

**PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA
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PhRMA 2015 SPECIAL 301 **OVERVIEW**

PhRMA 2015 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 of protection for intellectual property rights. The TRIPS 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. For these reasons, WTO members, including the United States, have an important role to place in not only effectively implementing, but in reiterating and enforcing TRIPS standards among themselves.

A country cannot be said to adequately and effectively protect intellectual property rights within the meaning of its trade obligations 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.

High technology, innovative industries are essential engines of export and job growth for the U.S. economy, and it is critical now more than ever, given the increasingly competitive global environment, that the United States takes a strong position in enforcing international rules that maintain this comparative advantage, particularly in the biopharmaceutical industry.¹

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. 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.³ Of those IP-intensive industries, intangible assets account for over 90 percent of the innovative biopharmaceutical industry's market value.⁴

The innovative biopharmaceutical industry is a good example of how intellectual capital contributes to the U.S. economy. In 2011, the biopharmaceutical sector

¹ Adapted from Burns, L.R., The Biopharmaceuticals Sector Impact on the U.S. Economy: Analysis at the National, State, and Local Levels (Washington DC, Archstone Consulting LLC, March 2009) (Burns Report).

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.

⁴ 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.

supported \$789 billion in U.S. economic output, including direct and indirect effects.⁵ In 2013, U.S. biopharmaceutical goods exports totaled nearly \$51 billion, making the innovative biopharmaceutical sector the fourth largest exporter among R&D-intensive industries.⁶

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.⁷ 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.⁸ 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 2013 by the National Science Foundation, the U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business R&D, representing more than 20 percent of all domestic R&D funded by U.S. businesses.⁹ Investing more than a half-a-trillion dollars since 2000, with over \$50 billion invested in R&D in 2013 alone,¹⁰ 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.¹¹ These figures highlight the pressing need to defend this sector's IP rights against infringement. There are more medicines in development in the United States than in the rest of the world combined¹² in large part due to IP protections and other strong incentives that foster the environment needed to support continued research and development investment.

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

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. TradeStats Express: State Export Data, available at: <http://tse.export.gov/TSE/TSEhome.aspx>; Industry R&D data from National Science Board of the National Science Foundation, "Science and Engineering Indicators 2013," 2013; Industry export data from PhRMA analysis of data from United States International Trade Administration.

⁷ Pham, N.D. (2010).

⁸ Battelle Report.

⁹ Based on PhRMA calculation of data from the National Center for Science and Engineering Statistics. National Science Foundation. "Business R&D Performance Remained Virtually Unchanged in 2010," Table 2 (NSF 13-324). Arlington, VA: NSF, 2013, available at www.nsf.gov/statistics/infbrief/nsf13324/nsf13324.pdf (last visited Feb. 6, 2015).

¹⁰ Pharmaceutical Research and Manufacturers of America. "PhRMA Annual Membership Survey." 2013.

¹¹ 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.

¹² Adis Insight, "R&D Insight Database" (February 2013).

and 2011.¹³ 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.¹⁴ 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.¹⁵

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.”¹⁶ This is due in large part to the scientific research-intensive nature of this sector, which contributes to high development costs. Creating a new medicine takes, on average, an investment of ten to fifteen years and nearly \$2.6 billion according to the most recent estimates.¹⁷ Such investment inherently involves a high degree of uncertainty in the screening process for new compounds or molecules, the rigors of pre-clinical testing and clinical trials, and the fact that only a small number of marketed medicines recoup or exceed R&D costs.¹⁸

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 resources will be protected if they are successful, and that they will have the opportunity to earn a return on investment. A clear legal framework provides the certainty, security, and predictability necessary for this sector’s

¹³ 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).

¹⁴ D.M. Cutler, et al., The Value of Antihypertensive Drugs: A Perspective on Medical Innovation. *Health Affairs* 26(1): 97–110 (2007).

¹⁵ D.M. Cutler (2007).

¹⁶ See, e.g., Grabowski, H., Patents, innovation, and access to new medicines, *J Int'l Economic Law* 2002:849-860.

¹⁷ J. A. DiMasi, et al., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, Tufts Center for the Study of Drug Development (2014), press release available at http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study (last visited Feb. 6, 2015).

¹⁸ Pharmaceutical Research and Manufacturers of America. “Drug Discovery and Development: Understanding the R&D Process.” Washington, DC: PhRMA, 2014; J.A. Vernon et al., Drug Development Costs When Financial Risk Is Measured Using The Fama-French Three-Factor Model, *Health Econ. Letters* 19:8 (2010) at 1002-1010.

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. Robust IP protections also have important ripple effects throughout the countries that implement and enforce them. Economic research consistently confirms that developing countries benefit tremendously from respecting IPRs.¹⁹ Specifically, there is a strong, positive, and well-recognized correlation between foreign direct investment inflows and reliable IP regimes.²⁰ For example, a January 2014 study by economists Robert Shapiro and Aparna Mathur examined the economic impact of India's current approach to intellectual property rights, as it affects pharmaceutical products and foreign direct investment (FDI).²¹ That study concluded that "inflows of foreign direct investment vitally affect the pace of development and growth in India's pharmaceutical industry and across much of the rest of the nation's economy. Those inflows, in turn, depend substantially on the strength and integrity of India's commitment to protect and enforce the intellectual property rights of foreign direct investors."²²

It is also well established that developing countries in particular gain from high-quality and high-quantity technology transfers associated with FDI. R&D expenditures rise at an increasing rate, so that strong IPR protections stimulate effectively greater

¹⁹ See, e.g., L. Branstetter and K. Saggi, Intellectual Property Rights, Foreign Direct Investment and Industrial Development, *Econ. J.* 121 (Sept. 2011) at 1161-1191, available at www.researchgate.net/publication/46466845_Intellectual_Property_Rights_Foreign_Direct_Investment_and_Industrial_Development/file/9fcfd50a5bd5ba2896.pdf (last visited Feb. 6, 2015); S. Adams, "Intellectual Property Rights, Investment Climate and FDI in Developing Countries," *Int'l Bus. Research* 3:3 (July 2010), available at <http://www.ccsenet.org/journal/index.php/ibr/article/download/6515/5131> (last visited Feb. 6, 2015).

²⁰ R. Cavazos Cepeda, et al., Policy Complements to the Strengthening of IPRS in Developing Countries, OECD Trade Policy Papers No. 104 (Sept. 2010), OECD Publishing, available at <http://dx.doi.org/10.1787/5km7fmwz85d4-en> (last visited Feb. 6, 2015); S. Claessens and L. Laeven, Financial Development, Property Rights, and Growth, World Bank, Policy Research Working Paper Series 2924 (Nov. 2002), available at <http://elibrary.worldbank.org/content/workingpaper/10.1596/1813-9450-2924> (last visited Feb. 6, 2015); J. Lee and E. Mansfield, Intellectual Property Protection and U.S. Foreign Direct Investment, *Review of Economics and Statistics*, Vol. 78 (1996).

²¹ R. Shapiro and A. Mathur, How India Can Attract More Foreign Direct Investment, Create Jobs, and Increase GDP: The Benefits of Respecting the Intellectual Property Rights of Foreign Pharmaceutical Producers (Jan. 2014), available at http://www.sonecon.com/docs/studies/FDI_IP_and_the_Pharmaceutical_Sector_in_India-Shapiro-Mathur-Final-January2014.pdf (last visited Feb. 6, 2015).

²² *Id.* at 4.

gains in developing countries than in high-income ones.²³ Shapiro and Mathur also predicted that “India could well become a global center for innovative drug development and production, increase the life expectancy of its people, expand output and employment, and achieve considerable cost savings in medical care and government subsidies” by increasing its IPR protection.²⁴

These trends are particularly true with respect to the innovative biopharmaceutical industry. IP not only attracts innovative medicines to a market, but “it can also impact whether that nation’s scientists and physicians will play a role in global drug development, and if drugs will be developed for locally endemic conditions.”²⁵ The presence of innovative pharmaceuticals provides increased benefits to a country’s economy and the health of its population. For example, there is robust, empirical evidence across countries of various income levels that the “patent policies governments adopt strongly affect how quickly new drug therapies are launched in their countries. Longer duration, and stronger, patent rights substantially speed up diffusion.”²⁶

PhRMA member companies are also 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.²⁷

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.”²⁸ 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.²⁹ 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

²³ R. Falvey, et al., Intellectual Property Rights and Economic Growth, Internationalisation of Economic Policy Research Paper No. 2004/12 (2004), available at <http://ssrn.com/abstract=715982> (last visited Feb. 6, 2015).

²⁴ R. Shapiro and A. Mathur at 4.

²⁵ Scientific American Worldview: A Global Biotechnology Perspective (2014) at 36-37.

²⁶ I. Cockburn, et al., Patents and the Global Diffusion of New Drugs, NBER Working Paper No. 20492 (Sept. 2014), available at <http://cep.lse.ac.uk/pubs/download/dp1298.pdf> (last visited Feb. 6, 2015).

²⁷ IFPMA Survey, validated by LSE Health and Social Care at the London School of Economics and Political Science.

²⁸ Remarks by Bill Gates at the World Economic Forum, Gates Foundation Press Conference (January 29, 2010).

²⁹ See www.globalhealthprogress.org.

third largest funder in the world, ahead of all countries but the United States.³⁰ 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.³¹ Without these efforts, which are threatened when IP protections are eroded and the incentives for innovating new medicines are undermined, access to effective, sustainable healthcare for the developing world's patients would be impossible.

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

³⁰ Moran, M. et al., "Neglected Disease Research and Development: A Five Year Review," Policy Cures, (2012).

³¹ 2013 Medicines in Development – Infectious Diseases Report, Pharmaceutical Research and Manufacturers of America (December 2013).

(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.³²) 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

³² 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.

after the fact in legal disputes concerning the validity of the patent through several mechanisms. For example:

- The Canadian judiciary has created an additional, heightened standard for demonstrating patentable utility that has so far been applied only in pharmaceutical patent cases and which is inconsistent with international practice. This “promise doctrine” has led to the invalidation of at least 20 pharmaceutical patents on innovative drugs already in use by Canadian patients.
- 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.
- 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, Brazil, Canada, China, Colombia, Costa Rica, Ecuador, India, Peru, the Philippines, 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. In another example, Ecuador's public pharmaceutical firm routinely seeks CLs to copy successful innovative products introduced in the market without a clear demonstration of an urgent public health emergency or due process provided to the patent owners consistent with Ecuador's international obligations, leading to six CLs issued in 2014 alone. Finally, Russia is actively considering implementing a CL regime that may take cost into account in the CL determination.

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, through the European Medicines Agency has issued policies

permitting access to and publication of clinical trial data that have the potential to harm patient privacy, the integrity of the regulatory system, and incentives for pharmaceutical research and development. Similarly, in 2014, Canada passed sweeping legislation that would permit the Health Minister to broadly share undisclosed test data without safeguards to protect against unfair commercial use. 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, the European Union, Honduras, India, Malaysia, Mexico, Morocco, Nicaragua, Peru, 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. That said, note that in Australia, for example, deficiencies in its patent enforcement system are exacerbated by the government’s policy of seeking damages from the innovator after it loses patent enforcement litigation – a policy which may be spreading to other markets.

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, Egypt, El Salvador, the European Union, Guatemala, Honduras, India, Korea, Malaysia, Mexico, Nicaragua, Peru, the Philippines, Russia, Taiwan, Thailand, Turkey and Vietnam.

Patent Term Adjustment and Restoration – Finally, a prerequisite for ensuring that a patent holder can fully enjoy the commercial benefits of its IP rights 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, China, Costa Rica, Dominican Republic, Guatemala, Malaysia, New Zealand, Thailand, Turkey, and Vietnam.

C. 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 2014 Russia proposed a decree stipulating that only drugs from Russia, Belarus and Kazakhstan would be eligible 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.

D. 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.

E. 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 2012 analysis, approximately 53 countries proposed or implemented cost containment measures impacting the biopharmaceutical sector.³³ 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 prices and reimburses most, if not all, medicines used in that country.

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.³⁴ 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

³³ Ross Consulting, analysis for PhRMA, August 2012.

³⁴ 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.

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)³⁵ if all countries re-referencing Greek prices through formal and informal links are included.³⁶ Similarly, in April 2009, the Government of Turkey 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. In recent years the Turkish lira has devalued as compared to the Euro by more than 50 percent, but the exchange rate used for reference pricing has remained the same. It is estimated that the global spillover effect of Turkey’s fixed exchange rate reduced industry revenues in 2013 by \$2.95 billion.³⁷

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 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 the 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 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

³⁵ 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.

³⁶ Charles River Associates. International Reference Pricing: Relationship Mapping, Re-Referencing, and Economic Spillover Impact. April, 2011.

³⁷ Charles River Associates, International, “Quantifying the Wider Impact of Turkey’s International Reference Pricing System” (Aug. 2014).

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,³⁸ 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;”³⁹ 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].”⁴⁰

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.”⁴¹ Nevertheless, certain countries are in egregious violation of such principles leading to a downward spiral in the prices for medicines with damaging results for PhRMA members. For example, Saudi Arabia uses a burdensome and non-transparent IRP system which bases the Saudi price on the lowest price in a basket of 30 countries, several of which are not comparable to Saudi Arabia in terms of their level of economic development, populations or patient needs.⁴² Moreover, beginning in 2012 IRP can be used in

³⁸ European Commission Report: Cost-Containment Policies in Public Pharmaceutical Spending in the EU (Sept. 2012).

³⁹ 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. 6, 2015).

⁴⁰ European Commission Report: Cost-Containment Policies in Public Pharmaceutical Spending in the EU (Sept. 2012).

⁴¹ WHO/HAI Project on Medicine Prices and Availability (Working Paper 1: External Reference Pricing). May 2011.

⁴² International Reference Pricing Analysis for PhRMA: Saudi Arabia, Charles River Associates, London (Jan. 2011).

the reimbursement negotiation process and includes consideration prices across a reference basket that includes Greece and Portugal, two countries which are severely suffering from the Euro and economic crisis.

Even developed, fiscally sound European countries 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 patient access to medicines in poorer countries, contributes to supply shortages via parallel trade, and can cause launch delays.

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.

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, on August 20, 2011, Spain imposed a mandatory 15 percent rebate on all medicines sold in Spain for ten or more years.

Other examples of cost containment measures include price controls in India and Colombia. 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;⁴³ even medicines and vaccines which are offered free of charge often do not reach the patients who need these medicines.⁴⁴ 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.⁴⁵ Moreover, reimbursement guidelines in Mexico do not provide a clear understanding of the required information or how dossiers are evaluated, resulting in 75% of submissions being rejected for a reason not identified by the guidelines as a criteria for review, and the reasons for rejection are non-transparent, lack a formal review process, and often change from submission to submission. 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 the ability for companies to recoup significant investment costs to ensure future R&D, 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

⁴³ "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. 6, 2015).

⁴⁴ "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. 6, 2015).

⁴⁵ AMIIF 2011 Report.

average regulatory approval period exceeded 900 days in 2012.⁴⁶ 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 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.

F. 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.

⁴⁶ AIFD Situation Assessment Survey of CTD Applications (Dec. 2012).

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.”⁴⁷ 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.⁴⁸ 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

⁴⁷ Id.

⁴⁸ 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. 6, 2015).

in developing markets are believed to be counterfeit.⁴⁹ 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.⁵⁰ A 2009 International Policy Network study also found that fake tuberculosis and malaria drugs kill 700,000 people a year in developing countries.⁵¹ By contrast, counterfeiting is estimated to affect less than 1% of medicines sold in industrialized economies with developed regulatory and enforcement systems.⁵²

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.”⁵³ 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.⁵⁴ 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....”⁵⁵

Although 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 and often linked to organized crime), 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

⁴⁹ The World Health Organization, IMPACT, at www.who.org (2008).

⁵⁰ 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).

⁵¹ Harris, J., et al., Keeping It Real, *Health Issues*, International Policy Network (May 2009).

⁵² 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. 6, 2015).

⁵³ IOM, *Countering the Problem of Falsified and Substandard Drugs* (Feb. 2013).

⁵⁴ Pharmaceutical Security Institute analysis.

⁵⁵ IOM, *Countering the Problem of Falsified and Substandard Drugs* (Feb. 2013).

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 supporting the development and adoption of an international convention to criminalize and combat counterfeit medical products, such as The Medicrime Convention.⁵⁶

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 Turkey be designated as a Priority Foreign Country in USTR's Special 301 report for 2015. 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.

⁵⁶ 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. 6, 2015).

B. Priority Watch List

PhRMA believes that 14 countries should be included in the 2015 Priority Watch List. PhRMA urges USTR to take bilateral (and multilateral as appropriate) action to remedy these significant concerns regarding IP protections and enforcement.

Although last year PhRMA recommended that India be designated as a Priority Foreign Country, the IP issues outlined in USTR's 2014 Special 301 Report remain significant areas of concern. PhRMA welcomes improved dialogue between the U.S. and Indian governments on IP in 2014, including the reestablishment of the Trade Policy Forum and the High-Level IPR Working Group. However, a sustained effort of heightened engagement is required in order to translate India's commitments into substantive and real policy change in India's patent laws and policies. For these reasons, PhRMA requests that India be designated on the Priority Watch List in the 2015 Special 301 Report and that USTR conducts a further Out-of-Cycle Review, so that the U.S. Government can dedicate the required bilateral attention necessary to make progress on the serious IP and market access barriers confronted by U.S. businesses in India, assess whether sufficient progress has been made through the High-Level IPR Working Group, and constructively engage with the Indian Government on how to quickly and effectively resolve these problems.

Also due to the large number of CLs issued by Ecuador in 2014 without demonstration of the need for such licenses and without sufficient due process, PhRMA requests that Ecuador be placed on the Priority Watch List for the 2015 Special 301 Report. This is a change from PhRMA's requests in previous years to reflect the deteriorating IP environment in Ecuador.

C. Watch List

The PhRMA submission identifies 17 trading partners which should be included on the Special 301 Watch List in 2015. These are economies 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

TURKEY

PhRMA and its member companies face significant market access barriers in Turkey, including deficiencies in Turkey's intellectual property framework, slow and unpredictable government product registration, and reimbursement and pricing systems. 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. Consistent with Turkey's international obligations, the RDP term should begin when a product receives marketing authorization in Turkey.
- **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 periods.
- **Government price controls:** The Turkish Government continues to impose unrealistic pharmaceutical budgets that disregard parameters such as economic

growth, inflation and exchange rate fluctuations, and result in forced price discounts at unsustainable levels that hinder access to innovative medicines.

For these reasons, PhRMA requests that Turkey be designated a **Priority Foreign Country** for the 2015 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, does have protective terms for patent rights holders; however in practice the IP Courts' interpretation is quite narrow, with most court decisions being determined against the patent holder. Another crucial matter is that because most IP Court Judges in Turkey lack the technical expertise to hear patent issues, most patent infringement proceedings are referred to expert panels, whose conclusions are almost always followed. Considering that the expert examination system has serious deficiencies – both in terms of procedural and substantive expertise – few patent related actions receive appropriate judicial review in Turkey.

Draft Law number 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 of 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.

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 (RDP) for a period of six years for products registered in the EU, limited by the patent protection period of the product. RDP 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 RDP currently begins on the first date of marketing authorization in any country of the

European Customs Union. Considering the extended regulatory approval times and 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 RDP, undermining incentives needed for innovators to undertake risky and expensive research and testing. Regulatory approvals need to be granted by MOH within 210 days; if not, the six year period of RDP 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 RDP has been changed by the Regulation to Amend the Registration Regulation of Medicinal Products for Human Use.⁵⁷ The change that has been introduced is incompatible with EU standards in that it eliminates RDP 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 RDP.

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.⁵⁸ 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 is 539 days.

The MOH's revisions to the Registration Regulation have compounded these delays.⁵⁹ Effective March 1, 2010, a Good Manufacturing Practices (GMP) certificate that is issued by the MOH 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.

⁵⁷ Official Gazette No. 27208 (Apr. 22, 2009).

⁵⁸ Official Gazette No. 25705 (Jan. 19, 2005) (Registration Regulation).

⁵⁹ 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).

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. According to the most recent survey by the Turkish Association of Research-based Pharmaceutical Companies (AIFD), at the end of June 2014, AIFD's members reported that GMP inspections were pending for 887 product-site pairs. The GMP certification timeframe is growing steadily every year. AIFD therefore estimates, based on a survival analysis projection that takes into account both pending and completed inspections, the mean GMP certification timeframe is 768 days as of June 2014.⁶⁰ In addition, the survey determined that GMP certificates related to 289 product-site pairs expired in 2014 and 378 certificates will expire in 2015. As yet, however, the MOH has not implemented regulations for conducting the GMP recertification process.

