

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)
SPECIAL 301 SUBMISSION 2010

**PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA
(PhRMA)
SPECIAL 301 SUBMISSION 2010**

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)
SPECIAL 301 SUBMISSION 2010

Table of Contents

Introduction	4
Priority Foreign Country	26
Thailand	28
Section 306 Monitoring	34
China	36
Priority Watch List Countries	44
ASIA-PACIFIC	46
India	48
Indonesia	52
Korea	56
New Zealand	60
Philippines	64
CANADA	68
Canada	70
EUROPE	78
Overview: European Union	80
The Czech Republic	84
Israel	88
Italy.....	94
Poland	98
Russia	104
Turkey	110
LATIN AMERICA	116
Argentina	118
Brazil	122
Chile	128
Venezuela	134
MIDDLE EAST/ AFRICA/ SOUTH ASIA	138
Algeria	140
Lebanon	144
Pakistan	148

<u>Watch List Countries</u>	152
ASIA-PACIFIC	154
Australia	156
Malaysia	158
Taiwan	160
Vietnam	166
EUROPE	168
Finland	170
France	174
Hungary	178
The Netherlands	182
Norway	186
LATIN AMERICA	188
Colombia	190
Costa Rica	194
The Dominican Republic	196
El Salvador	198
Honduras	200
Mexico	202
Nicaragua	206
Panama	208
Peru	210
MIDDLE EAST	214
Saudi Arabia <i>with OCR</i>	216
<u>Countries of Note Without Designations</u>	220
Germany	222

PhRMA SPECIAL 301 SUBMISSION 2010 OVERVIEW

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)
SPECIAL 301 SUBMISSION 2010

PhRMA SPECIAL 301 SUBMISSION 2010 OVERVIEW

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 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). The TRIPS Agreement requires all WTO Members to establish functional intellectual property systems. Its obligations extend to rights such as patents, undisclosed information, trademarks and copyrights. It also requires efficient registration procedures and effective enforcement regimes. 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. We believe that this has been borne out by improvements in public health and in the general economic performance of a number of middle income developing countries in every region of the world that have met or exceeded their WTO TRIPS obligations. Because it concerns both the definition and enforcement of rights, the TRIPS Agreement is an important step toward effective protection of intellectual property globally.

One of the concessions made by the United States in the TRIPS Agreement was to provide developing countries with a number of extended transition periods to implement it. The developing country WTO Members were given a five-year grace period to implement most of their obligations, while the least developed WTO Members were given an eleven-year transition period. Additional concessions were made to developing countries to allow delay of product patent protection for pharmaceutical products, and more recently to least developed countries to allow a further transition for patent protection until the year 2016. The first of these transition periods ended on January 1, 2000, and as of January 1, 2005, all but the least developed countries were subject to all provisions of the TRIPS Agreement. These trading partners have benefited tremendously from the trade liberalizations of the Uruguay Round, many of which represented significant U.S. concessions. These countries are also home to industries that aggressively compete with U.S. industries dependent on effective intellectual property protection – particularly in the biopharmaceutical sector.

Despite the end of the transition period on January 1, 2005, for the full implementation of the TRIPS Agreement by most WTO Members, 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. Especially troubling is the failure of almost all the developing countries on which we report to implement their TRIPS Article 39.3 obligation to prevent unfair commercial use of undisclosed test data. PhRMA member companies believe it is now time to refocus government efforts on core commercial priorities, and that U.S. commercial interests would be best served by a strong high-level and consistent commitment to full implementation of TRIPS, including those provisions concerning protection of undisclosed data.

An important area of concern is counterfeit drugs. Weak regulatory and IP enforcement regimes in some countries contribute to this problem, which increases health risks to patients, particularly those in poor populations. PhRMA believes this problem may increase in significance, and that the assistance of the United States throughout the Special 301 process and through other forums will be essential to ensuring delivery of safe medicines to patients. Counterfeiting is further discussed in both this introductory chapter as well as individual country chapters.

In addition, ensuring meaningful implementation of FTA obligations is an increasing need. The Special 301 process is an important tool in facilitating compliance with these important agreements.

While proper implementation and enforcement of national IP legislation and regulations are a key focus of this report, it is also important to recognize that activities a particular country may take can be viewed as an international role model. Often countries will take active positions on IP issues within international fora such as the UN system including WIPO, the WTO, and WHO or as a regional expert willing to share guidance with allied governments. While this is beneficial when sharing best practices for strengthening IP regimes, it can also pose a threat when countries actively advocate the widespread adoption of positions that could erode IP. Thus, it is important to recognize both a country's domestic activity concerning IP regime implementation and enforcement, as well as their role in purveying their positions through international advocacy activity.

In late 2009, a study examining the biopharmaceutical industry's contributions to the U.S. Economy underscored the importance of advocacy on behalf of one of America's leading edge high-technology industries. According to this study, in 2008 America's biopharmaceutical companies were responsible for over 3.2 million jobs (direct, indirect, and induced) across the United States and \$626.6 billion in total output. The report contains a state-by-state breakdown of these figures, demonstrating why so many U.S. states are actively competing to attract biopharmaceutical companies.

These figures highlight the critical importance of the work of U.S. trade negotiators to open foreign markets, encourage the adoption of policies that do not discriminate against foreign-based companies and promote innovation in the global trading regime. High technology industries such as the biopharmaceutical industry are the engine of U.S. growth, and it is more critical than ever that the United States takes a strong stand in favor of the open trading rules that will allow such growth to continue.¹

A recent statement by Assistant United States Trade Representative Stanford K. McCoy in testimony to the Congress confirmed this point: "...one of our key comparative advantages in the global marketplace is the ability of our large and small enterprises and their workers to occupy the leading edge of the market. It is our innovation and creativity that keeps us there, and the ability to secure the fruits of that innovation and creativity that helps to secure our place in the global economy."²

Economic Growth and Improved Health Through Innovation

America's biopharmaceutical research companies are one of the largest contributors of funding for development of innovative cures for diseases affecting patients of both the developed and developing regions in Latin America, Asia and Africa. The U.S. pharmaceutical sector is responsible for 80% of the world's R&D in health care biotechnology, and more than 2,900 compounds were in development or seeking regulatory approval in the U.S. in 2009.³ The compounds in development include 300 potential medicines for rare diseases, 800 potential treatments for cancers, particularly lung cancer and breast cancer; 300 new approaches for heart disease and stroke; and 97 new treatments to fight and prevent HIV/AIDS.⁴

In the last decade, biopharmaceutical research companies have provided over \$9.2 billion in direct assistance to healthcare for the developing world. This includes donations of medicines, vaccines, diagnostics, and equipment, as well as other materials and labor – totaling over \$2.4 billion in 2007 alone.⁵

America's biopharmaceutical companies are among the largest funders of the research and development necessary to cure neglected and major diseases in the developing world, investing more than \$365 million into new cures and treatments in

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

² *Protecting Intellectual Property Rights in a Global Economy: Current Trends and Future Challenges: Hearing Before the House Comm. On Oversight and Government Reform, Subcommittee on Management, Organization and Procurement, 110th Cong.* (2009) (statement of Stanford K. McCoy, Assistant U.S. Trade Representative, Office of the United States Trade Representative).

³ PhRMA. PhRMA Annual Member Survey, Washington, DC, 2009; Adis R&D Insight Database, Wolters Kluwer Health, accessed 13 February 2009. Burrill and Company analysis based on publicly available data, 2009.

⁴ Pharmaceutical Research and Manufacturers of America, www.phrma.org.

⁵ IFPMA. IFPMA Partnerships Survey. November 2008.
http://www.ifpma.org/fileadmin/pdfs/webnews/20081114Release_Partnerships_Survey_19Nov08_Final.pdf.

2008, alone. They support research and development centers around the world dedicated to finding innovative diagnostics, medicines and vaccines for diseases such as malaria, TB, sleeping sickness and dengue fever.⁶

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.⁷ Examples of these programs include: The Global Fund to Fight AIDS, the Accelerating Access Initiative, the Medicines for Malaria Venture, the Polio Eradication Initiative, Roll Back Malaria, The Global Alliance for Vaccines and Immunization, the Global Alliance for TB Drug Development, and the Global Alliance to Eliminate Lymphatic Filariasis.⁸

Moreover, the contributions of America's biopharmaceutical companies support innovative efforts to developing drugs and treatments that can be safely and easily administered in situations where there are limited healthcare resources, such as treatments that can be sustained in hot climates where refrigeration is not available. All of these innovations are highly dependant on the incentives offered by IP.

Without these innovative efforts, access to effective, sustainable healthcare by the developing world's patients would be impossible. But beyond the efforts of individual companies, experience shows that while access to medicines is critical, product donations alone will not improve health care in the developing world. Long-term success depends on biopharmaceutical research companies working with governments and others to address the underlying barriers to health care, such as weak and fragmented health systems and inadequate resources to scale up proven solutions.

Medical and health care technology innovation is a critical tool for helping to solve many of the health challenges confronting the developing world and biopharmaceutical research companies are acknowledged global leaders in developing and deploying innovative medical and healthcare technologies. In laboratories in a growing number of research centers around the world, biopharmaceutical research companies are investing and focusing on developing innovative medicines specifically to meet developing world needs.

II. Counterfeit Medicines

The increasing prevalence of counterfeit medicines is an area of particular concern and one that demands an aggressive, coordinated response among all U.S. trading partners. The Pharmaceutical Security Institute (PSI) has confirmed this upward

⁶ Moran, M. et al, Neglected Disease Research and Development: New Times, New Trends, The George Institute for International Health, (2009). The report is available at:
http://www.thegeorgeinstitute.org/shadomx/apps/fms/fmsdownload.cfm?file_uuid=9072CD41-01A5-1E41-113B-0752D7FE2DCE&siteName=iih

⁷ See www.globalhealthprogress.org

⁸ See www.globalhealthprogress.org

trend evidenced through its research.⁹ Counterfeit drugs 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 illicit products threaten the health and safety of consumers throughout the world, with PSI reporting the presence of counterfeits in 115 countries during 2008.

