

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)
SPECIAL 301 SUBMISSION 2012

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PhRMA SPECIAL 301
SUBMISSION 2012
EXECUTIVE SUMMARY

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 2008, the U.S. biotechnology sector was responsible for 80 percent of the total global biotech R&D spend.¹ President Obama has driven 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 Burrill and Company, analysis for PhRMA based on publicly available data, 2009.

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.

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 slow downs 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 2010, our industry invested an estimated \$67.4 billion in research and development for new medicines, \$49.4 billion of which was invested in research conducted by PhRMA members, and \$37.4 billion of which was invested in the United States.⁹ 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 These figures highlight the pressing need to defend this sector's IP rights against infringement. For example, more medicines are in development in the United States than in the rest of the world combined, with the United States accounting for approximately 3,050 medicines in development in 2009, in large part due to IP protections and other strong incentives that foster the environment needed to support continued research and development investment.¹¹

A 2007 study on the "Economic Effects of Intellectual Property-Intensive Manufacturing in the U.S." 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.¹² According to the study, from 2000-2004, the one manufacturing area that expanded its workforce was the biopharmaceutical sector, and "jobs in pharmaceutical companies increased by more than 8 percent over this period."¹³ These figures are driven in large part by exports. In 2010, the biopharmaceutical industry exported \$46.6 billion, or approximately 4 percent of total U.S. goods exports, making the United States the world's third largest pharmaceutical exporter. This made the biopharmaceutical sector among the top five U.S. exporting industries.¹⁴ Our industry has shown strong export performance in the recent past, increasing exports by more than 150 percent in the last decade.¹⁵

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

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 Burrill & Co., analysis for PhRMA, 2006-2011 (includes PhRMA research associates and nonmembers); Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey (Washington, DC: PhRMA, 2011).

¹⁰ Battelle Report.

¹¹ Adis R&D Insight Database, Wolters Kluwer Health (accessed 28 February 2011).

¹² Shapiro, R. and Pham, N., Economic Effects of Intellectual Property-Intensive Manufacturing in the United States, World Growth (July 2007).

¹³ Id. at 3.

¹⁴ U.S. International Trade Commission, Trade DataWeb, accessed January 13, 2012, at <http://dataweb.usitc.gov/> (query run of U.S. domestic exports classified by 4-digit NAIC code 3254).

¹⁵ Id.

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.”¹⁶ 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.¹⁷ 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.¹⁸ 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: “While 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.”¹⁹

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

¹⁷ Edwin Mansfield, Patents and Innovation: An Empirical Study, *Management Science*, Vol. 32, No. 1 (1986).

¹⁸ 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. 6, 2012).

¹⁹ *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.²⁰

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."²¹

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.²² 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 \$365 million into new cures and treatments in 2008 alone – making them the third largest funder in the world, ahead of all countries but the United States.²³ 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.

²⁰ IFPMA Survey, validated by LSE Health and Social Care at the London School of Economics and Political Science.

²¹ Remarks by Bill Gates at the World Economic Forum, Gates Foundation Press Conference (January 29, 2010).

²² See www.globalhealthprogress.org.

²³ Moran, M. et al., Neglected Disease Research and Development: New Times, New Trends, The George Institute for International Health (2009).

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.²⁴) 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: Brazil, Canada, Colombia, India, the Philippines, and Saudi Arabia.
- **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: Colombia, India, Turkey, Venezuela, 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 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: Canada, Chile, China, Colombia, Poland, Saudi Arabia, Spain, Venezuela, Korea, and Ecuador.

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

- **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: Argentina, Australia, Costa Rica, the Dominican Republic, El Salvador, Honduras, India, Malaysia, Mexico, Nicaragua, Peru, the Philippines, Portugal, 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 and innovative sectors by requiring investment in local manufacturing facilities as a condition of market entry. In Indonesia, for example, a government decree that came into effect in 2010 sets unreasonable conditions for market entry – companies must either establish a factory in Indonesia or transfer sensitive IP to a local Indonesian company in order to market their products.
- **De Facto Bans on Imports** – Some countries have begun to introduce policies that prevent market entry. For example, Turkey does not recognize the internationally-accepted certification of good manufacturing practices (GMP) from other countries unless those countries have mutual recognition agreements (MRAs) 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 serves 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 over foreign companies.
- **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, Colombia, Costa Rica, the Dominican Republic, Ecuador, El Salvador, Honduras, India, Israel, Jordan, Korea, Lebanon, Mexico, Nicaragua, Peru, Russia, Saudi Arabia, Taiwan, Thailand, Tunisia, Turkey, the 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 analysis, approximately 39 countries of 43 studied proposed or implemented material cost containment measures impacting the biopharmaceutical sector in just a 15 month period ending in March 2011.²⁵ In fact, with regard to such measures, the biopharmaceutical sector is unique compared to other industries in that in the vast majority of markets in

²⁵ Ross Consulting: Review of Global Government Pharmaceutical-Related Cost Containment Activity: January 2010 through March 2011. May 2011.

which we compete the government is the predominant, if not sole, healthcare provider making our industry especially vulnerable to government cost containment measures. Moreover, international organizations such as the International Monetary Fund (IMF), European Central Bank (ECB), and the World Bank are increasingly recommending 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.²⁶

PhRMA recognizes the significant fiscal challenges that foreign governments face particularly given the current global financial crisis and seeks to be a partner in finding solutions. While some governments such as Ireland and Spain are making positive efforts to work with the research-based pharmaceutical industry in a predictable, transparent, and consultative manner to mitigate these economic pressures, an increasing number of governments are proposing and implementing particularly egregious cost containment measures in the absence of meaningful engagement with industry. Such cost containment policies typically put short-term government objectives ahead of long-term strategies and ultimately impede the flow of medicines to patients, undercut return on investment for developers over a product's life cycle, which effectively diminishes the value of patent protection, and slows future innovation.

Examples of some of the more common cost containment measures include *ad hoc* government price cuts, international and therapeutic reference pricing, mandatory rebates, and many others.

- **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. Korea is an example of a market that implemented dramatic government price cuts in 2010 and 2011 resulting in government-mandated price reductions on hundreds of medicines. Colombia has also implemented several cost containment measures including maximum price caps for pharmaceutical products in 2011. And in Turkey, where the GMP requirement mentioned above severely restricts PhRMA member companies' commercial activities, cumulative cuts since 2009 have reduced government prices by more than 40 percent. These *ad hoc* government price cuts create a deeply uncertain and unpredictable operating environment for the innovative pharmaceutical industry that relies on long-term planning to make the vital investments for the development of new medicines.
- **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

²⁶ 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.

calculated by considering the price of the same medicine across a set (or “basket”) of countries using one of several possible methodologies. Where a government sets price based on the lowest price in a reference basket, it can create a downward spiral in terms of prices for medicines, and may result in product shortages for medicines patients need. For example, in 2011 Saudi Arabia revised its reference pricing basket that includes 30 countries (a large majority of which have considerably lower socio-economic status compared to Saudi Arabia which has one of the highest per capita incomes in the world), taking the lowest price in its reference basket to set the price of new products.²⁷

- **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 Romania pharmaceuticals with therapeutically and pharmacologically comparable active ingredients (including both innovative and generic medicines) are clustered, and the lowest priced medicine in the group is used to set a product’s price. Greece recently incorporated TRP as a cost containment mechanism and Poland expanded its existing TRP system.
- **Mandatory Rebates**: Rebates are measures whereby payers achieve a lower real purchase cost than what they would have incurred at list price level. In rebate systems, a price reduction is negotiated with the payer while maintaining the official list price of a product. Ad-hoc mandatory rebates can negatively impact a company’s ability to plan ahead, and contribute to creating a highly unpredictable business environment. For example, in late 2010, the German Ministry of Health implemented an increase of the mandatory rebate from 6 to 16 percent on non-reference priced medicines. The 16 percent rebate will remain in place thru 2013. Moreover, Spain imposes a 15 percent rebate on medicines that have been on the market for over 10 years with no generic or biosimilar authorized in the Spanish market.

In today’s global environment, cost containment measures implemented in one country can both directly and indirectly impact the price of medicines in many other countries. For example, international reference pricing can create a powerful downward spiral of prices for medicines. For instance, a recent analysis of a theoretical 10 percent price cut in Greece would have a global ripple effect of nearly \$2.9 Billion due to referencing and re-referencing relationships around the world.²⁸

In addition to price controls and other cost containment policies, 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

²⁷ International Reference Pricing Analysis for PhRMA: Egypt, Saudi Arabia, Charles River Associates, London, Jan. 2011.

²⁸ Charles River Associates. Economic Spillover Effects of International Reference Pricing, May 2011.

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 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. In addition, these systems tend to be non-transparent and methodologically unsound. 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.

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.²⁹ For example, recent estimates indicate that between 10 to 30 percent of medicines sold in developing markets are believed to be counterfeit.³⁰ 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),

²⁹ 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.

³⁰ The World Health Organization, IMPACT, at www.who.org (2008).

several common deficiencies contribute to the growing prevalence of pharmaceutical counterfeiting in worldwide markets. Weak enforcement due to inadequate remedies, penalties, resources and commitment is the most significant problem, and one that undermines the effectiveness of all relevant laws, including prohibitions against trademark counterfeiting, as well as drug regulatory controls. 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 2012 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 17 countries should be included in the 2012 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 25 countries which should be included on the Special 301 Watch List in 2012. 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

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

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 has established an unrealistic pharmaceuticals budget for 2012 by insisting on the budget figures projected in 2009 and not updating the budget to reflect the healthcare system's actual needs. The outdated budget figures disregard parameters such as economic growth, inflation and exchange rate fluctuations, and impose forced price discounts at unsustainable levels that hinder access to innovative medicines.

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 Protection

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. The assessments given by the EU in the Turkey 2010 Progress Report on Accession, "Chapter 4.7: Intellectual property law," noted that no progress had been made in the legislative framework for intellectual property rights.

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 850 days³¹ 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.³² 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 in product development and clinical research to benefit patients, including increased efficacy and safety, as well as new indications, from new

³¹ AIFD Situation Assessment Survey of CTD Applications, June 2011.

³² Official Gazette No. 27208 (Apr. 22, 2009).

combinations of separate molecules, and such products 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 General Directorate of Pharmaceuticals and Pharmacy, 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.³³ 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 850 days in 2011.³⁴

The MOH's recent revisions to the Registration Regulation have compounded these delays.³⁵ 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 300 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 550 applications to conduct GMP inspections, requiring inspections at almost 330 overseas sites.³⁶ MOH does not have the time or resources to complete these GMP inspections in a timely manner and there is no 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 must join and participate in the PIC/S (Pharmaceutical Inspection Convention and Co-operation Scheme) that provides guidance on

³³ Official Gazette No. 25705 (Jan. 19, 2005) (Registration Regulation).

³⁴ AIFD Situation Assessment Survey of CTD Applications, June 2011.

³⁵ 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).

³⁶ AIFD GMP Inspections Survey, September 2011.

international GMP standards; and 2) Turkey will need to negotiate mutual recognition agreements with each participating country. In the meantime, registration of new medicinal products will be substantially delayed, which, in turn, hinders patients' access to innovative medicines. To avoid imposing this unnecessary non-tariff barrier to trade, Turkey, as a temporary measure, should revert to recognizing GMP certificates accepted by institutions like the FDA, EMA, or other PIC/S members for medicinal products. Such 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.

Pricing and Reimbursement

In Turkey, pharmaceuticals' pricing is regulated by the MOH General Directorate of Pharmaceuticals and Pharmacies. 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).³⁷

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.³⁸ 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 mandatory 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.
- Original products with generics: Turkey reduced prices for originals and generic products from 66 percent to 60 percent of the reference price (previously original products were at 100 percent and their generics were at 80 percent of the reference price). However, if the reference price decreases at some point in the future, no further price reductions are imposed until the

³⁷ AIFD Market Access Survey, March 2011.

³⁸ In Turkey, pharmaceutical pricing is governed by the MOH Pricing Decree (June 30, 2007, last amended on Mar. 12, 2009) and Notifications (Sept. 22, 2007, last amended on June 11, 2010). Reimbursement is made pursuant to the Healthcare Implementation Guideline (SUT) (Mar. 25, 2010, last amended on Aug. 6, 2010) as promulgated by the Social Security Institute (SSI).

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 mandatory 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 7.5 percent were also imposed as of December 2010 with a total mandatory 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 saving 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).

Another significant concern is that the Government's pharmaceutical budget for 2012 was fixed in 2009 and has not been updated to reflect the actual budgetary needs of the population. The 2012 budgetary allocation disregards parameters such as economic growth, inflation and exchange rate fluctuations. This allocation is unlikely to be sufficient given the increased demand for government provided health care services. (Turkey spends only approximately 6 percent of its GDP on health care expenses, compared to an OECD average of 8 percent.) Turkey's annual health care costs are likely to increase at a greater pace than budgeted. As a result, new government price cuts or additional mandatory discounts remain a constant threat.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 China remain concerned over the Government of China's lack of effective regulatory data protection, infrequent and lengthy reimbursement updates, and restrictive government pricing policies. In addition, 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:** Despite some very positive steps taken by the Government of China to stem the flow of counterfeits, the production, distribution and sale of counterfeit medicines remains rampant.
- **Government Pricing:** PhRMA is concerned that government pricing policies being considered by the Government of China could create an unfavorable business environment, further reduce reward for innovation, restrict patient access to quality medicines and undermine China's healthcare and innovation policy objectives.

For these reasons, PhRMA requests that China be subject to **Section 306 Monitoring** for the 2012 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

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 6-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.

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 submit published material and reference regulatory decisions by foreign regulatory agencies as justification for approval. Limited local clinical trials are also required.

China’s deference to published material and regulatory decisions by agencies outside of China is reliant on clinical data developed by originator companies. Published data merely summarize the data included in the original filing and alone are usually insufficient to prove the safety and efficacy of a 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 or public summaries thereof gives an unfair commercial advantage to non-originator companies because non-originator companies do 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 commitment to reducing counterfeit medicines and PhRMA applauds China for undertaking a series of actions towards achieving that goal

In 2011, 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. PhRMA applauds and encourages more of these law enforcement efforts, and urges the central government to continue to reward and ensure law enforcement efforts in this area at provincial/local level. PhRMA applauds China's decision to make the special campaign a permanent effort and urges China to continue its focus on counterfeit pharmaceuticals, given the significant threat they pose to the safety of the Chinese people and global public health.

As part of its enforcement efforts, China has been working to tackle the sale of counterfeits on the Internet. In 2010 and 2011, China worked across ministries to shut down several websites selling fraudulent medicines. We hope that China's efforts to stop counterfeit drugs sold on the Internet will continue and increase in 2012. We encourage China and the USG to increase cooperation related to counterfeit medicines sold on the Internet, given the role of the Internet in the global counterfeit drug trade.

In 2009, China made a significant legal step by upgrading 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.

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. The unregulated distribution of API exposes patients to serious health risks and degrades 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 5 year plan. 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

Although recently improved, China's clinical trial application (CTA) submission requirements remain burdensome relative to other countries' drug regulatory procedures. China maintains comparatively extensive data requirements for pre-clinical studies and before initiating clinical studies. Moreover, applicants are unable to supplement applications as new information is discovered or made available, and must repeat the same procedures for every clinical protocol with no abbreviated process. Taken together, these requirements make it extremely difficult to integrate Chinese patients into regional or global trials intended to expedite the availability of meaningful new therapies in China. In order to mitigate some of these arduous requirements, PhRMA recommends that the SFDA develop new practices that are in line with international best practices.

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 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 a comprehensive essential drugs policy aimed at making pharmaceuticals available to the underserved populations across China. PhRMA wishes to ensure 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 their quality and relative value. Such a system will ensure that the best products are available to the patients who need them most.