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 yet 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 September 2014, the MOH indicated that it would initiate marketing authorization reviews in parallel with GMP inspections, but only for products deemed highly innovative (Category I products), although no official policy has been published. The outcome of this declaration should be carefully monitored. Since this announcement the inspection process for category 2 products has slowed, with no indication when reviews of products deemed as category 2, 3, or 4 will be conducted. Finally, there still is no clearly defined or transparent process for determining the category classification of products.

⁶⁰ AIFD GMP Inspections Survey (Nov. 2014).

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 non-transparent and maintains lengthy timelines as a result of frequent delays in decision-making and erratic meeting schedules. On average, according to the AIFD survey, it takes 409 days for a registration decision on pharmaceutical products that hold marketing authorization and more than 650 days for products with pending marketing authorization applications.

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

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 2010-2012 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 2015 was recently reduced to at 18B TL to offset the 2014 pharmaceutical budget deficit. 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. In recent years the Turkish lira has devalued as compared to the Euro by more than 50 percent, but the exchange rate used for reference pricing has remained the same. The estimated cost on industry revenues in 2013 was \$2.95B.⁶¹

Orphan Drug Guidelines

Support for Orphan Drugs has not been thoroughly addressed by Turkish legislation. Turkey's implementation of a comprehensive Orphan Drug Guideline is necessary to facilitate the development and commercialization of drugs to treat rare diseases. PhRMA's members are encouraged that the Ministry of Health has been working on Orphan Drug Guidelines, which were shared with industry representatives for discussion in 2010. However, not only have these guidelines not progressed since 2010, the latest draft establishes a prevalence standard that is much stricter than those in other parts of the world. Specifically, the draft defines "a prevalence of not more than

⁶¹ Quantifying the wider impact of Turkey's External Reference Pricing system: A summary." Charles River Associates. September 2014.

1 in 10,000 persons in the population” far exceeding, for example, the EU standard of “a prevalence of not more than 5 in 10,000 persons”. This would exclude from the legislation many patients with a rare disease, which would greatly undermine the import of these guidelines. Expediting the adoption and implementation of an EU-consistent Orphan Drugs Regulation (including the EU definition of rare diseases) is of crucial importance to ensure Turkish citizens have access to the medicines they need and for Turkey to emerge as a globally-competitive economy in medical innovation.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 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 the lack of effective regulatory data protection and patent enforcement, inconsistent patent examination guidelines, lengthy and non-transparent regulatory approval process, delayed government reimbursement, restrictive government pricing policies, rampant counterfeiting of medicines and under-regulated active pharmaceutical ingredients. PhRMA is encouraged by China's ongoing work to amend the Drug Administration Law (DAL) as this provides a critical opportunity to enhance patient access to innovative medicines and address many of the following issues of concern. PhRMA is eager to continuing supporting China in this effort and urges an accelerated revision of the DAL.

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, but uncertainty remains as to when such data will be accepted. PhRMA is also concerned that the State Intellectual Property Office (SIPO) appears to be imposing new – and unfair or inappropriate – limitations on the use of post-filing data to satisfy inventive step requirements.
- **Regulatory data protection:** China committed as part of its accession to the World Trade Organization (WTO) to provide a 6-year period of regulatory data protection (RDP) against unfair commercial use for clinical test and other data submitted to secure approval of products containing a new chemical ingredient. In practice, however, China's RDP has not been effective. PhRMA continues to encourage meaningful implementation of China's commitment made during the 2012 meeting of the U.S.-China Joint Commission on Commerce and Trade (JCCT) to implement an RDP system that is consistent with international research and development practices and China's international obligations.
- **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 and recent procedural changes regarding the acceptance of multi-regional clinical trial (MRCT) data are further extending this timeline by an estimated two or more years. PhRMA is encouraged by the State Council's support for the hiring of

additional reviewers in the Center for Drug Evaluation (CDE), which should help to speed up the CTA and new drug application (NDA) approval processes. Accelerating the CTA and NDA review approvals will improve the efficiency of global drug development and reduce the time it takes for innovative new medicines to reach Chinese 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, new government pricing policies and procedures being considered by China have created an uncertain business environment and could 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. PhRMA looks forward to meaningful implementation of China's commitment made during the sixth meeting of the U.S.-China Strategic and Economic Dialogue in July 2014 related to effective regulatory control of APIs and anti-counterfeiting.

For these reasons, PhRMA requests that China be subject to **Section 306 Monitoring** for the 2015 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 – Supplemental Data

Pursuant to the 2006 patent examination guidelines,⁶² 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. Article 26.3 provides that the application must include a "clear and comprehensive description of the invention or utility model so that a technician in the field of the relevant technology can carry it out."⁶³ This is similar to provisions in U.S. patent law, the European Patent Convention, and Japanese patent law, as well as the Patent Cooperation Treaty (PCT).⁶⁴

⁶² See Guidelines for Patent Examination, State Intellectual Property Office (2010), Rule 17.

⁶³ Patent Law of the People's Republic of China (SIPO translation), Article 26, available at http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html (last visited Feb. 6, 2015).

⁶⁴ Patent Cooperation Treaty, 28 U.S.T. 7645 (1970), Art. 28.

In 2006, however, SIPO's examination guidelines were amended regarding the technical patent disclosure requirement for pharmaceutical compounds (though the Patent Law was not changed), causing examiners to require a significant amount of experimental data to satisfy Article 26.3, generally meant to mean data on the biological activity of the compounds to be present in the patent specification as filed. Further, this guideline was being applied to applications filed and even granted before the new standard was adopted. This requirement to disclose experimental data at the time of filing placed a much larger burden on companies than faced in the other IP5 Member States (i.e., the United States, the European Union, Japan, and Korea) and belied the timeline realities of pharmaceutical drug development. 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 PCT, of which China is a member, under these guidelines, SIPO would not accept data generated after the patent application was filed during patent prosecution. The adoption and implementation of this 2006 guideline caused concerns about the validity of existing patents granted prior to 2006 and caused denials of patents to medicines that had received patents in other jurisdictions.

It should also be noted that SIPO has been imposing unfair or inappropriate limitations on the use of post-filing data to satisfy inventive step requirements under Article 22.3 of China's Patent Law. In practice, SIPO does not consistently accept experimental data after the filing date of pharmaceutical patent applications that would ordinarily be provided to establish inventive step. In other cases, SIPO may accept experimental data during patent prosecution, but not if the data was created after the filing date. These practices cause significant uncertainty about the ability to obtain and maintain pharmaceutical patents in China when patents have been granted on those same inventions in other jurisdictions.

In December 2013, China committed through the U.S.-China Joint Commission on Commerce and Trade (JCCT) to change 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. This JCCT commitment is a critical step in the right direction, but implementation is essential. China's commitment should be executed in writing, and in a manner that is binding on Chinese patent examiners, patent appellate bodies and the courts. Further, for meaningful implementation, China must ensure that patent applications filed prior to 2006 are not being opposed based on retroactively applied standards, and that patent applications that were adversely affected prior to this commitment are reinstated. The JCCT commitment speaks broadly to the acceptance of post-filing, or supplemental, data, and should, therefore, address the inventive step issue as well. PhRMA appreciates the ongoing technical discussions between the U.S. and Chinese governments on the supplementation of data and welcomes the commitment by both sides in the 2014 JCCT to continue exchanges and engagement on specific cases. Like the 2013 commitment, implementation and follow-through is critically important. Uncertainty remains as to when such data will be accepted. Issuance of new patent examination guidelines with examples would be a good way to resolve this uncertainty.

Regulatory Data Protection

As part of its accession to the WTO in 2001, China committed to provide a six-year period of 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).⁶⁵ Indeed, China's Drug Administration Law (DAL) and Drug Registration Regulations (DRR), administered by the China Food and Drug Administration (CFDA), establishes a six-year period of protection for test data of products containing a new chemical ingredient against unfair commercial use.⁶⁶ Yet the law in practice 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. The term "new chemical ingredient" should be clearly defined in the DAL, DRR, and other relevant laws and regulations to include biologic and chemically synthesized drugs, recognizing the considerable investment by innovative biopharmaceutical companies in developing and proving safety and efficacy of a new product. China is currently going through the process of amending both the DAL and DRR.

Second, RDP should be granted to any product that is "new" to China, i.e., has 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.

During the December 2012 Plenary Meeting of the JCCT, China "agreed to define new chemical entity in a manner consistent with international research and development practices in order to ensure regulatory data of pharmaceutical products are protected against unfair commercial use and unauthorized disclosure."⁶⁷ Following many years of discussion in the JCCT and other venues, this commitment was a positive development. Unfortunately, this commitment remains unfulfilled. Effective implementation of this commitment is necessary. Although the U.S. Government has

⁶⁵ 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. Article 39.3 provides that a country must protect data submitted in the context of a drug registration application from unfair commercial use.

⁶⁶ 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.

⁶⁷ See Fact Sheet: 23rd U.S.-China Joint Commission on Commerce and Trade (Dec. 19, 2012, available at <http://www.ustr.gov/node/7979> (last visited Feb. 6, 2015)).

actively engaged CFDA to revise the definition of new chemical entity (including a recent technical workshop), little progress has been made.

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 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 by protecting innovators' investment in clinical trials. To meet these goals, China will need to ensure that it has regulatory and legal systems that are compatible with other major markets. While the systems need not be identical, implementation of a meaningful RDP mechanism can promote harmonization and enable companies to function more easily in multiple markets. PhRMA notes that it has been 14 years since China's WTO commitment to provide RDP. Thus, prompt and meaningful RDP reform should be a high priority.

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 the innovator later wins its patent litigation. This could undermine the goal of encouraging innovation in China. In fact, CFDA has approved infringing follow-on products, and research-based pharmaceutical companies have not been able to consistently resolve patent disputes prior to marketing of those infringing drugs. Further, although China's laws and regulations provide for injunctive relief, in practice injunctions are rarely, if ever, granted in the context of preventing premature follow-on product market entry due to high procedural barriers. 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.

Articles 18 and 19 of CFDA's DRR govern the current patent enforcement mechanism, recognizing patents associated with drug registration.⁶⁸ The DRR do not provide, however, an effective mechanism for enforcing an innovator's patent rights vis-à-vis regulatory approval of follow-on products. For example, the current DRR provisions 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."⁶⁹

⁶⁸ Provisions for Drug Registration (SFDA Order No. 28), Arts. 18 and 19.

⁶⁹ Id., Art. 18.

However, the patent laws require there to be sales in the marketplace before an infringement suit can be filed.

Although CFDA is in the process of revising the DRR, there are indications that the DRR amendments may not provide any improvements or, in fact, may undermine existing (albeit insufficient) patent enforcement tools. PhRMA and its member companies were very concerned by at least one proposed amendment to the DRR 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. Although more recent drafts of the DRR amendments would modify, but not delete, Article 19, failure to improve the existing mechanism will continue to inject uncertainty into the business environment for both innovators and follow-on manufacturers who seek to avoid litigation after product launch.

To avoid the unnecessary costs and time of litigating damages claims in patent litigation, to increase market predictability for both innovators and follow-on manufacturers, and following the model of other countries, China – through the DRR and DAL reform processes – should institute mechanisms 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.

Market Access Barriers

Clinical Trial Application Approval

Over the last few years, the China Food and Drug Administration (CFDA) has made significant strides to increase efficiency and transparency, but procedural changes in late 2013 to the clinical trial application (CTA) process regarding the acceptance of MRCT data is a departure from this previous, positive direction.

Research shows that imported new drugs are approved in China four to six years⁷⁰ after approval in other major markets and the recent procedural changes by the CFDA are further extending this timeline and delaying patient access to innovative medicines by an estimated two or more years. These changes to the approval process, which were issued without notice and without a transition period, have made an already lengthy regulatory process even longer and have created an unpredictable operating environment for multinational research-based pharmaceutical companies. PhRMA is encouraged by the clarifications related to the continued use of MRCTs in a draft

⁷⁰ Liberti, et al., Center for Innovation in Regulatory Sciences. *Characterizing the Influencers of Submission Lag Time for Medicines in the Emerging Markets* (August, 2012).

guideline released by the CFDA in late 2014 and the decision to increase the review staff at CDE.

To help China further integrate into the global innovation network, further steps should be taken to shorten the clinical trial application (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 to promoting trade with China. 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 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.

PhRMA appreciates and welcomes the commitment in the 2014 JCCT to significantly reduce the time-to-market for innovative pharmaceutical products. Specifically, we are encouraged that these commitments support the use of MRCT as a viable pathway to drug development in China and the implementation of new measures to reform the Certificate of Pharmaceutical Product (CPP) requirements. These actions should allow for drug development in China to occur simultaneously with global development. To ensure accelerated patient access to innovative treatments, China should take immediate steps to implement these important commitments. PhRMA and its members stand ready and look forward to working closely with the U.S. and Chinese governments to support this 2014 JCCT commitment.

Government Reimbursement List

Once drug approval is achieved in China, patients must often wait an additional five years or more⁷¹ before they receive access through national reimbursement. 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 delays market access to innovative pharmaceuticals and prevents their timely availability to patients. PhRMA recommends a defined timeline for NRDL updates to be implemented. A defined timeline would remove the ambiguity of when a formal update will occur, provide a more stable business environment and significantly improve patient access to innovative medicines.

Government Pricing Policies

China, as part of its WTO accession, committed 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.⁷² Notwithstanding that commitment, PhRMA is

⁷¹ IMS Consulting Group, *China Drug Lag and the Impact of Reimbursement Delays* (July, 2014).

⁷² 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.

concerned that government pricing policies being considered by the Government of China have created an uncertain business environment and could 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 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, within a broad sustainable healthcare system.

Counterfeit Medicines

Pharmaceutical counterfeiting poses global public health risks, exacerbated by rapid growth of online sales of counterfeit medicines 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. However, online distribution of counterfeit medicines and unregulated API remain the most serious challenges in China.

Under current pharmaceutical regulations, there is no effective regulatory control over the manufacture and distribution of API, which creates a major regulatory loop-hole that impacts negatively on the security of China's upstream drug supply chain. During the Sixth Meeting of the U.S.-China Strategic and Economic Dialogue in July 2014, China also committed to develop and seriously consider amendments to the DAL requiring regulatory control of API. To effectively reduce the risks caused by unregulated API to patient health, a multi-prong approach or "road map" is needed. 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. 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. These efforts to crack down on unregulated API must go hand-in-hand with China's current campaign against counterfeit drugs in order to enhance the effectiveness of China's national drug safety plan objectives.

China continued to coordinate joint special enforcement campaigns targeting counterfeit drug crimes.⁷³ It also appears that China is beginning to spend more efforts tackling the sale of counterfeits on the Internet. In 2013, CFDA and the State Information Office jointly led a 5-month crackdown campaign with collaboration of several ministries and offices against illegal online sales of drugs. 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.⁷⁴ PhRMA hopes that the U.S. Government will work with China to increase transparency of such campaigns including enhancing information sharing with drug manufacturers to help evaluate the effectiveness of online actions, and supporting enforcement efforts to protect patients. China's actions in this area could serve as a model for other countries facing similar challenges online.

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.

Finally, while we commend China for improvements in customs regulations, which include monitoring and seizure of imports and exports, Chinese Customs 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. This could include, for example, encouraging greater cooperation between Chinese Customs and the Public Security

⁷³ See, e.g., "2,000 Arrested in China in Counterfeit Drug Crackdown," Aug. 5, 2012, available at: http://www.nytimes.com/2012/08/06/world/asia/2000-arrested-in-china-in-crackdown-on-counterfeit-drugs.html?_r=0 (last visited Feb. 6, 2015); "China Detains 1,300 People Suspected of Making and Selling Counterfeit Drugs," Dec. 15, 2013, available at http://www.huffingtonpost.com/2013/12/16/counterfeit-drugs-china-medicine_n_4447483.html (last visited Feb 6, 2015).

⁷⁴ 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.

Bureau to ensure the identification and prosecution of those manufacturing and exporting counterfeit medicines.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 attributable to trade barriers related to intellectual property protection and market access.

PRIORITY WATCH LIST

ASIA-PACIFIC

INDIA

PhRMA welcomes improved dialogue between the U.S. and Indian governments on intellectual property (IP) in 2014, including the reestablishment of the Trade Policy Forum and the High-Level IPR Working Group. Moreover, India's Draft National IP Policy, issued in December 2014, recognizes the tremendous economic and socio-cultural benefits that a strong IP regime can bring to India through economic growth, employment, and a vibrant R&D environment. In this context, PhRMA and its member companies are optimistic that the Indian Government's openness and drive for innovation will yield progress on the IP challenges we have faced to date.

Despite these potentially positive signs, PhRMA and its member companies remain concerned 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 inconsistent with the new Government's goals of fostering a spirit of innovation, entrepreneurship, and R&D growth,⁷⁵ including inadequate IP protection and enforcement. 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 ambiguous clinical trials regulations. These policies are not likely to expand access and, in most cases, may even limit Indian patient access to innovative medicines. In fact, recent analysis shows that half of all new medicines launched worldwide between 2000 and 2009 faced a launch delay of five years or more in India.⁷⁶

India has considerable potential for attracting investment to the biopharmaceutical sector, but the country has failed to realize this opportunity fully because of such regulatory and legal obstacles. Policy reforms could substantially improve the business environment for the biopharmaceutical sector in India, in addition to supporting the new Government's "Make in India" program goals of fostering innovation, facilitating investment, and protecting intellectual property.⁷⁷ Further, to improve access to medicines in India, and to healthcare more broadly, we believe collaborative multi-sectoral approaches that meet both the Government's health policy objectives and ensure patient access to innovative medicines are needed to advance sustainable policy solutions to healthcare financing, delivery, infrastructure, and human resources challenges, among others. We welcome the opportunity to work with the Indian Government in designing an equitable approach and implementing a system that is appropriate to India.

⁷⁵ BJP Election Manifesto 2014, available at http://www.bjp.org/images/pdf_2014/full_manifesto_english_07.04.2014.pdf (last visited Feb 6, 2015).

⁷⁶ Ernst R. Berndt and Iain M. Cockburn. The Hidden Cost of Low Prices: Limited Access to New Drugs in India. *Health Affairs*, 33, no.9 (2014): 1567-1575.

⁷⁷ See www.makeinindia.com.

Key Issues of Concern:

- **Patent protection and enforcement:** 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 India's patents act, to the threat of compulsory licensing on specious grounds, to the narrow patentability standards applied in 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 nineteen products have had their patent rights undermined in India. In 2014, the continued denial of patent applications for innovative medicines under Section 3(d), the continued state-level marketing authorization for generic versions of on-patented drugs, and the continued threat of government-issued compulsory licenses (CLs) demonstrate that there have been no concrete policy improvements in India.
- **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:** An Inter-Ministerial Committee was constituted to propose a methodology to be applied to pricing of patented medicines before their marketing in India. It is unclear whether the Committee will start afresh or move forward with the previous Committee's proposal for 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 to adjust the reference price to account for purchasing power parity 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.⁷⁸ In addition, the National Pharmaceutical Pricing Authority (NPPA), without prior notice to any manufacturers, issued a notice setting prices for 108 non-scheduled diabetes and cardiovascular medicines evoking Para 19 of DPCO 2013. Such a decision fails to maintain transparency and predictability which are paramount to a robust environment for business investment.

⁷⁸ Government of India Speed Post No. 31011/5/2009/PI-II(pt), Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, Subject: Inter-Ministerial Committee on Prices of Patented Drugs. New Delhi, the 17th of February, 2014.

- **Clinical trials:** The Ministry of Health (MOH) and the Central Drugs Standard Control Organization (CDSCO) issued a number of regulations with an aim toward streamlining the regulatory regime. However, inconsistencies and ambiguities continue to prevail in the Indian regulatory space resulting in lack of clarity among trial sponsors about the process and procedure for clinical trials approval and procedure in India. In particular, the ambiguities in the definition of “trial related injury” and audio-visual recording of the informed consent process make the regulatory process increasingly cumbersome. 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 three years. In particular, the commitment to an ongoing technical work plan as part of the High-Level IPR Working Group offer opportunities to capitalize on the Indian Government’s expressions of interest in engaging on IP issues and to secure concrete commitments that demonstrate India’s genuine intention of fostering innovation and improving patient access to new medicines. We acknowledge the measured and cautious approach taken by the Government in responding to recent requests for compulsory licenses and the successes some companies have had in enforcing their patents in India at the preliminary injunction stage. Further, we believe that the heightened level of engagement sought through the Trade Policy Forum and the Special 301 Out-of-Cycle Review, as well as other bilateral engagements, has catalyzed productive dialogue and momentum, including the development of India’s draft National IPR Policy.

