

**PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA
(PhRMA)
SPECIAL 301 SUBMISSION 2013**

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PhRMA SPECIAL 301
SUBMISSION 2013
EXECUTIVE SUMMARY

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 US economy and continued medical breakthroughs that are saving the lives of patients all around the world.

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

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

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

II. The Value of Innovation, Intellectual Property and the Pharmaceutical Industry

U.S. innovation and ingenuity represent our comparative advantage in the global trading arena, and will continue to be essential to America's future prosperity and growth. Capitalizing on this advantage will be critical to sustaining and growing U.S. jobs in the biosciences, particularly in the biopharmaceutical sector, and their contributions to the nation's GDP. However, the U.S. innovative and IP-related sector, including the research-based biopharmaceutical industry, continues to face daunting challenges in protecting their IP. It is essential that the U.S. Government address these challenges to ensure this sector's continued economic sustainability and growth as well as to ensure that the United States remains a global leader in biotechnology – in 2011, PhRMA's member companies invested almost 80% of their research dollars in the United States.¹ President Obama has driven and is expected to continue driving an ambitious agenda that focuses on bolstering the economy, job growth and strengthening our education system to ensure that we attract and retain the world's best and brightest talent. Innovation and American competitiveness are integral to this growth, and PhRMA believes that medical innovation specifically will continue to play a crucial role in advancing patient health and spurring economic growth in the United States.

At the same time, ensuring the robust protection of intellectual property in these markets should not be viewed as a one-way street – it ultimately contributes to growing the economic strength of our trading partners in today's increasingly innovation-centered economies. As the National Economic Council states, "[o]ther countries understand that innovation is fundamental to their economic well-being and are finding new ways to advance their innovation agendas.... Innovation is the key to global competitiveness, new and better jobs, a resilient economy, and the attainment of essential national goals."²

Few industries provide more high-quality, high-paying, and high-productivity jobs in the United States than the biopharmaceutical sector. Industry employment (direct, indirect, and induced) in 2009 totaled 4.0 million jobs,³ including direct employment of over 674,000 Americans.⁴ Direct employment in the biopharmaceutical sector grew almost twice as fast as employment in the rest of the economy between 1998 to 2008.⁵ Each job in the biopharmaceutical sector contributed more than double the average contribution to GDP from jobs in the rest of the economy.⁶ For every dollar that biopharmaceutical companies contributed to gross domestic product (GDP) in 2008, the ripple effect of that activity supported another \$1.91 in contribution to GDP from other

¹ Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2012.

² A Strategy for American Innovation: Driving Towards Sustainable Growth and Quality Jobs, Executive Office of the President, Office of Science and Technology Policy (Sept. 2009).

³ Battelle Technology Partnership Practice, *The U.S. Biopharmaceuticals Sector: Economic Contribution of the Nation*, July 2011. Battelle Memorial Institute. Prepared for the Pharmaceutical Research and Manufacturers of America. (Battelle Report).

⁴ Id.

⁵ Id.

⁶ Id.

sectors.⁷ Nevertheless, our industry faces tremendous loss of revenue that has been widely attributed to fallout of the Global financial crisis, including the deep austerity measures in Europe, threatening jobs, slowdowns in research and development, loss of exports, increased pressure to outsource, and more.⁸

At the same time, PhRMA member companies make substantial investments in research and development, further fueling the U.S. economy and advancing public health through the discovery and development of new cures and treatment options for patients. In 2011, PhRMA members alone invested \$49.5 billion in research and development for new medicines, almost 80 percent of which was invested in the United States.⁹ Furthermore, the average biopharmaceutical company spends approximately \$105,000 on R&D per direct employee, more than ten times the average R&D spend per employee in manufacturing industries overall.¹⁰ Moreover, according to the most recent data from the National Science Foundation, the U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business R&D, representing nearly 20 percent of all domestic R&D funded by U.S. businesses.¹¹ These figures highlight the pressing need to defend this sector's IP rights against infringement. With more medicines in development in the United States than in the rest of the world combined, the United States accounts for approximately 3,240 products in development in 2011, in large part due to IP protections and other strong incentives that foster the environment needed to support continued research and development investment.¹²

A 2012 study by the U.S. Department of Commerce found that IP-intensive areas of manufacturing produce relatively much larger benefits to the U.S. economy, and that pharmaceuticals and biopharmaceuticals are generating the greatest such benefits.¹³ In fact, a recent study on "The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs, Wages, and Exports" found that R&D spending for the pharmaceutical industry had the fastest growth among IP-intensive sectors analyzed, increasing an average of 20.7 percent a year between 2000 and 2007.¹⁴ Moreover, our industry is a strong and growing source of exports. Growing nearly 50% over six years, it is estimated that the value of biopharmaceutical exports was \$260 billion between 2006 and 2011. In 2011 alone, the biopharmaceutical industry exported approximately \$48 billion,¹⁵ making the biopharmaceutical sector the fourth largest R&D intensive U.S. exporting industry.¹⁶

⁷ *Id.*

⁸ Sources including PricewaterhouseCoopers, *Exploring the Relationship between Revenues and Employment in the Biopharmaceutical Industry*, PwC Research Report, June 2009, Table 1; and Ryan, B., Deutsche Bank, "4Q'10 Review & Model Book," Feb. 14, 2011; Peterson, T., J.P. Morgan, "Pharma R&D Post-Mortem," Feb. 16, 2011.

⁹ PhRMA Annual Member Survey (Washington, DC: PhRMA, 2012).

¹⁰ Pham, N., *The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs Wages, and Exports*, NDP Consulting (April 2010), available at http://www.theglobalipcenter.com/sites/default/files/reports/documents/NDP_IP_Jobs_Study_Hi_Res.pdf (last visited Feb. 8, 2013).

¹¹ Science and Engineering Indicators 2012, National Science Foundation, Division of Science Resource Statistics. 2012.

¹² Adis R&D Insight Database, Wolters Kluwer Health (accessed 10 February 2012).

¹³ Intellectual Property and the U.S. Economy: Industries in Focus. United States Department of Commerce. March, 2012.

¹⁴ Pham, N., *The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs Wages, and Exports*, NDP Consulting (April 2010), available at http://www.theglobalipcenter.com/sites/default/files/reports/documents/NDP_IP_Jobs_Study_Hi_Res.pdf (last visited Feb. 8, 2013).

¹⁵ U.S. International Trade Commission, Trade DataWeb, accessed January 20, 2013, at <http://dataweb.usitc.gov/> (query run of U.S. domestic exports classified by 4-digit NAIC code 3254).

¹⁶ Industry export data from PhRMA analysis of data from United States International Trade Administration.

Because the benefits from the biopharmaceutical sector are so robust, it is critical that IP violations, the gravity of each violation in its effect on the rights holder, and the importance of the rights holder in the U.S. economy, is reflected in processes like 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.

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.”¹⁷ This is due in large part to the research-intensive nature of this sector, which contributes to high research and development costs. In knowledge-based sectors, such as the biopharmaceutical sector, intangible assets are often more valuable than tangible assets. This sector is reliant on the ability to raise capital to support the substantial investments in research and development needed to develop today’s treatments and tomorrow’s cures. When IP is infringed, biopharmaceutical companies are often unable to recoup their research and development investments, reducing the capital available to reinvest in more research and development. A survey of American research and development executives found that without patent protection, 60 percent of the projects which ultimately produced discoveries in pharmaceuticals would never have happened.¹⁸ IP rights and their enforcement assure inventors and companies that their investments in time, money, and human capital will be protected if they are successful, and that they will have the opportunity to earn a return on investment. A clear legal framework provides the certainty, security, and predictability necessary for this sector’s sustainability and growth. A lack of commitment to protect IP will impair future research and development investment, and discourage the capital investments that are so critical to developing new technologies that not only help patients, but create new jobs.

As discussed by Hassett and Shapiro (2011), U.S. intellectual property accounted for more than one-third of the market value of all U.S. stocks – \$8.1 trillion to \$9.2 trillion – equivalent to about 55 to 63 percent of America’s GDP and greater than the GDP of any other economy in the world.¹⁹ Given the dominant role of intellectual capital in the U.S. economy, the failure to adequately protect IP poses serious economic harm. Further, they note that: “[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.”²⁰

¹⁷ See, e.g., Grabowski, H., Patents, innovation, and access to new medicines, *J Int’l Economic Law* 2002:849-860.

¹⁸ Edwin Mansfield, Patents and Innovation: An Empirical Study, *Management Science*, Vol. 32, No. 1 (1986).

¹⁹ Hassett, K. and Shapiro, R., What Ideas Are Worth: The Value of Intellectual Capital and Intangible Assets in the American Economy (Sep. 2011), available at http://www.sonecon.com/docs/studies/Value_of_Intellectual_Capital_in_American_Economy.pdf (last visited Feb. 8, 2013).

²⁰ *Id.*

Providing Innovative Solutions to Healthcare Access in the Developing World

PhRMA member companies are actively engaged in solving the health problems of the developing world, and America's biopharmaceutical companies are one of the largest contributors of funding for innovative treatments 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.²¹

IP is not the barrier to patient access to medicines; rather it is the driver behind these types of efforts. 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."²²

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.²³ 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, investing more than \$525.1 million into new cures and treatments in 2011 alone – making them the second largest funder in the world, behind the United States National Institute of Health (\$1.2 Billion) and ahead of the Gates Foundation (\$448 million).²⁴ Without these efforts, which are threatened by the failure of many countries to adequately protect IP rights, access to effective, sustainable healthcare for the developing world's patients would be impossible.

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;
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.

²¹ IFPMA Survey, validated by LSE Health and Social Care at the London School of Economics and Political Science.

²² Remarks by Bill Gates at the World Economic Forum, Gates Foundation Press Conference (January 29, 2010).

²³ See www.globalhealthprogress.org.

²⁴ Moran, M. et al., Neglected Disease Research and Development: New Times, New Trends, The George Institute for International Health (2012).

III. Protecting IP Rights in Foreign Markets

1. 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 impairing future research and development investment, and discouraging the venture capital investments that are so critical to developing new technologies that not only help patients, but create new jobs for millions of Americans.

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

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.

2. 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.²⁵) Developing countries have increasingly put patent systems in place, but with mixed results.

- **Scope of Patentability** – 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. However, there are certain markets that restrict the scope of patent eligible subject matter in a manner that undermines the patenting of important biopharmaceutical inventions. These restrictions are inconsistent with international standards set forth in the TRIPS Agreement, and, perhaps more importantly, prevent U.S. businesses from realizing the potential of valuable inventions in these markets. Key trading partners with behavior of concern related to scope of patentability include: Argentina, Australia, Brazil, Canada, China, Colombia, Costa Rica, Finland, India, Peru, and Venezuela.
- **Patent Backlogs and Approval Delays** – A prerequisite for effective protection of intellectual property in a particular market is a patent office that grants patents on eligible inventions within a reasonable period of time. However, in some countries, there are unreasonable patent 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 adjust the patent term to offset any of the delays caused by the backlog. In some markets, the delays are so severe that half or more of the patent term is eliminated. Key trading partners with concerning patent backlogs and approval delay include: Argentina, Chile, Colombia, Dominican Republic, Indonesia, Malaysia, New Zealand, Turkey, and Vietnam.
- **Patent Enforcement** – Even where a country has adequate patent laws and a functioning patent office there must be an effective enforcement mechanism for the system to work. In addition, patent laws covering innovative biopharmaceuticals must not be undermined by any country whether through circumvention of the patent regime (e.g., mislabeled herbal supplements in Russia containing active pharmaceutical ingredients) or under the justification of industrial healthcare policy; otherwise, patents will be granted and recognized, but rendered meaningless. For this reason, the TRIPS Agreement and many bilateral and regional trade agreements call for signatories to establish adequate patent enforcement mechanisms. Key trading partners with inadequate patent protection mechanisms include: Algeria, Argentina, Australia, Brazil, Canada, Chile, China, Costa Rica,

²⁵ 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.

Dominican Republic, Ecuador, El Salvador, Finland, Guatemala, Honduras, India, Indonesia, Israel, Korea, Lebanon, Malaysia, Mexico, New Zealand, Nicaragua, Peru, Portugal, Russia, Saudi Arabia, Taiwan, Thailand, Tunisia, Turkey, Ukraine, Venezuela, and Vietnam.

- ***Early Resolution of IP Disputes and Marketing Approval*** – Our trading partners must provide adequate and effective protection of IP rights for the research-based pharmaceutical industry in order to sustain innovation and development of new medicines over the long term. To accomplish this goal, mechanisms are required which prevent marketing of patent infringing products. Providing mechanisms that facilitate resolution of patent infringement issues before the product in question is allowed to enter a market is an important tool for accomplishing this objective. Early resolution of patent disputes before the third party product in question gains marketing approval avoids, for instance, the need for complex litigation over damages for marketing an infringing product. Key trading partners with inadequate implementation of mechanisms for the early resolution of IP disputes and marketing approvals include: Algeria, Argentina, Australia, Canada, Chile, China, Colombia, Dominican Republic, El Salvador, Honduras, India, Korea, Malaysia, Mexico, Nicaragua, Peru, Portugal, Russia, Saudi Arabia, Taiwan, Thailand, Turkey and Vietnam.
- **Use of Compulsory Licensing and Other Mechanisms that Undermine IP Rights for Domestic Industrial Policy Purposes.** 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. This is a clear violation of the principle in TRIPS that patent rights should be enjoyable without discrimination as to whether products are imported or locally produced, and raises numerous other WTO concerns, including under the TRIMS Agreement. 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. These policies seriously undermine the Obama Administration's plans to increase exports of U.S. goods and grow the U.S. economy.
- **Preferential Trade Policies That Limit U.S. Companies' Abilities to Compete Globally and Undermine IP:** Many countries have erected barriers that impede our industry's ability to compete globally through policies that discriminate in favor of domestic companies and thus undermine IP rights. 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*** – Although 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 requiring investment in local manufacturing facilities as a condition of market entry. Algeria, for example, reinstated a decree it had previously discontinued as part of the WTO accession process (“Arrêté du 30 Novembre 2008 relatif à l’interdiction des produits pharmaceutiques et dispositifs médicaux destinés à la médecine humaine fabriqué en Algérie”, which took effect in 2009) that prevents the importation of pharmaceutical products if those products are also manufactured by other manufacturers locally. As a result, in order to enter the Algerian market, companies must invest in local manufacturing facilities. Hundreds of medicines are subject to this import restriction, which unfairly discriminates against innovative medicines and 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 a license, 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.

- **Protection for Pharmaceutical Test or Other Regulatory Data:** 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. Key trading partners with concerns relating to implementation and enforcement of regulatory data protection include: Algeria, Argentina, Australia, Brazil, Canada, Chile, China, Costa Rica, Dominican Republic, Ecuador, Guatemala, Honduras, India, Lebanon, Malaysia, Mexico, Nicaragua, Peru, Russia, Saudi Arabia, Taiwan, Thailand, Tunisia, Turkey, Ukraine, Venezuela, and Vietnam.

3. 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.

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

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

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

Foreign governments are increasingly employing a range of strategies to control prices and contain costs related to biopharmaceuticals. Based on a recent 2012 analysis, approximately 53 countries proposed or implemented cost containment measures impacting the biopharmaceutical sector.²⁶ In fact, the biopharmaceutical sector is unique in that it faces onerous price controls and other related measures in the vast majority of the sector’s export markets, and in many of these markets the government is the sole pharmaceutical purchaser.

Moreover, international organizations such as the International Monetary Fund (IMF), European Central Bank (ECB), and the World Bank have recently recommended the adoption of cost containment measures as a condition for relief assistance to governments under extreme duress, including Greece, Ireland and Portugal. Among recommended sectoral reforms, healthcare and pharmaceutical spending have been targets for profound unilateral spending cuts by such organizations, which appear to be solely for the benefit of short-term savings targets without regard for long-term impact.²⁷

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.²⁸ These

²⁶ Ross Consulting, analysis for PhRMA, August 2012.

²⁷ IMF, “Request for a Three-Year Arrangement Under the Extended Fund Facility,” IMF Country Report No. 11/127, June 2011; and IMF, “Romania: Letter of Intent, and Technical Memorandum of Understanding,” March 10, 2011.

²⁸ 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.

conclusions corroborate findings from a 2004 U.S. Department of Commerce Report that concluded price control policies can limit competition in some markets and require national health systems to forego the benefits of certain innovations in reducing health care costs dramatically impacting the U.S. biopharmaceutical industry's ability to enter and compete in new markets as well as its ability to compete in existing markets.

In addition to price controls, the biopharmaceutical sector has witnessed a surge in a number of cost containment measures, which in some cases have disproportionately targeted our sector. Such measures often have significant ripple effects in many markets. For example, *ad hoc* price cuts implemented in one country can directly and indirectly impact the price of medicines in many other markets due to international reference pricing where a government considers the price of a medicine across a set (or "basket") of countries to determine the price of medicine in its own country. This can create a downward spiral in terms of prices for medicines, and may result in product shortages for medicines patients need. For example, according to a recent report, in 2011 the modeled impact of a hypothetical 10 percent price drop in Greece would have cost industry \$390 million in Greece but \$1 billion in Europe (*i.e.*, 2.5 times more) and \$2.8 billion worldwide (*i.e.*, 7.0 times more) if all countries re-referencing Greek prices through formal and informal links are included.²⁹

PhRMA recognizes the significant fiscal challenges that foreign governments face and seeks to be a partner in finding solutions; however, some governments have proposed or implemented cost containment measures without a predictable, transparent, and consultative processes. Such cost containment policies typically put short-term government objectives ahead of long-term strategies that would ensure continued R&D into medicines that patients need most.

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

- **Ad Hoc Government Price Cuts:** *Ad hoc* price cuts include arbitrary measures employed by some countries to meet short-term budgetary demands without considering longer-term implications to innovation and other critical factors. For example, over the last few years, Turkey has ratcheted up the mandatory social security discount from 11 percent in 2009 to 41 percent at the end of 2011. Similarly, in April 2010, Greece implemented dramatic, albeit temporary, price cuts of up to 27 percent (21.5 percent on average).³⁰ Moreover, in addition to 20

²⁹ Charles River Associates. International Reference Pricing: Relationship Mapping, Re-Referencing, and Economic Spillover Impact. April, 2011.

³⁰ Hirschler, B., "EU drug prices face deepening austerity squeeze," Reuters, July 21, 2010.

percent price cuts to off patent medicines announced in 2010, in mid-2011 Korea announced plans to reduce off patent prices by as much as 26 percent in 2012.

- **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, mounting evidence points to the damaging nature of the policy including a 2012 European Commission Report by the Directorate-General for Economic and Financial Affairs which concluded that “[b]y 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.... is a deterrent to producers [to conduct business in those areas].”³¹

If IRP is to be used by a country, its methodology must be balanced and “the application of IRP should be objective and transparent, in order to provide opportunities for assessing its effects, make decision-makers accountable, reduce uncertainty for the pharmaceutical industry, and diminish the risk of discrimination and corruption.”³² Nevertheless, certain countries are in egregious 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.³³

- **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

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

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

³³ International Reference Pricing Analysis for PhRMA: Saudi Arabia, Charles River Associates, London, Jan. 2011.

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. Adhoc mandatory rebates can negatively impact a company's ability to plan ahead, and contribute to creating a highly unpredictable business environment. For example, in March 2010, the German Ministry of Health unexpectedly called for a "temporary" increase of the mandatory rebate from 6 to 16 percent on non-reference priced medicines. This policy has been implemented since August 2010. (Notably the anticipated budget shortfall that was cited to justify the temporary increase of the rebate never materialized. Nonetheless, the "temporary" rebate increase remains in force.) Similarly, on August 20, 2011, Spain imposed a mandatory 15 percent rebate on all medicines sold in Spain for ten or more years.

In addition to the more common mechanisms highlighted, numerous additional egregious policies are in play. For example, in November 2012, the Indian Union cabinet cleared the National Pharmaceutical Pricing Policy 2012 (NPPP 2012) which was notified in December 2012. The new policy prescribes price controls on all 348 drugs of the National List of Essential Medicines (NLEM) 2011. Under the new policy, ceiling prices for NLEM drugs will be fixed by taking the simple average of prices of all brands of the drugs that have more than 1% market share; however, expansion of price controls to a larger range of medicines will not substantially improve access to medicines in India, because lack of access is more a function of insufficient healthcare financing systems and inadequate healthcare facilities.³⁴ For example, medicines and vaccines which are offered free of charge often do not reach the patients who need these medicines.³⁵ In another example, Colombia has recently layered numerous government pricing and reimbursement control policies on top of one another including one that expands price controls to the private market.

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 the systematic evaluation of properties, effects, or other impacts of health care technology. 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

³⁴ "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. 8, 2013).

³⁵ "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, accessed at http://www.isid.ac.in/~pu/conference/dec_09_conf/Papers/NilanjanPatra.pdf (last visited Feb. 8, 2013).

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. 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.

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.

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

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

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

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

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

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

V. 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. 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. The extent of the worldwide counterfeiting problem is difficult to quantify, but all estimates suggest that counterfeiting of medicines is on the rise.³⁶ For example, recent estimates indicate that between 10 to 30 percent of medicines sold in developing markets are believed to be counterfeit.³⁷ 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), several common deficiencies contribute to the growing prevalence of pharmaceutical

³⁶ See generally, Incident Trends, at <http://www.psi-inc.org/incidentTrends.cfm>. The Pharmaceutical Security Institute, Inc., a not-for-profit, membership organization dedicated to addressing pharmaceutical counterfeiting issues, is based in Vienna, Virginia.

³⁷ The World Health Organization, IMPACT, at www.who.org (2008).

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. There is also a need to increase customs controls and international information-sharing in a world where counterfeit shipments follow ever-more convoluted itineraries, including stops at free trade zones.

VI. Country Designation Index

Priority Foreign Country or Section 306 Monitoring

PhRMA recommends that Turkey be designated a Priority Foreign Country under “Special 301” for 2013 and The People’s Republic of China continue under Section 306 Monitoring. PhRMA urges USTR to take aggressive action to remedy these violations, including the consideration of WTO dispute settlement, as necessary.

Priority Watch List Countries

PhRMA believes that 15 countries should be included in the 2013 Priority Watch List. PhRMA urges USTR to take aggressive action to remedy these violations, including the consideration of WTO dispute settlement, as necessary.

Watch List Countries

The PhRMA submission identifies 24 countries which should be included on the Special 301 Watch List in 2013. These are countries that will require continued or enhanced monitoring by USTR. In this context, the importance of public diplomacy has never been greater. In many cases, we understand the political barriers to legal reforms need to be addressed to provide rule-of-law protections such as regulatory data protection. Successful implementation will require a commitment from the U.S. Government to promote successful implementation of the WTO TRIPS Agreement.

PRIORITY FOREIGN
COUNTRY

TURKEY

The member companies of the Pharmaceutical Research and Manufacturers of America (PhRMA) face several market access barriers in Turkey, including discriminatory and unworkable government product registration, reimbursement and pricing systems, and deficiencies in Turkey's intellectual property framework. During the last decade, Turkey has undertaken reforms to modernize its economy and expand its health care system in many positive ways for Turkish patients. A general lack of transparency and inconsistency in decision making, however, has contributed to unclear policies that undermine Turkey's investment climate and damage market access for PhRMA member companies.

Key Issues of Concern:

- **Lack of Effective Patent Enforcement and Regulatory Data Protection:** Turkey does not provide an effective mechanism for resolving patent disputes before the marketing of follow-on products and inappropriately ties the regulatory data protection period to the patent term.
- **Delayed Regulatory Approvals:** The period required to complete the regulatory approval process for medicinal products significantly exceeds the 210 days stated in the regulations.
- **Untimely Implementation of Local Inspection Requirements:** Lack of resources and the absence of reasonable transitional procedures at the Ministry of Health (MOH) to conduct Good Manufacturing Practices (GMP) inspections at every pharmaceutical production facility are adding to the significant registration delays, thereby delaying patient access to innovative medicines and negating the benefits of the patent and data protection period.
- **Draconian Government Price Controls:** The Turkish Government established an unrealistic pharmaceuticals budget for 2010-12 by insisting on the budget figures projected in 2009 and not updating the budget to reflect the healthcare system's actual needs and economic growth. The outdated budget figures disregarded parameters such as economic growth, inflation and exchange rate fluctuations, and resulted in forced price discounts at unsustainable levels that hinder access to innovative medicines. Moreover, despite the rapidly growing demand of its population for innovative healthcare products and services, Turkey continues to impose unrealistic budget expenditures for pharmaceuticals in 2013, without releasing any of the existing burdens caused by confiscatory price discounts and exchange rate fluctuations.

PhRMA and its member companies strongly believe that given the dramatic impact on market access for innovative pharmaceutical products caused by the lack of resources and absence of adequate transitional mechanisms needed to efficiently implement Turkey's new GMP requirements, as well as the cumulative impact of repeated government price cuts, Turkey should be listed as a **Priority Foreign Country**. PhRMA greatly appreciates the U.S. Government's advocacy efforts to date

and encourages continued efforts to ensure that these and other problems described herein are quickly and effectively resolved.

Intellectual Property Protections and Enforcement

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.

Lack of Effective Patent Enforcement

Turkey today does not provide an effective mechanism for resolving patent issues before the marketing of follow-on products, such as generics. Effective mechanisms would help eliminate this problem by fostering early resolution of patent issues prior to marketing approval of the generic product.

Regulatory Data Protection

In 2005, the Turkish Government took positive steps toward establishing protection for the commercially valuable regulatory data generated by innovative pharmaceutical companies, and now provides regulatory data protection for a period of six years for products registered in the EU, limited by the patent protection period of the product. Regulatory data protection is an independent and separate form of intellectual property protection that should not be limited to the period of patent protection.

A significant concern for the innovative industry is that the period of regulatory data protection currently begins on the first date of marketing authorization in any country of the European Customs Union. Considering the extended regulatory approval times exceeding 1,100 days³⁸ in Turkey, and with the imposition of the new GMP barrier, current estimates are that it could take 4-5 years to register and reimburse a new medicine in Turkey. Under these adverse circumstances new products will receive, in practice, no more than one to two years of protection, undermining incentives needed for innovators to undertake risky and expensive research. Regulatory approvals need to be granted by MOH within 210 days; if not, the six year period of regulatory data protection should commence when local regulatory approval for the product is obtained in Turkey.

Another concern of the innovative pharmaceutical industry is that the legislation governing regulatory data protection has been changed by the Regulation to Amend the Registration Regulation of Medicinal Products for Human Use.³⁹ The change that has been introduced is incompatible with EU standards in that it eliminates regulatory data protection for combination products. Innovative companies invest considerable amounts of time and effort to develop products that provide increased efficacy and safety, as well

³⁸ AIFD Situation Assessment Survey of CTD Applications, January 2012.

³⁹ Official Gazette No. 27208 (Apr. 22, 2009).

as new indications, from new combinations of separate molecules. Such products are developed to benefit patients and should be eligible for data protection.

Market Access Barriers

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.⁴⁰ 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 regulatory approval period exceeded 1,100 days in 2011.⁴¹

The MOH's recent revisions to the Registration Regulation have compounded these delays.⁴² Effective March 1, 2010, a Good Manufacturing Practices (GMP) certificate that is issued by the Turkish Ministry of Health must be submitted with each application to register a medicinal product for each of the facilities at which the product is manufactured. The GMP certificate can only be issued by MOH following an on-site inspection by Ministry staff, or by the competent authority of a country that recognizes the GMP certificates issued by the Turkish MOH. However, for the reasons explained further below, neither option can be completed in a timely manner.

AIFD estimates that approximately 250 innovative products manufactured outside Turkey, including anti-infectives, antipsychotics, vaccines, cardiovascular, diabetes and oncology drugs, are currently awaiting registration by the MOH. Further, MOH has thus far received approximately 1,200 applications for 850 products to conduct GMP inspections, requiring inspections at almost 320 overseas sites.⁴³ MOH does not have the resources to complete these GMP inspections in a timely manner. It should be noted that there has not been any transitional mechanism to allow approval of pending applications while building up the adequate regulatory capabilities.

Furthermore, although the Amended Registration Regulation permits applicants to submit GMP certificates issued by competent authorities in other countries, it does so only to the extent that the pertinent country recognizes the GMP certificates issued by Turkey. There are, however, two significant hurdles to this mutual recognition arrangement: 1) Turkey is not a member of the PIC/S (Pharmaceutical Inspection Convention and Co-operation Scheme) that provides guidance on international GMP standards; and 2) Turkey will need to negotiate mutual recognition agreements with

⁴⁰ Official Gazette No. 25705 (Jan. 19, 2005) (Registration Regulation).

⁴¹ AIFD Situation Assessment Survey of CTD Applications, January 2012.

⁴² 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).

⁴³ AIFD GMP Inspections Survey, April 2012.

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 a measure 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.

Pricing and Reimbursement

In Turkey, pharmaceuticals' pricing is regulated by the MOH Pharmaceuticals and Medical Devices Agency of Turkey. The reimbursement system is based on a positive list and reimbursement decisions are the responsibility of the inter-ministerial Reimbursement Commission, led by the Social Security Institution (SSI). Reimbursement decision criteria are not clearly defined. The process is nontransparent and maintains lengthy timelines as a result of frequent delays in decision-making and erratic meeting schedules. On average, it takes over 345 days in reimbursement review for one product (from application for reimbursement to final decision).⁴⁴

Prior to 2009, the Turkish pricing system for medicinal products consisted of referencing the lowest price among five selected EU countries (France, Spain, Portugal, Italy and Greece) and the country or countries from which the product was shipped, and then reducing that reference price by 11 percent.⁴⁵ However, 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. If the reference price decreases at some point in the future, the discount is taken from the reduced reference price. PhRMA and its members encourage the Turkish Government, as part of the 2013-2015 Global Budget negotiations, to end the 9.5 and 8.5 percent discounts applied in 2010 and 2011 as these were implemented to address the budget overruns of 2010-11.
- 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

⁴⁴ AIFD Market Access Survey, March 2011.

⁴⁵ In Turkey, pharmaceutical pricing is governed by the MOH Pricing Decree (June 30, 2007, last amended on Nov. 11, 2011) and Notifications (Sept. 22, 2007, last amended on April 14, 2012). Reimbursement is made pursuant to the Healthcare Implementation Guideline (SUT) (Mar. 25, 2010, last amended on July. 28, 2012) as promulgated by the Social Security Institute (SSI).

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 allows for 7 percent growth per annum for 2011 and 2012. In the event that these caps are exceeded, additional price cuts are anticipated based on an unofficial protocol to which the industry agreed under the threat of more severe price cuts and measures. The protocol stipulates that the parties should avoid the need for *ad hoc* and unexpected implementations of therapeutic price referencing. Further, the protocol states 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).

