PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (P*h*RMA)
SPECIAL 301 SUBMISSION 2011

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PhRMA SPECIAL 301 SUBMISSION 2011 EXECUTIVE SUMMARY

EXECUTIVE SUMMARY

I. Importance of Special 301 and Effective Intellectual Property Protection

During the Uruguay Round negotiations that produced the World Trade Organization (WTO), the United States made significant progress toward establishing more consistent and effective intellectual property (IP) protection globally. The result of this effort was the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). 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 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. 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 review of PhRMA's individual country submissions demonstrates that many countries have significantly failed to meet their obligations to provide effective intellectual property protection for biopharmaceutical products. The actual protection and enforcement of intellectual property rights on the ground in those countries falls far short of the standards contained in TRIPS, as well as obligations under several U.S. free trade agreements (FTAs).

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 protection. 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 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% of the total global biotech R&D spend.[1] In his recent State of the Union address, President Obama offered 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 were also central themes in the President's address, 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. The President recognized this crucial point in his address, as he stressed the need for investments in biomedical research.[2] This was further demonstrated by the President's establishment of the Intellectual Property Enforcement Advisory Committee.

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."[3]

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 2008 totaled 3.1 million jobs,[4] including direct employment of over 686,000 Americans.[5] Direct employment in the biopharmaceutical sector grew at a faster rate than employment in the rest of the economy in that location from 1998 to 2008.[6] Each job in the biopharmaceutical sector contributed more than double the average contribution from jobs in the rest of the economy.[7] 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

[1] Burrill and Company, analysis for PhRMA based on publicly available data, 2009.
[2] Obama, Barack, State of the Union Address January 24, 2011.
[3] 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).
[4] The Biopharmaceutical Sector's Impact on the Economy of the United States, Archstone Consulting, 2010
[4] Id.
[5] Id.
[6] Id.
[7] Id.

contribution to GDP from other sectors.[8] Our industry has by no means been immune to the global downturn, however. From January to October of 2009, approximately 58,000 industry jobs were lost,[9] compounding earlier job contraction in 2007 and 2008.[10]

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 2009, our industry invested $65.3 billion in research and development for new medicines, $45.8 billion of which was invested in research conducted by PhRMA members, and $34.8 billion of which was invested in the United States.[11] 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.[12] 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 2,950 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.[13]

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.[14] 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% over this period."[15] These figures are driven in large part by exports. In 2009, the biopharmaceutical industry exported $46 billion, or approximately 5% of total U.S. goods exports, making the United States the world's third largest pharmaceutical exporter. This made the biopharmaceutical sector the second largest U.S. export sector (after aerospace products and parts).[16] Our industry has shown strong export performance in the recent past, with 2009 marking an increase from $36.7 billion in 2007 and $41.7 billion in 2008.[17]

Because the benefits from the biopharmaceutical sector are so robust, it is critical that IP violations, the gravity of each violation in its effect on the rights holder, and the importance of the rights holder in the U.S. economy is reflected in processes like the Special 301 and other U.S. Government initiatives. Enforcement must be a fundamental priority to support the U.S. economy and provide the incentive for continued innovation which leads to new medicines and improved health of Americans and patients globally.

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[8] Id.
[9] Matthew Herper, Layoffs Sting Big Pharma, Forbes (Nov. 13, 2009).
[10] Id.
[11] PhRMA, PhRMA Annual Member Survey (1981-2010).
[12] Adapted from N.D. Pham, "The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs, Wages, and Exports," (Washington, DC: NDP Consulting, 2010).
[13] Adis R&D Insight Database, Wolters Kluwer Health, custom data runs, February 2009, January 2010.
[14] Shapiro, R. and Pham, N., Economic Effects of Intellectual Property-Intensive Manufacturing in the United States, World Growth (July 2007).
[15] Id. at 3.
[16] U.S. International Trade Commission, Trade DataWeb, accessed February 1, 2011, at http://dataweb.usitc.gov/ (query run of U.S. domestic exports classified by 4-digit NAIC code).
[17] Id.

Failure to Protect IP Harms the U.S. Economy

Protecting the IP of U.S.-based innovative industries is critical to the future of our economy. A number of studies have found that patents and other IP protections are significantly more important to biopharmaceutical firms in "appropriating the benefits from innovation compared with other high tech industries."[18] This is due in large part to the research-intensive nature of this sector, which contributes to high research and development costs. In knowledge-based sectors, such as the biopharmaceutical sector, intangible assets are often more valuable than tangible assets. This sector is reliant on the ability to raise capital to support the substantial investments in research and development needed to develop today's treatments and tomorrow's cures. When IP is infringed, biopharmaceutical companies are often unable to recoup their research and development investments, reducing the capital available to reinvest in more research and development. 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.[19] 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 Shapiro and Hassett (2007), U.S. intellectual property accounted for an estimated one-third of the market value of all U.S. stocks – $5 trillion to $5.5 trillion – equivalent to about 45 percent of America's GDP and greater than the GDP of any other economy in the world.[20] Further, they estimate that the costs of IP infringement "may well constitute a significant drain on both national and world economies and impede the efficient exchange of goods, services, and ideas."[21] Thus, the failure to adequately protect IP can substantially impact the economic contribution of research and development-intensive sectors such as the biopharmaceutical sector.

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.[22] 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."[23]

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[18] See, e.g., Grabowski, H., Patents, innovation, and access to new medicines, *J Int'l Economic Law* 2002:849-860.
[19] Edwin Mansfield, Patents and Innovation: An Empirical Study, *Management Science,* Vol. 32, No. 1 (1986).
[20] Shapiro, R. and Hassett, K., The Economic Value of Intellectual Property (Oct. 2005), available at http://www.sonecon.com/docs/studies/IntellectualPropertyReport-October2005.pdf (last visited Oct. 27, 2010).
[21] Id.
[22] IFPMA Survey, validated by LSE Health and Social Care at the London School of Economics and Political Science.
[23] Remarks by Bill Gates at the World Economic Forum, Gates Foundation Press Conference (January 29, 2010).

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.[24] 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.[25] 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.

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.

[24] See www.globalhealthprogress.org.
[25] Moran, M. et al., Neglected Disease Research and Development: New Times, New Trends, The George Institute for International Health (2009).

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.[26]) Developing countries have increasingly put patent systems in place, but with mixed results. A particularly important concern for innovative biopharmaceutical companies has been recent efforts by a few middle-income countries (most notably, Brazil and Thailand) to undermine biopharmaceutical patents, largely for industrial policy purposes – such as supporting local industry or alleviating a short-term budget shortfall – through the issuance of compulsory licenses and other discriminatory government measures. Our members have also faced denials of pharmaceutical patent applications previously approved by national patent offices at the insistence of non-IP government ministries. This is exemplified in Brazil where the health regulatory agency (ANVISA) is authorized to review all patent applications on pharmaceutical products and/or processes. This review is in addition to the examination conducted by Brazil's patent office (INPI). As ANVISA and INPI do not apply the same patentability requirements, this generates uncertainty for patent applicants and undermines incentives for innovation.

    - ***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: Algeria, Argentina, Brazil, Finland, India, Peru, and Norway.

    - ***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

[26] 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.

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: Algeria, Argentina, Brazil, Chile, India, Israel, Malaysia, Peru, Taiwan, and Turkey.

- ***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.

- ***Early Resolution of IP Disputes and Marketing Approval -*** Our trading partners must provide adequate and effective protection of IP rights for the research-based pharmaceutical industry in order to sustain innovation and development of new medicines over the long term. To accomplish this goal, mechanisms are required which prevent marketing of patent infringing products. Providing mechanisms that facilitate resolution of patent infringement issues before the product in question is allowed to enter a market is an important tool for accomplishing this objective. Early resolution of patent disputes before the third party product in question gains marketing approval avoids, for instance, the need for complex litigation over damages for marketing an infringing product. Key trading partners with inadequate implementation of mechanisms for the early resolution of IP disputes and marketing approvals include: Algeria, Argentina, Australia, Brazil, Chile, China, Canada, India, Italy, Peru, Philippines, Poland, Turkey, and Taiwan.

- **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 intellectual property 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 will serve as a *de facto* ban on imports. The Turkish Government has publicly stated that the purpose of this policy is to promote local Turkish pharmaceutical companies 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, Chile, China, Canada, Hungary, India, Indonesia, Israel, Korea, Taiwan, Malaysia, Mexico, Peru, Poland, and Russia.

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 PCT, that facilitate the ability of companies to obtain patents in multiple jurisdictions should continue to be pursued.

4. <u>Engage on Foreign Government Price Controls and Cost Containment Measures that Undermine IP and Impede Market Access</u>

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 . . ."

Foreign governments are increasingly employing a range of strategies to control prices and contain costs related to biopharmaceuticals. Based on a recent 2010 analysis, approximately 39 countries proposed or implemented cost containment measures impacting the biopharmaceutical sector.[27] The biopharmaceutical sector is unique in that it faces onerous price controls in the vast majority of the sector's export markets, and in many of these markets the government is the sole pharmaceutical purchaser. According to a 2004 Department of Commerce study,[28] "such price controls can also delay or reduce the availability of some innovative medicines in foreign countries, with the effect of limiting competition and requiring national health systems to forego the benefits of these innovations in reducing health care costs." According to the study's findings,[29] the price controls maintained by OECD countries reduce the amount of global pharmaceutical R&D below what it would be otherwise under market-based conditions similar to those that exist in the U.S. This reduction falls in the range of $5 billion to $8 billion annually, once prices are fully adjusted. Such policies can therefore dramatically impact the U.S. biopharmaceutical industry's ability to enter and compete in new markets as well as its ability to compete in existing markets.

In addition to price controls, the biopharmaceutical sector has witnessed a surge in a number of cost containment measures, which in some cases have disproportionately targeted our sector. Such measures often have significant ripple effects in many markets. For example, *ad hoc* price cuts implemented in one country can directly and indirectly impact the price of medicines in many other markets due to international reference pricing where a government considers the price of a medicine across a set (or "basket") of countries to determine the price of medicine in its own country. This can create a downward spiral in terms of prices for medicines, and may result in product shortages for medicines patients need.

[27] IHS Global Insight, analysis for PhRMA, Dec. 2010.
[28] U.S. Department of Commerce. Pharmaceutical Price Controls in OECD Countries. Implications for U.S. Consumers, Pricing, Research and Development, and Innovation. December 2004.
[29] U.S. Department of Commerce. On December 21, 2004, the U.S. Department of Commerce, International Trade Administration, released the findings of its study on pharmaceutical price controls in the Organization for Economic Cooperation and Development (OECD) countries (hereafter referred to as the Commerce Study)

PhRMA recognizes the significant fiscal challenges that foreign governments face and seeks to be a partner in finding solutions; however, rather than addressing such concerns via predictable, transparent, and consultative processes, some governments have proposed or implemented cost containment measures. Such cost containment policies typically put short-term government objectives ahead of long-term strategies that would ensure continued R&D into medicines that patients need most.

Examples of key cost containment measures include *ad hoc* government price cuts, international and therapeutic reference pricing, mandatory rebates, and many others. Such measures can delay or reduce the availability of new medicines and can contribute to an unpredictable business environment in foreign markets for U.S. companies. Moreover, governments are increasingly engaging in product evaluation methods like health technology assessment as a barrier to market access and a cost containment tool. Key trading partners implementing concerning government price controls and cost containment measures that undermine IP and impede market access include: Algeria, Australia, Brazil, Colombia, Czech Republic, Egypt, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Jordan, Poland, Russia, Saudi Arabia, and Turkey.

- ***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. Greece is an example of a market that implemented dramatic government price cuts in 2010. In April 2010, Greece, for example, abruptly called for across the board price cuts of up to 27% (21.5% on average).[30] Key trading partners with concerning behavior regarding ad hoc government price cuts include: Algeria, Brazil, Germany, Greece, Italy, and Turkey.

- **International Reference Pricing (IRP):** IRP is a cost containment mechanism whereby a government considers the price of a medicine in other countries to establish the price in its own country. The reference price for a medicine is calculated by considering the price of the same medicine across a set (or "basket") of countries using one of several possible methodologies. 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, Egypt and Saudi Arabia have proposed expanding their reference baskets to 36 and 40 countries (respectively). Egypt will take the lowest price in the basket, less 10 percent. Saudi Arabia will take the lowest price in its reference basket. Both countries reference each other.[31]

- **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 Poland, 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.

[30] Hirschler, B., "EU drug prices face deepening austerity squeeze." Reuters. July 21, 2010.
[31] International Reference Pricing Analysis for PhRMA: Egypt, Saudi Arabia, Charles River Associates, London, Jan. 2011.

- **Mandatory Rebates:** Rebates are measures whereby payers achieve a lower real purchase cost than what they would have incurred at list price level. In rebate systems, a price reduction is negotiated with the payer while maintaining the official list price of a product. Ad-hoc mandatory rebates can negatively impact a company's ability to plan ahead, and contribute to creating a highly unpredictable business environment. For example, in March 2010, the German Ministry of Health unexpectedly called for an increase of the mandatory rebate from 6 to 16% on non-reference priced medicines. This policy has been implemented since August 2010.

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 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.

IV. 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.[32] For example, recent estimates indicate that between 10 to 30 percent of medicines sold in developing markets are believed to be counterfeit.[33] Although

[32] 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.
[33] The World Health Organization, IMPACT, at www.who.org (2008).

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

V. Country Designation Index

Priority Foreign Country or Section 306 Monitoring

PhRMA recommends that Thailand be designated a Priority Foreign Country under "Special 301" for 2011 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 Foreign Country:

- Thailand

Section 306 Monitoring:

- China

Priority Watch List Countries

PhRMA believes that 15 countries should be included in the 2011 Priority Watch List. PhRMA urges USTR to take aggressive action to remedy these violations, including the consideration of WTO dispute settlement, as necessary.

ASIA-PACIFIC

- India
- Indonesia
- New Zealand

CANADA

- Canada

EUROPE

- Czech Republic
- Hungary
- Israel
- Poland
- Turkey

LATIN AMERICA

- Argentina

- Brazil
- Chile
- Venezuela

MIDDLE EAST/ AFRICA/ SOUTH ASIA
- Algeria
- Pakistan

Watch List Countries

The PhRMA submission identifies 24 countries which should be included on the Special 301 Watch List in 2011. 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 data protection. Successful implementation will require a commitment from the U.S. Government to promote successful implementation of the WTO TRIPS Agreement.

ASIA-PACIFIC
- Australia
- Korea
- Malaysia
- Philippines
- Taiwan
- Vietnam

EUROPE
- Finland
- Germany
- Greece
- Italy
- Norway
- Russian Federation

LATIN AMERICA
- Colombia
- Costa Rica (CAFTA Chapter)
- Dominican Republic
- Ecuador
- El Salvador (CAFTA Chapter)
- Honduras (CAFTA Chapter)
- Mexico
- Nicaragua (CAFTA Chapter)
- Panama
- Peru

MIDDLE EAST/ AFRICA/ SOUTH ASIA
- Saudi Arabia
- Jordan

PRIORITY FOREIGN COUNTRY

THAILAND

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Thailand are concerned that the research-based innovative biopharmaceutical industry continues to be excluded from meaningful participation in Thailand's ongoing efforts to reform the health care system. Furthermore, it has become increasingly difficult for PhRMA's member companies to conduct business in Thailand while government policies are sustaining a marketplace that is no longer open or competitive. While PhRMA recognizes the efforts of Thailand's Ministry of Commerce and Department of Intellectual Property (DIP) to encourage dialogue, there has been little action on past pledges to foster a better environment for intellectual property holders in the research based biopharmaceutical sector or to increase meaningful engagement between key healthcare stakeholders and the Royal Thai Government. PhRMA hopes that, with the support of the U.S. Government, the necessary coordinated steps can be taken to institute meaningful dialogue and address these challenges. PhRMA and its member companies stand ready to work with the Royal Thai Government to ensure that progress is made.

Key Issues of Concern:

- Lack of sufficient stakeholder engagement on IP and market access issues;
- Compulsory licensing;
- Effective patent enforcement;
- Data protection;
- Counterfeit enforcement;
- Lack of meaningful participation in the development of policies related to innovation and medicine; and
- Discriminatory government procurement policies.

For these reasons, PhRMA requests that Thailand be designated as a **Priority Foreign Country** for the 2011 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Lack of Sufficient Stakeholder Engagement on Intellectual Property and Market Access Issues

Despite repeated calls for a meaningful, consultative dialogue mechanism between Thailand's healthcare stakeholders and the Royal Thai Government, no steps have yet been taken to put a system in place. Without a reliable and regular mechanism for offering input into Thailand's healthcare decision-making process, PhRMA's member companies remain vulnerable to decisions that negatively impact their businesses and the ability of Thai patients to receive life-saving pharmaceutical treatments. These include discussions on the establishment of government price controls, reforming national healthcare schemes, initiatives that force cost containment on the research-based pharmaceutical industry, and amending drug and patent legislation. PhRMA hopes that its members will have the opportunity to provide input into all of these policy discussions, and that such input will be meaningfully considered, in order to contribute to reforms that establish a sustainable healthcare system for Thailand. Furthermore, full and complete consultation on issues directly affecting individual companies, such as the recent extension of compulsory licenses, is greatly needed.

Intellectual Property Protection

Compulsory Licensing

Despite assurances that Thailand would be judicious in its use of compulsory licenses and consult with affected parties in ways consistent with the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights, the Ministry of Health resolved in 2010 to issue new compulsory licenses on Stocrin and Kaletra, ahead of their patent expirations on 31 December, 2011, and 31 January, 2012, respectively, and without prior consultation with the affected companies. Full and complete 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.

Effective Patent Enforcement

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

Data Protection

PhRMA member companies strongly encourage the Royal Thai Government to institute meaningful data protection that prohibits the Thai 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 exclusivity; (2) bring the country's regulations in line with international best practices by making clear that trade secret protection is provided to all confidential material whenever it is received by officials; (3) extend protection to new dosage forms, new indications, etc. and (4) require Thai FDA officials to protect information provided in confidence by the originator by ensuring that information is not improperly made public or made available for use or reliance by a subsequent producer of a generic pharmaceutical product.

Patent Prosecution and Incremental Innovation

PhRMA member companies strongly encourage the Royal Thai Government to recognize the significant health, scientific, and commercial benefits of incremental innovations. Patent applications that involve any new improvements, upgrades and next generation products should be reviewed in accordance with internationally recognized patentability criteria, and the patentability criteria must be used consistently among all technology dependent industries. PhRMA member companies were concerned that the Royal Thai Government commissioned a research project on "Evergreening Patents on the Impact on Thailand" without any input from the Subcommittee on Pharmaceutical and Medical Products, and that said project was based on

the falsity that patent terms can be perpetual. PhRMA member companies encourage the Royal Thai Government to work with all technology based industries and fully consult with industry when considering changes to patent examination guidelines to ensure that inventors continue to have an incentive to innovate and that all innovations are treated equally with respect to grant criteria.

New uses of an existing substance, new formulations or other modifications to an established product can have significant consequences for patient care, by providing superior therapy for a number of patients. Benefits occur in new diseases addressed, better safety profiles, greater efficacy for patients, and more convenient delivery for patients (for example where the number of tablets per day is reduced through a slow release mechanism.) Fostering incremental innovation also encourages stronger competition between products in a specific therapeutic class. Creating incentives for incremental innovation stimulates further pharmaceutical research into improvements by competitors in addition to the product originator.

Market Access Barriers

Lack of Meaningful Participation in the Development of Policies Related to Innovation and Medicine

In December 2008, the National Health Assembly (NHA) adopted a resolution to "Adopt Strategies for Universal Access to Medicine for the Thai People." There were seven strategies proposed under this resolution and five subcommittees were formed to work on these strategies, with the goal of passing the recommendations to policy-makers for action. The pharmaceutical industry has only limited representation on these subcommittees despite the fact that each of their findings could have a major impact on the pharmaceutical sector and the supply of pharmaceutical products to Thai patients.

On October 3, 2010, the Subcommittee on Pharmaceutical and Medical Products was formed under the National Committee for the Development of IPR Strategies. The Royal Thai Government invited member companies to recommend experts for participation on the Subcommittee by August 2, 2010. PhRMA and our member companies continue to request greater and more meaningful representation in these crucial subcommittees and working groups, not only in the interest of including all key stakeholders but so that our extensive knowledge of the healthcare industry can be fully utilized to benefit Thai patients.

Discriminatory Government Procurement Policies

Articles 60 and 61 of Thailand's procurement regulations require public hospitals to purchase their medicines and medical supplies from Thailand's state-owned pharmaceutical company, the Government Pharmaceutical Organization (GPO). These forced transactions prevent public hospitals and patients from having access to other medicines and create an artificial market for the GPO, thereby minimizing demand for innovative pharmaceuticals. These procurement regulations should be repealed.

The Pharmaceutical Research Manufacturers Association of Thailand (PReMA) estimates that current annual GPO revenue growth totals nearly 10% compared to research based industry growth of approximately 1%. Yet, the GPO, as a state enterprise, is exempt from

prohibitions against anticompetitive practices.[34] GPO is also exempt under the Drug Act (Articles 12 and 13) from having to obtain a license from the FDA to produce, sell, or import drugs.[35] This gives the GPO an unfair advantage over the research-based pharmaceutical industry and prevents it from having to compete on quality and value in the Thai market. During the first half of 2010, Thai Government officials suggested that exemptions for the GPO present in the Drug Act and Trade Competition Act would be reviewed, but to date no action has been taken.

PhRMA member companies also remain concerned with the Thai FDA's procurement regulations of Class 2 psychotropic and narcotic substances. These regulations permit non-registered, and potentially dangerous drugs to enter bids and win contracts under the Royal Thai Government tendering process. Many registration approvals for these non-registered drugs are given promptly after winning the tender. These practices prevent PhRMA member companies from fairly competing for these contracts and raise serious quality and safety concerns for Thai patients. PhRMA believes a reinstatement of a pre-registration process for these classes of drugs is needed urgently.

Counterfeit Products

PhRMA applauds recent raids and confiscations of counterfeit medicines by the Royal Thai Government in the second half of 2010. There is, however, an urgent need to further increase targeting of counterfeit pharmaceuticals and enhance penalties for criminals caught manufacturing, supplying, or selling counterfeit or unsafe medicines. Although the Royal Thai Government has recently acknowledged the need to suppress counterfeit medicines that are the result of trademark infringement, there is likewise an urgent need to acknowledge and take action against non-trademark counterfeit medicines also resulting from patent infringement. Due to the serious safety threat associated with counterfeit pharmaceuticals, a higher priority must be placed on curbing their distribution and use. PhRMA continues to support Thailand's National Intellectual Property Policy Committee and hopes that the policy recommendations made by the Committee will properly reflect the importance of stopping the spread of counterfeit

[34] Trade Competition Act B.E. 2542:
Section 4 "This Act shall not apply to the act of:
1)….
2) State Enterprises under the law governing budgetary procedure;"

[35] Drug Act B.E. 2510 as amended:

Section 12. No person shall produce or sell a modern drug or import or order a modern drug in to the Kingdom, unless he has obtained a license from the licensing authority.