As noted above, the issues outlined in USTR’s 2014 Special 301 Report remain significant areas of concern. A sustained effort of heightened engagement is required in order to translate India’s commitments into substantive and real policy change in India’s patent laws and policies. For these reasons, PhRMA requests that India be designated on the **Priority Watch List** in the 2015 Special 301 Report and that USTR conducts a further **Out-of-Cycle Review**, so that the U.S. Government can dedicate the required bilateral attention necessary to make progress on the serious IP and market access barriers confronted by U.S. businesses in India, assess whether sufficient progress has been made through the High-Level IPR Working Group, 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 substantive 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 27.⁷⁹ 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.

Compulsory Licenses on Patented Pharmaceutical Products

The previous Government set up a Committee under the Ministry of Health and Family Welfare (MoH Committee), which had 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 proceeded under the special provisions of Section 92 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 was reported that the Committee was considering whether to issue CLs under Section 92 on as many as 20 patented medicines across a wide range of therapeutic areas. While the Committee was formed under the previous Government, the current Ministry of Health continues to make recommendations to impose compulsory licenses for certain anti-cancer therapies under the Section 92 route.⁸⁰

⁷⁹ The additional patentability hurdle imposed by section 3(d) was recently reinforced by the Pharmaceutical Patent Examination Guidelines issued in October 2014.

⁸⁰ See, for example, “The Dasatinib Dance Continues: Compulsorily Licensing and Public Non Commercial Use” Nov. 11, 2014, available at <http://spicyip.com/2014/11/the-dasatinib-dance-continues-compulsorily-licensing-and-public-non-commercial-use.html> (last visited Feb. 6, 2015).

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. The Bombay High Court further interpreted the working requirement to specify that satisfaction of the working requirement "would need to be decided on a case to case basis" and that "the patent holder would nevertheless have to satisfy the authorities under the Act as to why the patented invention was not being manufactured in India."⁸¹ The Indian Supreme Court has refused to hear the appeal arising out of the Bombay High Court judgment thereby perpetuating the ambiguity of the CL criterion and terms of use.

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.⁸² 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 since foreign applicants are more likely to have filed patent applications for the same invention in other jurisdictions. 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 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. Further, Section 8 was enacted in 1970 when the information was only available from

⁸¹ *Bayer v. Union of India*, Writ Petition No. 1323 of 2013.

⁸² See, e.g., <http://thehill.com/blogs/congress-blog/campaign/316883-india-honors--not-dishonors--patent-laws> (last visited Feb. 6, 2015). 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.

the applicant; much of the information sought is now publicly available on patent office websites in most major countries.

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 (although a recent court decision indicates some flexibility for mere clerical errors). 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.⁸³

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 protection 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. Additionally, the draft National IPR Policy proposes to establish specialized patent benches; however, this would still require a significant amount of technical expertise and commitment of resources to be properly implemented. 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

Contrary to its TRIPS Article 39.3 obligation, India fails to ensure that there is no unfair commercial use of the regulatory data submitted by another party in securing marketing approval in a third country. Rather, when a pharmaceutical product has been previously approved by a Regulatory Authority in another country, India requires only limited clinical data (in some cases involving as few as 16 Indian patients). This is in lieu of requiring submission of the entire dossier for review by India's Regulatory Authority. Moreover, in some instances when an applicant seeks approval for a drug that has

⁸³ See, e.g., *Ajantha Pharma Limited v. Allergan*, Intellectual Property Appellate Board (2013).

already been approved abroad, Indian authorities waive the requirement to submit even this data.⁸⁴ In those circumstances, any subsequent approval of the drug in India is based entirely on the prior approval of the drug in a third country.

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. Approval by the Indian regulatory authorities based on third-country approvals amounts to indirect reliance on the clinical trial and other test data that underlie the third-country approvals. This indirect reliance results in unfair commercial use prohibited by TRIPS Article 39.3.

Market Access Barriers

Government Price Controls

PhRMA's members are 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.⁸⁵ 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.⁸⁶ We recognize the increased priority given by the Indian Government to issues of health care and health care access, and in particular, proposals to provide universal healthcare, insurance and medicines to Indian patients. The draft National Health Policy⁸⁷ is a step in the right direction to help reduce out-of-pocket expenditures and provide greater access for those below the poverty line and those seeking care in government hospitals. Still, 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.⁸⁸ 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.⁸⁹

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

⁸⁴ See Rules 122A and B of the Drug and Cosmetics Rules, 1945 (as corrected up to Nov. 30, 2004), available at http://www.wipo.int/wipolex/en/text.jsp?file_id=182377 (last visited Feb. 6, 2015).

⁸⁵ High Level Expert Group (HLEG) Report on Universal Healthcare Coverage for India, Instituted by Planning Commission of India, November 2011.

⁸⁶ "Health Systems Financing: The Path to Universal Coverage," *The World Health Report*, World Health Organization, 2010.

⁸⁷ "National Health Policy 2015 Draft." Ministry of Health & Family Welfare. December 2014.

⁸⁸ Analysis based on IMS MIDAS Data.

⁸⁹ "Health workforce, infrastructure, essential medicines", World Health Statistics 2013, The World Health Organization.

insufficient healthcare financing systems and inadequate healthcare facilities.⁹⁰ For example, medicines and vaccines which are offered free of charge often do not reach the patients who need these medicines.⁹¹ Further, a considerable body of evidence demonstrates that price controls contribute to lower investment in pharmaceutical research and development, ultimately harming patients who are in need of improved therapies.⁹²

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, and those patented medicines provided through health insurance. The Committee also considered whether the price negotiation of a patented medicine should be linked with its marketing approval. In 2014, an Inter-Ministerial Committee was constituted to suggest a methodology to be applied to pricing of patented medicines before their marketing in India.⁹³ The Committee is expected to take up the patented medicines pricing policy in early 2015, though it is unclear whether they will move forward with the existing recommendations or start afresh. PhRMA members are highly concerned that the existing recommendations represent an effort to significantly reduce the benefits of patent protection, which will de facto discriminate against importers, and will create an unviable government pricing framework and business environment for innovative pharmaceutical companies.

In August 2014, the National Pharmaceutical Pricing Authority (NPPA), without prior notice to industry, issued a notice setting prices for 108 non-scheduled diabetes and cardiovascular medicines beyond the scope of the existing Drugs Prices Control Order (DPCO), 2013, which sets ceiling prices for 348 essential medicines.⁹⁴ The notifications fall under Paragraph 19, which authorizes the NPPA “in case of extraordinary circumstances, if it considers necessary so to do in public interest, [to] fix the ceiling price or retail price of any Drug for such period, as it may deem fit.”⁹⁵ Subsequently, amid criticism from industry, it is reported that the DoP ordered the

⁹⁰ “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. 6, 2015).

⁹¹ “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. 6, 2015).

⁹² “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.

⁹³ Government of India Speed Post No. 31011/5/2009/PI-II(pt), Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, Subject: Inter-Ministerial Committee on Prices of Patented Drugs. New Delhi, the 17th of February, 2014.

⁹⁴ NPPA, Copies of Gazette Notifications for Ceiling Prices/retail price under DPCO, 2013, available at <http://www.nppaindia.nic.in/wh-new-2014/wh-new-44-2014.html> (last visited Feb. 6, 2015).

⁹⁵ Drugs (Prices Control) Order, 2013. Published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section(ii) dated 15th May 2013.

NPPA to withdraw the guideline under the DPCO that gave NPPA power to cap prices of non-essential drugs.⁹⁶ However, the notifications arbitrarily fixing the prices remain intact.⁹⁷ Further, it is reported that NPPA, without any mandate, has started an exercise to expand the National List of Essential Medicines, thus arbitrarily expanding the number of drugs subject to price control under the DPCO.⁹⁸ Transparency and predictability are paramount to a robust environment for business investment. These recent pricing decisions, as well as the broad authority granted to NPPA under this provision, do not respect the need for transparency, predictability, and trust in the decision-making process.

Finally, Paragraph 32 of the DPCO 2013 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

Presently, India permits 100 percent FDI in pharmaceuticals through the automatic route in the case of greenfield investments. FDI in the case of brownfield investments is permitted up to 100 percent under the Government approval route and subject to imposition of 'appropriate conditions'. Per this policy, outright purchases of brownfield projects require prior approval from the Foreign Investment Promotion Board (FIPB). Further, per Press Note no. 1 of 2014 issued on January 8, 2014, an additional condition was imposed for brownfield investment whereby non-compete clauses are not permitted in any of the agreements. Greater clarity is needed to eliminate ambiguities about the "appropriate conditions" that must be met for these investments. Further, these ongoing changes lead to an atmosphere of uncertainty for potential investors.

⁹⁶ Indian Express, "NPPA stripped of powers to cap non-essential drug prices," September 24, 2014, available at: <http://indianexpress.com/article/business/business-others/nppa-stripped-of-powers-to-cap-non-essential-drug-prices/#sthash.sbDX0d5Q.945mHOQF.dpuf> (last visited Feb. 6, 2015).

⁹⁷ Live Mint, "PILs challenge NPPA decision on price cap," October 10, 2014, available at: http://www.livemint.com/Companies/nu4BvUYJr78YhcZhTo005M/PILs-challenge-NPPA-decision-on-price-cap.html?utm_source=copy (last visited Feb. 6, 2015).

⁹⁸ Indian Express, "Denied once, NPPA begins work on new drug price control list," October 18, 2014, available at: <http://indianexpress.com/article/business/business-others/denied-once-nppa-begins-work-on-new-drug-price-control-list/#sthash.luSz5ekH.dpuf> (last visited Feb. 6, 2015).

Clinical Trials & New Drug Approvals

India has many of the components of an effective regulatory system, such as institutional capacity across central and state regulators and a robust technical framework. India also has several components to support a broader ecosystem for clinical research and drug development, such as the presence of a highly skilled workforce of qualified scientists, hundreds of medical colleges, and a large and diverse patient pool. Still, India faces the consequences of a burdensome and unpredictable regulatory environment as clinical trials move out of the country⁹⁹ and new medicines face significant launch delays.¹⁰⁰

We welcome the fact that the Ministry of Health (MOH) and the Central Drugs Standard Control Organization (CDSCO) have undertaken regulatory reform efforts with the goal of strengthening the regulatory regime. However, inconsistencies and ambiguities continue to prevail in the Indian regulatory space resulting in lack of clarity among trial sponsors about the process and procedure for clinical trials approval in India. In particular, the ambiguities in the definition of “trial related injury,” and audio-visual recording of the consent taking process make the regulatory process increasingly cumbersome. 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.¹⁰¹ The Government recently issued a proposal to enhance procedures for gathering and monitoring key information, particularly concerning patients. 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 patients.

Further, despite the July 3, 2014 CDSCO Office Order on waiver of local clinical trial requirements, industry still faces inconsistent application of requirements for local clinical trial data for approval of new drugs. While a Technical Committee, constituted by the MOH, has recommended development of a list of serious/life threatening diseases and the diseases of special relevance to the Indian health scenario where waiver of local clinical trial data for approval of new drugs can be considered, absence of any such list still leads to ambiguity. Greater clarity and predictability are needed for administrative procedures of drug registration applications and drug review standards and procedures.

Additionally, industry faces inconsistent application of requirements for local clinical trial data for approval of new drugs per CDSCO Guidance for New Drug Approvals.¹⁰² Under the current norms, all new drugs which have not been used in India

⁹⁹ Asia Sentinel “Southeast Asia Steals Indian Pharma,” July 14, 2014, available at <http://www.asiasentinel.com/econ-business/southeast-asia-steals-indian-pharma/> (last visited Feb. 6, 2015).

¹⁰⁰ Ernst R. Berndt and Iain M. Cockburn. The Hidden Cost of Low Prices: Limited Access to New Drugs in India. *Health Affairs*, 33, no.9 (2014): 1567-1575.

¹⁰¹ See <http://www.thehindu.com/sci-tech/health/videorecording-of-consent-for-clinical-trials-mandatory/article5380622.ece> (last visited Feb. 6, 2015).

¹⁰² CDSCO, “Guidance for New Drug Approval.” July 2011.

have to undergo trials on a specified minimum number of patients to gain marketing approval from the Drug Controller General of India (DCGI). However, the DCGI can grant an exemption if deemed to be in the “public interest.” Greater clarity and predictability are needed for administrative procedures of drug registration applications and drug review standards and procedures.

Import Policies

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 \$1.15B¹⁰³ in comparison to the \$1.22B¹⁰⁴ 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 with the World Health Organization (WHO) estimating that one in five drugs made in India are counterfeit.¹⁰⁵ 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, 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

¹⁰³ High Level Expert Group (HLEG) report on Universal Healthcare Coverage for India 2011, Instituted by Planning Commission of India.

¹⁰⁴ 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.

¹⁰⁵ WHO, “Counterfeit Medicines. Fact Sheet.” Revised 14 November 2006, available at http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html (last visited Feb. 2, 2015).

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 2014 attributable to trade barriers related to intellectual property protection and market access.

INDONESIA

PhRMA and its member companies operating in Indonesia remain concerned with the country's discriminatory market access barriers as well as limited anti-counterfeiting enforcement efforts. 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:** In the past 10 years (2004, 2007, and 2012), Indonesia has issued "government use"-type compulsory licenses (CLs) on nine patented pharmaceutical products despite concerns raised by the affected PhRMA member companies. PhRMA is troubled by Indonesia's decision to issue these licenses, which were promulgated without attempts to engage the affected PhRMA member companies in discussions to find more sustainable and long-term solutions and in a manner that appears inconsistent with Indonesia's international obligations. 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.
- **Ministerial Decree 1010 and 1799:** The local manufacturing and technology transfer requirements of Decree 1010 are discriminatory, implementation is not consistent, and they 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.
- **Registration Issues:** PhRMA's member companies continue to face burdensome regulatory delays in the registration process of new products, in contravention of Indonesia's own regulations. We understand that efforts to achieve stronger conformance with international best practices are being made with respect to regulatory timelines and processes as part of the ASEAN Pharmaceutical Regulatory Harmonization. We encourage the Indonesian Government to also make efforts to achieve stronger conformance with international best practices with respect to regulatory data protection and bioequivalence requirements.
- **Health Law:** On January 1, 2014, Indonesia implemented a Universal Health Care program (JKN) that currently covers approximately 50% of Indonesia's population and is intended to cover the full population by 2019. While the innovative pharmaceutical industry commends and supports the Indonesian

Government's efforts to date, challenges include inadequate financing, limitations in the existing healthcare infrastructure and unclear guidelines

- **Mandatory Halal certification:** On September 25, 2014, Parliament passed the Halal Products Law. As written, the Law has broad application to all consumables including pharmaceuticals and requires that producers label their products as "halal" or as "non halal", based on whether the products are halal certified. PhRMA's member companies are strongly supportive of religious and cultural sensitivities, but are concerned that this mandatory labeling requirement could have unexpected negative implications on patient health.
- **Pharmaceutical Reimbursement:** The selection criteria for new molecules to be listed on the Indonesian National Formulary (FORNAS) remains unclear. There is a lack of clarity over how products are selected for the formulary and whether these products will stay on the formulary. The pharmaceutical industry urges the Indonesian government to work with stakeholders to develop a methodology that explains the formulary selection process. In addition, decisions regarding approvals should be based on science and efficacy of a new medicine and the process should be clearly defined.

For these reasons, PhRMA requests that Indonesia remain on the **Priority Watch List** for the 2015 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 the past decade, Indonesia issued compulsory licenses (CLs) on 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 willing to work 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 their global pharmaceutical supply chains. 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 after the first importation with some exceptions, e.g., products under patent protection. 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. Following consultations between industry and the new leadership at the BPOM, there appears to have been some recent flexibility in the local manufacture requirement. 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

Registration Issues

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.

PhRMA's Members are encouraged to note that BPOM plans to hire 20 additional registration staff in 2015. Both BPOM and the industry have agreed to improve the know-how and skills of their registration staff in order to improve the timeliness of the regulatory review process.

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.

PhRMA's member companies strongly support the Government of Indonesia's efforts to implement a Universal Healthcare program. However, industry is concerned that current infrastructure and financing levels will be insufficient to achieve Indonesia's aspiration of full patient coverage by 2019. Industry, therefore, stands ready to work with the Indonesian Government and other stakeholders to expand universal healthcare in Indonesia in a manner that is both sustainable and that does not dilute the quality of healthcare available to Indonesian patients.

Mandatory Halal Certification

Indonesia's Mandatory Halal Certification Bill, enacted in September, 2014, mandates Halal certification and Halal labeling for food and beverages, medicines, cosmetics, chemical products, biological products, and genetically-engineered products. The legislation establishes a new Halal certification authority, and requires 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, but are concerned that this Act may have negative implications for patient health. In particular, significant questions remain regarding the process for securing halal certification and how the government will ensure that the new requirements do not impact patient access to the medicines they need.

Negative Investment List (NIL)

In 2014, the Government of Indonesia amended the NIL to increase the percentage of foreign ownership allowed in pharmaceutical firms designated as manufacturers from 75 percent to 85 percent. Many multinational research-based pharmaceutical companies are currently classified as distributors, or "PBF" enterprises, and many 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 85 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.

Lack of Transparency

The Indonesian Government's policies and regulations are regularly developed and implemented without providing multinational companies 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 extend access to its formal consultation process to incorporate input from stakeholders in the multinational private sector.

Counterfeit 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. Although new leadership at BPOM have focused their efforts on combatting counterfeit food and medicine products, the budget and resources for this effort remain inadequate. 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 2014 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 Korea's commitments in 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, the Ministry of Food and Drug Safety (MFDS) should ensure that the effective patent enforcement mechanism is based on the patents as granted by the Korean Intellectual Property Office and that new uncertainties are not embedded in the Korean system. Also, new proposed legislation on patent infringement damages sponsored by MOHW is likely to undermine this effective patent enforcement mechanism.
- **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 the South Korea-U.S. Free Trade Agreement (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 2015 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 an effective enforcement system for patents that was intended to implement some of its IP obligations under KORUS.¹⁰⁶ 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 have expressed concerns that it includes 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 presence of rewritten or amended claims alongside the patents as granted by the Korean Intellectual Property Office (KIPO) could create legal confusion and increase uncertainty for innovators and generics alike.

Unfortunately, legislation drafted in July 2014 to implement the effective patent enforcement system does not adequately address or explain MFDS’s practice of creating amended patent claims that differ from the patent claims granted by KIPO. As part of implementing the patent enforcement legislation, MFDS should ensure that the system operates only on the basis of the patents as granted by the KIPO (for example, for purposes of the proposed sales stay) and that new uncertainty is not embedded in the Korean system. PhRMA and its member companies continue to urge the Korean Government to use this opportunity to address the existing confusion and create greater business certainty for both innovators and follow-on manufacturers.

Additionally, MOHW has proposed amendments to the National Health Insurance Act in July 2014 that include a provision enabling the Korean Government to recover “improper profits” gained by original drug manufacturers as a result of an injunction (or an automatic stay of regulatory approval of a generic version of the innovator’s drug). Specifically, the draft provision would punish patent owners for enforcing their patent rights and would deter enforcement of intellectual property rights in a way that is both troubling and contrary to well-accepted international norms. Further, the proposed amendments undermine the purpose of the patent enforcement mechanism, which is intended to provide a balanced and predictable approach for resolution of patent disputes before launch of a follow-on product between follow-on companies (who have the benefit of being permitted to engage in acts that would otherwise be considered infringement of patents in order to prepare for launch of the follow-on drug) and innovator companies (who have the intellectual property rights granted to them through the patent(s) issued by the government).

¹⁰⁶ See U.S.-Korea Free Trade Agreement, Art. 18.9, para. 5.

Market Access Barriers

Predictability and Transparency in Government Policy-making

Since 2010, MOHW has repeatedly changed its pharmaceutical pricing and reimbursement policies without considering the long-term implications for innovation and market predictability, and in some cases disproportionately targeting innovative pharmaceutical companies. In spite of significant input from the pharmaceutical industry regarding the need to appropriately value innovative medicines following the 2012 global price cut, no progress has been made and subsequent consultation processes have proven perfunctory in most cases. This lack of predictability and transparency results in an uncertain business environment for the innovative pharmaceutical industry.

In addition to the substantial price cuts in 2012, MOHW announced in September 2013 that it would impose additional price constraints through its price-volume agreement (PVA) regime. Under the new rules, the PVA goes into effect if the reimbursement amount exceeds 10% of the amount reimbursed in the prior year and KRW 5 billion for the year. Pharmaceutical companies are concerned that the revised PVA, contrary to Korea's obligations under KORUS FTA, will not appropriately value innovative medicines during the patent period and will disproportionately harm innovative companies.