Although the prevalence of counterfeit medicines appears to be greatest in developing and least-developed markets, the counterfeit supply chain has no geographic boundaries, threatening every drug distribution channel in the world, including that of the United States. Recent estimates indicate that between 10 to 30 percent of medicines sold in developing markets are believed to be counterfeit.¹⁰ Not surprisingly, countries that lack adequate drug safety controls tend to be most vulnerable to counterfeit medicines. Moreover, in China, India and other countries with drug manufacturing capabilities, lax oversight not only leads to domestic sales of counterfeits, but also to significant exports. In fact, China is believed to be the world's leading supplier of unregulated bulk chemicals and active pharmaceutical ingredients. PSI has documented hundreds of instances where local authorities seized counterfeit products, and raw materials used in their production, shipped from China at diverse locations around the world. These seizures sometimes involved millions of dosage units.

The World Health Organization defines a "counterfeit medicine" as "one which is deliberately and fraudulently mislabeled with respect to identity and/or source."¹¹ This definition recognizes that any deceptively labeled pharmaceutical poses a significant danger to consumers, regardless of whether the product bears a counterfeit trademark or is substandard in any respect. Of course, many counterfeit medicines are of inferior quality or even toxic, evidencing a complete disregard for drug safety standards; and most counterfeit drugs violate important intellectual property rights. But the essential characteristic of a counterfeit medicine is deception as to identity or source, no matter what form that deception may take. Participants in the WHO's International Medicines Anti-Counterfeiting Task Force ("IMPACT") are taking important steps to better understand and address the threat of counterfeits. PhRMA's member companies support the valuable work of IMPACT and are troubled that certain countries are attempting to slow IMPACT's progress and discredit its activities. IMPACT has proven effective in promoting awareness of the public health dangers of counterfeit medicines and in forging international consensus on global strategies and solutions. It is imperative that the WHO and its member countries continue to support IMPACT's mission and activities.

In a recent study, U.S. Customs announced the following FY2009 statistics on seizures of Intellectual Property Rights (IP) infringing goods entering the U.S.:¹²

⁹ The Pharmaceutical Security Institute, Inc., a not-for-profit, membership organization dedicated to addressing pharmaceutical counterfeiting issues, is based in Vienna, Virginia.

¹⁰ The World Health Organization. IMPACT. www.who.org 2008.

¹¹ See the World Health Organization definition of "counterfeit medicines" at <http://www.who.int/medicines/services/counterfeit/overview/en>.

¹² *Intellectual Property Rights, Seizures and Statistic FY 2009*. U.S. Customs and Boarder Protection Published October 2009.

- China continues to be the top source country, by a very large margin, for counterfeit goods seized by U.S. Customs, accounting for \$204.7M or 79% of the total seizure value.
- Hong Kong and India were the second and third most significant source countries for seizures, respectively accounting for 10 percent and 1 percent of the total seizure value.
- Pharmaceuticals remained the top IPR categorized infringing commodity that also presents safety or security risks, accounting for 34% of all safety and security seizures by value.
- China remained the number one source country for safety and security commodities, with more than 62% of such seizures.
- India was the second highest source country for safety or security seizures, with 9% of the seizure value.

European counterfeit seizure statistics help provide a more complete picture of pharmaceutical counterfeiting activity worldwide. Whereas U.S. seizures declined slightly in 2009, with a notable drop in seizures of counterfeit pharmaceuticals, the European Union reported a sharp increase in both the number of articles detained (+126 percent) and the number of cases involving medicines (+57% increase). Although China was the main source country for infringing articles, it appears to play less of a role (or at least a less visible role) in the export of counterfeit medicines to the European Union. Instead, India was the most significant source country for IPR infringing medicines in the EU (accounting for 52%), followed by Syria (36%) and the UAE (8.7%). China accounted for less than 1% of medicines seized by EU Customs. Nevertheless, many experts, including PSI, believe that its role is actually much more significant, with Syria and the UAE serving as increasingly popular transshipment points for Asian produced counterfeit medicines.

Overall, the European statistics confirm that pharmaceutical counterfeiting activity is on the rise globally, and that an increasing number of countries are facilitating that trend, either as sources of Active Pharmaceutical Ingredient (APIs), finished products or diversion points.

Although most countries recognize counterfeit medicines as a threat to consumer health and safety, many lack the comprehensive framework of laws and controls necessary to safeguard the drug supply chain against counterfeit sales and exports. In countries like China, India, Russia, Brazil and Mexico (i.e., markets where pharmaceutical counterfeiting is believed to be a growing threat), several common deficiencies contribute to the growing prevalence of pharmaceutical counterfeiting in worldwide markets. Weak enforcement due to inadequate remedies, penalties, resources and commitment is the most significant problem, and one that undermines the effectiveness of all relevant laws, including prohibitions against trademark counterfeiting, as well as drug regulatory controls. There is as well a need to step up customs controls and international information sharing in a world where counterfeit shipments follow ever-convoluted itineraries, including stops at free trade zones. Law enforcers and regulators simply do not prioritize drug counterfeiting as a serious crime,

despite its potential dangers to consumers both in the U.S. and worldwide. In China, for example, the Government places too much reliance on ineffective administrative enforcement to address counterfeiting activities that are inherently criminal in nature. Although administrative enforcement officials can transfer cases to criminal authorities, they rarely do so, often because the administrative official is unable to satisfy the high quantitative threshold necessary to establish criminal liability.

Another contributing factor is the failure of drug safety regimes to address directly and fully the inherently pernicious nature of counterfeit medicines and to differentiate drug counterfeiting from other regulatory violations. In Brazil, for example, drug regulatory authorities lack the investigative and enforcement powers necessary to penetrate and attack organized counterfeit drug rings. As a result, regulatory authorities must refer pharmaceutical counterfeiting cases to criminal law enforcement officials, who often lack the expertise, resources and commitment to prosecute such offenses. In this regard, PSI reports a recent positive development. The intelligence arm of the Brazilian drug regulatory authority has been actively coordinating its work with federal law enforcement to conduct very successful joint actions against counterfeits.

Also problematic is the fact that many countries, including China, India and Brazil, limit administrative and/or criminal remedies to “substandard”, “adulterated” or “harmful” drugs. These evidentiary hurdles significantly slow, and in many cases prevent, effective enforcement against pharmaceutical counterfeiters. PhRMA commends the Chinese Government for issuing draft interpretations that would define the categories of harm necessary to establish criminal liability. Nevertheless, China’s track record of criminal enforcement remains spotty at best, and certainly insufficient to tackle the massive volume of counterfeit medicines produced in China for export. Moreover, any statutory requirement that conditions criminal liability on proof of harm ignores the inherently dangerous nature of all deceptively labeled medicines. Under Russian law, in contrast, all falsely labeled drugs are treated as counterfeits. However, drug counterfeiting offenses carry *no* administrative or criminal remedies in Russia -- an inexplicable omission that obviously facilitates counterfeiting activity. The training of prosecutors to fully utilize the available criminal law arsenal when going after counterfeiters, such as laws against smuggling, money laundering, tax evasion and the sale of unregistered products, could also be an effective tool to increase the deterrent effect of penalties.

Where counterfeit medicines utilize an unauthorized trademark, weaknesses in drug safety controls are exacerbated by inadequate IP remedies and enforcement. In Brazil, for example, trademark counterfeiting is generally viewed as a non-serious crime; thus, law enforcement authorities lack *ex officio* powers to investigate such offenses. Prosecutions there are often based on laws against the sale of illegal or smuggled products, which allow for *ex officio* actions and require a lower evidentiary threshold. And in Russia, criminal enforcement for trademark offenses is crippled by excessive evidentiary requirements and non-deterrent penalties, among other deficiencies.

However, even in countries with stronger IP regimes, trademark laws are inherently incapable of single-handedly protecting drug distribution channels against the various upstream and downstream activities that contribute to the proliferation of counterfeit medicines. For example, intellectual property laws offer little defense against sales of bulk active pharmaceutical ingredients (APIs) - the chemicals used to produce counterfeit medicines - which typically do not bear a counterfeit mark. Thus, to attack this link in the counterfeit supply chain, it is imperative that drug safety laws subject bulk APIs to the same controls as other pharmaceutical products. Unfortunately, in many countries, including Russia, the law is ambiguous as to whether bulk APIs are regulated pharmaceuticals; thus, oversight and enforcement is virtually non-existent. Similarly, there is very little oversight of the downstream wholesalers and pharmacies that contribute to the global manufacture and flow of counterfeit medicines, particularly as these distribution networks move online.

PhRMA is encouraged that China has recently taken steps to strengthen supervision of APIs, as groups in China appear to be the world's leading suppliers of unregulated bulk chemicals and active pharmaceutical ingredient. Under China's previous regime, API producers could avoid regulatory oversight by opting not to register a specific API with China's State Food and Drug Administration ("SFDA"). Registration was required only if the API producer declared its intention to manufacture an API for use in a finished pharmaceutical product. Absent this declaration, SFDA had no oversight authority, and the bulk API production went unregulated. Under China's new system, announced in June of 2008, all API manufacturers must register with the SFDA and provide information sufficient to identify illegal activity.

To ensure effective implementation of these important changes to China's drug regulatory regime, the Chinese Government recently committed through the JCCT to establish a Drug Master File system, enforce record-keeping requirements for companies that manufacture and sell APIs, and regulate unregistered Chinese companies advertising and marketing APIs at foreign trade shows and on the Internet. These are the type of initiatives necessary to reduce the production and export of bulk APIs. However, their effectiveness will depend on China's willingness to follow through with aggressive enforcement.