Section 13. The provision of Section 12 shall not apply to:

(1) The production of drugs by Ministries, public bodies and departments which have a duty to prevent or treat disease, and by the Thai Red Cross and Government Pharmaceutical Organization,

(3) The sale of herbal drugs which are not dangerous drugs, the sale of common household drugs, the sale of drugs, the sale of drugs by practitioners in the art of healing in the field of dentistry to their care of the sale of drugs by veterinaries to their treatment or prevention of animal disease or the sale of drugs by ministries, public bodies and departments which have a duty to prevent or treat disease and by the Thai Red Cross and Government Pharmaceutical Organization,

(5) The importation by ministries, public bodies and departments which have a duty to prevent or treat disease, and by the Thai Red Cross and Government Pharmaceutical Organization.

pharmaceuticals. The Thai Food and Drug Administration (Thai FDA) and law enforcement leadership should also provide more sufficient resources to train and equip Thai enforcement agencies so they may effectively address the problem. When offenders are convicted, the Thai judiciary should impose significant penalties, including prison terms, in order to create a practical deterrence. PhRMA remains willing to continue to work with governmental authorities to assist in this effort.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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 applaud China's efforts to bring safe, effective, affordable and convenient healthcare to its population. PhRMA believes that patients should be at the center of healthcare reform and looks forward to working with China to this end.

PhRMA also recognizes recent positive efforts by China to improve its enforcement capabilities related to counterfeiting, but several concerns remain on this front. In addition, China continues to fail to adequately protect regulatory data of PhRMA's members. Recent dialogues facilitated by the U.S. Government have been helpful in advancing discussions on China's efforts on data protection and counterfeiting, and should continue. PhRMA also has concerns about a number of market access barriers that negatively impact the environment for innovation in China.

Key Issues of Concern:

- Regulatory Data Protection: Relatively weak regulatory standards allow companies to rely on previously published summaries of other companies' clinical trial and other test data for marketing approval in China. An approval outside of China allows any manufacturer a pathway for approval that requires only minimal data. Allowing such reference to summaries of regulatory data in a company's new drug registration in China undermines the protection of regulatory data and compromises incentives for new product development and introduction.
- Patent Enforcement: China lacks sufficient mechanisms to ensure that patent issues are resolved before follow-on products are marketed.
- Counterfeiting: China has expressed a commitment to reduce counterfeit medicines that mislead and endanger patients. Over the last year, China has taken a number of positive steps including cross-Ministerial efforts to prevent illegal advertisers from selling counterfeits on the Internet through unregistered and illegal websites and enforcement initiatives that include raids on counterfeit factories and arrests. Though the problem of counterfeit medicines continues to exist as a widespread patient safety issue in China, China is taking actions that signal real improvements may be on the horizon. One of the key challenges continues to be the regulatory loophole in China's regulation of active pharmaceutical ingredients (API), which may be improved through increased local enforcement and improving central laws to protect patients from future crimes.
- Market and Patient Access Issues: Considering the lack of domestic healthcare funding in China, PhRMA remains concerned about how existing or proposed policies may impact market and patient access to innovative products, including: linkage of prescribing and dispensing practice, hospital administration practices, government pricing policies, some elements of China's essential drugs policy, and clinical trial application approval times.

For these reasons, PhRMA requests that the People's Republic of China remain under **Section 306 monitoring** for the 2011 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 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.

PhRMA views China's deference to published material and regulatory decisions by agencies outside of China as reliance 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. Reliance on summary data or approvals in countries outside of China 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. Such reliance may create safety concerns around generic products for which inadequate safety data are available to the Government of China.

Effective Patent Enforcement

Transparent mechanisms are needed in China to ensure that patent issues can be resolved before follow-on products, such as generic or biosimilar are marketed. While Articles 18 and 19 of China's updated *Drug Registration Regulation* refer to publication 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 current draft Amendment of the Patent Law exempts without condition 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 allow patent holder companies to file patent infringement suits before marketing authorization is granted to non-patent holders and afford sufficient time for dispute 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.

Market Access Barriers

Healthcare Funding

China contributes a relatively small percentage of its GDP to healthcare compared to other countries of comparable economic development. The majority of Chinese patients pay most of their healthcare expenses out-of-pocket. PhRMA supports the Chinese Government's effort to expand public health insurance and encourage greater uptake of private health insurance. Comprehensive reform of the healthcare sector will improve the quality and accessibility of medical care in China. PhRMA hopes to work with the Chinese Government to develop long-term policy solutions for a financially sustainable healthcare system.

Prescribing and Dispensing Practice

Unlike most industrialized economies, China permits hospitals and physicians to both prescribe and dispense medicine. This practice allows doctors and hospitals to profit from the medicines they prescribe. As a result, doctors have a financial motivation to prescribe products for which they can make the greatest return (for themselves and the hospitals that employ them) as opposed to prescribing products solely on the basis of medical need. The problem is exacerbated by inadequate funding for hospital and physician services. Because patient fees for medical services are low, doctors and hospitals supplement their income by charging mark-ups on medicines and prescribing additional medicines. Over-prescribing can lead to drug resistance to infectious diseases like tuberculosis and can contribute to adverse drug interactions.

Revenues available to hospitals and medical professionals from linking prescribing and dispensing practices significantly distort Chinese pharmaceutical prescribing practices by promoting sales of products for which the hospitals can make the largest profits. China has committed to reform the way hospitals are financed as part of its newly announced healthcare reforms. We encourage the U.S. Government to support these efforts.

Hospital Administration

Hospital bidding began in China with pilot projects in 1999–2000, and has expanded to include more than 80 percent of all hospitals. Under this structure, hospitals purchase between 75-100 percent of their pharmaceutical portfolio through bidding. Simultaneously, the National Development and Reform Commission (NDRC) removed the controls on profit margins within the distribution chain, thereby allowing hospitals to grow their portion of the total distribution profit margin. While this process allows hospitals to derive greater discounts on medicines, the cost savings are not passed on to patients.

Patient criticism of the high cost of medicines drives the Government to cut prices, but until recently, very little was done to address the disparity between ex-factory and retail prices. In 2006, the NDRC imposed a cap of 15 percent on hospital pharmaceutical mark-ups. Unfortunately, the Government's policy does not account for lost revenue as a result of the cap. To compensate for lost profits, hospitals have an incentive to "comply" with the policy by increasing the total number of prescriptions.

Government Pricing Policies

Pharmaceutical products are considered special commodities in China, and thus are subject to government price controls. In 1997, the NDRC was given jurisdiction over pharmaceutical pricing. 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 the market.

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. Such a positive step will help to ensure patients have access to healthcare. 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 make their way to the patients who need them most

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 State Food and Drug Administration (SFDA) develop new practices that are in line with international best practices.

Counterfeit Pharmaceuticals

Over the last year, the Chinese Government has expressed a commitment to reducing counterfeit medicines and has undertaken a series of actions towards achieving that goal. Although the prevalence of counterfeit drugs within and originating from China remains a substantial concern, their efforts to help protect patients within China and globally should be applauded. These efforts include coordination among Chinese authorities to reduce illegal sales of counterfeit medicines, including the large amount of medicines sold through illegal online websites.

Pharmaceutical counterfeiting is a global public health concern. The United States and China have agreed to work together to prevent the production, sale, and transit of fake medicines to our patients domestically and in other parts of the world. In this regard, China has taken positive steps in 2010 to step up enforcement operations, including raids of criminal manufacturing sites and arrests that 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 efforts to reward and recognize all local law enforcement efforts in this area. Additionally, China has been working to tackle one of the most complex and important problems involving counterfeit medicines: the sale of counterfeits through illegal online advertisements and "Internet pharmacies" claiming to sell legitimate products. The internet has enabled criminals to operate easily and anonymously through thousands of websites that advertise and sell fake medicines through business-to-business operations and fake online websites targeting consumers by purporting to be legitimate pharmacies. This is a shared priority for the United States, as echoed in the 2010 Joint Strategy of the Intellectual Property Enforcement Center in the Executive Office of the President. In 2010, China worked across ministries to target several websites that were knowingly violating Chinese laws set up to protect patients. It would be helpful to learn more about China's work in this area as part of the U.S.-China partnership and as a model for other countries, given the large number of websites globally offering counterfeit medicines for sale and the potential impact on patient safety and worldwide public health. We hope that China's work in this regard will continue and increase in 2011, as illegal internet sales is at the core of the worldwide counterfeit medicines problem.

China also made positive steps in 2009 by upgrading the Judicial Interpretations regarding the crime of drug counterfeiting, which significantly lowered the incriminating "threshold" for certain high-risk counterfeit products. To further resolve these issues, China is incorporating a provision in its on-going Draft 8th Amendment of the Criminal Code that will eliminate the incriminating threshold for all drug-counterfeiting activities. Should the draft become law and more resources be invested by the government in enforcing these laws, the deterrence against drug-counterfeiting in China should be greatly enhanced. We look forward to learning more about China's progress on this front.

Despite the above positive steps, a remaining challenge related to counterfeit medicines in China is the use and regulation of bulk chemicals or Active Pharmaceutical Ingredients (APIs). Bulk chemicals for drug use and other APIs are generally deemed pharmaceuticals under the PRC Drug Administration Law and thus are subject to its provisions; but in practice, many chemical companies produce bulk chemicals and advertise/sell them for medicinal uses only. In essence, they choose not to register with SFDA as required by law. The unregulated distribution of API may expose patients to serious and significant health risks and degrade consumer confidence in the global medicinal supply chain. As such, China has committed to close this regulatory loophole. In 2010 public reports, China indicates that they are looking at ways to improve their regulation of APIs in a way that will reduce counterfeiting. PhRMA commends SFDA's work to resolve this issue as an important step. PhRMA encourages SFDA to continue prioritizing this issue to help protect patients domestically and globally.

With regard to China's engagement in the international arena, China has shown a clear commitment to reducing counterfeit medicines through its public statements, which sends an important message to the world. Additionally, Chinese Customs Authorities have executed seizures on exports as well as imports, demonstrating a positive commitment to global health. PhRMA encourages this activity and hopes that recorded customs seizures will increase and continue as a clear metric of China's increased commitment in this area. Additionally, PhRMA

recommends enhanced cooperation of Chinese Customs Authorities and Law Enforcement with international authorities, including the United States. Likewise, PhRMA continues to commend China for its willingness to partner internationally on this issue and recommends that the U.S. Government encourage China to continue and even enhance its leadership on this issue in regional and multilateral forums that enable coordination on anti-counterfeiting, including Interpol, the World Customs Organization, APEC, and other international bodies that are attempting to combat counterfeit medicines. PhRMA supports the recent discussions at the 2010 meeting of the U.S.-China Joint Commission on Commerce and Trade and strongly encourages the U.S. Government to recognize China for its steps to reduce counterfeit medicines and continuing such dialogues in an effort to resolve this critical concern.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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 inadequate intellectual property protection and 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). The backlog of patent applications awaiting examination and the patent pendency period remained stagnant in 2010 at best, if not increased. Moreover, 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 prevent India's own innovative biopharmaceutical industry from developing, 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:

- Lack of Regulatory Data Protection (RDP);
- Narrow patentability standards;
- Patent Enforcement and Regulatory Approval;
- Government price controls; and
- Counterfeiting.

For these reasons, PhRMA requests that India be placed on the **Priority Watch List** for the 2011 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

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

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

Patent Enforcement and Regulatory Approval

India does not provide mechanisms for resolution of patent disputes prior to marketing approval. Such mechanisms are needed to prevent marketing of patent infringing products. To ensure proper patent enforcement the US Government should urge for the implementation of such mechanisms.

Backlog of Unexamined Patent Applications

There are presently around 200 Patent Examiners at the Indian Patent Office, with approximately 78,792[36] applications to be examined as of June 2010. The delays and quality compromises likely to be associated with this situation are untenable. PhRMA urges concerted efforts to increase the capacity of the Indian Patent Offices to quickly process this large work load.

Compulsory Licenses on Patented Pharmaceutical Products

Although India has to date never issued a compulsory license (CL) for a patented pharmaceutical product, the research-based pharmaceutical industry is concerned about the recent Discussion Paper on Compulsory Licensing issued on August 24, 2010.[37] The Discussion Paper contained a number of statements that suggest specific CLs are actively under consideration by the Government. Other statements in the Discussion Paper incorrectly implied that CLs are widely used by other governments, such as the United States.

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);
- Eliminating mention of price as a trigger to CL or clarifying what is meant by "reasonably affordable price". (Section 84(1)(a)(b) provides for CL if the patented invention is not available to the public at a "reasonably affordable price"); and,
- Removing the numerous triggers that provide a low hurdle to seeking a compulsory license.

In cases of CL for exports, India should ensure that proper anti-diversion measures are taken and that the CL is granted for humanitarian, non-commercial use only.

Standards for Patentability

Some of the standards for patentability in India are inconsistent with the TRIPS Agreement, depart from the mainstream of practice internationally, or are not transparent. Section 3(d) of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005 creates additional hurdles for pharmaceutical and chemical compound patents. Under this provision, salts, esters, ethers, polymorphs, and other derivatives of known substances are considered the same substance and thus not patentable, unless it can be shown that they differ

[36] The Commerce and Industry Minister Anand Sharma, in a written reply to the Lower House of the Indian Parliament on August 2, 2010, available at http://164.100.47.132/LssNew/psearch/QResult15.aspx?qref=89910 (last visited Jan. 8, 2011).
[37] Discussion Paper on Compulsory Licensing, Dep't of Industrial Policy and Promotion, Ministry of Commerce and Industry (Aug. 24, 2010), *available at* http://dipp.nic.in (last visited Jan. 8, 2011).

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. 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.

Market Access Barriers

Government Price Controls:

PhRMA member companies are extremely concerned about the requirement, under the Proposed National Pharmaceutical Policy 2006, for mandatory one-to-one government price negotiations prior to marketing approval of patented drugs launched in India after January 1, 2005. PhRMA member companies believe that this proposal represents an effort to reduce significantly the benefits of product patent protection, and will discriminate against importers of patented drug products.

Further, the draft policy contravenes the Government's stated goal of liberalizing the pharmaceutical sector by reducing government control over the pricing of pharmaceutical products in India. The proposed policy could bring 354 drugs under government price control in addition to the 74 drugs currently subject to price controls. This greatly expands coverage from the 2002 drug policy (now mired in litigation), which subjected only 37 drugs to government price controls.

Apart from the proposed National Pharmaceutical Policy 2006, Government price regulators also act arbitrarily and in a non-transparent manner in setting prices, and the existing pricing policy itself is marked by lack of transparency and clarity.

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%, 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%. 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. For the benefit of India's patients, import tariffs should be brought down to zero, the level of many WTO Members.

Counterfeiting

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

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

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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-counterfeit enforcement efforts as well as discriminatory intellectual property standards and market access barriers stemming from regulations that are instituted with little notice and no input from the research-based biopharmaceutical industry. This continues to be a problem at both the administrative level (for example, the Ministerial Decree 1010) and at the parliamentary level (for example, the Health Act). As a result, companies face severe market access constraints that could result in a market contraction. PhRMA and the research-based biopharmaceutical industry applaud the Government of Indonesia's decision to revoke and replace the Halal Labeling Decree in July 2010 with a new Decree (Regulation Number HK.03.1.23.06.10.5166) and hope that the necessary coordinated steps can be taken to institute meaningful reform and address the remaining key areas of concern.

Key Issues of Concern:

- Ministerial Decree 1010;
- Health Law;
- Non-Conformance to international best practices in the pharmaceutical registration process; and
- Counterfeit enforcement.

For these reasons, PhRMA requests that Indonesia be placed on the **Priority Watch List** for the 2011 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 Rights

Ministerial Decree 1010

Ministry of Health (MOH) Decree 1010/MENKES/PER/XI/2008 ("Decree 1010") formally implemented on November 3, 2010, impacts 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 approvals. As several of PhRMA's member companies do not manufacture products in Indonesia, and thus do not qualify for this status, they are classified as "distributors", or "PBF", enterprises. They are so classified even though these firms follow globally recognized good manufacturing and distribution practices and provide high quality pharmaceuticals to Indonesian patients in the same manner as other high quality biopharmaceutical manufacturers that manufacture in Indonesia. PBF enterprises are barred from the Indonesian market unless they either establish a drug manufacturing facility in the country or transfer sensitive intellectual property to a local Indonesian firm.

An amendment to Decree 245/1990 was signed into law on December 16, 2010 altering the definition of local manufacturing in Indonesia to include domestic packaging and labeling facilities. While PhRMA and its member companies continue to review the amendment at the

time of this submission, discriminatory aspects of the policy remain. This amendment also poses problems for companies that may wish to undertake toll manufacturing, among others.

Furthermore, even with the amendment to Decree 245/1990, Article 10.2 of Decree 1010 still requires local drug manufacturing for all pharmaceutical products that are 5 years past patent expiration. This measure is expected to have a significant market impact. PhRMA's members are seriously concerned about the discrimination that remains inherent in Decree 1010 and continues to seek a pragmatic solution that will permit all legitimate high quality pharmaceuticals to be traded, sold and distributed in Indonesia, regardless of origin.

Market Access Barriers

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, the Law, drafted with little real stakeholder input, 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 bill and provide constructive input during the drafting of the implementing regulations.

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 data protection, patent enforcement, and bioequivalence requirements.

Counterfeit Enforcement

Despite the establishment of a National Anti-Counterfeiting Task Force last year and recent commendable efforts by the Indonesian Government to launch an educational campaign seeking to minimize counterfeit medicines, unsafe and ineffective pharmaceutical products continue to be a significant and growing concern in the country. While PhRMA welcomes

Indonesia's attention to the problem of counterfeit medicines, there is an urgent need to expand national enforcement efforts. Increasing the penalties for criminals caught manufacturing, supplying, or selling counterfeits as well as spurious and unsafe medicines will also assist Indonesia to reduce the negative 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 2010 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. The Government of New Zealand remains the primary purchaser of pharmaceuticals in New Zealand. PHARMAC continues to impose stringent cost containment strategies,[38] 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 2011 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 was introduced to the New Zealand Parliament in July 2008 which is intended to replace the Patents Act of 1953. One notable omission from the proposed amendment is patent term restoration. On average, the regulatory approval process for new drugs in New Zealand takes about three years after the date of approval in the country of first launch. This delay is exacerbated by the uncertainty and tardiness of PHARMAC funding which is necessary for effective market access. Many countries, including the United States, Australia, and the European Union, have established mechanisms to restore patent terms for pharmaceutical products to recover time 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.

[38] 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 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 83 innovative new prescription-only medicines listed on the Pharmaceutical Benefit Scheme in Australia between May 2000 and October 2006, only 22 are currently reimbursed in New Zealand.[39] Many of these 22 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 procurement 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 form decisions about which products can be funded.

5. **Transparency and Rigor of Processes and Decision Making** – Public confidence will be enhanced if decision making processes are underpinned by transparency, fairness, timeliness and high standards of consultation and review. All stakeholders must be able to understand the true basis of decisions and rationales should be clearly stated. What is considered "value for money" should be comparable to other OECD countries 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.

[39] Michael Wonder, Senior Health Economist, Novartis: *Access by patients in New Zealand to innovative new prescription-only medicines; how have they been faring in recent time in relation to their trans-Tasman counterparts?* (June 2006).

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% 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 2010 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 highly concerned about Canada's intellectual property environment, which continues to be characterized by significant uncertainty and instability for U.S. pharmaceutical companies. Canada's intellectual property regime lags behind that of other developed nations in several significant respects, including the absence of an effective right of appeal under its patent enforcement mechanisms associated with generic marketing approvals. In addition, data protection is arbitrarily restrictive in scope, and Canada is one of the only developed nations without any form of patent term restoration. Canada also has a number of significant market access barriers that challenge U.S. pharmaceutical companies.

Key Issues of Concern:

Intellectual Property:
- Weak enforcement of patents;
- Increased patent disclosure requirements;
- Lack of patent term restoration;
- Legal challenges to data protection; and
- Canada's Access to Medicines Regime.

Market Access Barriers:
- Patented Medicine Prices Review Board;
- Common Drug Review;
- Pan-Canadian Oncology Drug Review; and
- Subsequent Entry Biologics.

For these reasons, PhRMA requests that Canada remain on the **Priority Watch List** for the 2011 Special 301 Report, and that the Report should specifically reference intellectual property issues confronting U.S. pharmaceutical companies. In addition, the U.S. Government should seek assurances from the Canadian government that the problems described herein are quickly and effectively resolved.

Intellectual Property

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 should not be allowed to continue unaddressed. 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 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the North American Free Trade Agreement (NAFTA). For example:

1. No Effective Right of Appeal

A patentee does not have an effective right of appeal under the PM (NOC) Regulations if it is unsuccessful in the first instance, whereas a generic drug producer does. This is because the Regulations provide that a generic product may be approved for marketing (through the issuance of an 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.[40] The patentee is then left with no alternative but to start a new proceeding outside of the framework of the PM (NOC) Regulations, i.e., commencing an action for patent infringement once the generic product enters the market, essentially having to restart a case it had already spent up to two years litigating under the Regulations.

In contrast, under the PM (NOC) Regulations, a right of appeal is available to the generic if the patentee prevails in the first instance. PhRMA member companies recommend that the U.S. Government strongly encourage Canadian authorities to rectify this fundamental and discriminatory imbalance through regulatory changes that will ensure there is a meaningful and effective right of appeal for patentees.

2. Limitation on the Listing of Valid Patents

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.

3. Patent Infringement Proceedings

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 above, can make it difficult for the patentee to prove its case.

[40] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359.

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 usually takes at least two years before an action for patent infringement is tried. By then the innovative company's market share can be severely eroded by the marketing of the generic product. Provincial 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 with attendant economic losses. These losses are serious and of growing concern.

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.

Increased Patent Disclosure Requirements for Inventions

In addition to the PM (NOC) Regulations issues set out above, due to a series of judicial decisions, uncertainty has arisen as to what exactly must be put in the patent disclosure relating to the work done by the inventors that led to the invention. While a number of cases have reiterated that the sufficiency requirement (see section 27(3) of the Patent Act[41]) only requires that the patentee set out what is the invention and how to put it into practice (which is consistent with TRIPS, NAFTA and the Patent Co-operation Treaty), other cases have suggested that there is now a new and additional requirement to set out more of the work done to arrive at an invention where the patent depends in the slightest on the concept of sound prediction of utility. It is clear that there is absolutely no statutory basis for this "heightened disclosure" requirement. In spite of this, a number of patents that protected a number of valuable products have been invalidated based on one form or other of this heightened disclosure requirement.

Limitations on 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. Additionally, PhRMA notes that the Canadian data protection regime has been

[41] Patent Act (R.S.C, 1985, c. P-4, as amended).

subject to repeated legal challenges by the generic industry. Although Canada's data protection regime was upheld at the appeal stage,[42] Canada's generic pharmaceutical association has sought leave to appeal that decision to the Supreme Court of Canada. In the event that lave for the appeal is granted, PhRMA member companies urge the U.S. Government to request that Canadian authorities not only vigorously defend the 2006 amendments to the data protection regime, and should an adverse decision arise, that the Canadian authorities should amend the regulations or introduce legislation to remedy the issue.

Canada should also be encouraged to provide greater clarity regarding the requirement that innovative products must be "marketed in Canada" in order to receive and to maintain protection of the associated clinical trial data. This additional requirement is not supported by the text of either Article 39.3 of the TRIPS or Article 1711 of the NAFTA. PhRMA members are concerned that the absence of any clarity in Canada's regulations may result in future situations where innovators either cannot obtain or lose data protection for reasons beyond their reasonable control. In the absence of further elaboration regarding the "marketed in Canada" requirement, it is also reasonable to assume generics will initiate legal proceedings to challenge innovator compliance with the requirement.

