grant oppositions and pre-grant oppositions citing a lack of inventiveness concluding that the patent applications are based on "old science" or failed to demonstrate an inventive step.

⁴⁹ GIPC 2014 International IP Index, available at <http://www.theglobalipcenter.com/GIPCindex/> (last visited Feb. 3, 2014).

Compulsory Licenses on Patented Pharmaceutical Products

The Government has set up a Committee under the Ministry of Health and Family Welfare (MoH Committee), which has been tasked with examining the medicines under patent which are required for various diseases such as HIV/AIDS, cancer, diabetes, Hepatitis C, TB, and MDR TB and which they assert are not affordable on account of the price barriers created by patents. The Government Committee is proceeding under the special provisions of Section 92 and Section 66 of India's Patents Act for grant of CLs, which would make it even more difficult for patent owners to defend their patents. In fact, it is reported that the Government of India is considering whether to issue CLs under Section 92 on approximately 20 patented medicines across a wide range of therapeutic areas. None of the grounds have been justified and the Government has not given any of the patentees a chance to be heard.

On March 9, 2012, India issued the first-ever CL for an anti-cancer patented pharmaceutical product. The research-based pharmaceutical industry is concerned that the findings in the CL decision on the working requirements contravene India's obligations under the TRIPS Agreement (as well as the General Agreement on Tariffs and Trade and the WTO Agreement on Trade-related Investment Measures), which prohibit WTO members from discriminating based on whether products are imported or locally produced. Moreover, India's use of CLs in these circumstances distorts provisions that were intended to be used in limited circumstances into tools of industrial policy. We further believe that resort to CLs is not a sustainable or effective way to address healthcare needs. Voluntary arrangements independently undertaken by our member companies can better ensure that current and future patients have access to innovative medicines. Statements from the Government incorrectly imply that CLs are widely used by other governments, both developed and developing.⁵⁰ These are misunderstandings and do not justify widespread use of compulsory licensing.

At a minimum, India should ensure that the CL provisions comply with TRIPS. India should also clarify that importation satisfies the "working" requirement, pursuant to TRIPS Article 27.1.

Unnecessarily Burdensome Patent Application Requirements

Section 8 of the Patents Act, as interpreted by recent jurisprudence, sets forth overly burdensome requirements that effectively target foreign patent applicants in a discriminatory manner. Section 8(1) requires patent applicants to notify the Controller and "keep the Controller informed in writing" of the "detailed particulars" of patent applications for the "same or substantially the same invention" filed outside of India. Section 8(2) requires a patent applicant in India to furnish details to the Indian Controller about the processing of those same foreign patent applications if that information is

⁵⁰ See <https://www.indianembassy.org/prdetail2164/note-on-indiaandrsquo%3Bs-intellectual-property-regime> and <http://thehill.com/blogs/congress-blog/campaign/316883-india-honors--not-dishonors--patent-laws>. These allegations of wide-spread use of CLs in the U.S. and the premise that CLs can resolve access problems in India have been refuted by OPPI and PhRMA.

requested. These additional patent application processing requirements have been interpreted in a manner that creates heightened and unduly burdensome patent application procedures that target foreign patent applicants – those most likely to have patent applications pending in other jurisdictions.

Moreover, the remedy for failure to comply with Sections 8(1) and 8(2) is extreme compared to other countries with similar (but less onerous) administrative requirements. In India, the failure to disclose under Section 8 can be treated as a strict liability offense that by itself can invalidate a patent. This is in contrast to a requirement that the failure to disclose be material and/or intentional as in the U.S. or Israel. Thus, India's disclosure requirement and remedy are each more burdensome as compared to other jurisdictions, thereby creating a barrier to patentability that has an unfairly greater effect on foreign patent applicants, and, in some instances resulted in India revoking patents on the grounds of non-compliance with this particular provision.⁵¹

Patent Enforcement and Regulatory Approval

Indian law permits state drug regulatory authorities to grant marketing approval for a generic version of a medicine four years after the original product was first approved. State regulatory authorities are not required to verify or consider the remaining term of the patent on the original product. Therefore, an infringer can obtain marketing authorization from the government for a generic version of an on-patent drug, forcing the patent holder to seek redress in India's court system. India should close this regulatory loophole in order to provide effective patent protection and enforcement for pharmaceutical patent holders.

Moreover, India does not provide mechanisms for resolution of patent disputes prior to marketing approval of third party products. Such mechanisms are needed to prevent the marketing of patent infringing products. There is a pending bill in the Indian Parliament that would establish fast-track IP Courts and assist in addressing disputes. To ensure proper patent enforcement, the U.S. Government should urge the Indian Government to implement such mechanisms as part of greater efforts to create an environment that supports innovation.

Lack of Regulatory Data Protection

TRIPS Article 39.3 requires India to provide protection for certain pharmaceutical test and other data, but India has not yet done so. India conditions the approval of pharmaceutical products on the prior approval by a Regulatory Authority in another country rather than requiring submission of the entire dossier for review by its Regulatory Authority. An applicant in India needs only to prove that the drug has been approved and marketed in another country and submit confirmatory test and other data from clinical studies on a very few (in some cases as few as 16) Indian patients.

⁵¹ See, e.g., *Ajantha Pharma Limited v. Allergan*, Intellectual Property Appellate Board (2013).

By linking approval in other countries that require the submission of confidential test and other data to its own drug approval process, India, in effect, uses those countries as its agents. Thus, India relies on test data submitted by originators to another country. This indirect reliance results in unfair commercial use prohibited by TRIPS Article 39.3.

Market Access Barriers

Government Price Controls

PhRMA's members are extremely concerned about the general lack of access to health care in India. For a country of over one billion with significant healthcare issues, the Indian Government spends only 1.2% of GDP on healthcare.⁵² India has an insufficient numbers of qualified healthcare personnel, inadequate and poorly equipped healthcare facilities, and most importantly lacks a comprehensive system of healthcare financing which would pool financial risk through insurance and help to share the cost burdens.⁵³ 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.⁵⁴ Despite decades of government price controls in India, the objective of which has been to improve access to medicines, essential medicines are still not easily accessible; for example, essential medicines may only be available at government pharmacies 20 percent of the time.⁵⁵

Expansion of price controls to a larger range of medicines will not substantially improve access to medicines in India because lack of access is more a function of insufficient healthcare financing systems and inadequate healthcare facilities.⁵⁶ For example, medicines and vaccines which are offered free of charge often do not reach the patients who need these medicines.⁵⁷ Further, a considerable body of evidence demonstrates that price controls contribute to lower investment in pharmaceutical

⁵² High Level Expert Group (HLEG) Report on Universal Healthcare Coverage for India, Instituted by Planning Commission of India, November 2011.

⁵³ "Health Systems Financing: The Path to Universal Coverage," *The World Health Report*, World Health Organization, 2010.

⁵⁴ Analysis based on IMS MIDAS Data.

⁵⁵ "Health workforce, infrastructure, essential medicines", World Health Statistics 2013, The World Health Organization.

⁵⁶ "A Study of Healthcare Accessibility," Dr. DY Patil Medical College, Pune, India, prepared for India Health Progress, Mar. 2011. Wagstaff, Adam, "Health System Innovation in India Part I: India's health system challenges," *available at* <http://blogs.worldbank.org/developmenttalk/health-system-innovation-in-india-part-i-india-s-health-system-challenges> (last visited Oct. 3, 2013).

⁵⁷ "India Turns to Mobile Phones in Bid to Improve Vaccination Rate," *India Real Time/Wall Street Journal*, Aug. 4, 2011. Patra, Nilanjan, "When Will They Ever Learn?": The Great Indian Experience of Universal Immunisation Programme", Dec. 2009, *available at* http://www.isid.ac.in/~pu/conference/dec_09_conf/Papers/NilanjanPatra.pdf (last visited Oct. 3, 2013).

research and development, ultimately harming patients who are in need of improved therapies.⁵⁸

The Department of Pharmaceuticals (DoP) Committee on Price Negotiation for Patented Drugs released a report in February 2013 which recommends an international reference pricing scheme with a purchasing power parity adjustment for government procured patented medicines, those patented medicines provided through health insurance. The Committee is also considering whether the price negotiation of a patented medicine should be linked with its marketing approval. PhRMA members are highly concerned that this proposal represents an effort to significantly reduce the benefits of patent protection, will discriminate against importers of patented drug products, and will create an unviable government pricing framework and business environment.

Last year, the DoP notified and began implementing the Drug Price Control Order (DPCO) 2013, which sets ceiling prices for 348 essential medicines by taking the simple average of all drugs with a market share of 1% or more. PhRMA advocated for a market-based policy, rather than a cost-based policy, in order to balance the need for affordability and industry competitiveness. The DPCO has faced ongoing challenges by NGOs before the Supreme Court, which has been monitoring the Government's progress through public interest litigation, as well as questions about accuracy of ceiling price calculations. Finally, the DPCO 2013 also includes Section 32 that exempts from the pricing formula, for a period of five years, new medicines developed through indigenous research and development that obtain a product patent, are produced through a new process, or involve a new delivery system. This section creates an unlevel playing field that favors local Indian companies and discriminates against foreign pharmaceutical companies.

PhRMA members believe that competitive market conditions are the most efficient way of allocating resources and rewarding innovation; however, the research-based pharmaceutical industry recognizes the unique circumstances in India and is committed to engaging with the Government to discuss pragmatic public policy approaches that will enable the development of simple and transparent government pricing and reimbursement mechanisms that provide access to medicines, reward innovation, include the patient perspective, and encourage continued investment into unmet medical needs.

Foreign Direct Investment (FDI) in Pharmaceutical Sector

The Indian government recently decided that the current policy in brownfield and greenfield projects in the pharmaceutical sector will continue, subject to the additional condition that in all cases of FDI in brownfield pharmaceutical projects, non-compete clauses will not be permitted in any of the agreements. Per this policy, outright

⁵⁸ "Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation," U.S. Dept. of Commerce, Int'l Trade Administration, Dec. 2004. Vernon, John, "Drug Research and Price Controls," *Regulation*, Winter 2002-2003.

purchases of brownfield projects require prior approval from the Foreign Investment Promotion Board. The new restrictions on the use of non-compete clauses have the potential to significantly undermine FDI in brownfield investments, given that without such clauses a local company may sell its business to a foreign investor only to use its knowledge, expertise and former goodwill (on which such sales are typically predicated) to immediately compete with the foreign investor. In short, these ongoing changes lead to an atmosphere of uncertainty for potential investors.

Clinical Trials

New clinical trials were halted after the Indian Ministry of Health and Family Welfare adopted rules that require broader compensation for participants who claim to have been injured due to a clinical trial. The tougher regulations, coming in response to public protests over reported deaths in clinical trials last year, have stopped or delayed a number of studies. The Indian government and Supreme Court had begun a process working with trial sponsors to modify the rules. The Court previously held that, rather than the Drug Controller, the Secretary of Health shall be accountable for the approval of all clinical trials related to Investigational New Drugs (IND), which had caused a significant decline in the number of approved trials. In response to public interest litigation, the Indian Supreme Court instituted a full moratorium on clinical trials, asking the Ministry of Health to justify its recent approvals and put forward an appropriate framework for approval of clinical trials.⁵⁹ In November, the Drug Controller General of India (DCGI) ordered that, in addition to obtaining written informed consent, audio-visual recording of the consent of each subject is mandatory in a clinical trial and effective immediately.⁶⁰ Such uncertainty in the regulatory process for clinical trials threatens the overall clinical research environment in India, as well as the availability of new treatments and vaccines for Indian patents.

Import Policies

Despite the stated intention by the Government to lower pharmaceutical duties, PhRMA member companies operating in India face high effective import duties for active ingredients and finished products. Though the basic import duties for pharmaceutical products average about 10 percent, additional duties commensurate with the excise duty applicable on the same or similar product, even when there is no such product manufactured in India, as well as other assessments, bring the effective import duty to approximately 20 percent. In fact, India collects more in taxation on pharmaceuticals than it spends on medicines. Broad analysis for 2011 indicates total annual Government expenditure on drugs in India around \$1.15B⁶¹ in comparison to the

⁵⁹ See "Ministry prepares response to Supreme Court on clinical trials," available at <http://www.livemint.com/Politics/VDBSdlqVHPd92OtTQ6Nx8I/Ministryprepares-response-to-SC-query-on-clinical-trial.html>.

⁶⁰ See "Videorecording of consent for clinical trials mandatory", available at <http://www.thehindu.com/sci-tech/health/videorecording-of-consent-for-clinical-trials-mandatory/article5380622.ece> (last visited Jan. 26, 2014).

⁶¹ High Level Expert Group (HLEG) report on Universal Healthcare Coverage for India 2011, Instituted by Planning Commission of India.

\$1.22B⁶² it receives in taxation of pharmaceuticals. Moreover, excessive duties on the reagents and equipment imported for use in research and development and manufacture of biotech products make biotech operations difficult to sustain. Compared to the other Asian countries in similar stages of development, import duties in India are very high.

Counterfeit Medicines

India is a major channel for the export of counterfeits to consumers worldwide. In cases where counterfeit pharmaceutical products bear a deceptive mark, civil and criminal remedies are available under India's trademark statute. However, the effectiveness of such remedies is undermined by judicial delays and, in criminal cases, extremely low rates of conviction.

Beyond these trademark-related deficiencies, weaknesses in India's drug regulatory regime can contribute to the proliferation of counterfeit pharmaceuticals and their global export. Even though pharmaceutical counterfeiting is first and foremost a drug safety violation, India has yet to enact drug laws that expressly address all aspects of drug counterfeiting, or to provide the kind of remedies and enforcement resources necessary to combat this growing problem. In India, criminal liability appears to be conditioned upon proof of adulteration or harm. This burdensome evidentiary requirement not only precludes criminal prosecution of many counterfeiters, it fails to acknowledge the inherent dangers of any deceptively mislabeled drug. Anti-counterfeiting enforcement is further undermined by poor interagency coordination and India's failure to provide administrative remedies for drug safety violations.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

⁶² 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, HLEG report on Universal Healthcare Coverage for India 2011.

TURKEY

PhRMA and its member companies face several market access barriers in Turkey, including discriminatory and unworkable government product registration, reimbursement and pricing systems, and deficiencies in Turkey's intellectual property framework.

During the last decade, Turkey has undertaken reforms to modernize its economy and expand its health care system in many positive ways for Turkish patients. A general lack of transparency and inconsistency in decision-making, however, has contributed to unclear policies that undermine Turkey's investment climate and damage market access for PhRMA member companies.

While PhRMA and its member companies appreciate the increased dialogue that exists between the Turkish Government and the innovative pharmaceutical industry in Turkey, still more attention needs to be paid to the link between the short-term impact of Turkish government policies and the ability of research-based pharmaceutical companies to continue producing new medicines and invest in this sector.

Key Issues of Concern:

- **Intellectual property protections:** Patents and data protection relating to pharmaceuticals have been officially recognized in Turkey since 1995 and 2005, respectively, but there remain significant areas needing regulatory and legislative improvement. Turkey does not provide an effective mechanism for resolving patent disputes before the marketing of follow-on products and concerns remain with the current draft revision to the patent law. Further, Turkey inappropriately ties the regulatory data protection period (RDP) to the patent term and the lack of RDP for combination products is still an unresolved issue. Finally, the combination of an RDP term that starts with first marketing authorization in the European Union and regulatory approvals delays results in a severe restriction on the actual period of RDP provided.
- **Delayed regulatory approvals:** The period required to complete the regulatory approval process for medicinal products significantly exceeds the 210 days stated in the regulations.
- **Local inspection requirements:** Lack of resources and the absence of reasonable transitional procedures at the Ministry of Health (MOH) to conduct Good Manufacturing Practices (GMP) inspections at every pharmaceutical production facility are adding to the significant registration delays, thereby delaying patient access to innovative medicines and negating the benefits of the patent and data protection period.
- **Government price controls:** The Turkish Government established unrealistic pharmaceutical budgets for 2010-12 by insisting on the budget figures projected

in 2009 and not updating the budget to reflect the healthcare system's actual needs and economic growth. The outdated budget figures disregarded parameters such as economic growth, inflation and exchange rate fluctuations, and resulted in forced price discounts at unsustainable levels that hinder access to innovative medicines. Moreover, despite the rapidly growing demand for innovative healthcare products and services, Turkey continues to impose unrealistic budget expenditures for pharmaceuticals in 2014, without releasing any of the existing burdens caused by draconian price discounts and exchange rate fluctuations.

For these reasons, PhRMA requests that Turkey be designated a **Priority Foreign Country** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Effective Patent Enforcement

Turkey does not provide an effective mechanism for resolving patent infringement matters. The Decree Law, currently in force, has some protective terms in favor of the patent holder; however in practice the IP Courts interpretation is quite narrow. For example, while the purpose of the Decree Law was to bring Turkish patent law into consistency with the European Patent Convention (EPC) and the Patent Cooperation Treaty (PCT), the manner in which Turkey's IP Courts interpret the Decree defeat that intent.

Draft Law, numbered 1/756 proposes amendments on the Decree Law concerning Protection of Patent Rights ("Patent Decree"). While the proposed Bill would rectify a number of the industry's concerns regarding the manner in which Turkey's IP Courts interpret the existing Patent Decree, other provisions raise concerns under the Turkish Constitution, the European Human Rights Convention, EPC, PCT and TRIPS. For example, the proposed decrease on the upper limit of the judicial fine for the crime of infringement makes infringement more attractive by reducing the deterrent. Similarly, the proposed deletion of the provision which gives the applicant for a patent some rights to bring proceedings (particularly important for Turkish national route patents where there is a pre-grant opposition period that can be used abusively absent this provision) would weaken the existing level of patent protection. PhRMA and its member companies will continue to monitor the Bill as it moves through Parliament, likely later this year.

Regulatory Data Protection

In 2005, the Turkish Government took positive steps toward establishing protection for the commercially valuable regulatory data generated by innovative pharmaceutical companies, and now provides regulatory data protection for a period of

six years for products registered in the EU, limited by the patent protection period of the product. Regulatory data protection is an independent and separate form of intellectual property protection that should not be limited to the period of patent protection.

A significant concern for the innovative industry is that the period of regulatory data protection currently begins on the first date of marketing authorization in any country of the European Customs Union. Considering the extended regulatory approval times, with an average of 934 days⁶³ in Turkey, and with the delays stemming from the GMP certification approval period, current estimates are that it could take 4-5 years to register and reimburse a new medicine in Turkey. Under these adverse circumstances, new products will receive, in practice, no more than one to two years of protection, undermining incentives needed for innovators to undertake risky and expensive research. Regulatory approvals need to be granted by MOH within 210 days; if not, the six year period of regulatory data protection should commence when local regulatory approval for the product is obtained in Turkey.

Another concern of the innovative pharmaceutical industry is that the legislation governing regulatory data protection has been changed by the Regulation to Amend the Registration Regulation of Medicinal Products for Human Use.⁶⁴ The change that has been introduced is incompatible with EU standards in that it eliminates regulatory data protection for combination products, unless the combination product introduces a new indication. Innovative companies invest considerable amounts of time and effort to develop products that provide increased efficacy and safety, as well as new indications, from new combinations of separate molecules. Such products are developed to benefit patients and should be eligible for data protection.

Market Access Barriers

Pharmaceutical Product Registration

Marketing of new drugs in Turkey is governed by the regulatory procedures prescribed by the Pharmaceuticals and Medical Devices Agency of Turkey, MOH for the approval of medicinal products. The data and documents required to register medicinal products are listed in the MOH's Registration Regulation of Medicinal Products for Human Use.⁶⁵ Although the legislation requires the Turkish MOH to assess and authorize the registration of medicinal products within 210 days, surveys by the Association of Research-Based Pharmaceutical Companies (AIFD) indicate that the average regulatory approval period was 934 days in 2012, and for many applications exceeded 1000 days.⁶⁶

⁶³ AIFD Situation Assessment Survey of CTD Applications (Dec. 2012).

⁶⁴ Official Gazette No. 27208 (Apr. 22, 2009).

⁶⁵ Official Gazette No. 25705 (Jan. 19, 2005) (Registration Regulation).

⁶⁶ AIFD Situation Assessment Survey of CTD Applications (Dec. 2012).

The MOH's recent revisions to the Registration Regulation have compounded these delays.⁶⁷ Effective March 1, 2010, a Good Manufacturing Practices (GMP) certificate that is issued by the Turkish Ministry of Health must be submitted with each application to register a medicinal product for each of the facilities at which the product is manufactured. The GMP certificate can only be issued by MOH following an on-site inspection by Ministry staff, or by the competent authority of a country that recognizes the GMP certificates issued by the Turkish MOH. However, for the reasons explained further below, neither option can be completed in a timely manner.

In addition to the regulatory approval delays, many innovative products manufactured outside Turkey, including anti-infectives, antipsychotics, vaccines, cardiovascular, diabetes and oncology drugs, are currently awaiting GMP inspections. Indeed, as of April 2013, AIFD's members reported that GMP inspections were pending on 1,447 applications covering 939 products, requiring inspections at more than 350 overseas sites.⁶⁸ Despite increasing the number of inspectors at the end of 2013, the MOH still does not have adequate resources to complete these GMP inspections in a timely manner. It should be noted that there has not been any transitional mechanism to allow approval of pending applications while building up the adequate regulatory capabilities.

Furthermore, although the Amended Registration Regulation permits applicants to submit GMP certificates issued by competent authorities in other countries, it does so only to the extent that the pertinent country recognizes the GMP certificates issued by Turkey. There are, however, two significant hurdles to this mutual recognition arrangement: 1) Turkey is not a member of the PIC/S (Pharmaceutical Inspection Convention and Co-operation Scheme) that provides guidance on international GMP standards; and 2) Turkey will need to negotiate mutual recognition agreements with each participating country. In the meantime, registration of new medicinal products will be substantially delayed, which, in turn, hinders patients' access to innovative medicines. To avoid imposing this unnecessary non-tariff barrier to trade, Turkey, as a temporary measure, should revert to recognizing GMP certificates accepted by institutions like the FDA, EMA, or other PIC/S members for medicinal products. Such measures should remain in force until MOH either has the staff and resources necessary to conduct GMP inspections in a timely manner, or Turkey has entered into mutual recognition agreements with the United States and other key trading partners, a prospect that PhRMA recognizes may not occur in the short-term. In addition, despite statements that the Ministry of Health would begin GMP inspections in parallel with marketing authorization reviews for priority products, this has yet to occur.

⁶⁷ Regulation to Amend the Registration Regulation of Medicinal Products for Human Use, Official Gazette No. 27208 (Apr. 22, 2009) (Amended Registration Regulation); MOH, *Important Announcement Regarding GMP Certificates*, (Dec. 31, 2009) (establishing an implementation date for the GMP certification requirement).

⁶⁸ AIFD GMP Inspections Survey (Apr. 2013).

Government Price Controls and Reimbursement

In Turkey, pharmaceuticals' pricing is regulated by the MOH Pharmaceuticals and Medical Devices Agency of Turkey. The reimbursement system is based on a positive list and reimbursement decisions are the responsibility of the inter-ministerial Reimbursement Commission, led by the Social Security Institution (SSI). Reimbursement decision criteria are not clearly defined. The process is nontransparent and maintains lengthy timelines as a result of frequent delays in decision-making and erratic meeting schedules. On average, it takes over 390 days in reimbursement review for one product (from application for reimbursement to final decision).⁶⁹

As part of a number of austerity measures for dealing with the global economic crisis and managing the mid-term budget, the Turkish Government in December 2009 made a number of significant revisions to this pricing system.

- *Original products without generics:* In December 2009, Turkey imposed an additional 12 percent discount over the existing 11 percent discount. In December 2010 and November 2011, further discounts of 9.5 and 8.5 percent, respectively, increased the total social security discount for innovative products to 41 percent. Although the latter discounts were imposed ostensibly to meet short-term budget overruns in 2010-2011, those cuts were retained in Turkey's pharmaceutical budget for 2013-2015.
- *Original products with generics:* Turkey reduced prices for originals and generic products from 66 percent to 60 percent of the reference price (previously original products were at 100 percent and their generics were at 80 percent of the reference price). However, if the reference price decreases at some point in the future, no further price reductions are imposed until the reference price is equal to or below 60 percent of the original reference price. No similar relief is provided to original products without generics; if the reference price decreases at some point in the future, the SSI discounts (41 percent), as noted above, are applied on top of the reference price decrease. The pricing and reimbursement system should, at a minimum, be revised to address this inequity. For original and generic products in this category, additional discounts of 9.5 and 7.5 percent were also imposed as of December 2010 and November 2011 with a total SSI discount of up to 28 percent for this category of products.
- *Government pharmaceutical budget caps:* The 2010 Government pharmaceutical budget was set at 10 percent less than actual Government spending in 2009, but allowed for 7 percent growth per annum for 2011 and 2012. Based on an unofficial protocol reached between the Turkish Government and the pharmaceutical industry, additional price cuts would be implemented if the budget caps were exceeded. The protocol stipulated that the parties should avoid the need for *ad hoc* and unexpected implementations of therapeutic price

⁶⁹ AIFD Market Access Survey (Jul. 2012).

referencing. Further, the protocol stated that prices may be allowed to increase if the budget caps are not exceeded.

Any predictability that these revisions brought was short-lived. Prior to October 2010, the Turkish Government failed to share any data with industry on actual pharmaceutical spending, despite being required to do so under the protocol. In November 2010, Turkey abruptly requested 1.6 billion (Turkish Lira) in savings measures from the pharmaceutical industry to cover projected overruns for 2010 and 2011, continuing to put a major burden on innovative products. In order to cover these alleged overruns, the Turkish Government instituted another round of additional discounts (9.5 percent) on medicines in December 2010. Similarly, in November 2011, the Turkish Government instituted additional discounts (8.5 percent for originals without generics and 7.5 percent for originals with generics and generics) to cover the 2011 budget overrun (estimated to be 0.9 billion TL).

Furthermore, although spending on pharmaceuticals in 2012 was 0.85 billion TL less than budgeted, no steps have been taken to revoke any of the several rounds of price discounts that generated this surplus.

A global budget for 2013-2015 has not been established, but the pharmaceutical budget for 2013 was set at 15.7B TL. This budget is based on suppressed demand, due to the GMP restrictions, and government prices that are artificially low due to the fixed exchange rate system (discussed below). As a result, this funding level is far below the needs of the Turkish population and does not provide an adequate reward for innovation.

- *Fixed Exchange Rate for Pharmaceuticals:* In addition, in April 2009, the GOT fixed the Euro to Turkish Lira exchange rate, for pharmaceutical pricing purposes only, to 1 Euro to 1.9595 Turkish Liras and has not adjusted it since. Based on the most recent 90 day average, this is an additional discount of more than 53 percent. Between July 2011 and July 2013, the fixed exchange rate resulted in price cuts equivalent to approximately \$2.5B. The combined impact of the price cuts and fixed exchange rate is close to \$3.0 billion in lost sales revenue.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

SECTION 306
MONITORING

THE PEOPLE'S REPUBLIC OF CHINA

PhRMA and its member companies operating in The People's Republic of China remain concerned over barriers to market access such as intellectual property protection challenges, including lack of effective regulatory data protection and patent enforcement, lengthy clinical trial application approval timelines, restrictive government pricing policies, and lengthy reimbursement updates. Despite positive actions by Chinese authorities in 2013, counterfeiting of medicines continues to be rampant in China and under-regulated active pharmaceutical ingredients continue to enable the production of unsafe medicines by global counterfeiters. PhRMA is encouraged by China's announcement in January 2014 to officially begin working on the next amendment to the Drug Administration Law (DAL) as this will provide a critical opportunity to address many of the following issues of concern.

Key Issues of Concern:

- **Patent examination guidelines:** In December 2013, China changed its patent examination guideline to allow patent applicants to file additional biological data after filing their applications and confirmed that its patent examination guidelines would no longer be applied retroactively. PhRMA recognizes and welcomes this positive step and looks forward to meaningful implementation.
- **Regulatory data protection:** Although China committed as part of its accession to the World Trade Organization (WTO) to provide a 6-year period of protection against unfair commercial use for clinical test and other data submitted to secure approval of products containing a new chemical ingredient, in practice the protection has not been effective. PhRMA looks forward to meaningful implementation of China's commitment made during the 2012 meeting of the U.S.-China Joint Commission on Commerce and Trade (JCCT) related to regulatory data protection (RDP).
- **Effective patent enforcement:** Transparent mechanisms are needed in China to ensure that patent issues can be resolved before potentially infringing pharmaceutical products are launched on the market. Neither China's Drug Administration Law nor the Provisions for Drug Registration provide an effective mechanism for enforcing an innovator's patent rights vis-à-vis regulatory approval of follow-on products.
- **Clinical trial application approval:** Currently, clinical trial application (CTA) approval in China is much longer than international practice. Accelerating the CTA review timeline will improve the efficiency of global drug development and reduce the time it takes for innovative new medicines to reach patients.
- **Government pricing and reimbursement:** The lengthy process for updating the National Reimbursement Drug List (NRDL) delays market access to innovative pharmaceuticals and prevents their timely availability to patients. In addition,

government pricing policies and procedures being considered by the Government of China could create an unfavorable business environment, further reduce reward for innovation, restrict patient access to quality medicines and undermine China's healthcare and innovation policy objectives.

- **Counterfeit medicines:** China has been implementing national plans to improve drug safety and severely crack down on the production and sale of counterfeit medicines, resulting in several positive and tangible actions on the enforcement front. However, the production, distribution and sale of counterfeit medicines and unregulated APIs remain rampant in China and continue to pose a threat to China and its trading partners. China's continued commitment and perseverance (and cooperation with its trading partners and industry) will be necessary to fulfill the declared objectives on drug safety and anti-counterfeiting.

For these reasons, PhRMA requests that China be subject to **Section 306 Monitoring** for the 2014 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Patent Examination Guidelines

In December 2013, China changed its patent examination guidelines regarding technical patent disclosure requirements for pharmaceutical compounds to allow patent applicants to file additional biological data after filing their applications. China also confirmed that its patent examination guidelines would no longer be applied retroactively. PhRMA applauds the progress made during Vice-President Biden's visit and through the U.S.-China JCCT. However, cases involving challenges to patents for drugs from applications filed prior to 2006 are still being successfully opposed with apparently retroactively applied standards. To ensure meaningful implementation of this commitment, China should also reinstate patent applications that were adversely affected prior to this recent change in practice.

Pursuant to the prior guideline (2006), the State Intellectual Property Office (SIPO) had been requiring a significant amount of biological data to support pharmaceutical patent applications submitted pursuant to Article 26.3 of China's patent law. This requirement to disclose experimental data at the time of filing has placed a much larger burden on companies than faced in the other IP5 Member States (i.e., the United States, the EU, Japan and Korea). Moreover, in contrast with the practices of the U.S. Patent and Trademark Office, Japan Patent Office, and European Patent Office, as well as the standard provided by the Patent Cooperation Treaty (PCT),⁷⁰ of which China is a member, SIPO would not accept data submitted during patent prosecution. The adoption and implementation of this 2006 guideline caused concerns about the validity

⁷⁰ Patent Cooperation Treaty, 28 U.S.T. 7645 (1970), Art. 28.

of existing patents granted prior to 2006 and caused denials of patents to medicines that had received patents in other jurisdictions.

Regulatory Data Protection

As part of its accession to the WTO in 2001, China committed to provide a six year period of regulatory data protection (RDP) for undisclosed test or other data submitted to obtain marketing approval for pharmaceuticals in accordance with Article 39.3 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).⁷¹ Article 39.3 provides that a country must protect data submitted in the context of a drug registration application from unfair commercial use. Indeed, China's Implementation Regulation of the Drug Administration Law (DAL) and Provisions for Drug Registration, administered by the China Food and Drug Administration (CFDA), establish a six-year period of protection for clinical test and other data of products containing a new chemical ingredient against unfair commercial use.⁷² Yet the law in application is ambiguous, inconsistent, and unevenly applied. As a result, China's regulatory environment allows for unfair commercial use of safety and efficacy data generated by PhRMA member companies.

China's RDP system in practice is inconsistent with TRIPS Article 39.3 in several ways. First, certain key concepts such as "new chemical ingredient" and "unfair commercial use" are undefined. This leads to the inconsistent and arbitrary application of the law by CFDA, in addition to confusion and uncertainty for sponsors of marketing approval applications.

Second, regulatory data protection (RDP) should be granted to any product that is "new" to China, i.e., have not been approved by CFDA. In practice, however, China grants RDP only to pharmaceutical products that are "new" to the world – in other words, products that make their international debut in China. That is at odds with the approach of other regulatory systems and even at odds with the approach taken in China for RDP for agricultural chemicals. In the 2012 U.S.-China Joint Commission on Commerce and Trade, China committed to define new chemical ingredient (referred to as "new chemical entity" in that commitment) in a manner that is consistent with international research and development practice. Unfortunately, this commitment was not fulfilled in 2013. PhRMA looks forward to working with China to achieve meaningful RDP in 2014.

Third, China's regulatory procedures permit non-originator, or follow-on, applicants to rely on a foreign regulatory agency's approval of the originator product in another market during the RDP term in China. This practice gives an unfair commercial advantage to the follow-on manufacturer by permitting it to rely on the full clinical data submitted by an innovator to a foreign regulatory agency – which the follow-on

⁷¹ Report of the Working Party on the Accession of China to the World Trade Organization, WT/MIN(01)/3 (Nov. 10, 2001), at para. 284.

⁷² See Regulations for Implementation of the Drug Administration Law of the People's Republic of China, Art. 35; Provisions for Drug Registration (SFDA Order No. 28), Art. 20.

manufacturer did not incur the costs to produce – while having to submit only a small amount of China-specific supplemental data to CFDA. CFDA should not approve follow-on drugs during the RDP period unless the follow-on applicant submits full clinical trial data that it has independently developed or received a license to cross-reference from the innovative drug manufacturer. This approach would be consistent with the goals of encouraging innovation in China.

Effective Patent Enforcement

If a follow-on company actually begins to market a drug that infringes the innovator's patents, the damage to the innovator may be irreparable even if it later wins its patent litigation. This could undermine the goal of encouraging innovation in China. Transparent mechanisms are therefore needed in China to ensure that patent issues can be resolved before potentially infringing pharmaceutical products are launched on the market. Article 19 of CFDA's Provisions for Drug Registration refers to recognition of patents associated with drug registration, and a maximum "two-year" period for submitting a registration application for a follow-on product before the underlying patent expires.⁷³ The Provisions for Drug Registration do not provide, however, an effective mechanism for enforcing an innovator's patent rights vis-à-vis regulatory approval of follow-on products.

PhRMA and its member companies are very concerned by a recently proposed amendment to CFDA's Provisions on Drug Registration that would eliminate Article 19, thereby abolishing China's only existing protection against marketing approval for patent-infringing products and seriously undermining incentives for biopharmaceutical innovation in China. CFDA's proposed amendment is inconsistent with China's innovation policy for the pharmaceutical industry.

The current Provisions for Drug Registration do not explicitly address the circumstances and processes through which disputes over the patents will be resolved prior to market entry by follow-on products. The regulation states that if an infringement dispute occurs during the application period, it "shall be settled in accordance with relevant laws and regulations on patent."⁷⁴ However, the patent laws require there to be sales in the marketplace before an infringement suit can be filed. In addition, the "Bolar exemption" provision in the Third Amendment of the Patent Law exempts any production of patented products from infringement as long as it is "for the purpose of providing information required for administrative examination and approval."⁷⁵ As a result, PhRMA member companies have not been able to consistently resolve patent disputes prior to marketing approval being granted to infringing products, leading to injury that is rarely compensable.

To avoid the unnecessary costs and time of litigating damages claims in patent litigation, and to increase market predictability, China should to institute mechanisms

⁷³ Provisions for Drug Registration (SFDA Order No. 28), Arts. 18 and 19.

⁷⁴ Id., Art. 18.

⁷⁵ Patent Law of the People's Republic of China (2008), Art. 69(5).

that ensure the originator manufacturer is notified of relevant information within a set period of time when a follow-on manufacturer's application is filed. China should also enable patent holders to file patent infringement suits before marketing authorization is granted for follow-on products and afford sufficient time for such disputes to be resolved before marketing occurs. This might include a form of automatic postponement of drug registration approval, either pending resolution of the patent dispute or for a fixed period of time.

In addition, although China's laws and regulations provide for injunctive relief, in practice injunctions are rarely, if ever, granted in the context of preventing premature generic market entry. Chinese proceedings set the bar impractically high regarding the criteria that should be met before an injunction is granted, therefore limiting this procedure as an effective enforcement tool in China even though injunctive relief would very likely be available on the same set of facts in other jurisdictions.

Market Access Barriers

Government Pricing Policies

China committed, as part of its WTO accession, to applying price controls in a WTO-consistent fashion, taking into account the interests of exporting WTO members, and without having the effect of limiting or impairing China's market access commitments on goods and services.⁷⁶ Notwithstanding that commitment, PhRMA is concerned that government pricing policies being considered by the Government of China could create an unfavorable business environment, further reduce reward for innovation, restrict patient access to quality medicines and undermine China's healthcare and innovation policy objectives. As pharmaceutical products in China are subject to government price control, PhRMA encourages the Chinese Government to engage innovative pharmaceutical companies to evaluate and implement an appropriate government pricing policy that recognizes quality-systems, innovation, and the value that our member companies' products bring to patients and China.

China's Reimbursement List

Over the past ten years, the Government of China has only undertaken two substantive updates (2004 and 2009) to its National Reimbursement Drug List (NRDL). The lengthy process for updating the NRDL (approximately 3-4 years) delays market access to innovative pharmaceuticals and prevents their timely availability to patients who need them. PhRMA encourages more frequent updates of the NRDL to ensure Chinese patients are better able to access these important products.

⁷⁶ Report of the Working Party on the Accession of China to the World Trade Organization, WT/MIN(01)/3 (Nov. 10, 2001), at para. 64.

Clinical Trial Application Approval

Over the last few years, the CFDA has made significant strides to increase efficiency and transparency. Additionally, the Center for Drug Evaluation (CDE) is undertaking a series of initiatives to encourage innovation, including developing detailed approval pathways and enhancing regulation of clinical trials.

To help China further integrate into the global innovation network, China should harmonize its regulatory framework with international regulatory standards and practices and strengthen its clinical infrastructure. Specifically, steps should be taken to shorten the CTA review process timeline. Currently, CTA approval in China is much longer than international practice. This is a significant barrier to global drug development and accelerating the CTA review timeline will improve the efficiency of drug development and reduce the time it takes for innovative new medicines to reach patients. Underlying the CTA delay is a misalignment between CFDA human resource capacity and growing industry innovation activities. In addition, the CTA amendment process is not aligned with international practices. While many countries accept CTA amendments after initial submission, changes in clinical trial protocols in China often require new CTA submissions, leading to a duplication of work for both companies and regulators. In order to further improve the regulatory environment in China, PhRMA recommends that the CFDA develop a more supportive regulatory framework that fosters innovation and that is in line with international best practices.

In addition, recent trends suggest CFDA has implemented new practices regarding the acceptance of data from multi-regional clinical trials (MRCT). Specifically, CFDA has rejected a number of recent import drug licensing (IDL) applications for products with non-pivotal MRCT studies. CFDA is also said to limit the use of MRCT data to support approval of new drug applications (NDA). These trends appear to primarily impact registration of biologic medicines, but might also have an impact on development of small molecule medicines. These trends, should they continue, would have a negative impact on innovation and slow the access of medicines to patients in China. Such actions represent a significant barrier to promoting trade with China and improving the health of Chinese people.

China's Essential Drugs Policy

PhRMA strongly supports China's development of essential drugs policy aimed at making pharmaceuticals available to the underserved populations across China. It is critical that China's essential drugs policy is consistent with international principles, and that the mechanism that the Central and Provincial governments put in place to procure and administer the products on the Essential Drugs List is transparent, predictable, includes provisions for appeal, and is not based solely on the cost of products, but recognizes their quality and relative value. Such a system will ensure that safe and efficacious essential medicines are available to the patients who need them most, within a broad sustainable healthcare system.