To combat the global proliferation of counterfeit medicines and APIs, U.S. trading partners must adopt and implement a comprehensive regulatory and enforcement framework, one that: (i) subjects drug counterfeiting activity to effective administrative and criminal remedies and deterrent penalties; (ii) adequately regulates and controls each link in the counterfeiting supply chain; (iii) trains, empowers and directs drug regulators, law enforcement authorities and customs to take effective and coordinated action, including against exports and online activity; and (iv) educates all stakeholders about the inherent dangers of counterfeit medicines.

III. Early Resolution of IP Disputes and Marketing Approval

To sustain innovation and development of new medicines over the long term, providing adequate and effective protection of intellectual property (IP) rights for the research-based pharmaceutical industry is essential. To accomplish that goal, mechanisms are needed which prevent grants of marketing approval for patent infringing products. Providing for dispute resolution on patent infringement before the product in question is allowed to enter that market is an important tool. Postponing marketing approval for any generic product known by regulatory entities to be covered by a patent until expiration of the patent or the resolution of legitimate patent disputes (often referred to as linkage) is important. Such a mechanism provides a “procedural gate” or safeguard, because it ensures that drug regulatory entities do not inadvertently contribute to infringement of patent rights granted by another government entity by granting marketing rights to a competitor of the innovative company. Legal mechanisms that allow for early resolution of patent disputes before the generic product in question gains marketing approval avoid the need for complex litigation over damages for marketing an infringing product.

IV. Market Access Barriers

In addition to seeking improvements in IP protection around the globe, we seek to diminish barriers which impede access to innovative medicines, undervaluing them in non-transparent and non-accountable ways that ultimately serve to discriminate against foreign based companies and undermine IP rights. Designed to achieve near-term cost-containment, these market access barriers abroad have the long term impact of harming American citizens by costing American jobs, undermining sustainable innovation, and creating higher prices for pharmaceuticals in the U.S.

Addressing global market access barriers will be an essential component of the Administration’s recently announced plan to dramatically increase U.S. exports. The recently released “Strategy for American Innovation: Driving Towards Sustainable Growth and Quality Jobs”, by the National Economic Council’s Office of Science and Technology Policy reiterated the importance of promoting American exports and ensuring fair and open markets for American producers.¹³ The report states that, “[i]t is imperative to create a national environment ripe for entrepreneurship and risk taking that allows U.S. companies to be internationally competitive in a global exchange of ideas and innovation. Through competitive markets, innovations diffuse and scale appropriately across industries and globally.”¹⁴ In a recent speech, Commerce Secretary Gary Locke announced a three-point plan to implement President Obama’s goal of doubling the nation’s exports over five years to \$3 trillion a year. According to Secretary Locke, the new National Export Initiative “will have a government-wide export-promotion strategy with focused attention from the president and his cabinet” and

¹³ A Strategy for American Innovation: Driving Towards Sustainable Growth and Quality Jobs, Executive Office of the President, Office of Science and Technology Policy, September 2009.

¹⁴ Id. at 2.

include rigorous enforcement on international trade laws to help remove barriers that hinder access to foreign markets.¹⁵

These concerns have been underscored in high profile studies and have received strong bi-partisan Congressional support. However, it will be critical for the U.S. Government to take action, and PhRMA members believe that the Special 301 review process can be a particularly useful trade tool which can be utilized to address the use of market access barriers in priority markets.

Market Access Barriers Abroad Threaten American Jobs and Vitality

The effects of market access barriers abroad undoubtedly threaten the U.S. economy in the form of reduced exports, less employment and direct harm to the American biopharmaceutical industry. The biopharmaceutical industry is a cornerstone of America's high-tech economy and depends on continued innovation and market access for growth. Market access barriers abroad provide a disincentive for stakeholders to put resources into biopharmaceutical companies and the innovation they foster.

The biopharmaceutical industry is a foundational piece of the American economy. According to the most recent data available, the industry:

- Had a total sector output of \$626.6 billion (direct, indirect, and induced) in 2008.
- Employed more than 685,000 people, with each job supporting an additional 3.7 jobs for a total of 3.2 million supported jobs in the sector (direct, indirect, and induced)¹⁶
- Contributed \$88.5 billion to the nations gross domestic product, which was triple the average contribution of other sectors

The biopharmaceutical industry is characterized by substantial and growing investment in R&D infrastructure, which has given the U.S. a competitive advantage in innovation. In fact, according to a 2006 Congressional Budget Office report, the U.S. biopharmaceutical industry continues to lead the nation in research and development and, as the most research-intensive industry in the U.S., invests five times more in research and development relative to their sales than other industries. In 2008 alone, the biopharmaceutical industry spent \$65.2 billion in discovering and developing new medicines.¹⁷ In fact, nearly one in five dollars in U.S. sales goes toward R&D.¹⁸ The vast majority of their R&D investment —\$50.3 billion —was invested by PhRMA's member companies – an increase of over \$2 billion from 2007. Of that amount, roughly 70%, or \$38 billion, was invested in the U.S.¹⁹

¹⁵Commerce Sec'y Announces Details of Obama's Export Initiative. <http://press.org/wire/article.cfm?id=1870>

¹⁶ Adapted from L.R. Burns, The Biopharmaceuticals Sector Impact on the U.S. Economy: Analysis at the National, State, and Local Levels (Washington DC, Archstone Consulting LLC, March 2009).

¹⁷ PhRMA 2009 Industry Profile

¹⁸ Id

¹⁹ Pharmaceutical Researchers and Manufacturers of America (PhRMA) PHARMACEUTICAL INDUSTRY PROFILE 2009. www.phrma.org

Moreover, the U.S. biopharmaceutical industry is the global leader in developing innovative medicines which benefit patients around the world. It consistently has had more compounds in development than the rest of the world combined. Right now, there are 2,900 medicines in development for all diseases.²⁰ Among these are:

- 300 potential medicines for rare diseases such as chronic sarcoidosis, an immune system disorder; Lennox-Gastaut syndrome, a severe form of epilepsy; and cystic fibrosis²¹
- 800 possible treatments for cancers, particularly lung cancer and breast cancer²²
- 300 new approaches for heart disease and stroke²³
- 97 new treatments to fight and prevent HIV/AIDS²⁴

Although the economic downturn has and will continue to affect American companies across sectors, the biopharmaceutical sector remains a source of high-quality jobs that boost employment and the tax base. It also achieves an unusually high rate of annual growth in output and net impact on the economy. This includes ripple effects that indirectly create jobs and businesses through supplying services to the industry and its employees.

Market Access Barriers Abroad Undermine Sustainable Innovation

The risks inherent in biopharmaceutical innovation are staggering and access barriers abroad exacerbate these risks. For every 5,000 to 10,000 compounds screened, only 250 enter preclinical testing, five enter human clinical trials, and one is approved by the Food and Drug Administration. Only two in ten drugs brings in enough revenue to recoup their research and development costs.

A Report by the U.S. Department of Commerce²⁵ provides evidence that access barriers abroad suppress revenues, in turn reducing worldwide private R&D investment by 11 to 16 percent (i.e., \$5-8 billion) annually. This reduction in global R&D means that up to four fewer new drugs are launched each year, reducing worldwide patient access to innovative medicines.

Despite the risks of R&D, the pharmaceutical industry has made tremendous strides in research and development to date, enhancing the quality and quantity of life, elongating productivity of workers, and reducing the need for other health services. Some key examples are as follows:

- Cancer. Since 1980 life expectancy for cancer patients has increased about 3 years, and 83% of those gains are attributable to new treatments, including medicines. Another study found that medicines have accounted for 50-60% of increases in survival rates since 1975.

²⁰ Adis R&D Insight Database (accessed December 2009).

²¹ <http://www.phrma.org/files/attachments/Orphan%202007.pdf>

²² http://www.phrma.org/files/attachments/meds_in_dev/09-046PhRMACancer09_0331.pdf

²³ <http://www.phrma.org/files/attachments/Heart%202009.pdf>

²⁴ <http://www.phrma.org/files/attachments/09-229PhRMAAIDS1209.pdf>

²⁵ U.S. Department of Commerce, "Price Controls in OECD Countries," (2004)

- Cardiovascular Disease. Death rates for cardiovascular disease fell a dramatic 26.4% between 1999 and 2005 according to a recent report by the American Heart Association. According to the lead researcher, Dr. Donald Lloyd-Jones, there would have been an additional 190,000 deaths in 2006 if death rates had remained at 1999 levels.
- HIV/AIDS. Since the approval of highly active anti-retroviral treatments in 1995 the annual number of AIDS deaths has dropped by over 70%. Today, patients have a range of treatment options, including different combinations of drugs that often keep them symptom-free for years. Hospitalizations have also decreased between 1996 and 2000 with increasing use of antiretroviral medicines, despite increases in the number of people infected with HIV/AIDS.
- Alzheimer's Disease. Patients taking cholinesterase inhibitors were 2.5 times more likely to progress slowly after two years compared to untreated patients and after five years they were only 1/5 as likely to be placed in a nursing home.

Today's scientific opportunities offer enormous potential for patients and society. Scientists are delving deeper into the molecular basis of disease than ever before. They are gaining a better understanding of genomics (the study of collections of genes and their role in the body and disease), proteomics (the study of the structure and function of proteins), and biomarkers (molecular, biological or physical characteristics that can help identify risk for disease, make a diagnosis, or guide treatment). One particularly promising trend that is coming out of researchers' increasing knowledge of these molecular underpinnings of disease is personalized medicine.

While considerable progress has been made toward diminishing the impact that diseases cause today, the pharmaceutical industry is on the cusp of breakthrough discoveries that will revolutionize the way these diseases are treated tomorrow. However, access barriers abroad restrict the ability of American pharmaceutical companies to recoup past research and development costs to reinvest in future research and development, thereby harming sustainable innovation that will bring us these medicines of tomorrow at a highly critical point in the history of research and development.