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 these issues 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.

No 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 in 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

[42] Canadian Generic Pharmaceutical Association v. The Minister of Health et al; Apotex Inc. v. The Minister of Health et al. (A-352-09/A-360-09); 2010 FCA 334 (Dec. 9, 2010), *available at* http://decisions.fca-caf.gc.ca/en/2010/2010fca334/2010fca334.html (last visited Feb. 10, 2011).

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developing nations in other forums on these same issues.

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. In 2009, private members' bills were introduced in both the House of Commons and in the Canadian Senate that would completely eliminate important intellectual property safeguards from the regime. While the Senate bill is no longer effective, in the House of Commons Bill C-393 passed Second Reading and could be brought back to the House of Commons for a third reading. Although the Canadian Government opposed Bill C-393, several members of the Government voted with the parliamentary opposition to refer the Bill to Committee. Since the next vote on Bill C-393 would determine if the proposed amendments become law, 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.

Market Access Barriers

Patented Medicine Prices Review Board (PMPRB)

The PMPRB is charged with review of prices of patented medicines in Canada, and is responsible for remedying excessive pricing, if found. Guidelines, as administered by Board Staff, calculate a maximum average factory gate price that a manufacturer can charge for a patented medicine. If a manufacturer's average price is above this price, the Board may allege excessive pricing, and a hearing may be commenced.

Pursuant to the *Patent Act*, the PMPRB has authority to regulate the prices of patented medicines sold in Canada and has the power to issue remedial orders requiring a manufacturer to reduce the price of a patented drug. From 1987 to 2006, the PMPRB initiated very few investigations or hearings into the pricing of drugs. However, in the past several years, the PMPRB has commenced numerous investigations and hearings, alleging excessive pricing by individual drug companies, including a number of U.S.-based companies.[43]

The PMPRB issued new Guidelines that took effect January 1, 2010. The new Guidelines increase the complexity of reporting, yet retain the link between the average transaction price of a product and its maximum average price as the measure of whether or not there is excessive pricing.

[43] *See*, *e.g.*, PMPRB Annual Report of 2009, *available at* http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1340&mp=91 (last visited Feb. 10, 2011).

On August 18, 2008, the PMPRB issued a Communiqué stating certain reporting requirements for patentees, effective January 2010. These requirements were challenged, and on July 17, 2009, the Federal Court set aside the Communiqué and held that the PMPRB has no authority to require patentees to report third party benefits. In its essence, the Court decision stands for the proposition that the only benefits (free goods, discounts, *etc.*) that must be reported under the regulations are those provided to direct customers of patentees. The Board, therefore, has no jurisdiction to require the reporting of other benefits.

Since the Federal Court decision, PMPRB has not indicated to patentees how it will implement the remainder of the reporting requirements of the Communiqué, as well as how the new Guidelines will be applied, creating significant uncertainty in the meantime for patentees. PhRMA member companies hope to continue working with the PMPRB to find mutually agreeable solutions to these challenges.

Common Drug Review

The CDR is a Federal/Provincial/Territorial (F/P/T) body that was created in 2003 by the F/P/T Ministers of Health. Its goal is to provide cost/benefit advice to F/P/T drug plans in order to help them with their public formulary listing decisions. However, despite recent dialogue with the pharmaceutical industry, the CDR has not been transparent in its operations. Furthermore, given that the CDR can only provide listing recommendations rather than decisions, the F/P/T drug plans who manage the formularies can accept or reject its advice without providing any rationale for their decisions.

In early 2007, the Standing Committee on Health (SCH) (a body of the Federal Parliament) reviewed the CDR and made five recommendations for its improvement: (1) undertake an evaluation; (2) increase transparency; (3) increase public involvement; (4) undertake a separate review for first-in-class drugs and drugs for rare disorders; and (5) establish a separate appeals process. The Federal Minister of Health agreed with most of the SCH's recommendations. While the Minister did not specifically support a separate appeals process, the Minister suggested that the current appeals process at the CDR must be improved. While the CDR has publicly stated that it would examine the SCH's recommendations, no progress has been made to date.

PhRMA member companies request that the U.S. Government urge the Canadian Government to implement the SCH's recommendations. The Canadian Government should also be encouraged to pursue policies to bring Canada closer to comparable nations with respect to access to new medicines.

Pan-Canadian Oncology Drug Review (formerly the Joint Oncology Drug Review)

On March 1, 2007, the Joint Oncology Drug Review (JODR) was implemented. It was intended to be an interim cross-jurisdictional review process for all oncology drugs, based on Ontario's then-existing review process for cancer drugs, the Committee to Evaluate Drugs (CED)-Cancer Care Ontario (CCO) Subcommittee. Generally, the process took three months to review each oncology drug product and its recommendations were forwarded to the provinces and territories to make final, independent decisions regarding reimbursement.

The November 2, 2010 Rx&D International Report on Access to Medicines 2009-2010, , shows that Canada is ranked 19 out of 29 OECD countries (including Scotland) when it comes

to the public reimbursement of oncology drugs reviewed by the Joint Oncology Drug Review (now the pan-Canadian Oncology Drug Review). Just over 50% of new cancer drugs (i.e., those reviewed by JODR since its inception in 2007) approved for sale in Canada by Health Canada are actually publicly covered by drug plans in this country compared to an average 65% in the other OECD countries.

In 2010, the Canadian Government advertised for the position of Executive Director, Pan-Canadian Oncology Drug Review (p-CODR). The new review process to be managed by the p-CODR is still being developed. It is expected that it will take four to five months to review new cancer drugs under the new system. Participating public drug plans will retain the right to make the final decision whether to publicly cover new oncology drugs.

Under many drug plan decision-making decisions in Canada, it is often unclear what weight is given to various factors involved in deciding whether to publicly cover certain drugs. Whatever criteria are developed under the new review process, it is imperative that they be science-based and focused on achieving appropriate health outcomes for patients.

Subsequent Entry Biologics (SEBs)

In March 2010, Health Canada issued its final Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs), addressing issues that would arise in the context of considering SEB submissions for regulatory approval. At the same time, changes to the guidance documents relating to the Patented Medicines (Notice of Compliance) Regulations (PM (NOC) Regulations) and the Food and Drug Regulations – Data Protection were also released.

While these guidance materials to some extent clarified the manner in which intellectual property will be protected, there are still uncertainties that may lead to litigation. For example, the SEB Guidance Document would still permit the use of a non-Canadian reference product as the comparator product, which may result in safety concerns and may also practically erode intellectual property protection for innovative biologics.

In addition, these Guidance Documents are administrative documents, as opposed to binding statutory or regulatory instruments. As such, PhRMA member companies are concerned that there may be administrative exceptions made to their contents in practice and/or application, and therefore innovators may be confronted with significant uncertainty and potential litigation with respect to future Health Canada approvals of SEBs. This is a particular concern in light of the many Canadian provincial jurisdictions involved in drug reimbursement.

In order to safeguard innovator rights, PhRMA members believe the U.S. Government should request that the Canadian Government move to create a separate regulatory pathway for the approval of SEBs.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

Overview: The European Union

The Pharmaceutical Research and Manufacturers of America (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.

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.

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.[44] Overall, however, interim injunctions to prevent accused products from remaining on the market until trial are granted in less than half the relevant cases.[45] This failure to provide effective remedies fundamentally undermines the exclusive rights conferred by a patent.

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

It is imperative for all pharmaceutical companies, innovative or otherwise, that there are dependable mechanisms to resolve potential patent infringement issues before follow-on product launch.[46]

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 declaration of non-infringement in individual Member States. The latter is similar to an application for declaratory judgment in the United States.

[44] *See*, e.g., Leo Pharma v. Sandoz, [2008] EWHC 541 and Novartis v Dexcel-Pharma, [2008] FSR 31.
[45] DG Competition, European Commission, "Pharmaceutical Sector Inquiry Final Report," para. 641, July 8, 2009.
[46] 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 Jan. 17, 2011).

However, there is no opportunity for innovator companies to resolve patent disputes well in advance of generic 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 generic product, which often makes resolution of disputes before actual launch impossible. In addition, resolving these disputes in this manner is often lengthy, expensive, and can result in significant market loss, even if the end ruling favours the company that produced the original molecule.

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

Further, in many cases, PhRMA member companies have experienced EU Member States providing financing for products, which are alleged to infringe, 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 advance information regarding relevant existing patents could be useful in assessing whether to await patent expiration or challenge the applicability of a patent and thus help avoid premature investments. It could also contain safeguards that delay or prevent approval of products alleged to infringe, pending judicial resolution.

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

A third concern for PhRMA members is the growing use of therapeutic reference pricing as a tool to reduce the price of innovative medicines with active patents. A growing number of countries (*e.g.*, the Czech Republic, Germany, Greece and Romania), are matching the government price of an innovative product to that of a generic product in the same therapeutic class. This *de facto* devalues the worth of the patent, reducing the remuneration a company can receive for an innovative product to the price level of a competing generic medicine.

Fourth, PhRMA members continue to suffer economic losses as a result of extensive parallel trading of medicines within the EU. The gains benefit mainly parallel traders themselves, and provide minimal benefit to national social security budgets. The Commission should encourage Member States not to impose price controls on products that are not reimbursed by the Member State, as recommended by G10, the effect of which would be to limit parallel trade.

A fifth concern by PhRMA members is that the EU’s ban on patient information bars patients from making informed choices and has a disproportionate impact on new and 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 member concerns.

CZECH REPUBLIC

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in the Czech Republic remain concerned that the Czech system for determining government pricing and reimbursement levels for pharmaceutical products, greatly diminishes the value inherent in pharmaceutical patents and constitutes a significant and discriminatory barrier to U.S. products. This and other market access barriers in the Czech system restrict patient access to advanced life-saving medical treatments developed by U.S. companies.

Key Issues of Concern:

- Therapeutic reference pricing devalues the worth of a pharmaceutical patent by linking that product's price to the lowest price in a therapeutic class. In many instances the lowest price is that of a generic medicine.
- The Czech Government has imposed a series of demand controls that discourage the prescribing of innovative pharmaceutical products.

For these reasons, PhRMA requests that the Czech Republic be placed on the **Priority Watch List** for the 2011 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 Rights

While many of the Czech Republic's cost-containment policies diminish the value of patents, the therapeutic reference pricing system (described further below) does so to such a degree that within the Czech Republic patents often provide no added benefit to PhRMA members. 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 Czech Republic's system dramatically undervalues the innovation and development costs involved in bringing the patented pharmaceutical to market.

Market Access Barriers

2008 Changes in Government Pricing and Reimbursement

Pricing and reimbursement decisions in the Czech Republic are governed by the State's Institute for Drugs' Control (SUKL).[47] SUKL is responsible for all three steps required for drugs to reach the market, including the medical evaluation of their efficacy and safety, and for setting their prices and reimbursement rates.

[47] Law 48/1997 on Public Health Insurance, para. 39a-p (2008).

Reimbursement Criteria

With respect to government reimbursement, the lowest price for the final customer of the reference product in any EU country is the basis for the reimbursement of the therapeutic reference group in the Czech Republic (external referencing). Law 48 sets pricing and reimbursement levels across broadly-created reference groups and clusters.

The Czech Government also uses a therapeutic reference pricing (TRP) system (internal referencing) for setting reimbursement rates for medicines. Law 48 represents an unnecessary and unjustified barrier to international trade because it functions as an obstacle to innovative products, all of which are imported, and is without scientific or technical justification, raising national treatment concerns under the General Agreement on Tariffs and Trade (GATT) as well as potential concerns under the World Trade Organization Agreement on Technical Barriers to Trade.

The TRP system clusters products into therapeutic groups. A patient prescribed any of the medicines in a cluster will be reimbursed the same amount (usually the price of the cheapest product in the cluster) regardless of whether the product is patented, off-patent or an infringing copy. In rare cases, the Government does award a reimbursement premium to a patented molecule, but this is not the norm. Moreover, a reimbursement cut for generic molecules nearly always triggers corresponding reimbursement cuts for the branded molecule.

If the Government cuts the reimbursement for a drug below the government determined maximum price, patients must make up the difference out of their own pockets. When reimbursement cuts target innovative drugs, these significant out-of-pocket payments inherently and negatively impact innovative drugs. Moreover, when a new generic enters a therapeutic group, it can trigger reimbursement cuts for all products in the group, including products still protected by patents.

Grouping patented products with generics and linking reimbursement for patented and generic products forces prices for imported patented products towards those of domestically-produced generics. This, in turn, undermines the value of pharmaceutical patents in that market segment. Through this regulation, the Ministry of Health (MOH) and the insurance funds are jointly fixing a maximum price that aims to prevent, restrict or distort competition. At the same time, it heavily favors the local generic manufacturers, who almost always produce at lower costs compared to innovative industry as they do not bear almost any costs related to research and development of new drugs. An effective remedy to this discrimination is denied to manufacturers at the local level (see below), and whether a remedy may be available under European law is subject to a referral to the European Court of Justice.

The MOH is currently preparing an amendment of the Law 48/1997 on public health insurance. It is anticipated that the amendment will come into effect in April or May, 2011. If approved by the Parliament, the proposed changes would further deteriorate the position of innovative industry in the Czech Republic. Major proposed changes include:

- Expedited government price/reimbursement approval for the first generic drug. The reimbursement price for all products in the therapeutic group will decrease by 32% regardless of patent status of other drugs in the group.[48]

[48] Amendment of Law 48/1997 on Public Health Insurance, para. 39b, section 5 as proposed by the MOH in October 2010.

- Expedited price/reimbursement approval for the first follow-on /biosimilar drug. The reimbursement level of all medicines in the therapeutic group will decrease by 15% regardless of patent status of other drugs in the group.
- New hurdles to obtain price/reimbursement approval for innovative drugs. Despite these new hurdles, innovative producers will be obliged to cover the full cost of treating patients continuing on a certain medication in the event that the temporary price/reimbursement term expires before the permanent price/reimbursement approval is granted.[49]

Demand Controls

The Czech Government also artificially suppresses demand for pharmaceuticals, targeting imported innovative, patent-protected molecules. The Government uses a system of prescription and indication limitations that specify which medical specialties may prescribe certain medications.[50] These limits severely suppress demand and restrict access to innovative medicines, lack any medical basis, and are applied in a discriminatory fashion. The prescribing limits on imported drugs are typically only eliminated when the patent expires and a generic product enters the market.

Finally, the Czech Government operates a system of individual physician prescribing budgets, under which each physician's prescribing of drugs is monitored and compared with previous prescribing levels. An individual physician who prescribes more in a given period than in the previous period faces substantial financial penalties, and a physician who prescribes less is financially rewarded. This system suppresses demand, particularly for higher priced drugs, because the budget is based on the price of drugs, not on the volume of drugs prescribed. While this system affects demand for all pharmaceuticals, imported innovative drugs, which are generally more expensive than domestically produced generics, are disproportionately impacted.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to trade barriers related to intellectual property protection and market access.

[49] Amendment of Law 48/1997 on Public Health Insurance, para. 39d, section 3 as proposed by the MOH in October 2010.
[50] Law 48/1997 on Public Health Insurance, para. 39b (2008).

HUNGARY

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Hungary remain concerned that Hungary routinely discriminates against innovative pharmaceuticals in favor of local generic producers. Despite recognition by the newly elected Hungarian Government that Hungary is facing a healthcare crisis, no new measures have been passed that increase the Hungarian population's access to advanced pharmaceutical treatments.

The Hungarian Government has repeatedly introduced a number of reforms to its reimbursement system to curb public spending. These measures, combined with cost-containment policies initiated in 2007, severely impact the ability of PhRMA member companies to effectively market their products in Hungary.

Key Issues of Concern:

- Volume restrictions on reimbursement for exceptional cases (limited number of patients regardless of the prevalence/incidence of diseases);
- Lowest EU price at the time of application for pricing and reimbursement;
- The reimbursement-volume contracts for new products (up to 4 year volume cap contract with 100% pay-back on gross price, including distributor margins, to patient in case of overspending) are now based on outcome criteria and/or compliance programs, and these measures may also be combined into one contract;
- The drug reimbursement budget has not grown since 2007 (and has decreased by HUF 4 billion in 2010), despite modest growth of the market, resulting in a growing burden for pharmaceutical companies and patients; and
- Only innovative products causing no additional budget impact were included on the reimbursement list in 2009 and 2010, which is incompatible with EU Directive 89/105/EC.

For these reasons, PhRMA requests that Hungary be placed on the **Priority Watch List** for the 2011 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

Data Protection

Since joining the European Union in 2004, the Hungarian Government has been required to implement the EU's "8/2/1" data exclusivity directive. The legislation to establish this protection was finally published in 2009. PhRMA encourages the US Government and its EU counterparts to carefully monitor the implementation of this directive to ensure adequate protection for pharmaceutical test data.

Market Access Barriers

The Government of Hungary provides health care to its citizens through the National Health Insurance Fund (NHIF). Pharmaceutical legislation that went into effect in January 2007 established new tax burdens and created new market access barriers for innovative pharmaceuticals. These include:

Financial barriers:

- A 12% tax on all reimbursed products;
- A claw-back system under which pharmaceutical companies are held financially responsible for any overspending in the retail pharmaceutical budget;
- A sales representative tax of approximately USD $25,000 per year, per representative;
- Mandatory, four-year, non-disclosed reimbursement-volume contracts for newly reimbursed products designed specifically to reduce volumes regardless of the real (epidemiology based) patient demand;
- Restrictions on reimbursement, limiting the number of indications, the number of centers, and specific prescribers;
- Quarterly reference pricing with de-listing (electronic bidding system) for Type 1 (generic) and Type 2 (therapeutic reference) reimbursement groups;
- Non-transparent formulation of Type 2 reference pricing groups;
- Cross-country referencing that incorporates the lowest European price at launch;
- Prescription directive limiting the prescribing choice of physicians.

Procedural barriers:

- There continue to be significant delays in seeking 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 ministerial decree publication process, which is 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;
- Introduction of reimbursement procedures for the purchase of pharmaceuticals at hospitals;
- Continuous review of drug reimbursement status, based on easily adjustable criteria; and
- Lack of clear use of pharmaco-economic data.

Hungary's efforts to cut its health care budget do not appear to be sustainable in the long run and are ultimately detrimental to its patients. The concept of baseline budgets is very

problematic for a number of reasons, including that it institutionalizes existing practice without regard to the needs of patients. The system provides a fixed upper-limit on NHIF financial exposure, and it also creates an environment that encourages market operators to increase sales volumes under certain circumstances. Ordinarily, this will lead to intensified pressure due to patient demand for increased funding of reimbursement.

Moreover, the budget-cutting claw back system creates an environment that discourages competition from new market entrants, who are disadvantaged relative to incumbents. The system also fosters conditions that discourage the entry of products with a high cost-to-price ratio, such as low-priced generic products or higher-priced innovative products.

An issue of growing concern for PhRMA member companies is a change to the only positive, significant measure that had been introduced by the Hungarian Government in recent years. In mid-2009, an R&D tax incentive was introduced that provided up to a 20 percent tax credit for eligible R&D investments. This was subsequently revised in early 2010 to allow all eligible R&D expenses to be fully deducted. However, the new Hungarian Government has since reversed course and no longer allows a blanket deduction from Health Fund taxes. Instead, the tax credit will be determined on a case-by-case, company-by company basis. Since PhRMA member companies based previous investment decisions on the existence of this tax incentive, PhRMA and its members are greatly concerned by this development.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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 the inadequate protection of pharmaceutical intellectual property (IP) rights. The level of IP protection provided by the State of Israel falls considerably short of international standards. Over the last ten years, the protection of pharmaceutical-related IP rights in Israel has systematically eroded. This deterioration has resulted, among other things, in the nullification of patent extension terms, slow and ineffective review and publication of patent applications (which is also subject to the abuse of pre-grant opposition procedures), and ineffective protection of innovators' clinical data. These and other market access barriers in Israel greatly inhibit the growth of the Israeli innovative pharmaceutical market.

PhRMA greatly appreciates the Israeli Government's commitment to legislate certain improvements in IP legislation in Israel in its correspondence with the U.S. Trade Representative from February 18, 2010. Specifically, the Government of Israel agreed to address four key issues discussed below: patent term extension, data protection, delays in registration of innovative pharmaceuticals, and the publication of patent applications. To date, however, none of the changes have been implemented. PhRMA believes that the agreement can lead to a long-standing improvement in the market access environment for innovative medicines in Israel. The issues discussed below do not address the Israeli Government's commitment but rather, the regulatory and business environment as it currently exists in Israel.

Key Issues of Concern:

- The Government's practices and inefficiencies with regard to the registration of innovative pharmaceutical products, which currently curtail 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).[51] 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 on a patent extension in Israel and retroactivity of the amendment;
- Lack of effective data protection (Pharmacist Ordinance, Article 47, July 2005);
- Lack of mandatory publication of patent applications within 18 months from the date of the priority date; and
- Pre-grant opposition to patent grants (Art. 30 of the Patent Act).

For these reasons – the de-facto situation on the ground and the concerns about the manner in which the Government chooses to implement the Memorandum of Understanding, PhRMA recommends that Israel be designated as a **Priority Watch List** country in the course of the 2011 Special 301 Review Process.

Intellectual Property Protection

Over the last ten years, the protection of pharmaceutical-related IP rights in Israel has eroded dramatically. Four areas are the focus of PhRMA's concerns: 1) The unfair outcomes

[51] Amendment no. 7, to Article 64 (Dec. 19, 2005).

created by the 2005 amendment to the Patents Act that considerably shortens the patent extension term and that would possibly nullify it completely; 2) Inadequate protection of regulatory registration data (data protection), including the linkage of data protection in Israel to terms granted in recognized countries; 3) Substantial delays in the grant of patents (unnecessarily burdensome system of pre-grant patent opposition) and the publication of patent applications; and (4) Significant delays in the registration of new drugs in Israel which, among other things, shortens the effective period of data protection of these products.

Patent Term Extension - Amendment no. 7, to Article 64

In December 2005, the Government of Israel introduced a new amendment to the Patents Act that makes it virtually impossible to obtain a meaningful patent term extension certificate in Israel. It requires that the patent term extension in Israel be aligned with the shortest of the extension periods granted to a patent protecting the pharmaceutical product claimed in the basic patent in any of 21 "Recognized Countries."

The amendment added new burdensome conditions, according to which a patent term extension cannot be obtained in Israel unless a similar application for an extension has been filed and obtained both in the United States and in at least one EU member country that is considered a Recognized Country.

Moreover, the new amendment is applied retroactively to all the extension orders and applications that were filed prior to the date of its entry into force. This application unfairly injures the interests of innovators, who have already launched new drugs in Israel under a policy which is based on the assumption that a meaningful extension will be granted.

Pharma Israel, the local association of the research-based pharmaceutical companies, estimates that this retroactive application will bring about a cumulative reduction of 180 years of patent extension certificates granted in Israel.

Data Protection – Pharmacist Ordinance, Article 47

As a member of the World Trade Organization, Israel was required to fully implement the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), no later than January 1, 2000. TRIPS Article 39.3 obligates WTO members to protect data submitted to prove safety and efficacy by innovative pharmaceutical companies against unfair commercial use. This protection is typically provided by regimes known as “data exclusivity" or regulatory data protection.