PVA should be applied in a flexible manner that ensures drug prices are predictable even when estimated volume fluctuates.

Separately, the Risk Sharing Agreement (RSA) system should be expanded to provide an alternative pathway for reimbursement listing to enhance patient access to innovative medicines regardless disease area and without the need to submit unrealistic statistical data. Currently the RSA is limited to rare or cancer disease areas only and dependent on submission of pharmaco-economic data with no exception.

Government price reductions have dramatically reduced revenues for both the domestic and multinational pharmaceutical industry operating in Korea, decreasing incentives for further investments in innovation. Government price cuts along these lines continue to create an unpredictable operating environment for innovative pharmaceutical companies that rely on long-term planning to make the vital investments necessary for the development of new medicines. These measures have significant impacts in other markets around the world given the number of countries that directly or indirectly reference Korean prices. 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, unpredictable and arbitrary government price reductions may discourage the investments required for the research-based pharmaceutical industry to grow and thrive.

Recent Reform Measures Adversely Impact New Product Pricing

In Korea, prices of new drugs are determined based on the weighted average price within the therapeutic class, including the prices of off-patent and generic drugs. As a result, government measures lowering existing drug prices impact, by extension, new drug pricing. In other words, 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 are inappropriately depressed.

The reimbursement prices of new drugs under the previous Drug Expenditure Rationalization Program has been far too low, less than half of the average OECD price for new drugs.¹⁰⁷ The further reductions of existing drug prices will therefore likely lead to significantly lower prices of new drugs in Korea.

In addition to very low prices, during 2007-2012 only 64% of rare disease drugs and 56% of oncology drugs applied for reimbursement listing have passed,¹⁰⁸ raising a significant patient access problem in the country.

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 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, and as such is making "determinations." Local data indicates that from 2007 through 2012, NHIS determined not to reimburse 59 (20.3%) of the 291 new medicines for which it was tasked to negotiate the reimbursed price. For anti-cancer drugs, the rejection rate (37.9%) was even higher – NHIS decided to reimburse only 18 of the 29

¹⁰⁷ EK Lee, "Price comparison among OECD countries" (2013).

¹⁰⁸ HIRA report (2012).

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 or 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. In light of the strict penalties for unethical business practices – including price reductions and since July 2, 2014, suspension or revocation of listing of medicines on the reimbursement list – it is critical that there is a clear understanding of how the EBP standards will be enforced.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 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 direction the Government of New Zealand is taking with respect to broader intellectual property protection as well as the policies and operation of New Zealand's Pharmaceutical Management Agency (PHARMAC). PHARMAC continues to impose stringent cost containment strategies,¹⁰⁹ 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 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 2015 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

¹⁰⁹ 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 included 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 (PBS) in Australia between 2000 and 2009, only 59 (43 percent) received reimbursement in New Zealand.¹¹⁰ 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.

¹¹⁰ 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 2014 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 commend 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 does not sufficiently value innovative medicines. The system would benefit from 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 to better provide Thai patients with life-saving pharmaceutical treatments.
- **Counterfeit medicines:** PhRMA's member companies recognize the advancements made by the Royal Thai Customs in enforcing intellectual property rights, but encourage 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 remain on the **Priority Watch List** for the 2015 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

Despite assurances that Thailand would be judicious in its use of compulsory licenses and consult with affected parties as required by the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Thailand continues to maintain a regime that uses the threat of compulsory licenses to force companies into unfair price negotiations. Further, royalty payments have not been made on products for which compulsory licenses have been issued. Thailand's compulsory licensing regime lacks sufficient due process and dialogue with affected companies, and suffers from a lack of transparency in the reasoning behind compulsory license decisions.

Patent Examination Backlog

In 2013, Thailand's Department of Intellectual Property 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 Patent Examination Guidelines were intended to 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, including 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. Further, 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, thereby reducing the effective patent term and 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, advances, 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 or 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.

Effective 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 are marketed. Effective patent enforcement could greatly enhance the business environment in Thailand by: (1) providing transparency and predictability to the process for both innovative and generic firms; (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 pharmaceutical industry would like to better understand the overall selection criteria and process for setting the ceiling purchasing price, known as the “Median Price,” for public procurement in Thailand. The current methodology and implementation of the Median Price setting process lacks clarity and transparency. The decision making process on the Median Price has been implemented in an *ad hoc* manner and often favors government GPOs. The government has selectively referenced generic prices to price innovative, life-saving medicine. The process has been implemented in a manner that is often arbitrary in nature. The government of Thailand should revise the current process to ensure that the pharmaceutical industry has an opportunity to provide timely input about innovative products for Thai patients. Greater stakeholder engagement between the pharmaceutical industry and the government regarding pricing decisions that affect the availability of innovative medicines for Thai patients would be mutually beneficial.

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.

New Drug Act Amendment

Thailand's new amendment to the Drug Act presently awaits approval by the Cabinet for passage to the National Legislative Assembly. Key concerns expressed by the innovative biopharmaceutical industry include articles related to patented medicines that would enable the regulatory authority to deny marketing authorization based on price and cost-effectiveness.

This proposed legislation disproportionately impacts innovative medicines, threatens patient access to innovative therapies, and undermines the government's goals of making Thailand a regional trading center and a leader in the area of medical innovation. The innovative biopharmaceutical industry recommends that the draft legislation be opened to comment through a transparent consultation process before it is passed on to the National Legislative Assembly.

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 (MoU) 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 2014 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 requirements:** Contrary to the Canadian Patent Act (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 and inequitable eligibility requirements on the listing of patents in the Patent Register. Recent jurisprudence under the regulations has also resulted in a heightened level of liability for lost generic manufacturer profits in cases where the innovator has sought an injunction but is ultimately unsuccessful.
- **Lack of patent term restoration:** Canada's intellectual property regime currently provides no form of patent term restoration (PTR). PhRMA member companies believe Canada should support innovation by adopting a PTR system consistent with the U.S. and other developed nations to ameliorate the effects of delays caused by its regulatory processes, which can significantly erode the duration of the intellectual property rights of innovators.
- **Standard for the disclosure of confidential business information:** In November, Canada enacted legislation to update its Food and Drugs Act (Bill C-17). Provisions in that law granted the Health Minister discretion to disclose a company's confidential business information (CBI) without notice to the owner of the CBI and in accordance with a standard that is both inconsistent with other similar Canadian legislation and Canada's treaty obligations under NAFTA and the TRIPS Agreement.

For these reasons, PhRMA requests that Canada be placed on the **Priority Watch List** for the 2015 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Heightened Utility Requirements

PhRMA members are concerned that recent decisions by the Canadian judiciary have created a heightened standard of patentable utility for pharmaceutical patents that is both inconsistent with common practice in other major countries and unpredictable, in practice, in Canada. This heightened standard has done great damage to the patent rights of innovative U.S. pharmaceutical companies.¹¹¹ 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, as these heightened standards have been applied nearly exclusively to pharmaceutical patents. Furthermore, as a result of mixed and conflicting case law from the Canadian court system on the heightened utility requirement, 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 from the Canadian Intellectual Property Office.

In Canada, innovators are now required to “demonstrate” or “soundly predict” the utility of a pharmaceutical as “promised” at the time of filing the patent application. Such a standard is fundamentally inconsistent with TRIPS, as well as the realities of 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.” 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 medicines and, in the long run, negatively affects the patients and families who rely upon our sector to innovate new cures and treatments.

¹¹¹ See, e.g., *Merck & Co. Inc. v. Apotex Inc.*, 2005 FC 755; *Abbott Laboratories v. Canada (Minister of Health)*, 2005 FC 1095; *Abbott Laboratories v. Canada (Minister of Health)*, 2005 FC 1332, aff'd 2007 FCA 153; *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283, aff'd 2006 FCA 64; *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 26, aff'd 2007 FCA 195; *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, aff'd 2009 FCA 97; *Shire Biochem Inc. v. Canada (Minister of Health)*, 2008 FC 538; *Glaxosmithkline Inc. v. Pharmascience Inc.*, 2008 FC 593; *Eli Lilly Canada Inc. v. Novopharm Limited*, 2009 FC 235; *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2009 FC 676, aff'd 2011 FCA 300; *Ratiopharm Inc. v. Pfizer Limited*, 2009 FC 711, aff'd 2010 FCA 204; *Lundbeck Canada Inc. v. Ratiopharm Inc.*, 2009 FC 1102; *Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.*, 2010 FC 230; *Pfizer Canada Inc. v. Ratiopharm Inc.*, 2010 FC 612; *AstraZeneca Canada Inc. v. Apotex Inc.*, 2010 FC 714; *Eli Lilly and Company v. Teva Canada Limited*, 2010 FC 915, aff'd 2011 FCA 220; *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, rev'g 2010 FC 447; *Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288, aff'd 2012 FCA 232; *Pfizer Canada Inc. v. Pharmascience Inc.*, 2013 FC 120; *Novartis Pharmaceuticals Canada Inc. v. Teva Canada Limited*, 2013 FC 283; *Alcon Canada Inc. v. Cobalt Pharmaceuticals Co.*, 2014 FC 149; *AstraZeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638; *Pharmascience Inc. v. AstraZeneca Canada Inc.*, 2014 FCA 133, rev'g 2012 FC 1189.

The Supreme Court of Canada (SCC) granted leave on a patent utility case early in 2014, and many stakeholders had hoped the SCC would provide some guidance or clarity on the issue.¹¹² However, the parties in that appeal settled prior to oral argument. More recently in December 2014, Apotex Inc. and Mylan Pharmaceuticals ULC each filed SCC applications for leave to appeal a Federal Court of Appeal decision in 2014 FCA 250 with respect to the promise doctrine. In light of these developments and the current unpredictability of the case law, PhRMA members urge the U.S. Government to press the Government of Canada to resolve this issue through, for example, clarifying amendments to the Patent Act. 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 realities 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

¹¹² On January 30, 2014, the SCC granted leave to Apotex to appeal a July 2013 Federal Court of Appeal (FCA) order declaring Sanofi’s PLAVIX® patent to be valid and infringed. (*Apotex Inc., et al. v. Sanofi-Aventis, et al.* (SCC Case No. 35562).

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 in PM (NOC) Proceedings

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 a 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.¹¹³ 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. Moreover, irreparable harm often results by the time the patent owner obtains a favorable decision in such a separate infringement case.

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. 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 in a way that will ensure there is a meaningful and effective right of appeal for patent owners while maintaining other patent enforcement tools.

While 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, these interlocutory injunction motions rarely succeed in Canada even if there is 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.¹¹⁴ By then, the innovative 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.

¹¹³ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359.

¹¹⁴ 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 patent if it obtained a Notice of Compliance (NOC). This judgment has also been appealed, further delaying any eventual damages award.

These various deficiencies frequently result in violations of the patent rights of PhRMA member companies operating in Canada with attendant, and often irreparable, economic losses.

PhRMA understands that the unratified final text of the Comprehensive Economic Trade Agreement (CETA)¹¹⁵ negotiated between Canada and the European Union contains a commitment to provide all litigants equivalent and effective rights of appeal, but the Canadian government has yet to provide any clarity with respect to how it will implement this commitment. PhRMA therefore will be closely monitoring the implementation of this commitment to ensure that the Government of Canada rectifies 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.

3. Limitation on Listing of Valid Patents and Inequitable Listing Requirements

Patent owners continue to be prevented from listing their patents on 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.

PhRMA members are also concerned with recent jurisprudence which held that an innovator cannot list a patent claiming a single medicinal ingredient of a Fixed Dose Combination (FDC) product on the Patent Register.¹¹⁶ This is contrary to Health Canada's long standing policy, as set out in the Health Canada Guidance Document, which explicitly allows for such a practice.¹¹⁷ As a result of this recent jurisprudence, the law now requires that a patent precisely claim all medicinal ingredients contained in the FDC product as approved in the Notice of Compliance.

The impact of this jurisprudence is significant since many FDC drugs on the Patent Register may be impacted by these decisions. Furthermore, new FDCs that obtain market approval will also be ineligible for listing. The effect of this ineligibility is that a patent cannot obtain the benefits of the PM (NOC) Regulations, such as the regulatory stay preventing immediate generic market entry.

¹¹⁵ See CETA, Final Text as of Sept. 26, 2014, as published by the European Commission, available at http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf (last visited Feb. 6, 2015).

¹¹⁶ The three decisions from which this issue arose are: *Gilead Sciences Inc. v. Canada (Minister of Health)*, 2012 FCA 254; *ViiV Healthcare ULC v. Teva Canada Limited et al*, 2014 FC 328; and *ViiV Healthcare ULC v. Apotex Inc. et al*, 2104 FC 893. ViiV has appealed these decisions.

¹¹⁷ Available at, http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/patmedbrev/pmreg3_mbreg3-eng.pdf (last visited Feb. 6, 2015).

Industry Canada recently indicated that they are working to amend the PM (NOC) Regulations to restore Health Canada's previous practice.¹¹⁸ PhRMA urges the U.S. Government to press the Government of Canada to expedite the amendments and to implement them in a manner that will prevent any harmful effects to its members.

4. Heightened Level of Liability for Lost Generic Profits.

The PM (NOC) Regulations allow an innovator to seek an order preventing a generic manufacturer from obtaining Notice of Compliance, on the basis that the innovator's patent covers the product and is valid. When the innovator seeks such an order, but is ultimately unsuccessful, Section 8 provides the generic manufacturer the right to claim lost profits for the period of time they could have been selling the product, but for the innovator's action. PhRMA members are concerned that Canadian courts have taken an approach to Section 8 damages that allows for excessive damages that are punitive in nature. The SCC recently granted leave with respect to a Section 8 damages case which is expected to go before the Court in 2015.¹¹⁹ PhRMA members urge the U.S. Government to notify the Government of Canada of the inequitable damages assessments that have arisen from recent Section 8 related decisions.

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 European Union 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. Canada's intellectual property regime includes no form of PTR system.

PhRMA member companies believe Canada should support innovation by adopting PTR to ameliorate the effects of delays caused by its regulatory processes, which can significantly erode the duration of the intellectual property rights of innovators.

PhRMA members urge the U.S. Government to engage with the Government of Canada on this issue, and encourage Canada to join the ranks of other industrialized countries who are champions of intellectual property protection internationally and to provide for PTR measures in Canada. The unratified final CETA text indicates that Canada has agreed to implement a "*sui generis* protection" period of between 2 to 5 years (noting, however, that the Government of Canada has separately stated that it

¹¹⁸ See http://www.ic.gc.ca/eic/site/020.nsf/eng/h_00595.html#sp_5

¹¹⁹ On November 3, 2014, the SCC granted leave to Sanofi-Aventis to appeal a March 2014 Federal Court of Appeal decision (*Apotex Inc. v. Sanofi-Aventis et al*, 2014 FCA 68) requiring Sanofi-Aventis to pay damages that are in effect punitive.

only plans to implement the minimum level of 2 years required by CETA).¹²⁰ Steps taken by Canada to implement meaningful protection that is equivalent in duration and effectiveness to the PTR regimes in the U.S. and in other developed nations (e.g., up to 5 years) would constitute an important positive precedent for further dialogue and negotiations with other developed and developing nations in other forums on these same issues. PhRMA is also concerned that the *sui generis* protection will not grant the full patent protections that PTR is intended to provide, i.e., may be implemented at the expense of other patent rights for innovators.

Standard for the Disclosure of Confidential Business Information

PhRMA members are concerned with provisions of the recently enacted Bill C-17, An Act to Amend the Food and Drugs Act,¹²¹ which could allow for an unprecedented disclosure of CBI contained in clinical trial and other data submitted by pharmaceutical companies to Health Canada in the course of seeking regulatory approval for medicines. The amendments could significantly impact incentives for drug innovation and are inconsistent with Canada's international treaty obligations.

There is particular concern surrounding issues of confidentiality, the definition of CBI and the threshold for the disclosure of CBI by Health Canada to governments and officials, as well as to the public. These amendments are inconsistent with the standards set out in other Canadian federal health and safety legislation, are inconsistent with Canada's treaty obligations under NAFTA and TRIPS, and are also inconsistent with the standards and practices of other national health regulators, including the FDA.

Moreover, the amendments do not differentiate between trade secrets and confidential business information, as is the case in the U.S. This is concerning in light of the lower disclosure thresholds that have also been implemented. Both NAFTA and the TRIPS Agreement require that CBI be protected against disclosure except where necessary to protect the public. For disclosure to the public, the amendments require a "serious risk," but it does not reach the standard set out in the treaty language since subjective and discretionary language has been included: the Minister may disclose CBI "if the Minister believes that the product may present a serious risk of injury to human health." (Emphasis added.) As such, it is not necessary that there be a serious risk of injury to justify the disclosure; rather the amendments merely require that the Minister believes the disclosure to be necessary.

The amendments also state that the Minister may disclose CBI to a person who "carries out functions relating to the protection or promotion of human health or safety of the public" and this can be done "if the purpose of the disclosure is related to the

¹²⁰ See <http://www.actionplan.gc.ca/sites/default/files/pdfs/ceta-technicalsummary.pdf> at p.19 (last visited Feb. 6, 2015).

¹²¹ See

<http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=6676418&File=4> (last visited Feb. 6, 2015).

protection or promotion of health or safety of the public.” There is no necessity requirement for the disclosure to occur, only that it be related to protecting or promoting health. NAFTA and TRIPS do not refer to disclosure for the promotion of health, but rather to disclosure needed to protect the health of the public.

Finally, the amendments provide inadequate protections to ensure that there is no unfair commercial use of the disclosed CBI as required by TRIPS Article 39.3. The potential recipients of the disclosed CBI are very broad, and there is no mechanism, such as a confidentiality agreement, to ensure that those recipients (or anyone else to whom they disclose that data) are not able to use the divulged CBI to secure an unfair commercial advantage.

PhRMA and its member companies raised concerns about these provisions in Bill C-17 prior to its passage. Those discussions with the Canadian Government have led to further consultations post-enactment with respect to the guidelines that will be used to administer the data disclosure process. Those guidelines may positively address some of the issues set out above, but are internal administrative guidance as opposed to binding law or regulations.

PhRMA members urge the U.S. Government to press the Government of Canada to ensure that the implementing regulations are consistent with Canada’s international treaty obligations.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2015 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

HUNGARY

PhRMA's member companies have been facing severe market access barriers in Hungary since the first implementation of the Hungarian Pharmacoeconomic Act (XCVIII/2006). The "Széll Kálmán Savings Plan" (2012-2014) decreased the retail pharmaceutical budget in 2012 by 15%, where it has since remained.

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 600 days. Currently there are 35 new active ingredients/new indications submitted for reimbursement, 14 of which are awaiting approval under a new item-based reimbursement system. 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 submission of new molecules or indications, resulting in some cases the lowest net prices around the world due to mandatory discounts in the form of sales taxes, non-transparent compulsory price-volume agreements and tender rebates. Future predictability is largely threatened by the claw-back system, under which pharmaceutical companies are held financially responsible for the overspending of the annual 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.
- **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 active ingredient is reimbursed in at least three of those Member States.
- **Biosimilar reimbursement rules:**
 - **Retail: Annual blind bidding system for biologics:** Bidding groups are selected based on the same indication (Jumbo grouping) resulting in the

delisting of any patented products in each group (unless strict price reduction rules are met). At least two products should remain in the preferred product range (reference price plus 10%) to ensure safe patient supply.

- **Item based reimbursement:** Under this new approach, Hungary invites separate item-specific tenders for the treatment of new patients and maintenance therapy.
- **Lack of effective dialogue between government and innovative companies:** 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. Conversely, local (generic) manufacturers participating in the 'Strategic Agreement with the Hungarian State' benefit from a protectionist economic policy and have direct channels to high level politicians and decision makers.

For these reasons, PhRMA requests that Hungary be placed on the **Priority Watch List** for the 2015 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). 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 to 4-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 and biologics occurring annually in the retail segment. The therapeutic reference groups have been created in a non-transparent manner;

- Regulated annual public procurement tender for high-value medications under the new item-based reimbursement system, subject to high rebates/discounts and applying strict quota system to control demand.
- 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. No opportunity to appeal reimbursement decisions;
- Delay in publication of the updated 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, while social and economic burden of disease is often disregarded.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 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 significant intellectual property issues, including patentability restrictions, the patent application backlog, and the lack of regulatory data protection as well as limitations on the transfer of capital abroad, and non-transparent import requirements.

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) established 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 (WTO) 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 restricts 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 2014.

For these reasons, PhRMA requests that Argentina remain on the **Priority Watch List** for the 2015 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 patentability 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, La Cámara Argentina de Especialidades Medicinales (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.