Counterfeit Medicines

Pharmaceutical counterfeiting poses global public health risks, exacerbated by rapid growth of online sales and the production and sale of unregulated active pharmaceutical ingredients (API) used to manufacture counterfeit products. China has been stepping up enforcement efforts against counterfeited drugs in recent years, both through legislative reforms and increased police activity at the provincial and local levels. In particular, China has been implementing national plans to improve drug safety and severely crack down on the production and sale of counterfeit medicines, resulting in several positive and tangible actions on the enforcement front. However, online distribution of counterfeit medicines and unregulated APIs remain the most serious challenges in China.

In 2013, China continued to coordinate joint special enforcement campaigns targeting counterfeit drugs, resulting in more raids of criminal manufacturing sites, seizures of mass quantities of counterfeit drugs (across therapeutic categories), arrests, and some prosecutions that help to send a clear message of deterrence to criminal counterfeiters.⁷⁷ We applaud China for continuing the pressure as criminal counterfeiters have started to industrialize their manufacturing and sales of fake drugs operations and increase utilization of the Internet.⁷⁸

The CFDA also announced the implementation of some other measures such as placing electronic drug monitoring codes (EDMC) on essential drugs that will allow authorities and consumers to trace legitimate products and verify that the drug in question originated with a registered manufacturer. The effectiveness of this new system remains to be seen as approximately 70% of drugs still lack electronic monitoring codes, and it is not yet clear if the system can be easily circumvented by counterfeiters. However, the EDMC system represents a significant step forward in securing China's legitimate drug supply and it should help their efforts to combat the distribution of illegitimate products. As such, the central government should continue to reward and promote law enforcement efforts in this area, including at the provincial and local levels, and to enhance the integrity of their national drug supply chain through the ongoing work to serialize and trace legitimate pharmaceutical products.

⁷⁷ See, e.g., "2,000 Arrested in China in Counterfeit Drug Crackdown," http://www.nytimes.com/2012/08/06/world/asia/2000-arrested-in-china-in-crackdown-on-counterfeit-drugs.html?_r=0 (Aug. 5, 2012) (last visited Jan. 28, 2014); "China Detains 1,300 People Suspected of Making and Selling Counterfeit Drugs," http://www.huffingtonpost.com/2013/12/16/counterfeit-drugs-china-medicine_n_4447483.html (Dec. 15, 2013) (last visited Jan. 28, 2014).

⁷⁸ The special action campaign that ran in the last half of 2013 focused on monitoring drug factories, the Chinese traditional medicine market, clinics, and Internet sites. It also promoted drug safety standardization and systemization. Since July 2013, the Ministry of Public Safety has eliminated more than 400 gangs, shut down more than 140 illegal websites and online shops, and arrested more than 1,300 suspects. The MPS has also seized counterfeit drugs amounting to a value of RMB 2.2 billion during the course of their campaign. Ministry of Public Safety Fought against the Online Sale of Drugs and Arrested 1,300 Suspects, available at: <http://news.qq.com/a/20131218/013137.htm> (last visited Jan. 21, 2014).

It also appears that China is beginning to spend more efforts tackling the sale of counterfeits on the Internet. PhRMA welcomes the recent launch by CFDA of a 5-month crackdown campaign against illegal online sales of drugs. The campaign, led by CFDA and the State Information Office, but including collaboration of several ministries and offices, represents positive steps to take action against counterfeit drug producers and suppliers doing business via the Internet. Notably, China is beginning to use high-level offices such as the State Information Office to promote effective coordination between several different agencies to monitor and shut down illegal drug websites. Reportedly, the government also demands major search engines to filter out fake drug posts, which is a significant partnership with the private sector aimed at protecting Chinese patients.⁷⁹ PhRMA hopes that the U.S. Government will work with China to increase transparency of such campaigns and evaluate the effectiveness of these online actions. China's actions in this arena could serve as a model for other countries facing similar challenges online.

Notably, cooperation between the U.S. FDA and China resulted in successful operations to shut down Internet sites that were exporting from China into the United States. PhRMA encourages China and the U.S. Government to continue and increase further their cooperation related to counterfeit medicines sold on the Internet, given the role of the Internet in the global counterfeit drug trade. This cooperation can serve as a best practice for other bilateral and multilateral efforts to reduce the global counterfeit drug trade. Cooperation between the U.S. and Chinese custom authorities could further enhance our governments shared goals to increase drug safety and crack down on the import and export of counterfeit products and unregulated APIs between our respective economies.

Despite these positive steps, a remaining challenge related to counterfeit medicines in China is the use and regulation of bulk chemicals or Active Pharmaceutical Ingredients (API).⁸⁰ Profit margins for counterfeiting drugs may run as high as over a thousand times more than the profits from drug trafficking. While China has strict qualification requirements for the pharmaceutical industry, in many cases, the raw materials for counterfeit drugs actually come from chemical plants. Many local chemical companies violate CFDA requirements by producing bulk chemicals without registration, then advertising and selling them as "Active Pharmaceutical Ingredients" to counterfeiters for illegal medicinal uses. China views drug manufacturers as having primary responsibility for drug quality and encourages all companies to purchase API

⁷⁹ Reportedly, search engines have been required to ensure that qualified websites are listed earlier in the search results, to conduct active searches for illegal online drug sales, to delete false and illegal medical advertising, and to report unqualified websites to the National Internet Information Office and the CFDA. In response, several Internet companies have stepped in to support the fight against counterfeit drugs. One of the most prominent companies, 360, introduced several products to provide users with accurate information on medicines and block false medical information websites, claiming that such sites accounted for 7.9% of all blocked websites or approximately 40,606 websites.

⁸⁰ In February 2013, Chinese press widely reported on the comment of World Anti-Doping Agency director general David Howman, who told reporters that "99 percent of the raw materials that are used through the Internet to make up in your kitchen or your backyard laboratory are emanating from China http://www.chinadaily.com.cn/sports/2013-02/19/content_16236168.htm (last visited Jan. 21, 2014).

only from the CFDA's approved and registered list of API manufacturers. Under current pharmaceutical regulations, chemical companies need only "self-report" if they are producing raw materials for pharmaceutical drugs, and there is no way to supervise companies that do not report pharmaceutical production, thereby creating a major regulatory loop-hole that impacts negatively on the security of China's upstream drug supply chain. One worrying trend has been the increasing number of pharmaceutical production companies deliberately using illegal or inferior APIs. The unregulated distribution of API by unregistered or unapproved manufacturers contributes to the global supply of counterfeit medicines, herbal supplements containing API, and counterfeit traditional Chinese medicines. As such, the ability of unregistered companies to sell API within and from China exposes patients globally to serious health risks and may degrade consumer confidence in the global medicinal supply chain.

China has committed publicly that it aims to address this issue and improve the regulation of API in a way that will reduce counterfeiting. In January 2013, CFDA announced a plan to survey all API producers in China to assess their compliance with recent EU API directives (2011/62/EU).⁸¹ PhRMA believes that China can address unregulated API as part of its stated drug safety objectives in the 12th five-year plan. To effectively reduce the risks caused by unregulated API to patient health, a multi-prong approach or "road map" is needed. While CFDA plays a critical role in developing future solutions, any significant reform plan will require coordination and consultation among all relevant ministries within the central government. Chinese law enforcement and regulatory authorities should be encouraged to focus their investigative and special campaign efforts on the suppliers to counterfeit drug manufacturers and specifically the unregulated API manufacturers in addition to finished pharmaceutical product producers. By focusing on API manufacturers, it may be possible to curb the development of unregulated medicines early on in the supply chain and to eliminate the quantity of substandard and counterfeit drug products circulating in the global supply chain. Targeted measures may include amending the Criminal Code to ease the burden of proof to prosecute brokers or API suppliers who knowingly deal with illegal APIs; empowering CFDA to regulate any party that manufactures API even if that party has not declared an intent to do so; empowering CFDA to penalize factors based on *prima facie* evidence of a product as having medicinal use or being an "API" or a "chemical drug substance" without cGMP certification; amending the DAL to require adherence to ICH Q7A (*Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients*) with meaningful penalties for failure to do so; and deepening cooperation with major Internet Service Providers, portal sites, and search engines for earlier identification and tracking of illegitimate API suppliers through B2B websites. These efforts to crack down on unregulated APIs must go hand-in-hand with China's current campaign against counterfeit drugs in order to enhance the effectiveness of their national drug safety plan objectives.

Finally, while we commend China for improvements in customs regulations, which include monitoring and seizure of imports and exports, Chinese Customs

⁸¹ See the public announcement by CFDA: <http://www.sfda.gov.cn/WS01/CL0050/77782.html> (in Chinese).

authorities rarely exercise their authority to monitor biopharmaceutical exports. Accordingly, PhRMA believes that more resources and support should be targeted to monitoring biopharmaceutical and chemical exports to ramp up efforts against counterfeiting and unregulated API producers.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

PRIORITY WATCH LIST

ASIA-PACIFIC

INDONESIA

PhRMA and its member companies operating in Indonesia remain concerned with the country's limited anti-counterfeiting enforcement efforts as well as discriminatory market access barriers. These barriers stem from the lack of legislative and regulatory transparency and advance consultation. As a result, PhRMA's member companies continue to face severe and emerging market access constraints.

Key Issues of Concern:

- **Compulsory licensing of patents:** Between 2012 and 2013, Indonesia issued "government use"-type compulsory licenses (CLs) on a total of nine patented pharmaceutical products. PhRMA is troubled by Indonesia's decision to issue these licenses without attempts to engage the affected PhRMA member companies in discussions to find more sustainable and long-term solutions. PhRMA member companies are prepared to work collaboratively with Indonesian authorities to find a solution which benefits HIV and Hepatitis B patients in Indonesia while maintaining adequate and effective intellectual property protection.
- **Non-conformance with international best practices:** PhRMA's member companies continue to face burdensome regulatory delays in the registration process of new products, in contravention of Indonesia's own regulations. Therefore, stronger conformance with international best practices is needed with respect to regulatory data protection and bioequivalence requirements.
- **Health law:** While Indonesia's pursuit of a strengthened healthcare delivery system is commendable, the Health Law as written could hinder the ability of PhRMA's member companies to provide safe, effective medicines to meet the needs of the Indonesian patients and medical community. As Indonesia drafts regulations to implement the 2009 Health Law, it is imperative that the Indonesian Government consult with industry and other stakeholders.
- **Trade bill:** PhRMA's member companies strongly support the desire of the Government of Indonesia to align national and regional trade policies; however the proposed trade bill contains several concerning provisions, including local content requirements that unduly promote the domestic industry to the detriment of U.S. pharmaceutical companies and measures to ensure the availability, price stability, and distribution of ill-defined "essential goods."
- **Mandatory Halal certification:** Legislation is moving through Indonesia's Parliament mandating halal certification for all pharmaceutical products. PhRMA's member companies are strongly supportive of religious and cultural sensitivities, but emphasize that any legislation should fully take into account the possibility of negative implications on patient health.

- **Ministerial Decree 1010 and 1799:** The local manufacturing and technology transfer requirements of Decree 1010 are discriminatory, and raise national treatment concerns under Article III of the General Agreement on Tariffs and Trade (1994) that will have lasting implications for market access and patient health in Indonesia. In order to prevent import restrictions on innovative medicines, it is imperative that a solution is reached to allow all legitimate high quality pharmaceuticals to be traded, sold and distributed, regardless of origin.

For these reasons, PhRMA requests that Indonesia remain on the **Priority Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Compulsory Licenses on Patented Pharmaceutical Products

In late 2012 and early 2013, Indonesia issued compulsory licenses (CLs) on a total of nine patented pharmaceutical products. PhRMA is troubled by Indonesia's recent decision to issue government use permits without attempts to engage the affected PhRMA member companies in discussions to find more sustainable and long-term solutions. We are further concerned that a number of patents on different products were aggregated together and dealt with as a group rather than considering each on its merits as required in Article 31(a) of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In addition, other than the stipulated remuneration, there is no ability to appeal the compulsory license or otherwise obtain judicial or other independent body review, as required by TRIPS Article 31(i).

These matters, among others, raise significant issues about the consistency of these CLs with Indonesia's obligations under the TRIPS Agreement and other international norms. Moreover, such drastic measures should only be used in extraordinary circumstances as a last resort rather than standard government practice. As a general matter, CLs are not a sustainable or effective way to address healthcare needs. Voluntary arrangements independently undertaken by member companies better ensure that current and future patients have access to innovative medicines. In that light, while PhRMA wants these issues addressed, we are also aware of the challenges presented by HIV/AIDS in Indonesia. PhRMA member companies are prepared to work collaboratively with Indonesian authorities to find a solution which benefits HIV patients in Indonesia while maintaining adequate and effective intellectual property protection.

Mandatory Transfer of Intellectual Property under Ministerial Decree 1010 and 1799

Ministry of Health (MOH) Decree 1010/MENKES/PER/XI/2008 ("Decree 1010"), formally implemented in November 2010, adversely affects the ability of multinational research-based pharmaceutical companies to obtain marketing authorization for their

products. Under Decree 1010, only companies registered as “licensing pharmaceutical industry” are granted marketing approval. As several of PhRMA’s member companies do not manufacture products in Indonesia, they are instead classified as distributors, or “PBF” enterprises. They are so classified despite following globally recognized good manufacturing practices in the same manner as other high quality pharmaceutical firms manufacturing in Indonesia. Multinational research-based pharmaceutical companies and other foreign companies are barred from the Indonesian market unless they (1) establish a local manufacturing facility; or (2) transfer sensitive intellectual property to another pharmaceutical firm with local manufacturing facilities in Indonesia. The first condition is not possible for many PhRMA member companies, given the structure of global pharmaceutical supply chain. As a result, the second condition poses a serious threat to intellectual property protection and patient safety.

Another key concern of PhRMA member companies with Decree 1010 is the requirement to locally manufacture imported products within five years of patent expiration. Even for companies with local manufacturing facilities in Indonesia, this is not always possible for several reasons, including the structure of their global pharmaceutical supply chains and lack of required technology within their local facilities for certain innovative products. Local manufacturing of these products would require a significant amount of investment which could make it prohibitive for these companies to maintain such products in the Indonesian market. Meanwhile, for companies that have no manufacturing facilities in Indonesia, this requirement poses an additional threat to intellectual property protections and patient safety.

Rather than amend Decree 1010 to mitigate damaging provisions, the MOH created Decree 1799 on December 16, 2010, altering the definition of local manufacturing and introducing the concept of partial manufacture. PhRMA’s member companies have sought clarification on several vague and conflicting provisions of Decree 1799 since its release. Furthermore, in July 2011, Indonesia’s National Agency of Drug and Food Control, known as BPOM, released a draft of the Brown Book containing implementation guidelines for several Decree 1010 and 1799 provisions. Final revisions to the Brown Book were released on September 14, 2011, following BPOM’s review of stakeholder comments, and some of the provisions in the revised Brown Book provided some leeway for PhRMA’s member companies in complying with the requirement to locally manufacture imported products within five years of patent expiration. While PhRMA’s member companies acknowledge the initial steps taken by BPOM to engage in consultations, key concerns remain unresolved and several provisions of Decree 1010 and 1799 still require further clarification.

In short, PhRMA’s member companies are concerned about the discrimination of Decree 1010 as well as the lasting implications to market access, intellectual property protection, and patient health if unresolved. It is imperative that a solution is reached permitting all legitimate high quality pharmaceuticals to be traded, sold, and distributed in Indonesia, regardless of origin. Industry has been in consultations with BPOM. However, further clarification is still needed to understand the implications of the

regulation and how companies should manage their businesses to comply with the regulation.

Market Access Barriers

Non-Conformance to International Best Practices in the Pharmaceutical Registration Process

PhRMA's member companies continue to face burdensome regulatory delays in the registration process of new products. There are a variety of causes for the unpredictable delays, which ultimately result in new products being temporarily or permanently blocked from entering the market. It is uncertain whether the lack of attention to new product applications is due to insufficient personnel capacity or other regulatory reasons. In addition to regulatory delays, PhRMA's member companies would like to see Indonesia take steps to bring the National Agency for Food and Drug Control (BPOM) further in line with international best practices, namely in regards to regulatory data protection and bioequivalence requirements.

Health Law

On September 14, 2009, Indonesia's parliament passed the "Health Law," a far-reaching piece of legislation that touches upon many aspects of healthcare, including pharmaceuticals. If implemented with minimal stakeholder input, the law could have implications for the ability of PhRMA's member companies' to provide safe, effective pharmaceuticals to meet the needs of the Indonesian medical community and patients. PhRMA and its member companies hope that they will be given the opportunity to engage actively in a discussion of the law and provide constructive input during the drafting of the implementing regulations.

Trade Bill

PhRMA's member companies strongly support the Indonesian Government's desire to align national and regional trade policies through the proposed trade bill. However, strong concerns remain with several provisions of the proposed legislation as well as the potentially significant ramifications if adopted into law. In addition to the Indonesian Government's commitment to provide full input and consideration ahead of implementation, PhRMA's member companies request to participate in industry consultations with the Indonesian Government on the development of this Bill and seek clarity on several of the trade bill's provisions. These provisions appear to include: (1) local content requirements, and (2) measures to ensure the availability, price stability, and distribution of ill-defined "essential goods."

Mandatory Halal Certification

Legislation is moving through Indonesia's Parliament to mandate Halal certification and Halal labeling for food and beverages, medicines, cosmetics, chemical

products, biological products, and genetically-engineered products. The legislation proposes to establish a new Halal certification authority as well as require pharmaceutical firms to hire a Halal specialist and disclose sensitive product formulas to the new Halal authority.

PhRMA's member companies recognize and support the religious and cultural sensitivities of all Indonesians. However, any measures taken to respect those sensitivities must also consider the negative implications they may have on patient health. Recognizing the need for balance, local stakeholders, including MOH, oppose requiring mandatory halal certification for medicines, preferring instead that such certification remain voluntary. The bill, if passed and implemented, would impose mandatory Halal certification requirements on medicines. This bill should exclude pharmaceutical products (medicines, chemical-biological products, and genetically-engineered products) from the scope of Halal certification.

Negative Investment List (NIL)

The Government of Indonesia currently limits foreign ownership of pharmaceutical firms designated as manufacturers to 75 percent. Many multinational research-based pharmaceutical companies are currently classified as distributors, or "PBF" enterprises, and some are 100 percent foreign-owned as permitted under the grandfather clause in the NIL. At present, the NIL requires any PBF enterprise to be 100 percent local-owned whereas multinational pharmaceutical companies' investment is capped to 75 percent foreign owned (subject to a "grandfather clause" for existing investments). These requirements limit Indonesia's ability to attract foreign investments in the pharmaceutical sector and hence limit the competitiveness of Indonesia's domestic pharmaceutical industry vis-à-vis its peers in the region. Although, the MOH and Indonesia Investment Coordinating Board (BKPM) have expressed some support for reducing these limitations in the NIL, there is currently no appetite for permitting 100 percent foreign-owned companies in Indonesia. PhRMA's member companies are aware that a review to amend the NIL is underway by the Indonesian Government and look forward to the outcomes of that process.

Import Regulations

Under Decree 39 (2010) companies with Producer Import Licenses (API-P) were allowed to import finished products with the support of an additional license called a Producer Importer (PI). Responding to a Supreme Court decision striking down aspects of Decree 39 (based on a challenge by local producers), the Indonesian Government issued Decree 27 (and amended by Decree 59), which, while allowing API-P holders to continue importing finished products, imposes additional bureaucratic burdens on importers to secure the PI. Specifically, the importer must now obtain a recommendation letter from certain technical ministries to be able to import finished goods, and show a "special relationship" between the importer and the foreign supplier, further impeding trade of imported goods in Indonesia.

Lack of Transparency

The Indonesian Government's policies and regulations are regularly developed and implemented without providing stakeholders an opportunity for consultation or a clear and transparent sense of the process whereby they will be implemented. This lack of transparency is an underlying concern in each of the issues specified above, and significantly contributes to the uncertainty PhRMA's member companies face regarding investment and intellectual property protections in the market. PhRMA's member companies propose that the Indonesian Government institutionalize a formal consultation process to incorporate input from key stakeholders, including those from the multi-national private sector.

Counterfeiting Medicines

Although PhRMA's member companies welcome Indonesia's ongoing efforts to promote the use of safe medicines, there is an urgent need to expand national enforcement efforts. Increasing and especially enforcing the penalties for criminals caught manufacturing, supplying, or selling counterfeit pharmaceuticals as well as unsafe medicines will greatly assist Indonesia's efforts to reduce the harmful impact of counterfeit medicines.

Research conducted by Masyarakat Indonesia Anti-Pemalsuan (MIAP), Indonesia's anti-counterfeiting society, suggests that losses incurred by the state as a result of counterfeiting practices continue to rise each year. Greater collaboration and government initiatives, such as a nationwide campaign and devoted budget to combat counterfeit products, are to be intensified to ensure the health and safety of the Indonesian people.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

KOREA

PhRMA and its member companies remain concerned with numerous intellectual property and market access issues. As one of the largest and fastest growing pharmaceutical markets in the world, Korea's efforts to reform its healthcare system are ongoing.

Key Issues of Concern:

- **Effective patent enforcement:** PhRMA member companies call for a system consistent with commitments in the South Korea-U.S. Free Trade Agreement (KORUS) that provides effective mechanisms to ensure patent enforcement issues can be resolved before follow-on products enter the Korean market. As part of implementing such a system, MFDS should stop rewriting claims of patents identified under the patent enforcement mechanism and should ensure that new uncertainties are not embedded in the Korean system.
- **Transparency, accountability and predictability:** Over the last few years, the Korean Ministry of Health and Welfare (MOHW) has made a number of significant policy changes, which have had wide and deep impacts on PhRMA's member companies operating in Korea. These changes have often been made without meaningful consultation with stakeholders, resulting in unnecessary negative consequences.
- **Government pharmaceutical pricing and reimbursement policies:** The current government pricing mechanism sets prices for new medicines considering the weighted average price for pharmaceuticals – including generics – within the same therapeutic class. This policy, combined with significant *ad hoc* price cuts, means that the government pricing system significantly undervalues innovative medicines. Consistent with KORUS, the MOHW should reform its government pricing policies, for example, by not using off-patent or generic prices in the calculation of prices for new, patented products, so that prices for new medicines appropriately reward innovation and encourage investment in the new medicines needed by the people of Korea.

For these reasons, PhRMA requests that Korea be placed on the **Priority Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Effective Enforcement of Patents

In March 2012, Korea introduced the framework of a patent enforcement system that was intended to implement some of its IP obligations under KORUS.⁸² To date, the system only includes a patent listing process and initial notification procedure; the remaining aspects of the system, including the availability of a 12-month stay of the marketing approval application in the event that there is a patent dispute, are being developed. These aspects of the system must be implemented by March 14, 2015, per the schedule in KORUS.

With regard to the listing process, our members are concerned that it requires the innovator to provide unnecessary descriptions of the patents and claims (beyond those required for listing in the equivalent “Orange Book” in the United States). This is a significant issue for our member companies, because the listed claims may be those used by follow-on applicants to determine whether they need to notify a patent holder either that their product does not infringe its patent or that the follow-on applicant believes that the patent is invalid. As a result, the patent enforcement system adopted by Korea could increase uncertainty as to the IP rights of innovators and generics alike.

Market Access Barriers

Predictability and Transparency in Government Policy-making

MOHW has a history of making and changing pharmaceutical pricing and reimbursement policies on a frequent basis; often with little transparency and opportunity for stakeholder input. This lack of predictability and transparency results in an uncertain business environment for the innovative pharmaceutical industry.

In addition to the lump-sum price cuts in 2012, MOHW announced in September 2013 (effective January 1, 2014) that it would impose additional price constraints through its price-volume agreement (PVA) regime. Under the new rules, the PVA price cut will apply to all drugs that increase their amount of reimbursement claim by 10% over the prior year’s amount and where the total value of those amounts for the year exceeds KRW 5 billion.⁸³

Our member companies are concerned that the revised PVA, contrary to Korea’s obligations under KORUS, will not appropriately value innovative medicines, and will discriminate against foreign companies. The revised policy applies retroactively to all products currently on the market. Furthermore, the revised PVA was introduced without

⁸² See U.S.-Korea Free Trade Agreement, Art. 18.9, para. 5.

⁸³ Korea’s PVA has four types under the prior rule. Under the prior rule, the PVA price cut was applied when a product’s claim amount increased by over 60% as compared to the amount of that product in the prior year (for Type 3 or Type 4). From January 2014, the rule of 10% over KRW 5 billion has been additionally applied for Type 3 and 4.

adequate industry consultation and is being enforced without a reasonable transition period.

The frequent, overlapping and unexpected government mandated price reductions imposed in Korea make it very challenging to manage businesses effectively and undermine market access.

Needless to say, through these government price reductions revenues for both the domestic and multinational pharmaceutical industry operating in Korea have been reduced dramatically. Government price cuts along these lines continue to create an unpredictable operating environment for PhRMA's member companies that rely on long-term planning to make the vital investments necessary for the development of new medicines. It takes 10-15 years of research and development to bring new medicines to market, which encompasses the necessary research, clinical trials and safety and effectiveness testing. Large arbitrary government price reductions may discourage the investments required for the research-based pharmaceutical industry to grow and thrive.

Market-based Actual Transaction Pricing

On October 1, 2010, MOHW instituted Market-based Actual Transaction Pricing (M-ATP). M-ATP, also known as an "incentives system for low price purchase," requires hospitals, clinics and pharmacies to disclose the actual price purchased for drug products. Where prices are lower than the official maximum reimbursement price (MRP), the Korean Government provides the hospital or other medical institutions a rebate from the NHI program of 70 percent of the difference between the price actually paid and the official MRP. The Korean Government determines the weighted average of actual transaction prices based upon data collected from across the market. These data are used to reduce the official MRP annually. In fact, according to interim analysis, the actual price-lowering effect of the M-ATP has been minimal and the M-ATP has provided the top 15 hospitals with significant advantages over other hospitals.

Although PhRMA and its member companies support the objectives of the M-ATP, which are the elimination of illegal rebates and greater transparency, the implementation of this system has led to various unintended consequences. Both innovative new drugs and older drugs are subject to pharmaceutical bidding, and some larger hospitals use their superior trading position in the market to maximize their commercial interests in this process. Negotiating tactics used by these larger hospitals include grouping single-source drugs or patented drugs into one category and asking for a certain percentage price discount for that particular group, or requesting submission of price quotes (*i.e.*, price discounts) in advance. The M-ATP exacerbates these practices by encouraging purchasing hospitals to select certain drugs based on the quantum of rebate that will be received, thus undermining the ability of prescribing doctors to choose the best available medicine for their patients. This, in turn, adversely impacts patient access to innovative medicines and hampers the ability of innovative pharmaceutical companies to recoup their investments.

As part of the additional price cuts announced on August 12, 2011, MOHW announced the one-year suspension of the M-ATP program. On November 22, 2012, MOHW announced the continued suspension of the M-ATP program until January 2014. Although we have continuously asked for complete abolishment of the incentive system, however, we are disappointed to see that MOHW has decided to reactivate the M-ATP from February 2014. PhRMA and its member companies have the serious concerns about M-ATP listed above. Furthermore, we note that the decision to reactivate M-ATP ignores broad-based stakeholder support for its abolition, and creates an environment of uncertainty which could adversely impact patient access to innovative medicines.

Recent Reform Measures Result in Adverse Impact on New Product Pricing

As a result of the implementation of these various government price reduction measures, existing drug prices were heavily impacted by dramatic price reductions. These price reductions will, by extension, impact the price of a new drug as the new drug price is currently derived using a weighted average which includes off patent drugs and generic prices. By instituting drastic price reductions on the off-patent and generic market, and referencing new drug prices to the price of these now heavily-discounted medicines, the government prices of new medicines will also be inappropriately depressed. The MOHW price of new drugs under the current Drug Expenditure Rationalization Program is already far too low, less than half of the average OECD price for new drugs.⁸⁴ The further reduction of government prices of existing drugs will likely lead to much lower new drug prices in Korea.

An effective dialogue with stakeholders, including the research-based biopharmaceutical industry, on valuing innovation will support MOHW's intention to promote greater pharmaceutical R&D in Korea and to improve the global competitiveness of the Korean biopharmaceutical industry in the future.

Independent Review Mechanism (IRM)

Under Article 5.3(5)(e) of the U.S.-Korea Free Trade Agreement and the side letter thereto, Korea agreed to "make available an independent review process that may be invoked at the request of an applicant directly affected by a [pricing/reimbursement] recommendation or determination." The Korean Government has taken the position, however, that reimbursed prices negotiated with pharmaceutical companies should not be subject to the IRM because the National Health Insurance Service (NHIS) does not make "determinations" and merely negotiates the final price at which a company will be reimbursed. However, this interpretation totally negates the original purpose of the IRM, which we believe should apply to the negotiation process for prices of all reimbursed drugs, particularly patented medicines.

In a normal market situation it would be appropriate for negotiations not to be subject to an IRM. However, NHIS is the sole "negotiator" for reimbursements in Korea,

⁸⁴ KRPIA internal analysis study (2012).

and as such is making “determinations.” Local data indicates that from January 2007 through January 2011, NHIS determined not to reimburse 18 of the 93 medicines for which it was tasked to negotiate the reimbursed price. For anti-cancer drugs, the approval rate was even lower – NHIS decided to reimburse only three of the six anti-cancer drugs that Korea’s Health Insurance Review and Service Agency had determined should be reimbursed.

Further, the reimbursement process with the NHIS cannot be considered as “regular negotiations.” Companies are required to submit data and rationale for their proposed price in advance; however, NHIS is not required to provide any explanation of supporting data for its proposed price. As a single-payer, NHIS is able to use its superior negotiating power to stipulate the lowest possible price. For these reasons, contrary to the position taken by the Korean Government, NHIS’s determination of whether a product should be reimbursed at a given ceiling price must be subject to an IRM.

Ethical Business Practices (EBP) Reform

Since the passage of several pieces of legislation in the National Assembly regarding “dual punishment” and revisions of the Medical Service Act, the Pharmaceutical Affairs Act and the Medical Device Act, MOHW has taken the lead in setting EBP standards through enforcement regulations under these laws. MOHW worked with industry to come to a consensus on the scope of allowable benefits (whether financial, educational or otherwise) from industry to health care professionals, including specified activities such as providing samples, product presentation meetings, clinical trials, post-marketing surveillance, special discounts based on speed of payment, sponsorship of participants at academic conferences. The laws became effective as of November 28, 2010, and the enforcement regulations were finalized on December 13, 2010. Although it had seemed that there was consensus between industry and the Korean Government, there are still some ambiguities in the final enforcement regulations, particularly in relation to lecture fees and consultation fees. Industry associations continue to reach out to the Government to resolve the remaining issues, but the Government does not appear to be receptive to addressing these issues.

Under Korea’s new patent enforcement system, the Ministry of Food and Drug Safety (MFDS) examines the Patent Listing Application and may issue up to two official notices if there is insufficient information provided. There appear to be limited options to challenge or appeal a decision not to list particular claim(s) or the way in which the MFDS has amended the claim(s). Specifically, the MFDS may publish its own version of the listed claims, rather than the actual claims that the company submitted as part of the application process. The MFDS does not provide applicants with a formal opportunity to comment on any changes to the listed claims (but in practice, are informally notifying the company of any changes). The MFDS has assured applicants that they will not amend the claims in a formulation/composition category if that amendment would reveal confidential information. Nonetheless, the effect of Korea’s approach is to insert uncertainty as to IP protections for both innovators and generic manufacturers.

Moreover, the unjustified rewriting of patent claims likely will impede accurate identification of generic products covered by recognized patents, resulting in confusion in the marketplace and thereby preventing effective implementation of Article 18.9.5 of the Korea-US FTA. PhRMA's members will continue to monitor implementation of the patent enforcement system and request that the U.S. Government engage with the Korean Government to urge MFDS to stop rewriting claims of patents identified under the patent enforcement mechanism and to ensure that new uncertainties are not embedded in the Korean system.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

NEW ZEALAND

PhRMA and its member companies operating in New Zealand remain concerned over the policies and operation of New Zealand's Pharmaceutical Management Agency (PHARMAC) as well as the direction the Government of New Zealand is taking with respect to broader intellectual property protection. PHARMAC continues to impose stringent cost containment strategies,⁸⁵ and operate in a non-transparent manner, creating an unfavorable environment for innovative medicines.

Key Issues of Concern:

- **Amendments to the Patent Act:** Recent revisions to the Patent Act of 1953 notably excluded patent term restoration, which is necessary for pharmaceutical products to recover a portion of the effective patent life lost due to the marketing approval process, and present additional intellectual property (IP) challenges.
- **Government pricing and reimbursement:** PHARMAC's reimbursement decisions severely limit New Zealand patient access to new medicines, and funding for new medicines is significantly delayed.
- **Biotechnology taskforce recommendations:** Despite steps taken toward an enhanced relationship between the government and the research-based biopharmaceutical pharmaceutical industry a decade ago, those recommendations have not been implemented. Positively, however, in 2012 the Ministry of Business, Innovation and Employment released a guideline on Government procurement including principles that PhRMA member companies would strongly support if applied to PHARMAC.

For these reasons, PhRMA requests that New Zealand be placed on the **Priority Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Amendments to the Patent Act

On September 13, 2013, the New Zealand Parliament amended the Patents Act of 1953. One notable omission from these amendments was patent term restoration. The combined effect of the New Zealand regulatory approval process and major delays related to PHARMAC funding result in a substantially shortened effective patent life. PHARMAC funding is necessary for effective market access in New Zealand. Many countries, including the United States, Australia, and the European Union, have

⁸⁵ Government reference pricing and parity pricing; cross-therapeutic deals; tendering, sole supply, price/volume contracts; special authority and restricted indications; delayed listing (on average three times longer than Australia).

established mechanisms to restore patent terms for pharmaceutical products to recover a portion of the effective patent life lost due to the marketing approval process.

The Patent Act amendments includes other problematic IP provisions, including an overly broad exemption from infringement for research on patented material, exclusion of methods of treatment and diagnosis from patentable subject matter, inclusion of Crown use provisions similar to compulsory licensing, but without sufficient restrictions, and provision of both pre- and post-grant challenge procedures that may be cumbersome to patent applicants.

Market Access Barriers

Government Pricing and Reimbursement

Though not explicitly stated, PHARMAC's reimbursement decisions suggest a pharmaceutical must achieve a cost per QALY (quality adjusted life year) of less than NZ\$10,000 to NZ\$15,000 to be considered cost effective. This is despite public spending in other areas of health proceeding at up to NZ\$100,000 per QALY. This approach, combined with the need to stay within a capped budget, means that many of the most effective medicines are not available to New Zealand's patients. Analysis has found that of the 136 innovative new prescription-only medicines listed on the Pharmaceutical Benefit Scheme in Australia between 2000 and 2009, only 59 (43 percent) received reimbursement in New Zealand.⁸⁶ Many of these 59 products have restricted reimbursement, such as reimbursement for limited indications. Ongoing monitoring of PHARMAC and PBS listing trends by innovative pharmaceutical industry association Medicines New Zealand continues to show the lag in access in New Zealand. Funding for new medicines in New Zealand is also significantly delayed, such that some medicines are only funded after they come off patent, even where there is no funded therapeutic alternative. PHARMAC is currently expanding to take responsibility for funding vaccines and hospital medicines and this increases the urgency needed to improve its processes.

PhRMA's member companies are advocating for the following key policy reforms in New Zealand:

1. **Patient Outcomes:** A national medicines policy should ensure the provision of quality medicines in a way that is responsive to patients' needs and achieves optimal health outcomes.
2. **Comparable Access:** A national medicines policy must ensure that New Zealanders have at least comparable access to medicines as access to other health technologies and to citizens of other OECD countries.

⁸⁶ Michael Wonder, Richard Milne: *Access to new medicines in New Zealand compared to Australia*, New Zealand Medical Journal, Vol. 124 No. 1346 (Nov. 2011).

3. **A Core Health Strategy:** Medicines play a vital role in the prevention, amelioration and treatment of disease, and as such a national medicines policy is integral to the achievement of all national health strategies and should have equal standing and priority. Medicines access should be aligned with other health policies and not disproportionately targeted for cost containment.
4. **Integrity and Public Confidence:** The current bundling of multiple products into a single funding contract creates incentives for the Government to subordinate clinical judgment to budget imperative. Determinations about which medicines are cost effective and are of clinical merit must be conducted independently before being used to inform decisions about which products can be funded.
5. **Transparency and Rigor of Processes and Decision Making:** Public confidence will be enhanced if decision making processes are underpinned by transparency, fairness, timeliness and high standards of consultation and review. All stakeholders must be able to understand the true basis of decisions and rationales should be clearly stated. What is considered “value for money” should be comparable to other OECD countries. Transparency and accountability are key principles in New Zealand institutions, with the exception of pharmaceutical funding. It is critical that these principles be applied equally to pharmaceutical funding.
6. **Recognition of the Value of Innovation:** A national medicines policy should recognize the value of innovation and innovative pharmaceuticals through the adoption of procedures that appropriately value the objectively demonstrated therapeutic significance of pharmaceuticals.
7. **Responsive Budget Management:** The pharmaceutical budget should be determined by people’s need for treatment and access benchmarks. Rather than conduct health technology assessments (HTAs) of products after the capped budget has been set, thus simply creating a priority list of new products competing for the limited funding available, HTAs should be used to establish budget estimates on an annual basis. The capped budget is a concern as there has been little to no growth (a total of 9.5 percent over the last 10 years) and savings from year to year are not accrued into the following year’s budget. The 2012-2013 pharmaceutical budget has been reduced, even though the clinical committee has recommended funding numerous new medicines that are still awaiting a positive reimbursement determination by PHARMAC.
8. **Partnership:** The achievement of timely access to medicines, quality use of medicines and other national medicines policy objectives is greatly enhanced by the maintenance of a responsible and viable industry environment in New Zealand. Coordination of health and industry policies and a consistent and more welcoming environment for innovation will better enable effective partnership with Government and other stakeholders to achieve improved health and economic outcomes.

Biotechnology Taskforce Recommendations

The New Zealand Government's Biotechnology Taskforce made the following recommendations in 2003 to enhance its relationship with the pharmaceutical industry and stimulate research investment:

- Introduce certainty and predictability into PHARMAC's funding by setting ongoing three-year funding rather than year-to-year funding.
- Develop an action agenda for the industry on public policy issues building on the local industry association's report "Bio-pharmaceuticals – A Pathway to Economic Growth."
- Review the channels through which the Government engages with the pharmaceutical industry.

The first recommendation was achieved initially with an announcement in September 2004 of annual budgets through 2007. Unfortunately this policy was rescinded and the subsequent budget for 2008-2010 was not published. To date, the Government has not implemented the second and third recommendations.

A Health Select Committee report in June 2011 recommended enhancing the engagement with the pharmaceutical industry around clinical research yet the Government declined to implement this recommendation.

In a positive development, in 2012 the Ministry of Business, Innovation and Employment released a guideline on Government procurement. Among other recommendations, the guideline includes the following principles:

- Be accountable, transparent and reasonable;
- Make sure everyone involved in the process acts responsibly, lawfully and with integrity;
- Stay impartial – identify and manage conflicts of interest; and
- Protect suppliers' commercially sensitive information and intellectual property.

These are the exact same principles that PhRMA and the innovative pharmaceutical industry would like to see New Zealand adopt as part of its pharmaceutical pricing and reimbursement system.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

THAILAND

PhRMA's member companies continue to have concerns over the intellectual property environment and market access barriers in Thailand.

Key Issues of Concern:

- **Intellectual property protections:** PhRMA's member companies recognize and comment the Department of Intellectual Property's inclusion of industry in the discussion and construction of the Patent Examination Guidelines. However, additional improvement in the intellectual property environment in Thailand remains necessary to avert negative impact on market access. Concerns include delays in obtaining pharmaceutical patents, inadequate regulatory data protection, and weak patent protection and enforcement regimes.
- **Market access and discriminatory government procurement:** Thailand's procurement regulations requiring public hospitals to purchase their medicines and medical supplies from the state-owned Government Pharmaceutical Organization (GPO) should be reviewed. These forced transactions create an artificial marketplace, as well as prevent public hospitals and patients from gaining access to certain life-saving medicines. The selection criteria and process for setting the ceiling purchasing price or so called "Median Price" for public procurement lack transparency and a stakeholder process whereby industry can provide timely input on government pricing decisions that affect the availability of innovative medicines to Thai patients.
- **Government engagement and consultation:** PhRMA's member companies stand ready to work closely with the Royal Thai Government to foster meaningful collaboration, address key issues of healthcare reform and discuss sustainable and constructive policy reform. A transparent and enduring mechanism that allows stakeholders to contribute to Thailand's healthcare decision-making process is needed to assure sustainable market access and better provide Thai patients life-saving pharmaceutical treatments.
- **Counterfeit medicines:** PhRMA's member companies recognize advancements made by the Royal Thai Customs in enforcing intellectual property rights, but encourages the Royal Thai Government to place a higher priority on curbing the distribution and use of counterfeit medicines through increased resources and penalties for criminals caught manufacturing, supplying, or selling them.