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 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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 remain concerned about government price control of medicines and inadequate intellectual property protection that poses significant market access barriers in India. India has so far failed to implement provisions to protect pharmaceutical test and other data, as required by Article 39.3 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Standards for patentability need to be amended to conform to prevailing international practice.

PhRMA and its member companies recognize that India has legitimate concerns regarding access to healthcare throughout the country and would like to be a partner in developing sustainable solutions to these problems. However, limiting IP protections and creating barriers to market access will only inhibit India's own innovative biopharmaceutical industry from developing products for India, while doing little to improve affordability 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 solutions.

Key Issues of Concern:

- **Compulsory Licensing (CL)**: Domestic companies have started filing CL applications with the Indian Patent Office, based in large part on price differences and contentions regarding Indian "patent working" requirements.
- **Lack of Regulatory Data Protection (RDP)**: 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 TRIPS Agreement and discourages the development of new medicines that could meet unmet medical needs.
- **Government Price Controls**: The Proposed National Pharmaceutical Policy 2006 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 has published a New National Pharmaceutical Pricing Policy 2011 that subjects all 348 Drugs on the National List of Essential Medicines (NLEM) 2011 to price controls.
- **Foreign Direct Investment (FDI) in Pharmaceutical Sector**: The Government of India has recently reviewed the policy on FDI imposing additional regulatory hurdles on FDI in the pharmaceutical sector.

For these reasons, PhRMA requests that India remain on the **Priority Watch List** for the 2012 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 Licenses on Patented Pharmaceutical Products

To date, India has not issued a compulsory license (CL) for a patented pharmaceutical product. However, the research-based pharmaceutical industry is concerned that domestic companies have started filing CL applications with the Indian Patent Office, apparently prompted in part by Government statements suggesting that CLs may be a means for ensuring availability and affordability of drugs worldwide.³⁹ Other statements from the Government incorrectly imply that CLs are widely used by other governments, such as the United States and Italy.⁴⁰

At a minimum, India should ensure that the CL provisions comply with TRIPS by:

- Clarifying that importation satisfies the “working” requirement (TRIPS Article 27.1); and
- Eliminating price as a trigger to CL. (Section 84(1) (b) of Indian Patent Act which would permit a CL if the patented invention is not available to the public at a “reasonably affordable price”).

In cases of CL for exports, India should ensure that in line 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 for humanitarian, non-commercial use only.

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.

³⁹ UNAIDS Press Statement, meeting between Indian Commerce and Industry Minister Anand Sharma and UNAIDS Executive Director Michel Sidibe, July 6, 2011, *available at* <http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2011/july/20110706psindia/> (last visited Feb. 6, 2012).

⁴⁰ 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. 6, 2012).

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

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.

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 of the TRIPS Agreement 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. From a policy perspective, Section 3(d) undermines incentives for innovation.

Backlog of Unexamined Patent Applications

There are presently around 200 Patent Examiners at the Indian Patent Office, with approximately 83,686 applications to be examined as of March 2011.⁴¹ The delays and quality compromises likely to be associated with this situation are untenable.

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,

⁴¹ Written reply to a parliamentary question on March 13, 2011 by Jyotiraditya Scindia.

civil and criminal remedies are available under India's trademark statute. However, the effectiveness of such remedies is undermined by judicial delays and, in criminal cases, extremely low rates of conviction.

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

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 which would pool risk and help to share cost burdens.⁴² 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.⁴³ 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.⁴⁴

Recently, the Government has published a draft National Pharmaceutical Pricing Policy 2011 (NPPP 2011) which prescribes price controls on all 348 Drugs of the National List of Essential Medicines (NLEM) 2011 in addition to the 74 drugs currently subject to price controls. Stakeholder consultations are ongoing.

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.⁴⁵ For example, medicines and vaccines which are offered free of charge often do not reach

⁴² "Health Systems Financing: The Path to Universal Coverage," *The World Health Report*, World Health Organization, 2010.

⁴³ "Pharmaceutical Pricing Policy in India," Organisation of Pharmaceutical Producers in India, Nov. 2010.

⁴⁴ "Health workforce, infrastructure, essential medicines", World Health Statistics 2009, The World Health Organization

⁴⁵ "A Study of Healthcare Accessibility," Dr. DY Patil Medical College, Pune, India, prepared for India Health Progress, Mar. 2011. Wagstaff, Adam, "Health System Innovation in India Part I: India's health system challenges," *available at* <http://blogs.worldbank.org/developmenttalk/health-system-innovation-in-india-part-i-india-s-health-system-challenges> (last visited Feb. 6, 2011).

the patients who need these medicines.⁴⁶ 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.⁴⁷

In addition, under the Draft National Pharmaceutical Policy 2006 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 2006, 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.

FDI in Pharmaceutical Sector

PhRMA members are concerned about policy actions that propose to create hurdles for FDI in the pharmaceutical sector. Vide Press Note 3 of 2011 (November 2011), the Ministry of Commerce and Industry, Government of India, reviewed the FDI policy with regard to the pharmaceutical sector. Foreign investors wishing to invest in existing Indian pharmaceutical companies will now need to apply for government approval. Currently there are no criteria for this approval process leading to an atmosphere of uncertainty for potential investors.

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 R&D 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.

⁴⁶ "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. 6, 2012).

⁴⁷ "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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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:

- **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.
- **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 could lead to compulsory licensing, price controls, local content requirements, new standards for all stages of pharmaceutical production, and restrictions on certain product components.
- **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 promote the domestic industry; import substitution measures, including import restrictions; and measures to ensure the availability, price stability, and distribution of ill-defined "essential goods."
- **Non-Conformance with International Best Practices:** PhRMA's member companies continue to face burdensome regulatory delays in the registration process of new products. Therefore, stronger conformance with international best practices is needed with respect to regulatory data protection, patent enforcement, 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 and encourage voluntary halal certification. At the time of this submission, PhRMA's member companies are evaluating the market access implications should this legislation be signed into law.

For these reasons, PhRMA requests that Indonesia remain on the **Priority Watch List** for the 2012 Special 301 Report and that the U.S. Government continues to seek resolution on the problems described herein.

Intellectual Property Protections and Enforcement

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. PBF enterprises are barred from the Indonesian market unless they (1) establish a local manufacturing facility or (2) transfer sensitive intellectual property to a local Indonesian firm. 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 Ministry of Health 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.

BPOM has advised PhRMA's member companies that a Q&A List would be issued by the end of 2011 providing additional clarification to Decree 1799 manufacturing provisions. As yet, the Q&A List has not been published, and there have been no consultations.

While PhRMA's member companies are hopeful the Q&A List may provide further guidance on Decree 1799 provisions, this will not resolve the fundamental concerns with Decree 1010. Indonesian subsidiaries of multinational research-based pharmaceutical companies should be classified as manufacturers as well as granted market access without a requirement to undertake local production. Furthermore, Article 10.2 and 10.3 of Decree 1010 provide that no later than five years after an imported pharmaceutical product goes off-patent, the transfer of sensitive technology must be made to a local Indonesian manufacturer. This measure is expected to have a significant market impact for U.S. research-based pharmaceutical companies and alone represents a major threat to market access. Implementation guidelines on Article 10.2 and 10.3 were provided in BPOM's Brown Book of September 14, clarifying in broad terms when a technology transfer may not be required. The Q&A List is expected to provide further clarification on Decree 1010 technology transfer requirements.

PhRMA's member companies are concerned about the inherent 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.

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, patent enforcement, 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 and drafted 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) expanded use of compulsory licensing for patented pharmaceutical products; (2)

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; (3) additional local content or manufacturing requirements on certain pharmaceutical products; (4) unique government-imposed standards on the procurement, storage, production, promotion and distribution of pharmaceutical products; (5) restrictions on certain components of pharmaceutical products; (6) requirements on the private sector to provide healthcare financing to the public sector; and (7) 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) 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."

Mandatory Halal Certification

Legislation is moving through Indonesia's Parliament that would mandate Halal certification for all pharmaceutical 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 are strongly supportive of religious and cultural sensitivities of all Indonesians and encourage voluntary Halal certification that provides patient choice. It is understood that there is significant opposition to the adoption of this legislation from local stakeholders. At the time of this submission, PhRMA's member companies are evaluating the market access implications should this legislation be signed into law.

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. At present, the Negative Investment List requires any 100 percent foreign-owned PBF enterprise wanting to pursue classification as a manufacturer to divest 25 percent of its ownership to a local partner. The Ministry of Health 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.

Anti-Counterfeiting Enforcement

While 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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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,⁴⁸ and operate in a non-transparent manner, making unpredictable funding decisions and creating an unfavorable environment for innovative medicines. In addition, a draft Patent Bill, if passed as written, fails to provide adequate incentives for innovation and adequate protection for intellectual property. This could potentially reduce New Zealand's 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 Amendment;
- Government Pricing and Reimbursement; and
- Biotechnology Taskforce Recommendations.

For these reasons, PhRMA requests that New Zealand be placed on the **Priority Watch List** for the 2012 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

Patents Act Amendment

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

⁴⁸ 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).

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.⁴⁹ 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.
5. **Transparency and Rigor of Processes and Decision Making** – Public confidence will be enhanced if decision making processes are underpinned

⁴⁹ Michael Wonder, Richard Milne: *Access to new medicines in New Zealand compared to Australia*, New Zealand Medical Journal, Vol. 124 No. 1346 (Nov. 2011).

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.
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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 2012.

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.
- **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.
- **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.

For these reasons, PhRMA requests that Thailand remain on the **Priority Watch List** for the 2012 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. Furthermore, royalty payments on the earlier compulsory licenses on Stocrin and Kaletra were not made. Complete and advance consultation on all compulsory licensing, and other policies and justifications for actions taken that directly affect individual companies, is essential for Thailand to provide adequate and effective protection of intellectual property rights.

Regulatory Data Protection

PhRMA's member companies strongly encourage the Royal Thai Government to institute meaningful regulatory data protection that prohibits the Thai Food and Drug Administration (FDA) or generic drug applicants, for a fixed period of time, from relying on the innovator's regulatory data to approve generic versions of the innovator's product. In order to do so, 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 confidential material whenever it is received by officials; (3) extend 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 generic or

biosimilar versions 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

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.

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 and 13) from having 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. Ongoing procurement and regulatory reform of CSMBS continues to have a negative impact on public hospitals and is of growing concern to Thailand's patients,

doctors, and healthcare industry at-large. The reforms established onerous reporting and audit requirements for prescribing innovative medicines and have led many physicians to cease providing innovative medicines to patients in favor of 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.

Anti-Counterfeiting Enforcement

PhRMA's member companies are encouraged by the Royal Thai Government's collaborative efforts in 2011 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 acknowledged their willingness to commence collaboration with industry to train and equip enforcement agencies. While the Royal Thai Government has acknowledged the need to suppress counterfeits through 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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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.

Several of the issues identified below have been raised by the European Union (EU) in the context of the Canada-EU Comprehensive Economic and Trade Agreement (CETA) negotiations. In addition, issues relating to effective patent enforcement and patent term restoration have been tabled by the U.S. Government in the context of the Trans-Pacific Partnership (TPP) negotiations with other countries. The Government of Canada has recently indicated an interest in joining the TPP negotiations. These two separate trade negotiation processes between Canada and its largest (United States) and second largest (EU) trading partners represent an important and time-limited opportunity to better align Canada's intellectual property regime with that of the United States and other developed nations.

Key Issues of Concern:

Intellectual Property:

- I. Weak enforcement of patents;
- II. Utility requirements which are inconsistent with the Canadian Patent Act (the Act), TRIPS, NAFTA and international norms;
- III. Limitations on regulatory data protection;
- IV. Lack of patent term restoration; and
- V. Canada's Access to Medicines Regime.

For these reasons, PhRMA requests that Canada remain on the **Priority Watch List** for the 2012 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

I. 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.⁵⁰ 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.

⁵⁰ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359.

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 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.

II. 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 than is imposed on other technologies in Canada.⁵¹ This heightened standard is inconsistent with common practice in other countries and international obligations against discrimination.

III. 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 period of exclusivity 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. To address this concern, Canada should also be encouraged to provide data protection for unmarketed medicines. 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.

These 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.

⁵¹ For example: *Eli Lilly Canada Inc. v. Apotex Inc.* 2009 FCA 97, *Eli Lilly and Company v. Teva Canada Limited* 2011 FCA 220, *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197, *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, and *Pharmascience Inc. v. Pfizer Canada Inc.*, 2011 FCA 102.

IV. 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.

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.

V. Implementation of the August 30, 2003 WTO General Council Decision on TRIPS and Public Health

On November 6, 2003, Canada introduced legislation to implement the WTO Decision, which is effectively a waiver, under particular circumstances, of a number of TRIPS obligations to which member nations would otherwise be bound in issuing compulsory licenses. Canada was one of the first countries to enact domestic legislation to permit its generic manufacturers to export under the compulsory license provisions of the WTO Decision. The bill and related regulations, now known as Canada's Access to Medicines Regime (CAMR), came into force on May 14, 2005. The Canadian legislation was reviewed in 2007, as required by the Patent Act. PhRMA applauded the Canadian Government's decision to leave CAMR "as-is".

The Canadian Government continues to receive unwarranted and inaccurate criticism related to the operation of CAMR. Although the Canadian Government opposed attempts to change CAMR in the last session of Parliament, it is anticipated that new efforts will be initiated to dilute intellectual property safeguards. PhRMA urges the U.S. Government to request that the Canadian Government maintain its existing legislative model without further disruptive and unnecessary changes to its current legislation.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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.⁵² Overall, however, interim injunctions to prevent accused products from remaining on the market until trial are granted in less than half the relevant cases.⁵³ 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.

⁵² See, e.g., *Leo Pharma v. Sandoz*, [2008] EWHC 541 and *Novartis v. Dexcel-Pharma*, [2008] FSR 31.

⁵³ 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.⁵⁴

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

However, there is no opportunity for innovator companies to resolve patent disputes well in advance of generic or biosimilar launch. This is because, in most EU Member States, it is not possible to bring patent infringement proceedings until just before or just after launch of the third party product, which often makes resolution of disputes before actual launch impossible. In addition, resolving these disputes in this manner is often lengthy, expensive, and can result in significant market loss, even if the end ruling favors the company that produced the original molecule.

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

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

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

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

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, Poland 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

⁵⁴ 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. 6, 2012).

patent, reducing the remuneration a company can receive for an innovative product to the price level of a competing generic medicine.

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 face several market access barriers in Hungary, including an unpredictable regulatory environment and legislative changes that are implemented on very short notice. The recent austerity measures intended to balance Hungary's budget have dramatically increased the complexity and severity of the market access barriers.

The Hungarian Government's intention to cut the drug reimbursement retail budget by one-third by 2013 (outlined in the Széll Kálmán (Savings) Plan), is unsustainable in the long-term and detrimental to Hungarian patients. For example, the concept of a baseline budget was institutionalized without regard to patients' needs.

Key Issues of Concern:

- **Increased "Crisis Taxes" Specific to the Pharmaceutical Sector:** Innovative pharmaceutical companies operating in Hungary are currently subject to the lowest government list prices in Europe and discounts of up to 50 percent due to mandatory price-volume agreements. PhRMA member companies requested, like other industries facing "crisis taxes," that the tax have a defined expiration date. However, an end date for the pharmaceutical crisis tax has not yet been established.
- **High Generic Government Prices:** Prices for generic medicines in Hungary are artificially high, creating a preferential pricing environment for an industry that is predominately Hungarian.
- **Research and Development (R&D) Tax Refund:** In mid-2009, a 20 percent R&D tax refund was introduced for eligible investments. In early 2010, it was revised to allow for a 100 percent refund of extra pharmaceutical sales tax on reimbursed products in case R&D expenses reach a certain threshold. However, in June 2011, the government retroactively changed the 2010 legislation, increasing the thresholds to qualify for the full R&D tax credit. PhRMA member companies made investment decisions based on the 2010 regulations.
- **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:** There is over a 2-year delay in the pricing and reimbursement process in Hungary. Moreover, the Hungarian

Government tends to approve new products only when neutral (or negative) budget impact is expected, unambiguously disregarding key innovations.