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

Argentina should accede to the Patent Cooperation Treaty (PCT), a step that would facilitate the filing and examination of patent applications in Argentina as it does now in more than 140 Contracting Parties. Accession to the PCT could allow Argentina to reduce its current patent application backlog and use the PCT system to reduce the review period for future patent applications. Although the Argentinean Senate approved Argentina’s accession to the Treaty in 1998, 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 or 2014, and will not likely be included in the 2015 Congressional agenda.

The Ministry of Economy and INPI took a number of significant steps to reduce the backlog of patent applications awaiting examination between 2005 and 2007. 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 is approximately 21,000 applications.

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 and burdensome; very few injunctions have been granted since 2005.

Market Access Barriers

Import Restrictions

In 2012, the Argentine administration 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. PhRMA applauds the January 15 ruling by the WTO Appellate Body finding that the restrictions are a breach of Argentina's WTO commitments, and trusts that Argentina will take action to bring itself into compliance. Although PhRMA member companies have not reported significant delays or rejections to import pharmaceutical products in 2014, 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 2014 attributable to trade barriers related to intellectual property protection and market access.

BRAZIL

PhRMA and its member companies operating in Brazil remain concerned regarding inadequate patent enforcement and regulatory data protection, non-transparent government pricing policies, and discriminatory patentability standards and patent procedures.

Key Issues of Concern:

- **Patentability standards and patent procedures:** Amendments to the Brazilian Patent Law in 1999 added Article 229-C, which inappropriately permits the health regulatory agency (ANVISA) to review all patent applications for pharmaceuticals products and/or processes, resulting both i) in application of patentability requirements contradictory and/or additive to those established by Brazilian Patent Law and adopted by the Brazilian Patent Authority (INPI) and ii) in duplicative, prolonged patent review processes that contribute to the already existing patent backlog that averages more than 10 years.
- **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 222 “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. To date, 48 lawsuits have been filed, 18 of which have been decided at the trial level.
- **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)¹²² 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.

¹²² 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 be placed on the **Priority Watch List** for the 2015 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 and Patent Procedures

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 of the potential sanitary risk aspects of the subject matter 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 of the patentability requirements by ANVISA. 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. As a result, the local innovative pharmaceutical industry association, INTERFARMA, has challenged the resolution in court. In addition, INPI has recently started blocking patent applications previously reviewed by ANVISA. This has caused additional patent examination delays and highlighted the challenge presented by ANVISA’s resolution.

Regulatory Data Protection (RDP)

Contrary to Article 39 of the TRIPS Agreement, Brazil continues to allow Government officials to grant marketing approval to third parties 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 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).¹²³ Per the binding opinion, 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" – the minimum 10 years of protection from the date that the patent was granted is not available.

¹²³ It should be noted that ABIFINA, a Brazilian association representing national companies with chemical interests, including many generics companies, recently filed a legal action in Brazilian court challenging the constitutionality of Brazil's guarantee of a minimum patent term of 10 years for all patents. The 10-year minimum has been critical for biopharmaceutical innovators, particularly in light of INPI's notorious patent review delays (discussed below). As such, INTERFARMA, among others, has successfully petitioned to participate in the legal action as *amicus curiae*.

Under Brazil's Patent Law, approximately 220 mailbox patent applications were granted a minimum of 10 years patent protection under Paragraph One of Article 40. In other words, because the patent applications were not reviewed within 10 years, the resulting patents qualified for the 10-year minimum protection provided by 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. To date, INPI has filed 48 lawsuits in Federal District Courts against the impacted mailbox patent holders seeking to invalidate their patents. Since April 2014, there have been six settlements and 18 trial level decisions. Adding to the uncertainty, eight of the 18 decided cases have ruled in favor of the patent-holder, with the remaining ten decided in INPI's favor.

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*. The elimination of the 10-year minimum term for these mailbox patents is particularly galling when the only reason for this minimum level of protection is that it took INPI more than 10 years to review the patent application. 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 (the most recent data available), 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 Rouseff authorized funding and filled new examiner positions in the last two years (including in the pharmaceutical and biotech fields), the addition of these new examiners has not mitigated the backlog.

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.

PhRMA notes with encouragement that the Brazilian Government has recognized the inaccuracy of the current price formula and is in the process of assessing possible modifications in the legal framework that regulates the annual price adjustment. We continue to believe 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).¹²⁴

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 does not adequately define the compensation that 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 PDPs, greater transparency in the process of selecting technological partners is required. Today, the processes, terms and conditions for companies interested in participating in PDPs 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

¹²⁴ The current tax system penalizes Brazilian patients that pay more taxes on medicines (approximately 32%) than any other population in the world.

(BNDES) and international partners without the necessary background and/or certified sanitary processes is causing delays in the deliveries of some PDPs. In other cases, technology providers that entered into PDP 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 competition and impedes Brazil's ability to foster local technology development in the pharmaceutical area.

A new PDP regulation (Portaria 2531/14) was issued in 2014 with participation of the private sector, which on its face appears to provide greater transparency and predictability. As yet, however, the new regulation is untested with no PDPs announced using the new model.

Bearing this in mind, PhRMA and our local sister association stand ready to contribute to this dialogue and the ongoing consultations to ensure that this mechanism does not lead to discriminatory treatment that could limit our members' 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.

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 commend ANVISA for hiring 280 new technicians and hopes that this will help the agency to reduce timelines in analysis of line extensions and other petitions. Other improvements ANVISA should consider include:

- 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 2014 attributable to trade barriers related to intellectual property protection and market access.

CHILE

PhRMA members remain concerned about the absence of effective regulatory data protection and patent enforcement, stemming from shortfalls in implementation of Chile's obligations under its free trade agreement with the United States. PhRMA also continues to be concerned about 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. Unfortunately, this legislation, introduced over three years ago, is unlikely to move forward in the near term. 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 limited efforts regarding implementation of IP-related obligations under the U.S.-Chile Free Trade Agreement, 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 2015.

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 would support 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).

PhRMA welcomed the government's work to introduce relevant draft legislation in January 2012. Unfortunately, that legislation has not received any attention since its introduction, and the impact of a lack of effective patent enforcement continues to worsen.

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. 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 (although, to industry's knowledge, this has not occurred to date);
- 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. The Industrial Property Law project sent to Congress in April 2013 as a result of this process does not include any amendments to the current RDP scheme; nor does there appear to be appetite for the Chilean Government to address RDP deficiencies at the present time.

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 a significant amount of time 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 2014 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:** The Ecuadorian Intellectual Property Institute has granted nine compulsory license petitions since 2010 and 12 applications are still pending. A compulsory license should only be granted when the need for such a license has been clearly demonstrated and in compliance with Ecuador's international obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
- **Regulatory data protection:** Although Ecuador has ostensibly taken the necessary steps to revise the Ecuadorian Intellectual Property Act to provide regulatory data protection (RDP) for undisclosed test data, the actual protection provided remains, in practice, inadequate.
- **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 medical use, in violation of TRIPS Article 27.1, and contrary to long-standing precedents.
- **Excessive patent fees:** Since October 2012, patent fees have significantly increased in Ecuador, in many cases far above fees for comparable services in other countries.
- **Government price controls:** In July 2014, Ecuador issued Decree 400 which establishes regulations for the setting of prices for medicines for human use and consumption. The Decree regulates government pricing for three categories of medications – Regulated, Direct Fixation and Free Pricing – but there remains significant uncertainty as to how the Decree will be implemented.

For these reasons and other emerging IP concerns, including Ecuador's Decree 522, PhRMA requests that Ecuador be placed on the **Priority Watch List** for the 2015 Special 301 Report. This is a change from PhRMA's requests in previous years to reflect the deteriorating IP environment in Ecuador. PhRMA urges the U.S. Government to continue seeking assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Compulsory Licensing

In October 2009, Ecuador issued Executive Decree No. 118, a compulsory license decree with the stated intent of improving access to medicines. Under this Decree, nine compulsory license petitions have been granted by the Ecuadorian Intellectual Property Institute (IEPI) since 2010, six of which were issued in 2014. To date, 32 applications for compulsory licenses have been presented; 12 of which are still pending, 2 were denied, 8 were desisted and 1 expired. Furthermore, ten of the 32 petitions received by IEPI were filed by Ecuador's public pharmaceutical firm, Enfarma.

PhRMA and its member companies are particularly concerned about the compulsory license process in Ecuador, in addition to the volume and rate at which such licenses are being granted. The compulsory licenses that have been granted to date have not been based on a clear demonstration of an urgent public health emergency or due process provided to the patent owners consistent with Ecuador's international obligations.

A close monitoring of this subject should be maintained to ensure that a compulsory license for a patent covering a medicine is granted only when there is a true health emergency and as a measure of last resort. Furthermore, it is critical that the guidelines for issuing 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 World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

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 Ecuadorian 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 Medical 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, including Ecuador,

have either been compelled by the ACJ not to grant second medical use patents or have chosen to honor Andean Community obligations, while ignoring their TRIPS obligations. The failure to provide patents for second medical uses adversely affects PhRMA 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.

Excessive Patent Fees

Since October 2012, fees for patents have drastically increased in Ecuador, particularly with regard to maintenance and examination fees. Maintenance fees have increased between 800% and 3529% (i.e., up to \$4,514 and \$20,760 for the 10th and 20th year, respectively). The cumulated annuities amount to \$24,964 for 10 years and \$139,767 for 20 years. These amounts are 12 and 24 times higher than Colombia, 7 and 12 times higher than Brazil, and 7 and 11 times higher than the United States, respectively.

Similarly, examination fees were raised from \$196 to between \$964 and \$1,510.40 depending on the number of pages or claims. Further, Ecuador now charges \$151.04 per page for claims exceeding 19 pages, significantly higher than the \$16 per page charged for international patent applications over 30 pages.

Other IP Concerns

In 2014, Ecuador issued Decree 522, which appears to limit the use of trademarks for any medicine once patents have expired. This measure appears to deny another important form of IP protection that is critical to ensure that innovator companies can distinguish their products from others. A trademark for a medicine helps doctors and patients identify the quality, safety, and intrinsic effectiveness of a given product – reputational capital that manufacturers strive to build over time.

Market Access Barriers

Government price controls

Ecuador has had a government price control system for pharmaceutical products since 1992. In July 2014, Ecuador passed a decree (No. 400) regulating the establishment of pricing for medicines destined for human use and consumption. Decree 400 creates three price control regulation categories: regulated, direct fixation, and free pricing.

New medicines deemed to be strategic fall within the first category – regulated – and are subject to price ceilings established by the National Council of Fixation and Revision of Prices of Medications for Human use and consumption (hereinafter the “Council”).

The second category – direct fixation – is intended to be applied in exceptional cases and consists of a unilateral determination of prices by the Council, in accordance with Decree 400. This category is used when the sale prices of a medicine has exceeded the ceiling established by the Council for the corresponding market segment, when new and strategic medications are sold that have not been previously subject to the price ceilings set by the Council, and when the holder of the sanitary registration provides false information to the government, i.e., is essentially a punitive category.

All other medicines are subject to free pricing under the third category, with the prices set by the sanitary registration holder notified to the Council, in accordance with the Decree.

This regulation has created uncertainty and unpredictability for pharmaceutical companies, due to - *inter alia* - an unclear definition of the scope of application and the criteria under which the Ministry of Health will categorize drugs as strategic under the first category of the regulation. Further, in referencing prices of products deemed to be in the same therapeutic area, the pricing system does not adequately account for differences in quality, efficacy or safety, thereby discouraging quality medicines in Ecuador, threatening patient safety and decreasing incentives to bring innovative medicines to the Ecuadorean market.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 attributable to trade barriers related to intellectual property protection and market access.

VENEZUELA

PhRMA member companies face several intellectual property and 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 unpaid debt between 2010 and October 2013, and since then payment delays 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, and price increases were suspended until mid-2013, The Law decree was reformed on January 23rd 2014, subsequent to which all medicines sold in Venezuela have been subject to government price controls that have not accounted for either inflation (62.3%) or devaluation of Venezuela's currency (46.5% for basic goods).

For these reasons, PhRMA requests that Venezuela remain on the **Priority Watch List** for the 2015 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 the local innovative pharmaceutical association, Cámara Venezolana del Medicamento (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 Administración 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 Administración 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.

In October 2013, the Government created CENCOEX (Centro Nacional de Comercio Exterior) to replace CADIVI, arguing irregularities in the previous system and lack of controls. As a result, for those importations made or services provided before October 2013 (deemed to be “old debt”), payments were suspended to “revise” the debt based on individual negotiations with each company based on goods imported, prices, etc. Since October 2013, the total amount of foreign currency authorized for pharmaceutical imports has decreased by 35%, resulting in payment delays exceeding 150 days (payments fluctuate depending of the month and size of the importation/company). In short, uncertainty persists as to the availability of foreign currency. Meanwhile, the government is using these foreign currency controls to develop selective import policies.

On March 2014, yet another foreign currency system (SICAD 2) was established for other goods and services not covered by the existing foreign currency exchange systems. As a result, depending on the nature of the goods or services, importing companies are subject to three greatly varying foreign exchange rate systems:

- CENCOEX – which applies to basic goods and medicines – imposes a fixed rate of 6.3 VEF per USD;
- SICAD1 – which applies to “non-priority” goods such as tourism, automobiles, and liquor – imposes a fixed exchange rate of 12 VEF to the USD; and
- SICAD2 – which applies to all goods and services not covered by CENCOEX – allows for a fluctuating exchange rate based on daily auctions (not to exceed 50 VEF per dollar). To date, the average exchange rate granted under the auctions has equated to 49.98 VEF to the USD.

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. On October 6 2005, the Government issued a Resolution to reform the previous price control for Essential Medicines, and established a system of notification to increase prices for all other medicines not covered by the Essential Medicines price controls. Since then, statistics released by the Central Bank of Venezuela and the National Institute of Statistics indicate that prices of medicines have not been revised to take into account accumulated inflation (more than 692 percent), or devaluation (almost 400 percent) between October 2003 and September 2014.

On July 18, 2011, the Venezuelan Government issued a Decree on Fair Costs and Prices (hereinafter “LCYPJ” as per its Spanish Acronym),¹²⁵ which established the National Superintendence of Costs and Prices (hereinafter the “SUNDECOP” as per its Spanish Acronym). In turn, SUNDECOP establishes the standards for the National Registry of Prices of Goods and Services, and has overall responsibility to regulate, supervise, control, and monitor prices, and set Maximum Retail Prices (PMVP) or the price range for goods and services, 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). This Decree was further revised on January 23, 2014, to establish a cost-based pricing system for locally produced medicines, thereby discriminating against imported medicines that remain subject to SUNDECOP’s fixed prices.

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 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 CAVEME, public entities disregarded these conditions and have awarded contracts to local goods and services without satisfying the terms of the Bidding Law.

¹²⁵ Official Gazette N° 39.715 (July 2011).

Counterfeit Medicines

As noted by the Direction of Drugs, Medicines and Cosmetics of the Health Ministry in 2010, and recent findings by the local Investigation Police department (CICPC, May 2014) 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 is taking moderate steps 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, encouraged by the efforts of the Pharmaceutical Industry, Chambers and Associations (such as CAVAME or Federación Farmacéutica Venezolana).¹²⁶

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 attributable to trade barriers related to intellectual property protection and market access.

¹²⁶ See <http://www.noticias24.com/venezuela/noticia/187872/aseguran-que-incidentes-causados-por-medicamentos-falsos-se-han-elevado-7/> (in Spanish) (last visited Feb 6, 2015); <http://www.radiomundial.com.ve/article/cicpc-detuvo-11-miembros-de-banda-dedicaba-la-falsificaci%C3%B3n-y-comercializaci%C3%B3n-de-medicinas> (in Spanish).

MIDDLE EAST/ AFRICA

ALGERIA

PhRMA and its member companies operating in Algeria believe that Algeria has the potential to be a promising market for innovative pharmaceutical products, based on the significant unmet medical needs of the country. Algeria also offers potential for investment and innovation in the medicines sector. Significant barriers remain, however, that impede market access for medicines and impact PhRMA member companies' ability to advance human health, and operate and invest in Algeria. PhRMA noted 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. Subsequent Ministers have reaffirmed that commitment. 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 generic products deemed to be 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.

Since 2013, all international companies face strong pressure from mandatory price decreases emanating from the Health Ministry and the Labor Ministry, without any clear process or guarantee that successful negotiations with the Health Ministry will result in reimbursement by the Labor Ministry:

- The Health Ministry exerts pressure on companies during the product market licensing phase and again during marketing authorization renewals;
 - The Labor Ministry's Reimbursement Committee pressures companies for additional discounts relating to reimbursement of new or already marketed products.
- **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 2015 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 deemed to be 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.

Ongoing discussions indicate that the Algerian Government is 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 decision¹²⁷ 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 decree¹²⁸ 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 discriminates unfairly 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,¹²⁹ negatively impacting Algerian patients.

¹²⁷ 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."

¹²⁸ Instruction #5 for the Generalization of Generics (Sept. 2003).

¹²⁹ Veille Media, "Pénurie de médicaments: le Snapo va interpellier le ministre de la Santé" (May 12, 2011).

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 of today, 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 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, posing 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 committee (CRM) process led by the Ministry of Labor (MOL):

- The MOH via the price committee (MOL is a member of this committee) 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 (MOH is member of 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 2014 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 very challenging environment for innovative biopharmaceutical companies investing and operating in this country.

In recent years, 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 delay in implementing expanded medical coverage for Moroccan patients. 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:** As yet, Morocco does not provide effective regulatory data protection to test and other data submitted to regulators during the marketing approval process. A recent draft Decree on Marketing Authorization has the potential to remedy this deficiency, in that it would require the Office of Drug and Pharmacy at the Health Ministry to implement effective RDP in Morocco. PhRMA and its member companies stand ready to work with the Moroccan Government to finalize and implement the draft decree.
- **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 advocating 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 2015 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 yet, Morocco does not provide effective regulatory data protection to test and other data submitted to regulators during the marketing approval process. A recent draft Decree on Marketing Authorization has the potential to remedy this deficiency, in that it would require the Office of Drug and Pharmacy at the Health Ministry to implement effective RDP in Morocco. PhRMA and its member companies stand ready to work with the Moroccan Government to finalize and implement the draft decree.

Separately, industry is also encouraged by recent updates to Intellectual Property Law 23-13 that would (1) improve the patent system; (2) consolidate the trademark system into a national regime; (3) reform the national system of industrial designs; (4) strengthen the enforcement of industrial property rights; and (5) modernize the patent application process.

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 the Health Ministry concurrently agreed with the pharmacists to increase their margins, effectively transferring the expected patient savings to local pharmacists.

In 2014, a new pricing decree was put in place that does not appropriately value innovative therapies. PhRMA and its member companies are concerned by the apparent lack of coordination among government ministries overseeing parts of the Moroccan health system, in particular the Health Ministry and Ministry of Commerce, Industry and New Technologies, but remain committed to engaging with the Moroccan Government to partner in developing government pricing and reimbursement policies that value innovation and increase patient access to new medicines.

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.

The proposed Marketing Authorization Decree has the potential to significantly reduce marketing approval times and increase transparency in the approval process. Given the serious market access barriers presented by the current system, the innovative pharmaceutical industry strongly supports prompt and efficient implementation of the New Marketing Authorization Decree.

Biosimilars

Alleged copies of innovative biologic products have been launched in Morocco without appropriate regulatory review because of the lack of a biosimilars approval pathway. The innovative pharmaceutical industry looks forward to working with the Government on the development of such a pathway as proposed in the Marketing Authorization Decree.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 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 the 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 (AUSFTA). 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 AUSFTA, 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 AUSFTA 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 Access to Medicines Working Group. Despite the advances on these obligations, there remain key provisions related to notification that have not yet been implemented.

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 Access to Medicines Working Group, including on remaining substantive initiatives required to improve access to innovative new medicines.

Key Issues of Concern:

- **Generally uncompetitive IP environment:** Strengthening regulatory data protection (RDP) 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 AUSFTA, 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 policy change was made without consultation and with retrospective application, and creates enormous uncertainty for pharmaceutical patent owners in Australia.
- **Ad hoc policy changes and lack of consultation:** The Australian Government continues to make important policy changes, particularly in relation to the Pharmaceutical Benefits Scheme (PBS), without adequate consultation with industry. In 2013, for example, the Australian Government 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. This change, which was done without industry consultation, has the potential to seriously undermine incentives for innovation and access to innovative medicines in Australia.