Market Access Barriers Abroad are Barriers to Trade

Government policies that impose market access barriers deny U.S. biopharmaceutical companies the ability to market or sell their products in many countries. These control mechanisms usually delay, deny, or inhibit the availability of new products to patients, often in favor of generic drugs produced domestically. Given that national health insurance schemes typically dominate country markets for pharmaceuticals, a product effectively cannot be marketed in a country until the national authorities have determined its reimbursement price, a process which can be cleverly used to delay a drug's market entrance for years. Moreover, because governments know that developers of new drugs face a ticking patent clock, they routinely confront them with the Hobson's choice of either accepting a lower price or a delay in launch.

The pricing and reimbursement entities in most countries tend to be highly opaque bureaucracies and the process of obtaining a government-approved price can be lengthy. Sometimes these delays become so lengthy that they become effective denials of market access. Governments often delay adding new products to national reimbursement lists merely to avoid the cost of providing those treatment options to patients or to benefit domestic generic drug makers. It is not uncommon for some foreign governments to make a policy decision to entirely close reimbursement lists to innovative pharmaceuticals. These processes all operate to delay market access (and to diminish the effective patent term) for many U.S. medicines.

Market Access Barriers Abroad Discriminate Against Imports and/or Foreign Innovative Producers

Foreign governments often use market access barriers for pharmaceuticals to favor domestic producers, which tend to be manufacturers of non-innovative pharmaceuticals (i.e., generic drugs) and other local players in the health care system. Countries without a domestic innovative industry tend to rely heavily on market access barriers on patented pharmaceuticals to balance their health care budgets. Local interests -- such as generic producers, wholesalers and pharmacists -- generally occupy a politically-favored position within these systems and have significant sway in the policy decisions of the domestic health system.

Policies creating market access barriers also typically result in market distortion that makes the cost of generic pharmaceuticals -- often produced primarily by domestic companies -- quite high. Many foreign generics markets are characterized by a lack of true market competition, which tends to raise prices above what they would be in a free market. In addition, many foreign systems actually mandate high prices for generics products, requiring them to be reimbursed at rates as high as 70% or even 90% of the price of original branded products. In the United States, where there is intensive price competition in the generics market, prices of generic pharmaceuticals tend to be much lower. In a letter to Congress that accompanied the Commerce Study, the Secretaries of Commerce and Health and Human Services asserted that “[i]n fact, U.S. consumers would pay, on average, 50 percent more for their generic medications if they bought them abroad.”

The country chapters of PhRMA’s 2010 submission provide numerous examples of the government pricing and reimbursement policies and practices that create market access barriers.

Lack of Transparency and Procedural Fairness Present Significant Hurdles to Access

Recent experience has revealed significant issues relating to the procedural fairness and transparency of systems governing pricing and reimbursement of pharmaceuticals in many countries. These deficiencies can undermine the factual basis

for decisions by excluding key stakeholders from effective participation in the decision-making process.

Most countries afford manufacturers or sellers some right of participation when making pricing or reimbursement decisions, but there are great differences in openness and accessibility. In many countries, such as China, Brazil, and India, governments obtain information from manufacturers or sellers that forms part of the basis for their decision-making, but the decision-making process itself is largely conducted in a non-transparent manner. Compounding the lack of transparency, manufacturers and other stakeholders often face substantial obstacles to challenging adverse decisions, in large part due to the lack of reasoned explanations for final determinations and the unwillingness of courts to scrutinize closely administrative decisions.

Another key concern relates to the frequent failure to provide rights of participation to all key stakeholders. When decisions are made about access to medicines under healthcare programs (i.e., whether products will be reimbursed and at what level), patients and healthcare providers will often have information that is essential to a fair decision. Yet many governments (including those in highly developed countries such as Australia, France, and Italy) afford patients little or no opportunity to participate in reimbursement decisions.

The need for effective rights of participation and transparency has been recognized in international agreements. For example, Article III.9 of GATT acknowledges that “internal maximum price control measures . . . can have effects prejudicial to the interests of contracting parties supplying imported products.” For that reason, Article III.9 provides that “contracting parties applying such measures shall take account of the interests of exporting contracting parties with a view to avoiding to fullest practicable extent such prejudicial effects.” Such a requirement underscores the essential nature of providing importers adequate rights of participation and taking into account those interests when a government is administering a price control system and any related measures.

In this vein, the recently concluded U.S.-Korea Free Trade Agreement builds on the transparency and due process provisions included in prior FTAs, including those addressing pharmaceutical pricing and reimbursement systems in the U.S.-Australia FTA. Under the terms of the FTA, Korea must revise its system to provide, among other things, greater rights of participation to stakeholders, issue full explanations for administrative decisions, and establish an independent review mechanism. These FTA provisions set an important precedent for mechanisms that should be adopted in other countries that place pricing and reimbursement constrictions on pharmaceuticals.

While the EU has adopted a Transparency Directive (Council Directive 89/105/EEC) designed to ensure the transparency and procedural fairness of member state pharmaceutical price and reimbursement regulations, the Directive has not lived up to its important objective. Many member states do not fully comply with the Directive, and manufacturers and sellers often find that key stages of the decision-

making process are not transparent. The Directive also does not go far enough in addressing the core problems, such as lack of a meaningful and independent review mechanism.

As detailed further in the country chapters that follow, transparency and procedural fairness concerns course throughout a broad range of countries administering pharmaceutical price and reimbursement controls. U.S. government advocacy in this area would, therefore, address needed ground for significant improvements. Basic elements of any system for participation -- lacking in many countries -- include:

- An opportunity to take part in key stages of the process, including, where relevant, shaping the questions to be answered and appearing before expert bodies before decisions are made.
- Full explanations of public decisions affecting access to medicines.
- Access to the underlying record on which decisions are made.
- An opportunity for review within the administrative system by an independent expert body with the power to revise or nullify unsound decisions. This is fundamental, because courts in most countries are reluctant to second-guess decisions based on scientific and technical data. In the absence of an independent expert appeal process, decisions are largely insulated from external review.
- Effective judicial review, especially to ensure that administrative appeals are conducted fairly and stakeholders are provided a right to effective participation.

Special 301 Covers Market Access Barriers

The Special 301 statute calls upon the 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 the patent holder the exclusive right to sell his invention in a market, but that right can be undermined by government policies which reduce the price down toward the marginal cost of production.

In these circumstances, the Special 301 statute calls upon USTR to designate a trading partner as a priority foreign country *even if* there were no apparent clear-cut violations of the country's TRIPS Agreement obligations in the operation or enforcement of its intellectual property rights laws. Section 182(b)(4) of the Trade Act of 1974, as amended, requires USTR, in making a PFC designation, to take into account whether a country is providing "adequate and effective protection . . . of intellectual property rights." A country that maintains IPR laws on the books but eviscerates the value of patented inventions through other regulations cannot be said to provide "adequate and effective protection." This is further reinforced in 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”

The Special 301 statute is designed to identify and address intellectual property rights practices and enforcement measures that injure American companies and workers, including those that impede market access for IP-intensive products. The very concept of intellectual property rights breaks down if a patent holder loses the ability to sell his or her product at a market-determined price. Instead, the patent holder must sell the patented product at a government-prescribed price or under government-prescribed conditions which impact price, which government purchasers have an incentive to drive down toward a product’s marginal cost of production – which, in effect, ignores the value of innovation inherent in new products. These systems take value away from the patent and are the equivalent of expropriating intellectual property.

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 and 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.

For more than two decades, the United States has routinely treated weak foreign intellectual property laws as a major trade issue. It is commonly accepted that widespread piracy and counterfeiting of products like sound or movie recordings, software or pharmaceuticals undermines the longevity and economic strength of those American industries. Foreign laws that diminish U.S. intellectual property value through other means -- *i.e.*, price and volume controls or policies that force manufacturers to forgo fair profits -- equally diminish the value of U.S. intellectual property rights and hurt U.S. exporters that rely on intellectual property protection.

Concerns outlined in this submission underscore the dangerous and detrimental nature of market access barriers abroad. PhRMA welcomes the Administration’s view of these inherent dangers and looks to the Administration and USTR specifically to take action by continuing to develop its strategy to address such practices. Such a move would be consistent with congressional directives found in the Medicare Modernization Act and the Trade Promotion Authority Act of 2002.

The conference report accompanying the Medicare Modernization Act of 2003 recognized the negative impact of market access barriers abroad and directed that “[t]he United States Trade Representative, the Secretary of Commerce, and the Secretary of Health and Human Services...shall develop a strategy to address such issues in appropriate negotiations.” Congress provided a similar policy direction in the Trade Promotion Authority Act of 2002 by directing USTR to seek “the elimination of government measures such as price controls and reference pricing which deny full market access for United States products.”

In light of these directives, PhRMA continues to call on the Administration to use the Special 301 process to advance a multi-front strategy. First, as recognized in USTR's 2009 Special 301 Report, bilateral consultations should be pursued to promote sustainable innovation by addressing market access barriers abroad. The 2009 Report stated that:

The United States also is seeking to establish or continue dialogues with OECD and other countries to address concerns and encourage a common understanding between developed countries on questions related to innovation in the pharmaceutical sector. The United States already has had such dialogues with Japan, and is seeking to establish ones with other countries. It also has established a dialogue on pharmaceutical issues with China.

We would like to see the USTR, HHS, the Commerce Department and other agencies move rapidly to advance the bilateral dialogue with Poland, one of PhRMA's highest priority countries. As detailed in our submission, Poland's approach to limiting the reimbursement/access to innovative medicines represents a substantial impediment to innovation. This is further exacerbated by the general lack of transparency in Poland's reimbursement process. For these reasons, we have included Poland in the priority watch list category to underscore the importance of advancing the dialogue in the near term. In structuring these bilateral consultations, the U.S. Government dialogue with Japan on pharmaceuticals under the 1998 "Birmingham Agreement" provides an important example of how such talks might be structured.