For these reasons, PhRMA requests that Hungary be placed on the **Priority Watch List** for the 2012 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). The new pharmaceutical legislation instituted in 2011 established additional tax burdens and market access barriers for innovative pharmaceuticals, both financially and procedurally.

The financial barriers include:

- A tax increase from 12 to 20 percent on all reimbursed retail products and an additional claw-back system, under which pharmaceutical companies are held financially responsible for the overspending of the retail pharmaceutical budget;
- A sales representative tax of approximately US\$50,000 per year, per representative (a 100 percent increase from the previous level);
- 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;
- Bi-annual reference pricing with de-listing (electronic "blind" bidding system) for Type 1 ("generic") and Type 2 ("therapeutic") reimbursement groups. The therapeutic reference groups have been created in a non-transparent manner.
- 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 post launch;
- Prescription directive limiting the prescribing choice of physicians; and
- Review of reimbursement of products with high consumption.

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 18 months;
- Introduction of a series of financial protocols with no transparent connection to the reimbursement procedure; and
- Lack of clear use of pharmaco-economic data.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers related to intellectual property protection and market access.

ISRAEL

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Israel remain concerned regarding intellectual property legislation and marketing approval deficiencies and delays.

Key Issues of Concern:

- The Government's practices and inefficiencies with regard to the registration of innovative pharmaceutical products, which currently curtail regulatory data protection periods and create a hostile and unstable environment for the commercial interests of U.S.-based companies;
- Nullification of Patent Term Extensions (PTE).⁵⁵ PTE has been largely nullified through the limitation of any PTE term to the shortest extension order among the "recognized countries." Other problems related to PTE include the conditions for the submission for a patent term extension in Israel and retroactivity of the amendment;
- The effects of the lack of mandatory publication of patent applications within 18 months from the priority date; and
- Pre-grant opposition to patent grants (Art. 30 of the Patent Act).

For these reasons, PhRMA requests that Israel remain on the **Priority Watch List** for the 2012 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

PhRMA greatly appreciates the Israeli Government's commitment to make certain improvements in its intellectual property legislation following the Memorandum of Understanding (MoU) with the U.S. Trade Representative dated February 18, 2010.

In that MoU the Government of Israel agreed to address four key issues: regulatory data protection, patent term extension, publication of patent applications, and delays in registration of innovative pharmaceuticals. To date, however, the only component in the MoU that has been implemented by the Government of Israel is data protection.

PhRMA continues to have serious concerns about the manner in which other components of the MoU would be implemented in pending legislation. PTE in particular should be fully available in accordance with the terms of the MoU. PhRMA and its member companies in Israel will continue to evaluate progress on these issues. We appreciate the continued support of the U.S. government in securing full compliance with the terms of the MoU.

⁵⁵ Amendment no. 7, to Article 64 (Dec. 19, 2005).

Market Access Barriers

Marketing Approval (Registration) Deficiencies and Delays

Under Article A2 of the MoU between the USTR and the Government of Israel, Israel committed to implement Government Decision No. 183 which requires that marketing approvals for new drugs be issued within 270 days from their submissions. Nevertheless, according to the last formal Ministry of Health (MOH) advisory dated June 29, 2011, the average registration time for 2010 was 16.5 months, much longer than previously advised, and almost double the 270 days agreed to in the MoU (which has since passed into law). Further, it is estimated that there are more than 250 medicines in Israel waiting for approval. As yet, Israel has issued no plan to address these delays, and current budgetary problems in the Institute for Standardization and Control of Pharmaceuticals of the MOH, as well as other inefficiencies, make it unlikely that these delays will improve in the near future.

Further, in 2010 the MOH introduced a new procedure that allows for prioritization of registration for select generic products, thus delaying the review and registration of innovative products. PhRMA is deeply concerned that this policy will further lengthen the already unreasonably long registration period for innovative products.

In addition, PhRMA member companies continue to be adversely affected by an amendment to Art. 47 of the Pharmacist Ordinance (dated 2002) that allows for a fast-track registration of generic products based on FDA or EMA approval. Generic products approved by these authorities are granted an automatic marketing authorization, unless the MOH objects to their registration within 70 days. Imported innovative products cannot take advantage of this fast track procedure. This amendment benefits only local generic producers, and thus appears to be inconsistent with GATT Article III obligations. A proposed amendment to the regulations, applying equal rights to innovative products, was rejected by the MOH in September 2009.

Finally, in July 2011, the MOH announced that it plans to increase registration related fees by 500 percent. This increase is not only unreasonable in its own right, but unacceptable especially in the context described above, where no action plan to reduce the registration period and improve efficiency has been published or implemented.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers related to intellectual property protection and market access.

POLAND

PhRMA's member companies face numerous market access barriers in Poland, including inadequate protection of intellectual property rights, discriminatory government pricing policies and arbitrary restrictions on access to physicians and pharmacists.

Key Issues of Concern:

- **Inadequate Legal Framework for Protecting Intellectual Property Rights:** Following Poland's accession to the EU, it has failed to remove from the market generic copies of centrally-registered patented drugs, and to implement EU data protection rules.
- **Government Reimbursement and Pricing Policies:** Poland's government pricing and reimbursement system is discriminatory, non-transparent, and is significantly backlogged. As a result, Poland lags far behind the other 26 EU Member States in approving new, innovative medicines for reimbursement.⁵⁶
- **Inappropriate Restrictions on Access to Physicians and Pharmacists:** Subsequent to a December 1, 2008 regulation, pharmaceutical professionals are unable to visit health care physicians and pharmacists unless the visits are pre-arranged, undertaken after working hours, and after obtaining the consent of the manager of the institution in question. Uncertainty regarding how these regulations apply has led many larger medical institutions to ban all contact between medical representatives and physicians, thereby limiting physician access to the latest drug information.

For these reasons, PhRMA requests that Poland be placed on the **Priority Watch List** for the 2012 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

Failure to Remove Illegal "Ghost" Drugs after EU Accession

As a result of Poland's accession to the EU, generic copies without a European Marketing Authorization that are copies of Centrally-Authorized Products (in accordance with Regulation No. 2309/93) became illegal starting May 1, 2004, the day of Poland's accession. Poland has an obligation to withdraw such generic products from the Polish market, whether or not they are included in the reimbursement list. Immediately prior to joining the EU on May 1, 2004, the Government granted "conditional" marketing authorization for approximately 400 "ghost" copies of innovative

⁵⁶ "Analysis of Access to Modern Drug Therapies – Comparison Between EU countries", Higher School of Business, National-Louis University.

pharmaceutical products; an act then justified as falling under a derogation period which allowed for compliance with certain regulations. As confirmed in 2008 by individual court rulings, Polish law does not recognize “conditional” authorizations in this situation; those actions by the Polish Government are inconsistent with EU rules and Polish pre-accession obligations. Unfortunately, additional conditional authorizations have been issued with retrospective grant dates preceding the date of EU accession and supposedly brought within the derogation by way of published amendments to the original list so that the list now covers over 1,000 drugs. Poland should remove the wrongfully approved products from the Polish market.

At the end of 2008, the European Commission submitted a case to the European Court of Justice (ECJ) against the Republic of Poland for allowing a “ghost copy” of the original product Plavix.⁵⁷ On December 22, 2010, the ECJ ruled that Poland had violated European Community law.⁵⁸ Specifically, the ECJ (fourth chamber) held that the Republic of Poland had failed to fulfil their obligations under Article 6(1) of European Parliament and Council Directive 2001/83, in conjunction with Article 13(4) of the Council (EEC) Regulation No. 2309/96, Article 89 and 90 of Regulation (EC) No. 726/2004 for placing and keeping generics of the reference product Plavix on the market after May 1, 2004. The Polish Government indicated in its response to the European Commission that it feels the issue has been resolved; PhRMA disagrees with the Polish Government’s assessment.

Market Access Barriers

Significant Reimbursement Backlog for Innovative Medicines

Between 2006 and 2011, only a small number of new molecules were granted reimbursement status;⁵⁹ including eight new patented products in 2010 and five new molecules in 2011. However there are still approximately 100 new molecules waiting for inclusion on the reimbursement list.

In 2008, the Ministry of Health (MOH) announced that the backlog had been eliminated by virtue of sending all pending applications to a Health Technology Assessment agency, the AOTM. However, the respective powers of the AOTM president, the AOTM Consultation Council and MOH in issuing and accepting recommendations for reimbursement are not clear. Current provisions do not meet the appropriate standards of transparency (e.g., a clear appeals procedure), and make the decision-making process lengthier and unpredictable. The transfer of applications to the AOTM body in no way mitigates Poland’s obligations under the EU Transparency Directive, including the requirement that it issue individual decisions within 90 days.

⁵⁷ *Official Journal of the European Union*, “(Case C-385/08)” June 12, 2008, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:313:0012:0013:EN:PDF> (last visited Feb. 6, 2012).

⁵⁸ “ECJ judgment: generic illegal in Poland” at <http://blog.dzp.pl/pharma/ecj-judgment-generic-illegal-in-poland/> (last visited Feb. 6, 2012).

⁵⁹ *Id.*

The AOTM's role and procedures were made a little clearer via updates to the Healthcare Law which came into force in 2009 and in 2011. The updates contain new mechanisms for creating guaranteed and non-guaranteed medical services (a "Basic Benefit Package"), and for clarifying the role of Health Technology Assessment in the reimbursement process. However, the updates leave many gaps in the transparency of the government pricing and reimbursement system. The regulations still *do not* require objective and verifiable decision-making criteria, justification of decisions, or comprehensive administrative and judicial appeals procedures. Guaranteed and non-guaranteed medical services is reviewed every year, and the AOTM has the power to issue a binding negative recommendation for a service, while its positive recommendations are still subject to a financial feasibility test by the MOH.

In addition, according to the updated Healthcare Law, the MOH has introduced high fees for the assessment of the HTA reports that are attached to drug dossiers submitted to the AOTM, an extra cost which relates in practice only to innovative molecules.

Government Pricing Policies

Similar to reimbursement decisions, government pricing decisions also are made by regulation and thus the merits of the decision cannot be appealed to or reviewed by an independent court.

The new Reimbursement Bill was passed by the Parliament and signed by the President of Poland on July 1, 2011. The new law includes the introduction of fixed prices and margins for drugs financed from public money. The bill is meant to both fully implement the Transparency Directive and impose a number of new cost containment measures: a reimbursement budget cap of 17 percent, expansion of therapeutic reference pricing, fixed margins and prices, and risk sharing agreements or claw backs.

Parliament also approved a clause that requires pharmaceutical companies to reimburse the government 50 percent of all costs above the National Health Fund's budget.

PhRMA member companies believe that many aspects of this bill will result in a less predictable market that continues to devalue innovative medicines. For example, the declared purpose for fixing government prices in the retail (pharmacy) sector is to encourage patients (who pay the highest percentage of the drug price above the public reimbursement limit) to switch to generic medicines. For hospital products, the Reimbursement Law is unclear as to how prices will be exactly determined, the impact of new tender rules, and the effect of switching from therapeutic programs per illness to drug programs per product (these define how some products, mostly distributed through Polish hospitals, reach patients; they often limit the number of patients that have access to a particular medicine).

Limitation in Access to Physicians and Pharmacists

Another regulation was adopted on December 1, 2008, which has had significant impact on U.S. pharmaceutical companies doing business in Poland. The regulation limits access to physicians and pharmacists by requiring that visit dates be pre-arranged, undertaken only after working hours, and after obtaining the consent of the manager of the institution in question. According to the regulation, additional formalities connected with sampling must also be followed, such as a declaration of the Marketing Authorization Holder submitted to the Pharmaceutical Inspectorate.

The lack of precise wording and implementation guidelines has created general confusion regarding the proper interpretation and implementation of the regulation, *e.g.*, how should companies respond to direct requests for information from physicians. Interpretation and practice differs from hospital to hospital and from region to region. Given the lack of guidance, many larger, important hospitals and medical institutions have simply banned all contact between medical representatives and physicians.

Lack of Meaningful Dialogue between MOH and PhRMA Member Companies

The MOH, despite initially declaring willingness to hold regular meetings with representatives of the pharmaceutical sector, has in effect put a stop to meaningful dialogue. Negotiations with individual companies concerning specific treatments are still held, but the MOH has made it clear that it does not consider industry bodies such as INFARMA, the Polish national association, a relevant interlocutor for broad policy discussions. Thus, PhRMA member companies' concerns and proposals related to Poland's healthcare sector are not considered when the Polish Ministry of Health advances policy proposals that significantly impact the operations of the pharmaceutical industry.

As a result, changes in the legislative environment sometimes happen very suddenly, without sufficient warning to enable an adjustment in the operational model of innovative pharmaceutical companies; for example, the change in regulations governing promotion and contact with physicians. Another factor aggravating this situation is the failure to implement new legislative standards that require MOH to provide public notice and opportunity for comment at the early legislative stage – *i.e.*, the creation of Legislative Assumptions. Currently these assumptions are kept confidential, which violates the legal standards governing the legislative process in Poland. PhRMA strongly encourages the U.S. Government to suggest that the Polish Government, including the Ministries of Economy, Health, and Finance, engage in a systemic and sustained dialogue with the innovative pharmaceutical industry with the goal of resolving these long-standing concerns.

Discrimination

The Government of Poland is discriminating against PhRMA's members by retroactively fining companies large sums of money for previously accepted import procedures. To date, civil damage claims have been filed by Poland's National Health

Fund against 31 pharmaceutical companies (including many U.S. companies present in Poland).

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 it brings to Portuguese patients.

Key Issues of Concern:

- **Ineffective Patent Enforcement:** Inadequacies in the manner in which Portugal enforces patents enable generics to be launched prior to the expiration of the originator's patent rights.
- **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 plans to reduce public spending on pharmaceuticals to 1.25 percent of GDP in 2012 and close to 1 percent in 2013.
- **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 2012 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 Protection

Ineffective Patent Enforcement Mechanisms

Patent protection is a crucial incentive to ensure 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 of requests for preliminary injunctions – provided naturally that it received sufficient resources to operate effectively.

However, and despite the fact that under the MOU the Portuguese Government is bound to make this court fully operational by the first quarter of 2012, in December 2011, the Government approved a Law submitting to compulsory arbitration any disputes arising from the invocation of intellectual property rights related to pharmaceuticals. There is no indication that this measure is temporary or an interim step during the time needed for the specialized court to become operational.

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”). However, the pharmaceutical goals contained in the MOU are simply not attainable, and could seriously jeopardize patient access to innovative medicines. Specifically, the Portuguese Government has agreed to reduce public spending on pharmaceuticals to 1.25 percent of GDP by the end of 2012 and to about 1 percent of GDP in 2013. To put these goals 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 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 are systematically faced with 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 of the criteria for determining reimbursement hinders the companies' ability to accurately portray and demonstrate the added-value of their products. In a context where the criteria according to which the regulator decides are not perfectly established and known beforehand, PhRMA member companies are systematically faced with the challenge of demonstrating and quantifying the value of innovation – an exercise which is increasingly disregarded by INFARMED.