For these reasons, PhRMA requests that Australia be placed on the **Watch List** for the 2015 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

The AUSFTA provides that when marketing approval is sought by an applicant for a generic product or “product for an approved use,” where the product or approved use is claimed by a patent, the Party (here, Australia) should “provide measures in its marketing approval process to prevent” marketing of the generic product or use during the patent term without consent or acquiescence of the patent owner. Further, if Australia permits a third party to request marketing approval for a product or approved use claimed by a patent, it “shall provide for the patent owner to be notified of such request and the identity of any such other person.” See Article 17.10, paragraph 4.

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 – originators are not notified by the generic company or the Therapeutic Goods Administration (TGA). As a result, originator pharmaceutical companies in Australia are routinely unaware of a potential infringement until after the generic product has received marketing approval (and has been listed on the ARTG) or has been considered for Pharmaceutical Benefits Scheme (PBS) listing. 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 AUSFTA.

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 *requesting* marketing approval as required by the AUSFTA because the PBS is not concerned with approval for sale in the Australian market; this is the role of the 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 AUSFTA.

The lack of notification and the unduly prejudicial penalties that can be imposed on patent holders for seeking to defend their intellectual property (including liability for damages as discussed in detail below) 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.

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 budget of the Department of Health (DOH) for 2013-14 and beyond. Due to the financial undertakings required by Australian courts and the length of time taken by the Court to resolve patent disputes and subsequently make relevant determinations on damages, the period of uncertainty for innovator companies is significant and costly. 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 IP through the due process provided by the patent system. In fact, it undermines the very value of those IP rights by increasing the costs and risks of protecting them. As such, 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. Member companies believe continuation of this policy is untenable and at least is a reminder of the importance of notification provisions, which, if effectively implemented, would partly address this issue. An effective patent enforcement system in place in Australia would allow patent holders and generic companies an opportunity to resolve most patent related issues well before they have an impact on pricing and reimbursement.

Regulatory Data Protection

RDP is an independent protection that prevents unfair commercial use of confidential data by a third party. Like other forms of IP protections, RDP 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. RDP protects any data thus generated against being used to obtain product registration by a third party, for a fixed period of time.

Strengthening the RDP 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 RDP for chemically synthesized and biologic medicines, with possible extensions for new formulations, new combinations, new indications, new populations (e.g., pediatrics) and new dosage regimens.

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).¹³⁰ 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

The Australian Government continues to make important policy changes, particularly in relation to the PBS, without adequate consultation with industry. In 2013, for example, the Australian Government unilaterally altered its existing policy on the scope, mechanism, and timing of price disclosure, effectively bringing forward price reductions and therefore savings to the PBS. This change was implemented through legislation in 2014 and the first price reductions were implemented in October 2014. This policy has the potential to seriously undermine incentives for innovation and access to innovative medicines in Australia, and could be avoided by a Government commitment to consult key stakeholders on important policy changes.

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 a 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.

¹³⁰ "Expenditure and Prescriptions Twelve Months to 30 June 2013," Australia Dept. of Health, at <http://www.pbs.gov.au/statistics/2012-2013-files/expenditure-and-prescriptions-12-months-to-30-06-2013.pdf> (last visited Feb. 6, 2015).

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 a high level of industry confidence in the independence and integrity of the Pharmaceutical Benefits Advisory Committee (PBAC) process so that Australian patients can receive access to the newest treatments as soon as possible.

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

PhRMA has concerns with the current conduct of post-market reviews of medicines listed on the PBS 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, which was to drive savings from the off-patent market to secure headroom for new patented 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. We acknowledge that important steps have been taken between the local Australian industry and the Australian Government to improve the process for post-market reviews; however, post-market reviews continue to be a concern for industry locally and globally.

Failure to Recognize the Value of Incremental Innovation

Inappropriate interpretations of sections of Australia's National Health Act (NHA) 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 NHA which allow for statutory price reductions when generic medicines are made available on the PBS. These sections of the NHA 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 is currently interpreting Sections 99ACB/D in a way that erodes the fundamental basis of the F1 formulary by treating new presentations of single brand medicines as generic competitors. This has recently occurred to a number of pharmaceutical companies in a range of disease areas.

New presentations of currently available medicines are brought to market for various reasons including introducing an improvement in medication delivery which enhances patient outcomes, to reflect a global technology change, or safety concerns related to the existing presentation. However, due to the Government's recent actions, pharmaceutical companies are discouraged from 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 so they can be brought to patients without triggering unreasonable price penalties.

Biosimilars

The current reimbursement settings that apply to biosimilars undermine the patent protection which is a foundation of the formulary structure established by the 2007 PBS reforms. Following the TGA's 2013 naming policy on biosimilars and the DOH's related interpretation of Section 99ACB of Australia's NHA, it was expected that most, if not all, biosimilars would enter the F1 formulary alongside the originator biologic (for example, biosimilars of the biological epoetin alfa were registered as epoetin beta and epoetin lambda and due to different names listed in the F1 formulary). This created uncertainty for industry as F1 is intended for single branded medicines, and the entry of biosimilars into this formulary may undermine intellectual property protection of the originator biologic. In January 2015, however, the TGA announced they would discontinue their previous naming policy but provided no further clarity to industry on future policy. This creates considerable uncertainty for industry regarding regulatory policy relating to biosimilars as well as consequent implications for reimbursement policy. The Australian Government should make the necessary administrative and/or legislative reforms to ensure the appropriate treatment of originator biologics and biosimilars. This is an area that requires the priority attention of the Government as a considerable number of biosimilars are anticipated to shortly enter the Australian market.

PhRMA acknowledges that local Australian industry and the Australian Government have sought to resolve the current interpretation of the NHA; however there has been little progress to date.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 attributable to trade barriers related to intellectual property protection and market access.

MALAYSIA

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. A unified listing system across government institutions could help to avoid duplication of efforts and give patients faster access to innovative medicines.

While industry commends the Malaysia Government for moving towards allowing companies to directly request inclusion on the national formulary, the industry is concerned by the proposal to require one year of post-marketing surveillance data prior to listing. Additionally, if local clinical trials have been completed for a product, it should be automatically listed on the national formulary to enable patients who were on the treatment to continue receiving the product after the clinical trial is completed. A policy is needed to bridge the gap for patients from the end of a clinical trial to the listing in the formulary.

- **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. For example, the Government of Malaysia has recently announced that it will grant three-year procurement contracts to companies who move production of imported products to Malaysia (with the potential for a two-year extension if those locally produced products are exported).
- **Goods and Services Tax (GST):** Malaysia will implement a 6% GST from April 1, 2015. To date, the Malaysian Government has legislated that only those

medicines listed on the National Essential Medicines List (NEML) will be accorded the GST “zero-rate” treatment. In light of the lack of clinical criteria the NEML presents, the confusion for patients, the administrative burdens associated in collecting this tax and the potential ramifications this additional cost may have on patient access, PhRMA strongly urges the Malaysian Government to accord the GST zero-rate for all medicines.

- **Counterfeit medicines:** There is great need for deterrent and enforcement of 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. While the industry welcomes the proposed enhanced penalties for counterfeiting of medicines contained in the Pharmacy Bill, action is required to advance this stalled legislation (pending for the last four years).

For these reasons, PhRMA requests that Malaysia be placed on the **Watch List** for the 2015 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 Protection

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 either prior to patent expiry of innovator drugs, or, in the event of a patent dispute, prior to 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 (RDP)

TRIPS Article 39.3 requires WTO members, including Malaysia, to protect proprietary test data submitted to market authorizing bodies, including the MoH, “against unfair commercial use” and against “disclosure.” The stated objective of

Malaysia's Directive (11) dlm. BPFK/PPP/01/03 Jilid 1 is "to protect the undisclosed, unpublished and non-public domain pharmaceutical test data ... for the purpose of scientific assessment in consideration of the quality, safety, and efficacy of any new drug product...."¹³¹

Further, paragraph 4.2 of that Directive provides:

An application for Data Exclusivity shall only be considered if the application in Malaysia for:

(i) New drug product containing a New Chemical Entity is made within eighteen (18) months from the date the product is first registered or granted marketing authorization; AND granted Data Exclusivity / Test Data Protection in the country of origin or in any country, recognized and deemed appropriate by the Director of Pharmaceutical Services....¹³²

As such, Malaysia requires the marketing authorization application of the new medicine to be filed within 18 months from the first worldwide regulatory approval in order to be considered as a "new chemical entity" and, thus, eligible for RDP in Malaysia. If the 18 month deadline is not met, the product loses data protection, allowing a follow-on molecule to be approved based on the originator's regulatory data during what should have been the data protection period. It is challenging – if not impossible – to meet the 18-month application requirement if the first worldwide registration was not in the EU or the United States (both are relied upon for the Certificate of Pharmaceutical Product (CPP) application).

In addition to this inappropriate time restriction on products eligible for RDP in Malaysia, the actual term of the protection in Malaysia is measured from the date of first approval in the world. Thus if a new chemical entity is registered in Malaysia one year after first approval in the world, Malaysia only provides four years of RDP. Indeed, the only instance in which an innovator can receive the full five years of RDP in Malaysia is if they seek marketing approval in Malaysia first. As such, this interpretation of RDP improperly penalizes innovators for first seeking marketing approval in other countries. As in other markets that seek to promote research and development into innovative medicines, Malaysia should measure the term of the RDP protection from the time that the new molecule is approved in Malaysia.

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

¹³¹ See paragraph 1.2 of Directive BPFK/PPP/01/037.

¹³² Id.

such amendments are implemented in order to avoid policies that deter or disfavor innovation across fields of technology. 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 accordance 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. Effective reform that streamlines listings to the national formulary could improve market access and patients' access to medicines.

Further, 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 of Malaysia's regulatory approval process for innovative pharmaceutical products. In November 2010, 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.

Further, the recent introduction of the Quest system for dossier submissions has created significant administrative hurdles in the processing of biopharmaceutical industry regulatory submissions and threatens to delay patient access to new medicines in Malaysia. Although additional resources have been allocated to develop the Quest

system, full deployment is not expected before the first quarter of 2016. In the interim, a rather time-consuming semi-manual process has been established.

Preferential Treatment of Local Manufacturers

Malaysia's National Medicines Policy (MNMP/DUNAS), 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 Medicine List (NEML). 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.

Additionally as part of its aspiration to achieve high income nation status by 2020 Malaysia, has in place various initiatives such as the National Key Economic Area program, offering economic incentives to enhance local manufacturing capacity and capability in pharmaceuticals. Under this scheme if a company locally produces a medicine that was previously imported, it is assured a 3-year tender purchase contract with the Government for that product (with the potential to extend that contract for an additional 2 years if the locally produced product is exported). Such measures discriminate against importers including many U.S.-based innovative pharmaceutical companies.

Goods and Services Tax (GST)

Malaysia will implement a 6% GST from April 1, 2015. To date, the Malaysian Government has legislated that only those medicines listed on the NEML (comprising approximately less than 25% of the total medicines available in Malaysia), will be accorded the GST "zero-rate" treatment. The proposed list does not reflect current treatment practice and potentially might overburden the government sector with patients moving from private to government institutions for cost reasons. In light of the lack of clinical criteria the NEML presents, the confusion for patients, the administrative burdens associated in collecting this tax and the potential ramifications this additional cost may have on patient access, especially for patients with advanced chronic diseases, PhRMA strongly urges the Malaysian Government to extend the GST "zero-rate" to all medicines.

Halal Pharmaceutical Guidelines

In April 2011, The Department of Standards Malaysia, under the Ministry of Science, Technology and Innovation (MOSTI), launched "Halal Pharmaceuticals: General Guidelines". These guidelines were developed by Standard Malaysia's Technical Committee on Halal Food and Islamic Consumer Goods under the authority of the Industry Standards Committee on Halal Standards (ISC I), comprising

representatives from a diverse set of Malaysian government, academic, and domestic pharmaceutical stakeholders.

As a general matter, PhRMA's member companies are strongly supportive of the religious and cultural sensitivities of all Malaysians and believe these guidelines should remain voluntary. PhRMA's members are concerned, however, by certain policy decisions that may indicate that these voluntary guidelines could be made mandatory. For example, in 2013, MoH indicated that halal logos could be affixed to over-the-counter medicines (albeit affirming that halal logos should not be affixed on other medicines). Similarly, questions in the government tender process concerning porcine content and whether the product has a halal certification, suggest that there may be preferential treatment for halal products in government procurement contracts.

Counterfeit Medicines

The counterfeiting of pharmaceutical products poses a serious threat to the health and 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. While the industry welcomes the proposed enhanced penalties for counterfeiting of medicines contained in the Pharmacy Bill, action is required to advance this stalled legislation.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 attributable to trade barriers related to intellectual property protection and market access.

THE PHILIPPINES

Despite recognized recent improvements, PhRMA member companies continue to face significant intellectual property and market access concerns in the Philippines. PhRMA members 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 (UHC) under the Aquino Government. It is recommended for the Government to appoint a dedicated UHC lead who will bring together an inter-agency task force whose mandate is to develop policies aimed at sustaining the gains of recent health reforms. PhRMA members fully support further progress towards improvement in the intellectual property and regulatory environment in 2015.

Key Issues of Concern:

- **Intellectual property protection:** The Cheaper Medicines Act amended the Philippines Intellectual Property Code to limit the patentability of new forms and uses of pharmaceutical products. The Act appears to be inconsistent with the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) since the limitation appears to be designed to discriminate against certain technologies. Additionally, the Philippines does not have a robust system or a set of coordinated procedures across relevant government agencies such as the Intellectual Property Office and the Food and Drug Administration to allow patent holders to effectively and efficiently resolve patent disputes prior to the marketing of generic copies of pharmaceutical products by third parties.
- **Price control mechanisms:** Despite the acknowledgment by the Department of Health (DOH) that the Maximum Drug Retail Price (MDRP) mechanism set out in the 2008 “Cheaper Medicines Act” has not effectively expanded patient access to medicines, it is anticipated that there will be calls to expand the coverage of the MDRP at the next meeting of the Quality Affordable Medicines Oversight Committee later in 2015. At the same time, a number of legislative bills propose to impose further *ad hoc* price controls that could be detrimental to improving patient access to medicines and increase the cost of doing business in the Philippines.
- **Government-mandated discounts:** Existing mechanism for cost-sharing for discounted medicines for seniors and individuals with disabilities is unclear and places, in practice, the entire cost burden for the discounts given on manufacturers and retailers.

- **Philippine National Formulary (PNF):** The PNF, from which the Government procures and reimburses medicines, was last revised in 2008. The outdated PNF negatively affects patient access to essential medicines, and serves as a barrier to PhRMA member companies participating in government procurement of medicines.
- **Government procurement offset program:** The recently rolled out countertrade and offset program for government procurement will effectively increase the cost of participating in such procurement activities and act as a barrier to innovative biopharmaceutical firms' participation in government tendering processes to the detriment of patient access to medicines.
- **Counterfeit medicines:** While campaigns to address counterfeit activities continue in partnership with PhRMA's member companies, a provision of the Cheaper Medicines Act allows products to be sold in "small quantities, not in their original containers" in certain retail outlets. This allowance undermines anti-counterfeit efforts and enforcement, and PhRMA member companies look to continue consultations with the Philippine Government on this issue.

For these reasons, PhRMA requests that the Philippines be placed on the **Watch List** for the 2015 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 (IPOP HL) on the intellectual property provisions and implementing rules and regulations of the Cheaper Medicines Act, PhRMA members continue to raise concerns that certain provisions in the Cheaper Medicines Act adversely affect effective protection of intellectual property and result in certain market access barriers. For example, certain provisions in the Cheaper Medicines Act limit the patentability of new forms and uses of pharmaceutical products, thereby discriminating against certain technologies, and raising questions as to its consistency with the TRIPS Agreement.

Effective Patent Enforcement

It is important that the Philippines adopt processes and mechanisms to allow for the efficient resolution of patent issues prior to the marketing of follow-on products by third parties. Such a mechanism was in place before a 2005 DOH Administrative Order (A.O. No. 2005-0001) took effect, but it resulted in PhRMA member companies having to pursue costly and time consuming legal remedies requiring lengthy litigation 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 member companies recommend that the government take a holistic approach with respect to IP rights to ensure that patents are effectively enforced by the Government of the Philippines. This would include a coordinated effort with the IPOP HL and the Food and Drug Administration of the Philippines (FDAP) to, among others, preclude issuance of a certificate of product registration for a follow-on medicine by FDAP until the relevant patents on the originator product have expired, or there has been sufficient time for resolution of a patent infringement dispute.

Market Access Barriers

Government Price Reductions/Strategies

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 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 persons with disabilities have resulted in the cost of the discount being borne entirely by manufacturers and retailers, i.e., with no contribution from the Government, disproportionately burdening PhRMA member companies.

Government Pricing Policies

The MDRP mechanism adopted under the Cheaper Medicines Act has stifled market access for PhRMA member companies, and, as acknowledged by DOH officials, has not resulted in effectively expanding patient access. Poverty serves as the primary cause for limited access to medicines¹³³ 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.

Despite recognizing that the MDRP mechanism has not improved patient access, it is anticipated that the MDRP will be expanded to more medicines when the Quality Affordable Medicines Oversight Committee convenes and as the election season begins in the Philippines this year.

¹³³ 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.

Meanwhile, 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, speed and due process are needed as to process and criteria for inclusion/review/exclusion on the PNF. Furthermore, 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.

PhRMA member companies continue their outreach to the Philippine Senate and House of Representatives with jurisdiction over current proposals that could significantly impact market access, distort the playing field 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, and mandatory price discounts on medicines for public sector employees, among others.

PhRMA 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, adversely affecting patient access, but also increase overall business costs and affect the ability of PhRMA member companies to place certain products on the market. A VAT exemption on medicines may help alleviate the negative consequences of previous pricing policies.

The Philippine National Formulary

The PNF is the country’s equivalent of the WHO Essential Medicines List. Conceptually, essential medicines intend to satisfy the health care needs of the majority of the population and should be flexible and adaptable to many different situations while remaining responsive to the current and emerging health threats, and in so doing, promote rational public use. Understandably, the PNF guides the procurement and reimbursement of medicines and vaccines in Government units and Government-owned/controlled corporations (GOCC) as a matter of policy. The PNF Manual was last revised in 2008, listing 627 products; compared to Thailand’s 740, Vietnam’s 750 and Malaysia’s 1,200. Within the last few years, a number of PNF process enhancements were introduced; however, there remain acknowledged challenges in keeping the process robust and transparent and the PNF Manual updated. Some of the timelines in the PNF registration process remain unclear and review for medicine inclusion has recently taken up to 3 years.

An outdated PNF not only negatively affects patient access to essential medicines and vaccines; it also becomes a barrier for PhRMA member companies to participate in government procurement of medicines and vaccines. It is imperative, therefore, that a fit-for-purpose and a transparent and efficient PNF listing process be put in place by the government.

Senior Citizens Discount

The unclear formula and inequitable sharing of the Senior Citizens Discount cost between retailers and manufacturers disproportionately burdens manufacturers. The delayed provision of clear guidelines has resulted in financial and operational issues, increasing the cost of doing business in the Philippines. Issues include the price used to calculate the discount (includes the retailer's mark-up), the volume of sales against which the discount is claimed (60% of all prescriptions) without means to confirm that the sales were in fact made to senior citizens, and the administrative burdens associated with the discount. These challenges create barriers to investment in the Philippines.

Government Procurement Offset Program

The Philippine Government recently rolled out an offset program for all government procurement of imported materials, equipment, goods and services valued at USD 1 million and over as per Executive Order 120 series of 1993. The offset obligation can be met through the performance of new exports of merchandise and services, industrial participation, and offset measures such as technology transfer, foreign direct investments, and grants and trainings.

The minimum offset level is 50 percent (i.e., at least USD 500,000) of the value of the supply contract and must be implemented within a maximum of three years. A monitoring fee pegged to the value of the offset will also be imposed by the PITC. Any breach in the offset agreement will result in the company paying the Philippine International Trading Corporation (PITC) a penalty equivalent to 5 percent of the unfulfilled balance of the offset obligations.

The offset program will effectively increase the cost of participating in such procurement activities and act as a barrier to innovative biopharmaceutical firms' participation in government tendering processes to the detriment of patient access to medicines.

Counterfeit Medicines

The Government of the Philippines continues to expand its anti-counterfeiting activities in partnership with PhRMA member companies and raise public awareness regarding the dangers of unsafe medicines. These efforts will continue in 2015 and PhRMA member companies hope to continue consultations with the Government of the Philippines on a provision of the Cheaper Medicines Act that allows products to be sold

in “small quantities, not in their original containers,” in certain 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 2014 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 the Government of Taiwan 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 (RDP) 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 effective patent enforcement and RDP, which discourages investment in innovative medicines for Taiwanese patients and intellectual property rights including all types of patent and data protection afforded by the Taiwan Intellectual Property Office (TIPO) and Taiwan Food & Drug Administration (TFDA), respectively.
- **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 continue to be low and do not adequately reflect or reward the value of those innovative medicines. Furthermore, the new government pricing and reimbursement system fails to recognize all forms of pharmaceutical innovation.
- **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 innovative 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 2015 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 RDP, this protection should clearly and consistently be provided to biologics and extended to new indications.