With the latest data released by SSI, it is estimated that spending on pharmaceuticals for 2010-2012 will be nearly 1.1 B TL less than the budgeted amount. Contrary, however to the unofficial protocol, none of the several rounds of discounts that led to this surplus are being revoked. PhRMA and its member companies strongly believe that creating a more predictable government pricing environment should be a goal of the 2013-2015 Global Budget period.

- Fixed Exchange Rate for Pharmaceuticals: In addition, in April 2009, the GOT fixed the Euro to Turkish Lira exchange rate, for pharmaceutical pricing purposes only, to 1 Euro to 1.9595 Turkish Liras and has not adjusted it since. Based on the most recent 90 day average, this is an additional discount of more than 15 percent. The combined impact of the price cuts and fixed exchange rate is close to \$2 billion in lost sales revenue.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

SECTION 306

MONITORING

THE PEOPLE'S REPUBLIC OF CHINA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in The People's Republic of China remain concerned over the lack of effective regulatory data protection, infrequent and lengthy reimbursement updates, and restrictive government pricing policies. Despite positive actions by Chinese authorities in 2012, counterfeiting of medicines continues to be rampant in China and under-regulated active pharmaceutical ingredients continue to enable the production of unsafe medicines by global counterfeiters.

Key Issues of Concern:

- **Regulatory Data Protection:** Although China committed as part of its accession to the World Trade Organization (WTO) to provide a 6-year period of protection for test data submitted to secure approval of products containing new chemical entities, in practice the protection has not been effective.
- **Counterfeiting:** China has issued a national plan to improve drug safety and severely crack down on the production and sale of counterfeit medicines, resulting in several positive and tangible actions on the enforcement front. However, the production, distribution and sale of counterfeit medicines and unregulated APIs remain rampant in China and continue to pose a threat to China and its trading partners. China's continued commitment and perseverance (and cooperation with its trading partners and industry) will be necessary to fulfill the declared objectives on drug safety and anti-counterfeiting.
- **Government Pricing & Reimbursement:** The lengthy process for updating the National Reimbursement Drug List (NRDL) delays market access to innovative pharmaceuticals and prevents their timely availability to patients. In addition, government pricing policies and procedures being considered by the Government of China could create an unfavorable business environment, further reduce reward for innovation, restrict patient access to quality medicines and undermine China's healthcare and innovation policy objectives.

For these reasons, PhRMA requests that China be subject to **Section 306 Monitoring** for the 2013 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 and Enforcement

Patent Examination Guidelines

In 2006, China revised its patent examination guidelines regarding the disclosure required to claim pharmaceutical compounds (though the patent law was not changed). Examiners have been applying these new guidelines to all applications, regardless of when they were filed. They have been requiring a significant amount of biological data

in the patent specification as filed, and they will not accept data submitted during patent prosecution. The adoption of this new guideline has caused concerns about the validity of existing patents granted prior to 2006. The Government's practice under the guideline contravenes the practice used by the USPTO, JPO, and EPO, as well as the standard provided by the Patent Cooperation Treaty (PCT), of which China is a member. This has caused denials of patents in China to medicines that have received patents in other jurisdictions. China should ensure new patent disclosure obligation regulations will not automatically prevent grant of patents filed before the date of the new regulation. China should also reinstate patent applications that were adversely affected and consider relevant data generated after patent applications are filed, consistent with the practice in the United States, EPO, Japan, Korea, and as provided for in the PCT.

Regulatory Data Protection

Following accession to the World Trade Organization (WTO) in 2001, China revised its laws to incorporate concepts from Article 39.3 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 39.3 provides that a country must protect data submitted in the context of a drug registration application from unfair commercial use. Inadequacies in China's current regulatory environment, however, allow for unfair commercial use of safety and efficacy data generated by PhRMA member companies.

The Implementation Regulation of the Drug Administration Law and the Drug Registration Regulation establish a six-year period of protection for test data of products containing a new chemical ingredient against unfair commercial use. The State Food and Drug Administration (SFDA) is responsible for upholding this law. Unfortunately, the current law is ambiguous as to how data protection is implemented. For example, certain key concepts such as "new chemical ingredient" and "unfair commercial use" are undefined.

Regulatory data protection (RDP) should be granted to any originator whose product is "new" to China. Unfortunately, in practice, China grants RDP only to pharmaceutical products that are "new" to the world – in other words introduced first 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.

China's regulatory procedures permit the SFDA to grant marketing approval to products that have previously been approved outside of China. Non-originator applicants can effectively rely on the originator's overseas marketing approval to meet their requirements for obtaining marketing approval in China, contrary to China's international obligations under the TRIPS Agreement to prevent such reliance.

China's open reliance on the originator's overseas marketing approval allows a subsequent manufacturer the ability to gain marketing approval in China. Supplemental data alone are insufficient to prove the safety and efficacy of a "new" product. The original data were necessary to demonstrate the safety and efficacy of the product and

were gathered over long periods of time and at great expense. Reliance on those data directly or indirectly by reference to summaries thereof gives an unfair commercial advantage to non-originator companies that did not incur the cost of generating their own clinical data to prove safety and efficacy.

Effective Patent Enforcement

Transparent mechanisms are needed in China to ensure that patent issues can be resolved before follow-on products are marketed. While Articles 18 and 19 of China's updated Drug Registration Regulation refer to recognition of patents associated with drug registration, and a maximum "two-year period" for submitting a registration application before the patent on the drug expires, the regulation does 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 revised regulation states that if an infringement dispute occurs during the application period, it "should be resolved according to patent laws and regulations." However, the patent laws require there to be sales in the marketplace before an infringement suit can be filed. In addition, the "Bolar Exemption" provision in the Third Amendment of the Patent Law exempts any production of patented products from infringement as long as it is "for the purpose of submitting information necessary for an administrative approval". As a result, PhRMA member companies have not been able to consistently resolve patent disputes prior to marketing.

To avoid costly patent litigation and to increase market predictability, China 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.

Counterfeit Pharmaceuticals

Pharmaceutical counterfeiting is a global public health concern. The Chinese Government has expressed a public commitment to reduce counterfeit medicines and PhRMA applauds China for undertaking a series of actions towards achieving that goal.

In 2011 and 2012, China increased coordination among authorities and waged a special enforcement campaign targeting counterfeits, resulting in more raids of criminal manufacturing sites, arrests, and some prosecutions that help to send a clear message of deterrence to criminal counterfeiters. In 2011, Premier Wen Jiabao announced the decision to make the special campaign permanent and to create the National Intellectual Property Enforcement Office, and SFDA announced plans to create a new Drug Safety Investigative Unit and Drug Complaint Center. In 2012, China conducted a nation-wide crackdown targeting 24 crime rings and resulting in the arrests of approximately 2,000 individuals and the seizure of \$180 million in counterfeit drugs.

PhRMA applauds China's increased enforcement measures under the National Drug Safety Plan and urges the central and government to continue to reward and ensure law enforcement efforts in this area, including at the provincial and local levels.

As part of its enforcement efforts, China has been working to tackle the sale of counterfeits on the Internet. From 2010-2012, China worked across ministries to shut down several websites selling fraudulent medicines. Reported cooperation between the U.S. FDA and China resulted in successful operations to shut down sites that were exporting from China into the United States. We hope that China's efforts to stop counterfeit drugs sold on the Internet will continue and increase in 2013. We encourage 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 multi-lateral efforts to reduce the global counterfeit drug trade.

Over the last several years, China has also sought to strengthen the legal framework to deter counterfeiting of medical products. In 2009, China upgraded the Judicial Interpretations regarding the crime of drug counterfeiting, which significantly lowered the incriminating "threshold" for certain high-risk counterfeit products. China then incorporated a provision in the 8th Amendment of the Criminal Code which eliminates the incriminating threshold for all drug-counterfeiting activities. These changes seem to be aiding successful enforcement.

PhRMA also applauds China's commitment to enhance the integrity of the national drug supply chain through the establishment of the Drug Complaint Center and its ongoing work to serialize and trace legitimate pharmaceutical products. PhRMA encourages China to explore how the system can be compatible with internationally recognized standards for coding product, in order to reduce the cost to manufacturers and prevent any inadvertently negative impact on global trade or drug availability.

PhRMA hopes to serve as a partner to China on reaching its declared drug safety objectives and by enhancing all the efforts discussed above. Increased coordination with industry (specifically the brand owners) to discuss coordination to combat counterfeiting and to share information, including samples of counterfeit product seized and information about quantities or crime rings, can help to increase industry's ability to protect their patients, understand trends, and aid law enforcement authorities all over the world.

Despite these positive steps, a remaining challenge related to counterfeit medicines in China is the use and regulation of bulk chemicals or Active Pharmaceutical Ingredients (APIs). Many chemical companies violate SFDA requirements by producing bulk chemicals without registration and advertising/selling them to counterfeiters for illegal medicinal uses. China views drug manufacturers as having primary responsibility for drug quality and encourages all companies to purchase APIs only from the SFDA's approved and registered list of API manufacturers. However, the unregulated distribution of API by unregistered or unapproved manufacturers contributes to the

global supply of counterfeit medicines, herbal supplements containing API, and counterfeit traditional Chinese medicines. As such, the ability of unregistered companies to sell API within and from China exposes patients globally to serious health risks and may degrade consumer confidence in the global medicinal supply chain. China has committed publicly that it aims to address this issue and improve the regulation of APIs in a way that will reduce counterfeiting.

PhRMA urges China to address unregulated API as part of its stated drug safety objectives in the 12th five-year plan, including by exploring ways to update the Drug Administration Law (DAL) to prevent the manufacture/sale/distribution of APIs. Initial steps might include a focus on the APIs most commonly used in counterfeits, as well as new legislation to make chemical companies liable if they knowingly sell unregulated chemicals for use in counterfeit medicines or Traditional Chinese Medicines (TCMs). PhRMA commends China's work to resolve this issue for the sake of patients harmed domestically and globally. PhRMA is willing to support and partner with the Chinese authorities where possible to advance our shared goal of promoting drug safety in China.

Market Access Barriers

Clinical Trial Application Approval

Over the last few years, the SFDA has made significant strides to increase efficiency and transparency. Additionally, the Center for Drug Evaluation (CDE) is undertaking a series of initiatives to encourage innovation, including developing detailed approval pathways and enhancing regulation of clinical trials. To help China further integrate into the global innovation network, China should harmonize its regulatory framework with international regulatory standards and practices and strengthen its clinical infrastructure. Specifically, steps should be taken to shorten the Clinical Trial Application (CTA) review process timeline. Currently, CTA approval in China can take 10 to 18 months, which is much longer than international practice. This is a significant barrier to global drug development and accelerating the CTA review timeline will improve the efficiency of drug development and reduce the time it takes for innovative new medicines to reach patients. Underlying the CTA delay is a misalignment between SFDA capacity and rising industry innovation activities. CTA review increased 14 percent annually between 2008 and 2010; however the size of the CDE staff remains unchanged. In addition, the CTA amendment process is not aligned with international practices. While many countries accept CTA amendments after initial submission, changes in clinical trial protocols in China often require new CTA submissions, leading to a duplication of work for both companies and regulators. In order to further improve the regulatory environment in China, PhRMA recommends that the SFDA develop a more supportive regulatory framework that fosters innovation and that is in line with international best practices.

China's Reimbursement List

Over the past 10 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, which takes approximately 3-4 years (acceptance on the NRDL and the following 3-years of updates to the Provincial Drug List), delays market access to innovative pharmaceuticals and prevents their timely availability to patients who need them. PhRMA encourages more frequent updates of the NRDL to ensure Chinese patients are better able to access these important products.

Government Pricing Policies

Pharmaceutical products in China are subject to government price controls. PhRMA encourages the Chinese Government to engage innovative pharmaceutical companies to evaluate and implement an appropriate government pricing policy that recognizes and rewards 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. PhRMA wishes to ensure that the 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 EDL 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, efficacious essential medicines are available to the patients who need them most, within a broad sustainable healthcare system.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

PRIORITY WATCH LIST

ASIA-PACIFIC

INDIA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in India acknowledge the massive challenge of extending healthcare access to the large and growing population of India and are committed to working closely with the Indian Government and other stakeholders to find appropriate solutions to this challenge. We have, however, serious concerns about public policy issues that affect our member companies, as well as the broader healthcare industry in India.

PhRMA and its member companies recognize that India has legitimate concerns regarding access to healthcare throughout the country and we acknowledge the challenges of the Government to make essential medicines available to the most vulnerable sections of society. However, we are concerned about inadequate intellectual property (IP) protections, including the recent issuance of a compulsory license, which pose significant market access barriers in India. Having created a strong domestic biopharmaceutical industry, India has so far failed to provide regulatory data protection to encourage new innovations carried out by both its own industry and PhRMA member companies. Standards for patentability need to be amended to conform to prevailing international practice.

Limiting IP protections and creating barriers to market access will only inhibit India's own biopharmaceutical industry from developing products for India, while doing little to improve accessibility of medicines for its population. Sustainable solutions to India's healthcare concerns should be found through programs that address the lack of healthcare financing. PhRMA and its member companies are willing to partner with the Indian Government in developing those public policy solutions.

Key Issues of Concern:

- **Compulsory Licensing (CL):** In March 2012, India issued its first CL.⁴⁶ The decision was based on price differences and Indian "patent working" requirements. The decision held that local manufacturing is mandatory to fulfill working requirements, which is not consistent with India's obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Additionally, recent media reports indicate that the Government of India has started the process of issuing CLs for the manufacture of three additional cancer drugs.
- **Lack of Regulatory Data Protection:** The Indian Regulatory Authority relies on test data submitted by originators to another country when granting marketing approval. This indirect reliance results in unfair commercial use prohibited by the

⁴⁶ Decision and Order on the Application for Compulsory Licenses under Section 84(1) of the Patents Acts, 1970 in Respect of Patent No. 215,758, March 2012.

TRIPS Agreement and discourages the development of new medicines that could meet unmet medical needs.

- **Government Price Controls:** The proposed National Pharmaceutical Policy would require mandatory one-to-one government price negotiations prior to marketing approval of patented drugs launched in India after January 1, 2005. Further, the Indian Government published the National Pharmaceutical Pricing Policy 2012 on December 7, 2012, that subjects all 348 drugs on the National List of Essential Medicines (NLEM) 2011 to price controls determined through a pricing formula set by the government.
- **Foreign Direct Investment (FDI) in Pharmaceutical Sector:** In April, 2012, the Government of India reviewed the policy on FDI requiring Government approval in case of FDI in brownfield investments that imposed additional regulatory hurdles on FDI in the pharmaceutical sector. The existing ambiguities and uncertainties with regard to the way forward and absence of fixed conditionalities/criteria to be followed by the Government in case of pharmaceutical mergers and acquisitions has resulted in delay in review of several such proposals.

For these reasons, PhRMA requests that India remain on the **Priority Watch List** for the 2013 Special 301 Report. In light of ongoing government reports recommending that India grant additional compulsory licenses, PhRMA also requests that the U.S. Trade Representative conduct an **Out-of-Cycle Review** of India during 2013 to develop a robust plan for quickly and efficiently addressing the problems described herein.

Intellectual Property Protection

Compulsory Licenses on Patented Pharmaceutical Products

India issued a compulsory license (CL) for an anti-cancer patented pharmaceutical product on March 9, 2012. We understand that this is the first CL issued in India. In addition, recent reports indicate that the Indian Government has started the process of issuing CLs for the manufacture of three additional anti-cancer medicines. Unlike the CL issued under Section 84 of the Patent Act in March, these CLs would fall under Section 92 of the Act – the public emergency provision that can be issued directly from the Indian Administration without a notice and comment period to the industry. The research-based pharmaceutical industry is concerned that the findings in the CL decision on the local working requirements are at odds with 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. We further believe that resorting to CLs is not a sustainable or effective way to address healthcare needs. Voluntary arrangements independently undertaken by our member companies better ensure that current and future patients have access to innovative medicines. We are also concerned about apparent inaccuracies and misunderstandings that appear to underpin the reasoning reflected in the decision. For example, statements from the Government incorrectly

imply that CLs are widely used by other governments (both, developed and developing), including the United States and Italy.⁴⁷ Those inaccuracies and misrepresentations cannot justify resorting to compulsory licensing.

India should ensure that the CL provisions comply with TRIPS by clarifying that importation satisfies the “working” requirement (as required by TRIPS Article 27.1). In cases of CL for exports, India should ensure that, consistent with the August 30, 2003 Decision of the TRIPS Council on Implementation of Paragraph 6 of Doha Declaration on TRIPS Agreement and Public Health, proper anti-diversion measures are taken and that the CL is granted only for export to eligible importing countries that lack manufacturing capacity and used in good faith to protect public health and not used for industrial or commercial purposes.

Lack of Regulatory Data Protection

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

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

Patent Enforcement and Regulatory Approval

Indian law permits state drug regulatory authorities to grant marketing approval for a generic version of a new medicine after four years of patent protection for the new medicine. State regulatory authorities are not required to verify or consider the remaining term of the existing patent. Therefore, an infringer can obtain marketing authorization from the government for an on-patent drug, forcing the patent holder to seek redress in India’s court system.

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. To ensure proper patent enforcement, the U.S. Government should urge the government to implement such mechanisms. Furthermore, PhRMA member companies report that even when their

⁴⁷ These allegations of wide-spread use of CLs in the U.S. and the premise that CL’s can resolve access problems in India have been refuted by OPPI and PhRMA. See http://dipp.nic.in/ipr-feedback/Feedback_OPPI_30September2010.pdf (last visited Feb. 8, 2013).

cases are filed in the Indian legal system, their ability to obtain redress for patent infringing product launches is extremely limited. We believe the Indian Government must also ensure that the existing laws and regulations can be properly enforced in a timely manner through its legal system.

Narrow Standards for Patentability

Some of the standards for patentability in India are not transparent and are inconsistent with the TRIPS Agreement. For example, section 3(d) of the Patents Act 1970 as amended by the Patents (Amendment) Act 2005 creates additional hurdles to the grant of certain chemical compound patents, and 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. These additional requirements for patentability beyond novelty, commercial applicability and non-obviousness are inconsistent with the TRIPS Agreement, in at least two respects. First, Article 27 requires that “patents shall be available for any inventions ... provided that they are new, involve an inventive step and are capable of industrial application.” Although the TRIPS Agreement also provides a non-extendable list of the types of subject matter that can be excluded from patent coverage, 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. Second, 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. Moreover, from a policy perspective, Section 3(d) undermines incentives for innovation.

Another example of the overly narrow standards for patentability in India is the Government’s recent revocation of a patent on a cancer therapeutic (a product that is patented in over 90 countries), using a “hindsight” analysis citing a lack of inventiveness rather than evaluating the invention at the time it was made based on objective criteria. The Supreme Court overturned the Patent Controller’s Order revoking the patent for failing to consider certain information deemed relevant by the Court. Still, the case was sent back to the Patent Controller for a *de novo* hearing within one month.

In addition, India’s Patents Act requires applicants to disclose the source and geographical origin of biological materials used to make an invention that is the subject of a patent applications. These requirements may be a basis for opposition or revocation proceedings; however, the necessary relationship to the patented invention is not clear. Therefore, these requirements not only create uncertainty over potentially valuable intellectual property rights, but appear to be inconsistent with India’s obligations under the TRIPS Agreement.

Counterfeiting

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

Beyond these trademark-related deficiencies, weaknesses in India's drug regulatory regime can contribute to the proliferation of counterfeit pharmaceuticals and their global export. Even though pharmaceutical counterfeiting is first and foremost a drug safety violation, India has yet to enact drug laws that expressly address all aspects of drug counterfeiting, or to provide the kind of remedies and enforcement resources necessary to combat this growing problem. Anti-counterfeiting enforcement is further undermined by poor interagency coordination and India's failure to provide administrative remedies for drug safety violations.

Market Access Barriers

Government Price Controls

PhRMA's members are extremely concerned about the general lack of access to health care in India. This lack of access is manifested in many ways, including insufficient numbers of qualified healthcare personnel, inadequate and poorly equipped healthcare facilities, and most importantly lack of a comprehensive system of healthcare financing to pool financial risk and help to share cost burdens.⁴⁸ However, India has thousands of manufacturers of pharmaceuticals who operate in a very competitive environment, and as a result, India has some of the lowest prices of medicines in the world.⁴⁹ Despite decades of government price controls in India, the objective of which has been to improve access to medicines, only 20 percent of Indians have adequate access to essential medicines.⁵⁰

On November 22, 2012, the Union cabinet cleared the National Pharmaceutical Pricing Policy 2012 (NPPP 2012), which was published on December 7, 2012. The new policy prescribes price controls on all 348 drugs of the National List of Essential Medicines (NLEM) 2011. Under the new policy, ceiling prices for NLEM drugs will be fixed by taking the simple average of prices of all brands of the drugs that have more than 1 percent market share. The Supreme Court has been monitoring the policy development through public interest litigation. The petitioner in the public interest litigation has challenged the new policy on constitutional grounds and is pressing the Supreme Court to direct the government to adopt a cost based pricing policy.

⁴⁸ "Health Systems Financing: The Path to Universal Coverage," *The World Health Report*, World Health Organization, 2010.

⁴⁹ "Pharmaceutical Pricing Policy in India," Organisation of Pharmaceutical Producers in India, Nov. 2010.

⁵⁰ "Health workforce, infrastructure, essential medicines", World Health Statistics 2009, The World Health Organization

Expansion of price controls to a larger range of medicines will not substantially improve access to medicines in India because lack of access is more a function of insufficient healthcare financing systems and inadequate healthcare facilities.⁵¹ For example, medicines and vaccines which are offered free of charge often do not reach the patients who need these medicines.⁵² Furthermore, 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.⁵³

In addition, under the Draft National Pharmaceutical Policy currently under consideration, there is a requirement for mandatory one-to-one government price negotiations prior to marketing approval of patented drugs launched in India after January 1, 2005. PhRMA's members believe that this proposal represents an effort to significantly reduce the benefits of product patent protection, and will discriminate against importers of patented drug products. Apart from the proposed National Pharmaceutical Policy, price regulators also act arbitrarily and in a non-transparent manner in setting prices, and the existing pricing policy itself is marked by a lack of transparency and clarity.

While competitive market conditions are the most efficient way of allocating resources and rewarding innovation, the research-based biopharmaceutical industry is committed to engaging with governments and other stakeholders to discuss principles and pragmatic public policy approaches that will enable the development of government pricing and reimbursement systems that reflect the value of products, include the patient perspective, and reward innovation.

Foreign Direct Investment (FDI) in Pharmaceutical Sector

PhRMA members are concerned about policy actions that propose to create hurdles for FDI in the pharmaceutical sector. In its Circular no. 1 of New Consolidated FDI for the financial year 2012-13, the Ministry of Commerce and Industry reviewed the FDI policy with regard to the pharmaceutical sector. Foreign investors wishing to invest in existing Indian pharmaceutical companies (brownfield investments) will now need to apply for government approval. Currently there are no fixed criteria for this approval process leading to an atmosphere of uncertainty for potential investors.

The Government has also suggested that brownfield pharmaceutical investments should be subject to additional manufacturing and investment requirements, yet there

⁵¹ "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. 8, 2013).

⁵² "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. 8, 2013).

⁵³ "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.

exist ambiguities and uncertainties on the way forward. Actions have been initiated to amend the Competition Act, 2002 to bring review of pharmaceutical mergers and acquisitions under the jurisdiction of the Competition Commission of India.

These ongoing uncertainties on various issues related to FDI such as the conditionalities to be imposed, Department/Authority that will finally be the regulator etc., has resulted in delayed review of several proposals for pharmaceutical FDI and has stalled large investments coming in to India.

Import Policies

Despite the stated intention by the Government to lower pharmaceutical duties, PhRMA member companies operating in India face high effective import duties for active ingredients and finished products. Though the basic import duties for pharmaceutical products average about 10 percent, additional duties commensurate with the excise duty applicable on the same or similar product, even when there is no such product manufactured in India, as well as other assessments, bring the effective import duty to approximately 20 percent. 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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

INDONESIA

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

Key Issues of Concern:

- **Compulsory Licensing of Patents:** Indonesia has recently issued "government use"-type compulsory licenses (CLs) on nine patented pharmaceutical products. PhRMA is troubled by Indonesia's recent decision to issue these licenses 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. This raises significant issues about whether such an approach is consistent with best practices and international norms. Moreover, such drastic measures should only be used in extraordinary circumstances as a last resort rather than standard government practice. Although PhRMA wants these issues addressed, we are also aware of the challenges presented by the HIV/AIDS epidemic in Indonesia. PhRMA member companies are prepared to work collaboratively with Indonesian authorities to find a solution which benefits HIV patients in Indonesia while maintaining adequate and effective intellectual property protection.
- **Health Law:** While Indonesia's pursuit of a strengthened healthcare delivery system is commendable, the Health Law as written could hinder the ability of PhRMA's member companies to provide safe, effective medicines to meet the needs of the Indonesian medical community and patients. The innovative pharmaceutical industry is concerned that the Health Law explicitly refers to Indonesia's patent regulation as a reference to be respected in performing the Government's special rights with regards to drug procurement, and asserts Indonesia's Patent Law is aligned to the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). PhRMA's member companies are concerned that this claim is not justified.
- **Non-Conformance with International Best Practices:** PhRMA's member companies continue to face burdensome regulatory delays of up to two years in the registration process of new products, in contravention of Indonesia's own regulations. Therefore, stronger conformance with international best practices is needed with respect to regulatory data protection and bioequivalence requirements.
- **Mandatory Halal Certification:** Legislation is moving through Indonesia's Parliament mandating halal certification for all pharmaceutical products. PhRMA's member companies are strongly supportive of religious and cultural

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

- **Trade Bill:** PhRMA's member companies strongly support the desire of the Government of Indonesia to align national and regional trade policies; however the proposed trade bill contains several concerning provisions, including: local content requirements that unduly promote the domestic industry to the detriment of U.S. pharmaceutical companies; import substitution measures, including import restrictions; and measures to ensure the availability, price stability, and distribution of ill-defined "essential goods."

For these reasons, PhRMA requests that Indonesia remain on the **Priority Watch List** for the 2013 Special 301 Report and that the U.S. Government continues to seek resolution on the problems described herein.

Intellectual Property Protections and Enforcement

Compulsory Licenses on Patented Pharmaceutical Products

Indonesia has recently 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 TRIPS Article 31(a). 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 our 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 the HIV/AIDS epidemic in Indonesia. PhRMA member companies are prepared to work collaboratively with Indonesian authorities to find a solution which benefits HIV patients in Indonesia while maintaining adequate and effective intellectual property protection.

Mandatory Transfer of Intellectual Property under Ministerial Decree 1010 and 1799

Ministry of Health (MOH) Decree 1010/MENKES/PER/XI/2008 (“Decree 1010”) formally implemented in November 2010, adversely affects the ability of multinational research-based pharmaceutical companies to obtain marketing authorization for their products. Under Decree 1010, only companies registered as “licensing pharmaceutical industry” are granted marketing approval. As several of PhRMA’s member companies do not manufacture products in Indonesia, they are instead classified as distributors, or “PBF” enterprises. They are so classified despite following globally recognized good manufacturing and distribution practices in the same manner as other high quality pharmaceutical firms manufacturing in Indonesia. Multinational research-based pharmaceutical companies are barred from the Indonesian market unless they (1) establish a local manufacturing facility; or (2) transfer sensitive intellectual property to another pharmaceutical firm with local manufacturing facilities in Indonesia. The first condition is not possible for many PhRMA member companies, given the structure of global pharmaceutical supply chain. As a result, the second condition poses a serious threat to intellectual property protection and patient safety.

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. 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. 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 1799 still require further clarification.

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

Mandatory Halal Certification

Legislation is moving through Indonesia’s Parliament to mandate Halal certification and Halal labeling for food and beverages, medicines, cosmetics, chemical products, biological products, and genetically-engineered products. The legislation proposes to establish a new Halal certification authority as well as require

pharmaceutical firms to hire a Halal specialist and disclose sensitive product formulas to the new Halal authority.

PhRMA's member companies recognize and support the religious and cultural sensitivities of all Indonesians. However, any measures taken to respect those sensitivities must also consider the negative implications they may have on patient health. Recognizing the need for balance, local stakeholders, including MOH, oppose requiring mandatory halal certification for medicines, preferring instead that such certification remain voluntary. The bill, however, is due to move forward in 2013, and would impose mandatory Halal certification requirements on medicines. This bill should exclude pharmaceutical products (medicines, chemical-biological products, and genetically-engineered products) from the scope of Halal certification.

Anti-Counterfeiting Enforcement

Although PhRMA's member companies welcome Indonesia's ongoing efforts to promote the use of safe medicines, there is an urgent need to expand national enforcement efforts. Increasing the penalties for criminals caught manufacturing, supplying, or selling counterfeit pharmaceuticals as well as spurious and 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 and that OTC medications are the most widely imitated product. Greater collaboration and government initiatives, such as a nationwide campaign and devoted budget to combat counterfeit products, are required to ensure the health and safety of the Indonesian people.

Market Access Barriers

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

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

Health Law

On September 14, 2009, Indonesia's parliament passed the "Health Law," a far-reaching piece of legislation that touches upon many aspects of healthcare, including pharmaceuticals. If implemented with minimal stakeholder input, the law could have implications for the ability of PhRMA's member companies' to provide safe, effective pharmaceuticals to meet the needs of the Indonesian medical community and patients. According to an unofficial translation and depending upon how the implementing regulations are drafted, the Health Law could pave the way for: (1) government-mandated price controls, which would cover branded generics and could extend to the innovative industry as well if the essential drug list is expanded; and (2) more onerous sanctions for pharmaceutical service quality standards violations. PhRMA and its member companies hope that they will be given the opportunity to engage actively in a discussion of the law and provide constructive input during the drafting of the implementing regulations.

Trade Bill

PhRMA's member companies strongly support the Indonesian Government's desire to align national and regional trade policies through the proposed trade bill. However, strong concerns remain with several provisions of the proposed legislation as well as the potentially significant ramifications if adopted into law. In addition to the Indonesian Government's commitment to provide full input and consideration ahead of implementation, PhRMA's member companies seek clarity on several of the trade bill's provisions. These provisions appear to include: (1) local content requirements, (2) inappropriate promotion of domestic industry, (3) import substitution measures, including import restrictions, and (4) measures to ensure the availability, price stability, and distribution of ill-defined "essential goods."