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

Debt owed by NHS hospitals to pharmaceutical companies has reached unprecedented levels, amounting to approximately €1.2 million in October 2011. Although the contractual payment term is 90 days, the average payment delay now exceeds 450 days.

Per the MOU, the Portuguese Government committed by the third quarter of 2011 to establish a strategy and a binding timetable to clear all arrears in the health sector and simultaneously to prevent the re-emergence of arrears. However, no

strategy has been developed; nor has the Government engaged in consultations with the industry to develop a solution.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 pharmaceutical imports and temporary limitations to transfer capital abroad. Also, there has been no progress to address the backlog of patent applications and the lack of protection for test and other data as required by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as well as the lack of an effective patent enforcement mechanism whereby innovative pharmaceutical companies may obtain injunctive relief against infringing follow-on products during the patent term.

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.
- **Lack of Effective Patent Enforcement:** Argentina does not provide measures which provide for effective patent enforcement efforts prior to marketing approval of follow-on pharmaceutical products.
- **Import Restrictions:** The government has told companies that in order to import their products, they must export the same amount; that is, for every dollar imported, there has to be one dollar worth of exports. This verbal decision imposes quantitative import restrictions that appear to be in violation of Argentina's obligations under Article XI of the General Agreement on Tariffs and Trade 1994 (GATT), and inappropriately restricts U.S. companies operations in Argentina.

For these reasons, PhRMA requests that Argentina remain on the **Priority Watch List** for the 2012 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.

Patent Application Backlog

The Ministry of Economy and the National Institute of Industrial Property (INPI) have taken a number of significant steps to reduce the backlog of patent applications awaiting examination. 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 8 to 9 years. According to private estimates, the overall patent backlog exceeds 16,000 applications.

Along with the delays, there is also growing concern over the increasingly restrictive patentability criteria being applied by INPI with regards to pharmaceutical applications, particularly in the evaluation of novelty and “inventive step.” Such restrictions would affect patents involving polymorphics, new salts and new esters, among others. PhRMA and its member companies will continue to monitor this closely.

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 imposed quantitative restrictions on imports that appear to contravene 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.

Pursuant to this unofficial policy, several companies have reported that shipments of various pharmaceutical products have been stopped by Customs. It has also been reported that these shipments were only released by Customs after the importer demonstrated a commitment to future exports of products or services, investment plans or capital disbursements. Although the Argentine Government appears to be justifying these restrictions on the basis of safeguarding its balance of payments, it is noteworthy that the country still enjoys a significant trade surplus that exceeded \$11.6 billion in 2010.⁶⁰ Whatever balance of payments issue may exist in Argentina, it would not appear, therefore, to be caused by excessive imports. Moreover, neither the obligation to export in order to import, nor the decision to stop products at Customs has been made in writing. At a minimum, therefore, Argentina has failed to provide the level of transparency and due process required of quantitative restrictions under GATT Article XIII.

Should this situation continue, our member companies could face product shortfalls that could ultimately prevent Argentinian patients from receiving the medicines they need.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers related to intellectual property protection and market access.

⁶⁰ See Central Bank of Argentina Macroeconomic Radar, *available* at http://www.bcra.gov.ar/pdfs/indicadores/Radar_i.pdf (last visited Feb. 6, 2012).

BRAZIL

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Brazil remain concerned regarding patentability standards and enforcement, 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, thereby duplicating the review already conducted by Brazil's patent office (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.
- **Adversarial Stance in Multilateral Negotiations:** Brazil continues to oppose international agreements ensuring adequate and effective intellectual property protections.
- **Government Price Controls:** The current system is excessively complex and lacks transparency. The innovative pharmaceutical industry stands ready to assist the Brazilian Government in developing a transparent and consistent pricing mechanism that appropriately rewards the value of innovative medicines.
- **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.

For these reasons, PhRMA requests that Brazil be placed on the **Priority Watch List** for the 2012 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

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 review 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 – that recommends that ANVISA limit its role in the examination process to health and safety concerns – an interministerial group was created to define the correct implementation of the decision released by the AGU Office. It was expected that the Interministerial Group would publish its conclusions by January 2, but as yet no report has been released.

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. While the 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 drug 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

The Government of Brazil has not supported multilateral negotiations to provide adequate and effective intellectual property protections. In fact, the Government of Brazil has opposed proposals to provide more effective protection and has introduced proposals to reduce the current level of protection.

In addition, the Government of Brazil has actively advocated the imposition of special disclosure requirements in patent applications related to inventions involving genetic resources. These special requirements could erect additional barriers for obtaining and enforcing patents without providing any significant benefits for holders of genetic resources. Not only has the Government of Brazil advocated imposition of these requirements within the framework of the Convention on Biological Diversity and the U.N. Food and Agricultural Organization, but also in the World Trade Organization, the World Intellectual Property Organization, and the World Health Organization. Brazil's efforts impede progress in improving rights to innovators in multilateral organizations.

Market Access Barriers

Government Price Controls

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.

In March 2011, the Government permitted a price increase of between 3.54 percent and 6.01 percent depending on the share of generic medicines in the therapeutic class.⁶¹ These figures do not take into account increases in manufacturers' costs, including government-mandated salary increases and the usual increases in the cost of doing business that exceed the rate of inflation as measured by the CPI.

The Brazilian Government has already recognized the inaccuracy of the price formula currently in use and spontaneously started to assess possible modification in

⁶¹ Official Gazette No. 49, Session 1, p. 1 (Mar. 14, 2011).

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 improve Brazilian ability to attract new investments in technology.

Public Private Partnerships – PPPs and Government Purchase

The Brazilian Government issued the federal law 12.349/10 granting preferences for national products and services in public purchases. The full implementation of this new policy still depends on the regulation that will define the requirements for a product or service to be considered “national” and thus entitled to a limited 25 percent overprice.

Our members understand the motivation behind the new public purchase policy and believe they can cooperate to improve Brazilian Government conditions to acquire products and services with high quality standards. Bearing this in mind, the pharmaceutical companies and local association stand ready to contribute to this dialogue and expect that the measures to be implemented do not lead to a 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 2011 attributable to trade barriers related to intellectual property protection and market access.

CHILE

PhRMA welcomes the Chilean Government's efforts during 2010 and 2011 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:** The innovative industry believes 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 to Watch List in 2012, and thus PhRMA requests that Chile remain on the **Priority Watch List**. 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 to any medicine already covered by a patent or patents covering the active ingredient until final decisions regarding the validity or non-infringement of the relevant patents can be made;
- 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).

Notwithstanding the Chilean government’s stated intentions and its preliminary work on patent enforcement legislation, PhRMA believes that the government’s concrete actions to date do not yet merit an upgrade in Chile’s Special 301 status from PWL to WL. However, PhRMA would welcome an Out-of-Cycle review of Chile if and when the Chilean government achieves final congressional approval of an effective patent enforcement system consistent with the aforementioned conditions.

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);
- The "full and complete denomination" of protected data will be published in the resolution granting the sanitary registration (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 2011 attributable to trade barriers related to intellectual property protection and market access.

DOMINICAN REPUBLIC

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in 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.

For these reasons, PhRMA requests that the Dominican Republic be placed on the **Priority Watch List** for the 2012 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.

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 January 6, 2012, there were 1,362 patent applications pending, out of which 858 were pharmaceutical or chemical patent applications. Moreover, only 98 patent certificates have been issued in the last 12 years, 59 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 2011 attributable to trade barriers related to intellectual property protection and market access.

VENEZUELA

PhRMA's member companies face several market access barriers in Venezuela, including non-existent intellectual property protections, draconian 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, as a means to control inflation. Although the government claims the Decree will limit "speculation," critics assert it will lead to shortages. As yet, it is unclear how the Decree, which is due to go into effect at the end of the year, will affect the prices of pharmaceuticals, which are already subject to 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 be placed on the **Priority Watch List** for the 2012 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

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.

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 that will create a new agency to limit profit margins for certain industries, including pharmaceuticals. That decree is due to be implemented by the end of the year. While the precise ramifications of the Law Decree are yet unknown, it is likely that it will mark the end of Venezuela's long-standing practice of allowing free-market pricing for non-essential medicines (accounting for approximately 90 percent of the market by value). Market-based pricing is essential in Venezuela in order to allow innovative pharmaceutical companies to subsidize WHO price-controlled medicines and to recoup the significant investment required to generate research data and the up-front costs of product launch.

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.

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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 pharmaceuticals products, investment and innovation. There are significant barriers, however, that continue to impede market access for medicines, and act as a deterrent to investment and innovation in this country.

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 to obtain the lowest possible price. The resulting price does not reward the significant investment involved in developing the innovative medicine; nor does it 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 2012 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, 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 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 access 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. Violation of Algerian patents observed in recent years has 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.

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 to obtain 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.

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 are prohibited. This decision

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".

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) has published lists of such products comprising hundreds of branded medicines. This importation policy is 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 endangering Algerian patients.

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 temporarily block importation as a cost-containment tool. The unintended consequence, however, is that it can 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 levels set by the government. The increased margins from these sales encourage pharmacists to switch prescriptions to generics, a switch that is allowed under the 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 has been applied to new companies, not to prior existing companies.

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 also invest in a distribution infrastructure.

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.

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 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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 2012 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. Three 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.

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 soon. 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. Consumers find it difficult to distinguish counterfeit or sub-standard products. This continuing trade in counterfeits may become a significant public health issue in Lebanon, despite surveillance efforts by the authorities.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers related to intellectual property protection and market access.

PAKISTAN

The Pharmaceutical Research and Manufacturers of America (PhRMA) member companies operating in Pakistan are currently facing new challenges as a result of the recently passed 18th amendment to the Pakistani Constitution (18th Amendment). Per that amendment the power of 22 federal ministries, including the Ministry of Health, was devolved to the provincial governments, resulting in great uncertainty as to how healthcare is regulated in Pakistan. This development compounded many pre-existing concerns, including inadequate protection of intellectual property rights, inappropriate government pricing policies and restrictive local manufacturing requirements.

Key Issues of Concern:

- Intellectual Property Protection
- Absence of Drug Regulatory Framework
- Government Pricing Policy
- Local Manufacture requirement

For these reasons, PhRMA requests that Pakistan remain on the **Priority Watch List** for the 2012 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

As a member of the World Trade Organization (WTO), Pakistan is required to implement Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which prohibits unfair commercial use of regulatory data. To date, Pakistan does not protect such data against unfair commercial use. Such protection should preclude direct and indirect reliance by the Ministry of Health (MOH) (or the successor Regulatory Authority post the 18th Amendment) on data used to support initial marketing approvals of original products and marketing approval decisions based on that data for a period not less than five years. Policies and procedures are also needed to safeguard the interest of innovators in case data are leaked after submission of the dossiers to health authorities. The concerned officials and other parties should be held accountable for violations of this protection.

Since 2004 the Pakistani Government has been discussing a draft law that would extend protection to pharmaceutical test data. PhRMA's member companies are concerned by the Government's inordinate delay. It is our understanding that the MOH made changes to the draft after it was agreed upon by all stakeholders. The MOH again asked stakeholders certain questions relating to minimum TRIPS compliance and how it should proceed. PhRMA member companies submitted their response through the

Pharma Bureau,⁶⁵ which represents innovative pharmaceutical companies in Pakistan. Subsequent to the passage of the 18th Amendment, the Government of Pakistan has not shown interest in resolving this issue. PhRMA member companies request assistance in expediting adoption of meaningful regulatory data protection.

Patents

Certain changes made to the Patent Ordinance of 2002 drastically impacted the effective enforcement of pharmaceutical patents. Per that Ordinance, Pakistan:

- Eliminated use patents;
- Restricted patent filings to single chemical entities for pharmaceutical and agrochemical inventions;
- Limited protection for derivatives or salts;
- Introduced onerous barriers to patenting biotechnology based inventions; and
- Established a mechanism for compulsory licensing if an invention has not been created in a manner that promotes the “transfer and dissemination of technology.”

The Pharma Bureau submitted comments to the IPO highlighting the anomalies and shortcomings of the Patent Ordinance in 2000, 2002, and last year. As yet, however, no action has been taken. At a minimum, the Patent Amendments of 2002 should be repealed, and Patent Ordinance 2000 should be restored.

Meanwhile, the MOH continues to register generic versions of patented products marketed by U.S. and other multinational pharmaceutical companies. As a result of these problems, patent protection in Pakistan remains inconsistent with Pakistan’s WTO obligations and disadvantages PhRMA member companies.

Mailbox Applications

Under the Patent Act, the IPO initially committed to process so-called “mailbox” patent applications within 18 months of receipt (a deadline that was subsequently extended to 27 months). To date, however, no mailbox applications have been processed. This lack of activity has compromised the rights of PhRMA member companies with pending applications. The proposed amendments to the Patent Ordinance 2002 aim to restore a meaningful deadline and should be supported.

Market Access Barriers

Absence of Drug Regulatory Framework

After the 18th Amendment was passed in June 2011, the regulation of health became a provincial matter and the MOH was dissolved. Although Pakistan created a

⁶⁵ The National Association of Research Based Pharmaceuticals in Pakistan.

Commission to implement the 18th Amendment (Implementation Commission), there has been no provincial or transitional legislation to fill the void left by the MOH. Even worse, the provincial governments were not prepared to assume their new responsibilities, and thus did not have the capacity or expertise necessary to handle the intricate issues involved in regulating pharmaceuticals. As a result, all aspects of the drug approval process from registration of a new molecule to obtaining a pricing and reimbursement determination came to a standstill. In a positive development, the Implementation Commission appears poised to resurrect the National Drug Regulatory Authority that had been largely suspended since approved by the Federal Cabinet in 2002. However, the current situation remains one of extreme confusion and has significantly disrupted our member's operations and patient access to innovative medicines.

Government Pricing Policy

Historically, the Pakistani Federal Government arbitrarily set the prices of products at extremely low levels, which did not take into account the value of innovation. Moreover, although the Government had considered implementing a policy to adjust prices to compensate for devaluation and/or exchange rates fluctuation, this change was never implemented. As a result, government prices for pharmaceutical products have not been revised since 2001, even though the cumulative inflation since that time has been over 100 percent. Although the federal government had been in the process of developing a new pricing policy (and had solicited industry input in developing that policy), the Pakistani Government failed to approve the new pricing policy prior to the passage of the 18th Amendment. The new pricing policy, therefore, remains, in limbo.

Local Manufacture Requirement

Pakistan's former MOH established a local manufacturing requirement as a prerequisite for product registration despite the fact such measures discriminate against imported products and act as an import ban contrary to Pakistan's international obligations. In addition, the MOH placed restrictions on toll manufacturers. As a result of these restrictions, registration of new chemical entities was often denied. Although the MOH no longer exists, these restrictions appear to remain in force.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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. 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.
- **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 of key stakeholders, including industry, physicians, and patient groups, and denied Australian patients access to these innovative medicines. In a positive development, the Australian Government agreed at the end of September to work with stakeholders on this process going forward and to list the medicines deferred to date; nonetheless, the Australian Government has still reserved the right to defer more medicines in the future.

For these reasons, PhRMA requests that Australia be placed on the **Watch List** for the 2012 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 right that is used to prevent unfair commercial use of confidential data by a third party. Like other forms of IP rights, data protection stimulates companies to invest in innovation by ensuring for a limited time that potential competitors cannot take commercial advantage of the innovator's data. Companies must demonstrate that new products are safe and effective for human use. This requires extensive research, which can take many years and substantial financial investment to complete. Data protection protects any data thus generated against being used to obtain product registration by a third party for a fixed period of time.

Strengthening the data protection provisions in Australia, which are currently the weakest in the developed world, 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 and new dosage regimens.

Notice of Patent-Infringing Products

Australia 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.