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 declare 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. PhRMA urges the Government of Taiwan to establish and implement an effective system that will ensure meaningful patent protection and provide sufficient time to resolve patent disputes before follow-on products are approved to enter the market.

PhRMA appreciates the Taiwanese government's commitment to implement a patent database akin to U.S. Orange Book. It is critical that Taiwan continue to move forward expeditiously with the current plan of both a patent database and regulations governing the entire system. PhRMA will continue to work with both the U.S. and Taiwanese governments on implementation of this commitment.

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 two years of observation and evaluation, and despite efforts from National Health Insurance

Administration (NHIA), the outcome is disappointing. According to a study average drug prices in Taiwan continue to be low, around 53% of the A10-country median price. In short, the new system does not reflect or value the degree of innovation of those products and 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 most new drug prices are 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 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.
- *Drug Expenditure Targets:* Under the price adjustment scheme instituted in October 2013, only compound and combination patented products are afforded some protection from price cuts. In order to encourage innovation, however, these protections 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 (e.g., during the RDP term, pharmacovigilance or Risk Management Plan).
- *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 three 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.

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 2014 attributable to trade barriers related to intellectual property protection and market access.

VIETNAM

PhRMA's member companies face significant intellectual property and market access 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 (RDP), clarification of the scope of patentable subject matter, and implementation of effective patent enforcement mechanisms, 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 import 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 2015 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 RDP measures through the Drug Administration Vietnam (DAV). However, the implementation guidelines of the current Data Protection Circular fall short of making the necessary improvements.

As part of the implementation of Vietnam's obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Data Protection Circular provides, on paper, for five years of RDP. In practice, however, this protection has proved illusory. First, the Circular is not clear on whether the five-year term of RDP 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 RDP 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 TRIPS require; (2) data be classified as a "trade secret" under Vietnamese law, which as defined may not cover undisclosed confidential business information; and (3) the innovator prove "ownership" of the data in cases of dispute rather than the third party or government challenger. Finally, RDP is granted at the sole discretion of DAV; to our knowledge, no PhRMA member company has received RDP in Vietnam to date.

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 (see Article I, paragraph 2).

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 under decision 1545/QD-BYT). Second, Temporary Decision 2962 limits the innovative products eligible for tenders to those with "molecular patents" (since expanded to also include "dosage form patents" by Decision 1545). 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. While PhRMA's Members applaud efforts by the Ministry of Health to eliminate the requirement to conduct clinical trials in Vietnam in order to attain regulatory approval, they remain concerned that legislative reform to eliminate this requirement stalled and encourage the Vietnamese Government to eliminate this barrier to patient access immediately.

Further, 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.

Bioequivalence Study Requirements

Vietnam's policy exempts 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.

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 imposed on locally manufactured goods. The price monitoring system should be based on Price to Trade (PTT), which covers both locally manufactured and imported products.

Trading Rights and Distribution Restrictions

As part of Vietnam's WTO accession commitments, the country agreed to extend full import 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 2014 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 remain concerned that the European Medicines Agency's (EMA) policies to provide access to companies' regulatory submissions without adequate controls against potential misuse could 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 from unfair commercial use would be inconsistent with the EU's treaty obligations contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and would primarily benefit competitors who wish to free-ride off of the investments of innovators.
- **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 **Watch List** for the 2015 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 concerned that the EMA's policy (including new policies that will enter into force in 2016) to provide access to companies' regulatory submissions may substantially harm patient privacy, the integrity of the regulatory system, and incentives for pharmaceutical research and development. PhRMA has concerns that the limited access controls to prevent unfair commercial use of this information as proposed by the EMA could allow other commercial competitors to benefit from this information unfairly and 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,¹³⁴ 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, failure to protect confidential commercial information contained in regulatory submissions would be inconsistent with the EU's treaty obligations contained in the TRIPS Agreement. This would harm 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 could be used by third-party companies to seek approvals in other markets such as China.

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.¹³⁵ Overall, however, interim injunctions to prevent accused products from remaining on the market until trial are granted in less than half the relevant cases.¹³⁶ This failure to provide effective remedies fundamentally undermines the exclusive rights conferred by a patent.

¹³⁴ See Gymrek, M. et al., Identifying Personal Genomes by Surname Inference, 339 SCIENCE 6117 321-324 (2013).

¹³⁵ See, e.g., *Leo Pharma v. Sandoz*, [2008] EWHC 541 and *Novartis v. Dexcel-Pharma*, [2008] FSR 31.

¹³⁶ DG Competition, European Commission, "Pharmaceutical Sector Inquiry Final Report," para. 641 (Jul. 8, 2009).

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.¹³⁷

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 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, including through negotiation and implementation of the Transatlantic Trade and Investment Partnership.

¹³⁷ EFPIA, Submission to the European Commission in Relation to the Pharmaceutical Sector Inquiry (June 13, 2008).

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.¹³⁸

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 appropriate by a patient's physician or health care provider. To this end, the EU should

¹³⁸ OECD Health Policy Studies, Pharmaceutical Pricing Policies in a Global Market, 2008, p. 18.

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 2014 attributable to trade barriers related to intellectual property protection and market access.

GREECE

Despite fiscal consolidation and financial improvement in Greece, PhRMA's member companies still face several challenges and market access barriers, including measures undermining pharmaceutical innovation, 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 Government of Greece to recognize and protect innovation in the pharmaceutical sector by ensuring efficient, timely and transparent government pricing and Social Security Funds reimbursement procedures for medicines.

For these reasons, PhRMA requests that Greece remain on the **Watch List** for the 2015 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 economic crisis has affected the population's health status and also the investment attractiveness, due to the abrupt reduction in expenditure to health services as a result of the need for fiscal adjustment. In particular, the budget for public pharmaceutical expenditure, has suffered a nearly 60% decrease, during the period 2009-2014. Most of the savings in the pharmaceutical sector have been achieved through price decreases and rebates, while structural reforms are lagging.

- **Closed budget targets:** The extremely low closed budget for outpatient pharmaceutical expenditure and the continuous imposition of unsustainable cost-cutting measures to pharmaceutical companies jeopardize not only the healthcare system's viability, but also the sustainability of the innovative pharmaceutical industry in Greece. The target for pharmaceutical expenditure for 2014 and 2015 is set at €2bn, approximately 25% lower than 2013 actual spend. The inclusion of coverage for uninsured citizens in the spending target makes it even more likely that the budget will not be sufficient to meet the demands of the healthcare system.
- **Rebates and clawback mechanism:** Most of the Government's savings have been achieved through mandatory rebates and a clawback mechanism. In particular, pharmaceutical companies paid rebates totaling €274 million and €222 million in 2012 and 2013, respectively. In addition, the clawback amount covered by the industry was €78.9 million and €152.4 million in 2012 and 2013, respectively. The rebate plus clawback as a percentage of the total market is expected, when the full accounting is complete, to rise to 30% in 2014. The clawback covered by the industry for the first 6 months of 2014 amounted to €141 million, and industry fully expects an additional clawback for the second half of the year.

- **Government Pricing:** Medicines under patent are priced based on the average of the three lowest EU countries, resulting in some of the lowest prices in Europe (not even accounting for the rebates and clawback mechanism). Conversely, generics' prices in Greece are among the highest in Europe, thereby failing to capture savings that could be used to fund greater access to innovative medicines by Greek patients. PhRMA's member companies support the reform of the current international reference pricing system to include countries that are more closely aligned to Greece's level of economic, social, and healthcare status.

According to current legislation, a medicinal product is repriced when the patent on the active substance expires. Although pharmaceutical companies have filed the necessary documents with the National Organization of Medicines (EOF) to identify the patent expiration date, EOF has in some instances repriced on-patent medicines based on the expiration of the data protection period, in clear violation of the relevant legislation for the pricing of medicinal products.

- **Promotion of local generics through reimbursement:** The Greek Government has instituted a number of measures to promote locally produced generics to the detriment of the innovative industry. Examples include "jumbo" ATC4 clusters in the reimbursement list that couples patent, originator off-patent and generic drugs in the same pricing group, and reimbursing only an average reference price in each cluster, resulting in extremely high patient co-pays for on patent drugs.
- **New products' reimbursement:** The limited pharmaceutical budget resulted in significant delays in new products' pricing and reimbursement. After a three year delay, all products pending pricing and reimbursement were approved in February 2014 and April 2014. However, the pharmaceutical budget was not increased to reflect the availability of those new medicines, further exacerbating the anticipated rebates and clawback obligations.
- **Hospital and Social Security Funds (EOPYY) debts:** Although a considerable portion of the arrears were paid in 2013 and 2014, the state debt to the pharmaceutical industry remains high (nearly €1 billion) with risk for further future increases.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 attributable to trade barriers related to intellectual property protection and market access.

ITALY

PhRMA member companies continue to face several market access barriers in Italy. In 2013 and 2014, the innovative pharmaceutical industry did see some positive change. The new Prime Minister, Matteo Renzi, together with the Minister of Health, Beatrice Lorenzin, publicly recognized the strategic importance of the pharmaceutical industry for the Italian economy. As a consequence of this, for the first time since 2001, even in the process of the Spending Review, no negative measures affecting prices and/or funds for pharmaceuticals were adopted.

Notwithstanding this improved perspective within the Italian Government, the situation for innovative pharmaceutical companies remains quite complex: support for innovation and patent protection are often limited and undermined by measures adopted by national and regional authorities.

For these reasons, PhRMA and its member companies urge the Italian Government to intervene to reduce the existing market distortions, while consulting with the research-based pharmaceutical industry in developing a healthcare environment that rewards innovation and ensures patient access to innovative medicines.

Key Issues of Concern:

- **Delays, limitations and limited budgets for new drugs:** Pricing and reimbursement policies in Italy make for some of the worst access conditions and the lowest level of expenditure among the key EU countries for innovative medicines.
- **Therapeutic equivalence rules:** New rules to establish therapeutic equivalence or homogeneous therapeutic categories and to require off-label prescriptions based solely on cost jeopardize patent protection and the investments for clinical development, undermine the European regulatory framework for approving new medicines, may compromise patient safety create legal uncertainty with regard to product liability.
- **Claw back policies:** Disproportionate budget allocation and claw-back policies between the hospital and retail channels discriminate against U.S. pharmaceutical companies.

For these reasons, PhRMA requests that Italy be placed on the **Watch List** for the 2015 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 remains difficult in Italy. In 2012, the Italian Drug Agency (Agenzia Italiana del Farmaco - AIFA) announced the introduction of a new algorithm for the evaluation of innovation designed to support and speed-up pricing and reimbursement decisions. This new scheme is still being designed.

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 an average 427 days from EMA approval before a medicine is available in the Italian market, compared to 80 days in Germany, 109 in UK, and an average of 221 days throughout Europe;¹³⁹
- *Number of new medicines available*: only 35% of the medicines approved by the EMA between 2011 and 2013 were available for reimbursement¹⁴⁰ in Italy, compared to 69% in Germany, 66% in UK and an average of 52% throughout Europe;
- *Prices*: Prices of new medicines are 15% lower than the average prices in the UK, Germany, Spain and France.¹⁴¹

Failure to Adequately Value and Reward Innovative Medicines

Between 2011 and 2012, several regions and local health authorities tried to organize tenders in which they would group together patented and off-patent medicines deemed to be in the same therapeutic group based on evaluations of therapeutic equivalence established by local health committees. In 2012, a new law was introduced that stated that those evaluations could be carried out only by AIFA. In 2014, AIFA defined the rules and procedures to release those evaluations. Those rules do not specify the scientific criteria that should be followed to establish the equivalence and do not provide any consultation or appeal procedure for pharmaceutical companies. For these reasons, there is a strong likelihood that patented medicines will be forced to compete in tenders against generic medicines, where price is the only criteria.

Beyond (explicit) therapeutic equivalence for the purpose of conducting a tender, innovative pharmaceutical companies are increasingly facing attempts to introduce (implicit) therapeutic equivalence in Regional Decrees. Specifically, a number of regions are seeking to compel new patients to use biosimilars deemed to be in the same

¹³⁹ Farindustria (the National Industry Association) elaboration of IMS and CERM data.

¹⁴⁰ Elaboration of the CERGAS Bocconi (Centro di Ricerche sulla Gestione dell'Assistenza Sanitaria e Sociale 2011) based on IMS data.

¹⁴¹ Id.

therapeutic class, in some instances overriding the physician's professional judgment on the best medicine for his or her patients.¹⁴²

On March 20, 2014, Italy adopted Law Decree no. 36 promoting off-label use (i.e., uses for which the medicine has not been approved by the European Medicines Agency (EMA)). The Law Decree empowers the AIFA to assess the safety and efficacy of the given medicine for the off-label indication, and to take into account the comparative cost of any other medicine approved by the EMA for that indication. This measure:

- undermines the European regulatory framework for approving new medicines, may compromise patient safety, and creates legal uncertainty with regard to product liability;
- discourages the development of new medicines and/or indications and constitutes a disincentive for innovation.

Discrimination *vis-à-vis* retail pharmaceutical companies

The vast majority of innovative drugs are sold in the hospital channel in Italy. The public hospital pharmaceutical expenditure is capped at 3.5% of the National Healthcare fund (NHF), while retail expenditure is capped at 11.35% of the NHF.

Per Laws 222/2007 and 135/2012, pharmaceutical companies are required to refund 50% of any overspending in the hospital channel and at least the 66% of any overspending in the retail channel (this percentage varies according to the cost of distribution). The level of overspending in the two channels (and, in turn, the amounts that are clawed-back from the companies) demonstrate that the budgets caps are inadequate and disproportionately target hospital prescriptions. As a consequence of this inappropriate and disproportionate budget allocation, the clawback in 2013 for the retail channel was \$27 million (0.03% of the retail budget) while the clawback in the hospital channel was \$450 million (10% of the hospital budget). Furthermore the latest estimates from AIFA relating to 2014 public pharmaceutical expenditure indicate that there should be no overspending in the retail channel, whereas sales to the hospital channel are expected to exceed the restricted budget by \$1.2 billion, resulting in a clawback from pharmaceutical companies of approximately \$600 million.

This policy disproportionately impacts innovative biopharmaceutical companies, as 90% of the sales (by value) in the hospital channel are generated by innovative companies (including U.S.-based firms), while Italian companies operate almost exclusively in the retail channel. To remedy this imbalance, Italy should develop

¹⁴² See, e.g., Campania Region Commissioner Decree no. 27 of March 15, 2013; Umbria Region Committee Resolution no. 799 of July 15, 2013; Puglia Region Committee Resolution no. 216 of February 26, 2014; Basilicata Region Committee Resolution no. 492 of April 30, 2014; Marche Region Committee Resolution no. 974 of August 7, 2014.

pharmaceutical budgets that are based on real patient demand in the respective channels.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 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) had established a Working Group with all relevant stakeholders to review the pricing system, that process has stalled thus increasing the unpredictability of the environment.
- **Inadequate healthcare funding:** An “*access to Innovation*” study conducted by the innovative biopharmaceutical industry in Romania, 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 could bring five times more economic benefits in the long run than the initial costs. The study also found that new medicines could generate a positive impact of an additional 0.5% to the Romanian GDP due to higher worker productivity. As yet, however, the budget for reimbursed medicines remains stagnant at 2011 levels, with any increases only sufficient to cover prior year's arrears. 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.
- **Clawback taxes:** The innovative pharmaceutical industry has been the target of numerous misguided “clawback” tax regimes intended to increase healthcare revenue or control expenditure. The latest version of the clawback was implemented on October 1, 2011 and requires medicine producers to cover the entire reimbursed medicine budget deficit, including wholesale and retail margins. Based on recent proposals, PhRMA's members are concerned that the Ministry of Health plans to further reform its clawback tax regime in a way that would shift the burden of refunding spending beyond the Government's reimbursed medicine budget entirely to the innovative sector. For example, Romanian authorities are calling for higher taxes on innovative medicines than generic medicines, which would disadvantage R&D-based companies and could have anti-competitive effects.

- **Unpredictable, non-transparent reimbursement system:** The Romanian Reimbursement list is updated infrequently. Further, in an effort to control costs, 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. In addition, while highly supportive of the Romanian Government's first update to the reimbursement list since 2008, PhRMA's member companies are concerned that the Health Technology Assessment (HTA) process in Romania lacks transparency, misinterprets data and relies on poor assessments. PhRMA supports a transparent and predictable reimbursement process that rewards innovative companies for their significant investment in developing new medicines and encourages development of tomorrow's new treatments.

For these reasons, PhRMA requests that Romania remain on the **Watch List** for the 2015 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. 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.

Healthcare Funding

Patient access to healthcare in Romania is negatively impacted by the low-level of healthcare spending, with Romania last among EU member states in terms of health expenditure as a percentage of GDP. Romania should allocate more 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. Also, the budget for reimbursed medicines has remained flat, at the level of 2011, not taking into consideration real annual consumption.

Clawback Tax

In September 2009, the Romanian Government implemented a "Clawback Tax", as a temporary measure in response to the global recession. Since then, the Romanian economy has grown and the country has recovered, but this "temporary" measure remains in effect.

Effective October 1, 2011, the clawback mechanism 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 clawback 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 a result of the stagnant healthcare budget, the clawback tax rose to more than 20% in the second quarter of 2014. The percentage is also applied to the gross value of each pharmaceutical company's sales to the Sick Fund, including wholesale and retail profit. In other words, PhRMA member companies must compensate the budget for payments the government makes to wholesalers and pharmacists.

The innovative biopharmaceutical industry in Romania is working to be a solution partner with the Romanian Government to remedy its inadequate health spending and inefficient allocation of health care resources.

Reimbursement Delays

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 National Medicines Agency, there are approximately 200 applications pending reimbursement approvals. The last complete updates to the reimbursement list were made in 2005 and 2008. No exceptions are made for life saving drugs, even for those approved under a fast-track process in other countries within the European Union.

In July 2014, 17 orphan molecules were added to the reimbursement list, as well as 23 new molecules that passed the HTA process. However, the majority of innovative medicines are still pending reimbursement. 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 the EU Transparency Directive, which sets specific deadlines for reimbursement decisions (90 days).

Payment Terms and Debt

Following the enforcement in 2013 of the EU Directive on late payments, payment terms in Romania 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 infringement of EU legislation. The innovative pharmaceutical industry commends the Romanian Government for this progress, and stands ready to work with the authorities in developing sustainable financing and allocation of healthcare resources solutions.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 attributable to these trade barriers.

RUSSIA

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

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 (RDP) 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. However, revisions to these protections were included in amendments to the Law on the Circulation of Medicines (approved by the Russian Duma on December 9, 2014, but yet to be finalized into law). PhRMA and its member companies welcome some of the revised provisions (e.g., the introduction of specific mechanisms to implement RDP), but are concerned that that some of the provisions weaken RDP protection for innovative medicines in Russia.
- **Effective patent enforcement:** Currently, there is no mechanism in place to enable patent holders to attempt to resolve patent disputes prior to the granting of follow-on product marketing authorization. This in turn has led to the approval and marketing of follow-on products, despite the fact that a patent for the original drug is still in force. The draft amendments to the Law on the Circulation of Medicines do not include provisions that would

For these reasons, PhRMA requests that Russia be placed on the **Watch List** for the 2015 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved. While PhRMA continues to believe that resolving the key barriers listed in this report is critical to developing a healthcare system that properly rewards and supports access to pharmaceutical innovation, PhRMA's members commend Russia for addressing a number of key concerns in the recently amended Law on the Circulation of Medicines (approved by the Russia Duma on December 9, 2014).

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 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.¹⁴³

Russia's commitment to six years of RDP is embedded in Article 18.6 of the Law on the Circulation of Medicines, as passed in 2010:

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.¹⁴⁴

¹⁴³ 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.

¹⁴⁴ Federal Law No. 61-FZ, "Law on the Circulation of Medicines" (Apr. 12, 2010).

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 elements that are contrary to, or do not effectively implement, RDP consistent with Russia's 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 follow-on medicines, without reference to the six years of RDP or to Article 18.6. Further, administrative regulations governing drug registration approved in 2013 totally disregard Russia's WTO obligation to provide RDP.