We would also like to see bilateral consultations pursued in other OECD countries (such as Italy, and Canada) to address government-imposed market access barriers and other trade distorting measures. Similar to the situation in Poland, the market access barriers maintained in these developed countries undermine intellectual property rights, deny patients access to the most innovative medicines, drive US prices, and undermine sustainable innovation.

Second, we would like to see the Administration use ongoing and new bilateral and multilateral trade negotiations to pursue a positive agenda on pharmaceutical market access issues. For example, the outcome of the U.S. – Korea FTA negotiations benefited from a two-way discussion on Korea's complex and discriminatory listing system. The outcome was a negotiated text that included provisions on pharmaceuticals and specific steps to improve the transparency and accountability of the pricing and reimbursement listing process. The Korean Government agreed to an independent review of pricing and reimbursement decisions, which is intended to enhance the accountability of the process.

Third, we would like to see the Administration ensure that U.S. trading partners are abiding by national and international commitments in the area of pharmaceuticals. PhRMA commends USTR's work thus far to ensure that countries adhere to Article III of the GATT 1994, as well as the TRIPs and TBT agreements. In recent years, USTR invoked paragraph 9 of Article III in requesting in the context of the WTO Trade Policy

Review of the European Union that the EU identify the steps being taken at the supra-national and member-state levels to ensure their price control regimes “avoid to the fullest practicable extent effects prejudicial to the United States,” as required by Article III. PhRMA strongly encourages USTR to remain vigilant in pressing the EU and its member states to fully comply with WTO rules and the EU’s transparency directive, neither of which have been fully followed in key EU markets. Similarly, we would like to see countries in other regions that do not abide by their international obligations be held accountable.

V. Designations Countries and Issues

Priority Foreign Country or Section 306 Monitoring

PhRMA recommends that Thailand be designated Priority Foreign Countries under "Special 301" for 2010 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 19 countries should be included in the 2010 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
- Korea
- New Zealand
- Philippines

CANADA

- Canada

EUROPE

- The Czech Republic
- Israel

- Italy
- Poland
- Russia
- Turkey

LATIN AMERICA

- Argentina
- Brazil
- Chile
- Venezuela

MIDDLE EAST/ AFRICA/ SOUTH ASIA

- Algeria
- Lebanon
- Pakistan

Watch List Countries

The PhRMA submission identifies 19 countries which we believe should be included on the Special 301 Watch List in 2010. 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 that political barriers to legal reforms need to be addressed to provide rule-of-law protections such as data exclusivity. Successful implementation will require a commitment from the U.S. Government to promote successful implementation of the WTO TRIPS Agreement.

ASIA-PACIFIC

- Australia
- Malaysia
- Taiwan
- Vietnam

EUROPE

- Finland
- France
- Hungary
- The Netherlands
- Norway

LATIN AMERICA

- Colombia

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)
SPECIAL 301 SUBMISSION 2010

- Costa Rica
- The Dominican Republic
- El Salvador
- Honduras
- Mexico
- Nicaragua
- Panama
- Peru

MIDDLE EAST

- Saudi Arabia

Countries of Note Without Designations

- Germany

PRIORITY FOREIGN
COUNTRY

THAILAND

PhRMA and its member companies operating in Thailand are concerned that the research-based innovative biopharmaceutical industry has been prevented from meaningfully participating in Thailand's efforts to reform the health care system. In 2009, PhRMA welcomed Thailand's announcement that it intended to foster a better environment for intellectual property industries and increase dialogue between healthcare stakeholders and the Royal Thai Government. However, to date, there has been little action taken on these pledges. PhRMA hopes that, with the support of the U.S. Government, the necessary coordinated steps can be taken to turn these ambitious visions into a reality, and stands ready to work with the Royal Thai Government to ensure that progress is made.

Key Issues of Concern:

- Lack of Sufficient Stakeholder Engagement on Market Access Issues and Intellectual Property
- Intellectual Property Protection and Anti-Counterfeiting
- Patent Linkage and Data Protection
- Lack of Meaningful Participation in the National Health Assembly Process
- Discriminatory Government Procurement Policies

For these reasons, PhRMA requests that Thailand be designated as a **Priority Foreign Country** for the 2010 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 Market Access Issues and Intellectual Property

Despite calls for a consultative dialogue mechanism between Thailand's healthcare stakeholders and the Royal Thai Government by both industry and the Abhisit Administration, no steps have yet been taken to create an ongoing system wherein PhRMA member companies can meaningfully contribute and voice their policy concerns. 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 could have a major impact on their businesses and on the ability of Thai patients to receive life-saving pharmaceutical treatments. These include discussions on amending drug and patent legislation, establishment of government price controls, reforming national healthcare schemes, and initiatives that force cost containment on the research based pharmaceutical industry, but do not address the fundamental inefficiencies in the Thai healthcare system. PhRMA hopes that its members will have a chance to provide input into all these policy discussions and contribute to reforms that establish a sustainable healthcare system for Thailand.

Intellectual Property Protection

Intellectual Property Protection and Anti-Counterfeiting

PhRMA applauds Thailand's renewed commitment to combat counterfeits, generally through high profile enforcement actions, but urges that more be done to target counterfeit pharmaceuticals. In 2009, Thailand's enforcement actions have primarily focused on media and consumer apparel products. Thus far, pharmaceutical anti-counterfeiting efforts have not been raised to the degree needed to address the problem. Due to the serious safety concerns raised by counterfeit pharmaceuticals, a higher priority should be placed on curbing these practices. PhRMA supports the formation of 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 pharmaceuticals. As first steps, PhRMA recommends that the Thai legislature implement laws with stricter penalties for pharmaceutical counterfeiters. The Thai Food and Drug Administration (Thai FDA) and law enforcement leadership should provide adequate resources to train and equip Thai enforcement agencies to deal with counterfeiting. When offenders are convicted, the Thai judiciary should impose significant penalties, including prison terms, in order to create a practical deterrence.

Patent Linkage and Data Protection

The Thai FDA does not have a formal patent linkage system to prevent regulatory approval of generic versions of pharmaceuticals that are still covered by a valid patent. Pursuing patent infringers who would have otherwise been denied regulatory approval places a significant and unnecessary burden on PhRMA member companies as well as the Thai court system. PhRMA encourages Thailand to introduce an effective patent linkage system as soon as possible. In the interim, PhRMA would like to see the Thai FDA play a constructive role in averting litigation caused by premature generic approvals.

In 2007, implementing Ministerial regulations of the Trade Secrets Act of 2002 were issued by the Thai FDA. While the regulations provide trade secret protection that prohibits disclosure of confidential information, the regulations fail to prohibit the Thai FDA or generic drug applicants, for a fixed period of time, from relying on the originator's regulatory data to approve generic versions of the originator's product. That protection (referred to as Data Protection) should be established by Thailand to ensure unfair commercial use of innovators' data does not occur.

PhRMA encourages Thailand to (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 Thailand'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 data 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 Act Revision

PhRMA applauds the inclusion of our sister organization, PReMA, on the Patent Act revision committee, but is concerned that the nature of the amendments do not address systemic problems of the patent registration system, and may serve to erode patent rights and stifle innovation. Initial meetings on the Department of Intellectual Property's patent revision initiative have proposed the creation of a post-grant opposition mechanism (either with or without retaining the existing pre-grant opposition process).

PhRMA does agree that reforms are needed to improve the Thai patent registration system which has a backlog of patent applications in the thousands. Effective reform will start with ensuring there is an adequate number of patent examiners and that all patent examiners are sufficiently trained. When these resources are available there can then be additional reforms to create a predictable and efficient patent system that stimulates and rewards innovation.

Other proposed revisions to the Patent Act include expanding the grounds and simplifying the process of issuing compulsory licenses. PhRMA is concerned that such proposed patent reforms are inconsistent with the assurances from the Abhisit administration that compulsory licensing will only be used as a last resort. Other actions by the Thai government indicate that the use of compulsory licensing remains a cost containment tool to be used when negotiating with individual PhRMA member companies. In addition, the National Health Assembly working subcommittees listed as an objective their desire to use compulsory licensing against 10 medicines.

Market Access Barriers

National Health Assembly

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 an eye to passing the recommendations to policy-makers for action. The pharmaceutical industry has representation on only two of the five NHA subcommittees, despite the fact that the findings of all five subcommittees could have a major impact on the pharmaceutical sector and the supply of pharmaceutical products to Thai patients. Furthermore, objectives for each of the subcommittees (including those in which the pharmaceutical industry participates) were discussed and developed before the pharmaceutical industry had any input in the process. This has led to an agenda and process driven by only a select group of stakeholders. PhRMA has asked the Royal Thai Government to reexamine this process to ensure greater transparency so that the NHA has input and participation from all relevant stakeholders and provides equal treatment to all participants.

Regulatory Issues

Removal of Product Registration Requirement for Narcotic Drugs and Psychotropic Drug Category 2

The Narcotic Department under the Thailand FDA revised the term of reference (TOR) for purchasing requirements of narcotic and psychotropic drugs. The revision effectively removed the need for a formalized pre-registration requirement for narcotic drugs and psychotropic drug category 2 from April 2009. Prior to the revocation, a company was required to submit a registration dossier to Thai FDA who would review the technical, quality and safety information data submitted in the dossier and then grant marketing authorization. This registration process ensured that the drug (both innovator and generic) met quality, safety and efficacy requirements and were manufactured under GMP requirements. In addition, marketing authorization holders were required to have a safety monitoring program of the product.