For these reasons, PhRMA requests that Thailand be placed on the **Priority Watch List** for the 2014 Special 301 Report, but that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Patent Examination Backlog

Thailand's Department of Intellectual Property has finalized the Patent Examination Guidelines to complement the Thai Patent Act. The innovative biopharmaceutical industry was invited to provide its input during the drafting, which was appreciated. The new Patent Examination Guidelines would set clear benchmarking and examination rationale which would enhance transparency in patent registration as well as help ensure balance and fairness with respect to innovative products.

However, unresolved issues remain how to clear the patent backlog and ensure that there are sufficient resources to maintain the patent registration process. The waiting-period for a patent review and grant in Thailand is unpredictable and averages 10 years after application submission. These long patent grant delays create uncertainty regarding investment protection and increase the risk that there will be infringement during the pending/review periods. Patent term adjustments are not available in Thailand to compensate for unreasonable patent office delays, further exacerbating the uncertainty caused by its patent grant delays.

Patent Protection for New Uses

PhRMA's member companies strongly encourage the Royal Thai Government to recognize the significant health, scientific, and commercial benefits of new uses for existing pharmaceuticals. Patent applications for new improvements, upgrades, and next generation products should be reviewed in accordance with internationally recognized patentability criteria as well as applied consistently among all technology dependent sectors. Although industry representatives have been asked to sit on the Patent Amendment Committee and Patent Examination Guideline committee, PhRMA's member companies encourage the Royal Thai Government to work with all technology-based industries so that the patent system can improve for the benefit of all innovators in all fields of technology. This approach will ensure that the incentive for innovation is preserved as well as that all technologies are granted equal treatment with respect to patent grant criteria and patent prosecutions.

Regulatory Data Protection

Ministerial regulations issued by the Thai Food and Drug Administration (FDA) regarding the Trade Secrets Act of 2002 do not provide regulatory data protection that would prevent generic drug applicants, for a fixed period of time, from relying on the innovator's regulatory data to gain approval for generic versions of the innovator's product. The Act aims only to protect against the "physical disclosure" of confidential information.

PhRMA's member companies strongly encourage the Royal Thai Government to institute meaningful regulatory data protection. Specifically, Thailand should: (1) implement new regulations that do not permit generics producers to rely directly or indirectly on the originators' data, unless consent has been provided by the originator, for the approval of generic pharmaceutical products during the designated period of protection; (2) bring the country's regulations in line with international standards by making clear that data protection is provided to test and other data submitted by an innovator to obtain marketing approval; (3) provide protection to new indications; and (4) require Thai FDA officials to protect information provided by the originator by ensuring it is not improperly made public or relied upon by a subsequent producer of a generic pharmaceutical product.

Patent Enforcement

PhRMA's member companies strongly encourage the Thai FDA to implement effective mechanisms to allow for sufficient time to resolve patent disputes before follow-on products (e.g., generics) are marketed. Such a system would prevent regulatory approval of follow-on products of pharmaceuticals that are still covered by a valid patent and remove a significant and unnecessary burden on PhRMA's member companies as well as the Thai court system. Effective patent enforcement could greatly enhance the business environment in Thailand by: (1) providing transparency and predictability to the process for both the innovative and generic firm; (2) creating a more predictable environment for investment decisions; and (3) ensuring timely redress of genuine disputes.

Market Access Barriers

Discriminatory Government Procurement

As a result of special procurement privileges granted to Thailand's Government Pharmaceutical Organization (GPO), competition remains increasingly difficult for PhRMA's member companies. Procurement Regulation B.E. 2535 (Sections 60-62) issued by the office of the Prime Minister, requires that hospitals affiliated with the Ministry of Public Health must spend 80 percent of their allocated health budget on medicines listed on the National List of Essential Medicines (NLEM). Furthermore, products produced or supplied by the GPO must be selected for hospital procurement when using public funds, even when sold at higher prices. The GPO is also exempt under the Drug Act (Articles 12 and 13) from the requirement to obtain a license from the Thai FDA to produce, sell, or import pharmaceutical products. Moreover, in 2013, the Ministry of Public Health issued a new policy granting locally produced generics an accelerated registration approval system and exclusive access to government procurement contracts.

Civil Service Medical Benefits Scheme (CSMBS) Reform

The Civil Service Medical Benefits Scheme (CSMBS) is an integral component of public employment in Thailand, reimbursing the full healthcare costs for each civil servant. The Cost-containment Measures, such as mark-up rates that discriminate between innovative and generic medicines, implementation of Non-NLEM prescription criteria, prior authorization for high-cost drugs, reimbursable indications, and prospective payment (DRG OPD, Out-patient capitation control) are being developed without a clear and transparent process. Specifically, the recent October 2013 Comptroller General directive, the implementation of which has been delayed, creates different and discriminatory mark-up rates for generic and innovative medicines. The innovative biopharmaceutical industry recognizes that the directive has been delayed and is prepared to work with all parties on a policy that will address the needs of government and also recognize the value of innovative medicines. In addition, the onerous reporting and audit requirements for prescribing innovative medicines have led many physicians to cease providing innovative medicines to patients in favor of drugs listed on the NLEM, which are mostly generics.

Government Procurement Price Controls

The innovative biopharmaceutical industry recognizes that it has been invited to provide inputs on the selection criteria and process for setting the ceiling purchasing price or so called “Median Price” for public procurement. Through this process, we look forward to developing criteria that are transparent and a stakeholder process whereby industry can provide timely input on government pricing decisions that affect the availability of innovative medicines to Thai patients.

National List of Essential Medicines (NLEM)

Thailand’s National List of Essential Medicines (NLEM) is predominantly based on a policy of cost containment. Although there have been some improvements in 2013 in terms of the criteria, process and rationale for NLEM revisions, it remains imperative that there is continuous dialogue between industry and the government on the listing process.

Restricted Advertising

PhRMA believes that communication on disease awareness is an essential part of public health education. Restrictions on advertising and disease awareness activities have stifled patient education programs. The Thai FDA needs to issue clear guidelines on acceptable disease awareness programs so that these activities can resume in a manner that benefits Thai patients.

Counterfeit Medicines

PhRMA's member companies are encouraged by the Royal Thai Government's efforts to develop the National IPR Center of Enforcement; however, most of the focus has been on products such as clothing and media, rather than on pharmaceuticals. Enforcement has also been limited to those illicit products sold online. Moving forward, there is also an urgent need to address counterfeits in the pharmaceutical sector and enhance penalties for criminals caught manufacturing, supplying, or selling counterfeit or unsafe medicines. While the Royal Thai Government has acknowledged the need to suppress counterfeits in a Memorandum of Understanding for "Cooperation on Prevention and Suppression of Trademark Infringing Pharmaceuticals" signed on September 2010, no action has yet been taken to implement the MoU. There is also an urgent need to take action against non-trademark counterfeit pharmaceuticals.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

CANADA

CANADA

PhRMA and its member companies operating in Canada are extremely concerned about Canada's intellectual property environment, which continues to be characterized by significant uncertainty and instability for U.S. innovative biopharmaceutical companies. Canada's intellectual property regime lags behind that of other developed nations in several significant respects.

Key Issues of Concern:

- **Heightened utility requirement:** Contrary to the Canadian *Patent Act*⁸⁷ (the Act), Canada's treaty obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the North American Free Trade Agreement (NAFTA), and established international norms, the Canadian judiciary has created a heightened standard for patentable utility.
- **Weak patent enforcement:** The Canadian Patented Medicines (Notice of Compliance) Regulations include several key deficiencies that weaken Canada's enforcement of patents, including the nature of patent dispute proceedings, lack of effective right of appeal for patent owners, and limitations on the listing of patents in the Patent Register. While Canada has stated that it will take action to address the right of appeal issue in the context of the Comprehensive Economic and Trade Agreement (CETA) recently announced with the European Union (EU), PhRMA members note that Canada also appears to be intent on making additional changes to its patent enforcement system that may remove or weaken other existing rights of patent owners.
- **Lack of patent term restoration:** Canada's intellectual property regime currently provides no form of patent term restoration (PTR). PhRMA member companies note that Canada recently agreed to adopt a form of PTR in the context of the CETA, but concerns remain regarding the conditions and limitations within the agreed upon PTR mechanism.
- **Limitations on regulatory data protection:** PhRMA members continue to have serious concerns about the potential loss of regulatory data protection (RDP) under the relevant Canadian regulations if the innovator drug is not being marketed in Canada. The restrictions imposed by Canada on the scope of RDP in this respect are unfair and arbitrary, and find no basis in the text of either Article 39.3 of the TRIPS Agreement or Article 1711 of the NAFTA.

For these reasons, PhRMA requests that Canada be placed on the **Priority Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to

⁸⁷ R.S.C., 1985, c. P-4.

seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Heightened Utility Requirements

PhRMA members are concerned that recent decisions by the Canadian judiciary have created a heightened standard for patentable utility for pharmaceutical patents. This heightened standard is inconsistent with common practice in other countries, and has done great damage to the patent rights of innovative U.S. pharmaceutical companies.⁸⁸ It is also inconsistent with Canada's international trade treaty obligations because it (i) imposes onerous and unjustified patentability criteria, narrowing the scope of inventions that receive patent protection; and (ii) discriminates against innovative pharmaceutical companies. Furthermore, and given the mixed and conflicting case law from the Canadian court system on utility, it is unclear precisely what standard must be met by innovators in order to address the issue and safeguard their intellectual property. This issue must be addressed given that it undermines the ability of innovative pharmaceutical companies to enforce and defend their existing patents in the court system, and also limits their ability to obtain new patents with the Canadian Intellectual Property Office (CIPO), which has adopted this more burdensome utility test at the examination level.

Under Canada's heightened utility test, innovators are now required to "demonstrate" or "soundly predict" the effectiveness of a pharmaceutical "promised" at the time of filing the patent application in order to meet the utility requirement. Such a standard is fundamentally inconsistent with TRIPS, as well as the R&D timeline for pharmaceuticals. To meet the utility requirement, TRIPS, and all developed countries, require only that an invention be "useful" or "capable of industrial application." In the case of a new medicine in the United States, for example, the utility prong of the internationally-accepted patent test is satisfied by identifying a specific disease against which the claimed compounds are useful. Unlike in Canada, in the rare event that a patent is challenged for lack of utility in the United States, U.S. courts focus on actual utility and will also consider evidence developed and submitted after the filing of the patent application in determining utility. Canadian courts have, in contrast, sometimes required evidence more appropriately considered in the regulatory approval phase of drug development in order to establish utility. It is not reasonable or financially feasible to require pharmaceutical firms to undertake substantial risks and spend millions of dollars on clinical drug development before a patent application is even filed. Canada's "promise doctrine" discourages the investment of significant resources to develop new

⁸⁸ On May 16, 2013, the Supreme Court of Canada denied Eli Lilly's leave application regarding its ZYPREXA (olanzapine) patent, upholding the lower court decisions invalidating Eli Lilly's patent on the basis that the utility promised by the patent had not been demonstrated and could not have been soundly predicted. (*Eli Lilly Canada Inc. v Novopharm Limited*, May 16, 2013 (SCC Case No. 35067, Federal Court of Appeal decision — 2012 FCA 232, and Federal Court decision — 2011 FC 1288).

medicines and, in the long run, negatively affects the patients and families who rely upon our sector to innovate new cures and treatments.

PhRMA members urge the U.S. Government to press the Government of Canada to resolve this issue. The promise doctrine effectively imposes a higher utility standard to the patentability of pharmaceutical inventions than to other inventions. TRIPS requires that there be no discrimination as to the field of technology. Furthermore, this heightened utility standard is fundamentally incompatible with the lifecycle of pharmaceutical development, and is causing significant commercial uncertainty for U.S. pharmaceutical companies operating in Canada.

Weak Enforcement of Patents

In 1993, the Patented Medicines (Notice of Compliance) Regulations (the PM (NOC) Regulations) were promulgated for the stated purpose of preventing the infringement of patents by the premature market entry of generic drugs as a result of the “early working” exception. However, serious and systemic deficiencies remain with the PM (NOC) Regulations that need to be addressed. There is ample evidence that the PM (NOC) Regulations do not reliably provide “expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements,” as required under the TRIPS Agreement and NAFTA. For example:

1. Proceedings under the PM (NOC) Regulations

With respect to patents that are listed on the Patent Register, when a generic producer files an Abbreviated New Drug Submission seeking marketing approval on the basis of a comparison to an already approved brand-name product, it must address any such listed patents that are relevant. In doing so, the generic producer may make an allegation that patents are not valid or will not be infringed. It must notify the patent owner of any such allegation. The patent owner then has a right to initiate judicial procedures to challenge any such allegation. If procedures are triggered, approval of the generic drug is stayed for a maximum period of up to 24 months pending judicial review.

In the United States, such a challenge to an allegation of non-infringement or patent invalidity proceeds as a full action for infringement on the merits. However, under the Canadian PM (NOC) Regulations, a challenge proceeds by way of summary judicial review aimed only at determining if the allegation is “justified.” As a result of the summary nature of the proceeding, there is no discovery and there may be constraints on obtaining and introducing evidence and cross-examination. This, in combination with various other limitations and shortcomings discussed below, can make it difficult for the patent owner to prove its case.

2. No Effective Right of Appeal

The summary nature of Canada's initial patent infringement proceedings means that a patent owner, unlike a generic drug producer, does not have an effective right of appeal. This is because the PM (NOC) Regulations provide that a generic product may be approved for marketing (through the issuance of an Notice of Compliance, or "NOC") following a decision by the Court in the first instance in favor of the generic producer; once the NOC issues, an appeal filed by the patent owner becomes moot.⁸⁹ The patent owner is then left with no alternative but to start a new proceeding outside of the framework of the PM (NOC) Regulations, *i.e.*, commencing an action for patent infringement once the generic product enters the market, essentially having to restart a case it had already spent up to two years litigating under the Regulations.

In contrast, a right of appeal is available to the generic under the PM (NOC) Regulations if the patent owner prevails in the first instance. While Canada has stated that it will take action to address the right of appeal issue in the context of the Comprehensive Economic and Trade Agreement (CETA) recently announced with the EU, PhRMA members remain concerned that Canada also appears to be intent on making additional changes to its patent enforcement system that may remove or weaken other existing rights of patent owners.⁹⁰

PhRMA member companies ask that the U.S. Government strongly encourage Canadian authorities to rectify this fundamental, discriminatory, and unjustifiable imbalance in legal rights and due process through regulatory changes that will ensure there is a meaningful and effective right of appeal for patent owners within the PM (NOC) Regulations, and that balance is restored without removing or weakening other existing rights of patent holders, including, without limitation, the right to sue generics for monetary damages under the Act for patent infringement.

A patent owner may separately choose to proceed later by way of a patent infringement action, and may apply for an interlocutory injunction to maintain its patent rights and to prevent the market entry of the generic product or to seek its withdrawal from the market. However, given the elevated thresholds imposed by the Canadian judiciary these interlocutory injunction motions rarely succeed in Canada despite compelling evidence of infringement. Additionally, it often takes at least two years before an action for patent infringement is tried, and far longer to obtain damages once a generic has been successfully sued for infringement.⁹¹ By then, the innovative

⁸⁹ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359.

⁹⁰ See <http://actionplan.gc.ca/sites/default/files/pdfs/ceta-technicalsummary.pdf> at p.19, where the Government of Canada stated that, in the context of the CETA negotiated outcomes, "Canada agreed to a general commitment to ensure that litigants are afforded equal rights of appeal, which gives scope for Canada to end the practice of dual litigation."

⁹¹ For example, on July 16, 2013, the Federal Court released a decision granting the largest award of damages for patent infringement in Canadian history. *Merck & Co., Inc. v. Apotex Inc.* (2013 FC 751) ("Merck"). While the award quantum was widely reported, less reported was the fact that the case dated back to 1993 when Apotex first served a Notice of Allegation in which it undertook not to infringe Merck's

company's market share can be almost completely eroded by the marketing of the generic product. Provincial and private payer policies mandating the substitution of generics for brand-name products guarantee rapid market loss. Despite its limitations as a remedy for innovators, the ability to sue generics for infringement under the Act remains an important legal mechanism for patent holders to protect their rights in Canada, and it must not be removed or diluted in the context of the implementation of a right of appeal for innovators under the PM (NOC) Regulations.

3. Limitation on the Listing of Valid Patents

Furthermore, patent owners continue to be prevented from listing their patents in the Patent Register established under the PM (NOC) Regulations if the patents do not meet certain arbitrary timing requirements or are of a type not eligible for listing. Most of these restrictions are not present in the United States under the Hatch-Waxman Act. The effect of these rules is to deny innovative pharmaceutical companies access to enforcement procedures in the context of early working for any patent not meeting these arbitrary listing requirements.

4. Section 8 Damages Interpretation

PhRMA members are also concerned regarding the uncertainty and evolution of the scope of the Section 8 damages stemming from recent judicial interpretations. Generally Canadian Federal Court decisions have held firm on the notion that damages under Section 8 of the PM (NOC) Regulations should be compensatory in nature based upon the calculation of the generic loss attributable to its delayed market entry. However, recent Federal Court decisions suggest that generics may be entitled to damages based upon hypothetical market models that could result in a patentee being compelled to compensate the individual generic for damages in excess of the total generic market for the relevant product.⁹² PhRMA members believe this is an erroneous interpretation of the scope of Section 8 damages, and one that if upheld would be punitive to innovators rather than compensatory for generics.

These various deficiencies frequently result in violations of the patent rights of PhRMA member companies operating in Canada with attendant economic losses. These losses are serious and of growing concern, and negatively impact the U.S. balance of trade with Canada.

PhRMA members urge the U.S. Government to press the Government of Canada to rectify these issues through appropriate legislative or regulatory changes that will ensure that PhRMA members have meaningful and effective patent protection under either the PM (NOC) Regulations or alternative procedures and remedies.

patent if it obtained a Notice of Compliance (NOC). This judgment has also been appealed, further delaying any eventual damages award.

⁹² For example, see *Sanofi-Aventis v. Teva Canada Limited*, 2012 FC 551, and *Sanofi-Aventis v. Teva Canada Limited*, 2012 FC 552 (both under appeal).

Lack of Patent Term Restoration

Patent Term Restoration (PTR) provides additional patent life to compensate for a portion of the crucial effective patent life lost due to clinical trials and the regulatory approval process. Most of Canada's major trading partners, including the United States, the EU and Japan, offer forms of PTR which generally allow patent holders to recoup a valuable portion of a patent term where time spent in clinical development and the regulatory approval process has kept the patentee off the market. In these countries up to five years of lost time can be recouped.

In the context of the CETA Agreement, Canada recently announced that it would provide up to two years of patent protection for pharmaceutical products to recover some of the time lost during clinical trials and regulatory approval processes.⁹³ PhRMA members are encouraged by this announcement given that Canada's intellectual property regime currently includes no form of PTR system. However, at a maximum period of two years, the proposed PTR period in Canada would be lower than the maximum of five years provided to patent owners in other developed nations, including the United States, the EU and Japan. In addition, it is reported that the proposed PTR mechanism could include an exception for Canadian-made generic drugs to be exported during the period of additional protection, which is not found in the United States' system, or any other nation's PTR mechanism.

PhRMA members urge the U.S. Government to engage with the Government of Canada on this issue, and encourage Canada to implement a PTR system that is consistent with existing systems in other industrialized countries in terms of the scope and duration of the protection provided to patent owners. Steps taken by Canada to implement meaningful PTR would constitute an important positive precedent for further dialogue and negotiations with other developed and developing nations in other forums on these same issues.

Limitations on Regulatory Data Protection

Article 39.3 of the TRIPS Agreement and NAFTA Articles 1711(5) and (6) require Canadian regulatory authorities to provide effective protection to prevent the unfair commercial use of clinical trial and other data submitted by innovative companies for market approval of their products. PhRMA member companies appreciate Canada's publication, in October 2006, of regulations implementing eight years of regulatory data protection (RDP) to prevent unauthorized parties from gaining unfair commercial benefit during the protection period through reliance on the clinical dossier generated through the significant investments of others. This was an important step in improving Canada's intellectual property regime.

⁹³ See <http://actionplan.gc.ca/sites/default/files/pdfs/ceta-technicalsummary.pdf> at p.19, where the Government of Canada stated that "Canada agreed to provide additional (sui generis) protection for pharmaceutical products protected by eligible patents in Canada".

However, our members continue to have serious concerns about the potential loss of RDP under the October 2006 regulations if the innovator drug is not being marketed in Canada. The restrictions imposed by Canada on the scope of RDP in this respect find no basis in the text of either Article 39.3 of the TRIPS Agreement or Article 1711 of the NAFTA. Canada's obligation to protect data pursuant to these treaty provisions is not in any way lessened simply because the approved medicine or vaccine is not marketed in Canada.

These current and potential restrictions on the scope of RDP are unfounded and arbitrary, and they have a serious adverse impact on the ability of PhRMA members to protect from unfair commercial use the significant efforts and expenditures made in producing these data. The Government of Canada is aware of this issue but has to date taken no steps to ensure that the data of PhRMA member companies in this respect is otherwise protected against unfair commercial use.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

THE EUROPEAN UNION

PhRMA member companies are facing a variety of government restrictions in the European Union (EU) that undermine the ability of PhRMA member companies to enjoy the full benefits of their patents and that predominantly affect innovative products relative to their generic counterparts. With the global economic downturn and its direct impact on European economies in particular, EU Member States are taking additional measures to contain public expenditures and in the process, creating unfair and harmful environments for U.S. research-based industry leaders.

Key Issues of Concern:

- **EMA data disclosure policy:** PhRMA and its member companies are very concerned that current practices of the European Medicines Agency (EMA) and proposals being advanced through the EMA and the European parliament to provide virtually unrestricted access to and publication of biopharmaceutical companies' clinical trial regulatory submissions and data will substantially harm patient privacy, the integrity of the regulatory system, and incentives for pharmaceutical research and development. Failing to protect confidential commercial information contained in regulatory submissions is inconsistent with the EU's treaty obligations contained in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and primarily benefits competitors who wish to free-ride off of the investments of innovators. We are especially concerned that proposals to disclose regulatory clinical study reports (CSRs) in their entirety – a class of document that the EMA has traditionally considered to be commercially confidential information – will allow competitors to submit innovators' documents to gain regulatory approval in non-European countries.
- **Effective patent enforcement:** The EU and its Member States lack an effective mechanism to allow for sufficient time to resolve legitimate patent disputes before market launch of a follow-on product (e.g., generics or biosimilars). Although follow-on products have several opportunities to challenge existing patents, there is no opportunity for innovator companies to resolve patent disputes in advance of generic or biosimilar launch. In addition, even if an innovator successfully challenges an infringing product in court, they are rarely restored to the position that they would have been in but for the market entry of the patent infringing product. This failure to provide effective remedies fundamentally undermines the exclusive rights conferred by a patent.
- **Government price controls:** Among numerous other price controls that are in effect, a number of EU Member States are either basing the price of patent protected innovative products on groups that include the price of generics in the same therapeutic class and/or are using the price of the medicine in countries undergoing heavy fiscal crisis (e.g., Greece and Portugal) to establish the medicines price in their own country. Such practices harm patients and undermine innovation. Furthermore, EU legislation requires transparent

processes for such national pricing and reimbursement decisions, but these requirements need to be enforced more rigorously and broader oversight of national practices should be in place.

For these reasons, PhRMA requests that the EU be placed on the **Priority Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

EMA Data Disclosure Policy

PhRMA and its member companies are very concerned that current practices of the European Medicines Agency (EMA) and proposals being advanced through the EMA and the European parliament to provide unrestricted access to clinical trial data will substantially harm patient privacy, the integrity of the regulatory system, and incentives for pharmaceutical research and development. According to the EMA's draft *Publication and Access to Clinical-Trial Data* policy that was issued for public comment on June 24, 2013, the EMA will publish the full clinical study report following approval of a medicine's marketing authorization application. PhRMA has strong concerns that doing so will jeopardize confidential commercial information that represents much of the value generated through the research and development process. Also, because it is possible that even anonymized patient-level data can lead to re-identification of individual patients,⁹⁴ patient willingness to participate in future trials may be impacted and the individual consent forms that include protection of personal information may be violated. Disclosure of such data also encourages second guessing of the EMA's expert regulatory decisions, thereby undermining patient trust in the safety and effectiveness of approved medicines.

Further, failing to protect confidential commercial information contained in regulatory submissions is inconsistent with the EU's treaty obligations contained in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This harms incentives to invest in biomedical research. The primary beneficiaries of such non-public information are competitors who wish to free-ride off of the investments of the innovators. This is also concerning since, once disclosed in Europe, the regulatory documents can be used by third-party companies to seek approvals in other markets such as China. The European Parliament is considering a similar proposal as

⁹⁴ See Gymrek, M. et al., Identifying Personal Genomes by Surname Inference, 339 SCIENCE 6117 321-324 (2013).

part of its replacement of the Clinical Trial's Directive⁹⁵ with a new clinical trial regulation.⁹⁶

Effective Patent Enforcement

When a generic product is launched and remains on the market until infringement is proved in patent litigation, harm may be caused to the patent owner which cannot be compensated through damage awards. This reasoning is often cited by English courts, and some EU courts, for granting pre-trial interim injunctions.⁹⁷ Overall, however, interim injunctions to prevent accused products from remaining on the market until trial are granted in less than half the relevant cases.⁹⁸ This failure to provide effective remedies fundamentally undermines the exclusive rights conferred by a patent.

A mechanism to resolve legitimate patent disputes before launch of a follow-on product (e.g., generics or biosimilars) would alleviate this problem. It would also help prevent unnecessary, costly and time-consuming litigation regarding the amount of damages and problems associated with removing an infringing follow-on product from the market.

It is imperative for all pharmaceutical companies, innovative or otherwise, that there are dependable mechanisms in Europe to resolve potential patent infringement issues before follow-on product launch.⁹⁹

Currently there are three mechanisms available to generic companies to “clear the path” of patents that may be obstacles to launch and marketing: 1) file an opposition with the European Patent Office; 2) pursue a revocation/nullity action in individual Member States; or 3) apply for a declaration of non-infringement in individual Member States. The latter is similar to an application for declaratory judgment in the United States.

However, there is no opportunity for innovator companies to resolve patent disputes well in advance of generic or biosimilar launch. This is because, in most EU Member States, it is not possible to bring patent infringement proceedings until just before or just after launch of the third party product, which often makes resolution of disputes before actual launch impossible. In addition, resolving these disputes in this

⁹⁵ Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

⁹⁶ Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

⁹⁷ See, e.g., *Leo Pharma v. Sandoz*, [2008] EWHC 541 and *Novartis v. Dexcel-Pharma*, [2008] FSR 31.

⁹⁸ DG Competition, European Commission, “Pharmaceutical Sector Inquiry Final Report,” para. 641 (Jul. 8, 2009).

⁹⁹ EFPIA, Submission to the European Commission in Relation to the Pharmaceutical Sector Inquiry (June 13, 2008), available at <http://www.concurrences.com/IMG/pdf/e-C-2.pdf> (last visited Oct. 15, 2013).

manner is often lengthy, expensive, and can result in significant market loss, even if the end ruling favors the company that produced the original molecule.

There is thus an unjustifiable and commercially significant imbalance between the rights of innovator patent owners and generics to resolve patent issues before product launch in most EU Member States.

Further, in many cases, PhRMA member companies have experienced EU Member States reimbursing infringing products, or approving prices for their purchase by government procurement agencies without regard to whether or not the products infringe third party patents.

Additionally, depending on the details of the system, a mechanism that allows generic companies to obtain information regarding relevant existing patents could be useful in assessing whether to await patent expiration or challenge the applicability of a patent and thus help avoid premature investments. It could also contain safeguards that delay or prevent approval of products alleged to infringe, pending judicial resolution.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has proposed adoption of an “early resolution” mechanism to the European Commission and PhRMA supports this approach in Europe.

Market Access Barriers

Government Price Controls

Many EU member states are engaging in practices that restrict availability of and limit access to state-of-the-art medicines. Exacerbated further by the economic and financial crisis gripping many countries, such practices harm patients and innovation. Moreover, since the U.S. research-based industry is the world leader in the development of new medicines, PhRMA members and their innovative products disproportionately bear the brunt of these measures as they undermine the financial incentive for privately sponsored research and development. Furthermore, even though EU legislation requires transparent processes in making such national pricing and reimbursement decisions, these requirements need to be enforced more rigorously and broader oversight of national practices should be in place.

Therapeutic Reference Pricing

The growing use of therapeutic reference pricing as a tool to reduce the price of innovative medicines with active patents is a concern for PhRMA member companies. More specifically, a growing number of countries (e.g., the Czech Republic, Germany, Greece, Poland and Slovenia) base the price of a patented medicine on a group of medicines in the same therapeutic class, including generics. This *de facto* devalues the worth of the patent, reducing the remuneration a company can receive for an innovative product to the price level of a competing generic medicine.

International Reference Pricing

International reference pricing (IRP) is a mechanism whereby a government considers the price of a medicine in other countries to establish the price in its own country. Initially used on an informal basis to validate prices paid in countries of similar economic standing, countries that are fiscally strong such as Germany are now formally referencing prices in countries with much weaker economies like Greece and Portugal (Germany's IRP becomes active if government price negotiations fail following the quick assessment under Germany's AMNOG legislation) and, as such, IRP creates a complexity of pricing relationships between countries and beyond that not only leads to low prices, but also undermines incentives for price differentiation that could improve access in poorer countries, contributes to supply shortages via parallel trade, launch delays. Such unintended consequences of IRP are explained in a 2008 OECD study.¹⁰⁰

Dissemination of Information to Patients and Health Care Professionals

In order to make informed decisions, health care professionals and patients need to have access to information concerning their health care options. This includes understanding the benefits and risks associated with a medicine deemed to be medically appropriate by a patient's physician or health care provider. To this end, the EU should permit manufacturers to make information available to health professionals and patients about their approved medicines via their internet sites, based, of course, on such information being truthful, not misleading and balanced and limited to indications for which the relevant regulatory authority has granted market approval for that medicine.

Regulatory Transparency

Finally, the general regulatory environment should be improved with regard to reliability, transparency, and accountability, as well as improving access to patients for innovative new medicines.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

¹⁰⁰ OECD Health Policy Studies, Pharmaceutical Pricing Policies in a Global Market, 2008, p. 18.

HUNGARY

PhRMA's member companies have been facing severe market access barriers in Hungary since the first implementation of Hungarian Pharma-economic Law (XCVIII/2006). Between 2011-2014, the drug reimbursement budget was reduced by approximately 15%, and the reimbursement regime in Hungary remains highly volatile.

The austerity measures driving these savings were included in legislative changes that were implemented with very short notice. However, PhRMA member companies are committed to maintaining an active dialogue with government authorities to promote a system that is fiscally responsible and meets the health care needs of Hungarian patients.

Key Issues of Concern:

- **Reimbursement delays:** The delay in the pricing and reimbursement process in Hungary has increased to more than 2.5 years, the longest in the EU, resulting in more than 30 new innovative products/indications waiting for approval. Moreover, the Hungarian Government tends to approve new products only when neutral (or negative) budget impact is expected in relation only to the drug budget (not the drug's impact on other parts of the healthcare system), unambiguously disregarding key innovations.
- **Market sustainability:** Innovative pharmaceutical companies operating in Hungary are currently subject to the lowest list prices in Europe at the time of the official reimbursement decision and in some cases the lowest net prices around the world due to mandatory discounts of up to 50 percent in the form of sales taxes and non-transparent compulsory price-volume agreements. Future predictability is largely threatened by the claw-back system, under which pharmaceutical companies are held financially responsible for the overspending of the shrinking retail pharmaceutical budget. As a result, companies are unaware of what their total liability will be and unable to influence the amount of their liability for overspending. Meanwhile, the overdue debt of hospitals is estimated to be €185 million.
- **International reference pricing extension:** In July 2013, the Hungarian Government expanded the scope of its international reference pricing system to new uses, indications and combinations. Per this system, the price cannot be higher than the price of a medicinal product that contains the same or a similar active ingredient that has the lowest price among the products actually in circulation in any Member State of the European Union or the European Economic Area, and the preparation is reimbursed in at least three of those States.
- **“Extra” reimbursed sales taxes for the pharmaceutical sector:** PhRMA member companies requested, like other industries facing “crisis taxes,” that the

year 2011 increase of the reimbursed drug sales extra tax from 12 percent to 20 percent should have a defined expiration date. However, an end date for this tax increase has not yet been established. Moreover, since August 2012, an additional 10 percent reimbursed sales tax has been imposed on IP protected products reimbursed for more than six years without generic competition.

- **Blind bidding system for biologics/biosimilars:** The Hungarian Government held its first annual blind bidding for outpatient biosimilar drugs in March 2012. Bidding groups were selected based on the same indication (Jumbo grouping) resulting in the delisting of patented products that do not have biosimilar competitors. The first round of the bidding resulted in the relevant originator products being removed from the reimbursement list. However, unlike chemically synthesized products, biological molecules cannot be shown to have the “same” active ingredient, and seemingly minor changes in (or differences in) starting materials and manufacturing processes can result in clinical differences between the biosimilar and its reference product. Therefore, given that a biosimilar is highly similar to, but not the same as a reference biologic, caution is warranted and expected with respect to substitution of biosimilars in relation to jumbo group bidding.
- **Lack of effective dialogue between government and industry:** Despite receiving comprehensive proposals from the innovative pharmaceutical industry, the Hungarian Government does not give meaningful consideration to this input. The lack of appropriate consultation or regular dialogue with stakeholders precludes the effective leveraging of the innovative pharmaceutical and other healthcare stakeholders’ international expertise.

For these reasons, PhRMA requests that Hungary be placed on the **Priority Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

The Government of Hungary provides healthcare to its citizens through the National Health Insurance Fund Administration (NHIFA). Pharmaceutical legislation instituted in 2011 and 2012 established additional tax burdens and market access barriers for innovative pharmaceuticals, both financially and procedurally. The financial barriers include:

- A sales tax of 20 percent on all reimbursed retail products (Tax I) and an additional claw-back system (Tax II), under which pharmaceutical companies are held financially responsible for the overspending of the retail pharmaceutical budget;
- Ten percent extra sales tax applied on innovative products reimbursed for more than six years without generic competition;

- A sales representative tax of approximately US\$50,000 per year, per representative;
- Mandatory, 3-year, non-disclosed reimbursement-volume contracts for new innovative reimbursed products designed specifically to reduce the volume of the products used regardless of the real patient need for the specific medicines;
- Restrictions on reimbursement compared to the product's label, limiting the number of indications, the number of centers, and specific prescribers;
- Reference pricing with de-listing (electronic "blind" bidding system) for Type 1 ("generic") and Type 2 ("therapeutic") reimbursement groups occurring every 6 months. The therapeutic reference groups have been created in a non-transparent manner;
- Regulated annual public procurement tender for high-value medications, requesting high rebates/discounts and applying strict quota system to control demand.
- The annual bidding procedures for biologic medicines where the winning bid is not judged on therapeutic value, but merely on price. This has resulted in the delisting of some innovative medicines prior to a biosimilar of that compound being available and reimbursed;
- Review of combination products every 6 months, resulting in reimbursement cuts and high co-payments for several patented combination products, regardless of the affects these cuts may have on patient adherence;
- Revision of financial protocols to selected disease areas;
- Cross-country referencing that incorporates the lowest European price at launch and allows 20 percent threshold over the average of the three lowest European prices for subjectively selected product classes;
- Prescription directive limiting, in some instances, the prescribing choice of physicians;
- Review of reimbursement of products with high consumption;
- Expansion of the scope of its international reference pricing system to new uses, indications and combinations; and
- Devaluation of local currency: no opportunity to adjust official ex-factory prices according to actual price level in EU reference countries.

The procedural barriers include:

- Significant delay in reimbursement approvals for new-in-class products, new indications, reimbursement adjustments on therapeutic or other changes, and approval for new entities eligible for public procurement. These are all subject to a lengthy, non-transparent and unpredictable approval process by the Ministry of Economy and ministerial decree publication process that are incompatible with EU Directive 89/105/EC (which mandates that reimbursement decisions should be made within 90 days). The decision-making process is dominantly influenced

by the macroeconomic conditions of Hungary and has nothing to do with the outcome of the HTA-analysis and the proven clinical benefits of the single medications. The current average waiting time for a new innovative product to gain reimbursement exceeds 2.5 years;

- No opportunity to appeal reimbursement decisions;
- Introduction of a series of financial protocols with no transparent connection to the reimbursement procedure; and
- Lack of clear use of pharmaco-economic data. Budget impact becomes main evaluation criterion for determining whether a product will be reimbursed.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

UKRAINE

PhRMA and its member companies operating in Ukraine face growing intellectual property and market access concerns.

Key Issues of Concern:

- **Intellectual property protections:** PhRMA's member companies are highly concerned by the non-transparent introduction of a regulatory initiative (Resolution of the Cabinet of Ministers of Ukraine No. 877 dated December 4, 2013) aiming to implement a compulsory licensing mechanism for pharmaceutical products.
- **Price regulation measures:** Reference pricing mechanisms that the Ukrainian Government is implementing in pilot projects on state regulation of prices for anti-hypertension and insulin medicinal products create direct preferences for locally produced drugs and market barriers for imported products.
- **Import licensing law:** In a positive development, some of the most concerning aspects of Law No. 5038-VI "On Import Licensing for Medicinal Products" (July 4, 2012) and the Import Licensing Conditions (established by Ministry of Health Order No. 453 dated May 30, 2013), were postponed by Ministerial Order No. 960 (November 11, 2013) until March 2016. Nonetheless, implementation of the Import Licensing Conditions will need to be monitored closely to ensure that they do not discriminate against foreign manufacturers.
- **Transparency:** Regulations and laws are being adopted without adequate transparency and with little opportunity for PhRMA members to provide substantive input.

For these reasons, PhRMA requests that Ukraine be placed on the **Priority Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Compulsory Licensing Resolution

On December 4, 2013, the Cabinet of Ministers adopted Resolution No. 877 "On Approval of the Procedure for Granting Authorization to Use an Object of Intellectual Property Regarding a Medicinal Product by the Cabinet of Ministers of Ukraine" ("the Resolution"). With great assistance from the U.S. Embassy to Ukraine, representatives of the research-based pharmaceutical industry were finally included in the process in 2013. Nonetheless, despite several amendments to a draft of the Resolution, the contours of the proposed compulsory licensing mechanism remain vague. Some of the

innovative biopharmaceutical industry's proposals expressed during the discussion of the drafts with the Ministry of Health have been taken into account in the adoption of the final Resolution. However, essential problems and issues still have not been resolved and remain in the final adopted Resolution. PhRMA and its member companies are highly concerned that Ukraine could issue compulsory licenses in order to support the commercial interests of specific local companies to the detriment of U.S. manufacturers of innovative pharmaceuticals.

Market access barriers

Price regulation measures

In May 2013 the Cabinet of Ministers of Ukraine amended Resolution No. 340 (dated April 25, 2012) ("A Pilot Project on state price regulation for anti-hypertensive medicines"), thereby excluding most imported anti-hypertensive medicines from Ukraine's reimbursement lists.

On August 14, 2013, the Cabinet of Ministers launched another Pilot Project on state price regulation for insulin products (CMU Resolution No. 732, amended by CMU Resolution No. 952 on December 25, 2013). The reference pricing methodology proposed by the Ministry of Health (MoH) will challenge the ability of PhRMA's members to continue to sell insulin in the Ukraine, thereby resulting in less and potentially substandard treatment options for Ukrainian patients. Furthermore, there are administrative barriers for Ukrainian patients with diabetes to access the modern therapy, which are established by two Ministerial Orders (No. 160 dated March 23, 2011 and No. 618 dated July 18, 2013).