Only in March 2005 did Israel enact legislation after drawn-out negotiations with the U.S. Government. However, the enacted legislation is inadequate in providing effective data protection for pharmaceutical test data. The legislation, for instance, curtailed the period and scope of non-reliance on the data, while at the same time effectively permitting reliance on the originators’ dossiers for export.

Article 47D(2) of the Pharmacist Ordinance allows the MOH to rely on the innovator's data to register generic products during the exclusivity period. More importantly, the MOH can rely on the registration data to approve the export of generic products to other markets. This sub-standard type of protection ensures that local generic companies enjoy an unfair competitive advantage over their U.S. and other generic competitors when submitting generic products for registration in other markets.

While the United States precludes filing for generic marketing approval for five years (four years with a patent challenge) and the European Union allows approvals after 10 years (and prohibits filing for marketing approval for eight years), Article 47D (b) (2) leads to a protection period significantly shorter than five years in Israel. It provides either five years of exclusivity from the day of product registration in Israel, or 5.5 years of exclusivity from the day of the earliest registration in any of the "Recognized Countries" (as defined in Pharmacists Ordinance), whichever is shorter. However, because Israel ties data protection to the term granted in the "Recognized Countries," as explained above, the effective term of regulatory data protection in Israel today is less than five years. This is because it currently takes the MOH between 13 and 15 months on average, to approve a new pharmaceutical product in Israel, from the day it was registered in a Recognized Country.

Moreover, Article 47(D) of the Pharmacist Ordinance offers no protection for new indications, while the legislation in the United States and the European Union provide three years and one year, respectively. In addition, the United States provides three years exclusivity for new dosage forms.

Substantial Delays in the Grant of Patents – the System of Pre-Grant Opposition

The Israeli Patent System is based on an Examination-system, in which patent applications are thoroughly examined by technically competent examiners. However, current statistics from the Ministry of Justice suggest that it takes between 4 and 5 years on average until the examination of an application for a pharmaceutical or biotechnological patent is completed in Israel.[52] As a result of this unusually long examination process, U.S. innovators lose a significant part of effective patent life (*i.e.*, the time between grant of the patent and expiration) to which they are entitled.

Once an examiner deems that the invention is worthy of patent protection and accepts the application, under Article 30 of the Israeli Patents Act, any competitor may block the patent grant simply by filing an opposition to the patent application. Resolution of the opposition may take many more years so that the patentee is actually deprived of the remainder of the period of exclusivity to which it is entitled.

The legal incentive regimes for innovative pharmaceutical products in Israel are disappointingly inadequate, particularly relative to countries at similar levels of development. In most developed countries, any opposition proceedings are conducted after patent grant and it is not possible to block the granting of the patent. The flawed pre-grant opposition system has been rejected in the vast majority of developed countries.

The combination of the system of pre-grant opposition and the inadequate level of data protection essentially denies research-based pharmaceutical companies any meaningful tool to protect their marketed products against the premature and unfair launch of generic products. This problem is likely to be aggravated by the Patent Act's proposed amendments (Amendment – Publication of Patent Applications) which seeks to deny patent holders the right to use the principle of unjust enrichment when seeking remedies and damages in patent disputes (section 14 of the draft exposure bill).

[52] Patent Authority, Accelerated Examination. Ministry of Justice website, at http://www.justice.gov.il/MOJHeb/RashamHaptentim/Ptentim/application+for+fast+examination.htm (last visited Feb. 10, 2011).

Concerns Regarding the Publication of Patent Applications

Under the Israeli Patents Act, a patent application is published only after the examiner accepts the application. Until then, the application is confidential and the file is not open to the public (Article 165). With respect to the vast majority of applications filed in Israel, parallel applications are also filed internationally and particularly in the United States and Europe. Consequently, these applications are published in other jurisdictions well before the examination of the Israeli application has been completed. This renders meaningless the strict "confidentiality" prevailing over the Israeli applications. It also reduces the ability of the patent holder to claim retroactive damages, which are available only after publication in Israel.

Third parties in Israel may use the time gap between the publication of the patent application in Israel (which can be four years) and the publication in other countries (in Europe and the United States applications generally are published 18 months after their priority date) to exploit the patent without being accused of breaching the confidentiality of the Israeli patent application.

In 2010, the Ministry of Justice published a Draft Exposure Bill that presumes to address the need to publish patent applications within the period of 18 months. While this is a welcome step, PhRMA is very concerned that the Exposure Bill seeks to introduce a series of additional amendments whose common denominator is the intention to narrow and excessively restrict the right of the owners of the invention to due protection of their invention. Against the background of these additional amendments, the subject of early publication is of secondary importance.

The key additional restrictive provisions include the following elements:

1. *Negation of the grounds for damages (Section 14 of the memorandum)* – The Exposure Bill seeks to deny in advance, in a sweeping and excessive manner, the right of suit of an injured party in these and other situations. The Exposure Bill is also liable to impair the right of a patent owner, recognized in case law, to relief pursuant to the violation of the patent during the patent period and manifested, inter alia, in "accelerated entry" into the market following expiry on the basis of the "springboard" of an act of violation during the patent period.

This element constitutes a substantial change of the existing law, in accordance with which, in instances of unfair competition, the injured party enjoys the grounds of suit in accordance with the Unlawful Enrichment Law, independently of the question of the presence of a patent, and in accordance with which, even after the expiry of a patent, a party injured by other torts, such as deception and misrepresentation, may receive relief on account of such torts.

2. *Negation of the right to amend the patent application after publication (Sections 6 and 7 of the memorandum)* – the Exposure Bill seeks to prevent an award of damages for pre-grant infringement if the application is amended even in a technical, non-substantive manner. This element constitutes a substantial change of the existing law, and is inconsistent with international standards.

The arrangement established in the existing law – according to which the patent applicant is entitled to amend the details in the application during the period in which the application is pending, on the proviso that if the amendment is substantive the patent owner

shall not be entitled to enjoy the early date of submission of the application and the amendment shall be dated as of the time of its submission – is balanced and proper

3. *De-facto creating a dual opposition mechanism - (Sections 2, 4 and 11of the memorandum)* – The intention to open the examination file to public inspection will facilitate premature intervention and cause further unnecessary complications before the current formal pre-grant opposition stage (Article 30 in the patent act), which also takes place prior to the granting of the patent.

As a result of this proposal opposition proceedings will de facto take place both after the publication of the application as well as after the notification of acceptance.

4. *Retroactive application of the above components on pending applications (Section 15 of the memorandum)* – The proposed provisions above are retroactive, confiscate a property right, and violate Israel's Constitution.

Market Access Barriers

Marketing approval (registration) deficiencies and delays

The process of examining and approving a new pharmaceutical product for market practiced by the Ministry of Health (MOH) suffers from a wide range of deficiencies, including:

1. Although the MOH claims to have an independent and efficient regulatory review and examination mechanisms, it still requires that new products be first registered in one of the "Recognized Countries," prior to being examined by the health authorities in Israel.[53]

2. Lack of clear, transparent and non-discriminatory timeframes for the examination, approval (or rejection), and registration of new pharmaceutical products in Israel.

3. The inconsistency between the Government of Israel's statements concerning the time period required for the registration of new pharmaceutical products in Israel, and the *de facto* period that such registration currently takes.

Under the Pharmacist Ordinance, a new pharmaceutical product can only be registered in Israel after it has been approved for market use by a Recognized Country, most notably the leading health regulatory authorities in the United States or in the European Union (FDA or EMA).

In recent years, there has been a significant prolongation of the registration process of innovative products in Israel. Due to such delays, the average period for the registration of a new drug in Israel, from its date of approval in a Recognized Country, has increased from six months in 2003 to the current period of 13 to 15 months in 2010.

Moreover, current budgetary problems in the Institute for Standardization and Control of Pharmaceuticals of the MOH, as well as other inefficiencies, result in increasing delays in the examination of product registration dossiers, with no improvement foreseeable in the near future. Currently there are more than 200 medicines in Israel waiting for approval.

[53] Under the Pharmacist Ordinance, the list of Recognized Counties includes: the United States, the EU-15, Switzerland, Norway, Iceland, Japan, Australia, Canada and New Zealand.

While the Government of Israel committed in the February 18, 2010 agreement to reduce the time for registration approval, there has been no actual change and the promise has not been realized. The delays are approximately equal to those of 2009.

Furthermore, due to the highly problematic substandard data protection system, which links the terms of data protection in Israel to the earliest date of product registration in Recognized Countries (explained above), the ongoing regulatory delays and inefficiencies have a deep negative effect on the data protection period provided to U.S. innovators in Israel.

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.

Since the registration of a new product in Israel is conditioned by the approval and marketing of such a product in one of the Recognized Countries, there should be a limited timeframe of no more than 70-90 days for the market authorization of this product in Israel, from the date of submitting a registration file to the MOH.

Finally, in 2010 the MOH decided to expedite and prioritize the registration of a group of generic products, thus delaying the review and registration of innovative products. This decision was made without consulting or informing the research-based companies operating in Israel.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to trade barriers related to intellectual property protection and market access.

POLAND

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Poland remain concerned that the Polish market for pharmaceuticals is inherently biased against innovative products.

Key Issues of Concern:

- Government reimbursement and pricing policies are discriminatory, overly time-consuming and non-transparent. Although a few innovative drugs have been added to the reimbursement list since 2008, including in December 2010, Poland still lags far behind the other 26 EU Member States in approving new, innovative medicines for reimbursement.[54]
- The Ministry of Health (MOH), despite initially declaring its willingness to hold regular meetings with representatives of the pharmaceutical sector, has in effect put a stop to meaningful dialogue. While negotiations are held concerning specific treatments with individual companies, the MOH is not willing to discuss broader policy with the industry as a whole.
- Extremely restrictive regulations on advertisement and promotion of medicinal products that significantly limits access to physicians and pharmacists, making presentation of clinical research and knowledge sharing very difficult.
- An inadequate legal framework to protect intellectual property rights, combined with multiple failures to enforce data protection rules following Poland's accession to the EU.

For these reasons, PhRMA requests that Poland be placed on the **Priority Watch List** for the 2011 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 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

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

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.[55] On December 22, 2010, the ECJ ruled that Poland had violated European Community law.[56] Specifically, the ECJ (fourth chamber) held that the Republic of Poland had failed to fulfill 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 market generics of the reference product Plavix on the market after May 1, 2004. As yet, Poland has not indicated how it intends to implement the ECJ's decision.

Failure to Implement Data Protection Rule

Poland was required to provide innovative pharmaceuticals the European "8/2/1" term of data protection prior to its 2004 accession. Instead of passing legislation to establish this protection, the Polish Government submitted a derogation request that was refused in 2004 by the EU. The EU reiterated the need for full implementation of "8/2/1" data protection in 2008. Although the MOH has finally drafted amendments to the Pharmaceutical Law to implement data protection (language which was approved by the Council of Ministers in October 2010), the Bill has yet to be passed by the Parliament.

Market Access Barriers

Significant Reimbursement Backlog for Innovative Medicines

In the last three years a small number of new molecules were granted reimbursement status;[57] encouragingly, eight new patented products were added to the reimbursement list in December 2010. However there are still approximately 100 new molecules waiting for inclusion on the reimbursement list. As of March 2009, 43 of the applications for reimbursement submitted from 1998-2009 by the 13 international pharmaceutical companies that comprise the Local Area Working Group in Poland had still not received any official reply from the Ministry of Health.

In 2008, the 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.

[55] *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. 10, 2011).
[56] "ECJ judgment: generic illegal in Poland" *at* http://blog.dzp.pl/pharma/ecj-judgment-generic-illegal-in-poland/ (last visited Feb. 10, 2011).

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

The AOTM's role and procedures was made clearer via updates to the Healthcare Law which came into force last summer. 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 would be reviewed every year, and the AOTM would have the power to issue a binding negative recommendation for a service, while its positive recommendations will still be 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.

Industry is concerned with major healthcare reform legislation currently being considered that envisions significant changes to Poland's government pricing and reimbursement and clinical trials requirements. The Reimbursement Bill was presented as a significant element of the so-called healthcare package aimed at the restructuring the entire healthcare system in Poland. The draft Bill was released for consultation in September 2010. 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%, expansion of therapeutic reference pricing, fixed margins and prices, a tax on turnover, and risk sharing agreements or claw backs. The Bill has been discussed in Parliament and is expected to advance early in 2011.

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-agreed, 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 regarding this regulation has created general confusion and a lack of consistency concerning how the regulations should be interpreted and implemented, 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. Many larger, important hospitals and medical institutions, not having clear guidelines for implementation of the new regulation, 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. As a result, 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 2010 attributable to trade barriers related to intellectual property protection and market access.

TURKEY

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Turkey remain concerned about government registration of products, reimbursement and pricing policies, as well as Turkey's intellectual property framework. Over the last decade, Turkey has undertaken reforms to modernize its economy and expand its healthcare system in many positive ways for Turkish patients. A general lack of transparency and inconsistency, however, has contributed to unclear policies that could undermine Turkey's investment climate and damage market access for PhRMA member companies.

Key Issues of Concern:

- Medicinal products registration period taking longer than the 210 days stated in regulations;
- GMP inspection requirement for imported products delaying access to innovative medicines and minimizing the effective data protection period;
- Lack of transparent sharing of Government pharmaceuticals spending to manage Budget Cap system in 2010; and
- Lack of effective patent enforcement mechanism and supplementary patent protection.

For these reasons, PhRMA requests that Turkey be placed on the **Priority Watch List** for the 2011 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 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 the concern by fostering early resolution of patent issues prior to marketing approval of the generic product.

To be able to create an effective patent environment, it will be necessary to recognize up to five years additional protection for patented products per the adoption of Council Regulation No. 1768/92 (June 18, 1992), concerning the Creation of a Supplementary Protection Certificate for Medicinal Products and EC Regulation No. 1902/2006.

Data Protection

In 2005, the Government of Turkey took positive steps toward establishing protection for the commercially valuable data generated by innovative companies, and now provides data

protection for a period of six years for products registered in the EU, limited by the patent protection period of the product. 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 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 of almost two years in Turkey, and the four or more years that it will take to complete the new GMP applications, new products will receive, in practice, no more than one to two years of exclusivity, which will undermine most of the incentives for innovators to undertake risky and expensive research. Regulatory approvals need to be granted by MOH within 210 days, or the six year period of 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 data protection has been changed by the Regulation to Amend the Registration Regulation of Medicinal Products for Human Use.[58] The change that has been introduced is incompatible with EU standards in that it eliminates 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 combinations of separate molecules, all of which should be granted 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, Ministry of Health (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.[59] Although the legislation requires the Turkish MOH to assess and authorize the registration of medicinal products within 210 days, surveys by the Research Based Industry Association AIFD indicate that the regulatory approval period exceeded 600 days in 2009.

This delay in the regulatory approval process has been compounded by the MOH's recent revisions to the Registration Regulation.[60] Effective March 1, 2010, a good manufacturing practices (GMP) certificate 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 MOH. However, for the reasons explained further below, neither option can be completed in a timely manner.

AIFD estimates that approximately 290 innovative products manufactured outside Turkey, including anti-infectives, antipsychotics, vaccines, cardiovascular, diabetes and

[58] Official Gazette No. 27208 (Apr. 22, 2009).
[59] Official Gazette No. 25705 (Jan. 19, 2005) (Registration Regulation).
[60] 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).

oncology drugs, are currently awaiting registration by the MOH. Further, MOH has thus far received approximately 140 applications to conduct GMP inspections, requiring inspections at almost 80 overseas sites. AIFD estimates that within a year, MOH will receive applications to conduct GMP inspections at over 225 sites. MOH does not have the time or resources to complete this number of GMP inspections in a timely fashion. The ensuing delays will present significant market access barriers to U.S. pharmaceuticals. Moreover, this new GMP certification requirement disproportionately burdens U.S. and international pharmaceutical companies, who unlike their Turkish competitors had no prior reason to obtain MOH GMP certificates for their global production facilities.

Further, 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. Two significant hurdles remain, however, to such mutual recognition: 1) Turkey must join and participate in the PIC/S (Pharmaceutical Inspection Co-operation Scheme) that sets 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, will hinder 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 PIC/S 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 U.S. and other key trading partners.

Pricing & Reimbursement

In Turkey, reimbursement decision criteria are not set, the process is not transparent and the timelines are extremely lengthy. Until the end of 2009, the Turkish pricing system for medicinal products consisted of referencing the cheapest price among five selected EU countries (France, Spain, Portugal, Italy and Greece), and the country or countries from which the product shipped, and reducing that reference price by 11%.[61] However, as part of a number of austerity measures for dealing with the 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: Turkey imposed an additional 12% discount for social security, thus increasing the total social security mandatory discount for innovative products to 23%. 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 to 66% of the reference price (previously original products were at 100% and their generics were at 80% of the reference price). However, if the reference price decreases at some point in the future, no further price reductions are imposed until the reference price is equal to or below 66% of the original reference price. No similar relief is provided to original products without generics; if the reference price decreases at some point in

[61] 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).

the future, the mandatory discounts (23%), as noted in the above bullet, are applied on top of the reference price decrease. The pricing and reimbursement system should, at a minimum, be revised to address this inequity.

- Government pharmaceutical budget caps: The 2010 Government pharmaceutical budget is set at 10% less than actual spending in 2009, but allows for 7% 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 reluctantly agreed. The protocol claims that it 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. The lack of regular review of data in a transparent manner creates an unpredictable and unsustainable environment for PhRMA's member companies. In order to cover these alleged overruns, in December 2010, the Government of Turkey instituted another round of price cuts (9.5%) on innovative medicines.

Another significant concern is that the Government's pharmaceutical budgets for 2011-12 are unlikely to be sufficient given the increased demand for healthcare in Turkey (largely driven by increasing public access and coverage of health services). Turkey spends only approximately 6% of its GDP on healthcare expenses (compared to an OECD average of 8%), and annual health care costs are likely to increase at a greater pace than budgeted. As a result, there remains the constant threat of new government price cuts or additional mandatory discounts.

Moreover, the amended pricing decree has and will continue to have a disproportionate impact on the innovative pharmaceutical industry (approximately 70% of savings according to the local innovative pharmaceutical association AIFD).

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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 remain concerned that the Government of Argentina did not make any progress during the last year in resolving two if the most important issues for PhRMA's member companies: protection for undisclosed test and other data required by the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and effective patent enforcement.

Efforts to decrease the patent application backlog, which showed a significant improvement in 2005, 2006 and the first half of 2007, were halted. This situation should be promptly addressed in order "to avoid unwarranted curtailment of the period of protection" for patents, as required by the TRIPS Agreement.

Key Issues of Concern:

- Lack of regulatory data protection;
- Patent backlog and significant delays to examine patent applications;
- Lack of effective patent enforcement; and
- Difficulties for obtaining injunctive relief.

For these reasons, PhRMA requests that Argentina be placed on the **Priority Watch List** for the 2011 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

Data Protection

Argentina does not provide for protection of undisclosed 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 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 non-reliance, expressly permitting officials to approve pharmaceutical products on the basis of: (1) undisclosed test and other data submitted to officials in Argentina; or (2) prior approvals of the same or similar product in Argentina or certain foreign countries that require submission of undisclosed test and other data.

If data are submitted directly to Argentine officials, one provision of the Law requires that the data be protected against "dishonest" use and disclosure. But another provision requires Argentine officials to rely on the same data submitted by others, in contradiction of TRIPS Article 39.3. Moreover, the Law does not define "dishonest" use and does not provide sufficient details to provide a sound legal basis for protection, under the TRIPS Article 39.3, even if the provision requiring reliance was deleted.

If data is not submitted directly to Argentine officials, competitors may obtain marketing approval by relying on prior approvals in other countries based on the submission there of undisclosed 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 reliance for a period of time after the approval of the product associated with the submitted data.

Patent Application Backlog

Officials of the Ministry of Economy and the National Institute of Industrial Property (INPI) took a number of significant steps between 2005 and the first half of 2007 to reduce the backlog of patent applications awaiting examination. The Ministry increased the budget of the INPI. As a result, an additional thirty examiners and eleven administrative officials were hired.

Also, resolutions such as Resolution 372 of January 2004 (under which companies had to declare interest in their application, or they would be considered abandoned), 350 of December 2006, and 162 of June 2007 (which enabled companies to change the order of their applications so that more important applications would be examined first), increased the speed of the patent approval process. However, this move came to a halt in the second half of 2007. Even though a new Resolution (178 of July 2008), asking companies to once again declare their interest in their applications or they would be considered abandoned, was issued in order to reduce the backlog, INPI productivity has dropped.

Despite these efforts, there are still serious challenges in reducing the backlog and ensuring that the backlog does not increase again. For example, INPI must increase its ability to retain examiners. According to CAEME, the innovative biopharmaceutical association in Argentina, the current backlog in all areas amounts to approximately 19,000 applications with full examination fees paid.

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 “inventive step.” Such restrictions would affect patents involving polymorphics, 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 2010, the Lower House began the analysis for approval of the treaty, at committee level. There is no date set for voting.

Effective Patent Enforcement

Argentina should provide mechanisms which enable the timely resolution of patent issues before follow-on products, such as generics, are approved.

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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to trade barriers related to intellectual property protection and market access.

BRAZIL

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Brazil remain concerned regarding patentability standards and enforcement, data protection and discriminatory government pricing policies. The inauguration of a new Administration in Brazil offers a unique opportunity for the U.S. and Brazilian Governments to address some of these concerns in a mutually productive manner. PhRMA and its member companies stand ready to contribute to this dialogue.

Key Issues of Concern:

- Patentability standards;
- Compulsory licenses;
- Patent backlog;
- Anti-innovation positions advocated for and supported by Brazil in multilateral fora; and
- Government price freeze and controls.

For these reasons, PhRMA requests that Brazil be placed on the **Priority Watch List** for the 2011 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. In addition, ANVISA and INPI do not apply the same patentability requirements, thus generating uncertainty for patent applicants and undermining incentives for innovation. Given Brazil's leading role in the region, we believe that Article 229-C continues to be a harmful example, which could be adopted by other countries.

More importantly, despite 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, no effective measure has been taken to implement the recommendation or otherwise solve the problem.

Compulsory Licenses

PhRMA has previously highlighted mechanisms in Brazil to grant compulsory licenses for patents in the "public interest," and also noted that these mechanisms appeared to be "safety

valves" to be used in extraordinary circumstances when supplies of the patented products were not sufficient to meet demand.

PhRMA and its member companies believe that the Government of Brazil should modify its regime for granting compulsory licenses for the "public interest":

(1) to ensure that Article 71 only applies when there is a shortage in the supply of an article covered by a patent;
(2) to clarify the terms "public interest" and "public non-commercial use" to ensure that Article 71 is not used as a *de facto* government cost containment measure; and
(3) to eliminate provisions for the expropriation of privately held and undisclosed information.

PhRMA members believe that these amendments would reduce the level of uncertainty and help to improve the business environment for national and international companies in the pharmaceutical sector.

Patent Backlog

PhRMA member companies recognize the efforts implemented to improve patent examining operations at INPI. However, the backlog of patent applications is still large and the pendency period, according to the official gazette published on December 7, 2010, is ten years. We anticipate that the long pendency period could readily be reduced as has occurred in the trademark registration system. According to the official gazette published this in January 2011, INPI is currently examining trademarks filed in 2008. This is an improvement in length of time for examination as in 2005 it would often take 8 years for a trademark application to be examined by INPI.