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).⁶⁶ 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.⁶⁷ 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 breached the intent, if not strictly the letter, of the May 2010 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.

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. 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.

⁶⁶ 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. 6, 2012).

⁶⁷ "Submission to the Senate Finance and Public Administration Committee Inquiry into the Government's Administration of the Pharmaceutical Benefits Scheme," Medicines Australia, 18 July 2011, available at <http://medicinesaustralia.com.au/files/2010/02/20110715-sub-deferrals-senate-inquiry-FINAL-lodged.pdf>. (last visited Feb. 6, 2012).

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, particularly given the recent developments regarding the Cabinet deferral of listing certain new medicines.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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:

- **Lack of Effective Patent Enforcement:** PhRMA member companies call for a system consistent with commitments in the Korea-U.S. Free Trade Agreement (KORUS FTA) that provides effective mechanisms to resolve patent issues before follow-on products enter the Korean market.
- **Vague and Unclear Regulations Regarding Data Protection, Particularly in Regards to New Indications:** PhRMA and its member companies urge Korea to establish a full and complete data protection system consistent with international standards and the KORUS FTA.
- **Lack of 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.
- **Lack of 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 the KORUS FTA, the MOHW should reform its government pricing policies 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 2012 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 Enforcement of Patents

PhRMA member companies call for a system that provides effective mechanisms to resolve patent issues before a follow-on product (a generic or biosimilar) enters the market in Korea. This could improve the operating environment by: 1) providing transparency and predictability to the process for both innovative and generic companies; (2) creating more predictability needed to make investment decisions; and (3) ensuring timely resolution of genuine disputes. After the KORUS FTA is entered-into-force, Korea is obligated to institute such mechanisms within 36 months. PhRMA member companies urge the government to pass draft legislation fully implementing the patent enforcement provisions of the FTA as soon as possible.

Regulatory Data Protection

Korea currently implements post-marketing surveillance. During the post-marketing surveillance period, marketing approval cannot be granted to a third party unless that third party has submitted safety and efficacy data that is equivalent or of greater magnitude of the data submitted by the innovator company to obtain the first approval. Under this system, new drugs are in effect granted six years of protection from follow on products; and four years for new indications. Protection for new indications, however, is only given when they are recognized as having “distinctly different” efficacy and effect from those already approved new indications. Due to the lack of an objective definition of “distinctly different” in the applicable regulation, few new indications receive appropriate data protection. PhRMA and its member companies urge Korea to establish a full and complete regulatory data protection system consistent with international standards, and in line with the commitments made in the FTA.

Market Access Barriers

Lack of 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, which has led to a lower level of investment in new medicines, particularly by the Korean domestic industry.⁶⁸

For example, in addition to 20 percent price cuts on off-patent medicines announced in 2010, the MOHW revealed on August 12, 2011, that it plans to reduce off-

⁶⁸ Korean pharmaceutical companies invest 4-5 percent of their revenues in research and development, which is much less than 10-25 percent of their global counterparts. “R&D Activities in the BT Industry: Its Economic Effects and Policy Suggestion (Final Report)”, KRPIA, Mar. 2009.

patent medicine prices by as much as 26 percent.⁶⁹ The 2010 price cuts, which were introduced as a result of the “re-arrangement” plan (discussed below), were to be introduced over a three-year phase-in period, and thus were still ongoing when the latest price reductions were announced.

These latest price reductions are being implemented with little input by stakeholders, including industry. The aim and the grounds for changing specific pricing rules are not clearly understood by the industry. Rather, the details for each of the pricing policy changes were pre-determined by the government, and stakeholders were not allowed to provide any meaningful input or consultation in the process of developing these reforms.

Needless to say, if these government price reductions are implemented as planned, revenues for both the domestic and multinational pharmaceutical industry operating in Korea will be reduced dramatically. Government price cuts along these lines create an unpredictable operating environment for the pharmaceutical industry that relies on long-term planning to make the vital investments 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 safety and effectiveness testing. Large, arbitrary government price reductions are not conducive to the investments required for the research-based pharmaceutical industry to grow and thrive.

The Re-arrangement Plan

In 2010, the Korean Government resumed a review begun in 2007 of the country’s National Health Insurance (NHI) program, seeking cost-containment measures through pharmaceutical price reductions under the so-called “re-arrangement” process. As part of this effort, MOHW initiated in July 2010 an evaluation process for 47 therapeutic drug groups, and is currently implementing over three years a comprehensive price reduction plan. This action by MOHW reduces prices of most off-patent medicines by 20 percent.

Although PhRMA was pleased that the Korean Government decided to exclude all on-patent medicines and those drugs subject to the recent 20 percent price cuts from the price reductions, the MOHW price reductions of 2010 coupled with the proposed price reductions of 2011 will result in the prices of hundreds of off-patent medicines being cut by as much as 46 percent in a matter of three years.

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,” which requires hospitals, clinics and pharmacies to disclose the actual price purchased for drug products. Where prices are lower than the official maximum reimbursement price

⁶⁹ “Massive Reduction of Drug Price Will Reduce Burden Caused by Excessive Drug Price of People,” Korean Ministry of Health and Welfare, press release, Aug. 12, 2011.

(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. Meanwhile, the weighted average of actual transaction prices collected from across the market will be used to reduce the official MRP annually, and the first price reduction to the MRP was expected as early as July 2012.

While 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. 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.

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 are now subject to 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.⁷⁰

The MOHW price of new drugs under the current Drug Expenditure Rationalization Program is already far too low, less than half of the prices of new drugs from A7 or A9 countries.⁷¹ The further reduction of government prices of the existing

⁷⁰ On January 6, 2012, MOHW announced a plan to enhance competitiveness of the Korean pharmaceutical industry. As part of the announcement, MOHW noted that for comparators' weighted average price, MOHW will use the 2011 price, which was unaffected by recent price reduction. If implemented as described, new drug prices would maintain the current price level even after implementation of recent off-patent price reduction. The details of this new policy will not be finalized until March or April 2012.

⁷¹ "Global Price Benchmarking," Analysis prepared for KRPIA by IMS Health, Apr. 2009.

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.

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, lecture fees, consultation fees, and gifts of nominal value.

The laws became effective as of November 28, 2010 and the enforcement regulations were finalized in December 3, 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, consultation fees and gifts of nominal value. 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 2011 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:** 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.
- **Listing Pharmaceuticals on the National Formulary:** Malaysia's stringent process for listing pharmaceuticals on the national formulary curbs access to innovation by taking up to five years following regulatory approval. 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.
- **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.

For these reasons, PhRMA requests that Malaysia remain on the **Watch List** for the 2012 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 as well as deters the repetition of infringement. Timely and efficient patent protection 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 also 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.

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.

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.

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 sixty days. However, PhRMA's member companies continue to report lengthy delays. Effective reform that streamlines Malaysia's regulatory approval process to sixty days or less could greatly expand market access and patients' access to medicines.

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.

Anti-Counterfeiting Enforcement

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

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers related to intellectual property protection and market access.

THE PHILIPPINES

PhRMA's member companies face significant intellectual property and market access concerns in the Philippines. PhRMA's member companies also continue to see an improvement in dialogue with the Government of the Philippines and applaud ongoing efforts to engage on healthcare policy and other issues that affect the ability of companies to do business in the country. As a result of this consultative process, PhRMA upgraded its recommendation in 2010 that the Philippines remain on the Special 301 Watch List for 2011. We hope to see further progress towards improvement in the intellectual property and regulatory environment in 2012.

Key Issues of Concern:

- **Cheaper Medicines Act:** The Cheaper Medicines Act amended the Philippines Intellectual Property Code to limit the patentability of new forms and uses of pharmaceutical products. As a limitation designed to discriminate against certain technologies, the Act is inconsistent with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
- **Effective Patent Enforcement:** The Philippines should reinstate a mechanism to provide patent holders with a mechanism to resolve patent disputes prior to the marketing of follow-on products.
- **Price Reductions and Marketing Restrictions:** Department of Health (DOH) officials continue to acknowledge that the Maximum Drug Retail Price (MDRP) mechanism of the Cheaper Medicines Act has not resulted in expanded patient access. The advancement of universal quality healthcare should serve as the primary objective to expand access. Several legislative proposals in the Congress that propose further price reduction mechanisms and marketing restrictions could have a significant impact on market access if adopted.
- **Parallel Importation:** There is concern that the Philippines is permitting the parallel importation of unregistered pharmaceutical products. With limited infrastructure and monitoring mechanisms, the safety and quality of these imports is at risk or unlikely and the prevention of imported counterfeit medicines is not possible.
- **Anti-Counterfeiting Enforcement:** While anti-counterfeit activities in partnership with PhRMA's member companies continue, further consultations with the Philippines are necessary on a provision of the Cheaper Medicines Act allowing non-prescription products to be sold in "small quantities, not in their original containers" in retail outlets.

For these reasons, PhRMA requests that the Philippines remain on the **Watch List** for the 2012 Special 301 Report. PhRMA's member companies encourage the U.S. Government to raise these and other noted concerns as priorities for resolution during bilateral consultations with senior representatives of President Aquino's Administration. These consultations should also be expanded to include Congressional leaders, as a significant number of concerns continue to emerge by way of legislation. Successful resolution of these issues will greatly improve the intellectual property environment in the Philippines, fostering a stronger healthcare system and new investment through the embrace of innovation.

Intellectual Property Protections and Enforcement

Cheaper Medicines Act

While meaningful dialogue has taken place since 2010 with President Aquino's Administration and the Intellectual Property Office of the Philippines on the intellectual property provisions and implementing rules and regulations of Republic Act No. 9502: The Universally Accessible Cheaper and Quality Medicine Act of 2008 (Cheaper Medicines Act), there are a number of provisions which degrade intellectual property protections and serve as market access barriers. Specifically, the Cheaper Medicines Act amended the Philippines Intellectual Property Code to limit the patentability of new forms and uses of pharmaceutical products. As a limitation designed to discriminate against certain technologies, PhRMA's member companies continue to assert the Cheaper Medicines Act is inconsistent with the TRIPS Agreement.

Effective Patent Enforcement

It is important that the Philippines consider new implementing mechanisms for resolving patent issues prior to the marketing of follow-on products, such as generics. Such a mechanism was in place before a 2005 DOH Administrative Order (A.O. No. 2005-0001) took effect, which has resulted in PhRMA's member companies having to pursue costly and time consuming legal remedies to protect products from generic competition prior to patent expiration. If such issues were resolved prior to marketing of follow-on products, the Philippines could alleviate legal resource burdens as well as restore the rights of patent holders. PhRMA's member companies recommend the repeal of Administrative Order 2005-0001 and an agreement be signed by the Intellectual Property Office of the Philippines (IPOP HL) and the Food and Drug Administration of the Philippines (FDA) that a certificate of product registration for a generic medicine will not be issued by FDA unless the applicant can present a certification from IPOP HL confirming the patent of the molecule has expired.

Market Access Barriers

Price Reductions and Marketing Restrictions

While the MDRP mechanism adopted under the Cheaper Medicines Act continues to stifle market access for PhRMA's member companies, DOH officials continue to acknowledge that the mechanism has not resulted in expanded patient access. Poverty serves as the primary cause for limited access to medicines⁷² and the advancement of universal quality healthcare should be the primary objective to achieve a sustainable solution. Through enhanced coverage, an expansion in the benefits package, and the broader availability of health services, the Government of the Philippines can effectively expand access to medicines while promoting healthcare innovation that will attract new investment.

PhRMA's member companies continue to engage the Philippine Government on certain provisions of the newly proposed "Philippine Medicines Policy 2010: Ensuring Access to Medicines for Filipinos," as the proposal appears to potentially reintroduce government price controls and institute mechanisms to restrict pharmaceutical marketing practices. The proposed restrictions also include limits on detailed product materials, the elimination of prior approval of product materials by the DOH, and prohibitions on medical professionals attending industry conferences. PhRMA's member companies also continue outreach to the Philippine Senate and House of Representatives with jurisdiction over current proposals that could significantly impact market access and raise serious safety concerns, such as the establishment of a Drug Price Regulatory Board, requirements that pharmaceutical firms make generic versions of patented products available with a 20-25 percent discount, an annual submission of marketing expenditures, and mandatory price discounts on medicines for public sector employees.

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

Parallel Importation

There is concern that the Philippines is resorting to implementation of Rule 9 of the Implementing Rules and Regulations (IRR) of the Cheaper Medicines Act, allowing the parallel importation of unregistered pharmaceutical products. With the lack of adequate infrastructure and monitoring mechanisms in the Philippines, the safety and quality of parallel imports is at risk or unlikely, and the prevention of imported counterfeit medicines is not possible. PhRMA's member companies hope to work closely with the

⁷² University of the Philippines Blueprint from Healthcare 2010-2015 and Beyond; Imperatives for Health Care Financing Reform, Professor Emmanuel Leyco, Center for Legislative Development; IMS Health Philippines, 2009 Study Commissioned by the Philippines Department of Health.

Government of the Philippines to require the FDA to impose full registration requirements on parallel imports and for the Bureau of Customs to stop the importation of unregistered medicines.

Anti-Counterfeiting Enforcement

The Government of the Philippines continues to expand its anti-counterfeiting activities in partnership with PhRMA's member companies and raise public awareness regarding the dangers of unsafe medicines. These efforts will continue in 2012 and PhRMA's member companies hope to continue consultations with the Government of the Philippines on a provision of the Cheaper Medicines Act allowing non-prescription products to be sold in "small quantities, not in their original containers" in retail outlets. Such a provision works against ongoing anti-counterfeiting activities and endangers the health and safety of the country's citizens. The Philippines should adopt heightened criminal penalties for those caught manufacturing, supplying, or selling counterfeit medicines. PhRMA's member companies also advocate for expanded anti-counterfeit enforcement powers for IPOPHL.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 and others in the research-based pharmaceutical industry. This communication will ultimately help achieve the common goal of Government and industry; enabling patients to live longer, healthier, happier, 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 Taiwan patients;
- Government prices for new drugs do not adequately reflect the value of innovation. Increasingly, innovative pharmaceutical companies are required to sign Price-Volume Agreements (PVA) which unduly penalize innovators for developing successful products;
- 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, specifically the Drug Expenditure Target which is intended to help increase patients' access to innovative medicines and the Taiwan Government to maintain a financially stable healthcare system.

For these reasons, PhRMA requests that Taiwan be placed on the **Watch List** for the 2012 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

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.

Effective Patent Enforcement

Taiwan has not yet established systems to effectively prevent marketing of patent-infringing pharmaceutical products. The American Chamber of Commerce in Taiwan noted that “[i]n 2009, at least 35 patent-infringing drugs were approved in Taiwan, and many of them were subsequently included on the reimbursement lists.⁷³ 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 Taiwan 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. In 2009, the research-based pharmaceutical industry began a constructive dialogue with the government on reimbursement-pricing policy. This dialogue attempted to focus on how the BNHI could incorporate innovation as a factor in its pricing and reimbursement policies. However, the trend of decreasing reimbursement prices offered to new pharmaceutical products has continued, and the pricing process has become less

⁷³ 2010 White Paper, American Chamber of Commerce in Taiwan (ACCT), *available at* http://www.amcham.com.tw/component/option,com_docman/task,cat_view/gid,260/Itemid,377/ (last visited Feb. 6, 2012).

transparent and predictable. In 2010, the average price granted to new drugs reached a new low of 48 percent of the A-10 (10 benchmarked advanced economies) median and 68 percent of the A-10 lowest price.⁷⁴ Since inception of this new system in 2010, only two drugs have been classified as “breakthrough innovations” such that they qualified for the average of A-10 country prices (the highest category of classification).⁷⁵ More new drugs with evidence showing improvement in efficacy and safety should be granted prices at the average of A-10 countries. In the meantime, tools such as Price-Volume Agreements (PVAs) and Health Technology Assessments (HTAs) have been introduced. We urge BNHI to consult with industry in order to develop guidelines that make these two systems more transparent and predictable.⁷⁶

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.⁷⁷ 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.