The revised TOR has severely compromised the quality, safety and efficacy of this class of drugs to Thai patients. Under the revised requirement, pre-registration is not required. A company only needs to submit a Certificate of Free Sale, a Certificate of Analysis and Bioequivalent data. No authorized validation from a laboratory is required, nor is there any requirement to conduct studies on Thai population. The new procedure does not ensure quality, safety and efficacy, but is being used as a cost containment measure that effectively excludes PhRMA's member companies. PhRMA seeks the reinstatement of the previous pre-registration requirement for these classes of drugs, supplemented with a revised streamlined review process to ensure that quality, safe and efficacious drugs from both innovative and generics are being approved.

Discriminatory Government Procurement Policies

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 the demand for innovative pharmaceuticals. These procurement regulations should be repealed.

The Pharmaceutical Research and Manufacturers of Thailand (PReMA) estimates that GPO has a moving annual total growth of nearly 30% compared to the research based industry growth of approximately 3%. GPO has increased its market share from 9th to 8th place and in the third quarter of 2009 had a 60% growth in revenue.²⁶ Yet, the GPO, as a state enterprise, is exempt from prohibitions against anti-competitive practices.²⁷ 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.²⁸ This gives the GPO an unfair advantage over the research based pharmaceutical industry and protects it from having to compete on quality and value in the Thai market.

²⁶ IMS Thailand 3Q 2009

²⁷ 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;"

²⁸ 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.

The application for and grant of a license shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation

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,

(2) The production of drugs in accordance with the prescription of a practitioners in the vacationers medicine or practitioners in the art of healing for a particular patient or in accordance with the prescription of a veterinary for a particular animal,

(3) The sale of herbal drugs which are not dangerous drugs, the sale of common household dregs, 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,

(4) The personal bringing into the Kingdom of drugs required for personal use for thirty drugs,

(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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

SECTION 306 **MONITORING**

THE PEOPLE'S REPUBLIC OF CHINA

PhRMA and its member companies operating in 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 improving the effectiveness of China's efforts on data protection and counterfeiting, and should continue. Also, PhRMA has a number of market access concerns that negatively impact the environment for innovation in China.

Key Issues of Concern:

- **Regulatory Data Protection:** Weak regulatory standards allow companies to rely on previously published summaries of other companies' clinical trial data for marketing approval in China. Such summaries of regulatory data should not be sufficient for marketing approval, yet China allows reliance on such data, completely undermining the protection of regulatory data in China. This failure can create safety concerns as well as compromise incentives for new product development and introduction.
- **Patent Linkage:** A lack of patent linkage has led to costly patent litigation and to a lack of market predictability.
- **Counterfeiting:** While some positive steps have been taken to combat counterfeiting, it remains a major problem in China. Regulatory loopholes in China's regulation of active pharmaceutical ingredients enable the sourcing of unregulated products to downstream counterfeiters in and outside of China.
- **Market and Patient Access Issues:** PhRMA remains concerned about how existing or proposed market and patient access issues may impact patient access to innovative products, including: a lack of domestic healthcare funding, 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 2010 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 in an attempt to incorporate obligations under Article 39.3 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 39.3 provides that a WTO Member must protect data submitted in the context of a drug registration application from unfair commercial use. Inadequacies in China's current regulatory environment, however, allow for unfair commercial use of safety and efficacy data generated by PhRMA member companies.

The Implementation Regulation of the Drug Administration Law and the Drug Registration Regulation establish a six-year period of protection for test data of products containing a new chemical ingredient against unfair commercial use. The State Food and Drug Administration (SFDA) is the organization in China 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 undisclosed 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.

PhRMA applauds China's commitment at the 2009 meeting of the U.S.-China Joint Commission on Commerce and Trade to continue dialogue on this critical issue.

Patent Linkage

Patent linkage ensures that final marketing approval will not be granted to a generic drug applicant by the regulatory authority if a patent exists, until the patent has expired or is judged to be invalid or not infringed by a competent court or administrative body. 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 proceedings under which disputes over the patent status of a new product will be resolved.

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 essentially 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 resolve patent disputes prior to marketing approval.

To avoid costly patent litigation and to increase market predictability, China should allow patent holder companies to file patent infringement suits or otherwise resolve infringement disputes before marketing authorization is granted to non-patent holders and the infringing company has sales in the market. In addition, the SFDA should implement a form of automatic postponement of drug registration approval pending resolution of the patent dispute, or for a set period of time, similar to the U.S. practice of granting a 30 month stay of approval when the patent status of the compound is questioned.

Counterfeit Pharmaceuticals

Although the Chinese Government has undertaken a series of actions to combat drug counterfeiting, the prevalence of counterfeit drugs within and originating from China nevertheless remains a substantial concern.

Pharmaceutical counterfeiting is a global public health concern, but the solution requires implementation of adequate drug safety regulations at the national and local levels, as well as multilateral cooperation. The adequacy of China’s response to pharmaceutical counterfeiting must be measured against the framework and enforcement of laws that regulate the various links in the drug manufacturing and supply chain (including the export of Active Pharmaceutical Ingredients (APIs)) and China’s commitment to multilateral cooperation to address the problem.

In this regard, China has yet to enforce or put into place laws that address all aspects of drug counterfeiting activity or to provide the kind of resources and commitment necessary to combat this growing problem. For example, although China’s drug laws prohibit “fake” medicines, criminal liability is conditioned upon proof of actual harm. This burdensome and excessive evidentiary threshold all but precludes effective criminal prosecution against counterfeiters and is harmful to patients.

To help resolve these issues, China could enforce and/or amend its drug laws as necessary to prohibit and criminalize the manufacture, distribution, import or export of

any pharmaceutical that is deliberately and fraudulently mislabeled with respect to source or identity (consistent with the WHO definition of a counterfeit medicine), without the need to prove harmful effects or deficient quality. In addition, China could advance global cooperation on enforcement by identifying a single point of contact within SFDA to communicate with external parties about counterfeit medicines and creating an interagency pharmaceutical task force of law enforcers, regulatory authorities and customs agents to ensure adequate coordination among the various authorities with relevant oversight and enforcement responsibilities. Each of these officials must be given the investigative powers and mandate necessary to prosecute all links in the counterfeit drug chain, including manufacturers, wholesale and retail distributors, exporters of counterfeit medicines and related packaging and raw materials, as well as API producers who supply their products to drug counterfeiters.

Another potential concern is the use and regulation of APIs. Bulk chemicals and other APIs are generally deemed pharmaceuticals under the PRC Drug Administration Law and thus are subject to its provisions, but in practice, the issue of whether a specific API is to be regarded as a pharmaceutical is often left to the local regulator's discretion. According to the PRC Drug Administration Law, chemical companies are subject to government oversight by the State Food and Drug Administration (SFDA) only when a chemical company chooses to register a specific API product with SFDA. If a chemical company manufactures an API, but elects not to declare that the API will be used in a finished pharmaceutical good, under the current regulatory framework, the SFDA has stated that it lacks authority over the unregistered manufacturer.

The SFDA recognizes the importance of patient health and safety by regulating chemicals that will be used in finished pharmaceutical goods. However, under the current system described above, chemical manufacturers may sell and ship API products to locations within China and abroad with either no regard for the intended use of the API or flagrantly choosing not to comply with existing SFDA regulations. These unregulated and unethical practices by chemical companies contribute significantly to, and in some cases, aid and abet the counterfeit drug trade.²⁹ More troubling is the fact that the unregulated distribution of API may expose patients to serious and significant health risks and degrade consumer confidence in the global medicinal supply chain.

China has committed in bilateral dialogues to close this regulatory loophole, but its actions to date have been insufficient. PhRMA recommends that SFDA require chemical manufacturers that are advertising or selling API for a medicinal use to register with the SFDA and adhere to China's laws and regulations. These requirements should be enforced by SFDA. Additionally, the SFDA should require documentation to certify

²⁹ Under U.S. law, a supplier of active ingredient for a drug that will be marketed in violation of the Federal Food, Drug, and Cosmetic Act (FDCA) may, if the supplier is knowingly involved in the illegal activity, be charged with a conspiracy to commit that offense. 18 U.S.C. 371. In addition, a supplier who knowingly helps its customers in violating the counterfeit prohibition could be charged with aiding and abetting a violation of a U.S. federal statute. 18 U.S.C. 2.

that API intermediates or API are being exported only to pharmaceutical firms who have approved applications (or IND/CTA).

With regard to China's engagement in the international arena, China has noted the importance of fighting counterfeit medicines domestically, but has yet to display a commitment to preventing the export of counterfeit products to the global market. China should strengthen its efforts to control exports and increase its international and multilateral cooperation. PhRMA recommends that the U.S. Government encourage China to participate in the World Health Organization's IMPACT taskforce and increase cooperation with Interpol, the World Customs Organization, and other international bodies that are attempting to combat counterfeit medicines. PhRMA applauds recent progress made at the 2009 meeting of the U.S.-China Joint Commission on Commerce and Trade and strongly encourages follow-up and continuing such dialogues in an effort to resolve this critical concern.

Market and Patient 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 resistant 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 each separate profit margin 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. The NDRC maintains tiered pricing for patented, innovative and generic products. PhRMA encourages the Chinese Government to engage America's pharmaceutical companies to evaluate and implement an appropriate government pricing policy for innovative products.

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 the healthcare they so desperately need. The details of how this policy will be implemented are still under consideration by the Central Government and provincial governments, who will be undertaking the bidding process for products on the list. PhRMA wishes to ensure that the mechanism put in place by the Central and Provincial governments 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 pre-clinical and clinical requirements, and a requirement for full analytical testing of biological products, which is unique to China. 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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

PRIORITY WATCH LIST

ASIA-PACIFIC

INDIA

PhRMA and its member companies operating in India remain concerned about significant market access barriers and inadequate, and in some cases deteriorating, intellectual property protection in India.