The amendments to the Law on the Circulation of Medicines that passed in the Russian Duma on December 9, 2014, allow the submission of a registration application for follow-on medicines four years following the granting of marketing authorization for a reference small molecule drug and three years after marketing authorization of a reference biologic medicine. PhRMA members are concerned that this new proposal will further weaken RDP in Russia by creating the potential for marketing authorization of infringing follow-on products during a reference product's valid patent term.

At the same time the amendments introduce specific RDP mechanisms. For instance, the Federal Register of Medicines must include information noting the date when the originator's RDP period expires. Further, according to the amendments, the follow-on drug applicant must provide to the Ministry of Health the consent of the reference drug manufacturer within the application for registration of a follow-on product. However, it is still not clear if the implementation of these rules will be effective.

The United States Government should seek greater clarity on the actual implementation of the above provisions after they enter into force. The lack of clarity regarding data protection may create a situation of juridical uncertainty and could result in inconsistent legal interpretation by differing courts.

Effective Patent Enforcement

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. Follow-on 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. The amendments to the Law on the Circulation of Medicines do not include provisions for patent status review when a

company applies for marketing authorization, as proposed by the innovative biopharmaceutical industry.

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 follow-on 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 follow-on 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.

Compulsory Licensing

PhRMA and our member companies are concerned about draft policies that are being discussed in Russia to develop legislation to allow for the issuance of compulsory licenses (CLs) for innovative medicines. PhRMA is particularly concerned that these discussions have focused on cost as one factor to be considered in granting CLs. PhRMA will continue to closely monitor the development of this legislation.

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

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 in 2013.¹⁴⁵ 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 local manufacturers – a term not clearly defined. This constitutes clear discrimination against foreign manufacturers.

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 per an application process unveiled on August 13, 2014. 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. The list has yet to be formed.

According to a draft government decree on preferences in state purchases for locally produced drugs, only drugs manufactured in Russia, Belarus, and Kazakhstan would be eligible for government procurement tenders if two or more local manufacturers of drugs within the same product category (INN) apply for the state tender. For the purposes of this decree, local packaging within one of these countries will be sufficient (at least until January 1, 2016), pending further elaboration from Russia’s Trade Ministry on the level of production and the associated pricing preferences to be provided during state procurement of medicines.

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

¹⁴⁵ 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.

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 29 April 2014, Deputy Prime Minister Olga Golodets requested that the Ministries of Health, Industry and Trade, and Economic Development, the Federal Anti-Monopoly Service, and Federal Consumer Protection Service, together with the State Corporation "Rostechologies", submit to the Russian Government proposals for making Rostechologies the sole provider of immunobiological products and proposals on restriction of access of foreign immunobiological drugs for state procurement if there are locally-manufactured equivalent products and sufficient production capacities in Russia.

Similarly, General Director of the State Corporation Rostechologies and the Minister of Health have applied to Deputy Prime Minister with a letter that sets forth a number of proposals for support of the Russian local immunobiological industry. *Inter alia*, this letter suggests making Rostechologies the sole provider of immunobiological products for prevention of infective diseases until 2017. The letter also suggests suspending GMP requirements for facilities manufacturing immunobiological vaccines, which are state owned or owned by Rostechologies, until 2020.

If enacted these proposals would severely discriminate against U.S. firms in violation of Russia's WTO commitments, and severely limit patient access to immunobiological vaccines in Russia.

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 forth in the Law on the Circulation of Medicines, creates significant challenges for the registration of orphan drugs in Russia. Ministry of Health officials have acknowledged this issue. The amendments to the Law on the Circulation of Medicines include 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 newly passed procedure lacks sufficient detail to fully evaluate.

Biologic and Biosimilar products in Russia

Recent amendments to the Law on the Circulation of Medicines (December 9, 2014) define biologics and biosimilars in a manner that is inconsistent with international best practices. Further, although the proposed amendments create a general regulatory framework for biosimilars, the details will need to be fleshed out via bylaws. PhRMA's members welcome Russia's actions to better regulate biologics and biosimilars, but there remain some concerns regarding implementation of the relevant framework amendments (including assessment guidelines for biosimilar drugs, guidelines for determining the interchangeability of biologic drugs, etc.).

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 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.

For these reasons, PhRMA requests that Spain be placed on the **Watch List** for the 2015 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, Reimbursement and other cost-containment measures

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.

At the central level, since 2009, the Spanish Government has enacted four Royal Decrees (extraordinary procedures that allow the Government to dictate "laws" without a formal revision by the Parliament) that directly impact the innovative pharmaceutical industry and create an unpredictable and unstable business environment. These measures are directed to reduce pharmaceutical spending either with price reductions, or with mandatory discounts that place an additive strain on PhRMA members operating in Spain.

For example, on April 20, 2012, the Spanish Government enacted Royal Decree Law 16/2012, which modifies Law 29/2006 on the Guarantees and Rational Use of Medicines and Healthcare Products. This Decree included 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.
- Prescription by INN: Prescription by INN is the general rule for medicines and even if prescribed by brand, the regulation mandates automatic substitution of those prescriptions where the price of the branded product is not the lowest in the group. In addition, if the branded and the generic product have the same (lowest) government price, the regulation mandates to dispense the generic, thus clearly discriminating against the original brand.

- Selected Prices System (Art. 93 Bis): The MOH allows bids from 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.

These myriad Royal Decrees imposing overlapping cost-containment measures have resulted in a pricing and reimbursement environment that lacks predictability.

Similar measures, e.g., pricing restrictions, reference pricing, automatic substitution of branded medicines for generics, tenders grouping different medicines together because they share similar indications, 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 addition, the unsustainably low prices set in Spain are referenced by a number of other European countries to set their own pharmaceutical prices.

Finally, it is expected that biosimilars of monoclonal antibodies will enter the Spanish market in early 2015. Although the legislation provides that biologic products should always be prescribed by brand, no substitution should take place at the dispensing point, and imposes appropriate pharmacovigilance and traceability measures, the Spanish Government, particularly the Regional health systems, has not taken the measures necessary to prepare their systems and the healthcare community to adopt these legally and medically required practices.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 attributable to trade barriers related to effective intellectual property protection and market access.

LATIN AMERICA

COLOMBIA

PhRMA's member companies face several market access barriers in Colombia, including the issuance on September 18, 2014 of Decree 1782 on sanitary evaluation for biologics, which establishes an unprecedented third pathway for approval of non-comparable biologics that is not in line with WHO or FDA guidelines. This is in addition to constantly changing, discretionary government pricing policies paired with specific governmental initiatives that undermine the innovative pharmaceutical sector.

Key Issues of Concern:

- **Effective patent enforcement:** PhRMA 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 pharmaceutical 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, applies an unreasonably restrictive definition of patentable biologics.
- **Substandard biologics regulation:** On September 18, 2014, Colombia issued Decree 1782, which establishes the marketing approval evaluation requirements for all biologic medicines. As part of the Decree, Colombia has established an unprecedented "abbreviated" pathway for registration of non-comparable products, which is inconsistent with both WHO and FDA standards and could result in the approval of medicines that are not safe and/or effective.
- **Price control regulations:** Colombia's international reference pricing methodology could inappropriately be used to set the same 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. Moreover, the Government has recently announced that it plans to extend its price controls beyond just those medicines deemed not to be competitive, contrary to the premise that Colombia only imposes price controls where it deems that there is a lack of competition within a therapeutic area.

For these reasons, PhRMA requests that Colombia remain on the **Watch List** for the 2015 Special 301 Report.

Intellectual Property Protections

Effective Patent Enforcement

PhRMA member companies continue to be adversely affected by the Government of Colombia's failure to provide an effective patent enforcement mechanism. In April 2013, Columbia's National Institute of Food and Drug Surveillance (INVIMA - Instituto Nacional de Vigilancia de Medicamentos y Alimentos) 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.

Until very recently, patent litigation could take more than 8 years. The recent modification of the codes of civil and administrative procedure – replacing the old written system with an expedited oral procedure – are aimed at greatly reducing these delays. While the new law sets forth that the process should take no longer than one year, cases filed early 2014 are being scheduled for hearings in 2016. PhRMA will continue to 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 enforcement of these guidelines has not been consistent, and decisions continue to lack predictability. The innovative pharmaceutical industry will continue to monitor the development of these guidelines and stands ready to provide technical assistance.

PhRMA continues to have significant concerns about restrictions on the scope of patentable subject matter in Colombia. There have been several recent cases of denials of patents for these types of inventions in first instance decisions.

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, including Colombia, 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 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 has not been issued.

Market Access Barriers

Substandard Regulation on Biologics

On September 18, 2014, Colombia issued Decree 1782, which establishes the marketing approval evaluation requirements for all biologic medicines. As part of the Decree, Colombia has established an unprecedented abbreviated pathway for registration of non-comparable products, which is inconsistent with both WHO and FDA standards and could result in the approval of medicines that are not safe and/or not effective.

PhRMA members participated actively in the public consultations and engaged extensively with the Ministry of Health and their technical experts, specifically highlighting that the abbreviated "third pathway" created by the Decree is not in line with the WHO guidelines for approval of biologics. In contrast to the Full Dossier Route (for originators) and the Comparability pathway (pathway for Biosimilars) found in WHO guidelines, the "Abbreviated Comparability Pathway" as described in the Decree allows

for summary approval of non-comparable products and does not provide adequate controls or any clarity regarding how the safety or efficacy of a product approved via this pathway will be evaluated and assured.

PhRMA members urged the Colombian government to remove this third pathway from the Decree, to no avail. This route has been justified by the Colombian Ministry of Health, and ratified by the President, as a necessary tool to lower prices of medicines by promoting the swift entry into the market of competitors. However, shaping competition policy is not the appropriate role for a sanitary regulation, which should be strictly focused on ensuring the safety and efficacy of products.

Furthermore, per the Decree, a product approved via the “Abbreviated Comparability 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 would make it difficult to quickly trace and attribute adverse events to the correct product.

Price Control Regulation

The price control methodology currently in place in Colombia sets a maximum price for both the private and institutional 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.

The methodology does not clearly establish criteria to allow the enforcement of exceptions contemplated therein: such as the exclusion within a relevant market of a product which provides a significant technical benefit when compared with other products with the same active ingredient (i.e., tablets versus modified release tablets). This results in lack of enforcement of the exception and failure to recognize the value of incremental innovation.

Moreover, the Government has recently announced their intention to modify the existing pricing methodology to extend it to non-concentrated markets, where there are several competitors (none with high participation in the market) upon evidence that medicines in this situation have a higher price in the country when compared to other jurisdictions. This would be a radical change in the rationale of the pricing methodology in the country and would completely eliminate market freedom for even concentrated markets.

Finally, the recently approved Statutory Law of Health eliminated the National Pricing Commission which was the entity in charge of producing and enforcing price regulation in Colombia, and which was formed by representatives from the Ministry of Trade, Ministry of Health, and a representative from the Presidency. Henceforth this responsibility has been assigned exclusively to the Ministry of Health. PhRMA’s

member companies are concerned that this will 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 2014 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 2015 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 obligated the United States' trading partners to grant regulatory data protection (RDP) and develop a mechanism for effective patent enforcement. These provisions have not been sufficiently implemented by several of the CAFTA-DR trading partners.

Dominican Republic

The Dominican Republic Health Regulatory Agency has implemented RDP for new products; however no bylaw has yet been issued, resulting in lack of certainty as to the procedures for obtaining RDP. The Health Regulatory Agency is not granting RDP to new products receiving marketing approval after the entry into force of the law if a "request for protections" was not submitted upon filing – a requisite not required by law. Thus, the Agency is undermining RDP for qualifying products notwithstanding the new law.

El Salvador

El Salvador has not effectively implemented its international obligations, arising from CAFTA-DR Article 15.10.2, related to the effective enforcement of patents.

Honduras and Nicaragua

Neither Honduras nor Nicaragua has effectively implemented their international obligations, arising from TRIPS and the CAFTA-DR, related to RDP. Since 2008, when the Government of Honduras published draft regulations for consultation, it has not taken any further concrete steps to provide for RDP; thus, protection remains uncertain.

Similarly, the health authorities in Nicaragua have yet to promulgate a clear and transparent RDP 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 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.

Guatemala

Although the Guatemalan Ministry of Health (MOH) has not enforced two Ministerial decrees (Ministerial decrees 472-2012 and 871-2012) that threaten patent rights, such decrees remain in force. MOH Decree 472-2012 appears to be inconsistent with Articles 28(1)(a), 30 and 31 of TRIPS, the CAFTA-DR, and the Industrial Property Law of Guatemala, as well as Article 10.5 of the CAFTA-DR. PhRMA and its members are concerned that the decree may exceed the MOH's powers and negate patent rights granted in Guatemala. If this practice is permitted, the MOH may consider it as a means to override intellectual property rights in Guatemala without due process.

Decree 472-2012 declared a specific generic product to be of high therapeutic interest, and authorized its importation. The Decree did 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; nor did MOH conduct any consultations with the rights holder.

Decree 871-2012, “regulates” several acts, including acquisition, donation, lending and other acts, related to certain drugs. The MOH has not implemented the programs and actions authorized by the Decree, and thus it remains unclear as to how it will be implemented, generating uncertainty regarding respect for intellectual property rights in Guatemala.

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 proceedings to obtain patents, delaying patent approvals. Although requested compulsory licenses have not been granted to date, the referenced provisions represent a threat to IP rights. Patent applications have also been facing substantial delays, further exacerbating the patent office backlog.

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, even though the patent was not granted until after the obligation and applicable laws to provide PTA went into effect.

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 requires 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. 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.

Guatemala

Congressional Decree 3-2013, as amended, caps the PTA and PTR periods to 18 months and one year, respectively. As indicated for Costa Rica, 18 months may not be sufficient to compensate patent owners for the patent office delays in Guatemala.

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 figures released by ONAPI's Office of Access to Public Information, patent applications face significant delays in the Dominican Republic, resulting in increased patent term adjustment filings. As of June 2014, there were 1,379 patent applications pending (809 of these were pharmaceutical, chemical or biotechnological patent applications); moreover, only 236 patent certificates have been issued in the last 14 years.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 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.
- **Inadequate biosimilars regulation:** Recent additions and updates to the regulations covering approval of non-innovative biologics (biosimilars) are not specific on how the new provisions should be applied to products approved prior to the new biosimilars regime.

For these reasons, PhRMA requests that Mexico remain on the **Watch List** for the 2015 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 publication in the Official Gazette of formulation patents 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. Therefore, PhRMA members urge COFEPRIS to consult the Official Gazette and the Patent Office to verify that there is no patent infringement, 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 Mexico's 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 chemically synthesized (small molecule) and biologic 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, in drugs with patent or exclusive distribution, 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 public health 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. 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 innovative medicines submitted for institutional approval (IMSS, ISSSTE, Seguro Popular) have been listed on the key formularies. Furthermore, in 2013, IMSS approved only four new medicines for reimbursement while ISSSTE approved one.¹⁴⁶ 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.¹⁴⁷

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.

Finally, Mexico's consolidated procurement processes lack transparency and are not consistently applied. For example, a number of the tenders, contrary to Mexico's procurement rules, identify products beyond those listed in the National Formulary.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2014 attributable to trade barriers related to intellectual property protection and market access.

¹⁴⁶ Mexican Institute for Social Security, Formulary Inclusions and Exclusions 2011-2013; Mexican Institute of Security and Social Services for State Workers, Formulary Inclusions and Exclusions 2011-2013.

¹⁴⁷ EFPIA Patients WAIT Indicator 2010 and AMIIF 2011 report.

PERU

PhRMA and its member companies operating in Peru are concerned about the state of intellectual property protection and several discriminatory regulatory requirements that favor local producers 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 (RDP) 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.
- **Compulsory Licensing:** Earlier this year, a group of NGOs petitioned the MoH to issue a compulsory license on a patented HIV medicine. Although MoH has initiated a process to review the petition, to date neither the specific manufacturer nor the industry association have been permitted to participate in that review, raising significant due process concerns.
- **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, or impose excessive administrative burdens that serve no purpose other than delaying the marketing approval process and patient access to medicines.

- **Delays in implementing regulations on Biopharmaceutical Products:** The Ministry of Health (MoH) has been delaying implementation of the Pharmaceutical Product's Law and its regulations with regards to Biopharmaceutical Products for more than five years.

For these reasons, PhRMA requests that Peru remain on the **Watch List** for the 2015 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 RDP regime in February 2009. Since then, many new pharmaceutical products have been granted RDP for an average of 36 months (3 years). Although there were reported instances of PHA refusing to grant RDP to several biologic products, no recent cases have been reported.¹⁴⁸ Refusing to grant RDP to biologics is inconsistent with Peru's obligations under the WTO's TRIPS Agreement, Article 16.10.2 of the USPTA, and national law. Denying such protection will adversely affect PhRMA members attempting to introduce new products in Peru, and puts pressure on other trading partners in the region to refuse to protect this very important class of products.

To ensure that there are no future treaty violations, the Government of Peru should 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 below under "Duplicative Testing," Bill 995 requires public disclosure of confidential 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 USPTA 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

¹⁴⁸ That said, given the limited protection available and the other administrative burdens that have at different times been imposed on applicants seeking RDP, many innovative pharmaceutical manufacturers have been discouraged from seeking RDP in Peru, making it difficult to assess more recent PHA practice.

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. This is contrary to long-standing precedents and inconsistent with TRIPS Article 27.1. Andean member countries, including Peru, 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 members who dedicate many of their research investments to evaluating additional therapeutic benefits of known molecules 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.

Compulsory Licensing

On January 2014, a group of NGOs petitioned the MoH to issue a compulsory license on a patented HIV medicine. Although MoH has initiated a process to review the petition, to date neither the manufacturer nor the local innovative pharmaceutical industry association have been permitted to participate in that review and any technical analysis being undertaken is being done in secret, raising significant due process concerns. Moreover, neither MoH nor the Ministry of Commerce have responded to letters or offers of negotiation from the manufacturer or local innovative pharmaceutical industry association.

Market Access Barriers

Regulations on Biopharmaceutical Products

Although a revised Pharmaceutical Products Law was enacted five years ago to improve the regulatory process for seeking marketing approval of biopharmaceuticals in Peru, the MoH has repeatedly delayed issuing regulations to implement this Law. When

implemented, the new regulations are expected to significantly improve the currently subpar safety and efficacy standards in Peru.

A Constitutional judge has issued a preliminary injunction ordering the Peruvian Government to cease registering follow-on products based on the former law, until implementation guidelines are issued. However, the MoH has appealed the preliminary injunction, and the current draft guidelines include a transition mechanism that would further delay implementation of the Pharmaceutical Products Law for four more years.

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 of 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 products' importer 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.

Price Control Threat

Bill 2102/2012-CR, submitted before the Congress of the Republic of Peru, proposes the creation of a price regulation agency and the principles to be applied by that agency in regulating prices. In its current form, the Bill raises a number of issues under Peru's Constitution in that it infringes on the right to freely market products (Article 58) and does not stipulate the market failures that the Bill is designed to remedy (contrary to Article 61).

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 investment and 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 2014 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. PhRMA and its member companies appreciate the government's openness and eagerness in 2014, particularly the Ministry of Health, to collaborate and engage with our industry on regulatory and government pricing policies and intellectual property protections that promote patient access to new innovative medicines.

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 remain on the **Watch List** for the 2015 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 2013, PhRMA and its member companies became aware of local generics companies obtaining marketing licenses from the Health Ministry and then proceeding to engage in patent infringing acts in the marketplace. However, in 2014, and after engagement by the U.S. Government and the industry, the Ministry of Health stopped issuing marketing authorizations for copies of patented products, and the Minister of Health created a committee to examine the possibility of implementing an effective patent enforcement mechanism.

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 until after the expiration of any applicable patents.

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 do 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

Over the last two years, 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 2014 attributable to trade barriers related to intellectual property protection and market access.

TUNISIA

PhRMA and its member companies remain concerned about serious IP and market access issues in Tunisia, which 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 (RDP):** Tunisia has not complied with its own law and international obligations to provide RDP for test and other data submitted to the government for pharmaceutical product marketing approval.
- **Government pricing restrictions:** Tunisia requests price reductions without clear basis 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.
- **Public procurement:** PhRMA and its Member Companies are concerned about a recent incident in the public procurement process, whereby it appears that the terms of the tender were altered *ex post facto* to favor a local company. Tunisia has historically exhibited a procurement system that inspired confidence in its integrity; this recent development raises concerns about the predictably, transparency and discriminatory risks in public procurement for international companies. These concerns have been communicated recently to the government; as of this date we have not received a substantive response.

For these reasons, PhRMA requests that Tunisia be placed on the **Watch List** for the 2015 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 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 RDP. 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 RDP 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 RDP, 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 RDP 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 few 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 2014 attributable to trade barriers related to intellectual property protection and market access.