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. While there has been no official announcement of the PVA policy, this new policy was quietly instituted in a non-transparent and non-accountable manner in the meeting minutes of the Drug Review Committee on the BNHI website. In a letter sent by BNHI to the local innovative pharmaceutical trade association (IRPMA) on August 5, 2011, BNHI committed to revise the PVA guidelines so that they (1) are consistent with international practices; and (2) take into account IRPMA’s recommendations about threshold setting, financial risk sharing, *etc.* We urge BNHI to consult with the industry as these revised guidelines are developed to ensure that the new process is fair and transparent. To that end, industry also proposes that BNHI publish a standard PVA Agreement that provides a predictable model for industry.

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. As yet, however, the DET has not been implemented.

⁷⁴ 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. 6, 2012).

⁷⁵ Id.

⁷⁶ Id.

⁷⁷ Id.

In the interest of rewarding innovation, developing new medicines to meet Taiwan's unmet needs, and ensuring that Taiwan patients have access to these 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. Further, PhRMA asks the U.S. Government to encourage their counterparts in the Taiwanese Government to engage in renewed consultation with the innovative pharmaceutical industry to ensure that government pharmaceutical pricing and reimbursement policies are transparent and offer due process to interested stakeholders and are based on, scientific evidence and patient needs and benefits.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 2012 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 generic pharmaceuticals. Such a patent enforcement mechanism could greatly enhance the business environment by: (1) providing process transparency and predictability for both the innovative and the generic firm; (2) creating a more predictable environment for investment decisions; and (3) ensuring timely redress of genuine disputes.

Market Access Barriers

1. 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.

2. 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.

3. 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.

4. 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

1. 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 which 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.

2. 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 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.

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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 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); and
- *De Facto* therapeutic reference pricing.

For these reasons, PhRMA requests that Finland be maintained on the **Watch List** for the 2012 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.⁷⁸

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.

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

⁷⁸ *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).

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.

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

In Finland, the Pharmaceuticals Pricing Board confirms 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 still 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 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 Finnish system dramatically undervalues the innovation and development costs involved in bringing the patented pharmaceutical to market.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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; 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 lack of transparency and due process in 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-SpiBu). In addition, the comparator therapies so far selected under the GBA's new "rapid" benefit Health Technology Assessment (HTA) process appear to be guided by economic rather than medical considerations.

PhRMA and its member companies encourage a greater dialogue between PhRMA member companies and the German Government. Key issues that should be addressed in this 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 2012 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-SpiBu (Head Association of Statutory Health Insurance). If a manufacturer and the GKV-SpiBu cannot agree on a price, then an arbitration committee will make a binding decision, using EU prices as one reference point.
 - (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-SpiBu 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

So far, no drug has gone through the complete process until determination of the reimbursement price. To date, two companies – in anticipation of an unfavorable result – have decided not to market their new products in Germany because of concerns about inappropriate comparator therapies assigned by the GBA.⁷⁹

First experiences with the rapid benefit assessment indicate that the implementation of the advisory process by the GBA is still insufficient and dissatisfying for the industry. In particular, the data that must be submitted in the dossiers is even more extensive and is proving costly, both in terms of time and resources. Even more troubling, the selection of comparator therapies by the GBA so far seems to be guided by economic rather than medical considerations.

The law also requires manufacturers and the GKV-SpiBu to agree on a framework for the negotiation of the reimbursement price. Those negotiations did not reach a compromise and will now be decided by the arbitration board. The outstanding issue concerns European reference pricing.

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, will also apply 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.

⁷⁹ Global Insight, "AMNOG Blocks Second New Medicine in Germany, Industry Group Calls for Fairer Pricing Rules," Sept. 9, 2011.

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 selected EU-member countries. Although this change only affects a few manufacturers, the direct linkage of German and EU prices represents a disturbing paradigm shift, since prices in the vast majority of EU countries are set by governments and not by the free market.

Process and Transparency

Reimbursement decisions for pharmaceuticals in Germany's statutory health insurance system are made by the GBA, the top layer of the country's self-administration mechanism in healthcare. Voting members of the GBA are named by the federal associations of statutory health insurance funds, hospitals, and physicians. Patient representatives on the GBA have no voting power. With the passage of AMNOG, the GBA becomes 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 2011 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 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 new government prices and for making reimbursement approval decisions. Finally, the positive list reintroduced by the GOG fails to reward innovation and ensure patient access to new therapies.

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 paid for by the government. Medicines that are not reimbursed in some way by the government 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 distributors.

For these and other reasons described below, PhRMA requests that Greece remain on the **Watch List** for the 2012 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;⁸⁰ approximately 50 percent of this was owed to pharmaceutical companies.⁸¹

⁸⁰ Hellenic Association of Pharmaceutical Companies, *A Report on Public Hospital Debt Towards SFEE Member Companies*, at 3 (June 20, 2010).

⁸¹ *Id.* at 3.

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 Euros for the 2010 outstanding debts.

Nevertheless, according to the latest report from the SFEE (October 2011), approximately 32 percent (almost €435 million) of hospital invoices for 2010 remain unpaid, while for the first three quarters of 2011, almost 80 percent (just under €644 million) of hospital invoices had not been paid.

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

Additional 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 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 3 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.
- 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 do not follow any given timetable. This delay extended into 2011.

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. 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.⁸²

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.

Like other therapeutic reference pricing systems, the Greek system assumes that all products used to treat the same condition are interchangeable, without evidence to support this assumption. Treating medicines as if they are identical can harm patients, erode the benefits of patent protection, impede competition, and inhibit future innovation. Moreover, the prices set for each therapeutic group typically undervalue the cost of developing the innovative medicines included within the group.

⁸² Global Insight, *Fallout from Greek Repricing Continues as List of Expensive Hospital Drugs to Be Made Available in Pharmacies Revealed* (Sept. 16, 2010).

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 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. The positive list became effective as of January 1, 2012. SFEE and PhRMA members in Greece are actively working with the Greek Government to reform the positive list so it is not as punitive to innovation as the current model.

In late September 2011, the Greek Government announced an estimated shortfall of approximately €262 million for the year. Therefore, on October 7, the Greek Parliament approved another savings bill to ensure meeting the 2011 targets agreed with the Troika (the law was published in the Official Journal on 2 November 2011). The key provision is a new “entry ticket to the reimbursement system” to be paid as a one-off rebate for all reimbursed medicines – equivalent to 4 percent of total sales at ex-factory price. This rebate was in addition to the general rebate of 4 percent of reimbursed sales for 2011. Payment of these two rebates (which were due by the end of 2011), were offset against any outstanding state hospital debts and government bonds owned by a pharmaceutical company.

PhRMA strongly supports the development of a joint task force between local industry associations and the National Drug Organization, which aims to develop reform measures that support government fiscal targets while recognizing the value of innovation.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers related to intellectual property protection and market access.

ITALY

PhRMA's member companies face several market access barriers in Italy.

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 2012 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 the Italian Drug Agency (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:

- No 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 200 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 no 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.

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). As of 2010, expenditure on retail and hospital drugs was capped at 13.3 percent and 2.4 percent of the NHF, respectively. Any amount spent over the retail cap must be reimbursed by the pharmaceutical companies per their respective share of sales in this segment of the market. Retail overspending has to be paid back from pharmaceutical companies according to the method of the company budget AIFA determines every year. Hospital overspending has to be refunded directly by the Regions. Meanwhile, no other category of healthcare expenditures has faced similar budgetary restraints (although, as noted below, Italy has proposed imposing a cap on expenditure for medical devices in 2012). 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.

Discrimination between the different healthcare sectors is further evidenced by Law 122/2010. Pursuant to this Law, the Italian Government increased profit margins for pharmacists at the expense of wholesalers and the pharmaceutical companies. Specifically, the law reduces the margins for wholesalers by 3.65 percent – from 6.65 percent to 3.0 percent – and in turn increases the margin for pharmacists by the same 3.65 percent – from 26.7 percent to 30.35 percent. As a practical matter, the Law then imposes an additional mandatory 1.82 percent discount on pharmacists, but the pharmacists, on balance still see their margins increase (albeit by the lesser amount of 1.83 percent) while other sectors’ margins are cut. Moreover, the Law mandates a financial pay-back on retail prices of 1.83 percent from pharmaceutical companies. In short, the Law reduces the margins of pharmaceutical wholesalers and companies, yet also increases commercial margins of Italian pharmacies (that already have some of the highest margins in Europe).

Austerity measures proposed at the end of 2011 aim to save a further 1 billion euros in the 2013 pharmaceutical budget. Specific proposals include further reducing the cap on retail pharmaceutical expenditures to 12.5 percent of the NHF, or through a 35 percent clawback from the pharmaceutical companies on any drug overspend in Italy's hospitals. It is expected that a final decision will be made by April 2012. Medical devices will have a cap for the first time fixed at 5.2 percent of the NHF.

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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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, unnecessary 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 and fails to adequately differentiate between biologics, biosimilars, and generics. 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 medicine budget deficit, including wholesale and retail margins, as well as 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.

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 2012 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. Furthermore, the system needs more robust differentiation between biologics, biosimilars, and generics.

Funding

Patient access to healthcare in Romania is negatively impacted by the low-level of healthcare expenditure. In order to increase funding, on June 28, 2010, 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. Furthermore, the current iteration of the claw-back combined with therapeutic reference pricing stifles pharmaceutical innovation.

Since the Government did not reach its funding target, various new versions of the claw-back were proposed throughout 2011, ranging from a 50 to 100 percent claw-back on market growth and a 12 percent payback on the turnover of pharmaceutical producers. The latest proposal is to impose a claw-back on all reimbursed sales at purchasing power parity prices, thus forcing pharmaceutical producers to pay the claw-back not only on their turnover, but also on the margins of their customers (*i.e.*, wholesalers and pharmacists).

Effective October 1, 2011, Romania implemented a new clawback mechanism 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. 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 VAT. In other words, PhRMA member companies must compensate the budget for payments the government makes to wholesalers and pharmacists and for taxes obtained through VAT collection.

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 defined 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.

Generic medicines undergo an abbreviated and less costly registration procedure as they can enter the reimbursement list at any time, 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 2011 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:** Russia has committed to provide six years of regulatory data protection for pharmaceutical test data. PhRMA and its member companies look forward to the concrete implementation of this law upon Russia's accession to the World Trade Organization (WTO).
- **Local Clinical Trial Requirements:** According to the new "Law on the Circulation of Medicines" governing clinical trials, pre-registration clinical trials must be conducted in Russia (with some exceptions). The corresponding provisions have been implemented, causing delays in the registration of new products, thus limiting patient access to innovative medicines.
- **Greater Transparency in Government Pricing:** The Russian Government controls prices of drugs on the Essential Drugs List (EDL). The process to update the EDL (which typically occurs once a year) lacks transparency.

For these and other reasons, PhRMA requests that Russia be placed on the **Watch List** for the 2012 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

In September 2010 the Russian Duma passed legislation to implement regulatory data protection for a period ending six years after approval in Russia in accordance with commitments made to the United States and European Union for WTO accession. The provision will enter into force upon Russian accession, which is expected later in 2012. PhRMA and its member companies applaud this effort and will continue to work with Russian legislative and executive branch officials to ensure that the data protection regime provides effective and enforceable protection for pharmaceutical test data. However, it is vital for the implementation of the data protection provisions that the

Ministry of Health (MoH) amends its order regulating the procedure for a new product registration⁸³ and/or other relevant by-laws accordingly.

Market Access Barriers

Registration and Clinical Trials

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

Recently, Russian healthcare authorities have been talking to their U.S. and EU counterparts about the possibility of mutual acknowledgment (for registration purposes) of clinical trials conducted in a manner consistent with Good Clinical Practices. Although this dialogue indicates that the MoH are aware of the problem, only amending the “Law on Circulation of Medicines” to eliminate the requirement to conduct pre-registration clinical trials in Russia will solve the problem.

The new “Law on the Circulation of Medicines” also failed in providing more transparency in the registration process. In particular, the decision-making of the Ethics Committee is unpredictable and arbitrary.

The New Law on the Health Protection of Population

On November 22, 2011, Russia’s President signed into law a bill on the “Health Protection of the population”. The new law will be enforced from 2012 (with some exceptions).

The innovative pharmaceutical industry is closely monitoring implementation of the new law to ensure that it does not restrict market access. Key aspects that bear watching include:

- The new law sets restrictions on communications between healthcare professionals (HCP) and pharmaceutical companies. The consequences of these restrictions will depend on how they are implemented.
- In a positive development, the new law introduces an orphan disease definition, which provides an opening for discussions on the lack of orphan drugs regulations in Russia. To date, there is no definition of orphan drug in Russia and the “Law on the Circulation of Medicines” needs to be revised to provide a simplified registration procedure for orphan drugs.

⁸³ Order No. 759 N issued on Aug. 26, 2010.

- As a result of the new law, treatment standards have become less clear. Specifically, PhRMA and our member companies would appreciate greater clarity in how treatment standards are developed and if medicines included in the treatment standards, but not included on the Essential Drugs List (EDL) will be reimbursed.

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

The Russian Government controls prices of drugs on the Essential Drugs List (EDL). The process to update the EDL (which typically occurs once a year) lacks transparency.

The rules for registering prices of drugs on the EDL are set by the “Law on the Circulation of Medicines” and the correspondent guidelines approved by the MoH discriminate against foreign producers. Russian producers have a right to ask for a yearly adjustment of their registered prices according to the annual inflation rate, while no similar right is offered to foreign producers. Moreover, local producers are allowed to ask for a price increase citing rising production costs. Meanwhile, according to the “Law on the Circulation of Medicines” and to the MoH pricing guidelines, a price once registered by a foreign producer cannot be changed. This policy is discriminatory.

The Federal Antimonopoly Service Proposals

The Federal Antimonopoly Service (FAS), Russia’s competition authority, has been entertaining proposals that would significantly reduce market access for innovative pharmaceuticals. Specifically, FAS (at the urging of local constituents) is considering enacting a legal obligation for HCPs to prescribe medicines using only international non-proprietary names (INN) and to introduce interchangeability in the state procurement legislation. Both policies would discriminate against producers of innovative medicines and further restrict patients’ access to new treatments.

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 have not demonstrated similarity per the WHO guidelines and therefore fall short of international norms. The safety and efficacy of such products is unknown and could raise health concerns. Furthermore such products could easily enter into regional tendering programs, *inter alia*, which operate within the legal framework provided by Russian federal laws.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 Issues of Concern:

- **Ineffective Patent Enforcement:** Spain, contrary to its obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), does not adequately and effectively protect pharmaceutical product patents
- **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 remain on the **Watch List** for the 2012 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

Despite significant advances in modernizing its intellectual property (IP) laws in the last two decades, the current lack of harmonization between patent protection in Spain and the majority of other EU Members States results in a situation where generic versions of patent protected drugs can be introduced in Spain, while those same products receive full patent protection throughout most of the EU by way of product patents.

Patent harmonization problems exist in Spain which can compromise the rights of innovators. These problems have developed because under the terms of Spain's accession to the EU, the EU did not require Spain to recognize pharmaceutical product claims that had been made in European patent applications prior to October 7, 1992. However, Spain did recognize European pharmaceutical product patent claims in applications filed after that date. On January 25, 1995, the date on which the TRIPS Agreement took effect in Spain, the following types of patents existed in Spain:

- Patents, for which applications were filed and granted before October 7, 1992, and for which Spain did not give effect to pharmaceutical product claims;
- Patents, for which applications were filed on or after October 7, 1992, and for which Spain gave effect to pharmaceutical product claims; and
- Patent applications that were pending from before October 7, 1992, whose claims for pharmaceutical products would not be given any effect in Spain.