Effective Patent Enforcement

To improve business certainty, our member companies and the local association continue efforts to gain support for legislation that would establish clear mechanisms or processes through which marketing of patent infringing products can be prevented . The absence of explicit legislation leaves open the possibility of infringements, thus causing uncertainty for patent holders.

Data Protection

The Brazilian Government still fails, when approving marketing requests generated by third parties, to clearly prohibit for a reasonable time Government officials from relying on test and other data submitted by our member companies to prove the safety and efficacy of their products. While some steps have been taken in a positive direction 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.

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 would 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.

Market Access Barriers

Government Price Freeze and 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 2010, the Government permitted a price increase of between 4.45% and 4.83% depending on the share of generic medicines in the therapeutic class.[62] 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.

In addition to these restrictive government price controls, the Brazilian Government enacted CMED Resolution No. 4 on December 18, 2006. This cost-saving measure sets a mandatory price discount, or Price Adjustment Coefficient (CAP), of 24.69% for certain enumerated products.[63] On February 3, 2010 (Official Note No. 01), the Government adjusted the level of discount for 2010 to 22.85%.[64] Pharmaceutical manufacturers, distributors, representatives, medicines posts, movable units, pharmacies and drugstores must apply this minimum discount to the price of products sold to bodies of the "direct and indirect public administration of the Union, the States, the Federal District and the municipalities."

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to trade barriers related to intellectual property protection and market access.

[62] Official Gazette No. 45, Session 1, p. 1 (Mar. 9, 2010).
[63] Official Gazette No. 48, Session 1, p. 1 (Mar. 12, 2007).
[64] Official Gazette No. 24, Session 3, p. 3 (Feb. 4, 2010).

CHILE

In 2010, The Pharmaceutical Research and Manufacturers of America (PhRMA) and the local innovative biopharmaceutical association ("CIF") noted a new willingness among certain Chilean Government officials to discuss with the innovative biopharmaceutical industry the establishment of effective mechanisms for resolving patent issues before marketing follow-on products such as generics.

Unfortunately, the Chilean Government has not yet taken concrete action to adopt the regulatory and other changes needed to establish effective mechanisms consistent with the obligations contained in the U.S.-Chile Free Trade Agreement.

Regarding data protection, the current draft of the Health Ministry's new regulation would not provide adequate assurance that prior partial disclosures of data by foreign regulatory agencies could not be used to justify denial of data protection in Chile. In addition, the current draft would leave intact the objectionable provisions relating to data protection contained in Chile's intellectual property law.

PhRMA acknowledges and welcomes the Chilean Government's partial steps during 2010 to address the U.S. Government and innovative biopharmaceutical industry's concerns regarding the absence of effective patent enforcement and data protection.

However, PhRMA believes that the Chilean Government has not yet taken sufficient action to resolve these important and long-standing concerns, and that continued active U.S. Government involvement is vital in encouraging Chile to implement fully its intellectual property obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the U.S.-Chile Free Trade Agreement, and other bilateral trade agreements.

Moreover, PhRMA has become aware that the Direction of Purchases and Public Contracts of the Ministry of Finance has recently launched its rules for the acquisition of medications for the public health system including within the list, several generic products of innovative medicines that are currently protected by a patent in Chile. The Pharmaceutical Chamber (CIF) has officially expressed its concern to the Health, Finance and Economy Ministries, since these rules may exacerbate intellectual property infringements.

Key Issues of Concern

- Lack of Effective Patent Enforcement; and
- Failure to adequately implement Data Protection.

For these reasons, PhRMA requests that Chile remain on the **Priority Watch List** for the 2011 Special 301 Report and that the U.S. Government continue to seek effective implementation to resolve the problems described herein.

Intellectual Property Protection

Effective Patent Enforcement

Notwithstanding the requirement contained in Article 17.10.2 of the U.S.-Chile FTA, Chile has failed to establish mechanisms which provide effective opportunities to enforce patents before patent-infringing pharmaceuticals are approved and marketed. That Article requires Chile to provide mechanisms to "make available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent" and mechanisms to resolve patent issues expeditiously so patent infringing products are not marketed. The longstanding position of the Chilean Government has been that (1) the Public Health Institute (ISP) does not grant marketing approvals for new medicines; (2) the ISP lacks authorization to consider patent status in deciding whether or not to grant sanitary registrations, because the patent office has exclusive responsibility for intellectual property; and (3) Chile complies with Article 17.10.2 by enabling patent holders to pursue cases of alleged infringement through existing judicial channels.

PhRMA disagrees with each of these arguments:

- When the Free Trade Agreement came into force in January 2004, Supreme Decree 1876 (which establishes the responsibilities of the ISP) stated that the ISP was responsible for granting both sanitary registrations and marketing approval for new pharmaceutical products. In July of that year, the Health Ministry issued Health Decree 245/2003, which amended S.D. 1876 to eliminate all references to "marketing approval." As a result, no Chilean agency is currently responsible for granting marketing approval, since no regulation or law explicitly requires such authorization. Current regulations speak only of "sanitary approval," which is the only significant confirmation or sanction required in order to sell a pharmaceutical product in Chile. Sanitary registration is therefore tantamount to marketing approval in Chile.

- The obligation contained in Article 17.10.2 of the U.S.-Chile FTA (to notify a patent holder of the receipt of a request for sanitary registration/marketing approval of an infringing product, and to provide mechanisms to prevent marketing patent infringing products was conceived precisely to protect patent holders from having to bring suit – a lengthy, costly, and uncertain process – in order to defend its rights after an infringing product has entered the market. To comply with this Article, Chile must establish mechanisms to prevent the marketing of patent infringing products. This is not satisfied by enabling a patent-holder to defend itself, after a third party has requested and received a sanitary registration/marketing approval and marketed an infringing product.

According to the CIF, Chile's failure to an effective patent enforcement mechanism has enabled the ISP to grant sanitary registrations to 237 different copies of 73 patented medicines, in violation of the rights of the patent holders. In other words, each of those 73 patented medicines has, on average, 3.2 registered copies. Nearly half of those registered copies – 114 different patent-infringing products – have already entered the Chilean market. Additionally, there are serious concerns that the recent rules of the Ministry of Finance for the acquisition of medicines for the public health system have the potential to increase patent infringements.

After taking office in March 2010, the new government of President Sebastian Piñera established an inter-ministerial committee (including the ISP, the Industrial Property Institute and the

Economy, Health, and Foreign Ministries) charged with proposing an amendment to Chile's industrial property law aimed at establishing an effective patent enforcement mechanism. This committee is expected to make its proposed legislative amendment available for public comment in the near future. PhRMA looks forward to the opportunity to providing comment and working with the Chilean Government to ensure full and faithful implementation of the U.S.-Chile FTA.

Data Protection

Chile has failed to establish an adequate system to protect proprietary pharmaceutical test data against unfair commercial use and disclosure, as required by the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the EU-Chile Association Agreement, and the U.S.-Chile Free Trade Agreement. Chile's current data protection system is deficient for the following reasons:

- Because Chile's existing norms (contained in Law 19,996 and Health Decree 153/2005) do not clearly define what constitutes "disclosure" of test data, they enable the Chilean government wrongly to deny data protection based on prior partial disclosures either by the data owner itself (occasionally undertaken in the interest of transparency) or by foreign health regulatory agencies.

- The definition of what constitutes a "new chemical entity" is overly restrictive, excluding new uses, formulations, dosages, *etc.*, even though such innovations must be supported by new clinical data in order to obtain sanitary approval.

- Existing norms do not clearly establish that the government's obligation to maintain the confidentiality of pharmaceutical test data submitted to the regulatory authority does not expire after 5 years, while the obligation to prevent commercial use of the data does expire.

- Chile's data protection norms establish various conditions allowing the revocation or denial of the right to exclusive use that are not stated in TRIPS or Chile's bilateral trade agreements with the European Union and the United States. These conditions significantly weaken the applicability and usefulness of the available data protection.

Chile's previous government attempted to address the concerns of the U.S. Government and the pharmaceutical industry by preparing a new regulation governing pharmaceutical data protection. If enacted, the proposed regulation would have corrected some of the deficiencies described above. In January 2010 the Controller General of the Republic ruled, however, that the proposed regulation was inconsistent with certain provisions of Chile's industrial property law relating to the protection of non-disclosed information. It appears that a definitive solution of the deficiencies in Chile's data protection system will require new legislation.

According to data compiled by the CIF, since January 1, 2000 (the World Trade Organization's deadline for Chile to subscribe to and implement TRIPS, which requires the establishment of data protection), the ISP has granted premature sanitary registrations to ten imitative pharmaceutical products, relying, without due authorization, on clinical data belonging to other companies. Five of these cases have occurred since December 2005, when Chile adopted domestic legislation establishing data protection, and two have occurred since January 8, 2007, when Chile was first placed on USTR's Priority Watch List.

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 (until January 2009, the Industrial Property Department or DPI).[65] 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 2010 attributable to trade barriers related to intellectual property protection and market access.

[65] The DPI´s then-director, Bernardita Escobar, confirmed this figure in public testimony before the Economy Committee of the Chamber of Deputies in 2007.

VENEZUELA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Venezuela remain concerned about several intellectual property and market access issues. In addition to the great number and complexity of regulations and procedures necessary for innovative pharmaceuticals to reach the market, there has been a standstill in the granting of patents to pharmaceutical products due to the continuous deterioration of the intellectual property legal framework in this country.

Key Issues of Concern:

- Failing to provide adequate patent protection;
- Failing to adhere to obligations agreed to in the WTO and Paris Convention agreements; and
- Ineffective data protection.

For these reasons, PhRMA requests that Venezuela remain on the **Priority Watch List** for the 2011 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

In April 2006, Venezuela formally withdrew from the Andean Community (AC). According to this decision, all rights and obligations for Venezuela, including application of Intellectual Property Decision 486, are to have ceased as of that moment in accordance with Article 135 of the Cartagena Agreement. However, a legal void was created in Venezuela because no decision was made at that moment as to whether Decision 486 would continue to be applicable to any patents, or whether the Government would opt instead to apply the Industrial Property Law of 1956 (IPL) (the legislation in force in Venezuela prior to accession to the AC). Under the IPL, patents for pharmaceutical products are prohibited; data protection is not contemplated; and, in general terms, owner rights are reduced in ways not permitted by the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Paris Convention. The local innovative pharmaceutical association, Cámara Venezolana del Medicamento (CAVEME), has taken legal action before the Supreme Court of Justice (SCJ) asking for a decision to be rendered as to which legislation should be applicable in Venezuela (Andean Decision 486 or IPL). As of October 2010, SCJ has yet to issue a ruling.

According to the official Industrial Property Bulletin, Venezuela has not granted a single pharmaceutical patent since 2003, nor a patent of any kind since 2005.

Data Protection

In a departure from past practice (1998-2001) when a five-year period of data protection was enforced, Venezuela has not provided effective 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 CAVEME, since 2002, over 20 "copy" products corresponding to original medicines that should have each been covered under a five year term of data protection, obtained registration from the health authorities (Venezuelan National Institute of Health (INH)). As a result, individual research based pharmaceutical companies initially filed challenges against the Government in the courts to enforce data protection, with no results to date. Many companies also acted directly against marketers of the copy products at the Venezuelan Antitrust Agency (Procompetencia), which dismissed all unfair competition claims. Claims were 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

Venezuela established rigid and restrictive controls on access to foreign currency for all economic sectors in 2003. Although slight improvements were made to this policy in 2004, 2005 and 2006, uncertainty persists over the amount of foreign currency available at any given time due to variations in oil prices and lingering concerns regarding the Government's arbitrary use of this policy to develop a selective import policy, to control imports (as it has done in the past), to force changing import suppliers, or to audit import prices. The Government's policy results in an unpredictable investment environment for pharmaceutical companies.

Government Price Controls of Essential Medicines

Since 2003, Venezuela has imposed price controls for Essential Medicines (following World Health Organization (WHO) criteria) comprising close to one-third of the medicines marketed in-country. Venezuela has maintained this government price control policy since 2004. To date, prices of Essential Medicines have not been revised to take into account accumulated inflation, or devaluation in the same period, according to the Central Bank of Venezuela and the National Institute of Statistics, thereby adversely impacting companies and distorting the market.

Notwithstanding, WHO Essential Medicines represent only 35% of total products available in Venezuela and 10% of market value, and there is free market pricing for remaining medicines. Market-based pricing is essential to reward innovation and allow PhRMA member companies to recoup their investments in research and development, especially in the context of high inflation. Moreover, Venezuela's free pricing policy, which currently applies to a majority of products on the market, is a positive model for other countries in the region.

Non Production Certificate

Locally manufactured medicines in Venezuela have been exempted from Venezuela's value added tax (VAT) since 2002. In order to obtain an exemption of VAT for imported medicines, companies must request from the Government a certificate stating that the product is not manufactured in the country or is manufactured in insufficient quantities to 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. Because of the restrictions in currency availability, authorities have begun to allow only a restricted number of exemption certificates, thus affecting the access to currencies as well as the exemption of VAT, which creates a serious risk of 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 strenuously enforced by Venezuelan authorities and it is very common for public contracts to be: (1) awarded with complete disregard to the Bidding Law, or (2) based on 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 under which public entities may give preference to a local company over a foreign company only if certain conditions are met. However, according to CAVEME, public entities have shown disregard for 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 2009 Venezuela witnessed an increase in counterfeit medicines (more than 10% 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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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 innovative pharmaceuticals products. However, there are significant barriers that continue to impede market access for medicines.

Key Issues of Concern:

- Weak patent protection for pharmaceuticals;
- Importation restrictions;
- Government mandated price referencing;
- Volume controls through annual import quota for medicines;
- Unfair commercial practices of local pharmaceutical companies;
- New investments and commercial laws; and
- Delays in marketing authorization approval due to burdensome new regulatory requirements.

All of the above constitute major barriers that curtail access for innovative pharmaceuticals, impede trade, and jeopardize Algeria's chances of acceding to the WTO in the near future. For these reasons, PhRMA requests that Algeria be placed on the **Priority Watch List** for the 2011 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 these 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 undisclosed pharmaceutical test and other data from unfair commercial use and disclosure. PhRMA recommends that Algeria correct this deficiency through implementation of meaningful data protection.

Government Price Referencing

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.

Market Access Barriers

Importation Restrictions

On October 21 2008, the Algerian Government issued a decision[66] stipulating that, effective January 2009, the importation of pharmaceutical products that are being manufactured locally will be prohibited. This decision was essentially a reinstatement of a previous ministerial decree[67] that was suspended as part of the WTO accession process. Subsequently, the Ministry of Health (MOH) has published lists comprising hundreds of branded medicines.

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, 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.

Unfair Competition

Many local generic pharmaceutical companies are illegally offering pharmacies free goods. 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

[66] 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 médicine humaine fabriqué en Algérie".
[67] Instruction #5 for the Generalization of Generics (September 2003).

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 which unfairly discriminate against foreign 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% 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 prohibiting local manufacturers from selling products to wholesalers and requested 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.

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.

In addition, 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.

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 2010 attributable to trade barriers related to intellectual property protection and market access.

PAKISTAN

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Pakistan remain concerned that, although the overall investment environment in Pakistan is improving, innovative pharmaceutical companies still face critical market access barriers.

Key Issues of Concern:

- Inadequate data protection;
- The Ministry of Health (MOH) continues to disregard all patents, whether process, molecular or formulations at the time of registration and the majority of mailbox applications have not been granted or finally acted upon;
- The MOH maintains a local manufacturing requirement as a prerequisite for product registration;
- The MOH has placed unreasonable restrictions on toll manufacturing; and
- The current government pricing system is not transparent, and government prices of innovative products are set at extremely low and arbitrary levels. Government prices have not been revised since 2001 despite rapid increases in the inflation rate.

For these reasons, PhRMA request that Pakistan remain on the **Priority Watch List** for the 2011 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

Patents

In January 2001, a Patent Ordinance 2002 was promulgated which made incomplete, though promising, steps towards recognizing Pakistan's obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). To date, no clearly defined rules or regulations have been released on this legislation. More troubling than the absence of implementing regulations are changes made to the Act in 2002 that drastically inhibit the ability of PhRMA member companies to enjoy effective and meaningful patent protection in Pakistan. Amendments to the Patent Act, effective from October 2002:

- Eliminate use patents;
- Restrict patent filings to single chemical entities for pharmaceutical and agrochemical inventions;
- Limit the protection for derivatives or salts;
- Introduce onerous barriers to patenting biotechnology based inventions; and
- Establish a mechanism for compulsory licensing if an invention has not been created in a manner that promotes the "transfer and dissemination of technology".

Together, these and other amendments seriously undermine intellectual property rights in Pakistan.

Recently, the Intellectual Property Office (IPO) circulated proposed amendments to the Patent Ordinance 2000, and asked stakeholders to submit their proposals/suggestions. The Pharma Bureau[68] submitted comments to the IPO highlighting the anomalies and shortcomings of the Patent Ordinance 2000 and 2002. As yet, however, no action has been taken. At a minimum, the Patent Amendments 2002 should be repealed, and Patent Ordinance 2000 should be restored until a new, WTO-consistent ordinance is promulgated.

Meanwhile, the MOH continues to register generic copies of patented products of U.S. and other multinational pharmaceutical companies. As a result of these problems, current and expected patent protection in Pakistan remains inconsistent with Pakistan's WTO obligations and disadvantages U.S. based multinationals.

Mailbox applications

The IPO initially committed to processing the so-called mailbox patent applications within 18 months of receipt from January 1, 2005. This was a requirement of the Patent Act. However, little has happened since January 2005. The IPO extended the processing period to 27 months, but as yet no mailbox applications have been processed. As a result, there is no timeline and no apparent action. This lack of activity compromises 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.

Data Protection

As a WTO member, Pakistan is required to implement TRIPS Article 39.3 to prevent 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 MOH on data packages used to support initial marketing approvals of original products for a period not less than five years. Protection should extend to the data itself, as well as to conclusions based on that data, so that an application not filed by the innovator could not be granted at least until the full term of protection has expired unless such party either generated its own supporting data or obtained consent of the party that owns the data. 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 responsible for violations of this protection.

The Pakistani Government is currently discussing a draft law that would extend protection to pharmaceutical test data. PhRMA member companies are now deeply concerned by the MOH's inordinate delay. It is our understanding that the MOH made changes to the draft after it was agreed upon by all stakeholders. Most recently, the MOH asked stakeholders certain questions relating to minimum TRIPS compliance and how it should proceed. PhRMA member companies submitted a response through the Pharma Bureau and the MOH has promised to move the process forward once it receives input from other stakeholders. PhRMA member companies request assistance in expediting adoption of meaningful data protection.

[68] The National Association of Research Based Pharmaceuticals in Pakistan.

Market Access Barriers

Local Manufacture Requirement

Pakistan's MOH has 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 has placed restrictions on toll manufacturers. The result of these restrictions is that registration of new chemical entities is often denied.

Pakistan's local manufacturing restrictions raise yet another issue. Certain products are in fact manufactured in Pakistan, but as a result of Environmental, Health, and Safety compliance requirements, companies must restrict manufacturing to a small number of sites making continued production in Pakistan exceptionally difficult.

Government Pricing

The current government pricing system in Pakistan is another major market access barrier. The Government sets the prices of products at extremely low or arbitrary levels, which do not take into account the value of innovation. In addition, officials responsible for pricing at MOH lack the necessary expertise and technical know-how to make informed decisions.

Moreover, although the Government has considered implementing a policy to adjust prices to compensate for devaluation and/or exchange rates fluctuation, this change has not been implemented. Government prices for pharmaceutical products have not been revised since 2001 (government price increases are issued through public pronouncements), and the cumulative inflation during this period has been over 100%.

The Pricing Policy Board set up by the Government with representation of PhRMA member companies, local companies, and other key stakeholders, has formulated a final draft of the pricing policy. This policy will be sent to the Economic Coordination Committee (ECC) and finally to the Cabinet for approval. However, this process stalled following the passage of the 18th Amendment to the Constitution on April 19, 2010, which prompted a review by constitutional experts as to whether the MOH has the authority to implement the pricing policy. The current position is that the Ministry of Health has sent the final draft of the pricing policy to the ECC for their approval, and this is expected to be taken up during February 2011.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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 patent protection afforded to innovative pharmaceutical products, specifically the lack of sufficient advance notice of potentially patent-infringing products and the limited scope of 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.

The Memorandum of Understanding (MOU) signed in May 2010 between the Australian Government and Medicines Australia, representing most of Australia's pharmaceutical industry, was a welcome advance in efforts to ensure that Australian patients continue to have rapid access to the newest medicines. PhRMA member companies and their Australian affiliates continue to monitor the reforms of the Australian Pharmaceutical Benefits Scheme (PBS), and seek to work through a range of remaining issues with the Australian Government. We remain committed to ensuring that Government policies adequately recognize and reward innovation.

However, in late November 2010 a number of Australian Senators and Members of Parliament initiated a private members' Bill which would significantly undermine the patent protection afforded to innovative biopharmaceutical medicines. The Bill proposes to declare that all biological materials are not patentable inventions. There have been arguments put forward to an Australian Senate Committee Inquiry into gene patents that an express prohibition on gene patents (let alone all biological materials) would be contrary to Australia's obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights and the FTA. Notwithstanding these legal obligations, the proposed legislative change would have a profoundly negative impact on US-Australia trade in human use biopharmaceuticals.

Key Issues of Concern:

- Lack of sufficient advance notice of potentially patent-infringing products in order for patent holders to seek injunctive relief; and
- Lack of sufficient scope of data protection.

For these reasons, PhRMA requests that Australia be placed on the **Watch List** for the 2011 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

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. Notice provisions have not, however, been implemented in a workable way.

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 would be posted on the TGA's website within two days of a new product registration following regulatory approval. This mechanism has not yet been implemented, but would be a small step in the right direction. It does not replace, however, proper advance notice being provided to patent holders as is required under the FTA. Nor is it helpful for products which will never seek listing on the PBS. The good faith implementation of these assurances is critical to ensuring that Australia's intellectual property regime remains strong, and that the agreement is implemented.

Data Protection

Data Protection is an independent form of intellectual property right that is used to protect, for a fixed period of time, proprietary medicine safety and efficacy data against unfair commercial use by a third party. These data are submitted to the medicines regulatory agency to evaluate a new medicine's safety and efficacy. Like other forms of IP rights, it stimulates companies to invest in innovation by providing limited exclusive rights once the product enters the market. Companies must demonstrate that new molecules 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 could further enhance Australia's ability to compete for foreign investment in the knowledge-intensive and innovation-intensive biomedical sector that will drive future economic growth. Steps that Australia could take would be to extend data protection provisions to new formulations, new combinations, new indications, and new dosage regimens.

Market Access Barriers

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. Under Australia's National Health Care System, around 80% of prescriptions dispensed in Australia are subsidized under the PBS.[69] Accordingly, the PBS effectively controls access to the Australian pharmaceutical market. 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 new medicines. We note our concern, however, that the last meeting of the Medicines Working

[69] 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. 9, 2011).

Group was held in 2007 and are hopeful that the next meeting will be scheduled in the near future.