Negative Investment List

The Government of Indonesia currently limits foreign ownership of pharmaceutical firms designated as manufacturers to 75 percent. Many multinational research-based pharmaceutical companies are currently classified as distributors, or "PBF" enterprises, and some are 100 percent foreign-owned as permitted under the grandfather clause in the Negative Investment List. At present, the Negative Investment List requires any PBF enterprise to be 100 percent local-owned whereas multinational pharmaceutical companies' investment is capped to 75 percent foreign owned (subject to a "grandfather clause" for existing investments). These requirements limit Indonesia's ability to attract foreign investments in the pharmaceutical sector and hence limit the competitiveness of Indonesia's domestic pharmaceutical industry vis à vis its peers in the region. The MOH and Indonesia Investment Coordinating Board (BKPM) have expressed support for removing these limitations from the Negative Investment List so manufacturers may be 100 percent foreign-owned. PhRMA's member companies seek clarification on when the Negative Investment List will be amended.

The Negative Investment List regulation, particularly for the pharmaceutical industry sector, has created an uneven playing field between local and international pharmaceutical companies, resulting in reduced market share for innovative pharmaceuticals.

Import Regulations

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

Lack of Transparency

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

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

NEW ZEALAND

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in New Zealand remain concerned over the policies and operation of New Zealand's Pharmaceutical Management Agency (PHARMAC) as well as the direction the Government of New Zealand is taking with respect to broader intellectual property protection. PHARMAC continues to impose stringent cost containment strategies,⁵⁴ and operate in a non-transparent manner, creating an unfavorable environment for innovative medicines. In addition, a draft Patent Bill was recently scheduled for a second reading in parliament. The Bill, as written, fails to provide adequate incentives for innovation and adequate protection for intellectual property. This could potentially reduce New Zealand patients' access to innovative medicines. PhRMA would welcome the opportunity to work with the Government of New Zealand to find common ground on public policy alternatives to some of the provisions contained in the Bill – including patent term restoration and non-commercial use provisions.

Key Issues of Concern:

- Patents Act 1953 and Patents Bill
- Government Pricing and Reimbursement;
- Biotechnology Taskforce Recommendations; and

For these reasons, PhRMA requests that New Zealand be placed on the **Priority Watch List** for the 2013 Special 301 Report. PhRMA's member companies encourage the U.S. Government to raise these concerns as priorities for resolution during bilateral consultations with Australia as well as multilateral negotiations such as the Trans-Pacific Partnership.

Intellectual Property Protection

Patents Act Amendment

The Patents Bill that was introduced to the New Zealand Parliament in July 2008 is still pending and is intended to replace the Patents Act of 1953. One notable omission from the proposed bill is 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 established mechanisms to restore patent terms for pharmaceutical products to recover effective patent life lost due to the marketing approval process. PhRMA member companies urge the New Zealand

⁵⁴ 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).

legislature to amend the current bill to include patent term restoration in keeping with international best practices.

Market Access Barriers

Government Pricing and Reimbursement

Though not explicitly stated, PHARMAC's reimbursement decisions suggest a pharmaceutical must achieve a cost per QALY (quality adjusted life year) of less than NZ\$10,000 to NZ\$15,000 to be considered cost effective. This is despite public spending in other areas of health proceeding at up to NZ\$100,000 per QALY. This approach, combined with the need to stay within a capped budget, means that many of the most effective medicines are not available to New Zealand's patients. Analysis has found that of the 136 innovative new prescription-only medicines listed on the Pharmaceutical Benefit Scheme in Australia between 2000 and 2009, only 59 (43 percent) received reimbursement in New Zealand.⁵⁵ Many of these 59 products have restricted reimbursement, such as reimbursement for limited indications. 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.

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 citizens of other OECD countries.
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.
4. **Integrity and Public Confidence** – The current bundling of clinical assessment and reimbursement decisions 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.

⁵⁵ Michael Wonder, Richard Milne: *Access to new medicines in New Zealand compared to Australia*, New Zealand Medical Journal, Vol. 124 No. 1346 (Nov. 2011).

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 and meet WHO recommendations. Transparency and accountability are key principles in New Zealand institutions, with the exception of healthcare. It is critical that these principles be applied to healthcare.
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 need 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 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 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 2012 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 in Thailand. It has become increasingly difficult for PhRMA's member companies to conduct business in the country as a result of government policies that do not support an innovative or competitive marketplace. There is concern that the research-based pharmaceutical industry continues to be excluded from meaningful participation in ongoing efforts to reform the healthcare system. PhRMA hopes that, with the support of the U.S. Government, the necessary coordinated steps can be taken to address these significant challenges. Our industry stands ready to work with the new Royal Thai Government to ensure that progress is made in 2013.

Key Issues of Concern:

- **Intellectual Property Protections and Enforcement:** Improvement in the intellectual property environment in Thailand is necessary to avert further negative impact on market access. Concerns include compulsory licensing of pharmaceuticals, inadequate regulatory data protection and weak patent protection and enforcement regimes, and a threat to diverge from internationally recognized patentability criteria for incremental innovations.
- **Anti-Counterfeiting:** PhRMA's member companies recognize advancements made by the Royal Thai Customs in enforcing intellectual property rights, but encourages the Royal Thai Government to place a higher priority on curbing the distribution and use of counterfeit medicines through increased resources and penalties for criminals caught manufacturing, supplying, or selling them.
- **Market Access and Discriminatory Government Procurement:** The selection criteria and process for the National List of Essential Drugs (NLED) lacks transparency. As a result, many innovative medicines are not included on the NLED and are inaccessible to most Thai patients. Furthermore, when a product is not accepted for the NLED, the applicant is provided no explanation and left without recourse. Thailand's procurement regulations requiring public hospitals to purchase their medicines and medical supplies from the state-owned Government Pharmaceutical Organization (GPO) should also 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.
- **Government Engagement and Consultation:** While PhRMA's member companies stand ready to work closely with the new Royal Thai Government to foster meaningful collaboration and address key issues of healthcare reform, the Royal Thai Government, under pressure from Thailand's civil society, has excluded all healthcare stakeholders from participating. A transparent and enduring mechanism for offering stakeholder input into Thailand's healthcare decision-making process is needed to assure market access and better provide Thai patients life-saving pharmaceutical treatments.

For these reasons, PhRMA requests that Thailand remain on the **Priority Watch List** for the 2013 Special 301 Report. PhRMA's member companies encourage the U.S. Government to raise these concerns as priorities for resolution during bilateral consultations with the Royal Thai Government. Heightened advocacy for new mechanisms that improve policy consultation is also needed.

Intellectual Property Protections and Enforcement

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's Ministry of Public Health re-issued in 2011 their compulsory licenses on Stocrin and Kaletra, without prior consultation with the affected companies. The Government of Thailand seems to be using the threat of new compulsory licenses to pressure further price negotiations. In the recent Cabinet Resolution on Healthcare Cost-containment Measures if price negotiations for patented drugs – one of the measures' requirements – are not conducted. Furthermore, royalty payments on the earlier compulsory licenses on Stocrin and Kaletra were not made. Complete and advance consultation with companies that will be directly affected by any compulsory license, is essential for Thailand to provide adequate and effective protection of intellectual property rights, and all policies and justifications for actions that will directly affect individual companies should be thoroughly discussed and explained,

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 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 all materials submitted by an innovator to obtain marketing approval; (3) provide protection to new indications; and (4) require Thai FDA officials to protect information provided by the originator by ensuring it is not improperly made public or relied upon by a subsequent producer of a generic pharmaceutical product.

Patent Enforcement

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

Patent Prosecution and Incremental Innovation

The waiting-period for a patent review and grant in Thailand is unpredictable and averages 10 years after application submission. These long patent grant delays create uncertainty regarding investment protection and increase the risk of infringement during the pending/review periods. Patent term restoration, or adjustment, has never been established in Thailand's legal framework, further exacerbating the uncertainty caused by its patent grant delays.

PhRMA member companies are concerned regarding the inclusion of the term "surprising effect" in the recently circulated Draft Patent Examination Guidelines as an additional justification for pharmaceutical patents, because the term might be misinterpreted in a way that hinders patent evaluation and approval. Further explanation is required of the context of this new "surprising effect" patent criteria.

PhRMA's member companies strongly encourage the Royal Thai Government to recognize the significant health, scientific, and commercial benefits of incremental innovations. Patent applications for new improvements, upgrades, and next generation products should be reviewed in accordance with internationally recognized patentability criteria as well as applied consistently among all technology dependent sectors. Although industry has been asked to sit on the Patent Amendment 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.

Anti-Counterfeiting Enforcement

PhRMA's member companies are encouraged by the Royal Thai Government's collaborative efforts in 2012 to enforce anti-counterfeiting through the Creative Economy initiative. 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. The Thai FDA and law

enforcement leadership have signaled their willingness to collaborate with industry to train and equip enforcement agencies. While the Royal Thai Government has acknowledged the need to suppress counterfeits in a Memorandum of Understanding for “Cooperation on Prevention and Suppression of Trademark Infringing Pharmaceuticals” signed on September 2010, there is also an urgent need to take action against non-trademark counterfeit pharmaceuticals. PhRMA’s member companies support the continuation of Thailand’s National Intellectual Property Policy Committee and hope that policy recommendations made by the Committee will properly reflect the importance of halting the spread of unsafe medicines and enhance inter-agency coordination on enforcement.

Market Access Barriers

Discriminatory Government Procurement

As a result of special procurement privileges granted to Thailand’s Government Pharmaceutical Organization (GPO), competition has become 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 Drugs (NLED). 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 12,13) from the requirement to obtain a license from the Thai FDA to produce, sell, or import pharmaceutical products. Thai FDA procurement regulations permit non-registered and potentially dangerous Class 2 psychotropic and narcotic substances to enter bids and win contracts under the Government’s tendering process.

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 recent Cabinet Resolution on Cost-containment Measures, including price negotiation of Non-NLEM drugs, Non-NLEM Prescription Criteria, Reimbursable Indications, and Prior Authorization for high-cost drugs, is being developed without a clear and transparent process. 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.

National List of Essential Drugs

Thailand’s National List of Essential Drugs (NLED) is predominantly based on a policy of cost containment. Delisting of medicines can and has occurred, and if a product is on the NLED, the Thai government institutes a ceiling price (median price) which controls the price of the innovative medicines. Furthermore, the NLED listing and delisting process does not have clear criteria. The rationale for NLED revisions are not made known to PhRMA’s member companies or the general public. Transparency

around the NLED process would give companies the ability to discuss with government NLED cost issues and their products, and could lead to more choices for Thai patients.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

CANADA

CANADA

The Pharmaceutical Research and Manufacturers of America (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. Notably and 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.

Furthermore, Canadian laws remain deficient due to the absence of an effective right of appeal under its pharmaceutical patent enforcement mechanisms and the failure to provide patent term restoration.

Key Issues of Concern:

Intellectual Property:

- Weak enforcement of patents;
- Utility requirements which are inconsistent with the Canadian Patent Act (the Act), TRIPS, NAFTA and international norms;
- Limitations on regulatory data protection; or
- Lack of patent term restoration.

For these reasons, PhRMA requests that Canada remain on the **Priority Watch List** for the 2013 Special 301 Report. In addition, the U.S. Government should seek assurances from the Canadian government that the problems described herein are quickly and effectively resolved, thereby underscoring Canada's intent to meet the expected high standards to be included in the TPP Agreement related to intellectual property rights protection.

Intellectual Property Protection and Enforcement

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 patentee of any such allegation. The patentee then has a right to initiate judicial procedures to challenge any such allegation. If procedures are triggered, approval of the generic drug is stayed for a maximum period of up to 24 months pending judicial review.

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

2. *No Effective Right of Appeal*

In turn, the summary nature of Canada’s initial patent infringement proceedings means that a patentee, unlike a generic drug producer, does not have an effective right of appeal. This is because the PM (NOC) Regulations provide that a generic product may be approved for marketing (through the issuance of an Notice of Compliance, or “NOC”) following a decision by the Court in the first instance in favor of the generic producer; once the NOC issues, an appeal filed by the patentee becomes moot.⁵⁶ The patentee is then left with no alternative but to start a new proceeding outside of the framework of the PM (NOC) Regulations, *i.e.*, commencing an action for patent infringement once the generic product enters the market, essentially having to restart a case it had already spent up to two years litigating under the Regulations.

In contrast, a right of appeal is available to the generic under the PM (NOC) Regulations if the patentee prevails in the first instance. PhRMA understands that the European Union has requested that Canada remedy this glaring deficiency in the context of their ongoing free trade negotiations. PhRMA member companies recommend that the U.S. Government strongly encourage Canadian authorities to rectify this fundamental, discriminatory, and unjustifiable imbalance in legal rights and due process through regulatory changes that will ensure there is a meaningful and effective right of appeal for patentees.

While a patentee 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

⁵⁶ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359.

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. 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.

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

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

3. *Limitation on the Listing of Valid Patents*

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

PhRMA members urge the U.S. Government to engage the Government of Canada to rectify these issues through regulatory changes that will ensure that meaningful and effective patent protection is available under the PM (NOC) Regulations.

Application of Utility requirements that are Inconsistent with TRIPS, and International Norms

PhRMA members are concerned that recent decisions by the Canadian judiciary have created a heightened standard for patentable utility for pharmaceutical patents. This heightened standard is inconsistent with common practice in other countries. 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. This issue must be addressed given that it undermines the ability of innovative pharmaceutical companies to enforce and defend their existing patents in the

court system, and also limits their ability to obtain new patents with the Canadian Intellectual Property Office (CIPO).

Limitations on Regulatory Data Protection

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

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

PhRMA member companies are also concerned about the potential implications of a recently announced consultation relating to data protection inquiries, which could be used by generic manufacturers to challenge awards of data protection to innovative products in Canada.⁵⁷

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

Lack of Patent Term Restoration

Patent Term Restoration (PTR) provides additional patent life to compensate for 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 Community 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.

⁵⁷ Health Canada, Data Protection Inquiries Process Improvements, Fall/Winter 2012.

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, as appropriate, to 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. Steps taken by Canada in this direction on PTR would constitute an important positive precedent for further dialogue and negotiations with other developed and developing nations in other forums on these same issues.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

OVERVIEW: 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.

First, government price controls can have harmful effects on patients and innovation. EU legislation requires transparent processes for national pricing and reimbursement decisions, but these requirements need to be enforced more rigorously and broader oversight of national practices should be in place. 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 the failure of EU member states to adhere to these requirements. Restricting the availability of state-of-the-art medicines limits patient access to new drugs and undermines the financial incentive for privately sponsored research and development. The economic and financial crisis gripping many countries in Europe has exacerbated the impact of these policies on PhRMA member companies. Countries that have successfully engaged PhRMA members in a dialogue when designing cost-containment measures have created more effective policies that both ensure efficient access to medicine and support for innovation.

Moreover, as per Recommendation XI of the G10, any member state price control system should only apply to products effectively dispensed and reimbursed in that Member State by its national health insurance system.

A second concern arises from a common situation: 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.⁵⁸ Overall, however, interim injunctions to prevent accused products from remaining on the market until trial are granted in less than half the relevant cases.⁵⁹ This failure to provide effective remedies fundamentally undermines the exclusive rights conferred by a patent.

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

⁵⁸ See, e.g., *Leo Pharma v. Sandoz*, [2008] EWHC 541 and *Novartis v. Dexcel-Pharma*, [2008] FSR 31.

⁵⁹ DG Competition, European Commission, "Pharmaceutical Sector Inquiry Final Report," para. 641, July 8, 2009.

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.⁶⁰

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 favours 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.

EFPIA has proposed adoption of an “early resolution” mechanism to the European Commission and PhRMA supports this approach in Europe.

A third concern for PhRMA members is the growing use of therapeutic reference pricing as a tool to reduce the price of innovative medicines with active patents. A growing number of countries (e.g., the Czech Republic, Germany, Greece and Romania), are matching the government price of an innovative product to that of a generic product in the same therapeutic class. 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.

⁶⁰ EFPIA, Submission to the European Commission in Relation to the Pharmaceutical Sector Inquiry, June 13, 2008, *available at* <http://www.efpia.org/content/default.asp?PageID=559&DocID=4892> (last visited Feb. 8, 2013).

A fourth concern by PhRMA members is that the EU's ban on patient information for prescription medicines bars patients from making informed choices and has a disproportionate impact on new and/or more effective innovative medicines, which increasingly are developed in the United States.

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.

The following EU member country chapters give greater detail to PhRMA and its members' concerns.

HUNGARY

PhRMA's member companies have been facing severe market access barriers in Hungary since the first implementation of Hungarian Pharma-economic Law (XCVIII/2006). This environment significantly worsened with the introduction of the Hungarian Government's Széll Kálmán Savings Plan I and II, which introduced severe pharmaceutical reimbursement budget cuts in the frame of an overall governmental budget balancing program for 2011-2014. The drug reimbursement budget is planned to be reduced by 60 percent during this period. The cumulative impact of these measures will reduce the 2013 public drug spending budget to a level below what was funded in 1994 and constitute only 0.6 percent of the GDP. The industry believes that this reduction is draconian and will not meet Hungarian patients' needs, and could result in medicine shortages as funds will not exist to purchase needed medicines.

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

Key Issues of Concern:

- **Market Sustainability:** Innovative pharmaceutical companies operating in Hungary are currently subject to the lowest list prices in Europe and in many cases the lowest net prices around the world due to mandatory discounts of up to 50 percent in the form of sales taxes and non-transparent compulsory price-volume agreements. Future predictability is largely threatened by the claw-back system, under which pharmaceutical companies are held financially responsible for the overspending of the shrinking retail pharmaceutical budget. As a result, companies are unaware of what their total liability will be and unable to influence the amount of their liability for overspending.
- **“Extra” Reimbursed Sales Taxes Specific to the Pharmaceutical Sector:** PhRMA member companies requested, like other industries facing “crisis taxes,” that the year 2011 increase of the reimbursed drug sales extra tax from 12 percent to 20 percent should have a defined expiration date. However, an end date for this tax increase has not yet been established. Moreover, as of August 2012, an additional 10 percent reimbursed sales tax was imposed on IP protected products reimbursed for more than six years without generic competition.
- **Tendering for Biosimilars:** The Hungarian Government held its first annual tender for biologic products in March 2012. The bidding rules allow price competition between two similar but biologically different drugs that may result in different outcomes for different patients. The product that wins the bid is given a dominant position in the market, making it difficult, if not impossible, for other biologic products to compete. Since biologics, unlike generic small molecule

drugs, are not biochemically identical, the narrowing of products available in the market can have negative consequences for patients. Recognizing this, the World Health Organization does not currently endorse automatic substitution for biologic medicines. The product that was not awarded the tender due to price was removed from the reimbursement list. The next round of bidding starts in January 2013.

- **Frequent change and retroactive legislation on R&D Tax Incentives:** In mid-2009, Hungary enacted legislation that provided for a 20 percent refund of the extra reimbursed sales tax (which at that time was set at 12 percent) for eligible R&D investments made that year. In early 2010, the legislation was revised to allow for a 100 percent refund for R&D expenses incurred in 2010 over a certain threshold. However, in June 2011, the government retroactively changed the 2010 legislation by increasing the R&D spending requirements to qualify for the tax refund. In December 2011 the Government announced a new set of criteria for the 2011 R&D incentives.
- **Lack of Effective Dialogue between Government and Industry:** Despite receiving comprehensive proposals from the innovative pharmaceutical industry, this input is not given meaningful consideration. The lack of appropriate consultation or regular dialogue with stakeholders precludes the effective leveraging of the innovative pharmaceutical and other healthcare stakeholders' international expertise.
- **Long Delay in Granting Reimbursement:** The delay in the pricing and reimbursement process in Hungary has increased to more than 22 months, resulting in more than 30 new innovative products waiting for approval, as recent industrial reviews demonstrated. Moreover, the Hungarian Government tends to approve new products only when neutral (or negative) budget impact is expected in relation only to the drug budget (not the drug's impact on other parts of the healthcare system), unambiguously disregarding key innovations.

For these reasons, PhRMA requests that Hungary be placed on the **Priority Watch List** for the 2013 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved. In particular, PhRMA and its member companies encourage the U.S. Government to foster regular consultation with the Hungarian Ministry of National Resources and the Ministry of National Economy; draw attention to the impact of restrictive measures that negatively impact the healthcare sector, such as *ad hoc* and retroactive legislation; and highlight the importance of a timely and fair pricing and reimbursement system.

Market Access Barriers

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

The financial barriers include:

- A tax increase from 12 percent to 20 percent on all reimbursed retail products (Tax I) and an additional claw-back system (Tax II), under which pharmaceutical companies are held financially responsible for the overspending of the retail pharmaceutical budget;
- Ten percent extra sales tax applied on innovative products reimbursed for more than six years without generic competition;
- A sales representative tax of approximately US\$50,000 per year, per representative;
- Mandatory, 3-year, non-disclosed reimbursement-volume contracts for new innovative reimbursed products designed specifically to reduce the volume of the products used regardless of the real patient need for the specific medicines;
- Restrictions on reimbursement compared to the product's label, limiting the number of indications, the number of centers, and specific prescribers;
- Reference pricing with de-listing (electronic "blind" bidding system) for Type 1 ("generic") and Type 2 ("therapeutic") reimbursement groups occurring every 6 months. The therapeutic reference groups have been created in a non-transparent manner;
- The annual bidding procedures for biologic medicines where the winning bid is not judged on therapeutic value, but merely on price. This has resulted in the delisting of some innovative medicines prior to a biosimilar of that compound being available and reimbursed;
- Review of combination products every 6 months, resulting in reimbursement cuts and high co-payments for several patented combination products, regardless of the affects these cuts may have on patient adherence;
- Revision of financial protocols to selected disease areas;
- Cross-country referencing that incorporates the lowest European price at launch and allows 20 percent threshold over the average of the three lowest European prices for subjectively selected product classes;
- Prescription directive limiting the prescribing choice of physicians;
- Review of reimbursement of products with high consumption; 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, reimbursement adjustments on therapeutic or other changes, and approval for new entities eligible for public procurement. These are all subject to a lengthy and restrictive approval by Ministry of Economy and ministerial decree publication process, incompatible with EU Directive 89/105/EC (which mandates

that reimbursement decisions should be made within 90 days). The current average waiting time for a new innovative product to gain reimbursement exceeds 22 months;

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

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

PORTUGAL

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Portugal are concerned that Portugal has ineffective mechanisms to enforce patents and is implementing policies that do not adequately reward the value of innovation and the benefits innovative medicines bring to Portuguese patients.

Key Issues of Concern:

- **Ineffective Patent Enforcement:** As a general matter, it is very difficult to secure timely resolution of patent disputes in Portugal. Moreover, in December 2011, the Portuguese Government instituted measures requiring compulsory arbitration for all pharmaceutical patent disputes. This change makes it more likely that a generic infringing on an innovator's patent will be able to launch their product on the market before the patent dispute is resolved.
- **Unrealistic Budget Restrictions:** Pursuant to the Memorandum of Understanding on Specific Economic Policy Conditionality among the Portuguese Government and the European Commission, the European Central Bank and the International Monetary Fund (MOU), executed in May 2011 (and updated in September 2011), the Portuguese Government planned to reduce public spending on pharmaceuticals to 1.25 percent of GDP in 2012 and close to 1 percent in 2013. Recognizing the budgetary demands faced by the Portuguese Government, the pharmaceutical sector agreed to reduce the pharmaceutical budget for 2012 to 1.2 percent of Portugal's GDP. Despite this significant concession, the Portuguese Government continues to indicate that it will restrict the 2013 budget for pharmaceuticals to only 1 percent of GDP.
- **Government Pricing Policies:** In November 2011, the Portuguese Government implemented a new pricing regime for pharmaceutical products which establishes therapeutic reference pricing, whereby government prices for innovative medicines are set based on prices for older and/or generic medicines deemed to be in the same therapeutic class.
- **Government Reimbursement Process:** PhRMA member companies operating in Portugal are finding it increasingly difficult to launch products due to: (1) systematic delays in reimbursement procedures; (2) an unbalanced "claw back" mechanism; and (3) a lack of transparent and objective reimbursement criteria.

For these reasons, PhRMA requests that Portugal be placed on the **Priority Watch List** for the 2013 Special 301 Report and that the U.S. Government continues to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections and Enforcement

Ineffective Patent Enforcement Mechanisms

Patent protection is a crucial incentive to foster investment in pharmaceutical R&D and reward innovation. Effective and prompt judicial mechanisms are essential to ensure that innovative companies are not faced with the launch of patent-infringing generics onto the market. Effective protection of patent rights can be achieved if the patent holder is able to obtain a preliminary injunction based on the presumption of validity of the patent within a reasonable timeframe. However, in Portugal it is very difficult to secure timely resolution of patent disputes.

Obtaining a preliminary injunction in Portugal is subject to complex legal and procedural hurdles and systemic delays. PhRMA member companies operating in Portugal have found that it often takes the Courts of Commerce one to two years to issue a preliminary decision in cases seeking injunctive relief, and final decisions may take up to three years. During this period, there is a risk that patent-infringing generics may enter the market.

PhRMA member companies welcomed the decision adopted by the Portuguese Government, in 2008, to create a court specializing in industrial property rights within the judicial system. Companies hoped that such a court would provide a more expedited and efficient adjudication process for requests for preliminary injunctions – provided naturally that it received sufficient resources to operate effectively.⁶¹ This hope, however, has been superseded by the Portuguese Government's decision in December 2011, to institute measures requiring compulsory arbitration for all pharmaceutical patent disputes. This change means that pharmaceutical patent holders do not have access to the specialized IP court and makes it more likely that a generic infringing on an innovator's patent will be able to launch their product on the market before the patent dispute is resolved.

Market Access Barriers

Unrealistic Pharmaceutical Budgets

The innovative pharmaceutical industry recognizes that the purpose of the MOU was to reduce public expenditure and to balance the budget of the National Health System ("NHS"). For this reason, the pharmaceutical sector signed a Protocol with the Government agreeing to 2012 budget cap of just over €2 million, representing a 13 percent reduction on the previous budget and 1.2 percent of Portugal's GDP. Despite agreeing to these significant savings, the Portuguese Government continues to indicate that it will restrict the 2013 budget for pharmaceuticals to only 1 percent of GDP. To put this goal in context, the average of public spending on pharmaceuticals across Europe (EU 15 and 27) is approximately 1 percent of GDP in the retail setting alone. Reducing

⁶¹ Despite some delays, the specialized IP court was established during the second quarter of 2012. The court already has a significant backlog, as it lacks adequate staffing to manage the influx of claims.

total pharmaceutical spending in both the hospital and retail settings to this level will significantly reduce our members' access to the Portuguese market.

Government Pricing Policies

Government pharmaceutical pricing policies should be preceded by a thorough and comprehensive analysis of their potential impact and an open dialogue with the relevant stakeholders. Moreover, any change to the legal framework should take into consideration the consequences of the policies on the investment climate and the need to guarantee stability, predictability, transparency and objectivity. In practice, the Portuguese Government has often ignored these principles, creating increasing difficulties in planning and management for PhRMA member companies.

Successive government pricing measures have had a negative impact on PhRMA member companies. In May 2010, the Portuguese Government increased marketing margins of wholesalers and pharmacies from 6.87 percent to 8 percent, and from 18.25 percent to 20 percent, respectively. Retail sales prices, however, remained unchanged meaning that these increased profits for Portugal's wholesalers and pharmacists were at the expense of the pharmaceutical industry.

In October 2010, a few months after these distribution margins were increased, a six percent reduction in the price of reimbursed medicinal products was adopted *via* the imposition of an obligatory discount.

PhRMA member companies are particularly concerned with the new pricing regime approved by the Government in November 2011. Under this new regime, products may be aggregated for the purpose of establishing the government price not only by reference to their molecule but also by reference to their therapeutic indication. There being no objective criteria defined in the law as to how these therapeutic reference groups will be established and evaluated, it is highly likely that innovative products will be grouped with older or generic drugs for the same indication, despite the considerable differences in terms of efficacy and/or safety profile.

Government Reimbursement Process

PhRMA member companies operating in Portugal are finding it increasingly difficult to launch products due to: (1) systematic delays in reimbursement procedures; (2) an unbalanced "claw back" mechanism; and (3) a lack of transparent and objective reimbursement criteria.

In Portugal, the reimbursement of retail pharmaceuticals, on one hand, and the purchase by NHS Hospitals of hospital products, on the other, is dependent on a prior favorable decision rendered by the National Authority of Medicines and Health Products (INFARMED). The innovative pharmaceutical companies systematically face considerable delays by the public authorities in making this decision and the failure to comply with the legally-established time limits for settling these types of procedures. In

fact, data posted on the INFARMED website indicates that the average delay for a decision to be rendered by this Authority with regard to the purchase by NHS Hospitals of products containing new substances is approximately 390 days. Similar delays exist in the retail setting where a decision on reimbursement takes, on average, more than 1 year.

Furthermore, sales to NHS Hospitals (and increasingly to the pharmaceutical retail sector) are governed by short-term agreements between the pharmaceutical companies and INFARMED. As a general rule, these agreements establish an annual maximum value of sales per product (*i.e.*, a revenue cap), and any expenditure above this revenue cap must be reimbursed by the pharmaceutical manufacturer. In other words, these agreements impose a 100 percent claw back above a specified revenue level. This cap is established based on INFARMED's exclusive assessment of the total number of potential patients that may benefit from the new product, the total number of potential patients the NHS is willing to support with the new product, and the expected market share of the new product considering the therapeutic alternatives. The sources INFARMED uses to establish specific cap limits and the methodology employed to calculate those caps are not released to the public or the affected pharmaceutical companies. Because the formulation of the cap is founded on a relatively static view of the healthcare situation, new products generally have the lowest volume threshold and a limited ability to grow according to real market (*i.e.*, physician and patient) demand. Innovative products that serve unmet medical needs are therefore forced to accept a limitation on revenues before the market can reasonably assess the number of patients that would benefit from the therapy. This creates a market that inherently favors older, more established products, many without caps, at the expense of new, innovative medicines.

In addition, the lack of transparency regarding the criteria used by INFARMED to determine reimbursement hinders the companies' ability to portray and demonstrate the added-value of their products. In this context, it is incredibly challenging for PhRMA member companies to demonstrate and quantify the value of innovation – an exercise which is increasingly disregarded by INFARMED, in any event.

The situation has become even more challenging for PhRMA member companies following the changes to Portugal's reimbursement regime, enacted in May and October 2010, and which included:

- (a) the reduction of reimbursement levels, which may hinder patient access to innovative treatments; and
- (b) the extension of the conditions to delist medicines from reimbursement.