Import Licensing

The Law "On amending certain Laws of Ukraine with regard to licensing imports of medicinal products and defining the term "Active Pharmaceutical Ingredient (API)" (No. 5038-VI) was adopted on July 4, 2012. Pursuant to this law, the State Administration of Medicinal Products developed the Import Licensing Conditions ("Conditions") (established by MoH Order No. 453 dated May 30, 2013), which became effective on December 1, 2013. Ostensibly, the Conditions were imposed to implement similar standards to those in the EU, but fail to take into account differences between the EU and the Ukraine in terms of importation systems, laboratory capacity and distribution models. Following an intensive dialogue with the State Administration on Medicinal Products between July and November 2013, amendments to the Import Licensing Conditions were adopted at the end of last year (MoH Order No. 960, November, 8, 2013) that postpone some of the less-defined aspects of the Conditions until March 2016. Nonetheless, given that local producers will not have to obtain a similar license (and the history of favoring local production), PhRMA members are strongly concerned that any developments with these regulations need to be monitored to ensure that they do not discriminate against foreign producers of medicines.

Transparent Legislative Environment and Predictable Regulatory Policy

Greater legislative transparency and a predictable regulatory environment are necessary factors if the Government's reform agenda is to be successful. PhRMA and its member companies are ready to share best international and European practices related to healthcare reform broadly, and government pricing and reimbursement of pharmaceuticals in particular. Unfortunately, many of the measures discussed above were adopted without ample engagement with stakeholders, including PhRMA member companies.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

LATIN AMERICA

ARGENTINA

PhRMA and its member companies operating in Argentina are concerned about limitations on the transfer of capital abroad, non-transparent import requirements, and significant intellectual property issues, including patentability restrictions, the patent application backlog, and the lack of regulatory data protection.

Key Issues of Concern:

- **Restrictions to patentability for pharmaceuticals:** The Argentine Government has amended the criteria for the granting of pharmaceutical patents. A joint Resolution by the Ministries of Health, Industry and the Patent Office (INPI) establishes guidelines/instructions which restrict the possible patentability of compositions, dosages, salts, esters and ethers, polymorphs, analogous processes, active metabolites and pro-drugs, enantiomers, selection patents and Markush-type claims. This is contrary to Argentina's obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
- **Regulatory data protection:** Argentina does not provide adequate data protection, contrary to its obligations under the TRIPS Agreement. Specifically, Law 24,766 permits Argentine officials to rely on the data submitted by originators to approve requests by competitors to market similar products.
- **Import restrictions:** Argentina has issued resolutions whereby importers must submit a Prior Import Statement (PIS) before placing an order to import goods. The resolutions provide no criteria for evaluating whether the PIS will be approved or rejected. Also, the government has told companies that in order to import their products, they must export the same amount; that is, for every dollar imported, there has to be one dollar worth of exports. This verbal decision imposes quantitative import restrictions that appear to be in violation of Argentina's obligations under Article XI of the General Agreement on Tariffs and Trade 1994 (GATT), and inappropriately restrict corporate operations in Argentina. Notwithstanding the uncertainties and lack of clear rules, companies have not reported significant delays or rejections to import pharmaceutical products in 2013.

For these reasons, PhRMA requests that Argentina remain on the **Priority Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Patentability Criteria

The Argentine Government has amended the criteria for the granting of pharmaceutical patents through a Joint Regulation (Nº 118/2012, 546/2012 and 107/2012) issued by the Ministries of Health and Industry and the Instituto Nacional de la Propiedad Industrial (INPI – Argentina Patent Office). It was published in the Official Gazette on Tuesday May 8, 2012, and became effective the next day. It sets Guidelines for Patentability Examination of Patent Applications on Chemical and Pharmaceutical Inventions. The regulation applies exclusively for applications submitted in the pharmaceutical area and applies to all future and pending applications. The application of such guidelines/instructions has led to the refusal of pharmaceutical patents for: compositions, dosages, salts, esters and ethers, polymorphs, analogous processes, active metabolites and pro-drugs, enantiomers, selection patents and Markush-type claims. Furthermore, processes for the manufacture of active compounds disclosed in a specification must be reproducible and applicable on an industrial scale to be patentable. The regulation ends by stating that “Whether to extend these Guidelines to pharmaceutical biotechnological inventions will have to be analyzed for the specific case.”

The imposition of additional patent criteria for pharmaceutical patents beyond those of demonstrating novelty, inventive step and industrial application is inconsistent with Articles 1 and 27.1 of the TRIPS Agreement, as well as Argentina’s obligations under the bilateral investment treaty, which was signed by the United States and Argentina on November 14, 1991, and entered into force on October 20, 1994.

On June 6, 2012, Argentina’s innovative biopharmaceutical industry trade association, CAEMe, joined by over 40 innovative biopharmaceutical companies, filed an administrative petition seeking to invalidate the Joint Resolution. That administrative review petition was dismissed on April 5, 2013. On August 30, 2013, CAEMe filed a civil complaint in federal court challenging the Joint Resolution, the administrative review dismissal, and application of the Guidelines to pharmaceutical patent applications. That complaint is currently pending.

The effect of Argentina’s patentability criteria is that a significant number of pharmaceutical patent applications are being unfairly rejected. Some sources estimate that up to 200 patents have been rejected in the past two years. But the actual number may be even greater: When publicly commenting on the Resolution on November 20, 2013 in an interagency meeting with representatives from the innovative biopharmaceutical industry and other industries, the Minister of Industry, Debora Giorgi, said over the past two years Argentina has rejected around 800 patent applications.

Regulatory Data Protection

Argentina does not provide for protection of test and other data in a manner that is consistent with its obligations under TRIPS Article 39.3, especially the requirement to protect such data against unfair commercial use, *i.e.*, reliance by Argentine officials on the data submitted by originators to approve requests by competitors to market the same or similar products during a specified period following the approval of the product associated with the submitted data. Specifically, Law No. 24,766 provides no period of protection against reliance, and does not define “dishonest” use.

Competitors may obtain marketing approval by relying on prior approvals in other countries based on the submission elsewhere of test and other data. In short, Argentine officials essentially use the review in these countries as their review. Argentina is obligated to ensure that such approvals are consistent with TRIPS Article 39.3, by preventing unauthorized reliance for a period of time after the approval of the innovative product in Argentina.

Patent Application Backlog

The Ministry of Economy and INPI took a number of significant steps to reduce the backlog of patent applications awaiting examination in the 2005-2007 period. However, in recent years INPI's productivity has dropped, and the average time for a patent to be granted in the pharmaceutical, chemical and biotech sectors is eight to nine years. According to some estimates, the overall patent backlog exceeds 16,000 applications.

Also, Argentina should accede to the Patent Cooperation Treaty, a step that would facilitate the filing and examination of patent applications in Argentina as it does now in more than 140 Contracting Parties. In fact, the Argentinean Senate approved Argentina's accession to the Treaty in 1998, but it was never discussed in the Lower House. During 2011, the Lower House resumed the analysis for approval of the treaty, at committee level, but with no results. The issue was not discussed in 2013. There is no date set for voting.

Preliminary Measures/Injunctive Relief

Articles 83 and 87 of Law No. 24,481 on Patents and Utility Models provide for the grant of preliminary injunctions. These Articles were amended in 2003 by Law 25,859 to fulfill the terms in the agreement to settle a dispute between the United States and Argentina (WT/DS171/13). The agreed-upon terms were intended to provide, under certain conditions, effective and expeditious means for patent owners in Argentina to obtain relief from infringement before the conclusion of an infringement trial. Unfortunately, these terms, as implemented in the Argentine legal system, have not had the intended effect. Member companies have reported that the process of obtaining injunctive relief has become very lengthy.

Market Access Barriers

Import Restrictions

The Argentine administration has established new regulations for import transactions. Resolutions 3252 and 3255 (published in the Official Gazette on January 10, and January 23, 2012, respectively) establish the obligation for all importers to submit a Prior Import Statement (PIS) to the Federal Tax Bureau. Under these regulations, the information included in the PIS will be sent by the Tax Bureau to the appropriate government agencies for consideration. Following agency consideration, the Bureau will advise importers of the outcome of this consideration and will also indicate whether any reviewing agency raised concerns. Should issues be raised, the importer is required to resolve those issues with the corresponding agency. However, the resolutions fail to provide criteria to clarify the potential scope of issues that could be raised, or to determine the status of the PIS. Nor do the resolutions provide a mechanism for an importer to appeal issues raised by an agency.

Further, the Argentine administration continues to impose quantitative restrictions on imports, in contravention of its international obligations under GATT Article XI. Specifically, pharmaceutical companies, among other industries, have been informed that they must balance their own foreign trade account; that is, for every dollar that they import, they must have one dollar worth of exports. Although PhRMA member companies have not reported significant delays or rejections to import pharmaceutical products in 2013, they continue to express concern about the uncertainties and lack of clear rules that create unpredictability in the market.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

BRAZIL

PhRMA and its member companies operating in Brazil remain concerned regarding discriminatory government pricing policies, patentability standards and enforcement, and regulatory data protection.

Key Issues of Concern:

- **Patentability standards:** Amendments to the Brazilian Patent Law in the 1999 added Article 229-C, which inappropriately permits the health regulatory agency (ANVISA) to review all patent applications for pharmaceuticals products and/or processes, sometimes contradicting the patentability requirements established by Brazilian Patent Law and adopted by the Brazilian Patent Authority (INPI).
- **Regulatory data protection:** Although Brazil has enacted federal laws to ensure adequate data protection for veterinary and crop products, Brazilian law still does not provide adequate regulatory data protection (RDP) for pharmaceuticals.
- **Patent term adjustment for mailbox patents:** INPI issued a binding opinion in September 2013 followed by the filing of related lawsuits to entirely invalidate approximately 170 “mailbox patents” (primarily pharmaceutical patents), alleging that the products covered by those applications should not have been granted a minimum 10-year patent term as measured from the patent grant date.
- **Government price controls and taxation:** The current system is excessively complex and lacks transparency. The innovative pharmaceutical industry stands ready to assist the Brazilian Government in developing a transparent and consistent pricing mechanism that appropriately rewards the value of innovative medicines.
- **Partnerships for Development on Production (PDPs)¹⁰¹ and Government purchasing:** There is no clear regulatory framework for the establishment of PDPs and Brazil lacks clear rules regarding the purchasing preferences offered to PDPs. The current PDP model limits competition and prevents Brazil’s ability to foster local technology development in the pharmaceutical area. It also remains unclear how Brazil will apply a recently enacted government purchasing program that offers preferences to locally manufactured products and services in public biddings.

¹⁰¹ The Brazilian PDPs follow the same principles of regular PPP agreements with adaptations designed to respond the specificities of the local pharmaceutical market

For these reasons, PhRMA requests that Brazil remain on the **Priority Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Patentability Standards

One of the most serious problems facing the pharmaceutical industry today in Brazil was created by Article 229-C, the 1999 amendment to the Brazilian Patent Law that authorizes the health regulatory agency (ANVISA) to review patent applications claiming pharmaceutical products and/or processes that may present a “health risk.” This review is in addition to and given equal weight as the examination conducted by the Brazilian Patent Office (INPI).

This “dual examination” is incompatible with Brazil’s obligations under the “anti-discrimination” provisions of Article 27.1 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In addition, ANVISA does not limit its role to the review the potential sanitary risk aspects of the patent application but also reviews the patentability requirements. ANVISA and INPI do not apply the same patentability review standards, thus generating uncertainty for patent applicants and undermining incentives for innovation.

In October 2009, the Federal Attorney General (AGU Office) issued an opinion recommending that ANVISA limit its role in the examination process to health and safety risks. As a result of that opinion, an inter-ministerial group was created to define the correct implementation of the decision released by the AGU Office. The inter-ministerial group recommended that ANVISA should analyze the patent application prior to INPI and only those applications that receive ANVISA’s approval should be submitted to INPI. The patent applications that do not receive ANVISA’s approval are extinguished without the proper examination by the patent authority (INPI), subject to an appeal to the Brazilian Courts.

In 2013, ANVISA enacted a new resolution establishing that patent applications considered strategic and of interest to the Brazilian Government will go through a substantive review on the patentability requirements. While Brazilian authorities argue the new administrative rule and flow bring more efficiency to the process, the unduly burdensome “dual examination” process continues to affect IP right holders. The process may have the effect of denying patentability to innovative treatments that meet urgent public health needs, thereby creating disincentives for the launching of innovative products in Brazil.

Regulatory Data Protection (RDP)

The Brazilian Government still adopts a flexible interpretation of Article 39 of the TRIPS Agreement to allow Government officials to grant marketing approval relying on

test and other data submitted by our member companies to prove the safety and efficacy of their products. While some positive steps have been taken to prevent inappropriate disclosure of these data held by the Government, additional efforts are needed to provide certainty that test and other data will be fully protected against unauthorized use to secure marketing approval for a fixed period of time.

Our member companies continue efforts to gain protection for their data through the Judiciary System, with limited success. The intense debate in the Judiciary demonstrates the lack of clarity in the Brazilian legal framework regarding RDP protection for pharmaceuticals. While the federal law 10.603/02 provides protection for veterinary and crop products, the Brazilian legislation still does not provide similar protection for pharmaceutical products for human use, resulting in discriminatory treatment.

Overall, Brazil lacks adequate protection for data submitted for innovative biopharmaceutical products. A period of data protection preventing ANVISA from relying on the innovator's data in approving a follow-on drug application is needed. Although there have been lawsuits seeking to secure a period of data protection for specific products, so far the cases are still pending in the Brazilian Courts, leaving innovators without reliable regulatory data protection. A productive dialogue among U.S. and Brazilian authorities could lead to an appropriate RDP regime for pharmaceutical products in Brazil by assuring that the domestic legislation meets high standards.

Patent Term Adjustment for Mailbox Patents

In September 2013, INPI issued a binding opinion regarding the patent term for pharmaceutical patent applications filed between January 1, 1995 and May 14, 1997 (known as "mailbox patents"). Brazilian Patent Law 9,279/96 Article 40 provides that "Patents will be given a 20-year protection from the date of filing" (caput) and "A minimum of 10-year protection will be given from the date of grant" (paragraph one). However, in the event that a company's patent was filed in Brazil after the country acceded to the WTO, but before the Patent Law came into force (mailbox period) – the "mailbox patents" – Article 229 of the IP Law limited the patent term to 20 years from the filing without the minimum 10years of protection from the date that the patent was granted.

Approximately 170 mailbox patent applications for which INPI failed to complete its examination by December 31, 2004 – as defined by Brazilian legislation – were provided a minimum of 10 years patent protection under Paragraph One of Article 40. INPI's September 2013 opinion has the effect of revoking the granted 10-year minimum terms for those mailbox patents. The opinion, however, is not self-executing, and INPI has filed approximately 30 lawsuits in the Federal Court against the impacted mailbox patent holders seeking to invalidate their patents.

INPI is seeking to invalidate the patents entirely or, in the alternative, to adjust the patent term expiration dates for the impacted patents to 20 years from the date of

filing. In either case, pharmaceutical patents are being targeted and the patent terms which were originally granted and upon which innovators have relied are now being challenged *ex post facto*. Further, the elimination of a minimum 10-year term for the mailbox patents is being received as particularly unfair given INPI's inability to meet its obligation to complete all mailbox patent examinations by December 31, 2004. This is another example of Brazil's deteriorating and unpredictable IP environment for pharmaceutical innovators.

Patent Backlog

While PhRMA recognizes efforts underway at INPI to reduce the patent backlog, delays in patent grants have continued to worsen, undermining otherwise valid patent rights and incentives for companies to bring innovative products to Brazil.

As of December 2013, INPI had a backlog of approximately 184,000 applications and estimated that the average time it took to receive a patent for a pharmaceutical product in 2013 was 10.2 years. Unfortunately, this is a significant increase from the average time for all patent applications of 5.4 years in 2011 and even 8.3 years in 2010. Although INPI states that it is committed to reducing the backlog by 2015 by hiring more examiners, this process follows the standard Government of Brazil hiring procedures, meaning that it is a complex and very slow track. Further, even though President Dilma authorized funding and positions have been filled in the last year, the newly hired examiners specialize in technologies other than pharmaceuticals or biotechnology.

The patent backlog for pharmaceutical patents in particular is further exacerbated by ANVISA's "dual examination" discussed above. As of December 2013, the average time it took for ANVISA to send a pharmaceutical patent application back to INPI with its decision on whether a patent can be granted was a little over one year.

Market Access Barriers

Government Price Controls and Taxation

A price control mechanism implemented with minimal input from the pharmaceutical industry allows price adjustments through a formula that excludes productivity gains. As a result, the average price increase is below the rate of inflation measured by the consumer price index (CPI). The methodology used to calculate the maximum annual permitted price increase does not reflect the characteristics of the pharmaceutical sector, and is the result of the application of an excessively complex and non-transparent formula. These restrictions are contrary to the free-market principles espoused by Brazil and create a less favorable environment for innovative pharmaceutical companies.

The Brazilian Government has already recognized the inaccuracy of the current price formula and began to assess possible modification in the legal framework that regulates the annual price adjustment.

This movement gives the Brazilian and U.S. authorities a good opportunity to exchange mutual experiences and define a positive benchmark designed to promote free enterprise and also to discuss other and more effective mechanisms to promote access to medicines, such as the implementation of less regressive taxes on medicines at the federal and state levels which, combined, add 34% to the price of medicines (the highest tax burden on medicines in the world).¹⁰²

Government Purchase and Partnerships for Development on Production (PDPs)

The Brazilian Government issued the federal Law 12.349/10 granting preferences for locally manufactured products and services in public tenders. More recently, an amendment to Portaria MDIC 279/11 provided a list of pharmaceutical products eligible for preference margins and defined the parameters for its application in public purchases. While the issuance of Portaria MDIC 279/11 brought more transparency to the purchase process, it still fails in defining the compensation that – according to the Law – must be offered by those companies that benefit from this mechanism.

Our members understand the motivation behind the new public purchase policy and believe they can cooperate to improve Brazilian Government conditions to acquire products and services with high quality standards.

Regarding the PDPs, greater transparency in the process of selecting technological partners is required. Today, the terms and conditions for companies interested in participating in the PDPs processes are not public, which negatively impacts Brazil's ability to attract more competitive proposals. An industrial policy designed to stimulate alliances between national companies funded by the Brazilian Development Bank (BNDES) and international partners without the necessary background and/or certified sanitary processes is causing delays on the deliveries of some PDPs. In other cases, technology providers that entered into PDPs agreements with the Brazilian Government cannot offer the most updated technology and/or are simply not able to develop the technology at all. This model limits the competition and impedes Brazil's ability to foster local technology development in the pharmaceutical area.

Bearing this in mind, PhRMA and local association stand ready to contribute to this dialogue and expect that the measures will not lead to discriminatory treatment that could limit their ability to compete in the market place.

Regulatory Burden

All participants in the pharmaceutical industry, innovative and generic alike, face numerous challenges stemming from the deadlines currently enforced by ANVISA.

¹⁰² The current tax system penalizes Brazilian patients that pay more taxes on medicines (approximately 32%) than any other population in the world.

While Brazilian legislation adequately addressed ethics, safety and efficacy standards, it did not provide a mechanism to ensure that ANVISA had adequate capacity to execute its assigned responsibilities. PhRMA and its members recognize that the current Board of Directors has demonstrated an awareness of this issue but this alone is insufficient.

The innovative pharmaceutical industry believes that a more efficient regulatory system in Brazil would require:

- More human resources and IT tools so that ANVISA could reduce timelines in analysis of line extensions and other petitions;
- More predictable processes, allowing companies to be prepared in advance, resulting in shorter "clock stops" and faster approvals; and
- Introduction of an expedited process for line extensions (at least similar to the deadline for new products) providing faster access to post-approval innovations.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

CHILE

PhRMA welcomes the Chilean Government's efforts during 2011 and 2012 to address concerns of the U.S. Government and the innovative biopharmaceutical industry regarding insufficient fulfillment of Chile's Intellectual Property (IP)-related obligations under the U.S.-Chile Free Trade Agreement, especially the absence of effective regulatory data protection and patent enforcement. PhRMA is concerned, however, about the current shortfalls in implementation of FTA obligations and also unreasonable delays in granting pharmaceutical patents.

Key Issues of Concern:

- **Ineffective Patent Enforcement:** PhRMA's member companies believe that the Chilean Government's draft legislative and regulatory proposals would, if approved by the Chilean Congress and implemented, represent a step toward compliance with Chile's treaty obligations. Any change in Chile's current Special 301 status must await final congressional approval and full implementation of the government's proposed legislative and regulatory modifications.
- **Regulatory Data Protection:** The Chilean Government's enactment in December 2010 of Supreme Decree 107 corrected several deficiencies in Chile's existing system for protecting proprietary pharmaceutical test data against unfair commercial use and disclosure. The correction of remaining weaknesses, however, will depend upon whether the government makes certain necessary changes to Chile's Industrial Property Law.

Notwithstanding the Chilean Government's positive statement of intentions and its efforts to date, PhRMA believes that the government's actions do not yet merit an upgrade from Priority Watch List (PWL) to Watch List (WL), and thus PhRMA requests that Chile remain on the **Priority Watch List** in 2014. However, PhRMA would welcome an **Out-of-Cycle Review** for Chile if and when the Chilean Congress gives final approval to acceptable patent enforcement legislation and modifies the Industrial Property Law to correct remaining weaknesses in Chile's data protection legislation.

Intellectual Property Protections

Effective Patent Enforcement

Notwithstanding the requirement contained in Article 17.10.2 of the U.S.-Chile FTA, Chile has thus far failed to establish a satisfactory mechanism to enable effective patent enforcement before marketing approval decisions are made and implemented. Article 17.10.2 requires Chile to "make available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent" and "not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner."

During 2011, the Chilean Government indicated to USTR and the innovative pharmaceutical industry its recognition of the need to enact new legislation aimed at establishing an effective patent enforcement mechanism that would bring Chile closer to compliance with its FTA obligations. PhRMA welcomes the government's work on new legislation and regulations, which it hopes will produce a final proposal that:

- Provides sufficient time prior to the grant of sanitary registration of a follow-on product to obtain a final decision regarding the validity or non-infringement of the relevant patents;
- Ensures that the patent holder will have access to the courts to assert its patent rights prior to the grant of sanitary registration for a potentially patent-infringing medicine; and
- Excludes the imposition of additional requirements or conditions that might prove unreasonable or unduly burdensome, and that might discourage reasonable patent enforcement efforts (*e.g.*, excessive bond requirements and disproportionately high fines for declarations subsequently judged to be inaccurate).

Regulatory Data Protection

Final enactment in December 2010 of Supreme Decree 107 resolved several longstanding concerns of the U.S. Government and PhRMA regarding deficiencies in Chile's regulatory data protection (RDP) system. Specifically, S.D. 107 establishes that:

- Only active ingredients previously registered with the ISP are ineligible for protection on grounds of not being a new chemical entity (Arts. 2 and 3) – the previous regulation said that active ingredients either “registered” or “authorized” previously by the ISP were ineligible;
- RDP is available only for complete data packages of which the applicant is the legitimate owner or authorized user (Arts. 4 and 5);
- RDP is automatically available if the data refer to an eligible new chemical entity and if the applicant complies with certain specified formalities (Art. 5) – thereby eliminating the ISP's authority to make case-by-case determinations of whether the data are in fact “undisclosed”;
- Protection covers all data submitted that relate to safety or efficacy of an eligible new chemical entity (Art. 5); and
- Once granted, RDP will be maintained regardless of any subsequent partial or complete disclosure by the data owner (Art. 9).

Nevertheless, Chile's RDP system still contains the following weaknesses, correction of which will likely require amendment of the Industrial Property Law. Specifically:

- RDP is unavailable for certain pharmaceutical innovations (*e.g.*, new uses, formulations, compositions, dosage forms, *etc.*) that require the presentation of

additional clinical test data as a condition of sanitary registration, but that do not involve a new chemical entity not previously registered in Chile;

- Prior voluntary disclosures by the data owner made in the interest of transparency can still justify denial of RDP;
- An applicant for sanitary registration must explicitly request RDP and provide a copy of the data for which protection is sought (Art. 4);
- RDP applicants are required to submit sworn statements and other formalities that could conceivably justify denial of RDP if judged to contain technical or procedural errors (Art. 4);
- RDP is only provided to data specifically identified (by title or name) in the sanitary registration application (Art. 6);
- It is not clearly stated that the ISP's obligation not to disclose protected data does not expire after 5 years; and
- S.D. 107 (Art. 10) repeats the IP Law's enumeration of various grounds for revocation or denial of the right to exclusive use that are not stated in TRIPS or Chile's bilateral trade agreements with the EU and the United States; these conditions significantly weaken the applicability and usefulness of the available data protection.

PhRMA understands that the Chilean Government is working on a reform of Chile's Industrial Property Law. In response to a public call for comments by Chile's Patent Office, the Chamber of the Pharmaceutical Industry of Chile (CIF) submitted a number of specific suggestions aimed at correcting the above-mentioned deficiencies in the context of this reform project. As of this writing, however, it is not clear whether the reform will address the innovative pharmaceutical industry's concerns regarding Chile's RDP system.

Although PhRMA recognizes that enactment of S.D. 107 constitutes an advance toward implementation of Chile's obligations regarding data protection under the U.S.-Chile FTA, TRIPS, and other multilateral agreements, it believes that full compliance with these obligations will require additional action by Chile to correct the aforementioned legislative deficiencies.

Delays in Granting Pharmaceutical Patents

For many years, applicants for pharmaceutical patents in Chile have had to wait an average of eight years to obtain final action on their applications by the Chilean patent office. In 2009, the Chilean Government established the Intellectual Property Institute (INAPI) as the successor agency to the DPI, in part, to remedy these unacceptably long delays. One of INAPI's stated objectives is to streamline the patent application review process by limiting the number of substantive office actions and facilitating rapid communication between applicants and examiners, thereby enabling it to rule more expeditiously on patent applications.

The administrative and procedural reforms implemented by INAPI to date have decreased waiting times, with most patent applications filed after 2007 receiving a definitive decision within 5 years. However, many patents filed prior to 2007 still do not have a final decision. Therefore, while PhRMA supports the Chilean Government's work to improve patent application processing times, it believes that further work must be done to expedite patent application reviews in Chile.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

VENEZUELA

PhRMA member companies face several market access barriers in Venezuela, including virtually non-existent intellectual property protections, government price controls, and restrictions on access to foreign currency.

Key Issues of Concern:

- **Intellectual property protections:** Venezuela has essentially not granted patent protection or regulatory data protection (RDP) to pharmaceuticals since 2002.
- **Foreign currency access:** In 2003, Venezuela established restrictive foreign currency controls. Since 2010, the total amount of foreign currency authorized for pharmaceutical imports has decreased by 35%, resulting in delayed payments exceeding 150 days. Uncertainty persists as to the availability of foreign currency. Meanwhile, the Venezuelan Government is using these controls to develop selective import policies.
- **Price controls:** On July 18, 2011, the Government of Venezuelan issued a Law Decree creating a new agency to limit profit margins for companies operating in areas such as food and medicine. The Decree went into effect on November 23, 2011, subsequent to which all medicines sold in Venezuela have been subject to government price controls. No price increases have been allowed since then despite inflation (62.3%) and devaluation of Venezuela's currency (46.5%).

For these reasons, PhRMA requests that Venezuela remain on the **Priority Watch List** for the 2014 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Pharmaceutical Patents

As a practical matter, Venezuela has not granted patent protection to pharmaceuticals since 2002. As a legal matter, Venezuela was obliged to grant patent protection to pharmaceuticals as a Member of the Andean Community (AC). However, in April 2006, Venezuela formally withdrew from the AC, and all rights and obligations for Venezuela, including application of Intellectual Property Decision 486, ceased upon withdrawal in accordance with Article 135 of the Cartagena Agreement. Although there was legal uncertainty as to whether Decision 486 still applied in Venezuela, a decision by the Supreme Court of Justice issued on March 17, 2011, confirmed that following Venezuela's withdrawal from the AC, Venezuela intellectual property law reverted to the Industrial Property Law of 1956 (IPL). The IPL prohibits the granting of patents for pharmaceutical products, and thus directly contravenes Article 27 of the World Trade

Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Paris Convention.

Regulatory Data Protection

Although Venezuela provided RDP between 1998 and 2001, it has not done so since 2002. It has instead granted second regulatory authorizations and relied on the original data during the period when data protection should be applied, raising serious concerns under TRIPS Article 39.3.

According to CAVEME, it has become common practice in the last decade for the health authority (the Venezuelan National Institute of Health (INH)) to grant sanitary registration to “copy” products before the expiration of the five-year data protection period. Individual research based pharmaceutical companies have filed challenges against the government in the courts to enforce data protection, with no results to date. Many companies have also acted directly against marketers of the copy products at the Venezuelan Antitrust Agency, which has dismissed all unfair competition claims. Claims were also brought by pharmaceutical companies to the Administrative Courts and then to the Supreme Court of Justice, but both courts denied preliminary remedies and continue to process claims with no decision in sight. On June 6, 2005, CAVEME sued the INH for not granting the data protection stipulated by TRIPS Article 39.3. The claim was accepted by the Court in 2006, but a decision has not been issued.

Market Access Barriers

Foreign Currency Access Policy

In 2003, Venezuela established restrictive controls on access to foreign currency for all economic sectors. Although the preferential (official) exchange rate may be used to fund finished medicines and pharmaceutical raw materials, requests by pharmaceutical companies to use foreign currency for transfer of capital and earnings, and to pay for technical assistance, business expenses or to import other goods and services indirectly related to the manufacture of medicines or the normal operation of companies, have generally been denied.

In February 2013, after devaluing the official exchange rate of the Venezuelan Bolivar from VEB 4.3 to 6.3 per USD, the Venezuelan government set up the Complementary System of Administration of Foreign Currency (Sistema Complementario de Administracion de Divisas or SICAD) to address the purchase of foreign currency by importers operating in Venezuela who do not have access to the Commission for the Administration of Foreign Currency (Comision de Administracion de Divisas or CADIVI). This step, at a time when the implicit exchange rate (M2/IR) is approximately six times the official exchange rate, seems to be necessary in order to control inflation and grant companies access to foreign currency.

Since 2013, the total amount of foreign currency authorized for pharmaceutical imports has decreased by 35%, resulting in payment delays exceeding 150 days. Uncertainty persists as to the availability of foreign currency. Meanwhile, the government is using these controls to develop selective import policies.

Government Price Controls

Beginning in 2003, the Venezuelan government imposed price controls for Essential Medicines (as defined by the World Health Organization (WHO)) comprising close to one-third of the medicines marketed in-country. Since then, statistics released by the Central Bank of Venezuela and the National Institute of Statistics indicate that prices of Essential Medicines have not been revised to take into account accumulated inflation (432 percent), or devaluation (169 percent) between October 2003 and July 2011.

On July 18, 2011, the Venezuelan Government issued a Decree on Fair Costs and Prices (hereinafter “LCYPJ” as per its Spanish Acronym).¹⁰³ The purpose and goals of this Decree will be materialized in the National System of Costs and Prices constituted by the National Superintendence of Costs and Prices (hereinafter the “SUNDECOP” as per its Spanish Acronym). SUNDECOP shall establish the standards for the National Registry of Prices of Goods and Services, and will have overall responsibility to regulate, supervise, control, and monitor prices, and it will also have the authority to establish Maximum Retail Prices (PMVP) or the price range for goods and services, among other activities.

The main objective of this Law is to establish and regulate prices on goods and services in the local market, including pharmaceuticals. The Decree went into effect on November 23, 2011, thereupon ending Venezuela’s long-standing practice of allowing free-market pricing for non-essential medicines (accounting for approximately 90 percent of the market by value). Since that time, all prices of medicines are subject to government control and no revision or adjustments have been made to account for inflation and currency devaluation.

Non Production Certificate

Venezuelan manufactured medicines have been exempted from Venezuela’s value added tax (VAT) since 2002. In order to obtain a VAT exemption for imported medicines, companies must request a certificate from the government, stating either that the product is not manufactured domestically, or that it is manufactured in insufficient quantities that will not satisfy patient demands. This certificate, initially intended for the sole purpose of demonstrating eligibility for the VAT exemption, is now also required by foreign exchange authorities to provide currencies at the official rate. As restrictions in currency availability increase, the authorities have restricted the number of exemption certificates and the amount of foreign currency requested, thus

¹⁰³ Official Gazette N° 39.715 (July 2011).

creating shortages at any given time of approximately 40% of medicines, to the obvious detriment of Venezuelan patients.

Government Procurement

The Venezuelan Bidding Law applies to government procurement of all goods and services, including pharmaceutical products, and mandates, other than in certain limited circumstances, a competitive bidding process. However, in practice the Bidding Law is not consistently enforced by Venezuelan authorities, and it is very common for public contracts to be: (1) awarded without regard to the Bidding Law, or (2) based upon broad interpretations of the exceptions set forth in the Bidding Law in order to avoid a competitive bidding process. The government's failure to enforce the Bidding Law results in a lack of transparency with respect to government procurement.

The Bidding Law contains local content criteria allowing public entities to give preference to a local company over a foreign company if certain conditions are met. However, according to the local innovative pharmaceutical association, Cámara Venezolana del Medicamento (CAVEME), public entities disregarded these conditions and have awarded contracts to local goods and services without satisfying the terms of the Bidding Law.

Counterfeit Medicines

As noted by the Direction of Drugs, Medicines and Cosmetics of the Health Ministry in 2010, Venezuela has witnessed an increase in counterfeit medicines (more than 10 percent of the market) as well as other illicit activities, such as smuggling, robbery and adulteration. This increase can be attributed to a combination of factors: (1) the Government's lack of attention and political will to address the problem; (2) administrative inefficiency; (3) lack of enforcement of existing laws, most of which are inadequate; (4) insufficient penalties; and (5) an ineffective judicial system that does not consider counterfeit medicines a priority. Venezuela should be encouraged to place a higher priority on curbing the distribution and use of counterfeit medicines through increased resources and penalties for criminals caught manufacturing, supplying, or selling them.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

MIDDLE EAST/ AFRICA

ALGERIA

PhRMA and its member companies operating in Algeria believe Algeria has the potential to be a promising market for new pharmaceutical products, investment and innovation. Yet significant barriers remain that impede market access for medicines and impact PhRMA member companies' ability to advance human health, and operate and invest in Algeria. PhRMA had some success in collaborating with the prior government in place until mid-2012, with that government publicly stating its support for a new strategy that better integrates the innovative pharmaceutical sector into Algeria's economy and healthcare system. PhRMA's member companies are hopeful for a similarly cooperative dialogue with the current government.

Key Issues of Concern:

- **Intellectual property protections:** Algeria has inadequate patent protection, ineffective mechanisms to enforce patents, and does not grant regulatory data protection.
- **Government mandated reference pricing:** Under Algeria's pricing system, some patented medicines with no generic equivalent on the market are nonetheless referenced against a generic product in the same therapeutic class. The resulting price does not recognize the value of innovative products, nor does it reward the significant investment involved in developing new medicines, or encourage the development of tomorrow's new cures.
- **Import restrictions:** Pharmaceuticals are subject to severe import restrictions including a virtual prohibition on imports of pharmaceutical products that are produced locally and annual import quotas on all other medicines.

All of the above constitute major barriers that curtail access for innovative pharmaceuticals, impede trade, deter investment, and jeopardize Algeria's chances of acceding to the WTO in the near future. For these reasons, PhRMA requests that Algeria remain on the **Priority Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Transition from Administrative Exclusivity

Pharmaceutical products were not eligible for patents in Algeria until the promulgation of Ordinance No. 03-07 on July 19, 2003. Before that date, in a good faith effort, Algerian authorities would not authorize the marketing of generic forms of pharmaceutical products covered by unexpired patents in their country of origin. In other words, Algeria provided *de facto* administrative exclusive marketing rights to pharmaceutical inventions *in lieu* of patents. PhRMA members relied on the protection afforded by these rights.

While the 2003 Ordinance extended patent protection to pharmaceutical products, it unfortunately did not include transitional provisions to require authorities to continue providing the exclusive marketing rights to pharmaceutical products that could not obtain patent protection under the Ordinance because of prior publications or sales. Accordingly, in 2005, Algerian health authorities abandoned the practice of providing *de facto* exclusive marketing rights to pharmaceutical products that could not benefit from the Ordinance, and started to approve the marketing of copies of products still covered by patents in their country of origin. Thus, PhRMA members lost the exclusive marketing rights upon which they had relied because of the lack of clear transitional provisions.

Lack of Effective Patent Enforcement

The interpretation of the current law by local authorities is that a copy of a product covered by an Algerian patent may be granted marketing approval while the original patent is still in effect and not invalidated in court. The absence of effective judicial remedies for preventing the infringement of basic patent rights, including the lack of injunctive relief that could prevent irreparable harm prior to the resolution of the case in court, puts the originator in an unfair position with no possibility to defend its rights. Violations of Algerian patents that have occurred in recent years have still not been corrected.

Lack of Regulatory Data Protection

Algeria does not protect pharmaceutical test and other data from unfair commercial use and disclosure. Algeria should correct this deficiency through implementation of meaningful regulatory data protection.

Market Access Barriers

Government Reference Pricing

Based on an inter-ministerial order issued in 2001, products having corresponding generics on the Algerian market are subject to reference pricing for reimbursement. Yet, in practice, some patented products with no generic equivalent on the market have been referenced against generics in the same therapeutic class in an apparent effort to compel the lowest possible price. Patents provide an incentive to innovate by providing a reward to inventors in the marketplace. By linking the reimbursement price paid for patented products to the lowest priced generic medicine in the same therapeutic class, the Algerian system dramatically undervalues the innovation and development costs involved in bringing the patented pharmaceutical to market. In addition, the process for setting prices is not transparent or reviewable, and does not provide for any specific appeal system. Moreover, as prices in the country of manufacture can become a reference for export markets, arbitrarily low prices in Algeria have the effect of deterring investment in Algeria as an export platform, thereby undermining the government's intention to become a regional export center.

Previous discussions indicated that the Algerian Government was increasingly aware of the contradictions and shortcomings of the government price control system, but to date, no reforms have been enacted that would improve the operating environment.

Import Restrictions

On October 21, 2008, the Algerian Government issued a decision¹⁰⁴ stipulating that, effective January 2009, the importation of pharmaceutical products that compete with similar products that are being manufactured locally is prohibited. This decision was essentially a reinstatement of a previous ministerial decree¹⁰⁵ that was suspended as part of the WTO accession process. Subsequently, the Ministry of Health (MOH) published lists of such products comprising hundreds of branded medicines, and this import policy continues to be implemented in a non-transparent and arbitrary manner.

Algeria's reinstatement of this policy on the importation of pharmaceuticals unfairly discriminates against PhRMA members, severely curtails market access for innovative pharmaceuticals, and is a significant barrier to trade. Moreover, these import restrictions have resulted in shortages of some drugs,¹⁰⁶ thereby impacting Algerian patients.

During discussions that started in 2011 and continued in 2012, Government officials signaled their intent to reform the system to improve access and minimize stock disruptions. As yet, however, the system remains unchanged.

Volume Control

Algeria continues to impose an annual import quota for medicines with the "requirement that each shipment receives prior clearance from the MOH". The Government practice is to block temporarily importation as a cost-containment tool. The unintended consequence, however, is that it leads to shortages in the market, to the detriment of Algerian patients.

Unfair Competition

Many local generic pharmaceutical companies are illegally offering free goods to pharmacies. Yet instead of benefiting patients or reducing the government's healthcare spending, these free goods are sold and reimbursed at the price levels set by the government. The increased margins from these sales introduce an element of profit-making whereby the pharmacist is encouraged financially to disregard the physician's

¹⁰⁴ The decision was published in November 2008 under the name "Arrêté du 30 novembre 2008 relatif à l'interdiction des produits pharmaceutiques et dispositifs médicaux destinés à la médecine humaine fabriqué en Algérie."

¹⁰⁵ Instruction #5 for the Generalization of Generics (Sept. 2003).