PhRMA is pleased to note that its member companies were consulted by the Department of Health and Ageing in an effort to develop a package of reforms that addressed Australia's need to control health care costs, while still preserving incentives for development of new medicines. This resulted in the May 2010 signing of a MOU noted previously. These reforms are complementary to the years of dialogue begun with the FTA and the Access to Medicines Working Group formed after the 2006 PBS reforms. We look forward to Parliamentary passage of the legislation needed to implement the MOU.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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 operating in Korea applaud the Korean Government's efforts in 2010 to engage with member companies and support innovative medicines. As one of the largest and fastest growing pharmaceutical markets in the world, Korea's efforts to reform its healthcare system are ongoing and the country has renewed its commitment to fostering innovation and investment in the pharmaceutical sector. In July 2010, the Ministry of Health and Welfare (MOHW) modified its approach to government pricing and reimbursement decisions to reward innovation and provide more transparency and predictability. In particular, PhRMA welcomed the new approach adopted by the Korean Government to the "re-arrangement" process.

Despite notable areas of progress, PhRMA and our member companies remain concerned with numerous intellectual property and market access issues. PhRMA and our member companies also strongly urge the passage and implementation of the KORUS FTA, which contains provisions that will help eliminate market access barriers for biopharmaceutical products and shore up the protection and enforcement of intellectual property rights in Korea.

Key Issues of Concern:

- Lack of effective patent enforcement; and
- Vague and unclear regulations regarding data protection, particularly in regards to new indications

For these reasons, PhRMA requests that Korea be placed on the **Watch List** for the 2011 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

PhRMA member companies call for a system that provides effective mechanisms to resolve patent issues before a follow-on product (such as a generic or biosimilar) enters the market in Korea. This could greatly enhance the business environment by (1) providing transparency and predictability to the process for both pioneer and generic companies; (2) creating a more predictable environment for investment decisions; and (3) ensuring timely redress of genuine disputes. In the event the KORUS FTA is adopted, Korea is obligated to institute such mechanisms within 36 months. PhRMA member companies urge that draft legislation implementing patent enforcement provisions of the FTA be passed as soon as possible.

Data Protection

Korea currently implements data protection via "New Drug Re-examination". During the New Drug Re-examination period, marketing approval can be granted only when a sponsor has submitted safety and efficacy data that is at least equivalent to, but not the same as, the data submitted by the innovator company to obtain the first approval. Under this system, new drugs

are granted six years of data protection; and new indications four years, but only 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 complete data protection system in line with the commitments made in the FTA.

Market Access Barriers

Market-based Actual Transaction Pricing

On October 1, 2010, MOHW instituted Market-based Actual Transaction Pricing (M-ATP). M-ATP, also known as an "incentives system for low price purchase," requires hospitals, clinics and pharmacies to disclose the actual price purchased for drug products. Where prices are lower than the official maximum reimbursement price (MRP), the Korean Government provides the hospital or other medical institutions a rebate from the NHI program of 70% of the difference between the price actually purchased 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 is expected as early as the first quarter of 2012.

While PhRMA and our 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.

Implementation of the M-ATP has led to increased confusion in the market since no clear standards are in place to ensure transparency and predictability in transactions along the supply chain. The M-ATP also exemplified conflicts with existing pricing policies. In particular, despite the 20% price reduction rule when the first generic comes onto the market, patented drugs continue to be subject to annual price reductions under the M-ATP during the patent term. Price-Volume agreements also are applied in which price is cut if volume increases by a certain amount. These represent duplication of price reduction measures and the inconsistency of the M-ATP with the existing pricing policies. PhRMA and its member companies recommend that corrective measures be taken to avoid double price reductions and ensure fair reward for innovation during the patent term of new pharmaceuticals.

Furthermore, the Korean Government has included certain exemptions to price reductions under the M-ATP, based on the amount of local R&D expenses. This is designed to promote local pharmaceutical R&D and will likely put global research-based pharmaceutical

companies at a disadvantage since only local R&D expenses are used to calculate the price cut exemptions.

Improved Reward for Innovation under the Re-arrangement Plan

In 2010, the Korean Government resumed a review of the country's 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 a comprehensive price reduction plan. PhRMA welcomes the Korean Government's decision to exclude from the price reductions all on-patent and those off-patent drugs previously subject to a 20% price reduction.

Recent Reform Measures' Adverse Impact on New Product Pricing

As a result of the implementation of the alternative re-arrangement plan and the M-ATP during 2010, existing drug prices are likely to face significant price reductions. This will then impact the price of a new drug as the new drug price is currently calculated using a weighted average which includes off patent drugs and generic prices. The new drug price under the current Drug Expenditure Rationalization Program is already far too low compared to other countries of comparable economic size, and the further reduced prices of the existing drugs will likely lead to much lower new drug prices in Korea. PhRMA and its member companies suggest that the new drug pricing process be improved to appropriately recognize the value of new drugs in consultation with all stakeholders including the research-based companies.

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, discounts on earlier 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, the final enforcement regulations prohibit lecture fees, consultation fees and gifts of nominal value. Industry associations are in active talks with the Government to resolve the remaining issues, with the expectation that all issues will be resolved in 2011.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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 innovative biopharmaceutical industry.

Key Issues of Concern:

- Data Protection;
- Patent and Trademark Laws;
- Effective Patent Enforcement;
- Preferential Treatment of Local Manufacturers; and
- Counterfeit Medicines.

For these reasons, PhRMA requests that Malaysia be placed on the **Watch List** for the 2011 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

Data Protection

PhRMA member companies welcome the Malaysian Government's intention to implement data protection measures in 2011 and applaud the country for its willingness to involve the pharmaceutical industry in recent technical consultations. However, the Government of Malaysia's current proposal ends the data protection period five years after the date of first marketing approval for the product anywhere in the world. From a practical perspective, the proposed duration of data protection would be far less than the five years contemplated by the spirit of the Directive and other effective data protection systems. The standard adopted by many other countries, which is necessary to provide adequate protection, would provide that data protection end at least five years after marketing approval is granted in Malaysia.

Patent and Trademark Laws

Proposed amendments to Malaysia's patent and trademark laws that include provisions for disclosure of traditional knowledge and genetic resources, as well as compulsory licensing, raise concerns for the research-based pharmaceutical and manufacturing industry, and PhRMA encourages a continued consultative process with stakeholders before such amendments are implemented. These proposed amendments also include provisions for 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.

Effective Patent Enforcement

PhRMA member companies strongly encourage adoption of effective mechanisms for resolving patent issues before marketing of follow-on products such as generics. This could greatly enhance the business environment by: (1) providing transparency and predictability to

the process for both the pioneer and the generic company; (2) creating a more predictable environment for investment decisions; and (3) ensuring timely redress of genuine disputes.

Market Access Barriers

Preferential Treatment of Local Manufacturers

PhRMA member companies remain concerned about provisions in Malaysia's National Medicines Policy (MNMP), implementation of which is currently under discussion. The MNMP prioritizes the medium and long-term goals set by the Government for the pharmaceutical sector, which appear to indicate potential price controls, generic drugs substitution, and favor generic and local manufacturers by promoting national self-reliance for drugs listed on the National Essential Drug List (NEDL). PhRMA member companies also remain concerned that the Government of Malaysia continues to prefer locally manufactured drugs in its procurement process, regardless of price, for off patent compounds. This preferential treatment discourages an open and competitive marketplace in Malaysia.

Counterfeit Enforcement

PhRMA supports close coordination between the U.S. and Malaysian Governments on anti-counterfeit initiatives, including training for regulatory and security officials as well as improving the resources and enforcement capabilities of Malaysia's intellectual property court system. Increasing the penalties for criminals caught manufacturing, supplying, or selling counterfeits will also help Malaysia achieve world class status as a hub for biotechnology and health care delivery. PhRMA member companies also advocate for the fast implementation of the newly proposed Pharmacy Bill where enhanced penalties for counterfeiting of medicines will be addressed.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to trade barriers related to intellectual property protection and market access.

THE PHILIPPINES

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in the Philippines applaud recent engagement efforts by the Philippine Government with industry on health care policy and other issues that affect the ability of companies to do business in the country. Through this consultative process we hope also to address current intellectual property and market access concerns and look forward to substantial progress as engagement continues.

Key Issues of Concern:

- The Cheaper Medicines Act is not consistent with the Philippines' obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS);
- Effective Patent Enforcement;
- Price Reductions and Marketing Restrictions;
- Parallel Importation; and
- Counterfeit Drug Enforcement.

For these reasons, PhRMA requests that the Philippines be placed on the **Watch List** for the 2011 Special 301 Report. In addition, since PhRMA recognizes that the Philippines Government will continue to make advances in intellectual property protection in 2011, specifically related to patent standards and enforcement, PhRMA encourages the U.S. Government to undertake an Out of Cycle Review of the Philippines prior to the 2012 Special 301 Report. This would ensure immediate recognition of further improvements to pharmaceutical IP protection in the Philippines.

Intellectual Property Protection

Concerns Regarding the Cheaper Medicines Act

PhRMA member companies hope to achieve progress in 2011 on outstanding concerns with IP-related provisions in the Universally Accessible Cheaper and Quality Medicines Act of 2008 (The Act). At present, The Act amends the Philippines Intellectual Property Code to limit the patentability of new forms and uses of medicines. This appears to discriminate against certain technologies in a manner inconsistent with TRIPS.

Effective Patent Enforcement

As PhRMA and America's research-based biopharmaceutical companies continue our consultative process with the Philippine Government in 2011, we also hope to explore the benefits of implementing mechanisms for resolving patent issues prior to marketing of follow-on products, such as generics. One such mechanism was in place before a 2005 DOH Administrative Order (A.O. No. 2005-0001) took effect. As a result of the Order, PhRMA member companies have had to pursue legal remedies that are both costly and lengthy in order to protect patented products from generic competition prior to the expiration of a patent term. The Government of the Philippines could resolve this situation, and free up legal resources for more pressing matters, by reinstating effective patent enforcement mechanisms.

Market Access Barriers

Price Reductions and Marketing Restrictions

While the Maximum Drug Retail Price Mechanism (MDRP) adopted under the Cheaper Medicines Act has recently impacted a number of PhRMA member companies' access to the Philippine market, Department of Health (DOH) officials tacitly acknowledged in 2010 that the MDRP may not have had the desired effect of expanding patient access. Going forward, PhRMA member companies hope to expand upon our dialogue with the Philippine Government in order to effectively expand patient access and address broader healthcare cost concerns.

PhRMA's member companies also hope 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 may 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 and our member companies will also continue outreach to the Philippine Congress (both the Senate and Lower House) where several proposals, including the establishment of a new Price Regulatory Board to review government prices of all medicines in the country, could significantly impact market access and raise safety concerns as physicians will be uninformed of product characteristics. PhRMA and member companies are working to engage the Philippine Government on the best way forward and stand ready to serve as an active partner to address this complex challenge.

PhRMA will also further consult with the Philippine Government on a recent policy that has mandated member companies and retailers to absorb a 20% discount on medicines plus a 12% value added tax. These discounts have resulted not only in the closure of drugstore outlets and the discontinuation of products, adversely affecting patient access, but have also increased overall business costs and may affect the ability of member companies to place certain products on the market.

Parallel Importation

Under the Cheaper Medicines Act, all government agencies and third parties are granted the authority to engage in parallel importation of patented drugs and medicines. This broad authority heightens concerns related to the lack of adequate infrastructure and monitoring mechanisms in the Philippines to ensure the safety and quality of parallel imports as well as prevent the importation of counterfeits. PhRMA and our member companies hope to work closely with the Philippine Government to monitor and reduce the risk of an increased flow of counterfeit medicines into and out of the country.

Counterfeit Drug Enforcement

The new Philippine Government continues to conduct and expand upon a number of high-profile activities, including partnering with PhRMA member companies, to raise awareness regarding the dangers of, and directly combat counterfeit drugs. PhRMA welcomes these very

positive developments and will continue to work closely with the Philippine Government in 2011 to undertake further concrete actions. PhRMA member companies also hope to consult the Philippine Government on a provision in the Cheaper Medicines Act that would allow non-prescription products to be sold in "small quantities, not in their original containers" in retail outlets. By addressing this provision, the Philippines can significantly improve the health and safety of its citizens. PhRMA member companies are eager to continue working with the Philippine Government to combat the threat posed by counterfeit medicines.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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:

- The data protection provision of Taiwan's Pharmaceutical Affairs Law covers only new chemical entities and not new indications; and
- Taiwan has yet to implement effective patent procedures in the context of the process for approving generics.

For these reasons, PhRMA requests that Taiwan be placed on the **Watch List** for the 2011 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

Data Protection

In January 2005, Taiwan passed 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 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. Linking the availability of data protection in Taiwan to the date of any other market launch is not consistent with the objectives of data protection rights and does not effectively prohibit unfair commercial use.

Effective Patent Enforcement

Taiwan has not yet established systems to effectively prevent marketing patent-infringing pharmaceutical products. In 2009, at least 35 patent-infringing drugs were approved in Taiwan, and many of them were subsequently included on the reimbursement lists.[70] 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

[70] 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. 11, 2011).

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 is meaningless, however, all the while 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. The decision-making process has also become less transparent and predictable. Price-Volume Agreements and Health Technology Assessments (HTA) have been used as tools to exclude certain products from the market or prolong the reimbursement process. In an effort to eliminate the long-standing "pharmaceutical price gap" (the difference between the after-discount actual transaction price at which healthcare providers buy drugs, and the higher price at which they are reimbursed by BNHI), BNHI has conducted frequent Price Volume Surveys (PVS) followed by substantial price cuts. As a result, on average, the price of original drugs in Taiwan is only 28% of the level in the United States.[71] 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.

The innovative pharmaceutical industry is currently engaged in a constructive dialogue with the government on reimbursement-pricing policy. This dialogue has focused on how the BNHI could incorporate innovation as a factor in its pricing and reimbursement policies and develop annual Drug Expenditure Targets (DET) to alleviate the need for the PVS system. Furthermore, Taiwan's Legislative Yuan recently passed legislation reforming the NHI. Included in this legislation is language establishing a DET and other articles endorsed by the innovative pharmaceutical industry. In the interest of rewarding innovation, developing new medicines to meet Taiwan's unmet needs, and ensuring that Taiwan patients are not deprived of access to these innovative drugs, PhRMA strongly recommends that the Government continue its dialogue with innovative pharmaceutical companies, and ensure that government pharmaceutical pricing and reimbursement policies are based on patient needs and benefits, scientific evidence, and a legal foundation rather than simple cost-containment objectives.

Regulatory Issues

A key concern of Taiwan is how to ensure the safety and efficacy of the drug supply. Taiwan has already established a good foundation on drug manufacturing standards through implementing GMP and cGMP standards. PhRMA also applauds the recent establishment of the Taiwan Food and Drug Administration (TFDA) under the Department of Health. PhRMA's member companies seek continuous improvements in the regulatory system so as to expedite the launch of innovative products in Taiwan. Recently some regulatory changes have been proposed by TFDA, including (1) relaxing the CPP requirements; (2) creating a streamlined procedure for new drug priority review; and (3) establishing a mechanism to issue "approval letter" to expedite the new drug reimbursement review process, to speed up patients' access to

[71] Id.

innovative new drugs. However, the enforcement of the above new proposals by TFDA and BNHI is also very critical. Next step, we hope that the CPP could be further relaxed with no extra conditions. Meanwhile, the lengthy review time could be shortened by simplifying the processes of PMF review and on-site inspection. PhRMA companies also urges the Taiwan government to continuously monitor the pharmaceutical product quality by API (Active Pharmaceutical Ingredient) and post-marketing variation control, so as to secure the welfare of Taiwanese people. To address these and other related concerns, PhRMA recommends the creation of an industry-TFDA task force.

Separation of Dispensing from Prescribing

The separation of dispensing from prescribing (SDP) in Taiwan is an official requirement but one which is not enforced, in part due to a lack of political will and to powerful hospital lobbying interests. Implementation of SDP is crucial to improving the quality of pharmaceutical care to patients. It would empower physicians to prescribe the most appropriate medications based on their professional expertise, not being influenced by revenue gained from dispensing drugs. It would also create a mechanism to ensure that pharmacists review each patient's prescriptions to prevent any duplication or contraindication between prescriptions from different physicians or hospitals. Recognizing the difficulty of making an abrupt change in current practices, the industry supports the idea of implementing SDP in phases, and it offers to aid this process by developing the necessary distribution systems to ensure that community pharmacies are properly served.

PhRMA appreciates and supports the Government's initiatives to separate prescribing and dispensing functions, including education to the general public about the benefits of implementing SDP. This should be followed up with a roadmap and timeline for full implementation of SDP. We have urged BNHI to monitor implementation of the new guidelines and consider reinstituting an incentive structure as part of its hospital accreditation system, and reinvigorating efforts to educate the general public about the benefits of implementing SDP.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to trade barriers related to intellectual property protection and market access.

VIETNAM

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Vietnam welcome the steps taken by the Government of Vietnam in 2010 to address some of the industry's market access concerns. However, progress on improving the country's intellectual property protections remains slow. Furthermore, many of the reforms proposed by the Government of Vietnam would not put Vietnam in line with international best practice, nor are they in line with those of their colleagues in ASEAN. PhRMA acknowledges the Government of Vietnam's efforts to consult on proposed reforms to the pharmaceutical sector and hopes to continue as an active stakeholder in addressing outstanding issues in the future.

Key Issues of Concern:

- Data protection;
- Effective patent enforcement;
- Clinical trial and quality testing requirements;
- CIF pharmaceutical pricing system;
- Investment restrictions; and
- Parallel importation.

For these reasons, PhRMA requests that Vietnam be placed on the **Watch List** for the 2011 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

Data Protection

PhRMA commends Vietnam for its continued pursuit of more meaningful data protection measures as well as their continued engagement on this important issue. Vietnam's Data Protection Circular has been signed into law and PhRMA is in close discussion with the Drug Administration Vietnam (DAV) to address data protection implementing guidelines which fall short of making improvements to the existing regime. PhRMA's top concerns include: (1) the Data Protection Circular requires that 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 (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) require; (2) in order to receive data protection, the data must be classified as a "business secret," also impermissible under TRIPS; (3) in cases of dispute, the burden of proof should rest with the third party or government challenger seeking to show the data in question does not satisfy the criteria for protection; and (4) the five-year term of protection should also apply in cases where the subsequent applicant provides bioequivalence data and then attempts to have regulators rely on the innovator's previously submitted data to show safety and efficacy.

Effective Patent Enforcement

PhRMA member companies strongly encourage adoption of mechanisms which enable resolution of patent issues before market entry by a follow-on product (*i.e.*, a generic product). This could greatly enhance the business environment by: (1) providing transparency and predictability to the process for both the pioneer and the generic company; (2) creating a more predictable environment for investment decisions; and (3) ensuring timely redress of genuine disputes.

Market Access Barriers

Clinical Trial and Quality Testing Requirements

PhRMA member companies remain concerned with domestic clinical trial requirements in Vietnam for the marketing approval of all drug products 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 FDA and EMA, but Vietnam does not possess the resources or infrastructure to achieve reliable clinical trial results. These regulations also apply to new variations of pharmaceutical products already registered in Vietnam, including both major variations (for example, a change in formulation or route of administration) as well as minor variations (*e.g.*, a change in excipients/preservatives). PhRMA requests an amendment of these regulations and that Vietnam permit regulatory officials to accept clinical trial data from overseas, encouraging them to do so when domestic capabilities are not in place.

Vietnam's required quality tests for all newly imported batches of vaccines and biological products, before such products can be granted a registration license, are scientifically unnecessary and time consuming. Conducted by the National Institute for Control of Vaccine and Biologicals (NICVB), which does not have the capacity (either in equipment or trained staff) to effectively conduct such tests, this requirement places a great burden on PhRMA member companies and delays the availability of crucial medicines to Vietnam's patients. Furthermore, many biological products that are not manufactured in batches must also comply with this policy.

CIF Pharmaceutical Pricing System

Vietnam's CIF (Cost, Insurance, and Freight) pharmaceutical pricing system creates unequal opportunities and restrictions between imported and locally produced pharmaceuticals. No clear guidance or set of conditions is provided for the initial setup or adjustment of the CIF price and many prices established for imported medicines are based on what is charged for the same or similar products in Vietnam's neighboring countries, without taking Vietnam's costly import-regime and local distributor requirements into consideration. Furthermore, this CIF pharmaceutical pricing system causes an additional delay in product approval for PhRMA member companies. The DAV has estimated 1,600 pricing applications were pending approval at the end of 2010.

Product Visa Renewal Process

Under current regulations, the Ministry of Health (MOH) requires pharmaceutical companies to reapply for product approval through product visas every five years. This

requirement has become a significant administrative burden for PhRMA member companies as the process for renewal or to obtain a product visa can take from eight months to more than one year. As a result, some medicines cannot be made available for patients in Vietnam.

Investment Restrictions

On January 1, 2009, in accordance with Vietnam's WTO commitments, 100% foreign-owned entities were granted the right to import pharmaceutical products into Vietnam. The pharmaceutical industry now awaits guidance from Vietnam's MOH on the importation requirements for importing entities, which could have a significant impact on how PhRMA's member companies do business in Vietnam. PhRMA's member companies hope that the MOH does not require changes to the current supply, which allows companies to contract with foreign-owned storage and logistical services companies that have been licensed by the MOH and who certify that their storage and delivery methods satisfy international standards. PhRMA's member companies only wish to exercise their legal right to become an importer of record. Therefore, PhRMA recommends that the MOH allow importing entities (either foreign or domestically owned) to assign storage of their products to approved service providers.

Parallel Importation

Parallel importation has a negative effect on investment by U.S. innovators in Vietnam and products that enter the country through this practice could carry significant health and safety risks associated with counterfeiting, improper handling, and packaging. Furthermore, there are no clear guidelines or established criteria under which Vietnam grants permission for parallel imports and parallel importation approval data (reasoning, product name, and approved quantity, for example) lacks transparency.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

FINLAND

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Finland are concerned about the Finnish Medicines Act (FMA 2008), especially concerning 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 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 2011 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

The 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 WTO 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 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.[72]

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 consequence of this inferior patent protection, regulatory reforms, such as mandatory substitution and reference pricing, have severe adverse effects for PhRMA member companies.

This was 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 reference group, it was nevertheless possible for its reimbursement status to be deteriorated by other measures, *e.g.*, by the Finnish authorities cancelling the reimbursement during the reimbursement period. According to the reimbursement provisions of the Finnish Sickness Insurance Act (1224/2004), the Pharmaceutical Pricing Board (PPB) may, at its own initiative, decide that the confirmed "reasonable wholesale price and reimbursement status" of a pharmaceutical product should be cancelled. According to Chapter 6, Section 8 of the Sickness Insurance Act (of 2006), PPB can make this decision when, for example, a generic product containing the same active ingredient as an innovative product has been included in the reimbursement system, regardless of whether the innovative product is protected by a valid analogous process patent.

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

[72] *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).

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 economic 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%, lower special category at 72%, and upper special category at 100%).

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 2010 attributable to trade barriers related to intellectual property protection and market access.

GERMANY

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Germany remain concerned about significant market access barriers that discriminate against innovative pharmaceutical products. In 2010, the market environment in Germany worsened and is expected to be increasingly challenging in 2011.