Under the subject matter and the transition rules of the TRIPS Agreement (Articles 70.2 and 27.1), PhRMA believes that Spain should have converted process patents for which applications had been filed before October 7, 1992 to pharmaceutical product patents, no later than January 25, 1995. Similarly, under TRIPS Article 70.7, Spain was required to provide for the addition of product claims to any applications for process patents that were still pending on January 1, 1995. Spain, however, did not do so. As a result, holders of such pharmaceutical process patents have had weaker patent protection in Spain than is required by the TRIPS Agreement.

Court Decisions in Favor of Innovative Pharmaceutical Industry

In many separate decisions issued after August 2007, Spanish courts have repeatedly confirmed the direct application of the TRIPS Agreement when judging whether innovative pharmaceuticals should be protected with product patents.⁸⁴ These decisions have protected intellectual property rights of innovators and are welcome outcomes. While the outcomes in these cases are correct and important, legislation or regulatory reform is still needed to incorporate these TRIPS protections into Spanish Law.

Suggested Action

Given that Spain was not required to recognize pharmaceutical product claims that had been made in European patent applications prior to October 7, 1992, many Spanish translations of patent applications did not include product claims appearing in the European patent (following recommendations of the European Patent Office).

A potential accommodation, therefore, would be for the Spanish Patent Office to publish the linguistic revisions of patents, including product claims that already exist in the original European Patent. It would then be easier for the judges to apply the doctrine

⁸⁴ These rulings are: a March 31, 2008 ruling in favor of Pfizer issued by the Commercial Court number 4 of Barcelona; August 7, 2007 and December 7, 2007 rulings issued by the Commercial Court Number 1 of Barcelona in favor of Eli Lilly (these rulings were confirmed on July 31, 2008); a July 30, 2008 injunction in favor of Janssen Cilag, and rulings by Commercial Court number 3 of Barcelona (October 2007) and Commercial Court number 6 of Madrid (November 2007) in favor of Merck Sharp and Dohme; first instance judgment dated October 16, 2006 handed down by Mercantile Court number 3 of Barcelona, which has been confirmed by the Court of Appeal of Barcelona (Judgment dated January 17, 2008); first instance judgment dated November 16, 2007 handed down by Mercantile Court number 4 of Barcelona, which has been confirmed by the Court of Appeal of Barcelona in its judgment dated March 27, 2009 (this ruling is now final); rulings dated August 3, 2007 and December 5, 2007, by which Mercantile Court number 1 of Barcelona granted interim injunctions in favor of Eli Lilly (these rulings were confirmed on July 31, 2008).

they are developing around the application of the TRIPS Agreement (Article 70.2 and 70.7) and the validity of product protection based on analogous process patents.

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 three Royal Decrees over the last 18 months 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, generic products are now subject to a 50 percent reduction in the first year (previous Decrees had made this reduction over multiple years). In turn, this price reduction affects the prices for innovative pharmaceuticals that are deemed to be in the same therapeutic reference groups with generic medicines.
- Royal Decree 8/2010 enacted a 7.5 percent 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 yet another Law – Royal Decree 9/2011 – which was designed to decrease pharmaceutical expenditure by €2.4 billion. This Decree includes several new detrimental measures:

- Imposes a 15 percent rebate on medicines that have been on the market for over 10 years with no generic or biosimilar authorized in the Spanish market. (Products subject to this 15 percent rebate are not subject to the 7.5 percent rebate imposed under Royal Decree 8/2010 (described above)).
- 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 in the same therapeutic group. Exceptions can be made when medical needs indicate that a certain brand is

required (but only if there is no generic available and there are a number of brands with the same active ingredient).

- Establishes a Cost-Effectiveness Committee to assess the value of medicines. It is imperative that the Spanish Government consults 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. The innovative pharmaceutical industry stands ready to assist the Spanish Government in establishing a predictable, transparent and objective government pricing system that adequately rewards innovation and encourages investment in new medicines.

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 2011 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 the Ukraine face growing intellectual property and market access concerns.

Key Issues of Concern:

- **Intellectual Property Rights:** Despite improvements in the rules governing IP enforcement, additional steps must be taken to ensure adequate protection for pharmaceutical patents and clinical test data.
- **Good Manufacturing Practices:** New rules governing the issuance of good manufacturing practices (GMP) certificates may create unnecessary registration burdens.
- **Transparency:** Regulations and laws are being adopted without adequate opportunities for PhRMA members to provide substantive input.

For these reasons below, PhRMA requests that the Ukraine remain on the **Watch List** for the 2012 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

January 16, 2012 Draft Amendment to Article 9 of the Law on Medicines (LAW 7412)

PhRMA and its member companies are concerned that a recently released draft amendment to Article 9 of the Law on Medicines could enable generic versions of patented medicines to be sold in Ukraine before expiration of the applicable patent term by eliminating the need for registration applicants to submit a document confirming the patent status of the medicine. According to paragraph 2 of the “explanatory note,” this amendment is being advanced in order “to find a balance between protection of IP rights and the possibility for obtaining an affordable price for medicinal products by Ukrainian citizens.” PhRMA strongly believes that this amendment and its purpose challenge Ukraine’s WTO commitments to uphold strong intellectual property rights (IPR) for pharmaceutical products.

November 3, 2011 Amendments to Article 9 on the Law of Medicines (LAW 7412)

PhRMA and its member companies greatly appreciate the November 3, 2011 amendments to Article 9 of the Law on Medicines (LAW 7412) that improve the IPR protection regime in Ukraine. However, we do have some concerns about the implementation of these changes, specifically:

- Since a clearly defined connection between the procedure of state registration and the validation of patent rights has been legislated, a patent database should be established at the level of the Ministry of Healthcare/State Expert Center or the State Service for Medicinal Products. This will allow the Ukraine Government to validate the patent status of a product submitted for registration.
- When applying for registration in Ukraine, it is unclear which documents are needed to demonstrate that the medicinal product has been registered elsewhere no earlier than two years before the application for its registration in Ukraine was filed.
- The rules defining how and which Government institution (e.g., the Ministry of Healthcare, the State Expert Center, or another state body) can refuse to register a medicinal product if the applicant is infringing data protection rights or patent rights of the reference medicinal product are unclear.
- When patent or data protection cases are being adjudicated, it is critical that the innovator and the generic applicant have access to all information necessary to effectively adjudicate the relevant rights. For example, in a data protection or patent infringement case, the courts should ensure that the Ministry of Health and/or State Expert provide the innovator's counsel with full access to the generic applicant's marketing authorization dossier, subject to appropriate confidentiality protections, in order to confirm whether a patent or data protection infringement has occurred. This transparency will help ensure the fairness of the court procedures.
- Enforcement of injunctions and other court orders in IP cases should be more effective, so that such judicial decisions can be used, for example, to prevent enjoined parties from participating in tenders and from importing goods subject to an injunction into the country.

Market Access Barriers

GMP Certification

On November 3, 2011, the Verkhovna Rada of Ukraine adopted amendments to the Law on Medicines (specifically – to Article 9), 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 manufacturing practices in the Ukraine. The governmental body responsible for issuing Good Manufacturing Practices (GMP) certificates in the Ukraine is *the State Service on Medicinal Products* (SSMP). 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 the 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 SSMP 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 SSMP 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 the SSMP should recognize GMP certificates issued by PIC/S Members so that Ukrainian patients have prompt access to safe and effective medicines. Requesting additional documents when the PIC/S GMP certificate is submitted along with the application for state registration of the medicine may result in the creation of non-tariff barriers for imported medicines.

Government Price Registration

A new price registration procedure was introduced by the Cabinet of Minister's Resolution No. 932 (August 8, 2011). This price registration regulation imposed unnecessary obstacles to the trade of medicines for both manufacturers/importers and hospitals. Since the new procedures may make it especially difficult for companies to register their prices, patient access to medicines may be impacted. Resolution No. 932 was adopted without consultations with the pharmaceutical community and the final wording of the document does not reflect any proposals provided by the innovative pharmaceutical industry. PhRMA and its members believe that because of the impact that this resolution may have on Ukrainian patients and their ability to access medicines, it is imperative that the Government consider the industry and other stakeholders' views and increase the transparency of the procedures.

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 issues related to government pricing and reimbursement of pharmaceuticals in particular. Unfortunately, many of the measures discussed above were adopted without ample engagement with stakeholders, including PhRMA member companies.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers related to intellectual property protection and market access.

LATIN AMERICA

CENTRAL AMERICA – CAFTA COUNTRIES

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in the Central American countries of Costa Rica, El Salvador, Honduras and Nicaragua observe that these countries have not effectively implemented some obligations in the CAFTA-DR related to the protection of intellectual property rights. In contrast, Guatemala has effectively implemented data protection (in force since Nov. 1, 2000), a patent enforcement mechanism and patent term adjustment/restoration.

Key Issues of Concern:

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

For these reasons, PhRMA and its member companies request that the Costa Rica remain on the **Watch List** for the 2012 Special 301 Report, and 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.

COSTA RICA, HONDURAS AND NICARAGUA

Intellectual Property Protection

Regulatory Data Protection

None of these countries have effectively implemented their 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. More specifically, Costa Rica enacted the “Undisclosed Information Law” but that Law contains exceptions or limitations that may be inconsistent with its international obligations (e.g., circumstances under which submitted data may be disclosed). The Government of Honduras published draft regulations in 2008, but the regulations for implementing data protection effectively were not promulgated. Similarly, the health authorities in Nicaragua have yet to promulgate a clear and transparent regulatory data mechanism that would comply with the CAFTA-DR.

Measures for the Effective Enforcement of Patents

None of these countries have effectively implemented their 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. Costa Rica amended its Patent Law to enhance enforcement of patents and the Health

Regulatory Agency took steps to implement the amendments. One step was to create a publicly available database to notify patent owners of requests for marketing approval of products that may, if marketed, infringe their patents. Unfortunately, according to the local research-based pharmaceutical association (FEDEFARMA), this database is not an effective tool for determining possible 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.

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.

EL SALVADOR

Measures for the Effective Enforcement of Patents

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.

GUATEMALA

Guatemala has improved certain practices related to patents and data protection to comply more closely with the CAFTA-DR and international norms. PhRMA and its members recognize and praise these efforts and look forward to continuing to work with Guatemalan officials to bring about further improvements in Guatemala’s IP systems.

PhRMA and its member companies also note progress on counterfeiting issues. 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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers in these Central American countries related to intellectual property protection and market access.

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:

- **Regulatory Data Protection**: Contrary to international practice, Colombia requires innovators to demonstrate that they undertook “considerable efforts” in preparing the data that must be submitted with the marketing approval application in order to benefit from data protection.
- **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**: Colombia takes up to five years to review and grant a patent, but does not adjust the patent term to reflect the patent life lost during the unreasonably long patent review process.
- **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.

For these reasons, PhRMA requests that Colombia remain on the **Watch List** for the 2012 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

Decree 2085 provides the domestic legal basis for proper implementation of Andean Decision 486, which protects test data from “unfair commercial use.” Decree 2085 establishes a five-year data protection period during which no third party may obtain a health registration for a pharmaceutical product relying on safety and efficacy studies filed by the innovator.

In November, the Andean Court of Justice issued a ruling upholding Colombia's data protection regime, Decree 2085/2002.⁸⁵ PhRMA and its member companies view the Andean Court's decision as a positive step.

Recent changes in procedure at the Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) regarding data protection concern PhRMA and its members. Until recently, INVIMA had presumed "considerable efforts" when innovative pharmaceutical companies filed their data packages for data protection. However, on several occasions INVIMA has now required that companies prove "considerable efforts" via:

- Time invested in R&D;
- Money invested in research;
- Technology employed in research; and
- Information regarding human resources

This change in procedure has not only resulted in legal uncertainty; it also raises questions of possible disclosure of proprietary business information that could then be used to deny protection in Colombia or elsewhere. PhRMA does not believe that conditioning regulatory data protection on such evidence can be justified under TRIPS.

Effective Patent Protection

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. If an efficient pre-launch patent enforcement mechanism is put in place, all market participants have legal certainty regarding the legal status of a particular product before they commit resources to commercial actions which may eventually be declared infringing after market launch. 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 adequate notice regarding the impending approval by the INVIMA of a potentially infringing product; (2) lack of legal standing to pursue infringement based solely on a health registration or an application; and (3) 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.

Colombian procedure does not provide adequate due process guarantees to effectively litigate patent enforcement. Additionally, litigation delays can often take more than 8 years. Solutions to these problems should be considered, including the possibility of a specialized court.

⁸⁵ Andean Tribunal of Justice, Process number 02-AI-2009, sentence of July 20, 2011.

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 indicated that consistent with its TRIPS obligations, it will grant patents for polymorphs, selection inventions, and pharmaceutical kits. To that end, the CPO is in the process of developing new examination guidelines for granting patents to polymorphs, selection inventions, and pharmaceutical kits. The innovative pharmaceutical industry will continue to monitor the development of these guidelines and stands ready to provide technical assistance.

- *Patents for Second Uses*

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.

The Colombian Health Ministry issued a specific regulation on Similar Biotherapeutics ostensibly in compliance with Law 1438 of 2011 which required a regulation to be issued according to international standards. The Ministry provided a seven-day comment period; substantially less than that provided for under the as yet unimplemented U.S. – Colombia FTA and Colombia's international obligations under the WTO Agreement on Technical Barriers to Trade. PhRMA and its members are also concerned that the regulation is substantively deficient and would not provide an effective means to ensuring the health and safety of Colombian patients.

Unreasonable Delays in Patent Grant

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 exclude pharmaceutical patents from any possibility of obtaining term adjustment.

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 sets 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 addition, in August 2011, the Ministry of Social Protection issued a new regulation establishing maximum reimbursement caps for molecules not covered by previous regulations. The new regulations impact PhRMA member companies, as well as the ability to ensure sustainable patient access to innovative therapies for Colombian patients. Further, the issuance of multiple regulations related to pharmaceutical prices has created an environment of legal uncertainty.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers 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
- Improper enforcement of Andean competition provisions for exercising patent rights
- New government price controls

For these reasons, PhRMA requests that Ecuador be placed on the **Watch List** for the 2012 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

Despite the October 2009 Executive Decree No. 118 establishing a special procedure for obtaining compulsory licenses to patents covering “priority” medicines, to date only one compulsory license has been granted. Although, the innovative pharmaceutical industry welcomes that no new compulsory licenses have been granted under the Decree, it would caution that this is likely due to the fact that few medicines in Ecuador are covered by patents and most that are patented face violations from copy products in the market.

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 World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Regulatory Data Protection

Articles 191 and 192 of the Ecuadorian Intellectual Property Act require the protection of undisclosed test data or other information submitted to obtain marketing approval of pharmaceutical products. These Articles are premised on Article 39.3 of TRIPS Agreement and Article 266 of Andean Decision 486.

Unfortunately, Article 191 of the Act does not provide sufficient details on the nature and duration of the protection against unfair commercial use. As a result, health authorities in Ecuador rely on data submitted by innovators to review the requests of competitors to market copies of the innovator's products almost immediately after the grant of marketing approval of the innovative product in Ecuador. According to the local innovative pharmaceutical association (IFI), it is common for the Ecuadorian health authorities to approve copies based on the data of the innovator within three months after approval of the innovative products.

As such, Ecuador does not provide enough protection against unfair commercial use of undisclosed data to meaningfully implement its obligations under TRIPS Article 39.3.