Key Issues of Concern:

- Lack of regulatory data protection (RDP)
- Inadequate intellectual property protection in terms of narrow patentability standards
- Lack of patent linkage and growing backlog of patent applications at the Indian Patent Offices.
- Poor enforcement of patents by courts.

For these reasons, PhRMA requests that India be placed on the **Priority Watch List** for the 2010 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

TRIPS Article 39.3 requires India to provide protection for certain pharmaceutical test and other data, but India has yet to do 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 the Regulatory Authority. An applicant in India needs only to prove that the drug has been approved and marketed in another country accompanied by confirmatory test and other data from clinical studies on only 100 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. In effect, India relies on test data submitted by originators to another country. This indirect reliance results in unfair commercial use prohibited by TRIPS.

Linkage of Patent Status and Marketing Approval

India does not provide a procedure for linking the patent system with the system for granting marketing approval of generic medicines. Implementation of such linkage would avoid the waste and inefficiencies that accompany approval of products which infringe patents. In the absence of linkage, generic companies have been able to receive marketing approval for products that have been patented by others. This is a great disadvantage for research-based companies because the courts offer limited

protection to holders of patents and take many years to come to resolution. Patent enforcement mechanisms and remedies for patent infringement are extremely weak. Thus, patent holders are undermined in their efforts to seek a legal remedy in instances of (often blatant) patent infringement.

Backlog of Unexamined Patent Applications

There are presently around 200 Patent Examiners at the four Indian Patent Offices around the country with around 45,000 Applications to be examined. The delays and quality compromises likely to be associated with this situation are concerning. PhRMA urges continued, concerted efforts to increase the capacity of the Indian Patent Offices to quickly process this large work load.

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 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.

Patent Compulsory Licenses

India should also ensure that the compulsory licensing (CL) provisions contained in India's Patent Act comply with TRIPS by:

- Clarifying that importation satisfies the "working" requirement (TRIPS Article 27.1);
- Either eliminating mention of price as a trigger to CL or clarifying what is meant by 'reasonably affordable price' (Section 84(1)(a)(b) of the Patent Act provides for compulsory license if the patented invention is not available to the public at a "reasonably affordable price").

- Removing the numerous triggers in the Patent Act that provide a low hurdle to seeking a compulsory license.

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

Counterfeiting

India can be a 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. Given that India's trademark authorities lack any administrative enforcement powers, these deficiencies in civil and criminal enforcement are all the more significant. Moreover, border enforcement in India is hampered by the Government's failure to institute a trademark recordation system – a staple of effective border enforcement.

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 significantly reduce 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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

INDONESIA

PhRMA and its member companies operating in Indonesia remain concerned that they continue to face market access barriers stemming from regulations that are promulgated with little notice and no input from the research-based biopharmaceutical industry. This has been a problem at both the ministerial level (for example, the Ministerial Decree 1010 and the Halal Labeling Regulations) and at the parliamentary level (for example, the Health Bill).

Key Issues of Concern:

- Weak counterfeit enforcement
- Ministerial Decree 1010
- Halal labeling Regulations
- Health Law
- Non-Conformance to international best practices in the pharmaceutical registration process

For these reasons, PhRMA requests that Indonesia be placed on the **Priority Watch List** for the 2010 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

Intellectual Property Protection and Anti-Counterfeiting

Despite the establishment of a National Anti-counterfeiting Task Force and recent efforts by Indonesia to stop piracy activities in certain sectors (e.g., optical disks), counterfeit medicines continue to be a significant problem in Indonesia. While PhRMA welcomes Indonesia's recent attention to the problem of counterfeit medicines (e.g., hosting the recent conference on counterfeit medicines with ASEAN, China, WHO and Interpol), PhRMA believes there is an urgent need to expand national enforcement efforts for counterfeit pharmaceutical products.

Market Access Barriers

Ministerial Decree 1010

Ministry of Health Decree 1010/MENKES/PER/XI/2008 ("Decree 1010") was issued in November 2008 and will affect the ability of certain multinational research-based pharmaceutical companies to obtain marketing authorization for their products after November 3, 2010. Under Decree 1010, only companies registered as "licensing pharmaceutical industry" will be allowed to obtain marketing approval. Several of PhRMA's member companies do not manufacture products in Indonesia for the

Indonesian market, and would not qualify for this status. Instead, these companies have been classified as “distributor”, or “PBF”, enterprises; however, these firms practice globally recognized good manufacturing and good distribution practices, and provide high quality pharmaceuticals to Indonesian patients in the same manner as other high quality biopharmaceutical manufacturers that manufacture in Indonesia. Once Decree 1010 comes into effect in 2010, PBF enterprises will be barred from the Indonesian market unless they either establish a factory in Indonesia or transfer sensitive IP to a local Indonesian company. PhRMA is concerned about the discrimination inherent in this Decree and seeks to find a pragmatic solution that will permit innovative pharmaceuticals to be traded, sold and distributed in Indonesia, regardless of origin.

Halal Labeling Regulations

On August 31, 2009, the National Agency of Drug and Food Control (BPOM) issued new regulations which could impose excessive barriers against certain pharmaceutical products of several of PhRMA’s member companies. According to the “Regulation Of Head Of The National Agency Of Drug And Food Control Republic Of Indonesia Number HK.00.05.1.23.3516” (“Halal Labeling Regulations”), pharmaceutical, cosmetic, and food products that do not conform to stipulated Halal requirements must now attach a new label and will be prevented from receiving a distribution license, unless the Muslim clerical body Indonesian Ulama Council (MUI) declares that there is an “emergency reason” to allow distribution of the product. The criteria for what constitutes an “emergency reason” have not been issued and both the healthcare industries and the general public fear that patients could face interrupted supply or lose access to current treatments and vaccines once the regulations take effect.

Health Law

On September 14, Indonesia’s parliament passed the “Health Law”, a far-reaching piece of legislation that touches upon many aspects of healthcare, including pharmaceuticals. The Law, drafted with little real stakeholder input, could have a dramatic effect on PhRMA’s member companies’ abilities to provide pharmaceuticals to meet the needs of Indonesian patients. Depending upon how the implementing regulations are drafted, the Health Law could pave the way for (1) expanded use of compulsory licensing or government use for patented pharmaceutical products; (2) imposition of 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 hopes that it will be given the opportunity to actively engage in a discussion of the Law 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 by the regulators at BPOM. 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 regulators' early implementation of Decree 1010 or whether it is due to other reasons, such as insufficient personnel capacity. In addition to regulatory delays, PhRMA's member companies would like to see Indonesia take steps to bring BPOM in line with international best practices, namely in regards to data protection, patent linkage, and bioequivalence requirements.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

KOREA

PhRMA continues to strongly support the earliest possible passage of the Korea-U.S. Free Trade Agreement (KORUS FTA) and the full implementation of its provisions.

While the operating environment in Korea has presented numerous long-standing challenges for PhRMA's member companies, Korea is also one of the largest and fastest-growing pharmaceutical markets in the world. The KORUS FTA contains provisions that help to tear down market access barriers and shore up protection and enforcement of intellectual property rights in Korea.

Key Issues of Concern:

- Korea is in the process of adopting a patent linkage system as part of the Korean Food and Drug Administration's drug approval system, and an independent appeal review process of its drug pricing and reimbursement systems, in line with commitments made in the pending KORUS FTA. We support this process and the efforts of the Korean Government. Korea's actions prior to enactment of the KORUS FTA will send an important signal as to whether Korea will follow the intentions of the FTA by regulating pharmaceuticals in a transparent, predictable and non-discriminatory manner consistent with accepted international practice.
- Legislators in the National Assembly have openly called for new legislation to permit the Korean Government to issue more easily compulsory licenses on drugs when the action is deemed in the public interest. The Korean Government should strongly resist such unreasonably vague proposals.

Despite limited progress in addressing PhRMA's priority issues in the context of the KORUS FTA, we remain concerned with many elements of the system, as detailed below. Given these concerns, we recommend that Korea be placed on the 2010 Special 301 **Priority Watch List**.

Intellectual Property Protection

PhRMA urges Korean authorities to move to implement their FTA commitments, including the establishment of a patent linkage system and an independent appeals mechanism, in as early a timeframe as possible and in coordination with interested stakeholders. These steps are vital to ensuring that the new government pricing and reimbursement system operates fairly and effectively.

Full and timely implementation by Korea of all of its FTA commitments will be essential to realizing the benefits that are expected to come from the KORUS FTA and for Korea to ensure that its new reimbursement system is implemented in a fair and transparent manner.

PhRMA looks forward to working closely with the U.S. and Korean Governments in the coming months to ensure that the KORUS FTA is ratified as soon as possible, that new and lingering concerns are addressed, and that the FTA commitments are implemented fully.

Compulsory Licensing

PhRMA has noted with concern calls in the Korean National Assembly and from the non-governmental community urging revisions to Korean laws and regulations for the routine use of compulsory licenses.³⁰ To date, the Korean Government has not taken any steps to weaken its intellectual property laws or to implement compulsory licenses under its existing laws and regulations. PhRMA appreciates the actions to date of the Korean Government and will continue to monitor the situation.

Market Access Barriers

Long-Standing Issues in Korea

The operating environment in Korea has for many years presented numerous challenges for PhRMA's member companies. Given that Korea has a single payer system, access to the national healthcare system is critical to a meaningful right to participate in the Korean market. Innovative products, which are mainly imported into Korea by U.S. and other multinational producers, only gained access to Korea's national healthcare system in August 1999. Since then, U.S. and other multinationals have continued to face a range of market access impediments, including shifting standards of review for having new innovative products listed on the national reimbursement list and lax enforcement of intellectual property rights.

Korea's policies have also long favored its domestic industry, which has a large share of the market.³¹ Adding to existing market access issues, on May 3, 2006, the Korean Government proposed an entirely new pricing and reimbursement system for pharmaceuticals which has introduced additional challenges, particularly for producers of innovative products. The KORUS FTA takes several strides forward in addressing these issues and ensuring that U.S. pharmaceutical companies have fair and non-discriminatory access to the Korean market.