¹⁰⁶ Veille Media, "Pénurie de médicaments: le Snapo va interpeller le ministre de la Santé" (May 12, 2011).

prescription, and switch the prescription to a generic. The pharmacist is not required to obtain the physician's approval for switching to a generic. The switch is allowed under current Algerian law, and even incentivized through tax deductions to pharmacists, yet another measure that discriminates unfairly against innovative pharmaceutical manufacturers.

Investments and Commercial Laws

In December 2008, the Algerian Government declared that any company engaged in foreign trade should have a minimum of 51 percent of local Algerian shareholders. This decision applies prospectively, not to companies engaged in foreign trade prior to December 2008. Despite the lack of success in attracting new investment, the new government has recently confirmed that this law will continue to be enforced for the foreseeable future.

Starting in 2009, importers have been required to secure letters of credit and set aside a percentage of the import value as a deposit on their purchase.

In May 2010, the MOH issued a circular that prohibits local manufacturers from selling products to wholesalers, and requires them to sell such products directly to pharmacies. Therefore, PhRMA members who invested in local manufacturing will now have to invest also in a distribution infrastructure. While this circular has never been applied, the uncertainty of the regulation continues to concern PhRMA members.

Cumbersome and Slow Regulatory System

Despite significant improvements in the MOH's registration process in 2013, the registration process remains slow and additional, burdensome requirements for obtaining registration to market pharmaceutical products, especially innovative products, have been implemented. As a result, patient access to innovative medicines in Algeria lags significantly behind neighboring peer countries. For example, all registration dossiers must be pre-authorized prior to acceptance for review, but there is no transparent process or timeline for completing this preliminary step of the process. After submission to the MOH, registration dossiers are on hold pending National Laboratory results, which causes further delay in the registration process.

In addition, the innovative industry continues to face significant access challenges within the reimbursement comity (CRM) process led by the Ministry of Labor (MOL):

- The MOH approves a price for the new medicine as part of the marketing approval process. But the CRM reimbursement process is entirely separate and the MOH marketing approval price is rarely accepted in the CRM process. As a result, manufacturers are required to enter into separate reimbursement negotiations with the CRM, and the new lower price must then be re-approved by

the MOH. These combined procedures are inefficient, redundant, and unfair to innovative pharmaceutical manufacturers.

- There is no clarity or fixed timeline between the first submission to the CRM of the dossier for reimbursement and the application at the pharmacy level. While the intent of the MOL is to reduce the maximum number of products on the list of reimbursable products, this particularly affects imported products so that a new (innovative) product has a very low chance of being reimbursed.

Finally, since June 2010, pharmaceutical companies have noticed lengthy delays of many months in approving variations for imported products already available on the market. The previous government had begun to recognize the negative impact that unnecessary delays have on patients and the business climate, but the backlog continues.

Industry Association License

Despite a multi-year effort by PhRMA's member companies to establish a local pharmaceutical association to engage in public policy advocacy on behalf of the innovative medicines sector, the Algerian Government continues not to grant the requested association license. PhRMA member companies hope the new Minister of Health will take the steps necessary for a license to be granted. PhRMA is unaware of any country that is a global leader today in innovative biotechnology or research-based pharmaceuticals where there is not a legally recognized association to coordinate with the government on health and industrial policy issues.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

MOROCCO

PhRMA and its member companies operating in Morocco are concerned about the deteriorating environment for innovative biopharmaceutical companies investing and operating in this country.

In early 2013, the Moroccan government announced a new economic policy prioritizing the innovative biopharmaceutical industry as a strategic sector within the national economy. PhRMA and its member companies welcomed this development as an opportunity to collaborate with the government to develop policies to achieve the goal of transforming the sector in Morocco into a regionally and globally competitive industry. Although the government had imposed price cuts in 2012, it was hoped that these cuts, combined with the government's announcement to prioritize the industry, would bring some long-term stability and predictability to the innovative biopharmaceutical market.

In reality, PhRMA and its member companies have observed a marked deterioration in the environment. Having announced the prioritization of the sector, the government has done very little to reach out to the innovative medicines sector to engage meaningfully on policies that would promote the sector. Even more concerning, the Health Ministry has pushed through a new pricing decree that imposes new burdens on manufacturers and undermines investor confidence.

Key Issues of Concern:

- **Lack of regulatory data protection:** Morocco does not provide effective regulatory data protection to test and other data submitted to regulators during the marketing approval process.
- **Discriminatory pricing policies:** The innovative biopharmaceutical industry has made many good faith efforts to reach a compromise with the Health Ministry on a new pricing regulation. While arguing that the Health Ministry should take a holistic view on the impact of pricing, including on Morocco's regional and global competitiveness and ability to attract new investment, the Health Ministry has tended to take a narrower view focused exclusively on cutting the prices of medicines.

For these reasons, PhRMA requests that Morocco be placed on the **Priority Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Regulatory Data Protection

The Moroccan Government has failed to provide regulatory data protection for test and other data submitted to regulators during the marketing approval process. This is particularly striking because beyond Morocco's WTO obligations, the country has also signed an FTA with the United States and a Special Economic Agreement with the European Union.

Morocco should move expeditiously to amend its legislation to address this serious gap in intellectual property protection. If Morocco is indeed serious about building up the innovative biopharmaceutical sector, implementing regulatory data protection will provide an essential cornerstone to fostering the development of an innovative biopharmaceutical sector.

Market Access Barriers

Government Price Cuts

In 2012, the industry reached a compromise agreement with the Health Ministry to reduce government prices by approximately 10 percent. Although industry voiced concerns that these government price cuts would undermine the incentives to invest in innovative medicines in Morocco, it was proposed that these cuts would increase patient access to new medicines and establish some longer-term stability and predictability.

What was unknown to the innovative industry at the time was that not long after reaching this compromise, the Health Ministry agreed with the pharmacists to increase their already high margins. In other words, rather than passing on the savings from the pharmaceutical price cuts to Morocco's patients, the Government transferred these savings to local pharmacists.

Further, the longer-term stability promised by these price cuts proved short-lived when in 2013 the Health Ministry published new draft pricing regulations that imposed an additional 6% discount on pharmaceutical manufacturers. The Health Ministry published the draft pricing regulations without any previous meaningful consultation with the industry, and then offered a scant 21 days to receive comments.

Morocco is a signatory to the WTO Agreement and has free trade agreements with the United States and the EU. All of these agreements specify the need for prior consultation, notification and transparency in legislation affecting trade and investment. The Moroccan Government's failure to meaningfully consult with industry prior to implementing this latest round of price cuts is inconsistent, therefore, with Morocco's international obligations.

Beyond the issue of treaty obligations, PhRMA and its member companies are concerned as a policy matter by the apparent lack of coordination among government ministries, in particular the Health Ministry and Ministry of Commerce, Industry and New Technologies, and its Investment Agency arm. Nonetheless, PhRMA and its member companies will continue to reach out in good faith to the government to try to mitigate the damaging impact of these policies.

Marketing Approval Delays

The regulatory system governing the licensing of new medicines is very outdated and outmoded. It can take two to three years for the Health Ministry to license a new medicine for human use. Given that companies are submitting abbreviated new drug dossiers to the authorities, it should be possible to review these files and issue an approval within a maximum of six months.

Because it is not possible to market a promising new medicine or vaccine in Morocco without obtaining a marketing license, the current system constitutes a serious barrier to market access.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

WATCH LIST

ASIA-PACIFIC

AUSTRALIA

PhRMA and its member companies remain concerned about an increasingly unstable and unpredictable operating environment in Australia and the lack of adequate intellectual property (IP) protection afforded to innovative pharmaceutical products in that country.

PhRMA and its member companies support the U.S.-Australia Free Trade Agreement (FTA). It has helped expand patient access to new medicines in Australia, a key priority for PhRMA. However, we also believe that there is much more that still needs to be done to further improve access to new and innovative medicines in Australia and strengthen Australia's IP regime.

In the Pharmaceuticals Annex to the FTA, the United States and Australia agreed on provisions for increased transparency and accountability, and enhanced consultation in the operation of Australia's Pharmaceutical Benefits Scheme (PBS). Annex 2-C of the FTA establishes four basic obligations that pertain to operation of the PBS, including agreed principles regarding the role of innovation, transparency, independent review process, and establishing a bilateral Medicines Working Group.

PhRMA believes that the work done to date in implementing these obligations has been significant and we look forward to seeing constructive outcomes from the Medicines Working Group, including on remaining substantive initiatives required to improve access to innovative new medicines. We note our concern, however, that the last meeting of the Medicines Working Group was held in 2007 and are hopeful that the next meeting will be scheduled in the near future. PhRMA requests that the U.S. Government raise the concerns described below as priorities for resolution during bilateral consultations with Australia as well as during multilateral negotiations such as the Trans-Pacific Partnership.

Key Issues of Concern:

- **Generally uncompetitive IP environment:** Strengthening regulatory data protection in Australia could, among other benefits, improve the country's attractiveness as a destination for foreign investment by global pharmaceutical companies and encourage companies to bring new medicines to Australia sooner. In addition, contrary to its obligations under the FTA, Australia does not provide patent holders with advance notice of patent-infringing products coming to market. Finally, the Australian Government has initiated court proceedings to recover damages from innovators in cases where patents on PBS-listed medicines have been revoked following an initial grant of a temporary injunction. This creates enormous uncertainty for pharmaceutical patent owners in Australia and is plainly bad public policy.
- **Review of Australian IP system:** There has been a large number of reviews of the Australian IP system including a review of compulsory licensing and Crown-

Use provisions in Australia; a review of patentable subject matter (aimed primarily at the issue of the patentability of genetic and biological materials); a review of the innovation patent system; and a root-and-branch review of Australia's patent system as it relates to pharmaceutical products. This creates uncertainty regarding the protection of intellectual property rights, which can impact investment decisions on research and whether to bring innovative medicines to Australian patients.

- **Ad hoc policy changes and lack of consultation:** In February 2011, the then Australian Government decided to require that the Cabinet review and approve all Pharmaceutical Benefits Advisory Committee (PBAC) recommendations prior to listing new medicines on the Pharmaceutical Benefits Scheme (PBS). Although this new layer of review was later modified, the Cabinet has deferred listing certain pharmaceuticals, which in some cases significantly delayed patient access to new medicines on the PBS. This decision represented a major departure from past practice and was taken without consultation with key stakeholders, including industry, physicians, and patient groups, leading to business uncertainty. Similarly, the Australian Government recently elected to unilaterally alter its existing policy on the scope, mechanism and timing of price disclosure, effectively bringing forward price reductions and therefore savings to the PBS. Once again done without consultation, this change has the potential to create unintended consequences which could be avoided if there were a commitment by Government to consult key stakeholders on important policy changes.

For these reasons, PhRMA requests that Australia be placed on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Regulatory Data Protection

Data Protection is an independent protection that is used to prevent unfair commercial use of confidential data by a third party. Like other forms of IP protections, data protection stimulates companies to invest in innovation by ensuring for a limited time that potential competitors cannot take commercial advantage of the innovator's data. Companies must demonstrate that new products are safe and effective for human use. This requires extensive research, which can take many years and substantial financial investment to complete. Data protection protects any data thus generated against being used to obtain product registration by a third party, for a fixed period of time.

Strengthening the data protection provisions in Australia so they are aligned with global best practice, could further enhance Australia's ability to compete for foreign investment in the knowledge-intensive and innovation-intensive biomedical sector that can drive future economic growth. Steps that Australia could take would be to extend

the term of data protection with possible extensions for new formulations, new combinations, new indications, new populations (e.g., paediatrics) and new dosage regimens.

Effective Patent Enforcement

Currently, originator pharmaceutical companies in Australia do not receive any notice of a third party's intention to enter the market with a product that may infringe a valid and enforceable patent prior to its listing on the Australian Register of Therapeutic Goods (ARTG). Originator companies are only able to access this information once the generic has already been registered on the ARTG, and even then the originator company itself has to actively go and find that information on the ARTG website. As a result, originator pharmaceutical companies in Australia are routinely unaware of a potential infringement until after the generic product has received marketing approval. While in recent years the Australian Government has been quicker to identify and publish newly approved generics on the ARTG website, this is still not what was envisaged in the U.S.-Australia FTA, the terms of which state:

if the Party [Australia] permits a third person to request marketing approval to enter the market with a product during the term of a patent identified as claiming the product....the Party [Australia] shall provide for the patent owner to be notified of such request and the identity of any such other person.

There is a serious impact on originator companies from generic medicines entering the market prior to the expiry of the originator patent, in part through mandatory and irreversible price cuts for innovator products listed on the PBS and through market share erosion whether the product is listed on the PBS or available through private prescription. Notification through the proposed listing of a generic on the PBS is not sufficient notification of a generic receiving marketing approval, because the PBS is not concerned with approval for sale in the Australian market; this is the role of the Therapeutic Goods Administration (TGA). Moreover, there is a subset of medicines on the Australian market that will not be listed on the PBS and therefore patent holders of these medicines will not receive the marketing approval notification envisaged in the FTA.

The lack of notification and the unduly prejudicial penalties that can be imposed on patent holders for seeking to defend their intellectual property significantly weakens an otherwise equitable intellectual property system in Australia. The Australian Government should implement an effective notification system so that patent holders are able to defend their intellectual property in a timely manner and without causing unnecessary delays to generic market entry.

Intellectual Property System Reviews

A strong, stable and predictable IP system is critical to Australia's ability to attract investment in pharmaceutical R&D and manufacturing. It is also critical to Australian patients being able to receive the latest treatments as quickly as possible.

Unfortunately, Australian governments have recently commissioned a significant number of IP-related reviews, the scope and timing of which make it clear that some key decision-makers within government may be looking to find ways to limit the scope of IP rights in that country. Some important reviews in the last 18 months include: a review of compulsory licensing and Crown-Use provisions in Australia; a review of patentable subject matter (aimed primarily at the issue of the patentability of genetic and biological materials); a review of the innovation patent system; and a root-and-branch review of Australia's patent system as it relates to pharmaceutical products. An interim report by the last of these reviews recommended, among other things, abolishing patent term extensions, allowing generic companies to manufacture patented medicines for export, and excluding IP from future trade negotiations. Implementing any of these recommendations would contravene Australia's obligations under existing international trade agreements and the spirit of ongoing negotiations in the Trans-Pacific Partnership, and seriously compromise Australia's ability to attract investment in the future.

Separately, PhRMA notes with concern the proposals that emerged in the Australian Parliament in 2011 to ban the patenting of all biological materials in response to concerns about the potential patenting of human genes. PhRMA was pleased to see a Parliamentary review of the proposed legislation recommended that it not proceed, but notes that late last year Australia's patent office initiated a new round of consultations on potentially expanding the list of technologies which would be *a priori* excluded from patentability.

The pharmaceutical industry, biotech industry, expert lawyers and medical researchers in Australia have repeatedly explained that such restrictions are not required given the principles of IP law, recent legislative reforms to Australian IP law (Raising the Bar Act 2012), and the risks this will constrain future scientific research and investment in new treatments. Members of the Australian Parliament have been also been engaged on this particularly sensitive topic. PhRMA is concerned about the risk of such proposals, which could be inconsistent with Australia's international obligations, being revisited again.

Innovator Liability for Damages

PhRMA is aware that the Australian Government has initiated court proceedings to recover damages in cases where patents on PBS-listed medicines have been revoked, following an initial grant of a temporary injunction. In addition, the Commonwealth has published a "watch-list" of products and companies that may be affected in the future by this approach. Provision for legal fees has been made in the Health Department's budget for 2013-14 and beyond. This action by the Australian

Government is of particular concern because there is no equivalent undertaking to compensate an innovator, or to restore the innovator's price, if a generic product is listed on the PBS and subsequently found by the courts to have infringed the innovator company's patent and is required to cease supply.

The Australian Government's actions are a threat to companies' rights to defend their intellectual property through the due process provided by the patent system. It could have an adverse effect on U.S. pharmaceutical companies' interest in seeking market access to Australia. Further, this measure is an industry-specific and technology-specific initiative that illustrates the potentially negative outcomes from the legislative amendments Australia implemented in 2004. This issue could easily be resolved if there were an effective patent enforcement system in place in Australia, which would allow patent holders and generic companies to resolve patent related issues well before they have an impact on pricing and reimbursement.

Market Access Barriers

Under Australia's National Health Care System, around 80 percent of prescriptions dispensed in Australia are subsidized under the Pharmaceutical Benefits Scheme (PBS).¹⁰⁷ Accordingly, the PBS effectively controls access to the Australian pharmaceutical market. The outcomes and processes involved in PBS listings are therefore critical to securing market access.

Ad Hoc Policy Changes

In February 2011, the Australian Government announced that the Cabinet would review and approve all Pharmaceutical Benefits Advisory Committee (PBAC) recommendations prior to listing new medicines on the PBS. Although this decision was later modified, the Government's action, which in some cases significantly delayed patient access to new medicines, represented a major departure from past practice and was taken without consultation with key stakeholders, including industry, physicians, and patient groups.

Similarly, the Australian Government recently elected to unilaterally alter its existing policy on the scope, mechanism, and timing of price disclosure, effectively bringing forward price reductions and therefore savings to the PBS. Once again done without consultation, this change has the potential to create unintended consequences which could be avoided if there were a commitment by Government to consult key stakeholders on important policy changes.

In light of this prior uncertainty, the innovative pharmaceutical industry welcomed and will closely monitor the commitment of the new Coalition government to follow the recommendations of the independent PBAC to list new medicines on the PBS.

¹⁰⁷ "About the PBS," Australia Dept. of Health and Ageing, at <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-aboutus.htm-copy2> (last visited Feb. 8, 2013).

Decline in the Number of New Medicine Listings

There has been a significant decline in the number of new innovative medicines listed on the PBS since 2009-10. In fact, access to innovative new medicines hit an historic low in 2011-12, with the lowest number of new medicines listed on the PBS in 20 years. For the first time in recent years, we are seeing comparable countries gain access to new medicines well before Australia, and, in some cases, new medicines have not been available to Australian patients at all. Much of this is related to the current administration of the PBS.

The purpose of the PBS is to provide timely, reliable and affordable access to medicines for Australian patients. Given especially the decline in new listings, there is a strong need to ensure that, moving forward, the PBS remains fit for purpose as new health technologies become available. There is also a need to ensure that industry confidence is restored in the independence and integrity of the PBAC process so that Australian patients can receive access to the newest treatments as soon as possible.

In light of these trends, the innovative pharmaceutical industry commends the new coalition Health Minister Peter Dutton for implementing pre-election commitments to list 48 medicines on the PBS in December 2013. Another positive development was the increase of the threshold for Cabinet review of PBS listings from \$10 million to \$20 million per annum. PhRMA and its member companies are hopeful that this is indicative of a renewed commitment in Australia to ensure that its patients have access to innovative medicines.

Lack of Transparency and Procedural Deficiencies in Government-initiated Post-market Reviews of PBS Listed Medicines

PhRMA has major concerns with the current conduct of post-market reviews of medicines in Australia. These reviews have potentially significant and negative outcomes for stakeholders, including commercial implications for industry and access to and quality use of medicines for patients.

The Australian Government's post-market reviews program must be improved to address serious policy implications and procedural deficiencies. Without appropriate policy consideration, post-market reviews will likely undermine existing PBS policy settings and Australia's National Medicines Policy:

- In the short term, post-market reviews undermine the intent of the PBS reforms of 2007 and 2010 to drive savings from the off-patent market to secure headroom for new medicines;
- In the longer term, post-market reviews and the associated driving down of prices for medicines, on top of existing price saving measures may jeopardise access to new medicines, which will be compared to the low cost medicines already on the market when considered by the PBAC.

PhRMA believes that post-market reviews must be conducted with transparent, predictable and rigorous procedures, and work must be done to improve the current deficient processes.

Failure to Recognize the Value of Incremental Innovation

Inappropriate interpretations of sections of Australia's *National Health Act* by the Government have recently led to instances of Australian patients being unable to access improvements in the delivery of medicines. Section 99ACB and Section 99ACD for combination products are parts of the *Health Act* which allow for statutory price reductions when generic medicines are made available on the PBS. These sections of the *Health Act* were established to:

- allow the Government to benefit financially when generic medicines are able to enter the market;
- provide headroom for new and innovative medicines in the F1 formulary; and
- allow for single brand medicines to be protected from unsustainable pricing actions prior to generic competition.

However, the Australian Government has begun interpreting Sections 99ACB/D in a way that erodes the fundamental basis of the F1 formulary by treating new presentations to single brand medicines as generic competitors. This has recently occurred to a number of pharmaceutical companies in a range of disease areas.

The intention of pharmaceutical companies in bringing new presentations of currently available medicines to market is often to introduce an improvement in medication delivery which enhances patient outcomes, or can be a result of a global technology change, or safety concerns surrounding the existing presentation. However, due to the Government's recent actions, several pharmaceutical companies are considering not bringing improved presentations to the Australian market because their listing will trigger a commercially unviable 16% statutory price reduction for both the old and new presentations. It is imperative that there is no disincentive to the introduction of incremental technology improvements and innovations so they can be brought to patients without triggering unreasonable price penalties.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property and market access barriers.

MALAYSIA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Malaysia hope to continue our engagement with the Government of Malaysia as it looks to improve the intellectual property and regulatory environment for the research-based pharmaceutical industry.

Key Issues of Concern:

- **Intellectual property protections:** Malaysia does not have an effective patent enforcement system whereby innovative pharmaceutical companies may resolve patent disputes before marketing approval is granted to infringing follow-on products during the patent term. In addition, its regulatory data protection (RDP) system fails to provide effective protection from the date of marketing approval in Malaysia.
- **Listing pharmaceuticals on the national formulary:** Malaysia's stringent process for listing pharmaceuticals on the national formulary curbs access to innovation. The evaluation and decision process lacks transparency, leaving the industry with great uncertainties that have led on many occasions to listing delays in the range of three to five years. Effective reform that streamlines listings could help Malaysia achieve its goal of world class status as a hub for healthcare innovation. This could be done by periodic update of the national Ministry of Health (MOH) formulary based on the most current treatment algorithm and evidence from international clinical practice guidelines. Direct submission by the manufacturers should also be considered to ensure a transparent process and that all related data can be presented in a timely manner. Additionally, products in clinical trials in Malaysia should be eligible for automatic listing in the national formulary to enable patients who were on the treatment to continue receiving them after the clinical trial is completed.
- **Preferential treatment of local manufacturers:** The Government of Malaysia indirectly discourages an open and competitive marketplace for international pharmaceutical compounds through procurement preferences for locally manufactured products.
- **Counterfeit medicines:** The need for deterrent and criminal penalties for those caught manufacturing, supplying, or selling counterfeit pharmaceuticals as well as closer coordination between the U.S. and Malaysian Governments on anti-counterfeiting initiatives. The industry welcomes the recent passage of the Pharmacy Bill, which imposes enhanced penalties for counterfeiting of medicines.

For these reasons, PhRMA requests that Malaysia be placed on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Effective Patent Enforcement

PhRMA's members encourage Malaysia to efficiently and effectively enforce the Patent Act. A competent and practical enforcement mechanism provides redress and solutions to infringements of IP rights and deters future infringement. Timely and efficient patent enforcement gives owners an appropriate period over which to recoup the value of their significant efforts and investment. For example, patent protection and enforcement would be enhanced by structured enforcement guidelines and a mechanism to curb unfair promotion and sale of generic drugs prior to: (1) patent expiry of innovator drugs; and (2) a court decision on patent disputes.

PhRMA's member companies strongly encourage the improvement and adoption of mechanisms that strengthen patent enforcement and the ability to resolve outstanding patent concerns prior to marketing approval of follow-on products, such as generics. These mechanisms could greatly enhance Malaysia's business environment by: (1) providing transparency and predictability to the process for both innovative and the generic pharmaceutical companies; (2) creating a more predictable environment for investment decisions; and (3) ensuring timely redress of genuine disputes.

Regulatory Data Protection

Regulatory data protection (RDP) should be granted to any product that is "new" to Malaysia. Unfortunately, in practice, Malaysia grants RDP only to pharmaceutical products that are "new" to the world – in other words, introduced first in Malaysia. That is at odds with the approach of other regulatory systems and is not consistent with Malaysia's international obligations under Article 39.3 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Furthermore, Malaysia's RDP regulation is contained in a directive rather than Malaysian law. As a result, it has been mired in litigation, further weakening the system.

Patent and Trademark Laws

Proposed amendments to Malaysia's patent and trademark laws that include provisions for disclosure of traditional knowledge and genetic resources, as well as compulsory licensing, raise concerns for the research-based pharmaceutical industry, and PhRMA encourages a continued consultative process with stakeholders before such amendments are implemented. These proposed amendments also include provisions for effective patent enforcement and patent term restoration and PhRMA member companies are eager to engage in meaningful dialogue with Malaysian Regulatory Authorities to build a regime in accord with international best practices.

Market Access Barriers

Listing Pharmaceuticals on the National Formulary

The lack of transparency in the evaluation and decision making process for listing pharmaceuticals on Malaysia's national formulary results in listing delays of up to five years beyond the date of regulatory approval. In July 2011, the Ministry of Health (MOH) issued guidance to PhRMA's member companies of Malaysia's intent to examine the process and consultations are presently underway. Effective reform that streamlines listings to the national formulary could improve market access and patients' access to medicines.

As the government pursues reforms aimed at improving access of medicines to its population, member companies hope that sufficient financing is provided to ensure that more patients can receive innovative medicines in as timely a manner as possible to achieve better health outcomes. For example, products in clinical trials in Malaysia should be eligible for automatic listing in the national formulary to enable patients who were on the treatment to continue receiving them after the clinical trial is completed. We hope that short term measures, such as cost containment policies, do not become a barrier to delay access and the government considers fair mechanisms to value innovations that are proven to raise the standards of care in Malaysia.

Regulatory Approval Process

PhRMA's member companies continue to advocate for further streamlining in Malaysia's regulatory approval process for innovative pharmaceutical products. In November 2010, Malaysia's MOH gave notice of their intention to streamline the approval process to 210 working days. However, PhRMA's member companies continue to report lengthy delays. Effective reform that streamlines Malaysia's regulatory approval process to 210 working days or less could greatly expand market access and patients' access to medicines. To help achieve this goal, PhRMA's members would encourage Malaysia, as a standard practice, to no longer require an applicant to submit a Certificate of Pharmaceutical Product (CPP) at the time of submitting their regulatory dossier. (Currently submission of the regulatory dossier without the CPP is allowed only on a case-by-case basis.) Instead the CPP could be provided later in the regulatory approval process.

Preferential Treatment of Local Manufacturers

Malaysia's National Medicines Policy (MNMP), which prioritizes the medium and long-term goals set by the Government for the pharmaceutical sector, endorses potential price controls, generic drugs substitution, and preferences for generics and local manufacturers by promoting national self-reliance for drugs listed on the National Essential Drug List (NEDL). PhRMA member companies submit that the Government of Malaysia should eliminate discriminatory preferences for locally manufactured

pharmaceuticals. This preferential treatment discourages an open and competitive marketplace in Malaysia.

Halal Pharmaceutical Guidelines

In April 2011, Halal pharmaceutical guidelines titled “The Malaysian Standard” were launched by the Technical Committee on Halal Food and Islamic Consumer Goods under the authority of the Industry Standards Committee on Halal Standards (ISC I). This committee comprises representatives from a diverse set of Malaysian government, academic, and domestic pharmaceutical stakeholders. PhRMA’s member companies are strongly supportive of the religious and cultural sensitivities of all Malaysians and believe these guidelines should remain voluntary.

The MOH has affirmed that they will adhere to the current policy of prohibiting the affixation of Halal logos on medicines. However, it remains a compulsory requirement to declare bovine/porcine content for procurement documentation. As such, there is further concern for potential direct or indirect preferential treatment in government procurement/tenders for domestic pharmaceutical manufacturers.

Counterfeit Medicines

The counterfeiting of pharmaceutical products poses a serious threat to the health of safety of Malaysia’s citizens. PhRMA member companies strongly support enhanced coordination between the U.S. and Malaysian Governments on anti-counterfeit initiatives, including training for regulatory and security officials. The addition of new resources and heightened enforcement capabilities for Malaysia’s intellectual property court system would serve as a strong compliment to these initiatives. Increasing the penalties for criminals caught manufacturing, supplying, or selling counterfeits will also help Malaysia achieve world class status as a hub for advanced health innovations and healthcare delivery. PhRMA members welcome the provisions in the Pharmacy Bill, which imposes enhanced penalties for counterfeiting of medicines.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

THE PHILIPPINES

PhRMA's member companies face significant market access and intellectual property concerns in the Philippines. PhRMA members, however, have seen an improvement in dialogue with the Government of the Philippines and applaud ongoing efforts to engage on healthcare policy and other issues that affect the ability of companies to do business and improve access to medicines in the country. Additionally, PhRMA member companies recognize the current investments and reforms that the government has made in their efforts to achieve Universal Health Care under the Aquino Government. We hope to see further progress towards improvement in the intellectual property and regulatory environment in 2014.

Key Issues of Concern:

- **Intellectual property protections:** The Cheaper Medicines Act amended the Philippines Intellectual Property Code in 2008 to limit the patentability of new forms and uses of pharmaceutical products. As a limitation designed to discriminate against certain technologies, the Act is inconsistent with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The Philippines also does not prevent unfair commercial use through regulatory data protection or any other mechanism as required by Article 39.3 of TRIPS. Additionally, the Philippines should reinstate a mechanism to allow patent holders to resolve patent disputes prior to the marketing of follow-on pharmaceutical products.
- **Price reductions and marketing restrictions:** Department of Health (DOH) officials continue to acknowledge that the Maximum Drug Retail Price (MDRP) mechanism of the Cheaper Medicines Act has not resulted in expanded patient access. Instead, the advancement of universal quality healthcare should serve as the primary objective to expand access. Several legislative proposals in the Congress that propose further price reduction mechanisms and marketing restrictions could have a significant impact on market access if adopted.
- **Parallel importation:** There is concern that the Philippines has not been able to stop parallel importation of unregistered pharmaceutical products. Without going through FDA registration and with limited infrastructure and monitoring mechanisms, the safety and quality of these parallel imports could pose a health risk. Parallel importation may also provide a venue for the entry of imported counterfeit medicines.
- **Counterfeit medicines:** While anti-counterfeit activities in partnership with PhRMA's member companies continue, further consultations with the Philippines Government are necessary on a provision of the Cheaper Medicines Act allowing non-prescription products to be sold in "small quantities, not in their original containers" in retail outlets.

For these reasons, PhRMA requests that Philippines remain on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Cheaper Medicines Act

While meaningful dialogue has taken place since 2010 with President Aquino's Administration and the Intellectual Property Office of the Philippines on the intellectual property provisions and implementing rules and regulations of Republic Act No. 9502: The Universally Accessible Cheaper and Quality Medicine Act of 2008 (Cheaper Medicines Act), there are a number of provisions which degrade intellectual property protections and serve as market access barriers. The Cheaper Medicines Act, for example, amended the Philippines Intellectual Property Code to limit the patentability of new forms and uses of pharmaceutical products. As a limitation designed to discriminate against certain technologies, PhRMA's member companies continue to assert the Cheaper Medicines Act is inconsistent with the TRIPS Agreement. Examination of patent applications subject to this provision of the Act has been delayed by the Philippines patent office. PhRMA member companies understand examination of these applications might begin in 2014 (examination guidelines were published in 2012), but effective patent term has been lost as a result of these delays. This illustrates the need for adoption by the Philippines Government of patent term adjustment that compensates for such losses in effective patent term.

Regulatory Data Protection

The Philippines has trade secret protection laws but does not provide mechanisms that prevent "unfair commercial use" of regulatory test data that is generated and used by innovators to meet safety and efficacy requirements for marketing approval. Consistent with TRIPS Article 39.3, PhRMA members urge the Philippines to adopt measures, such as regulatory data protection, that prevent "unfair commercial use" that occurs through direct or indirect reliance on protected regulatory test data.

Effective Patent Enforcement

It is important that the Philippines adopt mechanisms for resolving patent issues prior to the marketing of follow-on products, such as generics. Such a mechanism was in place before a 2005 DOH Administrative Order (A.O. No. 2005-0001) took effect, which has resulted in PhRMA's member companies having to pursue costly and time consuming legal remedies to protect products from patent infringement prior to patent expiration. If sufficient time were allowed to resolve such issues prior to marketing of follow-on products, the Philippines could alleviate legal resource burdens as well as restore the rights of patent holders. PhRMA's member companies recommend the repeal of Administrative Order 2005-0001 and that an agreement be signed by the

Intellectual Property Office of the Philippines (IPOP HL) and the Food and Drug Administration of the Philippines (FDA) recognizing that a certificate of product registration for a generic medicine will not be issued by FDA unless the applicant can present a certification from IPOP HL confirming the patent covering a particular product has expired.

Market Access Barriers

Price Reductions/Strategies and Marketing Restrictions

PhRMA members recognize the Aquino Government's continuing health reforms and overall investment in healthcare. In the 15th Congress, important health legislation has been passed to help achieve universal health coverage in the Philippines.

PhRMA members also support the current free market economy under the Aquino Government. While there have been no direct price cuts through the Maximum Drug Retail Price, there have been collateral price cut measures in the form of medicine discounts for special sectors such as senior citizens, persons with disabilities, national athletes, solo parents, and many others. Ambiguities in the implementation of laws related to the 20% discount granted to senior citizens and now persons with disabilities disproportionately burden PhRMA member companies. There remains a significant issue surrounding the burden sharing of the discount between the government and retailers and manufacturers, in that the government has failed to provide any incentive to the private sector in these initiatives, leaving the retailers and manufacturers to absorb the entirety of the discount.

While the MDRP mechanism adopted under the Cheaper Medicines Act continues to stifle market access for PhRMA's member companies, DOH officials continue to acknowledge that the mechanism has not resulted in expanded patient access. Poverty serves as the primary cause for limited access to medicines¹⁰⁸ and the advancement of universal quality healthcare should be the primary objective to achieve a sustainable solution. Through enhanced coverage, an expansion in the benefits package, and the broader availability of health services, the Government of the Philippines can effectively expand access to medicines while promoting healthcare innovation that will attract new investment.

PhRMA's member companies continue to engage the Philippine Government on certain provisions of the newly proposed "Philippine Medicines Policy 2010: Ensuring Access to Medicines for Filipinos," as the proposal appears to potentially reintroduce government price controls and institute mechanisms to restrict pharmaceutical marketing practices.

¹⁰⁸ University of the Philippines Blueprint from Healthcare 2010-2015 and Beyond; Imperatives for Health Care Financing Reform, Professor Emmanuel Leyco, Center for Legislative Development; IMS Health Philippines, 2009 Study Commissioned by the Philippines Department of Health.

There are also efforts to establish a Drug Price Reference Index within DOH where products that are considered to be equivalent on the basis of efficacy, safety and outcomes are grouped in “reference clusters” and a common reference price is set for all drugs in a cluster. In turn, this reference price will be used as a price ceiling for public procurement. Meanwhile, there is also concern about the publication and use of government procured drug prices for private procurement.

In ensuring greater access to new medicines, especially for patients who rely on government hospitals, greater transparency and due process is needed as to process and criteria for inclusion in the Philippine National Formulary.

Further, greater emphasis should be placed in formulary, procurement and reimbursement processes on health outcomes. For example, molecules covered by new government medicine access programs and health benefit packages are limited and not fully aligned with treatment guidelines.

Meanwhile, the proposed marketing restrictions also include limits on detailed product materials, the elimination of prior approval of product materials by the DOH, and prohibitions on medical professionals attending industry conferences. PhRMA’s member companies also continue outreach to the Philippine Senate and House of Representatives with jurisdiction over current proposals that could significantly impact market access and raise serious safety concerns, such as the establishment of a Drug Price Regulatory Board, requirements that pharmaceutical firms make generic versions of patented products available with a 20-25 percent discount, an annual submission of marketing expenditures, and mandatory price discounts on medicines for public sector employees.

PhRMA’s member companies also continue consultations with the Government of the Philippines on several policies that have mandated member companies and retailers to absorb discounts on medicines plus value added tax. These discounts may not only result in the closure of drugstore outlets and the discontinuation of products, adversely affecting patient access, but increase overall business costs and affect the ability of PhRMA’s member companies to place certain products on the market.

Parallel Importation

There is concern that the Philippines is resorting to implementation of Rule 9 of the Implementing Rules and Regulations (IRR) of the Cheaper Medicines Act, enabling the parallel importation of unregistered pharmaceutical products. With the lack of adequate infrastructure and monitoring mechanisms in the Philippines, the safety and quality of parallel imports is at risk or unlikely, and the prevention of imported counterfeit medicines is not possible. PhRMA’s member companies hope to work closely with the Government of the Philippines to require the FDA to impose full registration requirements on parallel imports and for the Bureau of Customs to stop the importation of unregistered medicines.

Counterfeit Medicines

The Government of the Philippines continues to expand its anti-counterfeiting activities in partnership with PhRMA's member companies and raise public awareness regarding the dangers of unsafe medicines. These efforts will continue in 2014 and PhRMA's member companies hope to continue consultations with the Government of the Philippines on a provision of the Cheaper Medicines Act allowing non-prescription products to be sold in "small quantities, not in their original containers" in retail outlets. Such a provision works against ongoing anti-counterfeiting activities and endangers the health and safety of the country's citizens. The Philippines should adopt heightened criminal penalties for those caught manufacturing, supplying, or selling counterfeit medicines. PhRMA's member companies also advocate for expanded anti-counterfeit enforcement powers for IPOPHL.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

TAIWAN

PhRMA and its member companies operating in Taiwan value the positive response during the recent discussions with Government on health policy reform measures designed to bring stability and predictability to the Taiwan pharmaceutical market. Some concerns remain, however, and PhRMA appreciates the willingness and commitment of the Government of Taiwan to continue its dialogue with PhRMA member companies as part of broad stakeholder consultations. This communication will ultimately help achieve the common goal of Government and industry; enabling patients to live longer, healthier, and more productive lives. PhRMA urges the Taiwanese Government to continue developing sound IP protections and drug pricing policies with stakeholder involvement.

PhRMA appreciates the recent positive engagement from the Government of Taiwan on ways to address the innovative biopharmaceutical industry's concerns regarding certain intellectual property (IP) protections. Specifically, the Government has recently expressed a willingness to work with the biopharmaceutical industry to enhance the current regulatory data protection and effective patent enforcement mechanisms. PhRMA welcomes the Government's renewed engagement, and looks forward to working with the Government toward the enhancement of biopharmaceutical IP in Taiwan.

Key Issues of Concern:

- **Intellectual property protections:** Taiwan lacks adequate systems for patent protection and regulatory data protection (RDP), which discourages investment in innovative medicines for Taiwanese patients.
- **New government drug pricing and reimbursement:** The second generation of National Health Insurance (2G NHI), which was implemented in January 2013, has made the process of new drug reimbursement review and decision making much more complicated due to the newly added Pharmaceutical Benefit & Reimbursement Scheme (PBRs) Joint meeting. As a result, the average prices and approval rate for new medicines have reached historical lows that do not adequately reflect or reward the value of those innovative medicines.
- **Drug expenditure target:** PhRMA recognizes the efforts of the Taiwan Ministry of Health & Welfare (MOHW) for establishing a two year pilot program on the Drug Expenditure Target (DET), and we urge the Government of Taiwan to engage industry on implementation to ensure continued patient access to good quality pharmaceuticals. The implementation regulation should fairly recognize the value of innovative medicines.

For these reasons, PhRMA requests that Taiwan be placed on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Regulatory Data Protection (RDP)

In January 2005, Taiwan passed RDP legislation to implement Article 39.3 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 39.3 of the TRIPS Agreement requires governments to prevent unfair commercial use of valuable test data gathered by innovative companies to secure marketing approval. Although the revised Pharmaceutical Affairs Law provides for five years of regulatory data protection, it does not cover new indications. New indications should also be protected under this legislation.

Effective Patent Enforcement

Taiwan has not yet established systems to effectively prevent marketing of patent-infringing generic pharmaceutical products. According to a recent industry survey conducted by International Research-Based Pharmaceutical Manufacturers Association (IRPMA) in Taiwan, at least 65 patent-infringing drugs were approved in Taiwan, and most of them were subsequently included on the reimbursement lists. This significantly disadvantages innovator companies, particularly in view of pending proposals to alter regulatory approval procedures. Under a 2005 revision to the Pharmaceutical Affairs Law, the Taiwanese Government asks patent-owners to register their patents upon receiving product licenses; thus, data similar to the Orange Book system in the United States is available. That change provides limited benefit, given that Taiwan does not have effective patent enforcement mechanisms in place.