Hospital Debt

By the end of 2011, NHS hospitals owed approximately €1.5 million to pharmaceutical companies. In 2012, the Portuguese Government negotiated discounts on this debt with most of the pharmaceutical companies, such that most of this debt has

now been repaid (though this remains an issue for those companies who were unable to negotiate a discount with the Government). Although, in theory, hospitals should not be able to exceed their approved budgets going forward (under a new purchasing framework), several hospitals lack the resources to comply with the new framework.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

UKRAINE

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Ukraine face growing intellectual property and market access concerns.

Key Issues of Concern:

- **Intellectual Property Protections:** Despite improvements in the intellectual property (IP) environment in Ukraine, additional steps must be taken to ensure effective protection for pharmaceutical patents and regulatory data.
- **Good Manufacturing Practices:** New rules governing the issuance of certificates confirming international good manufacturing practices (GMP) standards may create unnecessary market access burdens that are discriminatory to imported U.S. products.
- **Import Licensing Law:** The Law No. 5038-VI adopted on July 4, 2012 creates discriminatory conditions for imported medicines by means of establishing new barriers for importers without any sign of deregulation of Ukraine's pharmaceutical market.
- **Transparency:** Regulations and laws are being adopted without adequate opportunities for PhRMA members to provide substantive input.

For these reasons below, PhRMA requests that Ukraine remain on the **Priority Watch List** for the 2013 Special 301 Report and that the U.S. Government continues to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections and Enforcement

Effective Patent Enforcement and Regulatory Data Protection

Amendments to Article 9 of the Law on Medicines (Law No. 3998-VI dated November 3, 2011) improved the framework for IP protections in Ukraine, but there remain several deficiencies in Ukraine's IP system. Specifically, it remains unclear to PhRMA member companies at which stage, and under which authority a regulatory authority may deny registration of a medicinal product if there are applicable data protection or patent rights on the reference (original) medicinal product. In turn, because the patent procedural landscape is not clear, it is difficult to observe any positive outcomes from the November 3 amendments to Article 9 of the Law on Medicines.

Two new legislative initiatives would further weaken patent protection in Ukraine. The first concerns a proposal by the Cabinet of Ministers of Ukraine to the Parliament of Ukraine (Regulation No. 11209) to amend Article 9 of the Law on Medicines (September 13, 2012). Per the Cabinet of Ministers' proposal, marketing authorization applicants for follow-on products would no longer be required to submit a certified copy of the relevant

patent(s) for the innovator product or a license to manufacture and market a copy of the innovator product with their applications. These documents help ensure that generic applicants are not granted marketing authorizations while the underlying innovative product is still subject to patent protection. As such, eliminating the requirement to submit these documents with the marketing authorization application is a critical step backwards in ensuring effective patent enforcement.

Second, on November 14, 2012, the Ministerial Working group on Intellectual Property and Access to Medicines presented a Draft Resolution of the Cabinet of Ministers “On Approval of the Procedure for Granting Authorization to Use an Object of Intellectual Property Regarding a Medicinal Product by the Cabinet of Ministers of Ukraine” (“Draft Resolution”). Given that a number of the procedures are vague, PhRMA and its member companies are highly concerned that Ukraine could issue compulsory licenses in order to support the commercial interests of specific local companies, to the detriment of U.S. manufacturers of innovative pharmaceuticals.

Market Access Barriers

Local confirmation of international GMP certificates

On November 3, 2011, the Verkhovna Rada of Ukraine adopted amendments to the Law on Medicines, specifically – Article 9 (Law No. 3998-VI dated 03.11.2011) changing the procedures for the state registration of medicinal products. Companies are now required to file a document which confirms that the medicine was manufactured in a manner that complies with good manufacturing practices in Ukraine. The governmental body responsible for issuing Good Manufacturing Practices (GMP) certificates in Ukraine is *the State Administration on Medicinal Products* (SAMP). Although the industry strongly supports efforts to ensure that medicines are produced in facilities that meet global GMP standards, the innovative pharmaceutical industry is concerned that the law does not reflect the fact that Ukraine is a party to *the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme* (jointly referred to as PIC/S).

In light of this omission, industry is closely monitoring the development of implementing regulations (to be developed under the supervision of the SAMP and adopted by the Ministry of Healthcare) to ensure that they provide a mechanism for recognizing GMP certificates issued by PIC/S members. Ukraine’s membership in the PIC/S means that the SAMP can benefit from manufacturing site inspections performed by other PIC/S members, including receiving inspection reports prepared by other PIC/S members. PhRMA member companies believe that in those cases where the GMP certificate was issued by a PIC/S Member, SAMP should implement a simplified GMP procedure (as previously proposed by the Ukrainian Health Care authorities), so that Ukrainian patients have prompt access to safe and effective medicines.

Import Licensing

The Law “On amending certain Laws of Ukraine with regard to licensing imports of medicinal products and defining the term “Active Pharmaceutical Ingredient (API)” (No. 5038-VI) was adopted on July 4, 2012, and signed into law by the President on August 30.

The Law establishes new barriers for importers. The most disturbing provision of the Law, which requires obtaining a license for importation of medicines, will become effective on March 1, 2013. Since local producers will not have to obtain a similar license, and given the history of favoring local production, PhRMA members are strongly concerned that the new provisions will discriminate against foreign producers of medicines. As of yet, the Ukrainian regulatory authorities have not issued either a regulation or other proposal that describes either the licensing conditions or procedures for obtaining an import license. PhRMA and its members believe this Law is a protectionist measure drafted to favor domestic medicinal products/companies.

Transparent Legislative Environment and Predictable Regulatory Policy

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

No Clear Definition of Biosimilar Medicines

No progress has been made since July 2010, when Ukraine Health Care authorities assured (during the EU-Ukraine IP Dialogue) that the Law on Medicines would be amended to define biosimilar medicines.

This issue has become more critical in light of recent regulatory changes, whereby the Ukrainian Government decided that biologics should be registered using the same procedure as for small molecules. PhRMA members are highly concerned that Ukraine, applying the same rationale, could decide that biosimilars should be registered in the same way as generic copies of small molecules, despite the many differences between a generic copy of a small molecule and a biosimilar version of a biologic.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

LATIN AMERICA

ARGENTINA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Argentina are concerned about the restrictions imposed on patentability criteria for pharmaceutical patent filings, the lack of progress to address the backlog of patent applications and the lack of protection for data submitted to obtain regulatory approval. In addition, there are limitations on the transfer of capital abroad, which hamper operations. Also, regulations imposing prior import authorizations introduce uncertainty to trade operations since there are no clear criteria regarding approval or rejection of requests by members. Notwithstanding the uncertainties and lack of clear rules, companies have not reported significant delays or rejections to import pharmaceutical products in 2012.

Key Issues of Concern:

- **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.
- **Restrictions to Patentability for Pharmaceuticals:** The Argentine Government has amended the criteria for the granting of pharmaceutical patents. A joint Resolution by the Ministries of Health, Industry and the Patent Office (INPI) establishes guidelines/instructions which restrict the possible patentability of compositions, dosages, salts, esters and ethers, polymorphs, analogous processes, active metabolites and pro-drugs, enantiomers, selection patents and Markush-type claims. This is contrary to Argentina's obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
- **Import Restrictions:** Argentina has issued resolutions whereby importers must submit a Prior Import Statement (PIS) before placing an order to import goods. The resolutions provide no criteria for evaluating whether the PIS will be approved or rejected. Also, the government has told companies that in order to import their products, they must export the same amount; that is, for every dollar imported, there has to be one dollar worth of exports. This verbal decision imposes quantitative import restrictions that appear to be in violation of Argentina's obligations under Article XI of the General Agreement on Tariffs and Trade 1994 (GATT), and inappropriately restrict corporate operations in Argentina. It should be noted that this was not applied to pharmaceuticals in all cases.

For these reasons, PhRMA requests that Argentina remain on the **Priority Watch List** for the 2013 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

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.

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 could lead to the refusal of pharmaceutical patents for: compositions, dosages, salts, esters and ethers, polymorphs, analogous processes, active metabolites and pro-drugs, enantiomers, selection patents and Markush-type claims. Furthermore, processes for the manufacture of active compounds disclosed in a specification must be reproducible and applicable on an industrial scale to be patentable. The regulation ends by stating that “Whether to extend these Guidelines to pharmaceutical biotechnological inventions will have to be analyzed for the specific case.”

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

Patent Application Backlog

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

Also, Argentina should accede to the Patent Cooperation Treaty, a step that would facilitate the filing and examination of patent applications in Argentina as it does now in more than 140 Contracting Parties. In fact, the Argentinean Senate approved Argentina's accession to the Treaty in 1998, but it was never discussed in the Lower House. During 2011, the Lower House resumed the analysis for approval of the treaty, at committee level, but with no results. There is no date set for voting.

Preliminary Measures/Injunctive Relief

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

Market Access Barriers

Import Restrictions

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

Further, the Argentine administration continues to impose quantitative restrictions on imports, in contravention of its international obligations under GATT Article XI. Specifically, pharmaceutical companies, among other industries, have been informed that they must balance their own foreign trade account; that is, for every dollar that they import, they must have one dollar worth of exports.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

BRAZIL

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Brazil remain concerned regarding patentability standards and enforcement, the lack of adequate regulatory data protection and discriminatory government pricing policies.

Key Issues of Concern:

- **Patentability Standards:** Article 229-C, the 1999 amendment to the patent law, inappropriately permits the health regulatory agency (ANVISA) to review all patent applications for pharmaceuticals products and/or processes, sometimes contradicting the patentability requirements adopted by the Brazilian Patent Authority (INPI).
- **Regulatory Data Protection:** Although Brazil has enacted federal laws to ensure adequate data protection for veterinary and crop products, Brazilian law still does not provide adequate data protection for pharmaceuticals.
- **Stance in Multilateral Negotiations:** Brazil should demonstrate more consistency between its internal policies and the stance that it takes in international fora during discussions concerning health care and the value of innovation and leverage its leadership in the region and proactively promote international agreements that ensure adequate and effective protection for innovation in the healthcare area”.
- **Government Price Controls and Taxation:** The current system is excessively complex and lacks transparency. The innovative pharmaceutical industry stands ready to cooperate with the Brazilian Government to develop a transparent and consistent pricing mechanism that appropriately rewards the value of innovative medicines.
- **Public Private Partnerships (PPPs) and Government Purchasing:** There is no clear regulatory framework for the establishment of PPPs and Brazil lacks clear rules regarding the purchasing preferences offered to PPPs. Similarly, it remains unclear how Brazil will apply a recently enacted government purchasing program that offers preferences to national products and services.
- **Regulatory Burden:** As a result of inadequate IT resources and insufficient numbers of staff, there is a considerable backlog and undue delays in reviewing marketing approval applications.

Despite these many concerns, PhRMA and its member companies recognize that there have been some market access improvements in Brazil over the last twelve months, including the implementation of a clear and transparent process for including new products and technologies on the list of products available through the Brazilian Government’s Unified Health System (SUS) as well as efforts to increase the capacity (350 new hires) and capability of the Brazilian Patent Office (INPI). For these reasons, PhRMA continues to request that Brazil be placed on the **Priority Watch List** for the

2013 Special 301 Report, but would ask that the U.S. Government conduct an **Out-of-Cycle Review** so that any concrete progress made during the year to address the issues identified in this report could be recognized by improving Brazil's Special 301 designation to Watch List.

Intellectual Property Protection

Patentability Standards

One of the most serious problems facing the pharmaceutical industry today in Brazil was created by Article 229-C, the 1999 amendment to the patent law that authorizes the health regulatory agency (ANVISA) to approve all patent applications claiming pharmaceutical products and/or processes. This review is in addition to the examination conducted by Brazil's 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 and INPI do not apply the same patentability requirements, thus generating uncertainty for patent applicants and undermining incentives for innovation.

As a consequence of the opinion issued by the Federal Attorney General (AGU) in October 2009 – recommending that ANVISA limit its role in the examination process to health and safety concerns – an inter-ministerial group was created to define the correct implementation of the decision released by the AGU Office. According to the inter-ministerial group's recommendation, the process flow has been changed so that ANVISA now analyzes the patent application before INPI and only those applications that receive ANVISA's approval are submitted to INPI. The patent applications that do not receive ANVISA's approval are extinguished without the proper examination of the patent authority (INPI), and the applicant can only demand the IP protection in the Brazilian courts. While Brazilian authorities argue that the new administrative flow brings more efficiency to the process, duplicative examinations unduly impede pharmaceutical patent applications.

The Public Consultation no. 66/12 recently launched by ANVISA is another opportunity for patent applicants to contribute to a more efficient implementation of Article 229C. However the reference to "patentability requirements" – included in Article 4º of the draft regulation – appears to violate the AGU's recommendation and thus represents a significant concern for those who support pharmaceutical innovation in Brazil.

Regulatory Data Protection (RDP)

The Brazilian Government still adopts a flexible interpretation of Article 39 of the TRIPS Agreement to allow Government officials to grant marketing approval relying on test and other data submitted by our member companies to prove the safety and

efficacy of their products. While some positive steps have been taken to prevent inappropriate disclosure of these data held by the Government, additional efforts are needed to provide certainty that test and other data will be protected fully 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. Although federal law 10.603/02 provides adequate protection for veterinary and crop products, the Brazilian legislation still does not provide a similar benefit for pharmaceutical products, resulting in discriminatory treatment.

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.

In conclusion, Brazil lacks sufficient 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 medicine application is needed. Although there have been lawsuits seeking to secure a period of data protection for specific products, so far the Courts are split, leaving innovators without reliable regulatory data protection.

Progress in Multilateral Negotiations

In recent years, the Government of Brazil has been very active in leading global discussions on healthcare. We applaud the Government's interest in seeking creative solutions to improving access to healthcare for everyone. However, traditionally Brazil has not supported adequate and effective intellectual property protections in multilateral discussions. Since Brazil already recognizes the importance of providing incentives for innovation domestically, we urge them to integrate this concept into their multilateral leadership. Improving patient health requires a multi-stakeholder holistic approach and must start with improving healthcare infrastructure while still rewarding innovation.

Regulatory Burden

Although Brazil has strong regulatory approval standards, the process is delayed due to inadequate IT systems and an insufficient number of staff. An assessment made by the Federal Court of Audit (Tribunal de Contas da União – TCU) on the regulatory agencies reveals a worrisome situation. According to Minister José Jorge, rapporteur of the process that examined the agencies connected to the area of infrastructure, all of the agencies suffer from a lack of financial and political autonomy, incomplete boards and lack of transparency. The innovative pharmaceutical industry recognizes and welcomes ANVISA's efforts to reduce its timelines. Additional steps ANVISA should take include:

- Updating their IT systems and hiring more staff to meet the demand posed by the volume of marketing approval applications;
- Developing more predictable processes, so that applicants can be better prepared, resulting in less and shorter “clock stops”; and
- Introducing an expedited process for line extensions (at least similar to the deadline for new products) providing faster access to post-approval innovations.

Market Access Barriers

Government Price Controls and Taxation

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

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

This movement gives the Brazilian and U.S. authorities a good opportunity to exchange mutual experiences and define a positive benchmark designed to promote free enterprise and also to discuss other and more effective mechanisms to promote access to medicines, such as the implementation of less regressive taxes on medicines at the federal and state levels (which combined exceed 30 percent).

Government Purchase and Public Private Partnerships – PPPs

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

Our members understand the motivation behind the new public purchase policy and believe they can be a partner in developing policies that create a better business environment and, in turn, promote investment and production of high quality products.

Regarding the PPPs, greater transparency in the process of selecting technological partners is required. Today, the terms and conditions for companies interested in participating in the PPPs processes are not public which negatively impacts Brazilian capability to attract more competitive proposals. Further, some companies that entered into PPPs 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 damages Brazil's ability to foster local technology in the pharmaceutical area.

Bearing this in mind, PhRMA's member companies and local association stand ready to contribute to this dialogue and hope that the measures to be implemented will not lead to discriminatory treatment that could limit their ability to compete in the market place.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

CHILE

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

Key Issues of Concern:

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

Notwithstanding the Chilean Government's positive statement of intentions and its efforts to date, PhRMA believes that the government's actions do not yet merit an upgrade from Priority Watch List (PWL) to Watch List (WL), and thus PhRMA requests that Chile remain on the **Priority Watch List** in 2013. However, PhRMA would welcome an **Out-of-Cycle Review** for Chile if and when the Chilean Congress gives final approval to acceptable patent enforcement legislation and modifies the Industrial Property Law to correct remaining weaknesses in Chile's data protection legislation.

Intellectual Property Protection

Effective Patent Enforcement

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

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

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

Regulatory Data Protection (RDP)

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 system. Specifically, S.D. 107 establishes that:

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

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

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

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

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

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

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

Delays in Granting Pharmaceutical Patents

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

Despite the administrative and procedural reforms implemented by INAPI to date, PhRMA member companies have not yet seen any substantial reduction in the time required to obtain definitive decisions on their patent applications.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

CENTRAL AMERICA – CAFTA-DR COUNTRIES

DOMINICAN REPUBLIC

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in the Dominican Republic (DR) remain concerned about the lack of effective implementing regulations and practice for regulatory data protection, and an effective patent enforcement mechanism. There is also a serious patent backlog and a delay in market access of pharmaceutical products due to the extended time the health regulatory agency is taking to decide the grant of market approval.

Key Issues of Concern:

- No concrete regulatory data protection system applied by the health regulatory agency.
- No effective patent enforcement available before marketing approval decisions on follow-on products.
- Serious patent backlog at the Industrial Property Office (ONAPI) for patents filed before the amendments to the industrial property law.
- Patent Term Adjustment has been denied since the Industrial Property Office does not apply the “existing matter” provision contained in section 15.1.11 of the Dominican Republic-Central American-United States Free Trade Agreement (CAFTA-DR).

For these reasons, PhRMA requests that the Dominican Republic be placed on the **Priority Watch List** for the 2013 Special 301 Report. The country continues to avoid systematically the implementation of its commitments regarding regulatory data protection, effective patent enforcement and patent term adjustment among other obligations. This negatively impacts the industry’s legitimate IP rights, its ability to access the Dominican Republic and patient access to innovative medicines.

Intellectual Property Protection

Regulatory Data Protection

The DR health regulatory agency has failed to implement a system of regulatory data protection for new products. Although several meetings have taken place in order to promote such implementation, the agency resists any action on the issue, and thereby continues to deny regulatory data protection, inconsistent with its international obligations under CAFTA-DR and the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights.

Effective Patent Enforcement

The health regulatory agency has not implemented mechanisms to facilitate effective patent enforcement prior to marketing approval for follow-on products.

Patent Backlog

There is a significant backlog of unissued patent certificates by the DR Industrial Property Office (ONAPI)'s Invention Department. According to ONAPI's Office of Access to Public Information, as of May 30, 2012, there were 1,437 patent applications pending, out of which 949 were pharmaceutical or chemical patent applications. Moreover, only 146 patent certificates have been issued in the last 12 years, 76 of which were protected pharmaceutical and chemical inventions.

Patent Term Adjustment (PTA)

Provisions for patent term adjustment entered into force for the Dominican Republic on March 1, 2008. ONAPI has stated that PTA does not apply "retroactively" to applications that were submitted before March 2008.

Section 15.1.11 of the CAFTA-DR contains a general provision that parties committed to observe: "this Chapter gives rise to obligations in respect of all *subject matter existing* on the date of entry into force of this Agreement *that is protected* on that date in the Party where protection is claimed, or that meets or comes subsequently to meet the criteria for protection under this Chapter." (Emphasis added.) PhRMA and its member companies submit that per this provision, all patent applications granted, *i.e.*, protected, after March 2008 should be eligible for PTA. This position is supported by the Appellate Body's interpretation of parallel language in the "*Canada-Term of Patent Protection*" (WT/DS170/AB/R) dispute.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

VENEZUELA

The member companies of the Pharmaceutical Research and Manufacturers of America (PhRMA) face several market access barriers in Venezuela, including non-existent intellectual property protections, government price controls, and restrictions on access to foreign currency.

Key Issues of Concern:

- **Intellectual Property (IP):** Since 2002, Venezuela has essentially not granted patent protection or regulatory data protection to pharmaceuticals.
- **Price Controls:** On July 18, 2011, the Government of Venezuelan issued a Law Decree creating a new agency to limit profit margins for companies operating in areas such as food and medicine. The Decree went into effect on November 23, 2011, subsequent to which all medicines sold in Venezuela have been subject to government price controls.
- **Foreign Currency Access:** In 2003, Venezuela established restrictive foreign currency controls. Uncertainty persists as to the availability of foreign currency. It is feared that the government may use these controls to develop selective import policies.

For these reasons, PhRMA requests that Venezuela remain on the **Priority Watch List** for the 2013 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

Patents

As a practical matter, Venezuela has not granted patents 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

In a departure from past practice (1998-2001), when a five-year period of regulatory data protection was enforced, Venezuela has not provided effective regulatory data protection since February 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) – since 2002 it has become common practice 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.

Counterfeit Medicines and Other Illicit Activities

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

Market Access Barriers

Pharmaceutical market access in Venezuela mainly hinges on access to the official foreign exchange rate and government pharmaceutical pricing policies.

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, are generally denied.

Government Price Controls

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

On July 18, 2011, the Venezuelan Government issued a Law Decree (Ley de Costos y Precios Justos) stipulating price controls on certain industries, including pharmaceuticals, and creating a new agency (Superintendencia de Costos y Precios) to enforce those controls. The Decree went into effect on November 23, 2011, whereupon ended Venezuela's long-standing practice of allowing free-market pricing for non-essential medicines (accounting for approximately 90 percent of the market by value). Since that time, all prices of medicines are subject to government control and no revision or adjustments have been made to account for inflation.

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, thus creating a risk of medicine shortages.

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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

MIDDLE EAST/ AFRICA/ SOUTH ASIA

ALGERIA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Algeria believe Algeria has the potential to be a promising market for new pharmaceutical products, investment and innovation.

In a promising first step, the former Minister of Health announced in a meeting at PhRMA in Washington DC in June 2012 that his government will reduce the amount of time it takes to issue marketing authorizations for new pharmaceutical products, respect intellectual property rights, and encourage investment in the pharmaceutical sector. While these statements are encouraging, PhRMA notes that there are still significant barriers that impede market access for medicines and impact PhRMA member companies' ability to advance human health, and operate and invest in Algeria.

Key Issues of Concern:

- **Weak Intellectual Property Protection for Pharmaceuticals:** Algeria has inadequate patent protection, ineffective mechanisms to enforce patents, and does not grant regulatory data protection.
- **Government Mandated Price Referencing:** Under Algeria's pricing system, some patented medicines with no generic equivalent on the market are nonetheless referenced against a generic product in the same therapeutic class. The resulting price does not recognize the value of innovative products, nor does it reward the significant investment involved in developing new medicines, or encourage the development of tomorrow's new cures.
- **Importation Restrictions:** Pharmaceuticals are subject to severe importation restrictions including a prohibition on imports of pharmaceutical products that are produced locally and 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 2013 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

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. In 2005, however, 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.

Furthermore, the interpretation of the current law by local authorities is that a copy of a product covered by an Algerian patent may be approved, and that the copy product may have access to the market 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 observed in recent years have still not been corrected.

Finally, 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.

Despite these many ongoing and outstanding issues of concern, PhRMA notes that the previous Government, particularly in the period from mid-2011 to mid-2012, adopted an increasingly collaborative approach with the sector. Although these talks have not yet borne concrete results in many key areas, PhRMA is encouraged that the previous Government stated publicly its support for a new strategy that better integrates the innovative pharmaceutical sector into Algeria's economy and healthcare system.

Market Access Barriers

Government Reference Pricing

Based on an inter-ministerial order issued on July 21, 2001, products having corresponding generics on the Algerian market are subject to reference pricing for reimbursement. Yet, in practice, some patented products with no generic equivalent on the market have been referenced against generics in the same therapeutic class in an apparent effort to compel the lowest possible price. Patents provide an incentive to innovate by providing a reward to inventors in the marketplace. By linking the reimbursement price paid for patented products to the lowest priced generic medicine in the same therapeutic class, the Algerian system dramatically undervalues the innovation and development costs involved in bringing the patented pharmaceutical to market. In addition, the process for setting prices is not transparent or reviewable, and does not provide for any specific appeal system. Moreover, as prices in the country of

manufacture can become a reference for export markets, arbitrarily low prices in Algeria have the effect of deterring investment in Algeria as an export platform, thereby undermining the government's intention to become a regional export center.

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

Importation Restrictions

On October 21, 2008, the Algerian Government issued a decision⁶² 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 decree⁶³ 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 importation policy continues to be implemented in a non-transparent and arbitrary manner.

Algeria's reinstatement of this policy on the importation of pharmaceuticals unfairly discriminates against PhRMA members, severely curtails market access for innovative pharmaceuticals, and is a significant barrier to trade. Moreover, these importation restrictions have resulted in shortages of some drugs,⁶⁴ thereby impacting Algerian patients.

Again, in recent discussions, Government officials have signaled that their intent is to reform the system to improve access and minimize stock disruptions.

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 could lead 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

⁶² 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".

⁶³ Instruction #5 for the Generalization of Generics (Sept. 2003).

⁶⁴ Veille Media, "Pénurie de médicaments: le Snapo va interpeller le ministre de la Santé", May 12, 2011.

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, yet another measure that discriminates unfairly against innovative pharmaceutical manufacturers.

Investments and Commercial Laws

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

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

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

Cumbersome and Slow Regulatory System

The registration process remains slow and additional, burdensome requirements for obtaining registration to market pharmaceutical products, especially innovative products, have been issued. It is not uncommon for the review and registration of new medicines to take three to four years, leaving patients many years behind therapy levels in neighboring countries. For example, in October 2009, MOH issued a new requirement for pre-authorization prior to registration dossier submission acceptance, with no visibility on timelines and criteria. After submission to the MOH, registration dossiers are on hold pending National Laboratory results, which causes further delay in the registration process.

Finally, since June 2010, pharmaceutical companies have noticed lengthy delays 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. In recent policy discussions, the previous Health Minister pledged that his ministry would do "everything possible" to reduce the backlog and duration of new medicines reviews.

Industry Association

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 welcomed the former Minister of Health's commitment to resolving this outstanding issue, and hope the new Minister 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 2012 attributable to trade barriers related to intellectual property protection and market access.

LEBANON

PhRMA and its member companies operating in Lebanon remain concerned about the lack of adequate intellectual property protections in the Lebanese pharmaceutical market.

Following recent changes in the leadership of the Ministry of Health (MOH) and with the introduction of regulatory reforms, market access for innovative pharmaceutical products has improved; PhRMA member companies continue to monitor the changes in the regulatory system, however, and its impact on market access for innovative pharmaceutical products.

Key Issues of Concern:

- **Ineffective Regulatory Data Protection:** Lebanon provides no data protection for clinical data submitted in seeking regulatory approval. On the contrary, the Ministry of Economy (MET) holds the position that publication of any data in a medical journal/Internet permits the MOH to approve generics based on that data at any time.
- **Regulatory barriers:** The Ministry of Health (MOH) has not implemented an effective regulatory system to technically monitor and confirm bioequivalence studies. PhRMA's members recommend the establishment of a central laboratory to validate the quality of medicines, bioequivalence, and to create a pharmacovigilance system to track post-marketing quality concerns.
- **Parallel Importation:** Although Lebanon has introduced a new regulation to restrict parallel imports, grey market medicinal products, with their attendant risks to patients, remain an issue in Lebanon.

For these reasons, PhRMA recommends that Lebanon be placed on the **Priority Watch List** for the 2013 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

Patent Protection

In July 2000, Lebanon passed a new industrial property law, which represented a major improvement over the 1924 law. The 2000 law provides 20 years of product patent protection, as well as incentives for new foreign direct investment and technology transfer, specifically for the pharmaceutical sector. The 2000 law improved the environment for innovation.

The law provides a good basis for Lebanon's eventual accession into the World Trade Organization (WTO). PhRMA supports the Lebanese Government's efforts to

implement laws and regulations that are consistent with WTO standards, and Lebanon's eventual accession to the organization. Meeting WTO membership requirements, and in particular, obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), would help address longstanding trademark and patent issues, as well as provide needed clarification in the area of regulatory data protection.

In its present form, however, the patent law does not provide sufficient pipeline or transitional patent protection.

PhRMA remains committed to supporting the Government's efforts to modernize the copyright, trademark and patent laws through continued dialogue with the Lebanese authorities, and sponsorship of workshops aimed at elucidating the importance of IP protection in Lebanon.

Regulatory Data Protection

As a WTO applicant, Lebanon will be required to prevent unfair commercial use of pharmaceutical data. This is most commonly accomplished through implementation of data protection. Article 47 of the current patent law provides only a partial definition of confidential information, leaving the identification of such information to interpretation by the courts.

The new drug registration regime, issued in late October 2008, has incorporated some protections for regulatory test data and patents. Four years after publication, the industry is still awaiting the proper implementation of these provisions. To remedy the situation, a comprehensive provision preventing unfair reliance on pharmaceutical data (as it pertains to a regulatory approval requirement), is required in order to protect the intellectual property rights of research-based pharmaceutical companies.

PhRMA members have engaged in an active dialogue with MET concerning a new Unfair Competition Law. The MET has taken the position that publication of any data in a medical journal or on the Internet would constitute a disclosure of the data (even though the underlying data are not disclosed), thus permitting the MOH to approve generics at any time after approval of the innovative product. An effort was made to inform MET that publication of preliminary test data and results is ethically sound and helps inform the medical community as early as possible about scientific progress. Such publication, however, should not be perceived as giving up the rights in underlying proprietary data, and reliance on those publications for marketing approval is an unfair commercial use of the data. The MET appears to be unwittingly or deliberately confusing the disclosure issue with PhRMA member companies' objections to local companies relying on that data to secure approvals of unauthorized copies.

To the extent that Lebanon wishes to accede to the WTO, it must provide regulatory data protection for a defined period for all information submitted by an innovative drug manufacturer with its marketing approval application. To be TRIPS-consistent, MOH should protect regulatory test data from unfair commercial use during

the data protection period by refusing marketing approval for pharmaceutical product applications filed by third parties that rely on the same data or conclusions without the consent of the party that produced the data. In addition, MOH should protect such data from disclosure except where necessary to protect the public health.

PhRMA member companies engaged in a workshop on regulatory impact analysis to ensure that challenges around article 47 are addressed by establishing the appropriate documents and processes in collaboration with the United States Agency for International Development, the American Chamber of Commerce and the MOH.