The German healthcare system undeniably faces considerable financing challenges. Unfortunately, to remedy this, the German Government has chosen to assign the burden of cutbacks disproportionately to the innovation-based pharmaceutical industry; more than 60% of all planned savings for the German sick-fund system are targeted at pharmaceutical companies, despite total pharmaceuticals spending constituting only 18% of German healthcare spending.

In 2010, the Government passed a price moratorium on branded medicines and increased the mandatory rebate or "clawback" paid by manufacturers from 6% to 16%. Both measures are to remain in effect through 2013. In addition, the German Parliament passed a "Pharmaceutical Market Reform Law" (called "AMNOG" under its German acronym), which will create a new "quick assessment" of therapeutic benefit at the time of product launch and force centralized price/rebate negotiations on all new medicines and new indications 12 months after market launch. The new law became effective on January 1, 2011. Also as of January 1, 2011, the German Government reduced vaccine prices to the average price paid for that vaccine in selected EU-member states and the Government continues to encourage parallel importation of pharmaceuticals from other European countries.

Key Issues of Concern:

- A Government-mandated quick assessment of added therapeutic value;
- An increase of the mandatory rebate for reimbursed medicines from 6 to 16 percent;
- Parallel importation of pharmaceuticals from other countries; and
- Unreasonable restrictions on patient access to information about innovative pharmaceutical products.

For these reasons, PhRMA requests that Germany be placed on the **Watch List** for the 2011 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 healthcare funding shortfall, increased the mandatory rebate for patented products not covered by reference prices from six to 16 percent. This "short-term" 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 clawback 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 wholesale restructuring of the pharmaceutical market. In an effort to accelerate the perceived cost-saving effects of Health Technology Assessment (HTA) in Germany, a new process was established that builds on the system of benefit assessments undertaken by Germany's "IQWiG" HTA body. As a result, unimpeded market access and free pricing for medicines will remain in effect in German only for the first year after launch. The new procedure comprises:

- A quick assessment of every New Chemical Entity (NCE) (and probably even every new indication of an existing product) to be undertaken by IQWiG or another HTA body within 3 months after launch, based on a value dossier provided by the manufacturer.

- The German health system's self-regulatory body (GBA), then will decide at six months post-launch whether a new product provides additional therapeutic benefit.

- Effective 12 months after launch, a reimbursement price will be set. In determining the reimbursement prices, products will fall into one of three categories:

    (1) *Products with additional benefit*. Where it is determined that a product has additional benefit, centralized negotiations will be held between the manufacturer and the umbrella sick-fund organization. If a manufacturer and the sick-fund association 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.

    (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 sick-fund association do not agree.

A major industry concern about this new process is the difficulty of demonstrating additional benefit based on clinical endpoints or head to head comparisons at an early stage of a product's life cycle and the pure "yes-no" categorization of benefit that will form the basis for pricing/reimbursement decisions. A new chemical entity falling into categories (2) or (3) (as described above) will in most cases be referenced to generic prices, which will have a significant detrimental impact on the product before it even has the chance to prove itself in the market. Thus far, the Government has shown little willingness to provide viable appeal mechanisms for manufacturers as part of the new framework.

PhRMA members are also concerned that the German Government could implement therapeutic reference pricing even for products that do not undergo a quick assessment. If an innovative pharmaceutical product is "pharmacologically-therapeutically comparable" to another drug, *i.e.,* has at least one overlapping indication with another drug, it can be placed into the reference group, where government prices are based on the lowest price in that group (possibly a generic product). In this case the added value over the other drugs in the reference group are considered only in this overlapping indication and all other indications are not taken into account, irrespective of added value the drug may bring to those indications.

PhRMA and its member companies are also very concerned about the German Government's ability to handle – in a fair and deliberative manner – the large volume of assessments and decisions that will be necessary on the part of IQWIG, GBA, the sick-fund association, and other bodies. In addition, the prospect that existing products could be drawn into the quick assessment process creates enormous planning uncertainty for manufacturers and would subject them to a "double hit" (given that their products are already subject to the large mandatory rebate payments and price moratorium). Furthermore the mandatory rebate and the centrally negotiated prices with the sick funds will also apply to the private insurance system which covers about 10 % of the German population.

Finally, it is very disappointing that 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 medicines purchases with individual sick funds.

Furthermore, as of 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 sick-fund system (comprising 90% of the population) are made by the GBA, or "Joint Federal Committee," the top layer of the country's self-governance mechanism in health care. Voting members of the GBA are named by the federal associations of sick funds, hospitals, and physicians. Patient representatives on the GBA have no voting power. With the passage of AMNOG, the GBA will become even more powerful; an issue of great concern to manufacturers seeking continued open access to the health-care marketplace in Germany.

Concerns about the GBA's lack of 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 along with its "black box" character and lack of public checks (GBA officials are not publicly elected and do not serve at the pleasure of the Government) increasingly place this body beyond the reach of politics and public policy.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to these market access trade barriers.

GREECE

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Greece are increasingly concerned that the market for innovative medicines is deteriorating to an unsustainable level. As a result of Greece's significant economic crisis, the Greek Government (GOG) has indicated its intention to reduce pharmaceutical expenditures by 20 percent, with a goal of saving more than €1.4 billion per annum. PhRMA and its member companies are concerned that the impact of these cost-containment measures (described below) will radically change Greece's pharmaceutical market and might affect markets throughout Europe due to parallel trade and international reference pricing.

In addition, pharmaceutical spending in Greece has been exacerbated because it is primarily financed by social insurance funds, which, due to pension obligations, are running significant deficits. Specifically, whereas pharmaceutical spending accounts for only 25% of Greece's total healthcare spending, it accounts for 50% of social insurance fund spending. As a result, stabilizing pharmaceutical spending is crucial to achieving financial sustainability in Greece's social insurance system. (Given Greece's current economic woes, it is also an issue that is being closely monitored by the EU commission, international organizations like OECD and IMF, and the financial markets.) Fiscally sustainable healthcare spending can only be achieved if inefficiencies throughout the sector are addressed; however, the current reforms seem to focus mainly on the pharmaceutical sector.

Key Issues of Concern:

- Unpaid hospital debts totaling more than €3 billion;
- A reference pricing system that reduces government prices to some of the lowest levels in Europe, impacting both the Greek market and other markets due to international reference pricing; and
- Increased parallel exports from Greece, which could result in shortages in the Greek market.

For these and other reasons described below, PhRMA requests that Greece be placed on the **Watch List** for the 2011 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;[73] approximately 50% of this was owed to pharmaceutical companies.[74]

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.

Based on information received by SFEE, Greek government bonds have been issued for approximately 60% of the 2007 through 2009 past due debts and approximately 14% of 2010 hospital debts have been paid in cash.

According to an IMF/EU memorandum, Greece should not accumulate any new debt in 2011. The MOH has assented to this request and stipulated that hospitals receivables are to be settled in 60 days as required by Greek law. PhRMA believes that it is critical that the GOG refrains from incurring future debt and pays for the products it receives.

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 that have been announced so far include:

- In March 2010, the GOG passed Article 14 of Law 3840/10 which requires 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 the relative level of development in those countries. 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 attempt to introduce a reference price system failed, the GOG cut pharmaceutical prices by between 3 and 27 percent on May 3, 2010. The weighted

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

average price cut was 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 government price cut, some PhRMA members still have concerns about which government prices were referenced in the 22 countries. Ensuring transparency and predictability of the system is of critical importance to PhRMA members. PhRMA members are still concerned that the resulting low government prices in Greece will, in turn, significantly affect government prices in countries around the world that reference Greece. In addition, the low government prices have already led to a significant increase in parallel exports to other European markets, resulting in shortages in Greek pharmacies.[75]

- PhRMA notes that it is possible for Greece to realize the economic benefits of lowering prices without impacting the pharmaceutical market in other countries. Specifically, GOG could adopt a "dual pricing system" whereby prices for products sold to the national reimbursement system are regulated and prices for goods sold outside of Greece's national reimbursement system are based on market principles. Spain has adopted such a system and France is considering such a system.

- The GOG is considering the reintroduction of the reimbursement list (which was abolished in 2006). 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 the criteria used to make those decisions may not be verifiable and transparent. On July 9, 2010, the Greek National Organization for medicines produced a draft "negative" list that included 1,000 medicines that it proposes will no longer be reimbursed. This "negative" list mainly includes over the counter and life-style products. This list is expected to be in effect very soon until the larger "positive" reimbursement list is completed.

- PhRMA is concerned that the GOG has allowed private pharmacists to sell a selection of "highly-priced" hospital products that are used by outpatients at public hospital prices. PhRMA and its members do not believe that public hospital prices should be applied in the private sector, because this is likely to encourage parallel trade, which in turn could create product shortages to the detriment of Greek patients.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to these market access trade barriers.

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

ITALY

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Italy remain concerned that certain policies of the Italian Government and regional authorities are having a detrimental impact on the innovative pharmaceutical industry and pharmaceutical research and innovation worldwide.

Key Issues of Concern:

- Grouping patented and off-patent medicines in a single tender;
- Government-defined individual company budgets;
- Cost-containment policies that disproportionately impact innovative pharmaceuticals; and
- Market access delays following marketing authorization from the European Medical Agency.

For these reasons, PhRMA requests that Italy be placed on the **Watch List** for the 2011 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 Rights

Tendering

Several regions and Local Health Authorities are organizing tenders in which they group together patented and off-patent medicines. 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 innovation. 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 questions are greater.

Market Access Barriers

Company Budget Restrictions and Reimbursement Policies

Between 2001 and 2007, Italy adopted 18 different cost-containment measures that affected the pharmaceutical industry. Chief among these was Law 222/2007, which provides that the Italian Drug Agency (AIFA) has to establish a fixed-sales budget for each company operating in Italy. To the extent that retail sales exceed those budgets, the Law requires companies, pharmacists, and wholesalers to refund 100 percent of the overage. In addition, the Law imposed a budget ceiling for pharmaceutical spending at 14 percent of the National Healthcare Fund (NHF).

In 2009, the NHF budget ceiling was reduced by two laws:

1. Law 77/2009 (passed to provide funding for the Abruzzo Region after the earthquake) temporarily reduced the public pharmaceutical ceiling from 14% to 13.6% for 2009; and

2. Law 102/2009 (which was designed to find cost savings in response to the 2009 economic crisis) further reduced the ceiling to 13.3% for 2010 through 2012.

Furthermore, in 2010, the Italian Government enacted Law 122/2010, which imposes additional measures on the pharmaceutical sector:

1. Cuts prices on off-patent medicines by 12.5% and sets the maximum reimbursement price for equivalent drugs according to the average of prices in Europe;

2. Increases margins for pharmacists, at the expense of pharmaceutical wholesalers and companies.

3. Transfers the cost (€600 million) of H class drugs (drugs dispersed by hospitals) from the hospital budget to the retail budget, which, in turn, increases the risk of clawback for pharmaceutical companies in case of overspending.

In 2008 and 2009, there was no overspending in the retail market, but the cuts applied to the public pharmaceutical ceiling in 2009, and last year's transfer of the cost of H class drugs to the retail budget, will increase the risk that PhRMA member will be asked to pay a refund to the state budget in 2010.

In addition, Italy's 21 regional authorities continuously and autonomously introduce:

- measures, many of which limit, delay, the access of innovative and patented drugs in the retail and the hospital markets;
- demand-restrictions to limit the prescribing of innovative medicines, including through the:
  - development of prescription guidelines for physicians,
  - adoption of quantitative prescription targets for generics,.

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

The Italian Government's focus on controlling pharmaceutical expenditures is 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% and 2.4%, respectively, of the NHF. Meanwhile, no other category of health care expenditures faced similar budgetary restraints or limitations. As a result of this policy, public pharmaceutical expenditure grew only 5.7% over the last five years, whereas other health care costs increased by an average of 41.2% over the same period.

Similarly, the two laws adopted in 2009 introduced further cost containment measures on pharmaceuticals, but did not impose similar budget restrictions on other NHS costs and expenses.

Discrimination between the different health care 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% – from the current 6.65% to 3.0% – and in turn increases the margin for pharmacists by the same 3.65% – from 26.7% to 30.35%. As a practical matter, the law then imposes an additional mandatory 1.82% discount on pharmacists, but the pharmacists, on balance still see their margins increase (albeit by the lesser amount of 1.83%) while other sectors' margins are cut. Moreover, the Law mandates a financial pay-back on retail prices of 1.83% from pharmaceutical companies. In short, the Law reduces the margins of pharmaceutical wholesalers and companies with one hand, yet increases commercial margins of Italian pharmacies (that already have some of the highest margins in Europe) with the other hand.

Regulatory Approval, Market Access Delays and Limitations

As documented in the EFPIA 2009 study, "Patients W.A.I.T Indicator",[76] the average delay between a product receiving marketing approval (during the period of 2006 to 2008), and Italian patients actually having access to those medicines was 318 days.

In 2007, AIFA introduced a system for evaluating innovation, to be used in pricing and reimbursement decisions for new drugs. To date, however:

- No new drugs have been classified as "innovative" by AIFA; and
- 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.

Since 2007, several regions introduced Regional Formularies for H class drugs that have delayed market access for highly innovative drugs by an average 220 days beyond the date on which AIFA granted initial market authorization.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to trade barriers related to intellectual property protection and market access.

[76] *Available at* http://www.efpia.eu/content/default.asp?PageID=559&DocID=8485 (last visited Feb. 14, 2011).

NORWAY

PhRMA and its member companies operating in Norway remain concerned about the lack of product patent protection for a significant portion of the pharmaceutical products currently on the Norwegian market. The Norwegian Government should make changes to its policies to ensure that drugs currently protected by patents – including specifically analogous process patents – are not included on the Norwegian Medicines Agency's list of interchangeable drugs, but are treated, for reimbursement purposes, the same as drugs covered by product patents in Norway.

Key Issue of Concern:

- Lack of adequate product patent protection.

For these reasons, PhRMA requests that Norway remain on the **Watch List** for the 2011 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

Inadequate Product Patent Protection

Norway provided compound patents for pharmaceutical products beginning in 1992. The problem PhRMA member companies face in Norway today relates to pharmaceutical products with patents granted or pending prior to 1992. Specifically, legislation existing before 1995 bars product patent protection for products with process patent applications that were pending or granted before 1992. This outdated legislation places Norway well behind the overwhelming majority of developed countries in terms of intellectual property protection.

In the 2010 Special 301 Report, Norway was singled out as a country that "denies adequate and effective protection" for intellectual property rights. Norway was included because, as described above, it fails to provide robust product patent protection to pharmaceutical products currently on the Norwegian market with patents granted or pending before 1992. This practice is inconsistent with both European and other international standards, and renders Norway increasingly an outlier in its failure to provide adequate intellectual property protection.

In order to address this issue, PhRMA member companies do not suggest a change in patent legislation, but rather suggest that the Government change the present policy/rules for product eligibility for inclusion on the interchangeable drug list. Specifically, the Government should clarify that products addressed by analogous process patents, and generic versions of these pharmaceuticals, are ineligible for inclusion on the interchangeable list. This solution would not require new legislation, and it would not require any changes to Norway's patent system. It could be implemented quickly and with less difficulty than changes to the patent law.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to trade barriers related to intellectual property protection and market access.

RUSSIAN FEDERATION

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Russia continue to face significant market access barriers in Russia, that pose serious challenges to the innovative pharmaceutical industry including a discriminatory government pricing policy, a lack of transparency in healthcare systems, and insufficient intellectual property protections. The new "Law on the Circulation of Medicines" was enacted in April 2010 and entered into force on September 1. However, the law has been amended three times; demonstrating the imperfection of the new legislation and causing uncertainty within the Russian market.

Key Issues of Concern:

- Intellectual property protection;
- State regulation of prices of medicines on the Essential Drug List (EDL);
- Registration and clinical trials; and
- Draft law limiting interaction between healthcare professionals and industry representatives.

For these reasons, PhRMA requests that Russia be placed on the **Watch List** for the 2011 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

Data Protection

Currently, data protection is not implemented in Russia. In September 2010, however, the Russian Duma passed legislation to implement data protection for a period of 6 years in accordance with commitments made to the United States and European Union for WTO accession. The provision will enter into force upon Russian accession. 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 clinical test data. PhRMA and its member companies urge USG officials to carefully monitor the implementation of the data protection provisions.

Market Access Barriers

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

PhRMA and its member companies view the manner in which prices for drugs from the Essential Drugs List are established to discriminate against foreign producers. The latest prices (before March 31, 2010) were calculated by Roszdravnadzor on the basis of average weighted prices over the preceding six months. Foreign producers were required to provide price data on analogous drugs in 21 reference countries: the country of production, 19 European countries and Kazakhstan. Conversely, Russian producers were required only to provide the cost of production. This system of establishing prices fails to take into account the specific nature of

each national healthcare system and the resulting discrepancy in prices for pharmaceutical substances thereby unfairly discriminating against producers of imported products. Compounding the discriminatory nature of the policy, the price for locally produced medicines are adjusted according to annual inflation rate, while foreign products are not permitted such adjustments.

Registration and Clinical Trials

PhRMA and its member companies recognize and appreciate that the new law governing clinical trials, which entered into force on September 1, 2010, is more specific on the qualifications of trial personnel than the law it replaced. For example, the principal investigator must have no less than five years of experience in clinical trials. However, it remains unclear whether pre-registration clinical trials must be conducted in Russia, as a part of multinational trial.

Obtaining authorization to conduct clinical trials has also proven problematic for industry. Reviews of clinical trial applications will now be conducted by a new Ministry of Health department, created in September, 2010. The new department has not yet issued clear instructions including how and where to submit files or the names and contact information for appropriate points of contact, *etc*.

Draft Law on Ban of Sales Representatives Visiting Doctors

Russian officials are currently considering a draft Law on the "Health Protection of the population" that could seriously impact marketing practices of pharmaceutical companies. The draft law would impose restrictions on the contacts between medical and pharmaceutical professionals and pharmaceutical companies. Further, it prohibits members of the medical community from meeting with pharmaceutical company representatives during office hours. At the same time, the bill allows "meetings between company representatives and administrative officials specially authorized by the head of the medical organization." PhRMA and its member companies are concerned that if approved, this measure would discourage the type of transparent educational efforts they currently undertake and would deny doctors and patients important information about new treatment options.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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 made progress toward providing adequate and effective protection for intellectual property.

Key Issues of Concern:

- Lack of effective data protection; and
- Measures for the effective enforcement of patents

For these reasons, PhRMA requests that Costa Rica remain on the **Watch List** for the 2011 Special 301 Report, and requests 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

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 Government of Nicaragua has yet to promulgate regulations that are necessary for the effective implementation of data protection.

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 data base to notify patent owners of requests for marketing approval of products that may, if marketed, infringe their patents. Unfortunately, according to FEDEFARMA, the research-based pharmaceutical association in Central America, this data base 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 promulgate regulations that are necessary for the effective enforcement of patents.

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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to trade barriers in the CAFTA-DR countries related to intellectual property.

COLOMBIA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Colombia remain concerned that Colombia's enforcement of IP rights are diminishing and new risks threaten ongoing protection. Obstacles to obtain and enforce patent rights persist as the Colombian Patent Office (CPO) continues to deny patent applications for innovative products corresponding to patents that have been granted in many other countries. Furthermore, there are inconsistent and discriminatory standards for inventive level, as applied by the CPO, concerning patents in the pharmaceutical field. The current procedural norms prevent patent-holders from efficiently seeking effective remedies, such as preliminary injunctions, against infringing products prior to market launch. Also, the current patent application backlog is generating, on average, an unacceptable delay of seven to nine years for pharmaceutical patents before a preliminary decision is made.

Key Issues of Concern:

- Data protection;
- Effective patent enforcement;
- Scope of patentable subject matter; and
- Government price controls.

For these reasons, PhRMA requests that Colombia remain on the **Watch List** for the 2011 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

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.

PhRMA member companies continue to be concerned over the developments involving the legal action filed by the Colombian generic industry to have this type of protection eliminated via an Andean Non-Compliance Action against the Republic of Colombia (02-AI-2009). Although the Colombian Government and the Industry are taking necessary measures to actively defend the *status quo*, an unfavorable decision could result in the loss of test data protection in Colombia and result in significant commercial losses for PhRMA members. PhRMA supports the Colombian Government's efforts to retain meaningful data protection.

Additionally, there have been changes in procedure at the Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) regarding data protection, which are of concern to 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
- 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 requiring such evidence is warranted 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 titleholder from seeking effective enforcement of its patent prior to the commercial launch of a potentially infringing product. With an efficient pre-launch patent enforcement mechanism in place, all market participants (innovators, generics and the consumer) have legal certainty regarding the legal status of a particular product before they commit an act that 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.

Colombian procedure does not provide adequate due process guarantees to effectively litigate patent enforcement. Additionally, litigation delays can often take more than 8 years. Colombia could solve these delays by establishing an autonomous intellectual property court. Such a court could offer effective, expeditious and competent adjudication mechanisms for patent infringement issues.

Scope of Patentable Subject Matter

- *Patents for Improvements of Known Molecules (e.g.: polymorphs, isomers, processes)*

The Colombian Patent Office (CPO) continues to apply standards for patentable inventions that make it unjustifiably difficult to obtain patents in Colombia for innovations which are otherwise patentable in the rest of the world. In the past four years, the CPO has applied illegal *per se* subject matter rejections against polymorph and isomer patents. The most troublesome aspect of this situation is that these standards discriminate against the chemical arts, singling out research-based pharmaceutical companies. These standards may constitute a technical sector-specific protectionist barrier, favoring the local generic industry. These actions also violate Article 27 of the TRIPS Agreement, which generally prevents signatory countries from discriminating against inventions as to their field of technology. Although there was a

recent decision from the Colombian Council of State (2003-02256, decided August 13, 2009), which reversed a Patent Office rejection of a polymorph case, that single decision does not eliminate the problem. It was decided after seven years of litigation, and a prior contrary decision from the same court finding that other polymorphs for the same molecule were not patentable appears to remain in force.

- *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, in violation of TRIPS Article 27.1, and contrary to long-standing precedents. 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 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 considering that "all or part of living beings as they are found in nature ... existing biological material or that which can be isolated" is not considered an invention. This is an unreasonably narrow definition of patentable subject matter which undermines incentives for development in biotechnology.

Unreasonable Delays in Patent Grant

On average, pharmaceutical patent applications are delayed up to nine years before a preliminary decision is made, and until late 2006, there was an upward trend. In an effort to reverse this momentum, the SIC hired additional examiners during the first half of 2007 with the promise to show positive results by year end. However, to date, the impact of these measures has not taken effect. Furthermore, 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 restoration.

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 has tarnished the image of the registered trademark and has opened the door for copiers to freely take advantage of the innovator's trademark'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 Control

In 2006, the Government of Colombia modified its pricing policy for pharmaceutical products in a way that could unfairly limit free trade and discriminate against patented pharmaceutical products. Pursuant to the policy established in Circular No. 04, 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.

The National Commission on Pricing of Medications (NCPM) fixes the maximum public sale price of the medications included in the Direct Control Regime, according to the reference price obtained as an average of the three lowest prices of at least 4 of the reference countries.

In 2009 and 2010, the NCPM included several pharmaceutical products in the Regulated Freedom Regime, arguing (1) health and public reasons; (2) absence of therapeutic alternatives; or (3) very high market concentration.