Market Access Barriers

Reward for Innovation

Over the past two years, the industry has had a constructive dialogue with the Government on how to smoothly transition from the First Generation to the Second Generation of NHI in terms of new drug pricing and reimbursement processes. After almost one year of observation and evaluation, and despite efforts from National Health Insurance Administration (NHIA), the outcome is disappointing. Since January 2013, new drug pricing has reached a historical low of 42% of the A10-country median price, compared to 53% in 2012 and 80% in 1995-1997. The current pricing system for new drugs does not reflect or value the degree of innovation of those products, which adversely impacts patients' access to new and innovative medicines.

PhRMA and its member companies continue to discuss with Ministry of Health and Welfare (MOHW) and NHIA the following issues to improve the pricing and reimbursement policies and regulations:

Government pricing and reimbursement: A key factor suppressing new-drug prices is that in over 86% of the cases in 2010-2012, the prices were determined based on those

of reference drugs, many of which have gone through several price cuts and now stand at new lows. Under this process, new-drug prices continue to decrease to the new lows. To expedite Taiwanese patients' access to new drugs, NHIA should seriously consider policies that support products with proven efficacy and value. We urge NHIA to revise the appropriate regulations so that the pricing system better reflects pricing methodologies in other advanced economies, allows companies to recoup the significant investment required to develop a new medicine, and rewards innovation.

DET: Under the price adjustment scheme instituted in October 2013, only compound and combination patented products are eligible for price premiums. In order to encourage innovation, however, these price premiums should be available to all drugs granted patent protection by the Taiwan IP Office during their patent term (as well as those still subject to regulatory data protection).

Price-Volume Agreements (PVAs): Increasingly, innovative pharmaceutical companies are required to sign Price-Volume Agreements (PVA) which unduly penalize innovators for developing successful products. The Taiwanese Government should review the scope of the PVA principles which were announced over two years ago, particularly the thresholds for signing a PVA. PVAs unfairly require companies to bear the financial risk once spending on a drug exceeds the estimated budget, even though the volume of prescriptions is controlled by physicians. As a result, PVAs severely undermine the possibility of rewarding innovative medicines. We urge NHIA to meet with industry to review the PVA guidelines, particularly the threshold provisions, which have been implemented since August 2011.

Health Technology Assessment (HTA): PhRMA requests to work with the Taiwanese Government to build a sustainable and fair HTA system in Taiwan. The involvement of the pharmaceutical industry in developing the related policies is critical to ensuring effective implementation.

In the interest of rewarding innovation, developing new medicines to meet Taiwan's unmet needs, and ensuring that Taiwanese patients have access to innovative drugs, PhRMA strongly recommends that the U.S. Government encourage Taiwan's Government to implement a fair and reasonable price adjustment policy under DET. Furthermore, PhRMA asks the U.S. Government to encourage their counterparts in the Taiwanese Government to engage in renewed consultation with the innovative pharmaceutical industry to ensure that government pharmaceutical pricing and reimbursement policies are transparent and offer due process to interested stakeholders and are based on scientific evidence and patient needs and benefits.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

VIETNAM

PhRMA's member companies face significant market access and intellectual property concerns in Vietnam. Furthermore, many of the reforms proposed by the Government of Vietnam do not fall in line with international or regional best practices.

Key Issues of Concern:

- **Intellectual property protections:** The adoption of intellectual property protections that conform to international obligations and standards, including meaningful regulatory data protection, clarification on the scope of patentable subject matter, and implementation of effective patent enforcement, could greatly assist Vietnam in creating a more predictable environment for investment in innovation and enhance transparency and predictability.
- **Selection of innovative medicines for tender:** The institution of a new procedure for selecting innovative medicines for tender recognizes patents from only 16 national patent offices, and recognizes only certain types of pharmaceutical patents. The procedure also includes onerous and impractical requirements for submitting documents that have caused delays for companies applying for tender.
- **Clinical trial and quality testing requirements:** Domestic clinical trial requirements in Vietnam, mandated for marketing approval of pharmaceuticals that have not been made available in their country of origin for more than five years, are unnecessary and burdensome, lead to an escalation in costs and reduce the number of innovative medicines available to Vietnam's patients.
- **Reference pricing:** Vietnam's decision to use cost, insurance, and freight (CIF) prices as a benchmark to set pricing for pharmaceuticals relative to neighboring countries creates unequal opportunities and restrictions for imported and locally produced pharmaceuticals. Given the country's costly import regime, the reference pricing system should be based on Price to Trade (PTT).
- **Trading rights and distribution restrictions:** Vietnam's Ministry of Health (MOH) should provide clear guidelines for effective implementation of full trading rights in all pharmaceutical products. The MOH should also permit PhRMA's member companies to contract with foreign-owned storage and logistical service companies who certify their methods satisfy international standards.

For these reasons, PhRMA requests that Vietnam remain on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Regulatory Data Protection

Vietnam continues to engage with PhRMA's member companies on the adoption of meaningful regulatory data protection measures through the Drug Administration Vietnam (DAV). However, the implementation guidelines of the current Data Protection Circular fall short of making the necessary improvements. Specifically, the Circular is not clear on whether the five-year term of regulatory data protection applies in cases that involve a generic manufacturer relying on or referencing innovator data in support of its marketing approval application. Furthermore, the Circular conditions regulatory data protection on requirements that: (1) member companies submit a separate application for data protection, rather than receive automatic protection upon marketing approval as international standards and the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) require; (2) data be classified as a "trade secret" under Vietnamese law; and (3) the innovator prove "ownership" of the data in cases of dispute rather than the third party or government challenger.

Scope of Patentable Subject Matter

The Vietnamese National Office for Intellectual Protection (NOIP) has misconstrued Article 4.12 of the Law on Intellectual Property (2005) to omit "second use" inventions from the definition of "invention." Article 4.12 provides that an "invention means a technical solution in [the] form of a product or a process which is intended to solve a problem by application of laws of nature." The Ministry of Science and Technology expounded that definition in 2007 in Circular No. 01/2007/TT-BKHCHN, providing that patent protection will only be offered to an invention if it is a "technical solution," including a product or "a process (technological process; diagnosing, forecasting, checking or treating method)."

Notwithstanding the clear scope of a patentable invention as set forth in Vietnam's Law on Intellectual Property and Circular No. 01/2007/TT-BKHCHN, NOIP began to systematically reject any claims for "second uses" of existing pharmaceutical products in 2005. The rationale for many of these rejections purports to be grounded in the definition of "invention" found in Article 4.12 of the Law on Intellectual Property and in Article 25 of Circular No. 01/2007/TT-BKHCHN even though the result contravenes these cited sources. In all, NOIP has made "second use" inventions *de facto* ineligible patent subject matter. Yet NOIP is obligated to examine these inventions because "second use" inventions fall within the meaning of invention in TRIPS Article 27.1 and Vietnam's own definition of "invention" in Article 4.12 of the Law on Intellectual Property.

Patent Application Delays

PhRMA's member companies continue to face burdensome delays in the granting of patents, eroding the effective term of patent protection available for

innovative medicines. There are various reasons for these delays, including insufficient personnel capacity.

Effective Patent Enforcement

PhRMA's member companies strongly encourage Vietnam to adopt mechanisms which allow sufficient time for resolution of patent disputes prior to the grant of marketing approval for follow-on products. Such a patent enforcement mechanism could greatly enhance the business environment by: (1) providing process transparency and predictability for both the innovative and the generic firm; (2) creating a more predictable environment for investment decisions; and (3) ensuring timely redress of genuine disputes.

Market Access Barriers

Eligibility for Tendering Process for Innovative Products

In August 2012, the Ministry of Health issued Decision 2962 "Decision on Promulgating Temporary Regulation on Documents Needed In Order To Announce Lists of Original Proprietary Medicines, Medicines Used for Treatment Similar with Original Proprietary Medicines, Medicines with Documents Proving Bioequivalence." This Temporary Decision 2962 specified the documents and additional parameters for qualifying as an innovator pharmaceutical product for the bidding process. The specific provision is Article I, paragraph 2.

Article I. Documents need supply in order to announce medicines under lists of original proprietary medicines:

A written request to the Ministry of Public Health for announcement of original proprietary medicines (made in according to the Form in Annex 1 enclosed with this Decision).

2. Patent granted by one of competent intellectual property agencies (in the List specified in section V of this Regulation) for active ingredient of medicine containing an active ingredient or mixture of active ingredients if medicine contains many active ingredients, enclosing part referencing point requiring protection, determining scope of protection for corresponding medicine (original has consular legalized as prescribed; or a valid notarized copy as prescribed; or a copy certified by the seal of facility if the patent may search, define at websites supplying database of intellectual property agencies – in this case, it should indicate clearly address for search, name of intellectual property agency and search code).

Temporary Decision 2962 proscribes which patents will be accepted in two ways. First, it only recognizes patents from selected countries. Under the Temporary Decision

2962, patents will only be accepted from 14 National Patent Offices (since expanded to 16 offices). Second, Temporary Decision 2962 limits the innovative products eligible for tenders to those with “molecular patents.” This serves to exclude from the tendering process those pharmaceuticals with process patents or patents for second uses and combinations, thereby disregarding the benefits these medicines could bring to Vietnamese patients.

Further, the Vietnamese Ministry of Health issued Circular no. 11 (June 28, 2012) on tenders, requiring PhRMA member companies to prove that they are the innovators of a drug in order to have the brand listed. This regulation is unnecessarily burdensome, and has caused problems including, for example: (1) issues regarding burden of proof; (2) confusion within the Ministry itself as to documentation requirements; (3) a lack of any grandfathering mechanism for older products, which lack patent documents; (4) confusion caused by changes in ownership; and (5) limitations on the countries from which patent documents are being considered.

Clinical Trial and Quality Testing Requirements

PhRMA’s member companies continue to express concern with domestic clinical trial requirements in Vietnam for the marketing approval of all pharmaceuticals that have not been made available in their country of origin for more than five years. Not only is this practice unnecessary, given the stringent standards of regulatory authorities such as the United States Food and Drug Administration and European Medicines Agency, but Vietnam does not possess the resources or infrastructure to acquire reliable clinical trial results from domestic sources. These requirements also apply to new variations of pharmaceutical products already registered in Vietnam. PhRMA’s member companies urge Vietnam to permit regulatory officials to accept reliable clinical trial data collected from appropriate clinical trial sites located outside of Vietnam when domestic capabilities are not in place. Such an amendment could quickly improve patient access to new, life-saving medicines.

Vietnam’s requirement that all imported biological products and new batches of vaccines undergo quality testing is scientifically unnecessary and time consuming. These tests must be conducted by the National Institute for Control of Vaccine and Biologicals (NICVB), which does not have the capacity to effectively conduct such tests.

Certificate of Pharmaceutical Product (CPP)

CPP or a Free Sales Certificate (FSC) from the country of manufacturing or packaging is mandatory for all imported pharmaceutical products to secure marketing approval in Vietnam. This requirement can impose significant hurdles for PhRMA’s member companies when applying for registration. A CPP from any country should be acceptable to comply.

Product Visa Renewal Process

The MOH currently requires pharmaceutical firms to reapply for product approval through product visas every five years. This requirement has become a significant administrative burden since the process for renewal or to obtain a product visa can take from eight months to more than one year.

Under Circular 22/2009/TT-BYT (Circular 22) of November 24, 2009, it is not possible to submit a dossier for the renewal of market authorisation registration earlier than six months before the expiry of the product's existing registration. According to experience from several years, time to get such a renewal from the MOH/DAV normally exceeds six months, thus leading to an "off-visa" period for a product for several months. During this off-visa period, importation of the product is not permitted, and providing information to doctors about the product is very restricted. Particularly because all promotional materials must be withdrawn, no new materials can receive an authorization visa from the MOH, and all materials have to receive a new visa after the renewal.

In addition, during such an off-visa period, the participation in hospital tenders is not possible because most hospitals will not accept that the MOH documents that stipulate the product has been legally registered and is merely under a renewal process. Since a large part of the products are supplied to fulfil hospital tenders, companies might risk sanctions stipulated in contracts as they are not able to fulfil the tender contract obligations and for example, required to pay fines. Such a situation restricts the access to essential pharmaceutical products both for healthcare providers and patients, especially if patients are not able to get their needed treatments.

In summary, adequate lead time for submissions for renewal applications is necessary. If it would be possible to submit dossiers for renewal at least twelve months before the expiry date and extend registration periods of existing products duration, these problems could be avoided. This renewal application extension period should at least be allowed until the MOH and DAV backlog has been managed. With regard to hospital tendering restrictions on product importation, restrictions on product promotion and product information should be waived during the new process. Participation in tenders while the application for renewal is pending should be allowed.

Bioequivalence Study Requirements

Vietnam's policy exempts local generic manufacturers from important testing requirements, including exemptions for generic producers from conducting bioequivalence studies before applying for regulatory approval. Bioequivalence studies are designed to ensure that the generic product has the same therapeutic and chemical equivalence as the original innovative medicine. It is critical that these studies are conducted for all products to ensure that patients are receiving safe, effective and high-quality medicines.

Government Pricing and Reimbursement

Price Monitoring System

Vietnam has chosen to use cost, insurance, and freight (CIF) prices as a benchmark to compare pricing for pharmaceuticals with neighboring countries. This creates unequal opportunities and restrictions for imported versus locally produced pharmaceuticals. First, Vietnam's unique import regime – which currently relies on third party arrangements (companies are obliged to sell to a local firm with distribution rights) due to the lack of trading rights in the sector – results in inflated CIF prices within Vietnam relative to other regional markets that do not impose similar restrictions. Second, the adopted pricing circular only applies to imported products and no similar restrictions or requirements are posed on locally manufactured goods. The price monitoring system should be based on Price to Trade (PTT), which covers both locally manufactured and imported products.

Fixed Pricing and Currency Devaluation

Recent economic challenges in Vietnam have resulted in several recent devaluations of the Vietnamese Dong (VND). Inflation accompanying these devaluations has magnified their economic impact. With pharmaceutical products subject to government price controls, PhRMA's member companies cannot adjust to these devaluations and must absorb rapidly increasing costs. Vietnamese importing partners are in a similar position. Without direct adjustment to price control provisions on imported pharmaceuticals, research-based pharmaceutical companies will continue to face further disadvantage relative to local pharmaceutical firms.

Trading Rights and Distribution Restrictions

As part of Vietnam's WTO accession commitments, the country agreed to extend full trading rights to pharmaceutical products in January 2009. The extension of these trading rights also has foundation in Ministry of Industry and Trade regulations permitting the import and export of pharmaceutical products independent of government-approved channels. However, pharmaceuticals are also subject to regulations from Vietnam's MOH and DAV. At present, some pharmaceutical products with valid registration numbers are authorized by MOH for import into Vietnam without an import permit or certification of import orders. PhRMA's member companies urge the MOH to issue clear guidelines that embrace full trading rights for the export and import of finished pharmaceutical products.

Research-based pharmaceutical firms also face limited control over the distribution of their products and are required to partner with a local distributor. The pharmaceutical supply chain requires careful monitoring to ensure product safety, reliable maintenance (*i.e.*, an unbroken cold chain for vaccines), timely delivery, as well as the protection of sensitive proprietary technology. The MOH should permit PhRMA's member companies to contract with foreign-owned storage and logistical services

companies who certify that their methods meet international standards. In addition to direct importation/exportation, wholly owned subsidiaries should be permitted to engage local employees as professional sales representatives to educate physicians and end users about product availability, usage, and consistency with local laws and regulations.

Counterfeit Medicines

PhRMA's member companies applaud efforts by the National Institute for Drug Quality Control (NIDQC) to partner with the U.S. Government to raise awareness of the dangers posed by unsafe medicines and strongly support enhanced coordination on anti-counterfeit initiatives, including training for regulatory and security officials. NIDQC has also consulted with PhRMA's member companies on best practices to promote the use of safe medicines. Increasing the penalties for criminals manufacturing, supplying, or selling counterfeit medicines will help improve enforcement efforts.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

FINLAND

PhRMA and its member companies operating in Finland are concerned about the Finnish Medicines Act (“FMA 2008”), especially the changes that came into force on April 1, 2009. This Act established a new generic reference pricing scheme and repealed an important amendment to the Finnish Medicines Act (of 2006) (“FMA 2006”), which had ensured that an original product covered by an analogous process patent and its generic equivalent were not included on the interchangeable drug list.

Key Issues of Concern:

- **Patent protection harmonization:** The lack of patent protection for original products covered by an analogous process patent is symptomatic of broader inadequacies of intellectual property protection in Finland that could negatively impact government pricing in other markets that refer to pharmaceutical prices in Finland (in particular due to the non-application of Article 34 of the TRIPS Agreement).
- **Reimbursements:** The two-year delay on granting special reimbursement (following two year period in the basic reimbursement category) puts medicines for chronic conditions at a significant disadvantage.
- **Therapeutic reference pricing:** The Pharmaceuticals Pricing Board has implemented *de facto* therapeutic reference pricing by urging PhRMA member companies to lower the price of their innovative products if there are other products in the therapeutic class that are generic.

For these reasons, PhRMA requests that Finland remain on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Lack of Harmonized Patent Protection

Changes made by FMA 2008 compounded the negative effects of inferior patent protection for pharmaceutical products in Finland.

A lack of patent harmonization exists in Finland due to the fact that Finland did not recognize pharmaceutical product claims filed prior to January 1, 1995. However, Finland did recognize product claims in applications filed after that date. On January 1, 1996, the date on which the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) took effect in Finland, the following types of patents existed in Finland:

- Patents, for which applications were filed before January 1, 1995, and for which Finland did not accept pharmaceutical product claims;
- Patents, for which applications were filed on or after January 1, 1995, and for which Finland accepted pharmaceutical product claims; and
- Patent applications that were pending from before January 1, 1995, whose claims for pharmaceutical products would not be given any effect in Finland.

Under the subject matter and the transition rules of the TRIPS Agreement (Articles 70.2 and 27.1), PhRMA and its member companies believe that Finland should have converted the process patents for which applications had been filed before January 1, 1995 to pharmaceutical product patents, no later than January 1, 1996. At least, under TRIPS Article 70.7, Finland was required to provide for the addition of product claims to any applications for process patents that were still pending on January 1, 1996. Finland, however, did not do so. As a result, PhRMA and its member companies believe that, after regulatory data protection expiration, holders of such pharmaceutical process patents received inferior patent protection to that required by the TRIPS Agreement.

In addition, Finnish Courts have not applied the reversed burden of proof provided for by Article 34 of the TRIPS Agreement in preliminary injunction proceedings. This has expressly been confirmed as a requirement in a Court of Appeals proceeding to which the Supreme Court has not granted leave for appeal.¹⁰⁹

Finland was one of the last (if not the last) developed countries to accept product patent protection for pharmaceuticals. Therefore, most of the top-selling products on the Finnish market are still protected only with an analogous process patent. As a result of this inferior patent protection, regulatory reforms, such as mandatory substitution and reference pricing, have severe adverse effects for PhRMA member companies.

These adverse effects were corrected by an amendment to the FMA 2006 stating that the originator product and its generic equivalent may not be listed on the interchangeable drug list of mandatory generic substitution if the holder of the original marketing authorization has an analogous process patent in Finland and corresponding product patents for the active ingredient in at least five European Economic Area countries. In 2008, the Parliament of Finland passed the Government Bill on the reference price system that removed this amendment, that is, “the FMA 2008.”

The approved FMA 2008 includes an extension of the generic substitution system pursuant to which the generic substitution and reference price system now encompass products protected by analogous process patents, which should have been excluded from generic substitution until the expiration of their patent protection by virtue of the amendment of the Medicines Act enforced as of February 2006. Furthermore, if

¹⁰⁹ *Zeneca Inc. et al. v. Orion Oyj et al.*, Helsinki Ct. of Appeals, Decision No. 1446, Docket No. S08/361 (May 23, 2008); Sup. Ct. Decision No. 2484, Docket No. S2008/581 (Nov. 14, 2008).

there is a question of whether the generic product infringes the patent of the originator product, the burden of proof is on the originator company and not on the generic company.

Prior to implementation of the FMA 2008, even though an original product was not eligible for inclusion in the substitution list and thus to the pricing reference group, it was nevertheless possible for its reimbursement status to be deteriorated by other measures, *e.g.*, by the Finnish authorities cancelling the reimbursement during the reimbursement period. According to the reimbursement provisions of the Finnish Sickness Insurance Act (1224/2004), the Pharmaceutical Pricing Board (PPB) may, at its own initiative, decide that the confirmed “reasonable wholesale price and reimbursement status” of a pharmaceutical product should be cancelled. According to Chapter 6, Section 8 of the Sickness Insurance Act (of 2006), PPB can make this decision when, for example, a generic product containing the same active ingredient as an innovative product has been included in the reimbursement system, regardless of whether the innovative product is protected by a valid analogous process patent.

The current lack of harmonization between patent protection in Finland and other countries in the EU results in a situation where generic versions of patent-protected molecules can be introduced in Finland, while the very same molecules receive full patent protection throughout most of the EU by way of product patents.

Lack of harmonized patent protection has significant consequences for PhRMA member companies operating in Finland, including:

- **Faster inclusion of innovative products in the Finnish reference pricing system:** Finland’s reference pricing system requires that a reimbursed generic product already exist in a given therapeutic category in order for a reference group to be created. Innovative products are much more likely to be affected by reference pricing when more generic products are on the market and granted earlier access.
- **Price erosion in other EU Member States:** Prices set by the Government of Finland are referenced by many other European countries. As a result, early introduction of generic products in Finland not only can result in the creation of a reference price group that lowers the Finnish price, but also can lead to a reduction in prices set by other governments throughout Europe.
- **Parallel trade:** Due to Europe’s common market and the free flow of goods across EU Member State national borders, pharmaceutical products with lower government prices in countries like Finland are being exported to countries with higher prices. This problem is compounded in Finland, where generic products entering the market result in lower government prices for innovative products, many of which are still under patent protection elsewhere in Europe. As a result, Finland’s poor patent protection can lead to reduced government prices in Finland due to early market entry of generics, and lower prices in Europe as a

result of parallel trade. This, in effect, reduces the value of pharmaceutical intellectual property rights for PhRMA member companies.

PhRMA and its member companies encourage the U.S. Government to start a dialogue with the Government of Finland regarding the uneven implementation of the TRIPS Agreement in Finland and its consequences for U.S. pharmaceutical patent holders in the country.

Market Access Barriers

Two-Year Lead Time for Special Reimbursement of Medicines for Chronic Conditions

In Finland, the Pharmaceuticals Pricing Board sets the reasonable wholesale price and reimbursement. A Pharmaceutical company needs to apply for price and reimbursement with a written formal application. Reimbursement for medicines is valid in Finland only for a fixed period (maximum five years, usually one to two years) and extensions must be sought at least six months before the end of the reimbursement period. There are three categories of reimbursement (basic at 35 percent, lower special category at 65 percent, and upper special category at 100 percent).

Before a product can be reimbursed according to the lower or upper special category it needs to be in the basic reimbursement category for two years. There are some exceptions, but they are rare and usually those products have been in the basic category for over 1.5 years before they are granted special reimbursement status. This waiting period, as stipulated in Chapter 6 of the Health insurance Act, is unique compared to other EU countries (e.g., compared to other Scandinavian countries which reimburse at the same level as in the EU as soon as the product enters the market).

The reasoning in the legislation for this two year lead time is a claim of the need to accumulate clinical experience before putting medicines into the special reimbursement category. In practice, however, doctors are more likely to prescribe older medicines that have a special reimbursement status and lower co-payments than newer drugs subject to the basic reimbursement level, thus defeating the stated purpose of accumulating clinical experience. In addition, given that the average time for basic reimbursement for new pharmaceutical products is often much longer in Finland than in other European countries, clinical experience data has normally been accumulated from other EU countries by the time that the reimbursement decision in Finland is made. There are, therefore, no legitimate reasons for the two year delay.

Referencing Patented Product Prices to Generic Product Prices in the Same Therapeutic Class

As noted above, pricing and reimbursement decisions are made for a limited time period. In a situation where other products in the same therapeutic class have become generic and the price level for those medicines has declined, PPB has suggested to PhRMA members that in order to ensure continued access to the reimbursement

system, the government price should be reduced. While Finland expressly does not have therapeutic substitution, some pharmaceutical companies have received letters from the PPB urging them to lower the price if there are other products in the therapeutic class that are generic. As a result of this pressure, the price level of patented products declines gradually towards the generic price level even during the life of the patent.

Finland should maintain separate reference pricing systems for generics and patented products. Patents provide an incentive to innovate by rewarding innovators with a period of time to recoup their costs in the marketplace. By linking the reimbursement price paid for patented products to the lowest priced generic medicine in the same therapeutic class, the Finnish system dramatically undervalues the innovation and development costs involved in bringing the patented pharmaceutical to market.

Discriminatory Price Regulations Imposed on Innovative Medicines

Effective February 1, 2013, the Finnish Government imposed a 5 percent price cut on products not included in the (internal) reference price system on February 1, 2013. As this only affects innovative products, it discriminates against innovation and spares the generic/off-patent segment from making a commensurate contribution. Furthermore, as part of the savings package, the reimbursement levels were lowered, effective January 1, 2013, which undermined patient access to innovative therapies and may have lowered adherence rates.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

GERMANY

PhRMA's member companies face several market access barriers in Germany, including regulations following the 2010 health-care reform ("AMNOG"), issues with implementation of that reform, and increasing conflicts between public payers, self-governing bodies, and manufacturers.

Key Issues of Concern

- **Pharmaceutical Market Reform Law (AMNOG) and price controls:** The complete restructuring of the pharmaceutical market under AMNOG raises a number of concerns. Chief among these are the move away from market based pricing towards a payer dominated negotiation process including international reference pricing (early after launch), concerns around the confidentiality of rebates and other price discounts negotiated individually with PhRMA's member companies; the continuation of the price freeze; and the execution of the new benefit evaluations and rebate-setting mechanisms of the German's health system self-administrative Federal Joint Committee (GBA) and the Head Association of Statutory Health Insurance (GKV-SV).
- **Transparency in reimbursement decisions:** The GBA makes reimbursement decisions for pharmaceuticals in Germany's statutory health insurance system are made by the GBA. Although GBA's power has increased with the passage of AMNOG, its decision-making process lacks transparency, it is unwilling to engage in meaningful dialogue with industry, and there is no meaningful appeal mechanism. These are issues of great concern to manufacturers seeking continued open access to the health-care marketplace in Germany.

For these reasons, PhRMA requests that Germany be placed on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

2010 Healthcare Reform

On August 1, 2010, the German Government, responding to a supposed healthcare-funding shortfall (which did not materialize), increased the mandatory rebate for patented products not covered by fixed reference prices (FRP) from six to 16 percent. This "short-term" cost-containment measure, along with a price moratorium, remains in place, despite the fact that the legislation requires an annual review to determine whether the claw-back remains necessary. The new government has indicated that it plans to maintain the price moratorium, but to reduce the mandatory rebate from 16 to seven percent. We anticipate the law will pass in the first quarter 2014 and will be effective from April 1, 2014.

On January 1, 2011, the German Government implemented AMNOG, a complete restructuring of the pharmaceutical market. In an effort to accelerate the perceived cost-saving effects of HTA in Germany, AMNOG established a new process requiring a “rapid assessment” of added therapeutic benefit at new-product launch. As a result, unimpeded market access and free pricing for medicines will remain in effect in Germany only for the first year after launch. The new procedure comprises:

- A rapid assessment of every New Chemical Entity (NCE) and every new indication of an NCE within 3 months after launch, based on a value dossier provided by the manufacturer. The German health system’s self-administrative body GBA (Federal Joint Committee) can also select drugs from the existing market to become subjects of a rapid benefit assessment.
- The GBA then will decide at six months post-launch whether a new product provides additional therapeutic benefit. The GBA can execute the assessment on its own or charge the Institute for Quality and Efficiency in Healthcare (IQWiG) or another third party with the task.
- Effective 12 months after launch, a reimbursement price for each new product will be set. In determining the reimbursement price, products will fall into one of three categories:
 - (1) *Products with proven additional benefit.* Where it is determined that a product has additional benefit, centralized negotiations will be held between the manufacturer and the GKV-SV (Head Association of Statutory Health Insurance). If a manufacturer and the GKV-SV cannot agree on a price, then an arbitration committee makes a binding decision, using EU prices in 15 selected EU countries as one reference point, combined with data on turnover and purchasing power parity.
 - (2) *Products without additional benefit.* If a product is viewed as having no additional benefit, it will be subject to reference price clustering, using, if feasible, the current methodology to determine a reimbursement level.
 - (3) *Products without additional benefit/non-reference price.* If a reference price clustering is not feasible, a refund rate will be negotiated that may not be higher than the cost of a standard existing therapy (comparative therapy). Once again, an arbitration committee will make a binding decision if a manufacturer and the GKV-SV do not agree within six months.

Additional benefit is determined by comparison with an appropriate comparative therapy and classified in 6 levels (from extensive additional benefit to less benefit than the comparative therapy).

The comparative therapy shall be determined according to the international standards of evidenced based medicine and if there is more than one alternative, the most economic therapy shall be selected (preferably one from the therapeutic reference price system).

On February 1, 2011, the GBA issued procedural details of the assessment process, the content of the dossier to be provided by the manufacturer, and the advice to be offered by the GBA for the manufacturer prior to submission of the dossier.

Implementation of AMNOG

As of October 2013, the rapid benefit assessment including final GBA decision has been completed for 57 drugs, almost three quarters of which have been found to have no or marginal additional benefit. Seventeen drugs have gone through the complete process with rebate negotiations between manufacturer and GKV SV and final determination of the reimbursement price. 88% of the reimbursement prices lie under the average and 59% under the lowest of the European reference country basket.¹¹⁰ Some companies – anticipating an unfavorable result – have decided not to market their new products in Germany because of concerns about inappropriate comparator therapies assigned by the GBA.¹¹¹

Experiences with the rapid benefit assessment so far show technical implementation issues, different views in the assessment of clinical practice and relevance, method application and comparator selection. Although the GBA's advisory process has improved over the last month, the data that must be submitted in the dossiers are extensive and costly, both in terms of time and resources. Overall the process is more bureaucratic and formal than pragmatic. Even more troubling is that the selection of comparator therapies by the GBA seemed to be guided by economic rather than medical considerations. A modification of the law in 2013 allows more flexibility for the manufacturer to determine the comparator therapy and improved the process. The key challenges remaining are how to include independent medical expertise into the process by, for example, medical societies, and to change the governance of GBA in a way to reduce the omnipotence of the sick-funds association ("Spitzenverband Bund") which dominates the process from benefit assessment through negotiating the price.

According to the new law (14th amendment of Social Code Book V) intended to be effective from April 1, 2014, all products that have been on the market prior to AMNOG will be excluded (i.e., from 2011) from the AMNOG benefit assessment process. This clearly offers industry more planning certainty. Until this change, the GBA was able to include these products as they saw it appropriate.

¹¹⁰ H. Laschet, Implicon 6 (2013).

¹¹¹ See, e.g., Global Insight, "AMNOG Blocks Second New Medicine in Germany, Industry Group Calls for Fairer Pricing Rules," Sept. 9, 2011.

The inclusion of European reference pricing in the negotiation of the reimbursement price has also raised concerns, including the appropriate reference countries and the confidentiality of both the prices negotiated in those reference countries and the ultimate price negotiated in Germany (which, in turn, may be referenced in other countries). One key issue of concern is that European countries suffering most from the EURO- and economic crisis, such as Greece and Portugal are part of the basket of reference countries.

It should also be noted that the mandatory rebate and the centrally negotiated reimbursement prices with the statutory health insurance system, which covers approximately 90 percent of the German population, also applies to the private insurance system that covers the remaining 10 percent of the population.

Furthermore, the new requirement of centralized price negotiations could serve to greatly undermine the progress that has occurred in recent years toward selective, value-based contracting of medicine purchases with individual sick-funds. This regulation serves as a disincentive for competitive forces.

Effective January 1, 2011, the German Government extended its cost-containment measures to vaccines. Prices (as rebates) are fixed at the average of European prices in four EU-member countries. The direct linkage of German and EU prices represents a disturbing paradigm shift, since prices in the vast majority of EU countries are set by governments and not by the free market.

Process and Transparency

Reimbursement decisions for pharmaceuticals in Germany's statutory health insurance system are made by the GBA, the top layer of the country's self-administration mechanism in healthcare. Voting members of the GBA are named by the federal associations of statutory health insurance funds, hospitals, and physicians. While patient representatives on the GBA are increasingly vocal, they still have no voting power.

Concerns about the GBA's lack of process transparency, its unwillingness to engage in meaningful dialogue with industry, and the absence of mechanisms to appeal its decisions are growing. The primacy of payer interests in the GBA and lack of public checks (GBA officials are not publicly elected) increasingly place this body beyond the reach of politics and public policy. GBA effectively serves as the regulator (determines the comparator), the arbitrator (determines the additional benefit), and price-setter (negotiates the rebate), thereby effectively controlling the pricing process. It is imperative, therefore, that there be greater governance and transparency within the GBA.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

GREECE

PhRMA's member companies face several challenges and market access barriers in Greece, including measures undermining pharmaceutical innovation, non-transparent reimbursement, increasing government price rebates and claw back mechanisms, as well as outstanding debts owed by state-run hospitals and social security funds. PhRMA and its member companies encourage the U.S. Government to ask the GoG to recognize and protect innovation in the pharmaceutical sector by ensuring efficient and timely government pricing and Social Security Funds reimbursement procedures for medicines.

Key Issues of Concern:

- **Draconian cost-containment measures:** In the context of the Fiscal Adjustment program for Greece, and in order to meet the constantly decreasing public spend targets for pharmaceuticals, the Government of Greece (GoG), under strict TROIKA guidance, has been introducing and refining a series of measures for pricing and reimbursement since 2012. The public spend for pharmaceuticals has decreased by 50% since 2009 mainly through price decreases and return mechanisms, i.e., rebates/claw back. Further aggressive measures are expected in order to meet the savings targets for 2013 and 2014. The GoG should seek to spread cost-containment throughout the healthcare and pharmaceutical sector by ensuring rational and fair pricing policies for generic products and European-comparable margins for pharmacists and wholesalers.

Clear, predictable, and transparent government pricing procedures are critical for market access, contrary to current practice in Greece, where government prices of pharmaceuticals are determined through an international reference pricing system. Medicines that are not reimbursed in some way by the government (e.g., OTC medicines) should not be under any government price, supply chain or profit margin control. In addition, to ensure timely access to the market, the GoG should set a clear timeline for establishing government prices for new medicines and for making reimbursement approval decisions for those medicines. Last but not least, full transparency in public pharmaceutical spend is required before any overspend and subsequent claw back calculations are made and pharmaceutical companies are billed.

- **Promotion of local generics through reimbursement:** The GoG is taking a number of measures to promote locally produced generics to the detriment of the innovative industry (both on and off patent). Examples include “jumbo” ATC4 clusters in the reimbursement list (putting together on patent, off patent and generic drugs and reimbursing only the average of the three lowest-priced generics in each cluster), and patient co-pays for off patent drugs that do not apply to generic drugs.

- **Hospital and Social Security Funds (EOPYY) debts:** Although a considerable portion of the arrears were paid in 2013, the state debt to the pharmaceutical industry remains high (nearly €1 billion) with risk for further future increases.

For these reasons, PhRMA requests that Greece remain on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Cost-Containment Measures and Government Pricing

Cost-containment measures in Greece are being introduced in a series of sometimes overlapping administrative measures, adding significant complexity to the market.

During the period 2010-2012 the GoG yielded significant savings through continuous and intense pressure on prices of pharmaceuticals. Price reductions came from regular general price revisions (conducted twice per year) and also from decreases in wholesaler and pharmacist profit margin. As a result of these multiple rounds of price cuts, parallel exports to other European markets increased in 2010 (as a percentage of total sales to pharmacists/wholesalers). In 2011 and 2012, as a result of government-imposed exports bans, parallel exports decreased for specific products deemed critical by the National Organization of Medicines (EOF).¹¹²

In February 2013, after the transfer of pricing responsibilities from the MoH, a general price revision was conducted by EOF. According to the new pricing bulletin (PB), on patent and “unique” off patent products (with no generic on the market) were priced based on the average of the 3 lowest EU countries, while off patent products received progressive decreases based on retail price. Multiple errors in the PB led to subsequent corrective bulletins, which also included prices for new generics.

The PB issued in August 2013 included about 80 new presentations (SKUs) of original products, which were priced for the first time after 3 years. In the same bulletin prices of on-patent products were revised based on the average of the 3 lowest prices in EU countries.

PhRMA's member companies strongly encourage the GoG to implement a transparent and predictable pricing system. However, considering the immense pressure put on prices in the last 3 years, there is no room for further savings and an alternate pricing system should be considered by the GoG. PhRMA's member companies support the reform of the current pricing system to a simpler one, based on a basket of reference countries with more commonalities with Greece (e.g., similar macro-economic indices, epidemiologic profiles).

¹¹² 2012 IOBEE report on pharmaceuticals market based on EOF data, at 49, Graph 3.8, available at http://www.iobe.gr/docs/research/RES_05_A_03022013REP_GR.pdf (last visited Oct. 21, 2013).

Reimbursement

Following years of different reimbursement systems, in March 2013, the GoG reintroduced the positive reimbursement list, a system that was abolished in 2006. In the revised list products are mainly clustered at the ATC4 level including on patent, off patent and generics. At each cluster corresponds a reference reimbursement price, which is based on the lowest Daily Treatment Cost (DTC) of the three lowest-priced generic medicines in that therapeutic group that have at least a 4% market share. If the patient chooses a medicine with a retail price above the reference reimbursement price, he/she covers the entire difference when the active substance has a generic version and half of the difference when there is no generic equivalent, with EOPYY covering the remaining half. (Products with DTC below or equal to 0.3€ are fully reimbursed even if their retail price is higher than the reimbursement price.) Further changes in the reimbursement list will soon be implemented, including incentives for physicians to prescribe and pharmacists to dispense generics or other drugs that are priced below the reference reimbursement price.

Despite the recent pricing of some prioritized innovative drugs, reimbursement has not been finalized. Negotiations are ongoing at the MoH, TROIKA and industry stakeholders' level, but it is anticipated that further barriers will be posed for the inclusion of innovative drugs in the positive reimbursement list or rebates and caps will be implemented. These new barriers could cause significant delays in patient access to innovative treatments.

PhRMA's members strongly believe that all pharmaceutical products approved in Europe should immediately be available to patients in Greece, and appropriately reimbursed through EOPYY. As with the pricing system, the GoG needs to implement a simple, transparent reimbursement system that appropriately values innovation.

Hospital Debts

Since 2012, due to the bailout funds received by the GoG, some improvement has been seen in debt collections and overall state debt to industry. That said, as of December 31, 2013, the Hellenic Association of Pharmaceutical Companies (SFEE) estimated that its member companies were still owed approximately €970 million from the NHS and Military Hospitals and the EOPYY Insurance Funds.

PhRMA and its members believe that it is critical that the GoG refrains from incurring future debts and pays for the products they receive within the timeframe set by law.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

ITALY

PhRMA member companies face several market access barriers in Italy. Over the past ten years, Italy adopted more than 20 separate cost-containment measures affecting the pharmaceutical industry without consideration of the impact on the innovative pharmaceutical industry in Italy. PhRMA and its member companies urge the Italian Government to consult with the innovative pharmaceutical industry in developing a healthcare environment that rewards innovation and ensures patient access to new medicines. To this end, PhRMA's members appreciate the assistance and support they have received from the U.S. Embassy in Rome since 2011 in facilitating a dialogue with the Monti and Letta Governments.

Key Issues of Concern:

- **Market access delays and limitations:** Italy's pricing and reimbursement system and process for conducting tenders do not adequately reward innovation. In addition, there are significant regional delays in listing new medicines on hospital formularies despite assurances in 2010 to resolve these delays.
- **Cost-containment measures:** Innovative pharmaceutical companies continue to bear a disproportionate portion of budgetary measures in Italy. In addition, Italy imposes a strict cap on pharmaceutical spending, such that any amount spent over these limits is clawed back from pharmaceutical companies.