Market Access Barriers

Regulatory Barriers

The absence of clear criteria to distinguish between innovative and generic medicines is an ongoing concern. All registered products should be of high quality, with strong safety and effectiveness profiles. While bioequivalence is the criteria for registering generics, the MOH has not yet implemented an effective system to technically monitor and confirm bioequivalence studies submitted (*i.e.*, lab analysis, validation methods, analysis equipment, reference standards, qualified personnel).

Currently, the drug registration committee assesses a registration file based on a set of requirements according to a well-defined checklist and ensures that all sections required are included. PhRMA recommends that the MOH conducts a thorough validation and analysis of the quality and reliability of the content, through the establishment and activation of a central lab that would review and validate the quality of pharmaceuticals, in addition to requiring that the data submitted belong to the applicant and refer specifically to the submitted product. PhRMA also recommends the establishment of an effective pharmacovigilance system to track post-marketing adverse events or quality complaints post marketing.

The MOH announced recently that a new test laboratory, one of the most advanced in the Middle East, will be opened in Lebanon by the end of 2014. When fully operational, this laboratory should address the issue of quality and bioequivalence testing.

The new drug registration regime has improved regulatory processes. Innovative products are subject, however, to more onerous requirements than generics. Local manufacturers of “copy” products and importers of unauthorized copies are able to register with MOH, and sometimes be reimbursed by the Social Security Fund before registration of original products. Products manufactured by local companies enjoy a “fast-track” registration procedure and a significantly reduced list of requirements as compared to products imported from the United States or European countries. In effect, the system is discriminatory against imported products, which must undergo far longer regulatory approval timelines.

Lately, the MOH has started to conduct inspections of select manufacturing sites on an ad-hoc basis. PhRMA encourages such actions aimed at providing Lebanese patients with high quality medicines with strong safety and effectiveness profiles.

Parallel Importation

The new drug registration regime allows for parallel importation of pharmaceuticals through special import licenses granted by the Minister of Health. International experience, however, demonstrates that parallel importation presents risks to Lebanese patients by facilitating the importation of counterfeit, sub-standard or uncontrolled pharmaceuticals.

It is very hard to police the supply of medicines once the chain of supply from manufacturer to authorized importer is broken. Counterfeit and/or poor quality goods may enter the drug supply once this has occurred. Moreover, in the case of product withdrawal or recall, it may be very difficult for the manufacturer to identify parallel importers to alert them of recall decisions.

Although the MOH has taken measures to detect counterfeit products and publicly discloses information on counterfeited pharmaceutical products, trade in counterfeit pharmaceutical products in Lebanon persists, constituting a risk to public health since consumers find it difficult to distinguish counterfeit or sub-standard products. The Lebanese Government discovered products in the market that did not meet the government's safety and efficacy standards. PhRMA and our members encourage the U.S. Government to provide technical assistance that helps the Lebanese Government, particularly the Ministry of Health, re-establish the quality control laboratory that will allow them to address this important matter.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

WATCH LIST

ASIA-PACIFIC

AUSTRALIA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Australia remain concerned about the lack of adequate intellectual property (IP) protection afforded to innovative pharmaceutical products, specifically the lack of sufficient advance notice of potentially patent-infringing products and the limited scope of regulatory data protection. PhRMA and its member companies support the U.S.-Australia Free Trade Agreement (FTA). Patient access to medicines, a key priority for PhRMA, has been improved through implementation of the FTA. However, we believe that there is more that could be done to achieve the goal of providing access to new and innovative medicines.

Key Issues of Concern:

- **Need to Strengthen Regulatory Data Protection and Implement Effective Patent Protection:** The level of data protection offered in Australia is one of the weakest in the developed world. Strengthening data protection could, among other benefits, improve Australia's attractiveness as a destination for foreign investment by global pharmaceutical companies and encourage companies to bring new medicines to Australia sooner. In addition, contrary to its obligations under the FTA, Australia does not provide patent holders with advance notice of patent-infringing products coming to market.
- **Reduced Business Certainty Due to Large Number of Commissions Reviewing Australian IP System:** Current reviews of the Australian IP system include the Pharmaceutical Patent Review by IP Australia, Review into Compulsory Licensing by the Productivity Commission, Review into Innovation Patents by IP Australia and the Economics of Gene Patents by IP Australia. Certainty for our industry is very important when making investment decisions on research and bringing innovative medicines to Australian patients.
- **Politicization of the Government Pricing System:** The Australian Government decided in February 2011 to require that the Cabinet review and approve all Pharmaceutical Benefits Advisory Committee (PBAC) recommendations prior to listing on the Pharmaceutical Benefit Scheme (PBS). As a result of this new layer of review, the Cabinet deferred the listing of some new medicines on the PBS. This decision represented a significant departure from past practice and was taken without consultation with key stakeholders, including industry, physicians, and patient groups, and denied Australian patients access to these innovative medicines. In a positive development, the Australian Government has committed not to defer the listing of PBS medicines positively recommended by the PBAC that cost less than \$10 million in each forward estimate year through June 2014 (when the Memorandum of Understanding (MoU) expires). However, the Cabinet continues to reserve its discretion to consider and accept or reject all recommendations from the PBAC that have a financial impact.

For these reasons, PhRMA requests that Australia be placed on the **Watch List** for the 2013 Special 301 Report. PhRMA's member companies encourage the U.S. Government to raise these concerns as priorities for resolution during bilateral consultations with Australia as well as multilateral negotiations such as the Trans-Pacific Partnership.

Intellectual Property Protection

Regulatory Data Protection

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

Strengthening the data protection provisions in Australia, could further enhance Australia's ability to compete for foreign investment in the knowledge-intensive and innovation-intensive biomedical sector that can drive future economic growth. Steps that Australia could take would be to extend the term of data protection with possible extensions for new formulations, new combinations, new indications, new populations (e.g., pediatrics) and new dosage regimens.

Effective Patent Enforcement

Australia's patent system, however, traditionally has maintained a strong intellectual property regime for protecting innovative biomedical discoveries, including providing for patent term restoration. PhRMA understands that Australia's compliance with some key intellectual property provisions of the FTA was discussed in the process of certifying implementation of the Agreement. We further understand that U.S. negotiators sought and received an assurance that Australia's implementation of these FTA provisions within the existing arrangement of the Therapeutic Goods Administration (TGA) and the PBS would ensure patent holders receive advance notice to enable them to seek injunctive relief prior to patent infringing products entering the market.

Prior to the recent Federal election in Australia the Parliamentary Secretary to the Minister for Health proposed the implementation of more timely information being available about new registrations of medicines on the Australian Register of Therapeutic Goods. Information is now posted on the TGA's website within two days of a new product registration following regulatory approval. This mechanism is a step in the right direction, but it does not provide sufficient advance notice to patent holders as is

required under the FTA. The good faith implementation of those assurances is critical to ensuring that Australia's intellectual property regime remains strong, and that the agreement is implemented.

During 2012 the Australian Government commenced action against one company and threatened to take action against at least one other company to seek compensation if a patentee delays generic product entry through an interlocutory injunction and litigation which is ultimately found in favor of the generic company. It is conjectured that this action is based in part on 2004 amendments to the Therapeutic Goods Act (specifically Section 26D), introduced at the time of implementation of the AUSFTA by the Australian Parliament.

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

The Australian Government's actions are a threat to companies' rights to defend their intellectual property through the due process provided by the patent system. It could have an adverse effect on U.S. pharmaceutical companies' interest in seeking market access to Australia. Further, this measure is an industry-specific and technology-specific initiative that illustrates the potentially negative outcomes from the legislative amendments Australia implemented in 2004.

Proposals to prevent the patenting of human genes and biological materials

PhRMA notes with concern the proposals that emerged in the Australian Parliament in 2011 to ban the patenting of all biological materials in response to concerns about the potential patenting of human genes. PhRMA was pleased to see a Parliamentary review of the proposed legislation not recommend it proceed. However, there has been continuing discussion in Australia about whether there should be laws explicitly banning the patenting of human genes. The pharmaceutical industry, biotech industry, expert lawyers and medical researchers in Australia have repeatedly explained that such restrictions are not required given the principles of IP law, recent legislative reforms to Australian IP law (Raising the Bar Bill 2012) and the risks this will constrain future scientific research and investment in new treatments. PhRMA is concerned about the risk of such proposals being revisited in the future, particularly as they are likely to be contrary to the provisions of international IP agreements and the FTA.

Intellectual Property Reviews and Inquiries

The Australian Government has recently launched a significant number of intellectual property related reviews and inquiries including; an inquiry into Compulsory Licensing; Innovation Patents; Economics of Human Gene Patents and most recently the IP Australia Pharmaceutical Patent Review.

The number, scope and timing of these inquiries are seen as a continual attempt to erode intellectual property protection in Australia. Should the reviews lead to legislative amendments they could have a significant impact on Australia's intellectual property protections and a marked impact on future investment decisions.

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).⁶⁵ Accordingly, the PBS effectively controls access to the Australian pharmaceutical market. In May 2010, the Australian Government and the innovative pharmaceutical industry, represented by Medicines Australia, signed a Memorandum of Understanding which introduced much needed government price stability and other reforms to PBS, in exchange for significant price savings requested by the Australian Government. Several months later, the Australian Parliament codified the terms of this agreement. This agreement demonstrated the value of dialogue between government and industry, as well as the importance of stakeholder consultation prior to any decisions regarding major policy reforms.

In stark contrast, in February 2011, the Australian Cabinet announced it would review all recommendations to list new medicines in the PBS.⁶⁶ In accordance with this new policy, the Cabinet decided to defer listing a number of new medicines. Each of these medicines had undergone rigorous assessment and evaluation by the Pharmaceutical Benefits Advisory Committee (PBAC), and each had been recommended by the PBAC on the grounds of demonstrated clinical and cost-effectiveness. Previously, only those new medicines which the government expected would cost over AUD\$10 million per year were subject to review by the Cabinet. All other new medicines recommended by PBAC would normally be automatically listed. This introduction of a new layer of review was taken without any consultation with industry and other stakeholders such as patient groups and physicians, and was also outside the scope of the 2010 MOU, demonstrating a lack of faith in the dialogue between government and industry that had previously yielded such promising results.

PhRMA and its member companies strongly believe that the Australian Government reintroduced significant uncertainty by acting outside the terms of the 2010 MOU agreement. By deviating from long-standing practices and conventions in the PBS listing process the Australian Government significantly changed the business environment for companies in Australia; and did so without any consultation. It also did this by restricting Australians' access to medicines.

⁶⁵ "About the PBS," Australia Dept. of Health and Ageing, at <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-aboutus.htm-copy2> (last visited Feb. 8, 2013).

⁶⁶ "Submission to the Senate Finance and Public Administration Committee Inquiry into the Government's Administration of the Pharmaceutical Benefits Scheme," Medicines Australia, July 18, 2011, available at <http://medicinesaustralia.com.au/files/2010/02/20110715-sub-deferrals-senate-inquiry-FINAL-lodged.pdf>. (last visited Feb. 8, 2013).

On September 30, 2011, the Australian Government agreed to consult with patient groups and the innovative and generic pharmaceutical industries on this process going forward, and indicated that it would list on the PBS those medicines that had been deferred to date. The Government also agreed not to defer the listing of medicines expected to cost less than AUD\$10 million per year. PhRMA and its member companies welcome these developments and believe that they demonstrate the value of dialogue with stakeholders. This commitment was extended on October 1 through June 2014 when the MoU expires. However, the Australian Government has reserved the right to defer further medicines in the future. It has also introduced a special additional review process for one new medicine it has not yet decided to list. The implications for this new type of process remain unclear and there was no consultation with industry and patients on this process. At the time of writing, this new review process had run for over 18 months with still no outcome finalized.

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

PhRMA believes that the work done to date in implementing these obligations has been significant and we look forward to seeing constructive outcomes from the Medicines Working Group, including on remaining substantive initiatives required to improve access to innovative new medicines. We note our concern, however, that the last meeting of the Medicines Working Group was held in 2007 and are hopeful that the next meeting will be scheduled in the near future.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

KOREA

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

Key Issues of Concern:

- **Effective Patent Enforcement:** PhRMA member companies call for a system consistent with commitments in the South Korea-U.S. Free Trade Agreement (KORUS) that provides effective mechanisms to ensure patent enforcement issues can be resolved before follow-on products enter the Korean market.
- **Transparency, Accountability and Predictability in Government Policy-Making:** 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.
- **Reward for Innovation in Government Pharmaceutical Pricing and Reimbursement Policies:** The current government pricing mechanism sets prices for new medicines considering the weighted average price for pharmaceuticals – including generics – within the same therapeutic class. This policy, combined with significant *ad hoc* price cuts, means that the government pricing system significantly undervalues innovative medicines. Consistent with KORUS, the MOHW should reform its government pricing policies, for example, by not using off-patent or generic prices in the calculation of prices for new, patented products, so that prices for new medicines appropriately reward innovation and encourage investment in the new medicines needed by the people of Korea.

For these reasons, PhRMA requests that Korea be placed on the **Watch List** for the 2013 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 and Enforcement

Effective Enforcement of Patents

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

developed. These aspects of the system must be implemented by March 14, 2015, per the schedule in KORUS.

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

Under Korea’s new patent enforcement system, the Korean Food and Drug Administration (KFDA) examines the Patent Listing Application and may issue up to two official notices if there is insufficient information provided. There appear to be limited options to challenge or appeal a decision not to list particular claim(s) or the way in which the KFDA has amended the claim(s). Specifically, the KFDA may publish its own version of the listed claims, rather than the amended versions that the company submitted as part of the application process. The KFDA does not provide applicants with a formal opportunity to comment on any changes to the listed claims (but in practice, are informally notifying the company of any changes). The KFDA has assured applicants that they will not amend the claims in a formulation/composition category if that amendment would reveal confidential information. The effect of Korea’s approach is to insert uncertainty around the rights of innovators and of generic companies that seek marketing approval. PhRMA’s members will continue to monitor implementation of the patent enforcement system and request that the U.S. Government engage with the Korean Government to ensure that new uncertainties are not embedded in the Korean system.

Market Access Barriers

Predictability and Transparency in Government Policy-making

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

For example, in addition to 20 percent price cuts on off-patent medicines announced in 2010, the MOHW reduced prices for off-patent medicines again in April 2012, by as much as an additional 26 percent. The 2010 price cuts, which were introduced as a result of the “re-arrangement” plan, were initiated in January 2011 and are to be phased in over a three-year period, concluding in January of 2014. Taken together these price reductions bring off patent prices to the same price as generics.

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

As in the past, these latest price reductions were implemented with little input by stakeholders, including industry, and the aim and the grounds for changing specific pricing rules were not clearly understood. Rather, the details for each of the pricing policy changes were pre-determined by the Government, and any meaningful input or consultation by stakeholders was overlooked in the process of developing these reforms.

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

Market-based Actual Transaction Pricing

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

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

choose the best available medicine for their patients. This, in turn, adversely impacts patient access to innovative medicines and hampers the ability of innovative pharmaceutical companies to recoup their investments.

As part of the additional price cuts announced on August 12, 2011, MOHW announced the one-year suspension of the M-ATP program. On November 22, 2012, MOHW announced the continued suspension of the M-ATP program until January 2014. PhRMA and its member companies welcome this development, given the concerns about M-ATP listed above, but note that this is yet another example of the arbitrary manner in which the MOHW has been operating. Furthermore, we note that the program has only been suspended and may be reinstated at any time. The decision to repeatedly suspend, rather than to completely abolish M-ATP ignores broad-based stakeholder support for its abolition, and creates an environment of uncertainty which could adversely impact patient access to innovative medicines.

Recent Reform Measures Result in Adverse Impact on New Product Pricing

As a result of the implementation of these various government price reduction measures, existing drug prices were heavily impacted by dramatic price reductions. These price reductions will, by extension, impact the price of a new drug as the new drug price is currently derived using a weighted average which includes off patent drugs and generic prices. By instituting drastic price reductions on the off-patent and generic market, and referencing new drug prices to the price of these now heavily-discounted medicines, the government prices of new medicines will also be inappropriately depressed.⁶⁷ The MOHW price of new drugs under the current Drug Expenditure Rationalization Program is already far too low, less than half of the average OECD price for new drugs.⁶⁸ The further reduction of government prices of existing drugs will likely lead to much lower new drug prices in Korea.

PhRMA and its member companies are encouraged, however, by recent efforts of the MOHW to reform the new drug pricing policy to improve recognition of the value of new drugs in consultation with stakeholders including the research-based pharmaceutical industry. An effective dialogue on valuing innovation also will support MOHW's intention to promote greater pharmaceutical R&D in Korea and to improve the global competitiveness of the Korean biopharmaceutical industry in the future.

Independent Review Mechanism (IRM)

Under Article 5.3(5)(e) of the U.S.-South Korea FTA 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,

⁶⁷ In May 2012, MOHW indicated that the comparators' weighted average price, MOHW will use the 2011 price, which was unaffected by recent price reduction, which means new drug prices would maintain the current price level even after implementation of recent off-patent price reduction. However, it will remain valid until a new policy is established by April 2013. The details of this new policy have are still under consideration and have not been announced.

⁶⁸ KRPIA internal analysis study, 2012.

however, that reimbursed prices negotiated with pharmaceutical companies should not be subject to the IRM because the National Health Insurance Corporation (NHIC) 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, NHIC is the sole “negotiator” for reimbursements in Korea, and as such is making “determinations.” Local data indicates that from January 2007 through January 2011, NHIC determined not to reimburse 18 of the 93 medicines for which it was tasked to negotiate the reimbursed price. For anti-cancer drugs, the approval rate was even lower – NHIC decided to reimburse only three of the six anti-cancer drugs that Korea’s Health Insurance Review and Service Agency had determined should be reimbursed.

Further, the reimbursement process with the NHIC cannot be considered as “regular negotiations.” Companies are required to submit data and rationale for their proposed price in advance; however, NHIC is not required to provide any explanation of supporting data for its proposed price. As a single-payer, NHIC 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, NHIC’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 in 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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

MALAYSIA

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

Key Issues of Concern:

- **Lack of Effective Patent Enforcement and Regulatory Data Protection:** 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.
- **Anti-Counterfeiting Enforcement:** The need for deterrent and criminal penalties for those caught manufacturing, supplying, or selling counterfeit pharmaceuticals as well as closer coordination between the U.S. and Malaysian Governments on anti-counterfeiting initiatives. The industry welcomes the recent passage of the Pharmacy Bill, which imposes enhanced penalties for counterfeiting of medicines.
- **Listing Process of Pharmaceuticals on the National Formulary:** Malaysia's stringent process for listing pharmaceuticals on the national formulary curbs access to innovation by taking three to five years following regulatory approval with minimal transparency on the evaluation processes. Effective reform that streamlines listings could help Malaysia achieve its goal of world class status as a hub for healthcare innovation.
- **Preferential Treatment of Local Manufacturers:** The Government of Malaysia discourages an open and competitive marketplace for international pharmaceutical compounds through procurement preferences for locally manufactured products and regulations mandating that only local agents can participate in tenders.

For these reasons, PhRMA requests that Malaysia be placed on the **Watch List** for the 2013 Special 301 Report. PhRMA's member companies encourage the U.S. Government to raise these concerns as priorities for resolution during bilateral consultations with Malaysia as well as in multilateral negotiations such as the Trans-Pacific Partnership.

Intellectual Property Protections and Enforcement

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, structured enforcement guidelines and a mechanism to curb unfair promotion and sale of generic drugs prior to: (1) patent expiry of innovator drugs; and (2) a court decision on patent disputes would enhance patent protection and enforcement.

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.

Patent and Trademark Laws

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

Regulatory Data Protection

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

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

Anti-Counterfeiting Enforcement

The counterfeiting of pharmaceutical products poses a serious threat to the health of safety of Malaysia's citizens. PhRMA member companies strongly support enhanced coordination between the U.S. and Malaysian Governments on anti-counterfeit initiatives, including training for regulatory and security officials. The addition of new resources and heightened enforcement capabilities for Malaysia's intellectual property court system would serve as a strong compliment to these initiatives.

Increasing the penalties for criminals caught manufacturing, supplying, or selling counterfeits will also help Malaysia achieve world class status as a hub for advanced health innovations and healthcare delivery. PhRMA members welcome the recent passage of the Pharmacy Bill, which imposes enhanced penalties for counterfeiting of medicines.

Market Access Barriers

Listing Pharmaceuticals on the National Formulary

Malaysia's stringent and lengthy process for listing pharmaceuticals on the national formulary curbs access to innovation by taking up to five years following regulatory approval. In July 2011, the Ministry of Health (MOH) issued guidance to PhRMA's member companies of Malaysia's intent to examine the process and consultations are presently underway. Effective reform that streamlines listings to the national formulary could improve market access and patients' access to medicines.

Regulatory Approval Process

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

Preferential Treatment of Local Manufacturers

Malaysia's National Medicines Policy (MNMP), which prioritizes the medium and long-term goals set by the Government for the pharmaceutical sector, endorses potential price controls, generic drugs substitution, and preferences for generics and local manufacturers by promoting national self-reliance for drugs listed on the National Essential Drug List (NEDL). PhRMA member companies submit that the Government of Malaysia should eliminate discriminatory preferences for locally manufactured pharmaceuticals. This preferential treatment discourages an open and competitive marketplace in Malaysia. The Government of Malaysia should also open up the tender process rather than limit participation to local firms.

Halal Pharmaceutical Guidelines

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

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

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

TAIWAN

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Taiwan remain concerned regarding the lack of progress in discussions between industry and the Government on health policy reform measures designed to bring stability and predictability to the Taiwan pharmaceutical market. Nonetheless, 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 sensible drug pricing and reimbursement policies with stakeholder involvement.

Key Issues of Concern:

- Lack of adequate systems for patent protection and regulatory data protection, which discourages investment in innovative medicines for Taiwanese patients;
- Government prices for new drugs do not adequately reflect the value of innovation, although there has been some marginal improvement in pricing in 2011 and 2012. 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 a year ago, particularly the thresholds for signing a PVA;
- Continued reliance on biennial Price-Volume Surveys (PVS) which has been extremely disruptive to the pharmaceutical industry, hospitals and ultimately patients, while doing little to ensure the long-term financial sustainability of Taiwan's national health insurance system; and
- Uncertain implementation of critical components of the Second Generation National Health Insurance Act passed in January 2011, including 1) the Drug Expenditure Target, which is intended to help increase patients' access to innovative medicines and the Taiwanese Government to maintain a financially stable healthcare system and 2) the recently established Joint Meeting of DRIPS (Drug Reimbursement Items and Payment Standards), which will conduct a duplicative second review of the new drug pricing and reimbursement applications. This new process will further delay Taiwanese patients' access to innovative new medicines in 2013.

For these reasons, PhRMA requests that Taiwan be placed on the **Watch List** for the 2013 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 and Enforcement

Regulatory Data Protection

In January 2005, Taiwan passed regulatory data protection legislation to implement Article 39.3 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 39.3 of the TRIPS Agreement requires governments to prevent unfair commercial use of valuable test data gathered by innovative companies to secure marketing approval. Although the revised Pharmaceutical Affairs Law provides for five years of regulatory data protection, it does not cover new indications. In addition, the current law limits the applicability of data protection to registrations filed within three years from the first approval granted anywhere in the world for a product based on that new chemical entity. This requirement is not consistent with the objectives of regulatory data protection rights and does not effectively prohibit unfair commercial use. In summary, PhRMA urges that the regulatory data protection legislation be amended to cover new indications and abolish the limit on applicability.

Effective Patent Enforcement

Taiwan has not yet established systems to effectively prevent marketing of patent-infringing pharmaceutical products. According to industry surveys in 2012 conducted by International Research-Based Pharmaceutical Manufacturers Association (IRPMA) in Taiwan, at least 58 patent-infringing drugs were approved in Taiwan, and most of them were subsequently included on the reimbursement lists. This significantly disadvantages innovator companies, particularly in view of pending proposals to alter regulatory approval procedures. Under a 2005 revision to the Pharmaceutical Affairs Law, the Taiwanese Government asks patent-owners to register their patents upon receiving product licenses; thus, data similar to the Orange Book system in the United States is available. That change provides limited benefit, given that Taiwan does not have effective patent enforcement mechanisms in place.

Market Access Barriers

Reward for Innovation

The Bureau of National Health Insurance (BNHI) (a division of the Department of Health (DOH)) sets pharmaceutical prices for new innovative drugs that are extremely low compared to other countries. BNHI's drug reimbursement guidelines contravene internationally-accepted norms by severely restricting the use of innovative medicines and disregarding many innovative products' approved indications. Over the past year, the PhRMA member companies have had a constructive dialogue with the Government on pricing and reimbursement policy, and we would like to formalize this dialogue and ensure inclusion of other topics, such as PVA and HTA.

We appreciate the announcement by the BNHI Drug Committee to review a new drug and make the reimbursement decision based on an approval letter issued by the TFDA, although the effective reimbursement date would remain pending until the official license is submitted to BNHI. The time saved from early review, however, will be jeopardized by the future 2nd tier review under the Joint Meeting of DRIPS. PhRMA and its member companies continue to discuss with DOH and BNHI the following issues to improve the pricing and reimbursement policies and regulations.

PVS: In an effort to eliminate the long-standing “pharmaceutical price gap” (the difference between the after-discount actual transaction price paid by healthcare providers for drugs, and the higher price at which they are reimbursed by BNHI), BNHI has conducted frequent PVS followed by substantial price cuts. As a result, on average, the price of original drugs in Taiwan is only 28 percent of the level in the United States.⁶⁹ The pricing system for new drugs does not currently reflect the degree of innovation of those products, which adversely impacts patients’ ability to access new and innovative medicines.

DET: In January 2011, the Taiwan Legislature passed the Second Generation National Health Insurance Act which introduced the concept of annual Drug Expenditure Targets (DET) to provide predictability to the pharmaceutical industry with regard to the government’s pharmaceutical budget. It was also designed to alleviate the need for the biennial Price-Volume Survey (PVS) and associated price cuts. PhRMA’s members urge the Taiwanese Government to engage industry on the development of the DET, including by providing opportunities to comment on the draft implementation plan, and to implement DET as soon as possible given that the Second Generation NHI went in to effect in January 2013.

Joint Meeting – DRIPS: Another feature of the Second Generation National Health Insurance Act is the establishment of a new mechanism to formulate the Drug Reimbursement Item and Payment Scheme (tentatively called DRIPS). We hope that this new drug reimbursement decision-making process will not cause delays in patient access to innovative new drugs.

More reasonable new drug pricing: During April 2011 to March 2012, the average new drug price in Taiwan was 50.65 percent of the Advanced-10 countries’ median price, slightly increased against 47.81 percent the year before. We hope this trend continues and urge BNHI to revise the appropriate regulations so that the pricing system better reflects pricing methodologies in other advanced economies and allows companies to recoup the significant investment required to develop a new medicine and rewards innovation. Under the current system, only three drugs have been classified as break through innovation since January 2010.

⁶⁹ 2011 White Paper, American Chamber of Commerce in Taiwan (ACCT), available at http://www.amcham.com.tw/component/option,com_docman/task,cat_view/gid,284/Itemid,377/ (last visited Feb. 8, 2013).

PVAs: PVAs unfairly require companies to bear the financial risk once the spending on a drug exceeds the estimated budget decided by BNHI, even though the volume of prescription is controlled by physicians and thus severely undermines the possibility of rewarding innovative medicines. We urge BNHI to meet with industry to review the PVA guidelines, particularly the threshold provisions, which have been implemented since August 2011. To that end, PhRMA also proposes that BNHI publish a standard PVA agreement that provides a predictable model.

Patent definition for reimbursement price related regulations: Although the BNHI has implemented a pricing system for patented pharmaceutical products, it applies a different definition of “patented” than that applied by Taiwan’s IPO (Intellectual Property Office). PhRMA’s members urge the Taiwanese Government to recognize all forms of patent protections, e.g., compound, composition and indication, instead of only compound, when adjusting drug prices. Other protections, such as RDP and administrative protection, should also be recognized.

Price adjustment for “just off-patent drugs”: PhRMA supports a fair and sensible price adjustment mechanism for “just off-patent drugs”. However, drugs should not be subject to compounding price cuts within the same year, *i.e.*, discounted as “just off-patent drugs” and under regular price adjustments such as the PVS. At a minimum, PhRMA members urge the Taiwanese Government not to apply these price cuts retrospectively, *i.e.*, to products whose patents expired before the Amendment to the Act went into effect.

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

In the interest of rewarding innovation, developing new medicines to meet Taiwan’s unmet needs, and ensuring that Taiwanese patients have access to innovative drugs, PhRMA strongly recommends that the U.S. Government encourage Taiwan’s Government to implement the DET and discontinue use of the PVS system. 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 as well as 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 2012 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 and Enforcement:** The adoption of meaningful regulatory data protection, patent enforcement, and other intellectual property protections that conform to international standards would greatly assist Vietnam in creating a more predictable environment for investment, improve process transparency and predictability, promote innovation, and strengthen the country's healthcare system.
- **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; leading to an escalation in costs and reducing 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 compared to locally produced pharmaceuticals. Given the country's costly import regime, the reference pricing system should be based on Price to Trade (PTT).
- **Trading Rights and Distribution Restrictions:** Vietnam's Ministry of Health (MOH) should provide clear guidelines for effective implementation of full trading rights in all pharmaceutical products. The MOH should also permit PhRMA's member companies to contract with foreign-owned storage and logistical service companies who certify their methods satisfy international standards.

For these reasons, PhRMA requests that Vietnam remain on the **Watch List** for the 2013 Special 301 Report. PhRMA's member companies encourage the U.S. Government to raise these concerns as priorities for resolution during bilateral consultations with Vietnam as well as in multilateral negotiations such as the Trans-Pacific Partnership.

Intellectual Property Protections and Enforcement

Regulatory Data Protection

Vietnam continues to engage with PhRMA's member companies on the adoption of meaningful regulatory data protection measures through the Drug Administration Vietnam (DAV). However, the implementation guidelines of the current Data Protection Circular fall short of making the necessary improvements. Specifically, the Circular is not clear on whether the five-year term of regulatory data protection applies in cases

that involve a generic product relying on or referencing innovator data in support of its marketing approval application. Furthermore, the Circular conditions regulatory data protection on requirements that: (1) member companies submit a separate application for data protection, rather than receive automatic protection upon marketing approval as international standards and the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) require; (2) data be classified as a "trade secret" under Vietnamese law; and (3) the innovator prove "ownership" of the data in cases of dispute rather than the third party or government challenger.

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 prevent infringement of patents 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.