By means of Circular No. 02 of 2010, the NCPM decided the following:

1) The reference countries for determining reference prices of pharmaceutical products shall be those with similar GDP taking into account purchasing power parity.

    a) The reference countries are Argentina, Brazil, Chile, Colombia, Ecuador, Mexico, Panama, Peru and Uruguay.

    b) Reference prices shall be obtained from at least 4 reference countries.

2) The NCPM may fix maximum marketing margins. The margins can be general or specific for certain products.

3) The NCPM may fix maximum prices for the products to be reimbursed by the Social Security and Health System (SSHS).

4) The information of the prices reported by the companies will be processed and the information related to the minimum and maximum prices, the average prices reported, the total units sold, for each marketing channel, will be published.

In turn, the NCPM, by means of Circular No. 04, established the maximum price reimbursement prices to be paid by the SSHS.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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 the Dominican Republic continue to face a difficult climate due to the Dominican Government's failure to provide adequate intellectual property protection. On November 14, 2006, the Dominican Congress approved Law 424-06, implementing the "CAFTA-DR." Internal regulations, which must be adopted for the Dominican Republic to comply with test data protection and effective patent enforcement requirements contained in the Agreement, have yet to be issued or implemented. In addition, there is a significant backlog in the issuance of patent certificates by the National Office of Industrial Property (ONAPI). As a result, the ability of PhRMA member companies to enforce their IP rights is substantially diminished.

Key Issues of Concern:

- Ineffective patent enforcement mechanism;
- Failure to implement data protection; and
- Significant patent backlog.

For these reasons, PhRMA requests that the Dominican Republic remain on the **Watch List** for the 2011 Special 301 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 Data Protection and Effective Patent Enforcement Regulations

Chapter 15 of the CAFTA-DR and Dominican Law 424-06 for the Implementation of CAFTA-DR provide for the protection of pharmaceutical test data from unfair commercial use, and prohibit health authorities (Dirección General de Drogas y Farmacias) from granting regulatory approvals for the sale of pharmaceuticals subject to patent protection through a patent enforcement mechanism. However, regulations to implement these protections are still pending and have yet to be implemented by the Dominican authorities. As a result, the Dominican Republic is not fulfilling its commitments under the CAFTA-DR, and the ability of PhRMA member companies to enforce their IP rights is substantially diminished.

Patent Backlog

There is a significant backlog of unissued patent certificates by ONAPI's Invention Department. According to official statistics, as of February 2011, there were 1,144 patent applications pending at the Invention Department of ONAPI, out of which 919 were pharmaceutical or chemical patent applications.[77] Moreover, only 42 patent certificates have been issued in the last 10 years, 19 of which were protected pharmaceutical and chemical inventions.

[77] In accordance with certification issued by ONAPI´s Office of Access to Public Information on February 4, 2011.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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 the country's policies and procedures for the grant of compulsory licenses, the lack of a clear and effective system for protecting pharmaceutical test data, and other market access barriers in Ecuador.

Key Issues of Concern:

- Compulsory licensing;
- Data protection; and
- Government price controls and discrimination in favor of local manufacturers.

For these reasons, PhRMA requests that Ecuador be placed on the **Watch List** for the 2011 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

Presidential Decree 188 of 2009 designated most innovative medicines as "public health priorities" and established a special procedure for obtaining compulsory licenses to patents covering these priority medicines. This designation is overbroad. Realistically, there are classes of medicines (some covered by patents and some not covered by patents) for the treatment of most diseases. Thus, there is no need to designate all medicines in these classes as a priority as a practical matter.

Moreover, the procedure is biased in favor of the competitors of the patent owners. There is no real requirement to examine the merits or need for a compulsory license such as the existence of alternative therapies. While there are some clear procedures for competitors to follow to obtain a compulsory license, the rights of the patent owner to participate in the procedure are not clear. Specifically, there is little or no guarantee that the patent owner has effective notice and sufficient opportunity to oppose the grant of the license in a timely fashion. In other words, the procedure is not transparent and lacks procedural due process for patent owners. Nor is this merely a hypothetical concern; Ecuador granted a compulsory license on a patented medicine in 2010.

As a consequence, Ecuador should be strongly encouraged to revise the Decree 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.

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 supplement Article 39.3 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 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. 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 effective protection against unfair commercial use of undisclosed data generated to obtain marketing approval for pharmaceutical products in a manner that is consistent with its obligations under TRIPS Article 39.3.

Measures for the effective enforcement of patents

Ecuador does not provide measures that prevent the Government from facilitating patent infringement or that provide notice that marketing approvals of certain pharmaceutical products may lead to patent infringement.

Administration of the patent system

According to IFI, the research-based pharmaceutical association in Ecuador, there have been extensive delays in processing patent applications. While the Ecuadorian Intellectual Property Institute reported that it has improved its performance in 2010, the Institute has not provided statistics to support this claim.

Section 294 of Intellectual Property Act No. 83 of 1998 calls for the establishment of courts specializing in intellectual property. To date, however, these courts have not been established. Establishing such courts should be encouraged.

Market Access Barriers

Government price controls

The Government of Ecuador has a government price control system provided for in Law 2000-12 and ratified by the new Health Law passed in December 2006. This system covers all presentations of pharmaceutical products and provides for the following: "The profit margin by product for the manufacturer or importer shall not exceed 20%; for distributors the profit margin shall not exceed 10% per product, and for retail outlets the profit margin cannot be greater than 20% for brand-name products and 25% for generic medicines."

In addition, the prices for pharmaceutical products have not been reviewed by the Government since March 2003. According to IFI, accumulated inflation is exerting pressure on pharmaceutical companies operations, and causing distortions in the market that would not occur in an offer/demand system or a semi-regulated environment.

New regulations to improve the system have been drafted but not yet approved, and, therefore, the process should be monitored throughout 2011.

National preference in public procurement

Ecuador implemented an online reverse auction public purchases system in 2009. This system was used at first by Ecuadorian Social Security Institute (Instituto Ecuatoriano de Seguridad Social – IESS) to procure medicines in early 2009. In 2010, IESS changed its bid procedures by granting higher qualifications for national producers and discriminating against foreign producers. Before this change, price was the main variable considered in the auction process.

Ecuador has not yet published procurement rules for the medicines purchased by IESS and by Ecuador's public hospitals (which includes police and military institutions). The development of the new procurement rules should be closely monitored to ensure that the Government of Ecuador does not implement rules that discriminate against foreign suppliers.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 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, note that despite continued dialogue between PhRMA members and senior Mexican authorities representing the patent office (IMPI) and health regulatory agency (COFEPRIS), little to no progress was made in 2010 to address outstanding issues of crucial importance to the pharmaceutical industry. In March 2010, the heads of these agencies made separate commitments to the U.S. Government and PhRMA representatives to introduce legislative fixes to problems in data protection and patent enforcement mechanisms within six months. As of the writing of this report, however, no such proposals have been introduced. PhRMA and its member companies remain frustrated by the inability to remove infringing copies of patented products from the market place or prevent their launch. In addition, 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. The continuation of these problems is inconsistent with Mexico's commitments referred to above and counter to the protections envisaged under the North America Free Trade Agreement (NAFTA) and the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights.

Key Issues of Concern:

- Inconsistent implementation of the Patent Linkage Decree (Decree);
- Failure to provide data protection sufficient to meet its NAFTA obligations; and
- Failure of the Mexican IP system to effectively enforce patent rights.

For these reasons, PhRMA recommends that Mexico remain on the **Watch List** pending provision of data protection, a definitive solution to patent enforcement problems and determined actions to improve the IP system in a way that is strongly supportive of innovation.

Intellectual Property Protection

Effective Patent Enforcement

PhRMA members recognize that the 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 use and 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 effective patent enforcement 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 use and formulation patents in the Official Gazette. In addition, PhRMA and its member companies encourage IMPI to hasten patent infringement proceedings; use all available legal mechanisms to enforce its decisions; and implement procedures necessary to provide timely and effective preliminary injunctions.

Data Protection

In 2009, Mexico established an inter-agency commission to consider the issue of its NAFTA commitment when approving marketing requests generated by third parties, to clearly prohibit for a reasonable time Government officials from relying on test and other data submitted by PhRMA's member companies to prove safety and efficacy of their products. The Government also commissioned an economic impact study related to implementation of a data protection regime. In March 2010, the heads of COFEPRIS and IMPI committed to the U.S. Government during bilateral meetings that Mexico would introduce legislative language to ensure compliance with its NAFTA commitment. As of January 2011, no such language has been introduced and a request to review the economic impact study through Mexico's Freedom of Information Law was denied.

Reform on Biotech Drugs

Regulations to implement Article 167 Bis of the Regulations of the Health Law on biotech and biosimilar products, approved by the Mexican Congress in April 2009, have been under discussion for more than one year. One of the main issues still under discussion between industry representatives and Mexican authorities is the time period prior to patent expiry at which a company may conduct the studies needed to develop a generic or biosimilar without infringing the patent. In response to a Secretariat of Health (Salud) proposal to eliminate the time period entirely (allowing a generic company to begin development of a copy product or biosimilar at any time), the local innovative pharmaceutical trade association (AMIIF) proposed a 3 year period before patent expiry for generics and a 4 year period before patent expiry for biosimilars. Salud has not yet responded to this proposal. AMIIF believes that such a proposal will create certainty within the market and allow for development of generics and biosimilars in a timely fashion without unduly interfering with the rights of patent holders.

Counterfeit Drugs

PhRMA and its member companies deeply appreciate the increasingly important achievements in support of anti-counterfeiting efforts, under the coordinated efforts of COFEPRIS, IMPI, PGR, PFP and the local Prosecutor of the Jalisco State. These actions have resulted in the unprecedented closure of numerous pharmacies selling counterfeit medicines and the 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 2010 attributable to trade barriers related to intellectual property protection and market access.

PANAMA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Panama find that it has not effectively implemented its international obligations related to data protection and does not provide for effective enforcement of patents.

Key Issues of Concern:

- Data protection; and
- Measures for the effective enforcement of patents.

For these reasons, PhRMA recommends that Panama be included on the Special 301 **Watch List** in 2011 and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Data protection

Presidential Decree No. 305 of 2003 provides for protection of certain pharmaceutical test and other data from unfair commercial use and disclosure. To date, however, no implementing regulations have been promulgated.

Measures for the effective enforcement of patents

Panama should provide mechanisms which enable the timely resolution of patent issues before follow-on products, such as generics, are approved.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2010 attributable to trade barriers related to intellectual property protection and market access.

PERU

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Peru are concerned with the current state of intellectual property protection and several discriminatory sanitary regulations that favor local producers in Peru.

The U.S.-Peru Trade Promotion Agreement (USPTPA), which was signed in 2006 and modified in May of 2007, obligates Peru to protect pharmaceutical data, provide a pre-launch legal system that will provide the opportunity for patent holders to prevent the marketing of an infringing product, and establish a stronger intellectual property framework. 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 data protection for biologics;
- Lack of effective patent enforcement; and
- Market access barriers, including import barriers and duplicative testing requirements.

For these reasons, PhRMA recommends that Peru remain on the **Watch List** for the 2011 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

Data Protection

The Government of Peru established a data protection regime in February 2009. Since then, more than five new pharmaceutical products have been awarded with data protection for an average of four years. Nevertheless, since May 2010, the Peruvian Health Authority (PHA) has rejected data protection for two biotechnological pharmaceuticals. This refusal is inconsistent with Peru's obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights, the USPTPA, and its national law. Denying such protection will adversely affect PhRMA members attempting to introduce significant new products in Peru and will create pressure on other trading partners in the region to refuse to protect this very important class of products.

To remedy this ongoing treaty violation, the Government of Peru should, as committed to in the USPTPA, refrain from granting sanitary registrations to copies of any kind of innovative pharmaceutical products, regardless if these are synthesized or biotechnologically derived pharmaceutical products, for a term of five years, unless the applicants for such copies provided their own clinical data. After the five-year period lapses, a registration could be granted to a third party product relying on the innovator’s safety and efficacy information, provided the copy submits appropriate data.

Patent Enforcement

The Peruvian system for enforcing patents is a two-step, sequential process: (1) an administrative process for determining infringement within 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 because it does not provide for timely resolution of patent issues which could prevent marketing of infringing products.

Articles 16.10.4 and 5 of the Agreement require Peru to provide patent holders with an opportunity to seek injunctive relief if marketing approval is requested by an unauthorized manufacturer of a patented product. However, the only special measure implemented by the Peruvian Government under the above mentioned USPTPA obligation refers to the publication of the sanitary registration applications on the web page of the Health Authority (DIGEMID), which provides the patent holder notice of an intention to commercialize a potentially infringing product. This is not adequate because insufficient time before marketing of a generic is available to resolve any patent issues.

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. Such decisions constitute law in Bolivia, Colombia, Ecuador, and Peru. Andean member countries have either been compelled by the ACJ not to grant second use patents or chosen to honor Andean Community obligations, while ignoring 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 no further domestic appeals/remedies are possible.

Market Access Barriers

Peru has passed legislation such as the Pharmaceutical Products Law 29459, which requires increased regulatory oversight and procedures to ensure the safety and efficacy of pharmaceutical products. Although some regulations have been approved to achieve these goals, implementation is often slow and many regulations have been unnecessarily delayed. These delays cause uncertainty and present a market barrier that increases access and permanence costs.

Delays in passing and implementing regulations

Delays in passing implementing regulations are leading to the following critical problems:

1. *Lack of Specific Regulations for Biopharmaceutical Products*: Currently, the regulatory standards for seeking marketing approval of biopharmaceuticals in Peru are rudimentary, and thus insufficient to ensure safe and effective biological

pharmaceuticals. This jeopardizes not only the permanence of quality drugs in the market, but also public health. A new product specific regulation should be adopted for biopharmaceutical products approvals.

2. *Duplicative Testing*: Article 45 of Law 29459 provides that: (1) the first batch of any new pharmaceutical product must undergo 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. The regulations specifying how a laboratory may be certified by the PHA have been significantly delayed (over one year). Local generic manufacturers have capitalized on this delay by securing the introduction of a bill in the Peruvian Congress that would require duplicative local testing. If approved, the bill would impose a disproportionate burden on U.S. and international pharmaceutical companies, and thus presents an impermissible trade barrier.

3. *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 2010 attributable to trade barriers related to intellectual property protection and market access.

MIDDLE EAST

SAUDI ARABIA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Saudi Arabia remain concerned that the Saudi Government has been slow to implement the Exclusive Marketing Rights (EMR) agreement, has reduced protections for pharmaceutical patents, and does not provide adequate protection for pharmaceutical data.

Key Issues of Concern:

- Non-issuance of Exclusive Marketing Rights certificates to eligible applicants;
- Poor protection of pharmaceutical test data;
- A court decision that invalidates Gulf Cooperation Council patents for pharmaceuticals;
- Volatile government pricing policies;
- Non-transparent drug formularies; and
- Lengthy and expensive registration procedures.

For these reasons, PhRMA requests that Saudi Arabia be placed on the **Watch List** for the 2011 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

Non-transparent Implementation of the Exclusive Marketing Rights Royal Decree

PhRMA was encouraged by the signing of the Royal decree on Exclusive Marketing Rights (EMR): a mechanism put in place to remedy the difficulties faced by PhRMA members on patent protection. This initiative 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. This 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.

Per the Decree, pharmaceutical companies submit their EMR applications to KACST. KACST then reviews those applications, and forwards 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 right will expire on the same date the patent expires in the United States or the European Union; whichever comes first.

The problem, however, is that the Decree as implemented does not provide a transparent and reliable method for advising individual companies as to whether their EMR applications have been approved. In meetings held with KACST late last year, it reported that as of July 2010 it had reviewed nearly all of the 120 applications filed by various companies and that eligible applications were forwarded to the SFDA. However, no certificate or notice has been provided to the applicants to advise them that their products will benefit from EMR.

Although PhRMA and its member companies have discussed this shortcoming with the two relevant agencies, neither KACST nor the SFDA believes it has the mandate to issue EMR certificates. Rather, KACST points to the SFDA, noting that it is the latter's responsibility to enforce EMR. Conversely, SFDA points to KACST, arguing that SFDA is merely implementing the decision of the KACST as to whether the pharmaceutical product identified in an application is eligible for EMR.

PhRMA would like to thank the U.S. Government (USTR, Department of Commerce, Department of State, and the U.S. Embassy in Riyadh) which 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 Coast 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.

Data Protection

PhRMA member companies are concerned by the authorities' failure to provide effective 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 commitment 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 over the need to enforce their regulations on data protection; yet authorities insist they are not sharing the content of the drug registration file of the innovator product. However, the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 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 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 or review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data.

Data protection should be provided to innovative pharmaceutical products whether or not they are patented in Saudi Arabia or are covered by the EMR. Data protection is commercially important to products that may not be patentable. Saudi regulatory authorities should have the responsibility for keeping generic copies of pharmaceutical products off the market during the period of 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.

Market Access Barriers

Volatile Government Pricing Policies

PhRMA member companies are concerned by the volatility of Saudi Arabia's government pricing regime. The Government issued the draft of a new pricing regime in June 2008. The Government's efforts to seek industry and other stakeholder input into the draft policy is commendable, and is the result of U.S. Government advocacy encouraging Saudi Arabia to live up to its WTO accession commitments.

PhRMA member companies are concerned over the proposed government pricing policy in that it 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 that have been invested by innovative pharmaceutical companies in the development of these medicines.

In 2008, PhRMA member companies communicated to the SFDA specific public policy concerns pertaining to the proposed government pricing policy, mainly: (1) prices for pharmaceutical products in Saudi Arabia are already some of the lowest in the region; (2) when setting prices, the Saudi Government references countries with significantly lower standards of living; (3) the new policy proposes expanding the list of reference countries from 30 to 41 countries; (4) government prices are revised too frequently; (5) the categories of products that

are subject to price cuts are unknown ahead of time; (6) pharmaco-economics is proposed as a means to determine prices, but no clear criteria for the evaluation is given; (7) that there is a category of "post-patent pricing" with no definition of what this entails; and (8) the system fails to take into account exchange rates.

On November 1, with strong and invaluable support from the U.S. Embassy in Riyadh PhRMA members and the SFDA met to discuss a wide range of issues, including a new government pricing proposal. The dialogue was an important demonstration of the type of positive dialogue that can lead to an improved market for innovative pharmaceuticals in Saudi Arabia. PhRMA and its member companies look forward to additional opportunities to engage in similar discussions with Saudi authorities.

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.

SFDA is assisting private insurance companies in developing a drug formulary that would be used as the basis for mandatory private insurance for expatriates.

Regulatory Environment

In 2008, the SFDA initiated a dialogue with PhRMA member companies over a draft regulatory framework for drug approvals. This framework outlines requirements for various types of applications for marketing authorization and expedites patient access to innovative pharmaceuticals, which ensures public safety and develops new modalities to address potential public hazards. The new framework, of which has yet to be implemented, is also expected to speed up registration to a maximum number of 290 working days.

The current investment law allows 100% 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% during the first year, reaching a maximum of 70% 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 2010 attributable to trade barriers related to intellectual property protection and market access.

JORDAN

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in Jordan are concerned about the deterioration of intellectual property rights protection due to Jordan's interpretation of and noncompliance with its obligations under the World Trade Organization (WTO) Agreements on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Technical Barriers to Trade (TBT), and the General Agreement on Tariffs and Trade 1994 (GATT). The issues described below are especially concerning because Jordan has, since the signing of the Free Trade Agreement (FTA) with the United States in 2000, stood out as an example of how a country can grow its domestic pharmaceutical industry, while at the same time providing strong intellectual property rights protection for pharmaceuticals.

Key Issues of Concern:

- Failing to provide adequate data protection;
- Challenging deadline for marketing authorization applications;
- Failing to adhere to obligations agreed to in their WTO and FTA agreements;
- Unfair commercial advantage provided to local producers of generic drugs; and
- Inconsistent government pricing regime.

For these reasons, PhRMA requests that Jordan be placed on the **Watch List** for the 2011 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 weakened their data protection regime and continue to deny data protection to new indications. Protection for new chemical entities should include protection for new uses for a reasonable period of three years or otherwise provide an adequate period of data protection.

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 a "new chemical entity." If not, it will be denied data protection, allowing a generic of that molecule to enter the market. 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 is not in the EU or the United States, which are both relied upon for the Certificate of Pharmaceutical Product (CPP) application and for which the JFDA references for the one year pharmacovigilance, and other technical requirements, then meeting this 18 month deadline is further compromised.

When Jordan acceded to the WTO in 1999, Jordan stated that it would implement Article 39.3 of TRIPS by providing at least five years of data protection from the date of marketing

approval in Jordan.[78] Jordan did not state that it planned to place any limitations on the ability of pharmaceutical companies to avail themselves of this five years of protection. To the contrary, Jordan clarified that it intended to comply with its obligation under TRIPS Article 39.3 to protect data from unfair commercial use by implementing a period of non-reliance "for a period of at least five years from the date on which Jordan granted marketing approval to the person that produced the data."[79] Given these representations, Jordan should not unilaterally scale back this protection by implementing an 18-month filing window that may effectively provide no protection at all to some products. Imposing this additional filing criteria on pharmaceutical companies is inconsistent with Jordan's representations during the accession process that it would "apply fully" TRIPS Article 39.3 by providing five years of data protection from the date of marketing approval in Jordan.

Moreover, Jordan reiterated this commitment in its FTA with the United States when it agreed to provide data protection "pursuant to Article 39.3 of *TRIPS*." Not only does the FTA carry forward Jordan's obligation with respect to data protection for new chemical entities, it also states an explicit term of protection for new uses of three years. The FTA also explicitly extends data protection to reliance on evidence of marketing approval in another country.

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 to the detriment of innovative medicines and the benefits they bring to Jordanian patients. Per Article 52 (I) of the JPD, locally produced generic products are rewarded a 10% price benefit over innovative foreign products when considering tenders. This preferential treatment violates Jordan's obligations under the GATT Agreement 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).

Denied Representation at the Higher Council for Drugs

Despite representing more than 50% of the Jordanian pharmaceutical sector, the innovative pharmaceutical industry is denied representation at the Higher Council for Drugs at the JFDA, while local industry is more than well represented. The issues referred to the Council do not address the concerns of all stakeholders. Currently, we are working to ensure that all stakeholders' concerns are heard.

Burdensome Regulatory and Pricing Policies

Jordan has developed burdensome regulatory and government pricing policies, creating market barriers in support of their own drug industry at the expense of Jordanian patients and

[78] Report of the Working Party on the Accession of the Hashemite Kingdom of Jordan to the World Trade Organization ("Working Party Report"), WT/ACC/JOR/33, WT/MIN(99)/9 (3 December 1999), at ¶ 215. Jordan's commitment to "apply fully" all provisions of TRIPS is found at paragraph 230 of the Working Party Report, and it is paragraph 230 that is incorporated into Jordan's Protocol of Accession. Paragraph 215 is relevant context for determining to scope of Jordan's commitment to fully implement TRIPS Article 39.3.
[79] Working Party Report, at ¶ 215.

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. With the delay in market access, Jordanian patients suffer and must, for those who can afford to, travel outside the country for access to quality healthcare.

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. We recommend modifying the government's pricing strategy so that it is clear and consistent: 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, which inevitably increases the workload for the industry and JFDA. We propose that government prices should not routinely 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 2010 attributable to trade barriers related to intellectual property protection and market access.