For these reasons, PhRMA requests that Italy remain on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Regulatory Approval, Market Access Delays and Limitations

Access to innovative drugs in both the retail (pharmacies) and hospital channels remains difficult in Italy. The Italian Drug Agency (AIFA- Agenzia Italiana del FArmaco) in 2012 announced the introduction of a new algorithm for the evaluation of innovation designed to support and speed-up pricing and reimbursement decisions. As of the end of 2013, the Agency is still reviewing the process for implementation of this new scheme; therefore, the implementation likely will not take place before the second half of 2014.

In the meantime, market access in Italy remains difficult and with significant delays, especially in comparison with its peers in Europe:

- *Time to market:* it takes from 12 to 15 months to obtain the marketing authorization from AIFA, an additional 12 months to be included in the regional

formularies and 2 months more to be listed on the hospital formularies – i.e., more than two years on average;¹¹³

- *Prices*: compared to the average of its peers in Europe (UK, Germany, Spain and France), prices of new drugs in Italy are 15% lower;¹¹⁴
- *Expenditure for new drugs*: The expenditure for new drugs in Italy is 24% lower than its peers in Europe. In addition to the national ceilings for retail and hospital public pharmaceutical expenditure, sales of some new drugs are capped with refunding in case of overspending. As a result of this policy, uptake in Italy of these drugs as compared to the four peer EU countries identified above is significantly lower (i.e., over 40% lower).

At the end of 2012, the Monti Government introduced a “fast track” process for innovative drugs in order to reduce delays, with particular reference to the regional formularies. It is still too soon to know whether this new process will expedite listing on the regional formularies. However, the number of drugs that the AIFA has identified as “innovative” is still very limited, and the criteria for making this determination are undefined.

The vast majority of innovative drugs are sold in the hospital channel. The public hospital pharmaceutical expenditure is capped at 3.5% of the National Healthcare fund. Each pharmaceutical company receives a yearly budget from the National Drug Agency (AIFA). Pharmaceutical companies received the final 2013 hospital budget on October 1, 2013. The budgets assigned to each pharmaceutical company in 2013 were 18% lower than their actual sales in 2012. As of the date of this submission, the certification of the overspending and the resulting refund for 2013 have yet to take place, but it is anticipated that innovative companies will be asked to refund approximately 15% of their pharmaceutical sales in 2013. There are still discussions on how the companies' budgets have been calculated as well as on the “real” 2013 expenditure; 2014 budgets have not been received.

Regions Attempt to Overcome Patent Protection

Several regions and local health authorities organized tenders in which they group together patented and off-patent medicines deemed to be in the same therapeutic group. PhRMA and its member companies believe that grouping patented and off-patent medicines together in a single tender, and then deciding that tender solely based on the price of the offer, dramatically affects the ability of PhRMA member companies to recover an appropriate reward for patented medicines. This practice decreases the value of pharmaceutical intellectual property, which in turn lessens the incentive for innovation.

¹¹³ Farmindustria (the National Industry Association) elaboration of data, based on a survey carried out on associated companies in 2011.

¹¹⁴ Elaboration of the CERGAS Bocconi (Centro di Ricerche sulla Gestione dell'Assistenza Sanitaria e Sociale 2011) based on IMS data.

For medicines, tenders should be used solely for purchasing generic drugs that treat the same therapeutic condition, where the molecule is the same and the only criterion for making the purchasing decision can be cost. Further, lack of transparency in AIFA's and the Regions' decision-making processes risks changing the rules of competition (tendering) and/or discriminating against patients based on which region they live in.

Discrimination *vis-à-vis* Other Parts of the Healthcare System

The Italian Government's focus on controlling pharmaceutical expenditures is almost unique relative to other expenditures within Italy's National Healthcare system (NHS). Pharmaceuticals represent less than 15% of the total healthcare expenditure. In the 2006-2011 period, pharmaceutical expenditure grew only 2.3%, while the other goods and services purchased by NHS increased 17.5%. Despite comprising a relatively small percentage of health care expenses, 30% of the health care cuts implemented between 2012-2014 (4 billion euro over the three years) were imposed directly on the pharmaceutical sector. Further, pharmaceutical expenditure is the only element of the health care budget that is subject to annual caps whereby pharmaceutical companies must refund a portion of any overspend (60% in the retail channel and 50% in the hospital channel).

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

ROMANIA

PhRMA's member companies face several market access barriers in Romania, including reference pricing, inadequate healthcare funding mechanisms and significant delays in the reimbursement process.

Key Issues of Concern:

- **Government pricing:** In 2009, Romania implemented a government pricing system for innovative pharmaceutical products that sets prices at unsustainably low levels (the lowest price within a basket of 12 EU countries, with different geographical and economical outlooks). In addition, prices of prescription drugs in Romania are set by the government regardless of whether or not the drug is reimbursed. Although the Ministry of Health (MoH) has established a Working Group with all relevant stakeholders to review the pricing system, that process proceeds very slowly.
- **Inadequate healthcare funding:** An “*Access to Innovation*” study conducted by the local PhRMA affiliate, Local American Working Group, found that health performance indicators in Romania (including infant and overall mortality rates) were significantly lower compared to the rest of Europe, primarily due to a very low health care expenditure rate of 5.8% of GDP. The study also demonstrates that updating the list of reimbursed medicines will bring five times more economic benefits on the long run than the initial costs. Also, new medicines will generate a positive impact of additional 0.5% to the Romanian GDP due to regaining or maintaining the level of productivity of patients. However, at the moment, although the budget for healthcare has been increased to pay the arrears, the budget for medicines has remained flat at the 2011 level. Too often, the cost of financing, even this low level of funding, is borne by the pharmaceutical industry through claw-back taxes. The innovative biopharmaceutical industry stands ready to assist the Romanian Government in developing new healthcare funding systems that reflect more accurately the demand for healthcare services in Romania.
- **Claw-back taxes:** The innovative pharmaceutical industry has been the target of numerous misguided “claw-back” tax regimes intended to increase healthcare revenue or control expenditure. The latest version of the clawback, passed through an Emergency Government Ordinance on September 21 and implemented on October 1, 2011, requires medicine producers to cover the entire reimbursed medicine budget deficit, including wholesale and retail margins, and, until October 1, 2012, value added taxes (VAT). A similar MoH Working Group as for pricing is active on claw-back matters, but that Working Group has largely a consultative role. According to the latest developments, MoH is working on a new claw-back form that will differentiate between two types of medicines; the debate is whether it will be innovative versus generics or on-

patent versus off-patent. The update of the reimbursement list is conditioned by authorities by the revision of the claw-back tax and target deadline is April 1st.

- **Unpredictable, non-transparent reimbursement system:** As an initial matter, the Romanian Reimbursement list is updated infrequently. Further, reimbursement decisions in Romania are significantly delayed due to onerous requirements, such as continuous reimbursement for at least one-year in three other EU Member States before a manufacturer can apply for reimbursement in Romania. The last update of the reimbursement list took place in 2008 for medicines that received marketing authorization in 2007. Consequently, patients lack access to the latest advances in science and to the high tech minimally invasive therapies and other advanced technologies. The Government of Romania should ensure that new regulations and systems are developed in a predictable and transparent manner. Consultation with industry and other stakeholders is beneficial for Government and industry. The Romanian Government needs to reimburse medicines in a manner that rewards innovative companies for their significant investment in developing new medicines and encourages development of tomorrow's new cures and treatments.

For these reasons, PhRMA requests that Romania remain on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Government Pricing

The government pricing policy introduced in 2009 calculates a drug's price based on the lowest price paid in a reference basket of 12 EU countries. Under this new policy, generics and biosimilars are subject to a government price ceiling of 65 and 80 percent of the original price, respectively. Setting the government price at the absolute minimum discourages innovation. Romanian patients would be better served if the government price was based on the average price in the EU, as proposed by the local innovative biopharmaceutical industry to the MoH within the pricing Working Group. Moreover, MoH has announced intention to modify the pricing legislation in 2014 and we are concerned with those potential modifications which seem to be directed by cost-containment concerns rather than by patients' access to medicines.

Healthcare Funding

Patient access to healthcare in Romania is negatively impacted by the low-level of healthcare spending. As the AmCham EU noted with regards to investment in Healthcare, "more money doesn't necessarily mean better outcomes." However, in less developed countries like Romania, the first step would be to allocate sufficient funds to healthcare and concomitantly find solutions to optimize spending. Both the level of

financing and the efficiency of resource allocation in Romania are well below the EU average.

In order to increase funding, in September 2009, the Romanian Government implemented a “Claw-back Tax”. The ordinance taxes sales of drugs between five to 11 percent depending on total company sales. The negative effects of this could be diminished if the tax were applied more evenly and on reimbursed sales. Furthermore, the current iteration of the claw-back combined with therapeutic reference pricing stifles pharmaceutical innovation.

Effective October 1, 2011, Romania implemented a new claw-back mechanism, which acts as an expropriatory tax, whereby the medicine budget deficit (*i.e.*, the difference between the allocated budget and actual consumption) is calculated as a percentage of each pharmaceutical company’s sales during the prior quarter. Moreover, the medicine budget value is set by the Government regardless of the previous year’s medicine consumption. This claw-back amount is due within 55 days of the end of each quarter, regardless of whether the company has in fact received payment for the medicines from the Sick Fund, as happened in past years. The percentage is also applied to the gross value of each pharmaceutical company’s sales to the Sick Fund, including wholesale and retail margins and, until it was removed on October 1, 2012, VAT as well. In other words, PhRMA member companies must compensate the budget for payments the government makes to wholesalers and pharmacists (and previously for taxes obtained through VAT collection).

Therefore, insufficient healthcare financing and inefficient spending are the root of all shortcomings in the Romanian healthcare system. As a result, the local innovative pharmaceutical industry’s efforts are focused on offering to collaborate with the Romanian Government on this issue. In a joint effort, the Local American Working Group and AmCham Romania have submitted to the Government a position paper offering their concerns and recommendations on efficient healthcare financing solutions and reiterating their interest in engaging with the Romanian Government to develop the best solutions.

Reimbursement Update

The drug reimbursement list is rarely updated, and only when the Government decides to issue a special decision. According to the last evaluation of the HTA department in the MoH, there are about 200 applications pending reimbursement approvals. The last complete updates to the reimbursement list were made in 2005 and 2008. There were minimal updates in 2009 and 2011; in 2009, 10 HIV and oncology products were added and in 2011, four orphan drugs were approved for reimbursement. No exceptions are made for life saving drugs, even for those approved under a fast-track process in other countries within the European Union. To sustain innovation, the government should seek to improve the reimbursement system by making it more transparent, more predictable, and more regular in its timing, in accordance with

European legislation (the Transparency Directive) which sets specific deadlines for reimbursement decisions (90 days).

In 2012, as part of the agreement with the International Financial Institutions (IMF, EC, WB), the Government committed not to introduce any new medicines in the reimbursement list without an interim Health Technologies Assessment (HTA) based on objective and quantifiable criteria. An institutional framework (Protocol) was developed, in cooperation with the innovative pharmaceutical industry, and in June 2013 the HTA legislation was implemented (Order 724/2013). The Protocol also provided that the reimbursement list was to be updated by July 2013, but other priorities at the MOH (including payment terms) have pushed the reimbursement update to later this year.

At the end of 2013, MoH published results of its analysis of the extended INNs waiting list based on the new (June 2013) legislation which requires HTA-related criteria for assessment. The list could be finalized and enter to force by April 1, 2014, at the same time as the minimal ensured health services packages (which are still under development) and the new claw-back mechanism, which was designed to cover any cost overruns due to the new list. However, the April 1st deadline is not likely to be met since the 2014 health budget does not foresee any additional funds for addressing costs generated by the additional molecules.

Payment Terms and Debt

With regards to payment terms, the Romanian Association of International Medicine Manufacturers (ARPIM) has reported that the average time until payment was 330 days in 2012. Despite this reality, the Romanian Government has informed the IMF that it plans to reduce the payment term to 60 + 30 days (consistent with the EU's "Late Payments" Directive). Following the enforcement in 2013 of the EU Directive on late payments, the payment terms decreased from 300 days to 60+30 days at the beginning of 2014. The 2013 healthcare budget has been supplemented for this particular reason and most of the arrears have been settled in order to avoid running afoul of EU legislation.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

RUSSIA

PhRMA and its member companies operating in Russia face numerous market access barriers in Russia, especially in government procurement and discriminatory price registration. PhRMA's members are also concerned that the Russian Government is implementing policies that do not adequately protect intellectual property or reward the value of innovation and the benefits it brings to Russian patients.

Key Issues of Concern:

- **Regulatory data protection:** On August 22, 2012, Russia officially acceded to the World Trade Organization (WTO). Russia's commitments on regulatory data protection embedded in the "Law on the Circulation of Medicines" are an integral part of Russia's WTO obligations and came into force on the date of Russia's WTO accession. PhRMA and its member companies welcome this, but are concerned that the "Law on the Circulation of Medicines" and other applicable regulations still contain mechanisms that are contrary to, or do not effectively implement, regulatory data protection consistent with Russia's WTO obligations.
- **Effective patent enforcement:** Currently, there is no mechanism in place to ensure that the patent status of a drug is taken into consideration by marketing or other regulatory authorities in Russia when considering the approval of a generic substitute to a patented drug. This in turn has led to the approval and marketing of a generic product, despite the fact that a patent for the original drug is still in force. In addition, pharmaceutical innovators in Russia continue to face significant legal and practical challenges that limit their ability to effectively protect their innovative products against infringement, including the ability to secure remedies and injunctions that would reduce the risk of premature entry of infringing generic products to the Russian market.
- **Government pricing:** The Russian Government controls prices of drugs on the Essential Drugs List (EDL). Unfortunately, local and foreign manufacturers are treated differently in that respect, according to Russia's Law on the Circulation of Medicines. Generally speaking, local companies (including those who package their drugs in Russia) are able to adjust prices on an annual basis, while foreign firms are not. Furthermore, the EDL was not updated in 2012 or 2013. In fact, according to the Russian Government's Decree no. 2199-r (December 19, 2013) the EDL effective in 2012 and 2013 shall continue to be effective in 2014. This will impede Russian patient access to innovative medicines.
- **Government procurement:** In 2013, Russia's Industry and Trade Ministry drafted government regulations, which, if implemented, would severely limit access of foreign pharmaceutical manufacturers to public procurement of drugs and medical equipment.

- **Local clinical trial requirements:** According to the “Law on the Circulation of Medicines” governing, *inter alia*, clinical trials, pre-registration clinical trials must be conducted in Russia (with some exceptions). The corresponding practice has caused significant delays in the registration of new products, thus limiting patient access to innovative medicines.

For these reasons, PhRMA requests that Russia be placed on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Regulatory Data Protection

As part of its accession to the WTO in August 2012, Russia committed to provide a six-year period of regulatory data protection (RDP) for undisclosed information submitted to obtain marketing approval for pharmaceuticals in accordance with Article 39.3 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS):

The representative of the Russian Federation confirmed that the Russian Federation had enacted legislation and would adopt regulations on the protection of undisclosed information and test data, in compliance with Article 39.3 of the WTO TRIPS Agreement, providing that undisclosed information submitted to obtain marketing approval, *i.e.*, registration of pharmaceutical products, would provide for a period of at least six years of protection against unfair commercial use starting from the date of grant of marketing approval in the Russian Federation. During this period of protection against unfair commercial use, no person or entity (public or private), other than the person or entity who submitted such undisclosed data, could without the explicit consent of the person or entity who submitted such undisclosed data rely, directly or indirectly, on such data in support of an application for product approval/registration. Notice of subsequent applications for registration would be provided in accord with established procedures. During the six year period, any subsequent application for marketing approval or registration would not be granted, unless the subsequent applicant submitted his own data (or data used with the authorization of the right-holder) meeting the same requirements as the first applicant, and products registered without submission of such data would be removed from the market until requirements were met. Further, he confirmed that the Russian Federation would protect such data against any disclosure, except where necessary to protect the public or unless steps were taken to ensure that the data were protected against unfair commercial use.¹¹⁵

¹¹⁵ Report of the Working Party on the Accession of the Russian Federation to the World Trade Organization, WT/ACC/RUS/70, WT/MIN(11)/2 (Nov. 17, 2011), at para. 1295, incorporated in Protocol on the Accession of the Russian Federation, WT/MIN(11)/24, WT/L/839 (Dec. 17, 2011), at para. 2.

Russia's commitment to six years of RDP is embedded in Article 18.6 of the Law on the Circulation of Medicines:

The results of the nonclinical trials of medicinal products and clinical trials of medicinal products submitted by the applicant for state registration of the medicinal products shall not be obtained, disclosed, used for commercial purposes and for purposes of state registration without applicant's permission within six years from the date of the state registration of the medicinal product.

Violation of the prohibition specified by this Clause shall entail the responsibility in accordance with the legislation of the Russian Federation.

The circulation of medicines in the Russian Federation registered with violation of this Clause shall be prohibited.¹¹⁶

The enactment of data protection legislation in Russia is a positive development and is a welcome step towards fulfilling Russia's obligations according to TRIPS Article 39.3 and to creating a supportive environment for pharmaceutical innovation in Russia. It is not only an integral part of Russia's WTO commitments, but also an important mechanism to incentivize the research and development of new medicines.

PhRMA and its member companies are concerned, however, that the Law on the Circulation of Medicines and other applicable regulations contain mechanisms that are contrary to, or do not effectively implement, RDP consistent with Russia's new WTO obligations. In particular, the Law on the Circulation of Medicines provides no explicit implementing procedure or mechanism. This is further confused by Article 26 of the same law, which allows for the accelerated examination of the market authorization application of generic medicines, without reference to the six years of RDP or to Article 18.6. Recent amendments to the law proposed by the Ministry of Health include some proposals to improve the situation. But the Ministry has not proposed to expand its legal powers so as to be able to revoke drug registrations on the ground of RDP violations. Further, recently approved administrative regulations governing drug registration totally disregard the RDP issue.

The United States Government should seek greater clarity on the actual implementation of Article 18.6 of the Law on Circulation of Medicines, with particular respect to how it relates to Article 26 of the same law (allowing for the accelerated review of generic applications). The lack of clarity regarding data protection creates a situation of juridical uncertainty that should be avoided.

Effective Patent Enforcement

¹¹⁶ Federal Law No. 61-FZ, "Law on the Circulation of Medicines" (Apr. 12, 2010).

A mechanism is needed in Russia to ensure that patent issues can be resolved before infringing pharmaceutical products are launched on the market. Currently, there is no effective mechanism for otherwise enforcing an innovator's patent rights vis-à-vis regulatory approval of generic substitutes or biosimilars. Generic drug manufacturers can apply for and receive marketing approval for a generic product despite the fact that a patent for the original drug is still in force.

Further, pharmaceutical innovators face significant legal challenges that limit their ability to effectively protect their innovative products against infringement, including the ability to secure remedies, such as injunctions, that would reduce the risk of premature market entry by infringing generic products. Innovators face significant barriers to obtaining preliminary injunctions to prevent infringing products from entering the market because the Arbitration Procedural Court does not, in practice, grant preliminary injunctions to patentees in pharmaceutical patent infringement cases. Unreasonable court delays also deprive patent holders of relief in a timely manner even if injunctions were practicably available. As a result, PhRMA member companies have not been able to resolve patent disputes prior to marketing approval being granted to infringing generic products, leading to injury that is rarely compensable.

To avoid the unnecessary costs and time of litigating damages claims in patent litigation, and to increase market predictability, Russia should enable patent holder companies to file patent infringement suits before marketing authorization is granted for follow-on products and afford sufficient time for such disputes to be resolved before marketing occurs. This might include a form of automatic postponement of drug registration approval pending resolution of the patent dispute, or for a set period of time.

Mislabeled Herbal Supplements

Medicinal products marketed as herbal supplements containing only natural ingredients have been found in testing to contain one or more active pharmaceutical ingredients, some of which are still patent protected in Russia. These falsely labeled and marketed products can be purchased without a physician's prescription, endangering public health but also violating the patent holders' intellectual property rights. Russian authorities have been informed of the situation, yet fail to appropriately regulate such products, and allow them to remain in the market and available to consumers.

Market Access Barriers

State Regulation of Prices of Medicines on the Essential Drug List (EDL) and Reimbursement Debate

In February 2013, the Russian Ministry of Health approved its Drug Provision Strategy 2025 which includes pilot programs and a full-scale pricing and reimbursement system. Among the "tasks" established as part of the Strategy, the Government of

Russia also seeks to implement registers of patients eligible for free or discounted drugs in an outpatient setting, streamline pre-clinical, clinical, and production requirements, introduce a system of reference pricing, and increase the qualifications of medical and pharmaceutical workers.

While the Health Ministry's long-term Drug Provision Strategy provides an important opportunity for healthcare reform in the country, a fundamental objective of the Strategy is for the Russian Government to maintain control of drug prices through registration of the prices of medicines including on the EDL. The EDL system, however, has significant defects. For example, there is no developed or transparent assessment procedure for updating the EDL, and the EDL was not updated in 2012 or 2013. In fact, according to the Russian Government's Decree no. 2199-r (December 19, 2013) the EDL effective in 2012 and 2013 shall continue to be effective in 2014. The failure to update the EDL inhibits patient access to new medicines and is in conflict with the Law "On the Circulation of Medicines," which requires an update to the EDL at least once per year. This decision has been criticized by the medical community, patients' organizations and the chair of the State Duma (lower house) Committee on Health.

Other aspects of Russia's current pricing and reimbursement system limit market access of U.S. innovative biopharmaceutical companies. For example, the current Russian pricing and reimbursement system discriminates against foreign producers by allowing only domestic producers to request annual adjustment of their registered prices. Russia also imposes international reference pricing based on the lowest price in the basket of 21 reference countries (with a maximum price based on internal referencing of drugs priced in Russia with the same INN).¹¹⁷ This system is suboptimal as it incorrectly assumes that the economic conditions, patient populations and needs, and healthcare systems in the reference countries are relevant to Russia.

PhRMA and its member companies believe that Russia should adopt a pricing and reimbursement system that appropriately values and rewards innovation while increasing patient access to new medicines. PhRMA and its member companies look forward to engaging with the Ministry of Health in reforming the current system to meet these goals.

Discriminatory Practices in Public Procurement

Russia committed to working toward accession to the WTO Agreement on Government Procurement (GPA) as part of its accession to the WTO last year.¹¹⁸ To this end, Russia became an observer to the GPA on May 29, 2013 as a first step toward full accession to that agreement. Notwithstanding these commitments, Russia continues discriminatory practices in its government procurement system. The Government of Russia maintains a 15 percent price preference for "local" manufacturers at the federal and municipal procurement auctions. Other preferences are also being considered for

¹¹⁷ In November 2013 the MoH proposed to restrict the reference pricing basket to 15 countries.

¹¹⁸ Report of the Working Party on the Accession of the Russian Federation to the World Trade Organization, WT/ACC/RUS/70, WT/MIN(11)/2 (Nov. 17, 2011), at para. 1143.

local manufacturers – a term not clearly defined. This constitutes clear discrimination against foreign manufacturers, including PhRMA member companies.

At the same time that Russia expresses its intent to accede to the GPA, it continues to implement new measures that favor locally manufactured products in tender processes:

- In 2012, amendments to the “Law on the state procurement” regarding public procurement of drugs came into force. Those amendments require that for public procurement purposes, tender lots must be formed according to INNs except for those drugs put on a special list by the government. This practice discriminates against innovative drugs because although the law allows mentioning trade names in tender documentation, the list of such trade names is still to be compiled (see below).
- At the end of November 2013 the Russian government approved a decree that would allow public procurement of medicines according to their trade name in cases when drug substitution is impossible. The list of branded drugs to be procured will be developed by a special governmental sub-commission. There is no requirement for additional clinical trials to prove “substitutability” of the subject drug and references to international practice (in particular, European Medicines Agency and U.S. Food and Drug Administration data) are allowed. Still, procedures for inclusion lack transparency and leave room for arbitrary decisions.
- Also in 2013, Russia’s Industry and Trade Ministry drafted a few regulations proposing restrictions on public procurement of imported drugs and medical devices. According to a draft government decree on preferences in state purchases to locally produced drugs, only Russian and Belarusian drugs would be eligible for government procurement tenders if two or more local manufacturers are registered in the market in a particular product category (INN). Locally produced drugs for the purpose of this decree are drugs manufactured in Russia or Belarus, and “manufacturing” means full production cycle including API, or production of dosage forms, or primary and/or secondary packaging or labeling (although the last criterion will only be sufficient until December 31, 2014).

Registration and Clinical Trials

Overall, Russia’s clinical trial system is strong and accessible. Clinical trials in Russia benefit from highly qualified medical staff, adherence to Good Clinical Practices standards, relatively lower costs, and good access to patient populations. There is, however, room for improvement in some key areas like the clinical trial approval process to increase transparency and speed of approvals. Moreover, according to the Law on the Circulation of Medicines governing clinical trials, pre-registration clinical trials must be conducted in Russia before the medicinal product can be given market authorization (with some exceptions). The corresponding provisions have been

implemented, causing delays in the registration of new products, thus limiting patient access to innovative medicines.

The Ministry of Health has taken steps to increase the transparency of the decision-making procedures of the Ethics Committee related to clinical trials. PhRMA especially appreciates the Ministry's willingness to allow medical organizations, medical science bodies, medical universities, non-governmental organizations, churches and the media to propose candidates for this body.

Interaction between HCPs and Pharmaceutical Companies

On November 25, 2013 Vladimir Putin signed into law certain amendments to various legislative acts of the Russian Federation due to adoption of the Federal Law "On Health Protection of the Population," imposing further constraints on companies' interactions with healthcare professionals. A special chapter to that effect was added to the Law "On the Circulation of Medicines."

In particular, the revised law bans "creating obstacles for participation of competitor companies in scientific events for medical and pharmaceutical professionals organized and financed by a pharmaceutical company or companies". The law stipulates that representatives of sponsoring companies must not have more time to make a speech or more space for demonstration of their products or to have more advertising materials than other participating companies. Under the law, different terms of participation in an event are acceptable only if they are grounded in differences in companies' contributions to the event and if a financing agreement is concluded between the companies. These restrictions limit the beneficial and legitimate interaction and communication between pharmaceutical company representatives and healthcare practitioners.

FDI Barriers

On June 24, 2013, the Russian government expanded the scope of technologies deemed to be critically important for the domestic economy or defense to include biotechnology and vaccines. As a result, foreign manufactures of vaccines face greater challenges when investing in Russia. For example, the Russian Government's Commission on Foreign Investment's rejected Abbott Laboratories' bid for Petrovax, a Russian manufacturer of vaccines, on national security grounds.¹¹⁹

Orphan Drugs Legislation

The Law on the "Health Protection of the Population" introduced an orphan disease definition, though eligibility criteria are stricter than in the U.S. and the EU. There is still no definition of orphan drug in Russia's legislation and the general registration procedure, set by the Law on the Circulation of Medicines, creates

¹¹⁹ "Russia rejects Abbott Laboratories' plan to buy Petrovax," Reuters (Apr. 19, 2013), available at <http://www.reuters.com/article/2013/04/19/us-abbott-russia-idUSBRE9310GJ20130419>.

significant challenges for the registration of orphan drugs in Russia. Ministry of Health officials have acknowledged this issue. While developing amendments to the “Law on the Circulation of Medicines,” the Ministry proposed an accelerated registration procedure for orphan drugs that eliminates the need for otherwise obligatory local trials. Although industry, as a general matter, supports accelerated pathways for orphan drugs, the proposed procedure lacks sufficient detail to fully evaluate.

Biologic and Biosimilar products in Russia

While Russian law refers to “immunobiological products,” there is currently no specific definition for biological products or a specialized approval process for biosimilars. In 2013, the Ministry of Health developed draft amendments to the “Law on the Circulation of Medicines,” including proposed definitions for a biologic and a biosimilar. Although PhRMA’s members welcome this development, there remain some concerns regarding aspects of those proposed definitions. Furthermore, the proposed amendments do not address the lack of a regulatory pathway for biosimilars. As a result, a manufacturer of products that should be regulated as biosimilars must simply demonstrate that its product is bioequivalent to the innovator product (the same standard as for small molecule generic drugs) rather than demonstrate that the product is sufficiently similar to the original product in terms of quality, safety, and efficacy such that product may be considered biosimilar and therefore expected to produce the same clinical result. A purported showing of bioequivalence per the traditional generic pathway is not in line with global best practices for regulation of biosimilars. The lack of clear statutory definitions of biologics and biosimilars, combined with the lack of a regulatory pathway for biosimilars has facilitated the market entry of products which would not be approved under international norms, to the potential detriment of Russian patients.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

SPAIN

PhRMA's member companies face several market access barriers in Spain, most notably a non-transparent and unpredictable government pricing system. Spain's pricing and reimbursement system is unpredictable, lacks transparency and does not adequately reward innovative pharmaceutical companies for the significant investment required to develop a new medicine.

PhRMA encourages the U.S. Government to ask the Government of Spain to engage with the innovative pharmaceutical industry to develop a transparent and predictable pricing and reimbursement system that adequately rewards innovation and supports investment in future medicines.

For these reasons, PhRMA requests that Spain be placed on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Reference Pricing

Since the 2009 financial crisis, the Spanish Government, at both the central and regional level, has targeted the pharmaceutical industry by imposing draconian cost containment measures and reforms. As a result of these measures, innovative pharmaceutical manufacturers are highly concerned about their ability to meet Spanish patients' medical needs in 2013 and beyond.

At the central level, the Spanish Government has enacted four Royal Decrees over the last three years that directly impact the innovative pharmaceutical industry and create an unpredictable and unstable business environment. On June 1, 2010, the Spanish Government enacted two Royal Decrees:

- Royal Decree 4/2010 increased the price reduction for older products sold in Spain for which a generic version is available in the European Union but not in Spain. Such products are now subject to a 30 percent price cut. Meanwhile, if generic products are available in Spain, the reference price can be cut by 50 percent in the first year (previous Decrees had made this reduction over multiple years).
- Royal Decree 8/2010 enacted a 7.5 percent mandatory rebate on medicines (and medical devices) sold through the NHS that are not included in the reference pricing system, affecting both the hospital and retail markets.

On August 20, 2011, the Spanish Government enacted Law – Royal Decree 9/2011 – which was designed to decrease pharmaceutical expenditure by €2.4 billion. This Decree includes several new detrimental measures:

- Increases the mandatory rebate mentioned above to 15 percent for those medicines that have been on the market for over 10 years with no generic or biosimilar authorized in the Spanish market.
- Mandates that all prescriptions must refer to the international non-proprietary name (INN) for the active pharmaceutical ingredient, rather than a specific brand name. If a branded name product is prescribed, the pharmacist must fill the prescription with the lowest price medicine with the same molecule, dosage and form. Exceptions can be made for justified therapeutic medical needs.
- Establishes a Cost-Effectiveness Committee to assess the value of medicines. The innovative pharmaceutical industry requests that the Spanish Government consult with all interested stakeholders as it builds this Committee and works to define key terms such as value. Value should be broadly defined to consider unmet clinical needs, the degree of innovation, and the broader societal values of a specific treatment and emphasize long-term medical needs rather than just short-term budget implications.

On April 20, 2012, the Spanish Government enacted Royal Decree 16/2012, which modifies Law 29/2006 on the Guarantees and Rational Use of Medicines and Healthcare Products. This Decree includes several new detrimental measures:

- All medicines approved in the EU for at least ten years will be subject to reference pricing, regardless of whether the patent term has expired. In order to recoup the significant investment required to develop a new medicine, prices for innovative medicines should not be subject to reference pricing during their patent term. Moreover, the new regulation does not establish how these reference prices will be calculated.

These myriad Royal Decrees imposing overlapping cost-containment measures have resulted in a pricing and reimbursement environment that lacks predictability.

- Prescription by INN: Although the decree now permits physicians to prescribe branded medicines, it mandates automatic substitution of those prescriptions where the price of the branded product is not the lowest in the group.
- Selected Prices System (Art. 93 Bis): The MOH intends to allow companies to bid to be the providers of three types of high consumption medicines (those included in the Reference Pricing System, vaccines and those included in the Homogenous Groups with reduced contributions from patients). The innovative pharmaceutical industry is concerned that under this scheme, the MOH will group both patented and generic products in broad “therapeutic categories” whereby the value of the innovative products will be diluted by the generics in the tender basket.

Similar measures, *e.g.*, pricing restrictions, reference pricing, automatic substitution of branded medicines for generics, *etc.*, are being imposed at the regional level. Further, some regions are treating medicines with different pharmacological properties as if they were therapeutically equivalent for the purpose of pricing and reimbursement, without regard to the patent status and efficacy of those medicines. In turn, the unsustainably low prices set in Spain are referenced by a number of other European countries to set their own pharmaceutical prices.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

LATIN AMERICA

COLOMBIA

PhRMA's member companies face several market access barriers in Colombia, including the imminent passage of a proposed "abbreviated pathway" for biologic approval that is not in line with international guidelines. This is in addition to constantly changing, unbalanced and unclear government pricing policies paired with specific governmental initiatives to undermine patent protection for the pharmaceutical sector.

Key Issues of Concern:

- **Proposed Ministry of Health patent review:** PhRMA and its member companies are concerned about proposed legislation (Reform of the Health System in Colombia) that would establish a preliminary patent review mechanism in the Ministry of Health for all health-related products. The proposed mechanism would seriously undermine patent protection for health sector products, including biopharmaceuticals, and would violate Colombia's regional and international commitments.
- **Effective patent enforcement:** PhRMA's member companies continue to be adversely affected by the Government of Colombia's failure to provide an effective patent enforcement mechanism whereby a patent owner may seek to enforce its patent prior to the commercial launch of a potentially infringing product.
- **Scope of patentable subject matter:** Colombia, contrary to its obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), does not grant patents for second uses, and applies an unreasonably restrictive definition of patentable biologics.
- **Pending biosimilars regulation:** The fourth draft of the biosimilars regulation includes a third pathway for registration that permits an applicant to rely on "available information which is considered relevant to prove the [proposed biologic's] quality, safety and efficacy" that "originate[s] from" a specified health authority abroad. The proposed regulations provide inadequate detail to ensure that biosimilars approved via this pathway would be safe and effective.
- **Price control regulations:** The new international reference pricing methodology inappropriately sets the price for both the public and private segments of the market, does not account for different margins in the reference countries, and does not reflect the realities of the Colombian market *vis-à-vis* other jurisdictions. Furthermore the reference basket includes countries in financial distress such as Portugal and Spain.

For these reasons, PhRMA requests that Colombia be placed on the **Watch List** for the 2014 Special 301 Report. However, PhRMA would welcome an **Out-of-Cycle Review** for Colombia to monitor progress of the proposed health system reform

legislation that would establish a preliminary patent review mechanism in the Ministry of Health for all health-related products.

Intellectual Property Protections

Proposed Ministry of Health Patent Review

PhRMA and its member companies are concerned about proposed legislation (Reform of the Health System in Colombia) that would establish a preliminary patent review mechanism in the Ministry of Health for all health-related products. The proposed mechanism would seriously undermine patent protection for health sector products, including biopharmaceuticals, and would violate Colombian law and its commitments under the TRIPS Agreement, the U.S.-Colombia Free Trade Agreement and Andean Law. This proposal is particularly troubling in light of statements by Colombia's Minister of Health that he intends to use the patent review mechanism to lower biopharmaceutical prices. PhRMA and its members are committed to helping Colombian patients receive access to medicines; however, the proposed mechanism would undermine patient access to innovative medicines in the long term.

Effective Patent Enforcement

PhRMA's member companies continue to be adversely affected by the Government of Colombia's failure to provide an effective patent enforcement mechanism. In April 2013, INVIMA implemented mechanisms to ensure that patent holders have notice that a company is seeking marketing approval for a product that may potentially infringe their patents. Yet even with this development, patent enforcement is not entirely effective because Colombian civil and administrative procedures do not provide adequate due process guarantees to effectively litigate patent enforcement.

Additionally, litigation can often take more than 8 years. Although the recent modification of the codes of civil and administrative procedure – replacing the old written system with an expedited oral procedure – are expected to greatly reduce these delays, PhRMA will closely monitor the situation to ensure these promised efficiencies are realized.

Pharmaceutical innovators must have safeguards available to prevent infringing products from being launched upon regulatory approval but before relevant patents have expired. Further, having effective enforcement mechanisms in place in Colombia would provide an important balance to the Bolar provisions (Decree 729), which Colombia has now implemented, which allow what would otherwise be infringing activity prior to expiration of a patent for the purposes of generating information necessary for presenting an application for regulatory approval.

Scope of Patentable Subject Matter

Over the last few months, there have been positive developments by the Colombian Patent Office (CPO). For example, the CPO has adopted new examination guidelines for granting patents to polymorphs, selection inventions, and pharmaceutical kits that are consistent with its TRIPS obligations. The innovative pharmaceutical industry will continue to monitor the development of these guidelines and stands ready to provide technical assistance. PhRMA, however, still has significant concerns about restrictions on the scope of patentable subject matter in Colombia.

Second Use Patents

The Andean Court of Justice (ACJ) issued several legal opinions (89-AI-2000, 01-AI-2001 and 34-AI-2001) forcing Andean Community members to refuse recognition of patents for second uses. This is contrary to long-standing precedents and inconsistent with TRIPS Article 27.1. Andean member countries have either been compelled by the ACJ not to grant second use patents or have chosen to honor Andean Community obligations, while ignoring their TRIPS obligations. The failure to provide patents for second uses adversely affects PhRMA's members who dedicate many of their research investments to evaluating additional therapeutic benefits of known molecules (second uses) in order to provide more effective solutions for unsatisfied medical needs. The ACJ position is dispositive on the issue and no further domestic appeals or remedies are possible.

Trademarks

In 2003, INVIMA authorized a copier to use the registered trademark of a U.S. pharmaceutical company (and a member of the local R&D pharmaceutical association) without the trademark owner's authorization. Specifically, the copier was permitted to use the U.S. Company's trademark on its product's label in order to show it was the same as the original product (the approved legend is: "[COPIER PRODUCT] is bioequivalent to [ORIGINAL PRODUCT]") and without having to use any disclaimer. This undermines the basic function of the mark as an indicator of source and origin. It also tarnished the image of the registered trademark and opened the door for copiers to freely take advantage of the innovator's reputation. This unprecedented decision by INVIMA violates Andean Community Trademark Law and Colombia's domestic law. To date, this case has been litigated before the Council of State for more than seven years, and a final decision is not expected for one or two more years.

Market Access Barriers

Pending (substandard) Biosimilars Regulation

Colombia has notified the WTO of its fourth draft decree establishing the approval processes for biologic and biotechnological medicines. PhRMA members have participated actively in the public consultations and have engaged extensively with the

Ministry of Health and their technical experts in attempting to bring notice to the fact that, as drafted, the proposed decree is not in line with the WHO guidelines for approval of biosimilars. Enforcement of this proposed decree would put patients at serious risk, as it provides an “abbreviated approval” pathway depending on “the complexity” of the product (without any objective determination as how said level of “complexity” will be determined), whereby the applicant will be able to rely upon “information available globally” for another product “with the same active ingredient”. In contrast to the Full Dossier and Comparability pathways found in WHO guidelines, the “Abbreviated Pathway” as described in the proposed decree does not provide adequate controls or any clarity regarding how the safety or efficacy of a product approved via this pathway would be evaluated and assured.

PhRMA members have urged the Colombian government to remove the proposed “Abbreviated Pathway” from the proposed decree, to no avail. This abbreviated route has been portrayed by the Colombian Ministry of Health as a tool to lower prices of medicines by promoting the swift entry into the market of competitors.

Furthermore, per the proposed Decree, a product approved via the “Abbreviated Pathway” will use the same non-proprietary name as the innovator, despite the fact that the proposed similar biologic product is not the “same” as the innovative product. Assigning identical non-proprietary names to products that are not the same could result in inadvertent substitution of the products, and could make it difficult to quickly trace and attribute adverse events to the correct product.

Price Control Regulation

On May 22, 2013, the Government of Colombia issued yet another regulation covering the pricing of pharmaceuticals (Circular 03). As an initial matter, the frequency with which new pricing regulations are issued in Colombia creates legal uncertainty for PhRMA member companies, and undermines their ability to ensure sustainable access to innovative therapies for Colombian patients.