Anti-Counterfeiting Enforcement

PhRMA's member companies applaud recent 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.

Market Access Barriers

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 major regulatory authorities such as the United States Food and Drug Administration and European Medicines Agency, but Vietnam does not possess the resources or infrastructure to acquire

reliable clinical trial results from domestic sources. These requirements also apply to new variations of pharmaceutical products already registered in Vietnam. PhRMA's member companies urge Vietnam to permit regulatory officials to accept reliable clinical trial data collected from appropriate clinical trial sites located outside of Vietnam when domestic capabilities are not in place. Such an amendment could quickly improve patient access to new, life-saving medicines.

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

Certificate of Pharmaceutical Product (CPP)

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

Product Visa Renewal Process

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

Bioequivalence Study Requirements

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

Government Pricing and Reimbursement

Reference Pricing

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 due to the lack of trading rights in the sector – results in inflated CIF

prices within Vietnam relative to other regional markets that do not impose similar restrictions. Second, the adopted pricing circular only applies to imported products and no similar restrictions or requirements are posed on locally manufactured goods. PhRMA's member companies understand Vietnam's desire to compare prices with neighboring markets; however, when considering the price of a product elsewhere it is important to consider the cost at which the product is actually sold by the pharmaceutical company. In Vietnam, this cost is the price charged to the distributor, as companies are obliged to sell to a local firm with distribution rights. The reference pricing system should be based on Price to Trade (PTT), which covers both locally manufactured and imported products.

Fixed Pricing and Currency Devaluation

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

Trading Rights and Distribution Restrictions

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

Research-based pharmaceutical firms also face limited control over the distribution of their products and are required to partner with a local distributor. The pharmaceutical supply chain requires careful monitoring to ensure product safety, reliable maintenance (*i.e.*, an unbroken cold chain for vaccines), timely delivery, as well as the protection of sensitive proprietary technology. The MOH should permit PhRMA's member companies to contract with foreign-owned storage and logistical services companies who certify that their methods meet international standards. In addition to direct importation/exportation, wholly owned subsidiaries should be permitted to engage local employees as professional sales representatives to educate physicians and end users about product availability, usage, and consistency with local laws and regulations.

Government Tender Restrictions

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: (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; (5) limitations on the countries from which patent documents are being considered; and many other related issues.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

FINLAND

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

Key Issues of Concern:

- Lack of patent protection for original products covered by an analogous process patent
- Inadequate intellectual property protection in Finland could negatively impact government pricing in other markets that refer to pharmaceutical prices in Finland
- Two-year delay on granting special reimbursement (following two year period in the basic reimbursement category)
- *De Facto* therapeutic reference pricing

For these reasons, PhRMA requests that Finland remain on the **Watch List** for the 2013 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

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

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

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

Under the subject matter and the transition rules of the TRIPS Agreement (Articles 70.2 and 27.1), PhRMA and its member companies believe that Finland should

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

In addition, Finnish Courts have not applied the reversed burden of proof provided for by Article 34 of the TRIPS Agreement in preliminary injunction proceedings. This has expressly been confirmed as a requirement in a Court of Appeals proceeding to which the Supreme Court has not granted leave for appeal.⁷⁰

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

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

The approved FMA 2008 includes an extension of the generic substitution system pursuant to which the generic substitution and reference price system now encompass products protected by analogous process patents, which should have been excluded from generic substitution until the expiration of their patent protection by virtue of the amendment of the Medicines Act enforced as of February 2006. Furthermore, if there is a question of whether the generic product infringes the patent of the originator product, the burden of proof is on the originator company and not on the generic company.

Prior to implementation of the FMA 2008, even though an original product was not eligible for inclusion in the substitution list and thus to the pricing reference group, it was nevertheless possible for its reimbursement status to be deteriorated by other measures, e.g., by the Finnish authorities cancelling the reimbursement during the reimbursement period. According to the reimbursement provisions of the Finnish Sickness Insurance Act (1224/2004), the Pharmaceutical Pricing Board (PPB) may, at its own initiative, decide that the confirmed “reasonable wholesale price and

⁷⁰ *Zeneca Inc. et al. v. Orion Oyj et al.*, Helsinki Ct. of Appeals, Decision No. 1446, Docket No. S08/361 (May 23, 2008); Sup. Ct. Decision No. 2484, Docket No. S2008/581 (Nov. 14, 2008).

reimbursement status” of a pharmaceutical product should be cancelled. According to Chapter 6, Section 8 of the Sickness Insurance Act (of 2006), PPB can make this decision when, for example, a generic product containing the same active ingredient as an innovative product has been included in the reimbursement system, regardless of whether the innovative product is protected by a valid analogous process patent.

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

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

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

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

Market Access Barriers

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

In Finland, the Pharmaceuticals Pricing Board sets the reasonable wholesale price and reimbursement. A Pharmaceutical company needs to apply for price and reimbursement with a written formal application. Reimbursement for medicines is valid in Finland only for a fixed period (maximum five years, usually one to two years) and extensions must be sought at least six months before the end of the reimbursement period. There are three categories of reimbursement (basic at 42 percent, lower special category at 72 percent, and upper special category at 100 percent).

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

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

The Price of Patent Protected Products Is Referenced to the Prices of Generic Products in the Same Therapeutic Class

As noted above, pricing and reimbursement decisions are made for a limited time period. In a situation where other products in the same therapeutic class have become generic and the price level for those medicines has declined, PPB has suggested to PhRMA members that in order to ensure continued access to the reimbursement system, the government price should be reduced. While Finland expressly does not have therapeutic substitution, some pharmaceutical companies have received letters from the PPB urging them to lower the price if there are other products in the therapeutic class that are generic. As a result of this pressure, the price level of patented products declines gradually towards the generic price level even during the life of the patent.

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

Discriminatory Price Regulations Imposed on Innovative Medicines

The Finnish Government has announced it will impose a 5 percent price cut on products not included in the (internal) reference price system, effective February 1, 2013. As this will only affect innovative products, it discriminates against innovation and spares the generic/off-patent segment from making a commensurate contribution. Furthermore, as part of the savings package, the reimbursement levels will be lowered, effective January 1, 2013, which could undermine patient access to innovative therapies and lower adherence rates.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

GERMANY

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

Key Issues of Concern:

- **Pharmaceutical Market Reform Law (AMNOG) and Price Controls:** The complete restructuring of the pharmaceutical market under AMNOG raises a number of concerns. Chief among these are the move away from market based pricing towards reference pricing (early after launch); ensuring confidentiality of rebates and other price discounts negotiated individually with PhRMA's member companies; the continuation of increased mandatory rebates despite much stronger sick-fund finances than projected; and the execution of the new benefit evaluations and rebate-setting mechanisms of the German's health system self-administrative Federal Joint Committee (GBA) and the Head Association of Statutory Health Insurance (GKV-SV).
- **Opportunity to Engage with the German Government:** PhRMA and its member companies strongly encourage a greater dialogue between PhRMA member companies and the German Government. Currently there is little, if any, opportunity for the research-based pharmaceutical industry to engage with the German Government on health care policy issues. Key issues that should be addressed as part of an improved dialogue include the make-up of the reference country basket and the preservation of confidentiality around German rebate negotiation results. Innovative companies in Europe and the United States bear a disproportionate share of the mandatory rebate burden, and an annual evaluation and review of the continued necessity and/or level of the mandatory rebate are required.

For these reasons, PhRMA requests that Germany be placed on the **Watch List** for the 2013 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

2010 Healthcare Reform

On August 1, 2010, the German Government, responding to a supposed healthcare- funding shortfall (which did not materialize), increased the mandatory rebate for patented products not covered by fixed reference prices (FRP) from six to 16 percent. This "short-term" cost-containment measure, along with a price moratorium, will be in place until the end of 2013. Although the legislation requires an annual review to determine whether the claw-back remains necessary, the increase should be viewed as a new structural intervention rather than "emergency" legislation.

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

- A rapid assessment of every New Chemical Entity (NCE) and every new indication of an NCE within 3 months after launch, based on a value dossier provided by the manufacturer. The German health system’s self-administrative body GBA (Federal Joint Committee) can also select drugs from the existing market to become subjects of a rapid benefit assessment.
- The GBA then will decide at six months post-launch whether a new product provides additional therapeutic benefit. The GBA can execute the assessment on its own or charge the Institute for Quality and Efficiency in Healthcare (IQWiG) or another third party with the task.
- Effective 12 months after launch, a reimbursement price for each new product will be set. In determining the reimbursement price, products will fall into one of three categories:
 - (1) Products with proven additional benefit. Where it is determined that a product has additional benefit, centralized negotiations will be held between the manufacturer and the GKV-SV (Head Association of Statutory Health Insurance). If a manufacturer and the GKV-SV cannot agree on a price, then an arbitration committee makes a binding decision, using EU prices in 16 selected EU countries as one reference point, combined with data on turnover and purchasing power parity.
 - (2) Products without additional benefit. If a product is viewed as having no additional benefit, it will be subject to reference price clustering, using, if feasible, the current methodology to determine a reimbursement level.
 - (3) Products without additional benefit/non-reference price. If reference price clustering is not feasible, the reimbursement level will be fixed at the level of cost of standard existing therapy. Once again, an arbitration committee will make a binding decision if a manufacturer and the GKV-SV do not agree.

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

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

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

Implementation of AMNOG

As of August 28, 2012, the rapid benefit assessment including final GBA decision has been completed for 25 drugs. Two drugs have gone through the complete process with rebate negotiations between manufacturer and GKV SV and final determination of the reimbursement price. Some companies – anticipating an unfavorable result – have decided not to market their new products in Germany because of concerns about inappropriate comparator therapies assigned by the GBA.⁷¹

Experiences with the rapid benefit assessment so far show technical implementation issues, different views in the assessment of clinical practice and relevance, method application and comparator selection. The advisory process by the GBA is still insufficient and dissatisfying for the industry. The data that must be submitted in the dossiers are extensive and costly, both in terms of time and resources. Overall the process is more bureaucratic and formal than pragmatic. Even more troubling, the selection of comparator therapies by the GBA so far seems to be guided by economic rather than medical considerations.

The inclusion of European reference pricing in the negotiation of the reimbursement price has also raised concerns, including the appropriate reference countries and the confidentiality of both the prices negotiated in those reference countries and the ultimate price negotiated in Germany (which, in turn, may be referenced in other countries).

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

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

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

⁷¹ See, e.g., Global Insight, “AMNOG Blocks Second New Medicine in Germany, Industry Group Calls for Fairer Pricing Rules,” Sept. 9, 2011.

Process and Transparency

Reimbursement decisions for pharmaceuticals in Germany's statutory health insurance system are made by the GBA, the top layer of the country's self-administration mechanism in healthcare. Voting members of the GBA are named by the federal associations of statutory health insurance funds, hospitals, and physicians. Patient representatives on the GBA have no voting power. With the passage of AMNOG, the GBA has become even more powerful; an issue of great concern to manufacturers seeking continued open access to the health-care marketplace in Germany.

Concerns about the GBA's lack of process transparency, its unwillingness to engage in meaningful dialogue with industry, and the absence of mechanisms to appeal its decisions are growing. The overwhelming dominance of payer interests in the GBA and lack of public checks (GBA officials are not publicly elected) increasingly place this body beyond the reach of politics and public policy. Subcommittees play an important role in the benefit assessment process and decision-making. A membership of industry representatives in those subcommittees would increase transparency and acceptance of decisions.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

GREECE

PhRMA's member companies face several market access barriers in Greece, including non-transparent reimbursement and pricing procedures and outstanding debts owed by state-run hospitals and social security funds.

Key Issues of Concern:

- **Ever-Increasing Hospital and Social Security Funds (EOPYY) Debts**
- **Draconian Cost-Containment Measures:** Contrary to current practice in Greece, clear, predictable, and transparent government pricing procedures are critical for market access, as government prices of pharmaceuticals in Greece are determined through an international reference pricing system. In addition, to ensure timely access to the market, the Government of Greece (GOG) should set a clear timeline for establishing government prices for new medicines and for making reimbursement approval decisions for those medicines. In November 2012 the second wave of austerity measures in 2012 was introduced which comprised of new pricing rules, the reintroduction of the positive list that was approved in 2012 (albeit with changes against innovative drugs), mandatory prescription by international non-proprietary names (INN), and increasing patient copayment rates. These measures could significantly undermine pharmaceutical innovation.
- **Measures Undermining the Value of Innovative Medicines:** As part of the November / December 2012 price reassessment the Government applied an administrative price cut to all off-patent products based on their last pre "Loss of Exclusivity" (LOE) price. The GOG has determined that the LOE point is the date on which the Regulatory Data Protection period expires (i.e., 10 years after marketing authorization is granted in the EU), not the date on which the patent term expires as required by Greek Law. This decision could impact not only prices in Greece, but also prices in those countries that reference Greek prices in determining their prices for pharmaceuticals.

PhRMA and its member companies encourage the U.S. Government to ask the GOG to recognize and protect innovation in the pharmaceutical sector by ensuring efficient and timely government pricing and reimbursement procedures for medicines reimbursed by the Social Security Funds. Medicines that are not reimbursed in some way by the government (e.g., OTC medicines) should not be under any government price, supply chain or profit margin control. The GOG should also seek to spread cost-containment throughout the healthcare and pharmaceutical sector by ensuring rational and fair pricing policies for generic products and European-comparable margins for pharmacists and wholesalers.

For these and other reasons described below, PhRMA requests that Greece remain on the **Watch List** for the 2013 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

Outstanding Hospital Debts

Following the October 4, 2009 elections, the new GOG indicated that it would begin making payments on €6.5 billion in outstanding debts owed to pharmaceutical and medical device companies by the end of 2009;⁷² approximately 50 percent of this was owed to pharmaceutical companies.⁷³

On August 3, 2010, the GOG issued a new regulation stating that the pharmaceutical industry would receive cash for 2005 and 2006 balances and 1-year, 2-year and 3-year coupon bonds for 2007, 2008 and 2009 debts, respectively.

Throughout 2010, the Hellenic Association of Pharmaceutical Companies (SFEE) and PhRMA worked with the GOG in order to reach a settlement. As a result of these coordinated efforts, the balances for 2005-2006 were settled in cash by the Ministry of Finance. In October 2010, the Ministry of Health (MOH) announced that the debt owed for 2007 through the end of the third quarter of 2010 would be settled with bonds by the end of 2010. Further, it was agreed that the balance owed for the fourth quarter of 2010 will be settled by April 2011. Subsequently, the Ministry of Economy approved €600 million for the 2010 outstanding debts.

According to the latest report from SFEE (June 2012), the total public sector debt owed to pharmaceutical companies equals €1.55 billion (Public Hospitals: €850 million, Social Security Funds: €550 million, Military Hospitals: €150 million), for invoices of years 2010, 2011 and 2012. It should be noted that the major EOPYY has paid almost none of its debts to pharmaceutical companies accumulated in 2012.

Since then, the value of the bonds received to cover the 2012 debts were reduced by half per the Private Sector Involvement (PSI) agreement between the Greek Government and the International Monetary Fund (IMF), the European Central Bank, and the European Union, leading to a financial loss of almost €1 billion for pharmaceutical companies.

PhRMA believes that it is critical that the GOG refrain from incurring future debts and pay for the products they receive.

⁷² Hellenic Association of Pharmaceutical Companies, *A Report on Public Hospital Debt Towards SFEE Member Companies*, at 3 (June 20, 2010).

⁷³ *Id.*

Cost-Containment Measures

Cost-containment measures in Greece are being introduced in a series of sometimes overlapping administrative measures, adding significant complexity to the market. The most concerning measures introduced so far include:

Government Pricing

- In October 2012, the GOG issued a decree mandating a 50% reduction in the price of medicines after the expiration of their data protection, characterizing these products as off-patent even if their underlying compound patents are still in force. This has already caused confusion resulting in price reductions listed in recent Price Bulletins for medicines whose compounds were still on patent. PhRMA's member companies are concerned that in the future early generic entries could trigger price reductions before patent owners are able to enforce and defend their patents.
- In March 2010, the GOG passed Article 14 of Law 3840/10, requiring the recalculation of government prices of 6,000 pharmaceutical products, based on the average of the three lowest prices in 22 European countries, including Romania and Bulgaria. As a general matter, PhRMA's members do not believe that Romania and Bulgaria are appropriate countries to include in Greece's reference pricing system, given these countries' relative level of development. Nonetheless, our members have accepted their inclusion in the basket of reference countries as a temporary measure to help the GOG resolve its financial crisis.
- After its failed attempt to introduce a reference pricing system, on May 3, 2010, the GOG cut pharmaceutical prices by three to 27 percent with a weighted average cut of 21.5 percent. While the impact of this cut has been substantial in Greece, fears that these cuts could significantly affect other markets as a result of international reference pricing and parallel trade were mostly allayed following extensive industry advocacy in the relevant markets emphasizing the temporary nature of the Greek price-cuts.
- On September 6, 2010, a workable reference pricing system was finally implemented and the temporary price cuts were eliminated. While the new reference pricing system is substantially better than the across-the-board price cut, PhRMA members still have concerns about which government prices were referenced within the basket of 22 countries.
- In February 2011, the Ministry published a Price Bulletin approving the "correction" of certain government prices, which were published in September 2010.
- In July 2011, government prices for pharmaceutical products were adjusted to reflect the average of the three lowest prices in EU 22 countries and the final price bulletin was published in August 2011.

- A new government price bulletin was issued in December 2011, mainly including adjustments to the wholesaler margin for a number of medicines.

A full re-pricing followed in April/May 2012 to adjust prices for patented medicines to the average price of the three lowest EU countries (as per the existing legislation) and further decrease off-patent/generic medicines prices as per the legislation introduced in March 2012. In addition, a decrease of wholesalers/pharmacists margin was applied.

- In 2010, there was a significant delay in the introduction of new pharmaceutical products to the Greek market, since new price approvals by the Ministry did not follow any given timetable. This delay extended into 2011 and 2012. In January 2011, the GOG indicated it would reintroduce a positive price bulletin (a plan that was further amended in March 2012). As yet, however, no positive price bulletin has been issued, inhibiting patient access issues to new innovative therapies.

Ensuring a transparent and predictable pricing system is critical for PhRMA members. There is still concern that the resulting low government prices in Greece will, in turn, significantly affect government prices in countries where Greece is referenced. We welcome the Greek government's recent efforts to help discourage other countries from referencing Greek prices and encourage further action to bring the issue to the attention of governments around the world.

In addition, the low prices have already led to a significant increase in parallel exports to other European markets, resulting in shortages in Greek pharmacies.⁷⁴ We encourage the government to continue to monitor supply and suspend re-export as needed to ensure supply to Greek patients. Finally, the publication of a price bulletin for new medicines, which has been pending since January 2011, should be fulfilled, in order to ensure patient access to new innovative medicines.

Reimbursement List

In 2011, the GOG reintroduced the positive list for reimbursement, a system that had been abolished in 2006. Under the positive list, pharmaceuticals are classified into therapeutic categories based on the ATC classification of the pharmaceutical's active ingredient. The average price of the pharmaceuticals in each of these therapeutic categories is then used as the reference price and the maximum reimbursement price paid by the Social Security Funds for a medicine in that category. Each therapeutic category can include both innovative medicines as well generic or off-patent medicines. Only medicines that have a daily treatment cost below €0.3 are automatically included on the positive list. All other new drugs are subject to a 90 day processing period, thereby further delaying patient access to innovative medicines.

⁷⁴ Global Insight, *Fallout from Greek Repricing Continues as List of Expensive Hospital Drugs to Be Made Available in Pharmacies Revealed* (Sept. 16, 2010).

As noted above, a positive price bulletin has been promised since January 2011, and yet still has not been issued. As a result, the criteria of inclusion in the list, its structure and the level of recognition to innovation remain to be determined.

In November 2012, new legislation was introduced which restored the positive list. Under this legislation, products are generally clustered at the ATC IV level, in a manner that is disproportionately punitive to innovative medicines. Prices for products in each cluster are determined by the lower of the cheapest on patent drug, the cheapest off-patent medicine, or the average of the generic products included in the cluster. The patient is then responsible for covering any difference between the cluster price and the price of the medicine. This reference pricing system uses an overly broad concept of therapeutic interchangeability, which is not supported by any clinical evidence.

In addition, health care professionals (HCPs) are required to prescribe medicines using only the INN (i.e., the generic name) and the total value of innovative medicines prescribed by each HCP cannot exceed 15 percent of their annual prescribing value.

Finally, the new healthcare law of March 2012 introduced reimbursement limitations for new medicines entering the Greek market in 2012. The new system refers to reimbursement decisions and health technology assessments of relative organizations, in a significant number of EU countries, with some exceptions for orphan and other lifesaving medicines. This limitation in reimbursement could lead to significant delays in patient access to new innovative therapies.

PhRMA strongly believes that all pharmaceutical products approved in Europe should immediately be available to patients in Greece, and appropriately reimbursed through the various social security funds. PhRMA is concerned that the reintroduction of the positive reimbursement list will limit the availability of medicines to Greek patients, and that the criteria used to make those decisions may not be verifiable and transparent.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

ISRAEL

PhRMA's member companies face several market access barriers in Israel, including inadequate protection of intellectual property rights, and the absence of a pathway for the examination and approval of biosimilar drugs.

Key Issues of Concern

- **Patent Term Restoration:** PhRMA's member companies continue to have concerns about the manner in which the Government of Israel intends to implement patent term restoration based on regulatory approvals.
- **Biosimilars:** The absence of a scientifically-based, distinct pathway to examine and register biosimilars is a problematic trade barrier. Israel should develop an appropriate pathway for approving biosimilars and affirm a reasonable period of regulatory data protection for biologics consistent with its international obligations.

For these reasons, PhRMA requests that Israel be placed on the **Watch List** for the 2013 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

Patent Term Restoration

PhRMA continues to have serious concerns about the manner in which the Government of Israel intends to implement legislation concerning the patent term extension based on regulatory approvals.

Market Access Barriers

Biosimilars

In contrast to other developed countries, including the United States, the Ministry of Health has not established a separate, formal pathway for the examination, registration and use of biosimilar drugs in Israel. As a result, there is no framework to address such issues as the clinical trials that may be needed for the approval of a biosimilar in Israel; the process of examining and approving a biosimilar by the Ministry of Health; conditions under which a biosimilar may or may not be prescribed; creation of registries to monitor adverse drug reactions of biosimilars, etc. The default, therefore, is for the Ministry of Health to treat biosimilars as if they were generic, small molecule drugs both in terms of registration and in terms of substitution. This treatment, which is inconsistent with global recognition of the need for a separate pathway for approving biosimilars, places innovative U.S.-based companies at a disadvantage with regards to the protection and use of original biologic drugs.

Further, Israel's pathway for biosimilars should be accompanied by a reasonable period of data protection for biologics, consistent with its international obligations.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

ITALY

The Pharmaceutical Research and Manufacturers of America's (PhRMA) member companies face several market access barriers in Italy. Over the past ten years, Italian Governments adopted more than 20 separate cost-containment measures affecting the pharmaceutical industry. In addition, the regionalization processes prompted the Regions to introduce additional measures to control/reduce healthcare and pharmaceutical expenditures. These measures were exclusively aimed at containing expenditures without considering the impact on the innovative pharmaceutical industry in Italy. As a result of the cost-containment measures, a significant price gap compared to the rest of Europe exists for innovative drugs.

Key Issues of Concern:

- **Market Access Delays and Limitations:** Italy's pricing and reimbursement system and process for conducting tenders do not adequately reward innovation. In addition, there are significant regional delays in listing new medicines on hospital formularies despite assurances in 2010 to resolve these delays.
- **Discrimination Compared to Other Parts of the Healthcare System:** As of 2010, expenditure on retail and hospital drugs was arbitrarily capped at 13.3 percent and 2.4 percent respectively, of the NHF. Meanwhile, no other category of healthcare expenditures faced similar budgetary restraints. As a result of this policy, public pharmaceutical expenditure grew by only 5.7 percent over the last five years, whereas other healthcare costs increased by an average of 41.2 percent over the same period.

PhRMA and its member companies encourage the U.S. Government to engage with their counterparts in the Italian Government to seek timely pricing and reimbursement determinations and to urge the Italian Government to consult with the innovative pharmaceutical industry in developing a healthcare environment that rewards innovation and ensures patient access to new medicines.

For these reasons, PhRMA requests that Italy remain on the **Watch List** for the 2013 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Regulatory Approval, Market Access Delays and Limitations

Access to innovative drugs in both the retail (pharmacies) and hospital channels remains difficult in Italy. In 2007, AIFA introduced a system for evaluating innovation, to be used in pricing and reimbursement decisions for new drugs sold via the retail channel. To date, however:

- Only four new drugs have been classified as "innovative" by AIFA.

- Very few drugs have been classified as “potentially innovative.” To the extent that a few have received this classification, the additional monitoring obligations have discouraged patient compliance and created a bureaucratic burden for innovative pharmaceutical companies.

Similarly, sales to hospitals in Italy have been constrained since 2007 by the Regional Formularies. Depending on the region, listing on each formulary can take as long as 220 days, and that is after the 320 days taken by AIFA to grant marketing authorization following regulatory approval by the European Medicines Agency. The Regions and the Minister of Health committed to faster and more uniform access to innovative medicines at the November 18, 2010 State-Regions Conference; to date, however, this has only improved access for those drugs deemed to be “innovative” by the AIFA, which as noted above includes only four new drugs approved since 2007.

Access to medicines in hospitals has been further restricted by unrealistic budget constraints. Since 2008, expenditure on pharmaceuticals at hospitals has been set at 2.4 percent of the National Healthcare Fund (NHF), even though actual expenditure at that time was approximately 4 percent of the NHF. This cap creates continuous budget tensions and limits patient access to innovative drugs in Italy’s hospitals.

The AIFA system was recently modified by the Decreto Balduzzi (Law Decree 158/2012), that will allow for the immediate and automatic inclusion of innovative drugs on the Regional Hospital Formularies, after their national approval by AIFA. The Decree should be converted into a definitive law by November 12, 2012. Although PhRMA’s members welcome this development, it remains unclear what criteria will be applied to determine whether a new drug is “innovative”.

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

The Italian Government’s focus on controlling pharmaceutical expenditures is almost unique relative to other expenditures within Italy’s National Healthcare system (NHS). In 2012, expenditure on retail and hospital drugs was capped at 13.3 percent and 2.4 percent of the NHF, respectively. Meanwhile, no other category of healthcare expenditures has faced similar budgetary caps. As a result of this policy, public pharmaceutical expenditure grew by only 5.7 percent over the last five years, whereas other healthcare costs increased by an average of 41.2 percent over the same period.

Beginning in 2013, the Spending Review Law approved by the Italian Parliament on August 7, 2012, (Law 135/2012) will reduce the expenditure ceilings for retail and hospital drugs to 11.35 percent and 3.5 percent of the NHF, respectively. The combined spend of 14.85 percent, represents an overall reduction of 0.85 percent of the NHF. This reduction, combined with the other measures contained in the Law, will produce an expenditure reduction for pharmaceuticals of about €1.8 billion from 2012-2014.

Tendering

Several regions and local health authorities are organizing tenders in which they group together patented and off-patent medicines deemed to be in the same therapeutic group. PhRMA and its member companies believe that grouping patented and off-patent medicines together in a single tender, and then deciding that tender solely based on the price of the offer, dramatically affects the ability of PhRMA member companies to recover an appropriate reward for patented medicines. This practice decreases the value of pharmaceutical intellectual property, which in turn lessens the incentive for innovation. For medicines, tenders should be used solely for purchasing generic drugs that treat the same therapeutic condition, where the molecule is the same and the only criterion for making the purchasing decision can be cost. The challenge of operating a fair and effective tender for medicines is complicated greatly when tenders are used to purchase biologics, where health and scientific differences are greater.

Further, lack of transparency in AIFA's and the Regions' decision-making processes risk changing the rules of competition (tendering) and/or discriminating against patients based on which region they live in.

PhRMA's members appreciate the assistance of the U.S. Embassy in Rome in facilitating a dialogue between the Tuscany Region (the first region that adopted this approach) and representatives of industry (IAPG, Farindustria).

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 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, significant delays in the reimbursement process, and unpaid invoices.

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. In addition, prices of prescription drugs in Romania are set by the government regardless of whether or not the drug is reimbursed. **Inadequate Healthcare Funding:** The innovative pharmaceutical industry has been the target of numerous misguided “claw-back” tax regimes intended to increase healthcare revenue or decrease expenditure, as the case may be. The latest version of the clawback, passed through an Emergency Government Ordinance on September 21 and implemented on October 1, 2011, requires medicine producers to cover the entire reimbursed medicine budget deficit, including wholesale and retail margins, and, until October 1, 2012, value added taxes (VAT).
- **Unpredictable, Non-transparent Reimbursement System:** As an initial matter, the Romanian Reimbursement list is updated infrequently. Further, reimbursement decisions in Romania are significantly delayed due to onerous requirements, such as continuous reimbursement for at least one-year in three other EU Member States before a manufacturer can apply for reimbursement in Romania. The last update of the reimbursement list took place in 2008 for medicines that received marketing authorization in 2007.

PhRMA and its member companies encourage the U.S. Government to urge the Romanian authorities to ensure that new regulations and systems are developed in a predictable and transparent manner. Consultation with industry and other stakeholders is beneficial for Government and industry. In addition, the Romanian Government needs to reimburse medicines in a manner that rewards innovative companies for their significant investment in developing new medicines and encourages development of tomorrow's new cures and treatments. Finally, the innovative pharmaceutical industry stands ready to assist the Romanian Government in developing new healthcare funding systems that more accurately reflect the demand for healthcare in Romania.

For these and other reasons described below, PhRMA requests that Romania remain on the **Watch List** for the 2013 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Government Pricing

The government pricing policy introduced in 2009 calculates a drug's price based on the lowest price paid in a reference basket of 12 EU countries. Under this new policy, generics and biosimilars are subject to a government price ceiling of 65 and 80 percent of the original price, respectively. Setting the government price at the absolute minimum discourages innovation. Romanian patients would be better served if the government price was based on the average price in the three lowest countries in the reference basket.

Funding

Patient access to healthcare in Romania is negatively impacted by the low-level of healthcare expenditure. In order to increase funding, in September 2009, the Romanian Government implemented a "Claw-back Tax". The ordinance taxes sales of drugs between five to 11 percent depending on company turnover. The negative effects of this could be diminished if the tax were applied more evenly and on reimbursed sales. Furthermore, the current iteration of the claw-back combined with therapeutic reference pricing stifles pharmaceutical innovation.