Improper Enforcement of Andean Competition Provisions for Exercising Patent Rights

In April 2011, the Under Secretariat of Competition (USC) imposed a US \$550,000 fine on a PhRMA member company on the grounds of abuse of dominant position when enforcing its patent rights.

The fine was imposed following an investigation started in 2009 when a competitor filed a complaint with the USC against the PhRMA member company. The complaint was filed after the PhRMA member company won a legal injunction against a product being commercialized by the competitor, which infringed the patent of the PhRMA member company. According to the USC, obtaining injunctions against copiers based on patent right infringements limits competition and thereby is illegal. In effect, the PhRMA member company was punished by the government for exercising a right granted by the same government to enforce its patents.

Market Access Barriers

Government price controls

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

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 continue to apply to medicines in all three price control categories: “The profit margin by product for the manufacturer or importer shall not exceed 20 percent; for distributors the profit margin shall not exceed 10 percent per product, and for retail outlets the profit margin cannot be greater than 20 percent for brand-name products and 25 percent for generic medicines.” As a result, prices for medicines continue to be calculated on a cost-basis. Under the new Decree, certain costs (including the costs of providing samples) are no longer permitted.

Finally, under the Decree, biopharmaceutical manufacturers may only seek price increases once every 24 months, and such increases are capped by the rate of inflation in the prior year and the overarching 20 percent profit margin limit.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 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 Mexico has failed to undertake a serious review of the patent linkage system following the numerous cases where the Mexican Courts have produced resounding decisions recognizing the listing of use and formulation patents in the Official Gazette of pharmaceutical patents, including a notable ruling of the Mexican Supreme Court.

PhRMA member companies continue to share deep concern with regard to the inability to remove patent infringing products from the market place. 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 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

For these reasons, as explained in detail below, PhRMA requests that Mexico remain on the **Watch List** for the 2012 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 to which it aspires to join.

Intellectual Property Protection

Ineffective Patent Enforcement

PhRMA members recognize that the Linkage Decree of 2003 constituted a cornerstone for the recognition of pharmaceutical patent rights in Mexico. Nevertheless,

the application of the Decree continues to be problematic despite rulings in numerous court decisions, including by the Supreme Court, that formulation patents should be published in the Official Gazette. IMPI's reluctance to respect the Court rulings results in unnecessary, costly and time consuming court actions for both patent holders and the Mexican judiciary.

PhRMA and its member companies are increasingly concerned with the approval by COFEPRIS of copies of products which remain protected by patents including those listed in the linkage gazette (*i.e.*, not limited to use or formulation patents). 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 generic or copy pharmaceuticals 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 formulation 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)

The Mexican Government's commitment to analyze the need for RDP reform remains illusory despite reiterated affirmations in the past two years.

Mexico should approve RDP reform in a manner that guarantees compliance with NAFTA and meets its TRIPS obligations, in order to provide effective protection against unfair commercial use, as well as unauthorized reliance on innovators' dossiers, of data generated to obtain marketing approval for pharmaceutical products.

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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers related to intellectual property protection and market access.

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 on 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 biotechnological pharmaceuticals. 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 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), require duplicative testing by local laboratories or impose excessive administrative burdens that serve no purpose other than delaying the marketing approval process and patient access to medicines.

For these reasons, PhRMA recommends that Peru remain on the **Watch List** for the 2012 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 Protection

Regulatory Data Protection

The Government of Peru established a regulatory data protection regime in February 2009. Since then, more than eleven new pharmaceutical products have been granted data protection for an average of four years. Nevertheless, since May 2010, PhRMA member companies have reported that the PHA has rejected regulatory data protection for two biotechnological pharmaceuticals. This refusal is inconsistent with Peru's obligations under the WTO's TRIPS Agreement, Article 16.10.2 of the USPTA, and national law. Denying such protection will adversely affect PhRMA members attempting to introduce new products in Peru and 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 USPTA, refrain from granting sanitary registrations to third party follow-on versions of any kind of innovative pharmaceutical products, regardless if these 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.

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 and 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 USPTA 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 USPTA 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 secondary 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 regulations⁸⁶ 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 have introduced product specific requirements, requesting proof of safety and efficacy from innovators and biosimilars, which is a remarkable 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.
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 Peru have all been bases for delaying or even refusing marketing approval. These regulatory delays or measures present unnecessary trade barriers and

⁸⁶ 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.

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, the new regulations do not adequately specify how a laboratory may be certified by the PHA.

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.

If successful, this requirement would create an enormous trade barrier and a profitable but artificial industry for local laboratories. If the local generic manufacturers succeed, it would impose a disproportionate burden on U.S. and international pharmaceutical companies, and thus presents an impermissible trade barrier.

4. Import Barriers Impair Certain Clinical Trials: The ability to conduct comparative clinical trials using another company's products has been significantly hindered by the approval of Executive Decree 006-2007-SA. Specifically, Article 92 of that Decree mandates that even where a pharmaceutical is to be used solely for clinical trials, the importer must provide documentation that is only available to the manufacturer of such products.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers related to intellectual property protection and market access.

MIDDLE EAST/
AFRICA

JORDAN

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Jordan are concerned about the deteriorating environment in Jordan.

Key Issues of Concern:

- Deficient intellectual property rights protections (IPR) stemming from Jordan's interpretation and non-compliance with its obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the U.S.-Jordan Free Trade Agreement (FTA);
- Discrimination in favor of locally produced generic products;
- The lack of innovative medicines industry representation at the Higher Council for Drugs, the chief decision-making body governing the medicines sector; and
- Inconsistent regulatory and government pricing policies that delay market access, and deprive patients of access to promising new treatments.

For these reasons, PhRMA requests that Jordan be placed on the **Watch List** for the 2012 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

Jordan's health authorities have taken steps to weaken their data protection regime, and continue to deny data protection to new indications.

- Currently, no protection is granted for clinical data for new indications. Data protection for new chemical entities should also include protection for new uses for a period of three years.
- Jordan now requires the marketing authorization application of the new medicine to be filed within 18 months from the first worldwide regulatory approval in order to be considered as a "new chemical entity." If not, it will lose data protection, allowing a generic of that molecule to enter the market during what should be the data protection period.

- Meeting the 18-month deadline to file is complicated by a complex series of regulatory requirements established by the Jordanian Food and Drug Administration (JFDA), and the one year delay that is legally required to monitor the usage of the new drug in a larger population (pharmacovigilance). In addition, if the first worldwide registration were not in the EU or the United States, which are both relied upon for the Certificate of Pharmaceutical Product (CPP) application and which the JFDA references for the one year pharmacovigilance, and other technical requirements, then meeting this 18 month deadline is also challenging if not impossible.
- Jordan is not adhering to its WTO or FTA commitments. With Jordan's accession into the WTO in 1999, Jordan committed to applying fully all the provisions of the TRIPS Agreement, which was also incorporated into Jordan's Protocol of Accession. Paragraph 215 of Jordan Working Party Report requires Jordan to provide regulatory data protection from the date of marketing approval. In the Working Party Report, Jordan pledges to provide five years of data protection for new chemical entities. Under TRIPS Article 39.3 and paragraph 230 of its Working Party Report, Jordan is not permitted to modify or narrow its commitments unilaterally through the imposition of additional criteria for receiving data protection that would lessen the five-year period of protection.
- Through obligations in the FTA signed shortly after their accession into the WTO, Jordan committed to provide data protection, extending the period of non-reliance to both clinical test data and to evidence of receiving marketing approval in another country. Though a specific term of protection is not mentioned, it may be inferred that Jordan committed to five years through paragraph 22 of the FTA:
 - The FTA explicitly notes that Jordan will provide data protection “[p]ursuant to Article 39.3 of TRIPS[.]” As Jordan intended to implement Article 39.3 of TRIPS, providing five years of data protection from the date of marketing approval in Jordan, it follows that this is the basis for the parties’ agreement on data protection in the FTA as well.
 - Moreover, in footnote 11, it is stated that in situations where there is reliance on evidence of approval in another country, Jordan needs, at a minimum, to protect such information against unfair commercial use for the same period of time as in the other country.
 - Lastly, in footnote 10 of the FTA, it explicitly states that “protection for ‘new chemical entities’ shall also include protection for new uses for old chemical entities for a period of three years,” thereby confirming that new uses for old chemical entities would receive data protection as well, albeit for a shorter period of time.

PhRMA and its member companies are troubled by Jordan's unilateral modification of its WTO and FTA commitments. By imposing additional strict and unparalleled criteria for receiving regulatory data protection, Jordan is effectively denying the five-year period of protection for the majority, if not all, of new chemical entities' applications. PhRMA and its member companies have discussed these shortcomings with the two relevant agencies, however, neither the Ministry of Commerce and Industry nor the JFDA believe they are in violation of their international commitments.

PhRMA and its member companies stand ready to work with the Jordanian and U.S. governments to resolve these issues, but believe that to date, the Jordanian Government has not exhibited good faith or a serious intention to bring existing regulations into compliance with the country's long standing and unambiguous obligations.

Market Access Barriers

Local Preference in Government Tenders

Tenders of the Joint Procurement Procedures of Drugs (JPD) are designed to favor locally produced generic drugs, which restricts Jordanian patients' access to innovative medicines. Per Article 52 (I) of the JPD, locally produced generic products are rewarded a 10 percent price benefit over innovative foreign products when considering tenders. This preferential treatment violates Jordan's obligations under the WTO General Agreement on Tariffs and Trade (1994) to not discriminate between domestic and foreign pharmaceuticals (Article I), and that imported products "be accorded treatment no less favorable than that accorded to like products of national origin ..." (Article III:4).

Policy Denies Representation at the Higher Council for Drugs

Despite representing more than 50 percent of the Jordanian pharmaceutical sector, the innovative pharmaceutical industry is denied representation at the Higher Council for Drugs at the Jordanian Food and Drug Administration (JFDA), while local industry is more than well represented. The issues considered by the Council thus do not address the concerns of all stakeholders. As the Higher Council on Drugs has responsibility for policies governing the sector and affecting innovator companies, the policy of deliberate exclusion discriminates against companies that should be consulted on policy changes. PhRMA's member companies are working to ensure that all stakeholders' concerns are heard, and increase the level of consultation and transparency, but the Government has rebuffed all efforts to date that would allow a representative to attend on behalf of companies comprising 50 percent of the market.

Burdensome Regulatory and Pricing Policies

Jordan has developed burdensome regulatory and government pricing policies, creating protectionist market barriers in support of their own drug industry at the expense of Jordanian patients and the innovative pharmaceutical industry. Jordan's FDA mandates that prior to accepting the registration file of a new product; the product must be marketed for at least one year in a reference country. This policy ignores the fact that the products have already undergone significant pre-market safety testing and continue to be subjected to post-approval surveillance efforts. As a result, the policy creates unnecessary obstacles to trade in violation of Article 2.2 of the TBT Agreement.

Furthermore, the Jordanian Government sets pharmaceutical prices at the median of certain EU reference countries, or the lowest price paid either in Saudi Arabia or in the country of origin of any active pharmaceutical ingredient. As a result, the government pricing system is not consistent. PhRMA's members recommend modifying the government's pricing strategy to make it clear and consistent by taking the average of the reference prices, or reducing the list of reference countries so not to include the country of each manufacturer in the supply chain.

Currently, government prices are revised two years post registration, at renewals (every five years), and within four months of a price reduction in a reference country. These government price alignments are too frequent, and are an administrative and operational burden on the industry and JFDA. PhRMA's members recommend that government prices should not be revised more than once a year.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers related to intellectual property protection and market access.

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 IP 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 test data;
- Revocation of patents granted or substantively examined under Saudi Patent Law No. M/38 using standards that were not applicable at the time of examination;
- A court decision that invalidates Gulf Cooperation Council patents for pharmaceuticals
- Volatile government pricing policies; and
- Non-transparent drug formularies

For these reasons, PhRMA requests that Saudi Arabia be placed on the **Watch List** for the 2012 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

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 would like to thank the U.S. Government (USTR, Department of Commerce, Department of State, and the U.S. Embassy in Riyadh) all of whom have worked tirelessly on the EMR Agreement and urged continued attention to its implementation. PhRMA and its member companies stand ready to work with the Saudi and U.S. governments to resolve this implementation issue.

Recognition of GCC Patents in Saudi Arabia

According to Gulf Cooperation Council (GCC) Patent Law, the GCC patent is recognized in all Gulf countries. In this respect, paragraph (1) of Article (10) of the GCC Patent Law states: "The owner of a patent may sue anyone who uses his invention industrially without his consent in the GCC countries. If the patent covers a method of manufacturing a particular product the patent owner shall have the same right to direct products of the said method in the GCC countries using the same method." This text thus affords patent protection in all GCC countries and there is no need for the GCC patent holder to obtain a patent from the individual patent offices in the GCC States.

Patents issued by GCC members, including Saudi Arabia, are thus valid in all GCC countries. However, the 27th Administrative Circuit of the Saudi Board of Grievances issued judgment No. 41/d /e /27 of 1431 AH and invalidated a PhRMA member company's GCC patent in Saudi Arabia. The judgment dismissed the Plaintiff's claim of patent protection, claiming that GCC patents are not valid in Saudi Arabia and that a GCC patent is not a substitute for a Saudi patent. PhRMA urges the U.S. government to support the validity of GCC patents in Saudi Arabia.

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 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.

Market Access Barriers

Challenging Pricing Environment

PhRMA member companies believe that the new government pricing regime that entered into force in November 2011 will not lead to a more predictable environment for innovation, investment 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 the term “suitable price,” which will be the price chosen for a specific product, actually means, 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.

Further, the revised pricing decree was approved by SFDA before the end of the extended comment period. PhRMA submitted extensive written comments detailing economic, patient access, and trade-related concerns. However, before the stakeholder consultation period ended, media reported that the SFDA’s Board of Directors approved the new pricing decree. While some of industry’s comments were incorporated in the final decree, dozens of comments were ignored. Industry did not receive any written or specific responses to its detailed, multi-point submissions.

PhRMA member companies are ready to support a revised 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.

PhRMA and its member companies were pleased by Saudi authorities' announcement in September to delay the implementation of re-registration requirements until mid-2012. We are undertaking a study to demonstrate the effort required to implement this regulation, and would in any case recommend a phased-in implementation.

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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 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 recent deterioration in the intellectual property environment. In 2011, the Tunisian Government denied effective regulatory protection for pharmaceutical data submitted for receiving marketing approval related to one member company product.

Key Issues of Concern:

- Lack of regulatory data protection
- Government pricing restrictions
- Unbalanced representation in policy making commission affecting the sector

For these reasons, PhRMA requests that Tunisia be placed on the **Watch List** for the 2012 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. The innovator's request for marketing approval has been pending for 13 years.

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 to grant regulatory data protection beginning on January 1, 2000, and patent protection by January 1, 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 amount 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 and 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 respond that they are not sharing the content of innovative drug registration files. Despite these claims, a PhRMA member reports that Tunisia has approved a generic version of one of their innovative products for which they submitted their registration application in 1998, and which is still awaiting marketing authorization approval.

PhRMA and its member companies would like to seek the intervention of the U.S. Government to help resolve this dangerous precedent.

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. Combined these pricing policies result in prices that undervalue the cost of developing innovative medicines.

Unbalanced stakeholder representation

While local manufacturers are permitted to participate in the CNIP (Chambre Nationale de l'Industrie Pharmaceutique), foreign manufacturers are not offered similar representation on the CAM (commission d'attribution des marches). The innovative pharmaceutical industry should be represented on this committee, through the local association, SEPHIRE.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2011 attributable to trade barriers related to intellectual property protection and market access.