In terms of its substance, Circular 03 imposes a maximum price for both the private and government markets by setting the price at the level of the distributor. These markets are dissimilar in most characteristics, in that they service different patient populations via different business models. Last year, the Government of Colombia gave verbal assurances to industry that the private market would not be subject to the proposed pricing regulations, and Circular 1 of 2012 had clear language to that effect. The Government of Colombia’s reversal on this issue sends a troubling signal about its commitment to protecting private enterprise and encouraging market competition.

Per Circular 03, the maximum price for pharmaceuticals is set at the 25% percentile of prices in the reference countries. On August 23, 2013, the Government issued Circular 04 identifying the first 40 active principles to be subject to this new methodology (195 different product presentations). Particular concerns with the methodology include:

- 1) It does not account for different margins in the reference countries, and does not reflect the realities of the Colombian market *vis-à-vis* other jurisdictions.
- 2) The reference basket includes countries in financial distress such as Portugal and Spain.

Lastly, a provision in the pending bill for reform of the health system eliminates the National Price Commission (which includes representatives from the Ministry of Trade, Ministry of Health and one representative of the President) and assigns the competence to regulate drug prices exclusively to the Ministry of Health. This change would result in a one-sided approach that disregards trade and market considerations as well as promotion of innovation.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

CENTRAL AMERICA – CAFTA-DR COUNTRIES

PhRMA's member companies face several market access barriers, including inadequate intellectual property protections in Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, and Nicaragua. Although these countries made certain market access commitments under the Dominican Republic-Central American-United States Free Trade Agreement (CAFTA-DR), deficiencies in implementation of those commitments still remain.

Key Issues of Concern:

- Lack of effective regulatory data protection;
- Lack of effective patent enforcement;
- Compulsory license provisions that are inconsistent with international principles and norms;
- Lack of patent term adjustment for patent office delays; and
- Patent backlog.

PhRMA requests that Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, and Nicaragua all be placed on the **Watch List** for the 2014 Special 301 Report and that the U.S. Government continue to seek assurance that the issues herein described are quickly and effectively resolved.

Intellectual Property Protections

Regulatory Data Protection and Effective Patent Enforcement

The CAFTA-DR FTA obligated the United States' trading partners to grant regulatory data protection and develop a mechanism for effective patent enforcement. These provisions have not been sufficiently implemented in the Dominican Republic, Costa Rica, El Salvador, Honduras, or Nicaragua.

Dominican Republic

The Dominican Republic health regulatory agency has failed to implement a system of regulatory data protection for new products. Although several meetings have taken place in order to promote such implementation, the agency resists any action on the issue, and thereby continues to deny regulatory data protection, inconsistent with its international obligations under CAFTA-DR and the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Moreover, the health regulatory agency has not implemented mechanisms to facilitate effective patent enforcement prior to marketing approval for follow-on products.

Costa Rica

Costa Rica has not effectively implemented its international obligations, arising from TRIPS and the CAFTA-DR, to protect the regulatory data submitted by an innovator to obtain marketing approval. For example, although the Costa Rican Health Regulatory Agency has developed a publicly available database identifying those products subject to patent or RDP terms, the “Undisclosed Information Law” permits disclosure of clinical test data in certain situations, contrary to Costa Rica’s international obligations. Further, according to the local research-based pharmaceutical association (FEDEFARMA), this database is not an effective tool for determining possible patent infringement.

El Salvador

Recent changes in the regulatory system in El Salvador, introduced by Law 1008, have resulted in a new agency being responsible for regulating pharmaceuticals. This has resulted in a greater uncertainty regarding regulatory data protection and patent enforcement as the new authority has not included pending implementation in its working agenda.

El Salvador has not effectively implemented its international obligations, arising from CAFTA-DR Article 15.10.2, related to the effective enforcement of patents. PhRMA members supplied information on the pertinent patents in force in El Salvador and provided other technical assistance to government officials; yet workable systems have not been established.

Honduras and Nicaragua

Neither Honduras nor Nicaragua has effectively implemented its international obligations, arising from TRIPS and the CAFTA-DR, related to the protection of pharmaceutical test and other data. The Government of Honduras published draft regulations for consultation in 2008, but the regulations for effectively implementing regulatory data protection were not promulgated. Similarly, the health authorities in Nicaragua have yet to promulgate a clear and transparent regulatory data protection mechanism that would comply with the CAFTA-DR.

Neither country has effectively implemented its international obligations, arising from CAFTA-DR Article 15.10.2, related to the effective enforcement of patents, including those obligations which would prevent patent infringement. The Government of Honduras published draft regulations in 2008, but the regulations for implementing effective enforcement mechanisms were not promulgated. Similarly, the Government of Nicaragua has yet to implement effective mechanisms for enforcing patents prior to marketing approval decisions.

Compulsory Licensing and Patent Protection Issues

Costa Rica

Costa Rica amended Article 18 of Law No. 6,867 to provide that if a patent holder does not “work” their patent, either by local production or by importation, within three years of the patent approval date or four years of the patent application date, a third party may request a compulsory license (CL) to work the patent. However, the amended Law provides no exemption or mechanism to “stop the clock” while the innovator is seeking marketing approval, and inherently unable to “work” the patent.

In addition, contrary to its international obligations, Costa Rica fails to provide patents for certain types of claims, e.g., for polymorphs, dosages, and “Markush” or “Swiss-type” claims. In addition, Costa Rica requires in vivo studies to support patent applications for biologics. For those patent applications that will be considered, the Costa Rican patent office still has a considerable backlog. Further, according to a Patent Office decision, applicants are given only one opportunity to speak with the patent examiner before the final decision is issued. This limitation is not supported in Costa Rican law.

Further, after the implementation of CAFTA-DR, criminal penalties for patent and trade secret infringement were eliminated from the law, leaving only civil remedies available. Even then, our member companies operating in Costa Rica face difficult procedures and long judicial delays in patent enforcement proceedings.

Guatemala

The Guatemalan Ministry of Health (MOH) published in the Official Gazette, Ministerial decree 472-2012, whereby it declared a specific “generic” product to be of high therapeutic interest, and authorized its importation. The Decree does not consider the existence of a patent in force in Guatemala which covers a dose formulation for the product and which is in force through 2026; the MOH did not conduct any consultations with the rights holder nor did the MOH exhaust the existing provisions under the Industrial Property Law applicable to limitations to the patent rights. In addition, although the product is currently covered by regulatory data protection through 2015, the MOH has indicated that authorizing importation of the product does not violate this CAFTA-DR obligation, because Guatemala argues that the product will not be for commercial use.

The MOH Decree appears to infringe Articles 28(1) (a), 30 and 31 of TRIPS, the CAFTA-DR and the Industrial Property Law of Guatemala as well as Chapter 10 of the CAFTA-DR (Re: 10.5). PhRMA and its members are concerned that the decree may exceed the MOH’s powers resulting in an infringement to granted rights in Guatemala. If this practice is permitted, the MOH may consider it as a means to override intellectual property rights in Guatemala without exhausting any proceedings.

In October 2012, the MOH published a second decree, 871-2012, by which it “regulates” several acts, including acquisition, donation, lending and other acts, related to certain drugs. It remains unclear as to the objectives of the Decree and how it will be implemented, generating uncertainty regarding respect for intellectual property rights in Guatemala.

The MOH has not responded to the industry’s request for consultations nor has it replied to a similar request made by the Ministry of Economy and the National Competitiveness Program.

Dominican Republic

The Dominican Republic has implemented compulsory license provisions that are not compatible with international principles and norms. These provisions allow parties to seek compulsory licenses in the course of patent proceedings, delaying patent approvals.

The Dominican Republic patent office has accepted private petitions in the course of patent proceedings requesting that if the patent is granted a compulsory license should be issued immediately. To date, the patent office has neither denied nor accepted those petitions, instead electing to suspend review of the underlying patent applications.

Patent Term Adjustment (PTA) and Restoration (PTR)

Dominican Republic

Provisions for PTA to restore a portion of the patent life lost due to patent office delays entered into force for the Dominican Republic on March 1, 2008. ONAPI has stated that PTA does not apply “retroactively” to applications that were submitted before March 2008.

Section 15.1.11 of the CAFTA-DR contains a general provision that parties committed to observe: “this Chapter gives rise to obligations in respect of all *subject matter existing* on the date of entry into force of this Agreement *that is protected* on that date in the Party where protection is claimed, or that meets or comes subsequently to meet the criteria for protection under this Chapter.” (Emphasis added.) PhRMA and its member companies submit that per this provision, all patent applications granted, *i.e.*, protected, after March 2008 should be eligible for PTA. This position is supported by the Appellate Body’s interpretation of parallel language in the WTO *Canada-Term of Patent Protection* dispute (WT/DS170/AB/R).

Costa Rica

CAFTA-DR provides PTA and PTR to compensate a patent owner for unreasonable curtailment of the effective patent term resulting from patent or marketing

approval processes. Costa Rica rules implementing this provision set a maximum combined extension term – for either patent office or marketing approval delays – of 18 months. Too often, however, 18 months is not sufficient to compensate patent owners for these types of delays in Costa Rica. For instance, there are patent applications that have been waiting for a patent examiner to be appointed for more than eight years. Similarly, there can be significant delays during the marketing approval process. As such, the combined 18-month maximum extension for both types of delays can be woefully insufficient.

Patent Backlog – Dominican Republic

There is a significant backlog of unissued patent certificates by the Dominican Republic Industrial Property Office (ONAPI)'s Invention Department. According to ONAPI's Office of Access to Public Information, as of May 30, 2012, there were 1,437 patent applications pending, out of which 949 were pharmaceutical or chemical patent applications. Moreover, only 146 patent certificates have been issued in the last 12 years, 76 of which were protected pharmaceutical and chemical inventions.

Counterfeit Medicines

The Costa Rican Customs Authority lacks a strategic and effective plan to ensure permanent monitoring and prevention of counterfeit goods, including medicines, and smuggling operations. In a recent meeting, the Customs Authority, represented by sub-director Mr. Benito Cogui, was clear that its main interest was not in protecting IP rights and ensuring patient safety, but in tax collection. This interest is unlikely to change absent direction from the Ministry of Health regarding the need to prioritize enforcement against counterfeit medicines.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

ECUADOR

PhRMA and its member companies operating in Ecuador are concerned with several intellectual property and market access barriers.

Key Issues of Concern:

- **Compulsory licensing:** As of the date of this paper, the Ecuadorian Intellectual Property Institute is currently considering 14 compulsory license petitions. Compulsory licenses should only be granted when a need for such license has been clearly demonstrated and in compliance with Ecuador's international obligations under World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
- **Regulatory data protection:** Although Ecuadorian law ostensibly provides for regulatory data protection, those protections are, in practice, inadequate in light of Andean Community jurisprudence.
- **Restrictions on patentability:** Notwithstanding the fact that Ecuador has granted patent protection for second use patents, the Andean Court of Justice issued several legal opinions forcing Andean Community members, including Ecuador, to refuse recognition of patents for second uses, in violation of TRIPS Article 27.1, and contrary to long-standing precedents.
- **Government price controls:** In 2011, a new law required that the Ecuadorian Government revise the Price Control Regulation of Drugs within 60 days. To date, the government has issued over a dozen failed proposals with effective stakeholder input. PhRMA stands ready to partner with the Ecuadorian Government to develop a new government pricing methodology that improves patient access and provides the incentives for our member companies to engage in necessary R&D.

For these reasons, PhRMA requests that Ecuador remain on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Compulsory Licensing

In October 2009, Ecuador implemented Executive Decree No. 118 intended to improve access to medicines and reducing drug costs, but, in effect, at the expense of intellectual property rights and protection of pharmaceutical patents. For example, Decree No. 118 established a special procedure for obtaining compulsory licenses (CLs) for patents covering "priority" medicines, to date three compulsory licenses have been granted, two of them for the same active ingredient.

Fourteen compulsory license petitions are currently being considered by the Ecuadorian Intellectual Property Institute (IEPI). Three were rejected on technical grounds; another one expired; and one petition was withdrawn by the petitioner. In 2012, IEPI's Director informed the local innovative pharmaceutical association (IFI) that while there is no government policy to issue compulsory licenses on all patented drugs, IEPI will review all CL petitions submitted to the Institution on a case-by-case basis.

A close monitoring of the application of this decree should be maintained to ensure that a compulsory license for a patent covering a medicine is granted only when a need for such license has been clearly demonstrated and to ensure that the guidelines for obtaining a compulsory license are clear and provide due process for the license applicant and the patent owner in accordance with Ecuador's obligations under the TRIPS Agreement.

Regulatory Data Protection

Although Ecuador has ostensibly taken the necessary steps to revise the Ecuadorian Intellectual Property Act to provide protection for undisclosed test data or other information submitted to obtain marketing approval of pharmaceutical products, the actual protection provided remains, in practice, inadequate. This is because the implementation of RDP in Ecuadoran law prohibits the *release* of undisclosed test or other data except to protect the public interest, but, in practice, *reliance* on such data by a generic manufacturer seeking marketing approval is not considered an act of unfair competition. This renders RDP in Ecuador not only ineffective but also inconsistent with Ecuador's obligations under TRIPS Article 39.3

Second Use Patents

The Andean Court of Justice (ACJ) issued several legal opinions (89-AI-2000, 01-AI-2001 and 34-AI-2001) forcing Andean Community members to refuse recognition of patents for second uses, in violation of TRIPS Article 27.1, and contrary to long-standing precedents. Decisions granting patent protection for second uses were the law in Bolivia, Colombia, Ecuador, and Peru. Andean member countries have been compelled by the ACJ to not grant second use patents, thereby disregarding their TRIPS obligations. The failure to provide patents for second uses particularly affects pharmaceutical companies, which dedicate many of their research dollars to evaluating additional therapeutic benefits of known molecules (second uses) in order to provide effective solutions for unsatisfied medical needs. The ACJ position is dispositive on the issue, and to date, no further domestic appeals/remedies are possible.

Market Access Barriers

Government price controls

Ecuador has had a government price control system for pharmaceutical products since 1992. In June 2011, Executive Decree No. 777 to fix, revise and control medicine prices was issued.

This decree created three price control categories: regulated, monitored and direct fixation. The first one – regulated – is similar to the prior system under which a biopharmaceutical manufacturer would have to apply for a government price for all medicines from the National Council for Medicine Prices Fixation and Revision. Under the new Decree, only “regulated” medicines, *i.e.*, those medicines considered “strategic”, require price approval from the Council. Although guidelines to the Decree were issued on August 31, 2011, it remains unclear which medicines are considered “strategic.”

The second category – monitored – applies for “non-strategic” medicines with the same active principle ingredient. For medicines falling under this category, the biopharmaceutical manufacturer must notify the government of its pricing structure, supporting its notification with all necessary documents (*e.g.*, import documents, sanitary registry, FOB and distributor price certification, *etc.*).

The third category – direct fixation – is applied in those cases when the information requested by the Council wasn’t presented on time or is false, the price in pharmacies is higher than the one approved or notified, or the product was sold without an approved or notified price. This essentially punitive category is in addition to any separate civil or penal sanctions that may be imposed.

Additionally, the profit margin limitations applied by the 2000 Generics Law continue to apply to medicines in all three price control categories under this Decree: “The profit margin by product for the manufacturer or importer shall not exceed 20 percent”

In October 2011, the Act of Regulation and Control of Market Power ordered the reform of the Price Control Regulation of Drugs within 60 days of the issuance of the Law. Since that time, the authorities have developed at least 15 proposals, none of which have appropriately valued the significant cost and time involved in developing a new medicine. PhRMA stands ready to partner with the Ecuadorian Government to develop a new government pricing methodology that improves patient access and provides the incentives for our member companies to engage in the research and development needed to discover tomorrow’s treatments and cures.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

MEXICO

PhRMA and its member companies operating in Mexico remain concerned over significant market access barriers, including challenges in accessing Mexico's formulary, and continuing efforts to improve enforcement of intellectual property rights protections.

Key Issues of Concern:

- **Intellectual property protections:** PhRMA and its members recognize that the leaders of COFEPRIS and the Mexican Patent Office (IMPI) have expressed commitments to improve application of Mexico's 2003 Linkage Decree and to provide protection for data generated to obtain marketing approval for pharmaceutical products. Despite these commitments, however, implementation of a substantive RDP reform is still pending and use patents are still not listed in the Official Gazette, and thereby are denied protection under the patent linkage decree.
- **Market access delays:** Despite recent improvements to the marketing approval process for pharmaceutical products, significant barriers to the public market for medicines remain due to the length, non-transparent and unpredictable reimbursement process. As many plans in the private market follow public formulary listing decisions, the private market is significantly impacted as well.
- **Pharmacovigilance:** It is imperative that Mexico review and update its current pharmacovigilance regulations, given the recent inter-institutional agreements allowing for recognition of sanitary registrations issued by the Mexican health regulatory agency (COFEPRIS) in some Latin American countries (Ecuador, El Salvador and Colombia).

For these reasons, PhRMA requests that Mexico remain on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Ineffective Patent Enforcement

PhRMA members recognize that the Linkage Decree of 2003 constituted a cornerstone for the recognition of pharmaceutical patent rights in Mexico. The August 2012 publication of an additional annex of the Official Gazette in which formulation patents were listed, is an additional positive step toward the goal of eliminating unnecessary, costly and time consuming court actions to obtain appropriate legal protection for member companies' intellectual property. PhRMA members strongly trust that COFEPRIS will consult the Official Gazette, including the identified formulation patents, before the issuance of a marketing authorization.

Both of Mexico's NAFTA partners provide patent enforcement systems for product, formulation and use patents. It is therefore inappropriate for Mexico to only provide effective patent enforcement for active chemical substances. Furthermore, effective patent enforcement mechanisms inherently prevent the marketing of follow-on products when such marketing would infringe valid patent rights.

Further, PhRMA member companies continue to share deep concern with regard to the inability to remove patent infringing products from the marketplace. Obtaining effective preliminary injunctions or final decisions on cases regarding IP infringement of within a reasonable time (as well as collecting adequate damages when appropriate) remain a rare exception rather than the norm. This is clearly inconsistent with Mexico's commitments under the North America Free Trade Agreement (NAFTA) and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

PhRMA's members encourage Mexican authorities to establish uniform criteria consistent with Court precedents ordering the listing of use patents in the Official Gazette. In addition, PhRMA and its member companies encourage the Mexican Government to hasten patent infringement proceedings; use all available legal mechanisms to enforce the Supreme Court's decisions; and implement procedures necessary to provide timely and effective preliminary injunctions.

Regulatory Data Protection

PhRMA and its members recognize that the leaders of the Mexican health regulatory agency (COFEPRIS) and the Mexican Patent Office (IMPI) have expressed commitments to provide protection for data generated to obtain marketing approval for pharmaceutical products. Despite this commitment, implementation of substantive regulatory data protection (RDP) reform is still pending

In June 2012, Mexico's health regulatory agency, COFEPRIS, issued guidelines to implement RDP for a period of not less than five years – an important step toward fulfilling Mexico's obligations under TRIPS and NAFTA. PhRMA and its members initially welcomed this decision as an important confirmation of the Calderon Administration's recognition of its obligations and its intention to fully implement the NAFTA provisions. As guidelines, their validity may be questioned when applied to a concrete case, and they could be hard to enforce or revoked at any time. Therefore, PhRMA members strongly urge the passage of regulations on RDP to provide industry with greater certainty regarding the extent and durability of Mexico's commitment to strong IP protection within the Trans-Pacific Partnership agreement. In addition, PhRMA members remain concerned with the apparent distinction made by the regulatory authorities between the provision of RDP to small and large molecule drugs. It is the view of the innovative biopharmaceutical industry that, consistent with TRIPS, RDP should be provided regardless of the manner in which the medicine is synthesized.

Potential Abuse of the “Bolar” Exemption

Mexico allows generic manufacturers to import active pharmaceutical ingredients and other raw materials contained in a patented pharmaceutical for “experimental use” during the last three years of the patent term, per a *Roche v. Bolar* exemption. Mexico fails, however, to impose any limits on the amount of raw materials that can be imported under this exception. Given some of the import volumes reported, PhRMA’s members are highly concerned that some importers may be abusing the Bolar exemption by stockpiling and/or selling patent-infringing, as well as potentially substandard, medicines in Mexico or elsewhere. Therefore, PhRMA’s members encourage Mexican authorities to establish clear criteria for the issuance of import permits, respecting patent rights and reflecting the import of adequate and necessary quantities required for testing bioequivalence.

Market Access Barriers

Market Access Delays

Key market access issues in Mexico concern the excessive times taken for formulary inclusion and the 5-year registration renewal process. Both significantly exceed stated time frames. COFEPRIS, under the leadership of Mikel Arriola, has made important improvements in the approval process despite limited resources and cost-containment pressures. Industry applauds Commissioner Arriola’s efforts to improve the efficiency and technical capability of COFEPRIS.

Though COFEPRIS has made important and welcomed improvements in its operating efficiency over the past few years, additional efforts are required. Delays beyond the control of the research based industry contribute to the unavailability of new pharmaceutical therapeutic options for Mexican patients. Typically the review time taken by COFEPRIS continues to exceed stated review times and is far lengthier on average than that taken by other regulatory agencies, namely the Food and Drug Administration in the United States and the European Medicines Agency in the European Union.

Following COFEPRIS approval, there remain significant barriers for patients, primarily those covered by public institutions, in accessing life-saving and enhancing interventions. This additional delay is caused by the lengthy, uncertain and non-transparent reimbursement system used in Mexico.

After COFEPRIS grants marketing authorization to a new medicine, the Inter-institutional Commission of the Basic Formulary of Inputs of the Health Sector decides which drugs should be included in the national formulary. From here, the Coordinating Commission for the Negotiation of Prices of Medicines and Other Medical Supplies decides on a recommended price for all public institutions. Following this recommendation, the various public institutions (Mexican Institute for Social Security (IMSS), Institute of Security and Social Services for State Workers (ISSSTE), Petroleos Mexicanos (PEMEX), etc.) engage in additional reviews and further price negotiation. At

each step, clinical and pharmaco-economic dossiers, which take manufacturers significant time and expense to create, are required. On average in the last 3 years, only 5% of new medicines submitted for institutional approval (IMSS, ISSSTE, Seguro Popular) have been listed on the key formularies. Furthermore, in 2013, IMSS approved only 4 new medicines for reimbursement while ISSSTE approved none. Further, the institutional approval process is an inefficient and non-transparent process, during which, for example, products with regulatory approval and wide reimbursement throughout the world are denied listing based on alleged inadequate efficacy or safety.

Accordingly, reimbursement delays add, on average, over two years to the access process, if made available at all in the public sector. On average, it takes 2,000 days for Mexican patients to access innovative medicines compared to 230 days in other countries.¹²⁰

Throughout this reimbursement process, the public market for medicines is effectively closed. As many plans in the private market follow public formulary listing decisions, the private market is significantly impacted as well.

Pharmacovigilance

It is imperative that Mexico review and update its current pharmacovigilance regulations, given the recent inter-institutional agreements allowing for recognition of sanitary registrations issued by COFEPRIS in some Latin American countries (Ecuador, El Salvador and Colombia). Some of those sanitary registrations were issued under previous regulations, such as in the case of the biotechnological products approved before 2011, without the requirements now applicable which include clinical trials. It is a concern that such authorizations, which do not comply with current regulatory standards, may be relied upon in other countries.

Counterfeit Medicines

PhRMA members deeply appreciate increasing important achievements on the anti-counterfeiting front this year under coordinated efforts of COFEPRIS, IMPI, Attorney General, Federal Police and the local prosecutor of the Jalisco State, resulting in unprecedented closure of pharmacies selling counterfeit medicines and imprisonment and criminal prosecution of individuals engaged in these reprehensible activities.

These coordinated endeavors are essential to keep containing counterfeiting activities. Increasingly routine investigations, raids, and consequent prosecution of these crimes plus public condemnation of offenders to engage in pharmaceutical counterfeiting will protect and increase the health of the Mexican population.

Damage Estimate

¹²⁰ EFPIA Patients WAIT Indicator 2010 and AMIIF 2011 report.

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

PERU

PhRMA and its member companies operating in Peru are concerned about several discriminatory regulatory requirements that favor local producers and the state of intellectual property protection in Peru.

The U.S.-Peru Trade Promotion Agreement (USPTPA), which was signed in 2006 and amended in 2007, obligates Peru to protect pharmaceutical data, provide a pre-launch legal system that will provide patent holders with sufficient time and opportunity to try to prevent the marketing of an infringing product, and establish a stronger intellectual property framework. Peru has failed to adequately comply with these obligations. Although PhRMA and its member companies do not consider the USPTPA a model for future trade agreements, PhRMA has monitored implementation of the USPTPA, and has been closely monitoring the enforcement of the implementation regulations since its entry into force in February 2009. Peru's numerous failures to implement its USPTPA commitments set a poor precedent and raises doubts about Peru's commitment to implement the high standards we would expect to be included in the Trans-Pacific Partnership (TPP) agreement.

Key Issues of Concern:

- **Regulatory data protection:** The Peruvian Health Authority (PHA) has rejected regulatory data protection for several biologic products. This is inconsistent with Peru's obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the USPTPA.
- **Ineffective patent enforcement:** Peru has failed to adequately implement Article 16.10.3 of the USPTPA, in that the current law does not provide patent holders with sufficient time and opportunity to seek injunctive relief prior to the marketing of an infringing product.
- **Regulatory barriers:** To its credit, Peru has introduced a number of measures to help ensure the quality, safety and efficacy of pharmaceuticals. However, implementation of these measures has been delayed and a number of these regulations are impractical in that they request documents that may not be issued in the country of manufacture (e.g., Batch Release certificates for biological pharmaceuticals), or impose excessive administrative burdens that serve no purpose other than delaying the marketing approval process and patient access to medicines.

For these reasons, PhRMA requests that Peru remain on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Regulatory Data Protection

The Government of Peru established a regulatory data protection regime in February 2009. Since then, a dozen new pharmaceutical products have been granted data protection for an average of 36 months (3 years). Nevertheless, since May 2010, PhRMA member companies have reported that the PHA has rejected regulatory data protection for several biologic products. This refusal is inconsistent with Peru's obligations under the WTO's TRIPS Agreement, Article 16.10.2 of the USPTPA, and national law. Denying such protection will adversely affect PhRMA members attempting to introduce new products in Peru, puts pressure on other trading partners in the region to refuse to protect this very important class of products.

To remedy this ongoing treaty violation, the Government of Peru should, as it committed to in the USPTPA, refrain from granting sanitary registrations to third party follow-on versions of any kind of innovative pharmaceutical products, regardless if they are synthesized or biotechnologically derived pharmaceutical products, for a term of at least five years, unless the applicants for such versions base their applications on their own clinical data.

In addition, as explained above under "Duplicative Testing," Bill 995 requires public disclosure of this data as a precondition of obtaining a sanitary registration (by virtue of the obligation to use internationally recognized bibliographic sources freely accessible to the public), which clearly violates Article 16.10.2 of the USPTPA and Article 39 of the TRIPS Agreement.

Patent Enforcement

The Peruvian system for enforcing patents is a two-step, sequential process: (1) an administrative process for determining infringement by the Institute for Defense of Competition and Intellectual Property (INDECOPI) that takes two years on average; and (2) a judicial action in a civil court to recover damages, which can commence only after the administrative process is exhausted. This judicial action takes four years on average, a duration which discourages patent owners from enforcing their patents. The system is ineffective in that it does not provide for timely resolution of patent issues which could prevent marketing of infringing products.

Article 16.10.3 of the USPTPA requires Peru to provide patent holders with sufficient time and opportunity to seek injunctive relief prior to the marketing of an allegedly infringing product, if a sanitary registration is requested by an unauthorized manufacturer of a patented product. However, the only measure implemented by the Peruvian Government under the above mentioned USPTPA obligation refers to the publication of the sanitary registration applications on the web page of the PHA, which provides the patent holder notice of an intention to commercialize a potentially infringing

product. This notice alone is not adequate to provide the ability to seek and obtain a remedy before the marketing of the infringing product.

Second Use Patents

The Andean Court of Justice (ACJ) issued several legal opinions (89-AI-2000, 01-AI-2001 and 34-AI-2001) forcing Andean Community members to refuse recognition of patents for second uses, in violation of TRIPS Article 27.1, and contrary to long-standing precedents. Decisions granting patent protection for second uses were the law in Bolivia, Colombia, Ecuador, and Peru. Andean member countries have been compelled by the ACJ to not grant second use patents, thereby disregarding their TRIPS obligations. The failure to provide patents for second uses particularly affects pharmaceutical companies, which dedicate many of their research dollars to evaluating additional therapeutic benefits of known molecules (second uses) in order to provide effective solutions for unsatisfied medical needs. The ACJ position is dispositive on the issue, and to date, no further domestic appeals/remedies are possible.

Market Access Barriers

Processing Delays

To date, the PHA's implementation of the new regulations still unduly focuses on administrative details and formatting, with less emphasis on the substance of the application, i.e., whether science supports granting a product marketing approval. For example, failure to provide documentation in the exact format required by the PHA is a basis for delaying or even refusing marketing approval. These regulatory measures and delays present unnecessary trade barriers and have a negative impact on individual companies' plans to bring products to market in Peru.

Duplicative Testing

The PHA's regulations include numerous provisions that create unnecessary confusion and market access barriers. Article 45 of Law 29459 provides that: (1) the first batch of any pharmaceutical product after registration or renewal must undergo complete quality testing in Peru (even if quality testing has already been performed at the manufacturing facility overseas); and (2) subsequent quality testing on further batches may be performed outside Peru as long as the laboratory conducting that testing has been certified by the PHA. However, these certifications have been delayed and at the current rate, the processing time and backlog are expected to grow.

In addition, regulations provide that the PHA will accept quality testing of manufacturers certified by health authorities of high sanitary vigilance countries, such as the United States, in Good Laboratory Practices or Good Manufacturing Practices, provided the GMP covers GLP and the authority so states. However, the new regulations do not adequately specify how a laboratory may be certified by the PHA or

which documents are necessary to prove that the foreign authority certification covers the laboratory area (Good Laboratory Practices).

Unfortunately, local generic manufacturers are trying to capitalize on this uncertainty by pressing authorities to request local duplicative testing of all batches of all pharmaceutical products. The former Peruvian Minister of Commerce has supported this pressure by sending a letter to the Minister of Health.

Further, former Peruvian Congress Chairman Daniel Abugattas introduced Bill 995/2011-CR (“Bill 995”), which was approved by the Health Committee of the Congress in June 2012 without considering the Minister of Health’s written technical position, which concluded that the bill would cause a non-technical market access barrier, and adversely affect prices of medicines. If approved by the Congress, Bill 995 would make it mandatory for a pharmaceutical manufacturer to conduct duplicative testing in Peru of every batch of imported pharmaceutical products.

In addition, Article 5 of Bill 995 would require all technical information relied upon in a sanitary registration application to “be extracted from internationally recognized bibliographical sources, freely accessible to the public....” Innovators, as first registrants, need to use confidential undisclosed information, such as clinical studies and other information on safety and efficacy, as well as product specifications, formulas and other technical product information, to obtain sanitary registrations for their products. Preparing these data requires significant investment, both of time and money. It is for this very reason that Article 16.10.2 of the USPTPA obliges Peru to not disclose this data, nor allow reliance thereon by a generic applicant for at least five years after the initial sanitary registration application is granted (which depending on how quickly the sanitary registration is granted in Peru, may be measured from the date of the sanitary registration in the United States or in Peru). Requiring public disclosure of these data as a precondition of obtaining a sanitary registration would be an inappropriate circumvention of Article 16.10.2 of the USPTPA, and violate Peru’s broader international obligations under Article 39 of the WTO TRIPS Agreement and the Technical Barriers to Trade Agreement.

In short, the bill, if approved, would impose a disproportionate burden on U.S. and international pharmaceutical companies, thereby creating a significant trade barrier for imported medicines and a profitable but artificial industry for local laboratories. Currently, the Plenary Session of the Congress has submitted the bill back to the Health Committee for further analysis.

Clinical Investigation Standards

The National Health Institute (INS) is working on measures to increase sanctions and raise clinical authorization requirements far above international standards. This has created significant uncertainty regarding ongoing clinical studies and could discourage future clinical trials in Peru.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

MIDDLE EAST / AFRICA

EGYPT

PhRMA and its member companies operating in Egypt are concerned about the deteriorating intellectual property and market access environment in Egypt. Egypt is one of the most populous countries in the Middle East-Africa region. There is tremendous unmet medical need in the country.

During the past several tumultuous years, PhRMA and its member companies have tried to work in good faith with Egyptian officials to address health and industrial issues. While serious challenges remain, PhRMA notes that, for the most part, Egyptian officials have shown a willingness to meet and discuss issues of concern, and have expressed interest in supporting the innovative biopharmaceutical industry and encouraging investment in the country.

Key Issues of Concern:

- **Intellectual property protections:** Egypt lacks regulatory data protection and effective patent enforcement, enabling manufacturers to obtain marketing licenses for follow-on products prior to the expiration of the patent on the original product.
- **Approval delays for new medicines:** Non-transparent, outdated regulatory system leads to unnecessarily long review periods, depriving patients from promising new medicines and posing a technical barrier to market entry.

For these reasons, PhRMA requests that Egypt be placed on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Regulatory Data Protection

Egypt does not provide regulatory data protection, and some officials have consistently opposed enacting regulations that would offer a minimum period of protection to ensure that manufacturers of follow-on products are not obtaining an unfair commercial advantage by relying on data developed at great risk and expense by the innovator company. PhRMA and its member companies have proposed that the Egyptian Government adopt a minimum RDP period calculated from the date of registration.

Effective Patent Enforcement

Egypt does not provide an effective mechanism to ensure that marketing licenses are not granted to companies making products that infringe an originator's patent.

Some officials have opposed putting in place an effective patent enforcement system similar to the process used by the United States or, more recently, the regulation enacted in neighboring Saudi Arabia. In those countries, health officials receiving applications from generics companies are required to check for the existence of a valid patent. If the originator can demonstrate a valid patent, there should be a procedure in place whereby the Health Authority can either defer the file to a date for examination period closer to the date of the patent expiration and/or specify that the license is valid only after the expiration of the innovator's patent.

In recent months, PhRMA and its member companies have become aware of local generics companies obtaining marketing licenses from the Health Ministry, and then proceeding to engage in patent infringing acts in the marketplace.

As Egypt is a WTO member, has enacted patent laws, and issues patents through the Patent Bureau, it follows that the Health Ministry would have in place a system whereby it can defer market entry of newly licensed medicines prior to the expiration of the patent.

Market Access Barriers

Regulatory Approval Delays

We are encouraged that in recent months, under challenging circumstances, Egyptian officials have recognized that the government and industry should partner to streamline and modernize the existing system for reviewing and approving new medicines. In part, officials have realized that unnecessary delays in reviewing and licensing new medicines does not serve the best interests of patients who can benefit from advances in new medical technology. Officials seem sensitive, too, to the fact that outdated, sluggish regulatory systems are disincentives for investment in the sector.

To this end, officials have been working with industry on a set of proposals that would streamline the process to reduce review and licensing times to less than 12 months versus the two to three years that this process can take at present.

PhRMA believes that once harmonized to global best practices, it is possible to reduce the total time for this process to less than six months; in the meantime, a transparent process that would reduce times to 12 months would constitute a very clear improvement.

While PhRMA and its member companies appreciate the positive approach and collaboration on new proposals, as of this submission date, the time that takes to register new medicines ranges between 18 and 40 months or more for most products, which is clearly not meeting the needs of patients or the expectations of companies investing in the sector.

Government Pricing Policies

In recent months, the Health Ministry has rescinded Law 499, which discriminated against locally-made products by offering differential treatment of those products in the supply chain. In this case, the margins offered to actors in the supply chain for “locally-made” products were more favorable than those offered to imported medicines, creating unacceptable discriminatory treatment.

PhRMA commends the Health Ministry for suspending that law, and engaging in new negotiations. It is important that trading partners communicate the need for the new pricing regulations to avoid discrimination among local or foreign manufacturers and their products.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.

TUNISIA

PhRMA and its member companies operating in Tunisia are concerned about the market access barriers and deterioration in the intellectual property environment in Tunisia since 2011. These issues persist despite attempts by PhRMA member companies to engage the government on the impact of these issues on human health and the business and investment environment.

Key Issues of Concern:

- **Lack of regulatory data protection:** Tunisia has not complied with its own law and international obligations to provide regulatory data protection for test and other data submitted to the government for pharmaceutical product marketing approval.
- **Government pricing restrictions:** Tunisia requests price reductions without clear bases for doing so, which creates considerable unpredictability in the market. The biopharmaceutical industry is also being required to absorb the cost of the devaluation of the Tunisian Dinar. Taken in combination, these policies result in prices that undervalue the cost of developing innovative medicines.

For these reasons, PhRMA requests that Tunisia be placed on the **Watch List** for the 2014 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Lack of Regulatory Data Protection

PhRMA member companies are concerned by the Tunisian Government's failure to provide effective regulatory data protection (RDP) for a period of at least five years after the date of marketing authorization of the innovator product in Tunisia.

After acceding to the World Trade Organization (WTO) in 1995, Tunisia agreed in 2000 to grant RDP in accordance with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) beginning in May 2005. To that end, the Tunisian Ministry of Health issued two circulars covering data protection. The first was issued on October 9, 2004, and was superseded later by another circular issued on May 3, 2005. Article 1 of the 2005 circular states that data protection will apply to new drugs "which are either imported or manufactured locally". Article 2 states that "[w]hen the approval for the sales of pharmaceutical products including new chemical entities is subject to the communication of undisclosed data which setting up requires considerable efforts, Tunisia shall protect such data against any unfair utilization on the market. Furthermore, Tunisia shall protect such data against any disclosure unless it is necessary to do so for the protection of the public or unless measures are taken in order to ensure the protection of such data against any unfair utilization on the market."

Further, Article 3 states that “[t]he data protection term starts as of the registration date of the application for the delivery of an authorization for the sales on the market (AMM) filed with the Pharmacy and Drugs Directorate, for five years starting from the date of the approval or refusal of the marketing authorization (AMM).”

While Tunisia’s law seems to provide for RDP in accordance with its international commitments, the country, in practice, does not effectively do so. In 2011, the Tunisian Ministry of Health granted marketing authorization to a generic product before the approval of the innovative product based on the innovative product’s test data. The innovator’s marketing authorization application had been pending for 13 years and was only approved nine months after marketing authorization was granted for the generic product. Moreover, the Ministry of Health then approved another generic substitute shortly thereafter.

Unfortunately, Tunisia has not complied with its own regulations or the WTO commitments which gave rise to the regulations to protect test and other data from unfair commercial use and disclosure. Member companies have approached the Tunisian authorities regarding the need to enforce their regulations on data protection, to which the Tunisian authorities have responded that they are not sharing the content of innovative drug registration files. PhRMA and its member companies seek the intervention of the U.S. Government to help resolve this troubling precedent and improve the enforcement of regulatory data protection in Tunisia.

Market Access Barriers

Government Pricing Restrictions

The Tunisian Health Authorities establish a price for a pharmaceutical product based on (1) prices of the registered product in the country of origin and (2) prices of other products deemed to be in the same therapeutic class. In addition, Tunisian health authorities impose a discount of a minimum of 12.5 percent compared to the price in the country of origin. According to PhRMA member company reports, in some cases the authorities are requesting additional price reductions of up to 50 percent. The criteria for these requests are not clear nor based in legislation, creating a highly unpredictable environment for the marketing of new medicines.

In addition, over the last two years, the Central Pharmacy of Tunisia has sought to pass on the losses it has incurred as a result of the devaluation of the Tunisian Dinar to innovative biopharmaceutical companies.

Taken in combination, these policies result in prices that undervalue the cost of developing innovative medicines and the value of those medicines in the healthcare system. In addition, the Central Pharmacy of Tunisia has blocked the importation of some international medicines, if additional price reductions are not provided. The capricious nature of the system constitutes a barrier to market access, in that

companies are not able to predict the system, and facilitates discrimination against U.S. pharmaceuticals.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2013 attributable to trade barriers related to intellectual property protection and market access.