Effective October 1, 2011, Romania implemented a new clawback mechanism, which acts as an expropriatory tax, whereby the medicine budget deficit (*i.e.*, the difference between the allocated budget and actual consumption), is calculated as a percentage of each pharmaceutical company's sales during the prior quarter. Moreover, the medicine budget value is set by the Government regardless of the previous year 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. The percentage is also applied to the gross value of each pharmaceutical company's sales to the Sick Fund, including wholesale and retail margins and, until it was removed on October 1, 2012, VAT. In other words, PhRMA member companies must compensate the budget for payments the government makes to wholesalers and pharmacists (and previously for taxes obtained through VAT collection). The latest clawback tax amounted to almost 33 percent of the pharmaceutical companies' reimbursed revenues.

Reimbursement Update

The drug reimbursement list is rarely updated, and only when the Government decides to issue a special decision. According to the Romanian Association of International Medicine Manufacturers (ARPIM), there are more than 130 molecules pending reimbursement approvals. The last complete updates to the reimbursement list were made in 2005 and 2008. There were minimal updates in 2009 and 2011; in 2009, 10 HIV and oncology products were added and in 2011, four orphan drugs were approved for reimbursement. Further, under Romania's reimbursement system, a

pharmaceutical manufacturer can only submit a reimbursement dossier 12 months after a product has been reimbursed in at least three other EU countries. No exceptions are made for life saving drugs, even for those approved under a fast-track process in other countries within the European Union. This has delayed the reimbursement process by 18 to 24 months. To sustain innovation, the Government should seek to improve the reimbursement system by making it more transparent, more predictable, and more regular in its timing, in accordance with European legislation (the Transparency Directive) which sets specific deadlines for reimbursement decisions (90 days).

Generic medicines undergo an abbreviated and less costly registration procedure as they can enter the reimbursement list automatically, without the need of a full update. This happens since the main reimbursement list includes only International Nonproprietary Names (INNs) and not commercial designations.

Payment Terms and Debt

Although official payment terms have been extended to 210 days, ARPIM reports that the average time until payment is 330 days and that the value of invoices exceeding the 210 days payment term is €1.3 billion. Despite this reality, the Romanian Government has informed the IMF that it plans to reduce the payment term to 90 days (consistent with the EU's "Late Payments" Directive). In light, however, of the current medicine budget deficit, the innovative pharmaceutical industry is concerned that this goal will be achieved by increasing the clawback tax.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

RUSSIA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Russia are concerned that the Russian Government is implementing policies that do not adequately protect intellectual property or reward the value of innovation and the benefits it brings to Russian patients. PhRMA's member companies face numerous market access barriers in Russia.

Key Issues of Concern:

- **Regulatory Data Protection:** On August 22, 2012, Russia officially acceded to the World Trade Organization (WTO). Russia's commitments on regulatory data protection embedded in the "Law on the Circulation of Medicines" (which took effect September 1, 2010) are an integral part of Russia's WTO obligations and came into force on the date of Russia's WTO accession. PhRMA and its member companies welcome this, but are concerned that the "Law on the Circulation of Medicines" and other applicable regulations contain mechanisms that are contrary to, or do not effectively implement, regulatory data protection consistent with Russia's new WTO obligations.
- **Effective Patent Enforcement:** Currently, there is no mechanism in place to ensure that the patent status of a drug is taken into consideration by marketing or other regulatory authorities in Russia when considering the approval of a generic substitute to a patented drug. This in turn can lead to the approval and marketing of a generic product, despite the fact that a patent for the original drug is still in force. In addition, pharmaceutical innovators in Russia continue to face significant legal and practical challenges that limit their ability to effectively protect their innovative products against infringement, including the ability to secure remedies and injunctions that would reduce the risk of pre-mature entry of infringing generic products to the Russian market.
- **Government Pricing:** The Russian Government controls prices of drugs on the Essential Drugs List (EDL). Unfortunately, local and foreign manufacturers are treated differently according to Russian government practices related to government prices; local companies are able to adjust prices on an annual basis, while foreign firms are not. Furthermore, the EDL was not updated in 2012, which will impede Russian patient access to innovative medicines.
- **Local Clinical Trial Requirements:** According to the "Law on the Circulation of Medicines" governing, *inter alia*, clinical trials, pre-registration clinical trials must be conducted in Russia (with some exceptions). The corresponding practice has caused significant delays in the registration of new products, thus limiting patient access to innovative medicines.

For these and other reasons, PhRMA requests that Russia be placed on the **Watch List** for the 2013 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

Russia's commitments on protection of undisclosed information and test data are summarized in paragraph 1295 of the Working Party Report on the Accession of the Russian Federation to the WTO, which had been incorporated in paragraph 2 of the Protocol of Accession of the Russian Federation to the WTO and became binding on August 22, 2012:

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.⁷⁵

Although the "Law on the Circulation of Medicines" refers to providing such regulatory data protection, it provides no implementing procedure or mechanism. While the Ministry of Health (MoH) said they were drafting amendments to the law to address this shortcoming, to date no draft has been made available. Still, PhRMA's members look forward to engaging with the Government on this effort to ensure that the resulting law provides effective regulatory data protection.

⁷⁵ Report of the Working Party on the Accession of the Russian Federation to the World Trade Organization, par. 1295, WT/ACC/RUS/70 (Nov. 17, 2011), *available at* http://www.ustr.gov/webfm_send/3224 (last visited Feb. 8, 2013).

Effective Patent Enforcement

Currently, there is no mechanism whereby the patent status of a drug is taken into consideration by marketing or other regulatory authorities in Russia when considering the approval of a generic substitute to a patented drug. This in turn can lead to the approval and marketing of a generic product, despite the fact that a patent for the original drug is still in force.

As a result it would be highly important to ensure that MOHSD establishes mechanisms to provide effective patent enforcement, such that any potential patent disputes can be resolved before the generic product is launched.

PhRMA and its member companies would also propose that Rospatent and the MOHSD create a joint database clearly indicating when a product's patent term and regulatory data protection period expire.

In addition, pharmaceutical innovators in Russia continue to face significant legal and practical challenges that limit their ability to effectively protect their innovative products against infringement, including the ability to secure remedies and injunctions that would reduce the risk of pre-mature entry of infringing generic products to the Russian market.

Currently there are no effective mechanisms that prevent entry of infringing products into the market before patent expiry, because the courts refuse to grant preliminary injunctions to patentees. It is practically impossible in the courts to meet the grounds for preliminary injunctions.

Moreover, unreasonable delays in the court system deprive patentees of the relief they are entitled to in a time effective way.

Finally, preliminary injunctions are not granted until after the first level of appeal has been heard. An early injunction is often the principal form of relief that a patentee desires. In particular in the healthcare industry, monetary damages rarely compensate for the actual harm done by the infringer, an injunction must be available quickly where the issue of infringement is clear and convincing. Moreover, preliminary injunctions should be enforceable at trial once infringement is found. The injunction should only be suspended pending appeals if enforcement would disproportionately favor the patentee.

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 allow the products to remain in the market and available to consumers.

Market Access Barriers

State Regulation of Prices of Medicines on the Essential Drug List (EDL) and Reimbursement Debate

The Russian Government controls prices of drugs through registering prices of the medicines included into the Essential Drugs List (EDL). The process to update the EDL lacks transparency.

Typically, the Russian government updates the EDL once a year. Last year the government issued a decree stating that EDL approved for 2012 would remain the same in 2013. It means that no new drugs were added to the EDL in 2012 which will inhibit patient access to new medicines. This decision has been criticized by the medical community, patients' organizations and the chair of the State Duma (lower house) HC committee.

Further, the Russian reimbursement system discriminates against foreign producers by allowing only domestic producers to request annual adjustment of their registered prices.

Russia also imposes international reference pricing based on the lowest price in the basket of reference countries. This system is suboptimal as it incorrectly assumes that the economic conditions, patient populations and needs, and healthcare systems in the reference countries are relevant to Russia. PhRMA and its member companies believe that Russia should adopt a pricing and reimbursement system that appropriately values and rewards innovation.

PhRMA and its member companies welcome the MOH's intention to introduce a new reimbursement system in Russia. Under this plan, pilot projects will be implemented in 2014 and full-scale reimbursement may be introduced not earlier than in 2016. The innovative pharmaceutical industry looks forward to working constructively with the MOH and other stakeholders in developing a pricing and reimbursement system that rewards innovations, increases patient access to new medicines, and meets many of the objectives outlined in the Pharma 2020 proposal.

Registration and Clinical Trials

According to the provisions of the "Law on the Circulation of Medicines" governing clinical trials, pre-registration clinical trials must be conducted in Russia before the medicinal product can be given market authorization (with some exceptions). The corresponding provisions have been implemented, causing delays in the registration of new products, thus limiting patient access to innovative medicines.

Lately, the MOH has taken steps to increase the transparency of the decision-making procedures of the Ethics Committee related to clinical trials. PhRMA especially

appreciates the MOH's willingness to allow medical organizations, medical science bodies, medical universities, non-governmental organizations, churches and the media to propose candidates for this body.

Interaction between HCPs and Pharmaceutical Companies

The Law on the "Health Protection of the Population" came into force (with some exceptions) on January 1, 2012. In July of 2012 the bill "On amending some legislative acts of the Russian Federation due to adoption of the Federal law Health Protection of the Population" was made publicly available. The bill, which was developed by the MOH, outlines further constraints to be imposed on companies' interactions with healthcare professionals.

In particular, it introduces a ban on "creating obstacles for participation of competitor companies in scientific events for medical and pharmaceutical professionals organized and financed by a pharmaceutical company or companies". It 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.

Discriminatory Practices in Public Procurement

In 2012, Russia's government maintained a 15 percent price preference for Russian and Belarusian manufacturers at the federal and municipal procurement auctions. It is a clear discrimination against foreign manufacturers, including PhRMA companies.

In 2012, amendments to the "Law on the state procurement" regarding public procurement of drugs came into force. It stipulates that for public procurement purposes, tender lots must be formed according to INNs with the sole exclusion of drugs put on a special list by the government. The Russian Government is now defining which drugs should be on that list. PhRMA and our members are concerned that, for example, one of the criteria is that excluded drugs must prove through clinical trials that the product cannot be substituted. Clinical trials, however, are designed to prove safety and efficacy, not whether an alternative therapy is substitutable for the subject medicine.

Orphan Drugs Legislation

The Law on the “Health Protection of the Population” introduced an orphan disease definition, though eligibility criteria are stricter than in the U.S. and the EU. There is still no definition of orphan drug in Russia’s legislation and the general registration procedure, set by the “Law on the Circulation of Medicines,” creates significant challenges for the registration of orphan drugs in Russia. The MOH officials acknowledge the issue. Recently they have promised to amend the “Law on the Circulation of Medicines,” including a specific registration procedure for orphan drugs.

Biologic and Biosimilar products in Russia

While Russian law refers to “immunobiological products”, there is currently no specific definition for biologics or for an approval process for biosimilars. The lack of clear statutory definitions for biologics and biosimilars has facilitated the market entry of products which would not be approved under international norms. Lately the MOH has expressed a wish to introduce a biosimilar definition in Russia’s legislation. PhRMA urges Russia to engage in a robust stakeholder consultation process with a view to adopting transparent scientific regulatory and legal standards on biologics and biosimilars that support innovation and protect patient safety.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

SPAIN

PhRMA's member companies face several market access barriers in Spain including inadequate protection of intellectual property rights and a non-transparent and unpredictable government pricing system.

Key Issue of Concern:

- **Reference Pricing:** Spain's pricing and reimbursement system is unpredictable, lacks transparency and does not adequately reward innovative pharmaceutical companies for the significant investment required to develop a new medicine.

PhRMA encourages the U.S. Government to ask the Government of Spain to engage with the innovative pharmaceutical industry to develop a transparent and predictable pricing and reimbursement system that adequately rewards innovation and supports investment in future medicines. In addition, PhRMA requests that the U.S. Government elevate its ongoing dialogue with the Government of Spain regarding its uneven implementation of the TRIPS Agreement.

For these reasons, PhRMA requests that Spain be placed on the **Watch List** for the 2013 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

Reference Pricing

Since the 2009 financial crisis, the Spanish Government, at both the central and regional level, has targeted the pharmaceutical industry by imposing draconian cost containment measures and reforms. As a result of these measures, innovative pharmaceutical manufacturers are highly concerned about their ability to meet Spanish patients' medical needs in 2012 and beyond.

At the central level, the Spanish Government has enacted four Royal Decrees over the last two years that directly impact the innovative pharmaceutical industry and create an unpredictable and unstable business environment. On June 1, 2010, the Spanish Government enacted two Royal Decrees:

- Royal Decree 4/2010 increased the price reduction for older products sold in Spain for which a generic version is available in the European Union but not in Spain. Such products are now subject to a 30 percent price cut. Meanwhile, if generic products are available in Spain, the reference price can be cut by 50 percent in the first year (previous Decrees had made this reduction over multiple years).

- Royal Decree 8/2010 enacted a 7.5 percent mandatory rebate on medicines (and medical devices) sold through the NHS that are not included in the reference pricing system, affecting both the hospital and retail markets.

On August 20, 2011, the Spanish Government enacted Law – Royal Decree 9/2011 – which was designed to decrease pharmaceutical expenditure by €2.4 billion. This Decree includes several new detrimental measures:

- Increases the mandatory rebate mentioned above to 15 percent for those medicines that have been on the market for over 10 years with no generic or biosimilar authorized in the Spanish market.
- Mandates that all prescriptions must refer to the international non-proprietary name (INN) for the active pharmaceutical ingredient, rather than a specific brand name. If a branded name product is prescribed, the pharmacist must fill the prescription with the lowest price medicine with the same molecule, dosage and form. Exceptions can be made for justified therapeutic medical needs.
- Establishes a Cost-Effectiveness Committee to assess the value of medicines. The innovative pharmaceutical industry requests that the Spanish Government consult with all interested stakeholders as it builds this Committee and works to define key terms such as value. Value should be broadly defined to consider unmet clinical needs, the degree of innovation, the broader societal values of a specific treatment, and emphasize long-term medical needs rather than just short-term budget implications.

On April 20, 2012, the Spanish Government enacted Royal Decree 16/2012, which modifies Law 29/2006 on the Guarantees and Rational Use of Medicines and Healthcare Products. This Decree includes several new detrimental measures:

- All medicines approved in the EU for at least ten years will be subject to reference pricing, regardless of whether the patent term has expired. In order to recoup the significant investment required to develop a new medicine, prices for innovative medicines should not be subject to reference pricing during their patent term. Moreover, the new regulation does not establish how these reference prices will be calculated.

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

- Prescription by INN: Although the decree now permits physicians to prescribe branded medicines, it mandates automatic substitution of those prescriptions where the price of the branded product is not the lowest in the group.
- Selected Prices System (Art. 93 Bis): The MOH intends to allow companies to

bid to be the providers of three types of high consumption medicines (those included in the Reference Pricing System, vaccines and those included in the Homogenous Groups with reduced contributions from patients). The innovative pharmaceutical industry is concerned that under this scheme, the MOH will group both patented and generic products in broad “therapeutic categories” whereby the value of the innovative products will be diluted by the generics in the tender basket.

Similar measures, *e.g.*, pricing restrictions, reference pricing, automatic substitution of branded medicines for generics, *etc.*, are being imposed at the regional level.

In turn, the unsustainably low prices set in Spain are referenced by a number of other European countries to set their own pharmaceutical prices.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

LATIN AMERICA

COLOMBIA

PhRMA's member companies face several market access barriers in Colombia, including inadequate intellectual property protections, and unfair government pricing policies.

Key Issues of Concern:

- **Effective Patent Enforcement:** PhRMA's member companies continue to be adversely affected by the Government of Colombia's failure to provide an effective patent enforcement mechanism whereby a patent owner may seek to enforce its patent prior to the commercial launch of a potentially infringing product.
- **Scope of Patentable Subject Matter:** Colombia, contrary to its obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), does not grant patents for second uses, and applies an unreasonably restrictive definition of patentable biologics.
- **Unreasonable Delays in Patent Grant:** Although PhRMA recognizes Colombia's effort to reduce the timeline for completing the patent review process, it still takes on average more than five years to review and grant a patent. Colombia does not adjust the patent term to reflect the patent life lost during the unreasonably long patent review period. Moreover, in violation of its TRIPS obligations, Colombia unfairly discriminates against pharmaceutical inventions by precluding the possibility of obtaining patent term adjustments for pharmaceutical patents.
- **Government Pricing and Reimbursement System:** In theory, Colombia has two separate systems for pricing all medicines consumed in the country and reimbursing those medicines provided under the Social Security Health System (SSHS). In practice, however, the maximum reimbursement levels set for the SSHS are used to set the government prices for those medicines even when they are not being reimbursed by the SSHS. This results in artificially low prices for certain medicines, which discourages future innovation. The Colombian Government is now considering a new pricing system that is due to go into effect on March 31.

For these reasons, PhRMA requests that Colombia remain on the **Watch List** for the 2013 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 member companies continue to be adversely affected by the Government of Colombia's failure to provide an effective patent enforcement

mechanism. This failure currently prevents a patent owner from seeking effective enforcement of its patent prior to the commercial launch of a potentially infringing product. To date, patent owners proceeding under Colombian law have only been able to obtain injunctive remedies after commercial acts have taken place (*i.e.*, the product has been launched, the active ingredient imported, or commercial offers have been made). The reasons for this have been: (1) lack of legal standing to pursue infringement based solely on a health registration or an application; and (2) lack of a time period during which market approval is automatically suspended until the patent infringement issue is adjudicated. PhRMA members request that these obstacles to effective patent enforcement be eliminated. The enforcement mechanisms would provide 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. In similar fashion, pharmaceutical innovators must have safeguards available to prevent infringing products from being launched upon regulatory approval but before relevant patents have expired.

In a positive development, and consistent with the terms of the U.S. – Colombia FTA, in April, INVIMA implemented mechanisms to provide effective patent enforcement. These mechanisms ensure that patent holders have notice that a company is seeking marketing approval for a product that may potentially infringe their patents. This benefit, however, may be ephemeral, because Colombian civil and administrative procedures do not provide adequate due process guarantees to effectively litigate patent enforcement. Additionally, litigation can often take more than 8 years. Although the recent modification of the codes of civil and administrative procedure – replacing the old written system with an expedited oral procedure – are expected to greatly reduce these delays, the industry will closely monitor the situation to ensure these promised efficiencies are realized. The industry also takes due note of the Colombian Patent Office's new jurisdiction over IP infringement cases and views this as a step in the right direction to the creation of a specialized court.

Scope of Patentable Subject Matter

Over the last few months, there have been positive developments by the Colombian Patent Office (CPO). For example, the CPO has adopted new examination guidelines for granting patents to polymorphs, selection inventions, and pharmaceutical kits that are consistent with its TRIPS obligations. The innovative pharmaceutical industry will continue to monitor the development of these guidelines and stands ready to provide technical assistance.

- *Second Use Patents*

The Andean Court of Justice (ACJ) issued several legal opinions (89-AI-2000, 01-AI-2001 and 34-AI-2001) forcing Andean Community members to refuse recognition of patents for second uses. This is contrary to long-standing precedents and inconsistent with TRIPS Article 27.1. Andean member countries have either been

compelled by the ACJ not to grant second use patents or have chosen to honor Andean Community obligations, while ignoring their TRIPS obligations. The failure to provide patents for second uses adversely affects PhRMA's members who dedicate many of their research investments to evaluating additional therapeutic benefits of known molecules (second uses) in order to provide more effective solutions for unsatisfied medical needs. The ACJ position is dispositive on the issue and no further domestic appeals or remedies are possible.

- *Patents for Biotechnology*

Article 15 of Andean Community Decision 486 excludes a great part of all biotechnology innovation, by stating that "all or part of living beings as they are found in nature ... existing biological material or that which can be isolated" is not considered an invention. This is an unreasonably narrow definition of patentable subject matter which undermines incentives for development in biotechnology.

Unreasonable Delays in Patent Grant

Although PhRMA and its members commend the Colombian government for its efforts to reduce the patent review period, on average, pharmaceutical patent applications are delayed over five years before a preliminary decision is made by the CPO. Nevertheless, the Colombian Government refuses to grant compensatory measures such as patent term adjustment to allow patent holders to effectively enjoy their rights. In fact, that possibility has been prohibited by recent modifications to the Andean IP Decision, which expressly preclude patent term adjustments for pharmaceutical patents.

The industry takes due note of the recent Patent Prosecution Highway Pilot Program between the USPTO and the CPO and views this as a positive step in potentially shortening patent review delays. The industry stands ready to assist the CPO in the implementation of local guidelines in furtherance of this program.

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 six years, and a final decision is not expected for two or three more years.

Market Access Barriers

Government Price Controls

In 2006, the Government of Colombia modified its pricing policy for pharmaceutical products. Pursuant to the policy established in Circular No. 04 of 2006, all medications must be classified in one of the following three regimes established by Law 81 of 1988: (1) Supervised Freedom Regime; (2) Regulated Freedom Regime; or (3) Direct Control Regime. In turn, the National Commission on Pricing of Medications (NCPM) fixes the maximum public sale price of the medications included in the Direct Control Regime, based on the average price for the same medication in the three lowest priced reference countries.

In 2010, the Government established a separate process for establishing the maximum reimbursement price for medicines covered by the SSHS. Specifically, Decree 4474 gave the Ministry of Health (MOH) the authority to fix the maximum reimbursement price that the SSHS will cover for pharmaceutical products not included in the Mandatory Health Plan, based on a methodology issued jointly by the Ministries of Finance and Health. This maximum reimbursement price is perceived by the market as the maximum final price to the consumer, thereby affecting the entire pharmaceutical supply chain. Per this authority, the MOH has issued four resolutions, which establish the maximum reimbursement price for 135 active ingredients.

Although these two systems are theoretically separate, in that one sets the government price and the other establishes the maximum reimbursement level for medicines covered by the SSHS, in practice they are both used to set the maximum government price. As a result, the maximum reimbursement price set by the MOH for 135 active ingredients sets the maximum price for those medicines even when they are not being reimbursed by the SSHS. This results in artificially low prices for certain medicines, which discourages future innovation.

In August 2011, and August 2012, the MOH issued new resolutions establishing maximum reimbursement prices for molecules not included in the Mandatory Health Plan and not covered yet by the previous resolutions issued by the MOH.

In December 2011 the NCPM issued a new circular stating that all medicines will be subject to a reference pricing system. Medicines with less than three competing products having the same active ingredient will be subject to an international reference price. The reference price shall be the lower price of at least 3 of the following reference countries: Argentina, Brazil, Chile, Colombia, Ecuador, México, Panamá, Perú, Uruguay and the OECD countries. All other medicines will have a reference price equivalent to the arithmetic mean of all the prices of all the competing products having the same active ingredient. This reference pricing system shall be enforceable as of March 31, 2013.

Finally in December 2011 and September 2012 the NCPM issued 2 circulars that added 27 medicines to the Direct Control Regime and fixed their maximum price for sales to the SSHS.

These profuse regulations create legal uncertainty for PhRMA member companies, and undermine their ability to ensure sustainable access to innovative therapies for Colombian patients.

Biosimilars Regulation

PhRMA's members will continue to work with Colombian officials and other stakeholders to ensure that the Colombian Health Ministry's regulation on "Similar Biotherapeutics" is consistent with international standards, as required by Law 1438 of 2011, to ensure the health and safety of Colombian patients. .

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

CENTRAL AMERICA – CAFTA-DR COUNTRIES

COSTA RICA

PhRMA's member companies face several market access barriers in Costa Rica, including inadequate intellectual property protections. Although Costa Rica has shown progress in meeting its obligations under the Dominican Republic-Central American-United States Free Trade Agreement (CAFTA-DR) in the areas of regulatory data protection and effective patent enforcement, deficiencies still remain.

Key Issues of Concern:

- Regulatory Data Protection and Effective Patent Enforcement;
- Compulsory license provisions that are not compatible with international principles and norms; and
- Patent backlog and criteria for patentability.

PhRMA requests that Costa Rica remain on the **Watch List** for the 2013 Special 301 Report and that the U.S. Government continue to seek assurance that the issues herein described are quickly and effectively resolved.

Regulatory Data Protection/Effective Patent Enforcement

In order to implement its obligations under the CAFTA-DR FTA to grant regulatory data protection and effective patent enforcement, the Health Regulatory Agency developed a publicly available data base identifying those products subject to patent or regulatory data protection terms. However, this positive step has been countered by the enactment of the “Undisclosed Information Law”, which contains language allowing for disclosure of clinical test data in certain situations, contrary to Costa Rica’s international obligations. Further, according to the local research-based pharmaceutical association (FEDEFARMA), this database is not an effective tool for determining possible patent infringement.

Patent Issues

Costa Rica amended Article 18 of Law No. 6,867 to provide that if a patent holder does not “work” their patent, either by local production or by importation, within three years of the patent approval date or four years of the patent application date, a third party may request a compulsory license (CL) to work the patent. However, the amended Law provides no exemption or mechanism to “stop the clock” while the innovator is seeking marketing approval, and inherently unable to “work” the patent.

In addition, contrary to its international obligations, Costa Rica fails to provide patents for certain types of claims, e.g., for polymorphs, dosages, and “Markush” or “Swiss-type” claims. In addition, Costa Rica requires in vivo studies to support patent

applications for biologics. For those patent applications that will be considered, the Costa Rican patent office still has a considerable backlog. Further, according to a Patent Office decision, applicants are given only one opportunity to speak with the patent examiner before the final decision is issued. This limitation is not supported in Costa Rican law.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

CENTRAL AMERICA – CAFTA-DR COUNTRIES EL SALVADOR, HONDURAS AND NICARAGUA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in the Central American countries of El Salvador, Honduras and Nicaragua observe that these countries have not effectively implemented certain obligations in the CAFTA-DR related to the protection of intellectual property rights.

Key Issues of Concern:

- Lack of Effective Regulatory Data Protection; and
- Ineffective Patent Enforcement.

For these reasons, PhRMA and its member companies request that El Salvador, Honduras and Nicaragua be placed on the **Watch List**. In addition, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

HONDURAS AND NICARAGUA

Intellectual Property Protection

Regulatory Data Protection

Neither country has effectively implemented its international obligations, arising from the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the CAFTA-DR, related to the protection of pharmaceutical test and other data. The Government of Honduras published draft regulations for consultation in 2008, but the regulations for effectively implementing regulatory data protection were not promulgated. Similarly, the health authorities in Nicaragua have yet to promulgate a clear and transparent regulatory data protection mechanism that would comply with the CAFTA-DR.

Measures for the Effective Enforcement of Patents

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.

EL SALVADOR

Health Regulatory Agency

Recent changes in the regulatory system in El Salvador, introduced by Law 1008, have resulted in a new agency being responsible for regulating pharmaceuticals. This has resulted in a greater uncertainty regarding regulatory data protection and patent enforcement as the new authority has not included pending implementation in its working agenda.

Effective Patent Enforcement

El Salvador has not 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. PhRMA members supplied information on the pertinent patents in force in El Salvador and provided other technical assistance to government officials; yet workable systems have not been established.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers in these Central American countries related to intellectual property protection and market access.

CENTRAL AMERICA – CAFTA-DR COUNTRIES GUATEMALA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Guatemala are concerned about recent decisions by the Ministry of Health (MOH) that represent a threat to or actual infringement of patent rights and regulatory data protection granted in that country.

Key Issue of Concern:

- Publication of two Ministerial Agreements that appear to violate TRIPS Articles 28(1)(a), 30 and 31 and the CAFTA-DR provisions related to the TRIPS Agreement (Re: 15.7).

For these reasons, PhRMA and its member companies request that Guatemala remain on the **Watch List** for the 2013 Special 301 Report. In addition, PhRMA requests the U.S. Government to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Ministerial Agreements that infringe patent and data protection rights granted in the country

The Ministry of Health published in the Official Gazette, Ministerial decree 472-2012, whereby it declared a specific “generic” product to be of high therapeutic interest, and authorized its importation. The Decree does not consider the existence of a patent in force in Guatemala which covers a dose formulation for the product and which is in force through 2026; the MOH did not conduct any consultations with the rights holder nor did the MOH exhaust the existing provisions under the Industrial Property Law applicable to limitations to the patent rights. In addition, although the product is currently covered by regulatory data protection through 2015, the MOH has indicated that authorizing importation of the product does not violate this CAFTA obligation, because Guatemala argues that the product will not be for commercial use.

The MOH Decree appears to infringe Articles 28(1) (a), 30 and 31 of TRIPS, the CAFTA-DR and the Industrial Property Law of Guatemala as well as Chapter 10 of the CAFTA-DR (Re: 10.5). PhRMA and its members are concerned that the decree may exceed the MOH’s powers resulting in an infringement to granted rights in Guatemala. If this practice is permitted, the MOH may consider it as a means to override intellectual property rights in Guatemala without exhausting any proceedings.

On October 4, the MOH published a second decree, 871-2012, by which it “regulates” several acts, including acquisition, donation, lending and other acts, related to certain drugs, through so called “technical norms” to be implemented by a certain MOH Program. The decree presents an unclear objective and generates great

uncertainty regarding future respect for intellectual property rights and other norms, such as those applicable to government procurement.

The MOH has not responded to the industry's request for consultations nor has it replied to a similar request made by the Ministry of Economy and the National Competitiveness Program.

Enforcement against counterfeit drugs

In November, 2011, the Guatemalan Congress approved a decree on counterfeit medicines, the first of its kind in the country. The decree provides for criminal penalties including three to five years of imprisonment for counterfeiting. The decree is an important step toward ensuring safe and effective medicines reach Guatemalan patients, but additional training, awareness, and education will be essential to ensure the decree does enhance the safety of the Guatemalan medicine supply.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers in this Central American country related to intellectual property protection and market access.

ECUADOR

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Ecuador are concerned with several intellectual property and market access barriers.

Key Issues of Concern:

- Compulsory licensing;
- Regulatory data protection; and
- Government price controls.

For these reasons, PhRMA requests that Ecuador be placed on the **Watch List** for the 2013 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

Compulsory Licensing

Per the October 2009 Executive Decree No. 118 establishing a special procedure for obtaining compulsory licenses (CLs) to patents covering “priority” medicines, to date two compulsory licenses have been granted, the first in 2010 and the second in 2012

Two additional compulsory license petitions are currently being considered by the Ecuadorian Intellectual Property Institute (IEPI), and a further two were rejected on technical grounds. IEPI’s Director has informed the local innovative pharmaceutical association (IFI) that while there is no government policy to issue compulsory licenses on all patented drugs, IEPI will review all CL petitions submitted to the Institution on a case-by-case basis.

A close monitoring of the application of this decree should be maintained to ensure that a compulsory license for a patent covering a medicine is granted only when a need for such license has been clearly demonstrated and to ensure that the guidelines for obtaining a compulsory license are clear and provide due process for the license applicant and the patent owner in accordance with Ecuador’s obligations under the 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,

those revisions are construed in the context of Andean Community jurisprudence. As a result, the actual protection provided remains, in practice, inadequate.

Market Access Barriers

Government price controls

Ecuador has had a government price control system for pharmaceutical products since 1992. In June 2011, Executive Decree No. 777 to fix, revise and control medicine prices was issued.

This new decree creates three price control categories: regulated, monitored and direct fixation. The first one – regulated – is similar to the prior system under which a biopharmaceutical manufacturer would have to apply for a government price for all medicines from the National Council for Medicine Prices Fixation and Revision. Under the new Decree, only “regulated” medicines, *i.e.*, those medicines considered “strategic”, require price approval from the Council. Although guidelines to the Decree were issued on August 31, 2011, it remains unclear which medicines are considered “strategic.”

The second category – monitored – applies for “non-strategic” medicines with the same active principle ingredient. For medicines falling under this category, the biopharmaceutical manufacturer must notify the government of its pricing structure, supporting its notification with all necessary documents (*e.g.*, import documents, sanitary registry, FOB and distributor price certification, *etc.*).

The third category – direct fixation – is applied in those cases when the information requested by the Council wasn’t presented on time or is false, the price in pharmacies is higher than the one approved or notified, or the product was sold without an approved or notified price. This essentially punitive category is in addition to any separate civil or penal sanctions that may be imposed.

Additionally, the profit margin limitations applied by the 2000 Generics Law continued to apply to medicines in all three price control categories under this Decree: “The profit margin by product for the manufacturer or importer shall not exceed 20 percent”

In October 2011, the new Act of Regulation and Control of Market Power ordered the reform of the Price Control Regulation of Drugs within 60 days of the issuance of the Law. Since that time, the authorities have developed at least 12 proposals, none of which have appropriately valued the significant cost and time involved in developing a new medicine. The innovative pharmaceutical industry stands ready to partner with the Ecuadorian government to develop a new government pricing and reimbursement methodology that improves patient access and provides the incentives for our member companies to engage in the research and development needed to discover tomorrow’s treatments and cures.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

MEXICO

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Mexico remain concerned over the pending Regulatory Data Protection (RDP) reform and full implementation of Mexico's "patent linkage" decree.

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 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. On the other hand, since July 31, 2012 the Official Gazette now includes an additional annex in which formulation patents are listed.

PhRMA member companies continue to share deep concern with regard to the inability to remove patent infringing products from the marketplace. Further, obtaining effective preliminary injunctions or final decisions on cases regarding infringement of IP rights 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).

Key Issues of Concern:

- Ineffective patent enforcement system
- Inadequate Regulatory Data Protection (RDP)
- Counterfeit drugs
- Use patents are not listed in the Official Gazette

For these reasons, as explained in detail below, PhRMA requests that Mexico remain on the **Watch List** for the 2013 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved. Resolution of these outstanding issues would also underscore Mexico's ability to meet the expected high standards to be included in the Trans-Pacific Partnership negotiations that it recently joined.

Intellectual Property Protections and Enforcement

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 July 31 publication of an additional annex of the Official Gazette in which formulation patents were listed, is an additional positive step toward the goal of eliminating unnecessary, costly and time consuming court actions to obtain appropriate legal protection for member companies' intellectual property. PhRMA members strongly trust that COFEPRIS will consult the Official Gazette, including the identified formulation patents, before the issuance of a marketing authorization.

Both of Mexico's NAFTA partners provide patent enforcement systems for product, formulation and use patents. It is therefore inappropriate for Mexico to only provide effective patent enforcement for active chemical substances. Furthermore, effective patent enforcement mechanisms inherently prevent the marketing of follow-on products when such marketing would infringe valid patent rights.

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 (RDP)

In June 2012, Mexico's health regulatory agency, COFEPRIS, issued guidelines to implement its obligation under the NAFTA to provide regulatory data protection for new chemical entities for a period of not less than five years. PhRMA and its members initially welcomed this decision as an important confirmation of the Calderon Administration's recognition of its obligations and its intention to fully implement the NAFTA provisions. As guidelines, their validity may be questioned when applied to a concrete case, and they could be hard to enforce or revoked at any time. Therefore, PhRMA members strongly urge the passage of regulations on regulatory data protection to provide industry with greater certainty regarding the extent and durability of Mexico's commitment to strong IP protection within the TPP agreement. The intent of NAFTA is to provide regulatory data protection for all medicines, regardless of their molecular character, for at least five years.

Counterfeit Drugs

PhRMA members deeply appreciate increasing important achievements on the anti-counterfeiting front this year too, under coordinated efforts of COFEPRIS, IMPI, PGR PF and the local Prosecutor of the Jalisco State, resulting in unprecedented

closure of pharmacies selling counterfeit medicines and now also imprisonment and criminal prosecution of individuals engaged in these reprehensible activities.

These coordinated endeavors are essential to keep containing counterfeiting activities. Increasingly routine investigations, raids, and consequent prosecution of these crimes plus public condemnation of offenders to engage in pharmaceutical counterfeiting will protect and increase the health of the Mexican population.

Market Access Delays

Key market access issues in Mexico concern the excessive times taken for regulatory reviews and formulary inclusion. Both significantly exceed stated time frames. In particular, the regulatory process is exceptionally slow in all respects, from new product approvals to reviews for additional indications. Much of the regulatory delay is caused by an under resourced COFEPRIS and cost containment pressures. Efforts have been made by the COFEPRIS Commissioner Mikel Arriola to improve the efficiency and technical capability and industry applauds this progress.

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 exceeds stated review times and is far lengthier on average than that taken by other regulatory agencies, namely the FDA in the United States and the EMA in the European Union. Though COFEPRIS has made important and welcomed improvements in its operating efficiency over the past few years, additional efforts are required.

Following COFEPRIS approval, significant barriers remain to patients, primarily those covered by public institutions, in accessing life-saving and enhancing interventions. This additional delay is caused by the lengthy, uncertain and non-transparent reimbursement system used in Mexico.

After COFEPRIS grants marketing authorization to a new medicine, the Inter-institutional Commission of the Basic Formulary of Inputs of the Health Sector decides which drugs should be included in the national formulary. From here, the Coordinating Commission for the Negotiation of Prices of Medicines and Other Medical Supplies decides on a recommended price for all public institutions. Following this recommendation, the various public institutions (Mexican Institute for Social Security (IMSS), Institute of Security and Social Services for State Workers (ISSSTE), Petroleos Mexicanos (PEMEX), *etc.*) engage in additional reviews and further price negotiation. At each step, clinical and pharmaco-economic dossiers, which take manufacturers significant time and expense to create, are required. In 2010 and 2011, only 49 percent and 36 percent, respectively, of newly approved medicines were included on the national formulary. From 2007 to 2011, on average, only 40 percent of applications for drug inclusion to formulary codes in CSG (Reimbursement List) were accepted.⁷⁶ These inclusion rates are reduced further as individual institutions must subsequently add

⁷⁶ Reference data for innovative medicines PWC 2011, AMIIF 2011 report.

them to their formulary (which is not a certainty) following a lengthy additional review process. 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.⁷⁷

Throughout this reimbursement process, the public sector is effectively closed. As many plans in the private sector follow public formulary listing decisions, the private market is significantly impacted as well.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection.

⁷⁷ EFPIA Patients WAIT indicator 2010 and AMIIF 2011 report.

PERU

PhRMA and its member companies operating in Peru are concerned with the state of intellectual property protection in Peru 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 Agreement, and has been closely monitoring the enforcement of the implementation regulations since its entry into force in February 2009.

Key Issues of Concern:

- **Lack of Regulatory Data Protection for Biologics:** The Peruvian Health Authority (PHA) has rejected regulatory data protection for two biologics. This refusal 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.
- **Import Barriers and Duplicative Testing Requirements:** To its credit, Peru has introduced a number of measures to help ensure the quality, safety and efficacy of pharmaceuticals. However, implementation of these measures has been delayed and a number of these regulations are impractical in that they request documents that may not be issued in the country of manufacture (e.g., Batch Release certificates for biological pharmaceuticals), or impose excessive administrative burdens that serve no purpose other than delaying the marketing approval process and patient access to medicines. Additionally, the Health Committee of the Congress has approved a bill (Bill 995/2011), that provides that all imported products shall duplicate all quality tests in local laboratories. It also requires that all technical information submitted in a sanitary registration application to "be extracted from internationally recognized bibliographical sources, freely accessible to the public....", which is not workable, since data is always confidential at the time innovators seek first approval, and is inconsistent with Peru's international obligations under the USPTPA and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to provide regulatory data protection.

For these reasons, PhRMA recommends that Peru remain on the **Watch List** for the 2013 Special 301 Report. In addition, PhRMA's members encourage the U.S. Government to raise these concerns as priorities for resolution during bilateral consultations with Peru as well as in multilateral negotiations such as the Trans-Pacific Partnership.

Intellectual Property Protections and Enforcement

Regulatory Data Protection

The Government of Peru established a regulatory data protection regime in February 2009. Since then, a dozen new pharmaceutical products have been granted data protection for an average of 36 months (3 years). Nevertheless, since May 2010, PhRMA member companies have reported that the PHA has rejected regulatory data protection for biotechnological pharmaceuticals. This refusal is inconsistent with Peru's obligations under the WTO's TRIPS Agreement, Article 16.10.2 of the USPTPA, and national law. Denying such protection will adversely affect PhRMA members attempting to introduce new products in Peru and will create pressure on other trading partners in the region to refuse to protect this very important class of products.

To remedy this ongoing treaty violation, the Government of Peru should, as committed to in the USPTPA, refrain from granting sanitary registrations to third party follow-on versions of any kind of innovative pharmaceutical products, regardless if they are synthesized or biotechnologically derived pharmaceutical products, for a term of at least five years, unless the applicants for such versions base their applications on their own clinical data.

In addition, as explained above under "Trade Barriers / Duplicative Testing", Bill 995 requires public disclosure of this data as a precondition of obtaining a sanitary registration (by virtue of the obligation to use internationally recognized bibliographic sources freely accessible to the public), which clearly violates Article 16.10.2 of the USPTPA and Article 39 of the TRIPS Agreement.

Patent Enforcement

The Peruvian system for enforcing patents is a two-step, sequential process: (1) an administrative process for determining infringement by the Institute for Defense of Competition and Intellectual Property (INDECOPI) that takes two years on average; and (2) a judicial action in a civil court to recover damages, which can commence only after the administrative process is exhausted. This judicial action takes four years on average, a duration which discourages patent owners from enforcing their patents. It 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, however, is not adequate to provide the ability to seek and obtain a remedy before the marketing of the infringing product.

Second Use Patents

The Andean Court of Justice (ACJ) issued several legal opinions (89-AI-2000, 01-AI-2001 and 34-AI-2001) forcing Andean Community members to refuse recognition of patents for second uses, in violation of TRIPS Article 27.1, and contrary to long-standing precedents. Decisions granting patent protection for second uses were the law in Bolivia, Colombia, Ecuador, and Peru. Andean member countries have been compelled by the ACJ to not grant second use patents, thereby disregarding their TRIPS obligations. The failure to provide patents for second uses particularly affects pharmaceutical companies, which dedicate many of their research dollars to evaluating additional therapeutic benefits of known molecules (second uses) in order to provide effective solutions for unsatisfied medical needs. The ACJ position is dispositive on the issue, and to date, no further domestic appeals/remedies are possible.

Market Access Barriers

Although Peru has introduced a number of regulations⁷⁸ that are intended to introduce procedures to ensure quality, safety, and efficacy of pharmaceutical products, implementation has been unnecessarily delayed by the PHA. In addition, these regulations include numerous provisions that create unnecessary confusion or trade barriers. Key concerns include:

1. Regulations on Biopharmaceutical Products: The former regulatory standards for seeking marketing approval of biopharmaceuticals in Peru were rudimentary, and thus insufficient to ensure safe and effective biological pharmaceuticals. The new regulations, although suspended until specific guidelines are approved, have introduced product specific requirements, requesting proof of safety and efficacy from innovators and companies producing biosimilars, which will be a significant improvement. While the innovative pharmaceutical industry welcomes these improved regulations, the requirement that a biopharmaceutical company must submit a "Batch Release Certificate" issued by the competent authority of the country of origin discriminates against biologics produced in the United States where the competent authority does not issue such certificates for all kinds of biological pharmaceuticals.

⁷⁸ See, e.g., Pharmaceutical Products Law 29459 and its associated regulations; Supreme Decrees 014 and 016-2011-SA; Pharmaceutical Establishments and Pharmaceutical Registrations Regulations, respectively.

2. Processing Delays: To date, the PHA's implementation of the new regulations has unduly focused 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, the PHA requires that copies of all "critical" documents (a term that is broadly defined) must include wet signatures by the original signing party. Similarly, minor discrepancies in the name and address of the applicant and the party identified on the Certificate of Pharmaceutical Product, references to pharmacopeias for excipients or failure to provide documentation in the exact format required by the PHA have all been bases for delaying or even refusing marketing approval. These regulatory delays or measures present unnecessary trade barriers and have a negative impact on individual companies' plans to bring products to market in Peru.
3. Duplicative Testing: 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 overseas); and (2) subsequent quality testing on further batches may be performed outside Peru as long as the laboratory conducting that testing has been certified by the PHA. However, these certifications have been delayed and at the current rate, the processing time and backlog are expected to grow.

In addition, regulations provide that the PHA will accept quality testing of manufacturers certified by health authorities of high sanitary vigilance countries, such as the United States, in Good Laboratory Practices or Good Manufacturing Practices, provided the GMP covers GLP and the authority so states. However, the new regulations do not adequately specify how a laboratory may be certified by the PHA or which documents are necessary to prove that the foreign authority certification covers the laboratory area (Good Laboratory Practices).

Unfortunately, local generic manufacturers are trying to capitalize on this uncertainty by pressing authorities to request local duplicative testing of all batches of all pharmaceutical products. The Peruvian Ministry of Commerce has recently supported this pressure by sending a letter to the Minister of Health.

Further, Peruvian Congress Chairman Daniel Abugattas introduced Bill 995/2011-CR ("Bill 995"), which was approved by the Health Committee of the Congress in June 2012 without considering the Minister of Health's written technical position, which concluded that the bill would cause a non-technical market access barrier, and adversely affect prices of medicines. If approved by the Congress, Bill 995 would make it mandatory for a pharmaceutical manufacturer to conduct duplicative testing in Peru of every batch of imported pharmaceutical products.

In addition, Article 5 of Bill 995 would require all technical information relied upon in a sanitary registration application to "be extracted from internationally recognized bibliographical sources, freely accessible to the public...." Innovators, as first registrants, need to use confidential undisclosed information, such as clinical studies

and other information on safety and efficacy, as well as product specifications, formulas and other technical product information, to obtain sanitary registrations for their products. Preparing these data requires significant investment, both of time and money. It is for this very reason that Article 16.10.2 of the USPTPA obliges Peru to not disclose this data, nor allow reliance thereon by a generic applicant for at least five years after the initial sanitary registration application is granted (which depending on how quickly the sanitary registration is granted in Peru, may be measured from the date of the sanitary registration in the United States or in Peru). Requiring public disclosure of these data as a precondition of obtaining a sanitary registration would be an inappropriate circumvention of Article 16.10.2 of the USPTPA, and violate Peru's broader international obligations under Article 39 of the WTO TRIPS Agreement and the Technical Barriers to Trade Agreement.

In short, the bill, if approved, would impose a disproportionate burden on U.S. and international pharmaceutical companies, thereby creating a significant trade barrier for imported medicines and a profitable but artificial industry for local laboratories.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

MIDDLE EAST / AFRICA

SAUDI ARABIA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in the Kingdom of Saudi Arabia remain concerned that the Saudi Government has not faithfully implemented the Royal Decree on Exclusive Marketing Rights (EMR), thereby permitting infringements of the rights granted by that Decree. As a result, Saudi Arabia provides inadequate patent protection and does not provide adequate protection for pharmaceutical test data submitted to receive marketing approval.

Key Issues of Concern:

- The SFDA and KACST are allowing IP violations to occur involving EMR-eligible products approved for marketing after introduction of the 2004 Patent Law;
- Deficient, sub-standard protection of pharmaceutical regulatory data;
- Volatile government pricing policies; and
- Non-transparent drug formularies.

In January 2013, Saudi authorities passed a new regulation that establishes a mechanism for providing effective patent enforcement and recognizes pharmaceutical patents issued by other Gulf Cooperation Council (GCC) members. Although this is a significant step forward, PhRMA requests that Saudi Arabia be placed on the **Watch List** for the 2013 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 and Recognition of GCC Patents in Saudi Arabia

On January 14, 2013, the Saudi Food and Drug Administration (SFDA) issued guidelines that appear to provide a mechanism for ensuring effective patent enforcement and that recognize patents issued by other GCC members. Going forward, applicants seeking marketing approval for their generic products will be required to provide a letter from either from the King Abdul Aziz City for Science and Technology (KACST) (which oversees the Saudi Patent Office) or the GCC Patent Office indicating the patent term expiration date for the underlying innovative product. SFDA will only accept applications that are filed no more than 24 months prior to the patent term expiration date and will only grant marketing authorization for the generic product once the patent has expired. Thus, in addition to providing a mechanism to ensure effective patent enforcement, this guideline should provide some greatly needed clarity on the validity of GCC patents in Saudi Arabia.

PhRMA and its members commend the SFDA for this action and thank the U.S. Government (USTR, Department of Commerce, Department of State, and the U.S. Embassy in Riyadh) for their support on these issues.

Sanctioning of IP Violations after KSA Joined WTO and Issued the Exclusive Marketing Rights Royal Decree

PhRMA was encouraged by the Royal Decree on Exclusive Marketing Rights (EMR). That decree established a mechanism to remedy difficulties faced by PhRMA members in the area of patent protection. It was jointly formulated by the Ministry of Health and King Abdul Aziz City for Science and Technology (KACST), which oversees the Saudi Patent Office and the Ministry of Commerce and Industry, and was approved by the King on September 30, 2009.

The mechanism applies to pharmaceutical products for which patent applications had been submitted under the repealed Patent Law issued by Royal Decree No. 38/M of 1989 and were still pending at the time of coming into force of the Law of Patents, Layout Designs of Integrated Circuits, Plant Varieties and Industrial Designs issued by Royal Decree No. 27/M on July 17, 2004.

Under the Decree, pharmaceutical companies submit their EMR applications to KACST. KACST experts then review those applications, and forward eligible applications to the Saudi Food & Drug Authority (SFDA) to ensure that the pharmaceuticals identified in the application receive exclusive rights for marketing and manufacturing in the Kingdom. The term of the exclusive marketing and manufacturing rights expire on the same date the patent expires in the United States or the European Union; whichever comes first. The SFDA issued the first EMR certificates on April 30, 2011, almost 2 years after the promulgation of the Decree.

The problem, however, is that the Decree as implemented does not provide exclusive rights for marketing and manufacturing for products approved after the date of introduction of the Law of Patents, Layout Designs of Integrated Circuits, Plant Varieties and Industrial Designs issued by Royal Decree No. 27/M on July 17, 2004. That effectively means that the IP violations that took place after July 17, 2004 are allowed to continue according to the interpretation of KACST and the SFDA. Although PhRMA and its member companies have discussed this shortcoming with the two relevant agencies, neither KACST nor the SFDA believes it should implement the EMR Decree in a retroactive manner to remedy IP violations that have taken place after the 2004 Patent Law was issued.

In addition, PhRMA member companies have been informed that for those patents which were already granted or substantively examined prior to the passage of the 2004 patent law, EMR protection is not available. The 2004 patent law did not supersede the law in effect for patents actually granted or substantively reviewed under Patent Law No. 38/M, and it should therefore not be applicable to retroactively revoke patents examined under the prior law. PhRMA strongly believes Saudi Arabia should respect the rights of patent holders who were legitimately and fairly granted patents in accordance with patent law 38/M.

PhRMA and its member companies stand ready to work with the Saudi and U.S. governments to resolve this implementation issue. Also, PhRMA and its members operating in Saudi Arabia are working with the Ministry of Commerce & Industry to conduct a workshop on intellectual property (IP) protection. This workshop is intended to address various IP issues, and hopefully will prove instructive as the Saudi government takes the necessary steps to fully implement its international obligations.

Regulatory Data Protection

PhRMA member companies are concerned by the authorities' failure to provide effective regulatory data protection for a period of at least five years from the date of marketing authorization of the innovator product in Saudi Arabia.

Article 5 of a Council of Ministers' Trade Secrets Protection Regulation (decision No. 50, dated 25/2/1426 H, April 4, 2005), states that the submission of information about secret tests or other data, obtained as a result of substantial efforts, for the approval of the marketing of drugs or agricultural products which utilize a new chemical entity, shall be protected by the competent authority against unfair commercial use for at least five years from the approval date. Unfortunately, the Kingdom of Saudi Arabia has not complied with its own regulation and WTO commitments which gave rise to the regulations.

Saudi Arabia's protocol of Accession to the WTO, states:

These Regulations provided for protection of undisclosed tests and other data submitted to obtain approval of a pharmaceutical or agricultural chemical against unfair commercial use for a minimum period of five years from the date of obtaining the approval including the establishment of the base price. No person other than the person who submitted such data could, without the explicit consent of the person who submitted the data, rely on such data in support of an application for product approval. Any subsequent application for marketing approval would not be granted a market authorization unless the applicant submitted its own data, meeting the same requirements applied to the initial applicant, or had the permission of the person initially submitting the data to rely on such data.

Member companies have approached Saudi authorities concerning the need to enforce their regulations on regulatory data protection; yet authorities insist they are not sharing the content of the drug registration file of the innovator product. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), however, imposes more than a non-disclosure obligation. Rather, TRIPS Article 39.3 additionally requires WTO member states to implement an effective system of pharmaceutical drug registration, which prevents "unfair commercial use" of data generated by others. This is fulfilled by preventing reliance on regulatory test data and approvals based on such data for a fixed period of time. In other words, the data may not be used to support marketing approval for follow-on products for a set amount of time unless authorized by the original submitter of the data.

Regulatory data protection should be provided to innovative pharmaceutical products whether or not they are patented in Saudi Arabia or are covered by the EMR. Regulatory data protection is commercially important to products that may not be patentable. Saudi regulatory authorities should not grant marketing approval for generic copies of pharmaceutical products or biosimilars products during the period of regulatory data protection. A generic or biosimilar product may still receive marketing approval during the data protection period, provided its manufacturer conducts its own pre-clinical and clinical trials, and independently seeks marketing authorization from regulatory authorities.

Market Access Barriers

Challenging Pricing Environment

PhRMA member companies believe that the new government pricing regime that entered into force in November 2011 has not contributed to a more predictable environment for innovation or market access. The new pricing regulation is ambiguous, leaving many questions about how the reform will be implemented, how prices will be determined, and how often the SFDA will have authority to change prices.

Key concerns include the lack of clear definition of how different factors examined in determining the final price will be weighted, how often and for what reasons prices can be recalculated, what is a “suitable price,” and a non-transparent and burdensome international reference price system that bases Saudi government prices on the lowest price in a basket of 30 countries. The regulation does not focus on market-based principles that promote competitiveness. Instead, it appears to put in place a system for automatic price reductions on medicines, irrespective of the significant amount of research and development costs undertaken by innovative pharmaceutical companies in the development of these medicines.

The Saudi Government also has started implementing an automatic 20 percent price reduction on products that lose marketing exclusivity or following loss of patent protection, regardless of the effective exclusivity period for these products.

PhRMA member companies are ready to support a revised government pricing policy that is transparent and predictable – two attributes that we believe are lacking in the 2011 regulation.

Challenging Regulatory Environment

In May and July 2011, SFDA posted a new regulation requiring all international pharmaceutical companies to re-register their medicines licensed for sale in Saudi Arabia, and that have been on the market for more than five years. It is estimated that there are currently approximately 8,000 medicines, including various formulations, registered for use in the KSA. Industry estimates that the new regulation would affect at least 5,000 of these products.

PhRMA and its member companies believe this new requirement is excessively burdensome for both member companies and SFDA. The regulation lists a number of requirements, including registration of the manufacturing site (which triggers site visits by Saudi inspectors), updates on clinical indications (uses) and changes to the label for the product, and other technical documents. The requirement specifies that new stability studies are necessary; adding another layer of complication and cost, given that many products may have been on the market for 10-20 years, or more.

Although PhRMA was pleased to see this regulation postponed until June 2013, we are concerned that providing all required documentation for the re-registration of products that have been available in the Saudi market for 10-20 years will constitute a market access barrier and deprive patients of treatments that have been available for many years.

Review and approval of new chemical entities is still prolonged and new product registration may take from 2-3 years. Given the unpredictable regulatory timelines and existing delays in patient access to promising new medicines, PhRMA is concerned that this additional burden on the regulatory system would create an even wider gap between Saudi patients and patients in the Gulf region and advanced economies.

Drug Formularies

PhRMA is also concerned about the lack of transparency in the selection and placement of drugs on tender formularies. If transparency issues are not addressed, drug formularies could constitute serious market access barriers.

The Saudi Government has established a National Unified Purchase Company (NUPCO) which is expected to procure drugs on behalf of all government agencies. In the past, each agency procured pharmaceuticals independently on the basis of its own drug formulary. PhRMA has learned, however, that NUPCO is in the process of developing a unified drug formulary, making the impact of NUPCO's decisions all the more significant for PhRMA members.

Investment Environment

The current investment law allows 100 percent ownership of companies by foreign investors, provided that they establish a manufacturing site in Saudi Arabia. Otherwise, PhRMA member companies can only be represented by a Saudi agent and their ownership share may only be 51 percent during the first year, reaching a maximum of 70 percent ownership in the third year. This requirement discriminates against multinational corporations, and is contrary to Saudi Arabia's WTO obligations.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2012 attributable to trade barriers related to intellectual property protection and market access.

TUNISIA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Tunisia are concerned about the deterioration in the intellectual property environment since 2011.

These issues persist despite attempts by PhRMA member companies to engage the new Government on issues related to intellectual property rights for pharmaceuticals and the impact of these policies on human health and the business and investment environment. The lack of progress is particularly frustrating in light of a landmark study commissioned several years ago, that recommended that Tunisia foster new economic sectors including renewable energy, biotechnology and logistics.

Key Issues of Concern:

- Lack of regulatory data protection;
- Lack of biosimilar regulations; and
- Government pricing restrictions.

For these reasons, PhRMA requests that Tunisia be placed on the **Watch List** for the 2013 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

Lack of Regulatory Data Protection

PhRMA member companies are concerned by the Tunisian Government's failure to provide effective data protection for a period of at least five years after the date of marketing authorization of the innovator product in Tunisia.

In 2011, authorities granted marketing authorization to a generic product before the approval of the innovator company's product in Tunisia. The innovator's request for marketing approval had been pending for 13 years and was only approved nine months after the generic's approval.

Tunisia became a member of the World Trade Organization (WTO) in 1995, thereby signing on to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Tunisia agreed in 2000 to grant regulatory data protection beginning on May 2005.

To that end, the Tunisian Ministry of Health issued two circulars covering data protection. The first was issued on October 9, 2004, and was superseded later by another circular issued on May 3, 2005. Article 1 of the last Circular states that data protection will apply to new drugs "which are either imported or manufactured locally".

Article 2 states that “[w]hen the approval for the sales of pharmaceutical products including new chemical entities is subject to the communication of undisclosed data which setting up requires considerable efforts, Tunisia shall protect such data against any unfair utilization on the market. Furthermore, Tunisia shall protect such data against any disclosure unless it is necessary to do so for the protection of the public or unless measures are taken in order to ensure the protection of such data against any unfair utilization on the market.”

Further, Article 3 states that “[t]he data protection term starts as of the registration date of the application for the delivery of an authorization for the sales on the market (AMM) filed with the Pharmacy and Drugs Directorate, for five years starting from the date of the approval or refusal of the marketing authorization (AMM).”

The TRIPS Agreement imposes more than a non-disclosure obligation. Rather, TRIPS Article 39.3 requires WTO member states to implement an effective system of pharmaceutical drug registration, which prevents “unfair commercial use” of data generated by others. This is usually fulfilled by preventing reliance on regulatory test data for a fixed period of time. In other words, the data may not be used to support other applications for marketing approval for a set period of time unless authorized by the original submitter of the data.

Regulatory data protection should also guard against partial reliance where other companies rely on summaries of clinical trials in foreign literature, or summaries of product approvals published by foreign drug approval authorities, or the fact that an innovator drug was approved to reduce the amount or type of data to be submitted by the generic company. These and other forms of indirect reliance constitute “unfair commercial use” contrary to Article 39.3 of the TRIPS Agreement. Moreover, approving a generic product without requiring any clinical data during the data protection period of the innovative product equates to “unfair commercial reliance” in violation of the TRIPS Agreement.

Regulatory data protection should be provided to innovative pharmaceutical products whether or not they are patented in Tunisia. Regulatory data protection is commercially important to products that may not be patentable. The Tunisian regulatory authorities should have the responsibility for keeping generic copies of pharmaceutical products off the market during the period of regulatory data protection.

In the absence of a registered patent, a copy may still receive marketing approval during the data protection period, provided its manufacturer conducts its own pre-clinical and clinical trials, and independently seeks marketing authorization from regulatory authorities.

Unfortunately, Tunisia has not complied with its own regulations, nor the WTO commitments which gave rise to the regulations. Member companies have approached the Tunisian authorities regarding the need to enforce their regulations on data

protection, to which the Tunisian authorities have responded that they are not sharing the content of innovative drug registration files.

PhRMA and its member companies would like to seek the intervention of the U.S. Government to help resolve this troubling precedent and improve the enforcement of regulatory data protection in Tunisia.

Market Access Barriers

Lack of Regulatory Framework for Biosimilars Approval

Tunisia does not have a clear definition of biosimilars in its current legislation, no clinical data requirements to support biosimilars approvals, and the rules for indication extrapolation are not clearly identified. There is also no official distinction between biosimilars and generic medicines. In order to ensure that patients have access to high-quality, safe and efficacious biosimilars, the Tunisian health authorities need to clarify these issues through the adoption of official legislation/regulations.

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 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.

Taken in combination, these pricing policies result in prices that undervalue the cost of developing innovative medicines. 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.

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