Continued Engagement on Issues of Concern is Necessary

Korea's efforts to reform its healthcare system are ongoing, and many specific elements of Korea's new pricing and reimbursement system, which was implemented on January 1, 2007, remain vague and, in some cases, appear to run contrary to the commitments Korea made in the KORUS FTA. At the writing of this submission, there are a number of issues that are of priority concern to PhRMA. These include:

³⁰ "Proposals to amend Patent Law", issued by National Assembly Member Cho, Seung Soo (Liberal New Party) and other 10 law makers" (proposal issued on Sept 17, 2009).

³¹ IHS Global Insight, South Korea Country Profile: Overview of Pharmaceutical Market, as of Nov 2009

- 1) Under the new government pricing and reimbursement system (the so-called Drug Expenditure Rationalization Plan or “DERP”), the lack of clear and verifiable criteria for decision making has posed a critical issue for innovative pharmaceuticals in the Korean market. The need for improved transparency, and support for enhanced recognition of innovation in government pricing and reimbursement decisions should be recognized, and appropriate corrective measures should be adopted as soon as possible in consultation with relevant stakeholders, including industry.
- 2) Korea announced the results of its pilot project on hyperlipidemia drugs in May 2008. Under the flawed analyses carried out by the Health Insurance Review Agency (HIRA), virtually all patented products were deemed not cost-effective and major price reductions were demanded. These results were not only out of sync with international norms, but were developed in a non-transparent process that failed to include key domestic and international stakeholders. Subsequently, however, the Ministry of Health, Welfare and Family and HIRA released detailed information as to how they arrived at their conclusions and have opened a dialogue with interested stakeholders to examine possible flaws in their analyses. It is imperative that Korea ensure that its analyses and conclusions are formulated in a rational, science-based manner and that the conclusions it reaches are not out of line with international norms. In addition, as Korea moves forward with the next group of drugs subject to re-evaluation, we urge Korean authorities to ensure that this process is fully-transparent and involves all stakeholders, including the innovative pharmaceutical industry.
- 3) Korea has introduced a pharmacoeconomic (PE) system under the DERP whose purpose is, among other things, to prove that a drug is cost-effective at a certain price. Despite Korea’s decision to adopt a PE system, innovative drug companies are virtually never granted the price at which their drugs are deemed by Korean authorities as cost-effective. Instead, there are so many price-cutting mechanisms built into the DERP that an innovative drug’s price can be reduced by the Government to less than 50 percent of the price at which it was initially determined to be cost effective within just a few years of introduction on the Korean market.³² Of key concern is the use of “Price-Volume Agreements” (PVAs). Under these agreements, if a drug is more popular than expected and its usage increases by a certain percentage as compared to forecasted sales, its price will be cut by the Government. In PhRMA’s view, this practice contradicts Korea’s FTA commitment to adequately reward innovation, and we believe that PVAs should be eliminated from the DERP system.
- 4) Under the DERP, Korea imposes an automatic 20 percent price reduction when generics are brought to market. This 20 percent price cut is imposed on the original pharmaceutical product, even when the product is still on-patent and the generic is infringing on that patent. It is essential that the current regulations be

³² PhRMA, “KOREA: Price-cutting Policies Under the DERP”, September 2008.

modified to ensure that the prices of on-patent products are not cut by the Government when an infringing generic product is brought to market.

- 5) The Korean Fair Trade Commission (KFTC) has been conducting an investigation of the conduct of both domestic and innovative pharmaceutical companies in the market since September 2006. We fully endorse the spirit of the KFTC's efforts to improve transparency and ethical business practices in the pharmaceutical market, and we hope that this will remain a priority under the new Administration in Korea. It is essential that the KFTC evaluate the conduct at issue in a fair and non-discriminatory manner, and that Korea applies globally-accepted legal standards to the pharmaceutical sector.

Given the unfortunate delay in ratification of the KORUS FTA, it is even more important that the U.S. Government work with the Korean Government to address concerns in these and other areas. Further, as Korea continues to implement elements of its new pharmaceutical pricing and reimbursement system, it will be critical that the U.S. Government works to ensure that these new policies are developed and implemented in a way that is fully consistent with FTA principles.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 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). PHARMAC is the primary purchaser of pharmaceuticals in New Zealand and continues to impose stringent cost containment strategies and operate in a non-transparent, unpredictable manner, creating an unfavorable environment for innovative medicines. The release of a draft Patent Bill, if passed as written, could impose an additional burden on PhRMA's member companies, as it fails to provide appropriate incentives for innovation and adequate protection for intellectual property. This could potentially reduce access by New Zealand patients 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 uses provisions. New Zealand is a potential future partner in a trade agreement and the research-based pharmaceutical industry would like to see these issues resolved expeditiously.

Key Issues of Concern:

- Patents Act Amendment
- Government Pricing and Reimbursement
- Biotechnology Taskforce Recommendations

For these reasons, PhRMA requests that New Zealand be placed on the **Priority Watch List** for the 2010 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 lack of timing of PHARMAC funding which is necessary for effective market access. Many countries, including the U.S., Australia, and the EU, have established mechanisms to restore patent terms for pharmaceutical products to recover time lost due to the regulatory 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.

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 about 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. One analysis³³ 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. Many of these 22 products have restricted reimbursement, such as reimbursement for limited indications.

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 do citizens in 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,

³³ 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?*

with the exception of healthcare. It is critical that these principles be applied to healthcare.

6. **Recognition of the Value of Innovation** - A national medicines policy should recognize the value of innovation and innovative pharmaceuticals through the adoption of procedures that appropriately value the objectively demonstrated therapeutic significance of pharmaceuticals.
7. **Responsive Budget Management** - The pharmaceutical budget should be determined by need and access benchmarks. Rather than conduct health technology assessments (HTAs) of products after the capped budget has been set, thus simply creating a priority list of new products competing for the limited funding available, HTAs should be used to establish budget estimates on an annual basis. The capped budget is a concern as there has been little to no growth (less than 3% annually over the 5 years up to 2009) and savings from year to year are not accrued into the following year's budget.³⁴
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 business and regulatory 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 the Government's relationship with the pharmaceutical industry and stimulate research investment:

- Introduce certainty and predictability into PHARMAC's funding by setting on-going 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

³⁴ Grocott R (2009) Applying Programme Budgeting Marginal Analysis in the health sector: 12 years of experience. *Expert Review, Pharmacoeconomics Outcomes Res.* 9(2), 181-187 (2009)

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 2009 attributable to trade barriers related to intellectual property protection and market access.

THE PHILIPPINES

PhRMA and its member companies operating in the Philippines are concerned about the deterioration of the intellectual property protection environment and the failure of the Philippine Government to address PhRMA's long-standing issues. PhRMA's members' most pressing concerns relate to the implementation of the Universally Accessible Cheaper and Quality Medicines Act of 2008 ("the Act"). PhRMA's concerns regarding the drafting of this Act and its implementing rules and regulations (IRRs) were not considered or addressed by the Government, and the IRRs contain several provisions that are inconsistent with the Philippines' obligations under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In particular, PhRMA's member companies continue to face numerous IP-related issues pertaining to patent linkage, parallel importation, data protection, and counterfeit drug enforcement. Many of PhRMA's concerns, in addition to the market access barriers detailed in other U.S. Government submissions, have been exacerbated by the inadequate system for stakeholder input in the policymaking process.

Key Issues of Concern:

- TRIPS-Related Concerns about the Universally Accessible Cheaper and Quality Medicines Act of 2008
- Parallel Importation
- Patent Linkage
- Counterfeit Drug Enforcement Activity
- Concerns Related to the Universally Accessible Cheaper and Quality Medicines Act of 2008's Maximum Drug Retail Price Mechanism (MDRP)

For these reasons, PhRMA requests that the Philippines be placed on the **Priority Watch List** for the 2010 Special 301 Report and that the U.S. Government continue to seek quick and effective resolution of the problems described herein.

Intellectual Property Protection

TRIPS-Related Concerns about the Universally Accessible Cheaper and Quality Medicines Act of 2008

Of significant concern to PhRMA member companies are IP-related provisions in the Universally Accessible Cheaper and Quality Medicines Act of 2008 that amend the Philippines Intellectual Property Code to severely limit the patentability of new forms and uses of medicines. This limitation on patentability only applies to new forms and uses related to medicines. It is thus inconsistent with TRIPS Article 27.1, which requires that patents be made available without discrimination with respect to the field of technology.

The Act creates a new ground for compulsory licensing under existing Philippine law: “Where the demand for patented drugs or medicines is not being met to an adequate extent and on reasonable terms, as determined by the Department of Health.” This new ground for compulsory licensing is applicable only to medicines and, therefore, is also inconsistent with the nondiscrimination requirements of Article 27.1 in TRIPS. In addition, if this new ground is utilized, the Act waives the requirement under the Intellectual Property Code (and the TRIPS Agreement) that a compulsory license can only be granted after the petitioner for the compulsory license has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions over a reasonable period of time.

Under Article 31 of TRIPS, a WTO member can only waive the requirement to make efforts to obtain authorization from the patent holder on reasonable commercial terms and conditions before issuing a compulsory license in three specific cases: 1) a national emergency or other circumstances of extreme urgency; 2) public non-commercial use; or 3) to remedy anti-competitive practices. Because the new basis for a compulsory license is not within the specific and limited exceptions provided under TRIPS Article 31, this amendment is inconsistent with TRIPS. In addition, provisions in the Act suggest that the safeguards related to compulsory licenses required by TRIPS Article 31 would not be preserved. TRIPS-required safeguards have been removed by: 1) deleting the provision in Section 74.2 of the current Intellectual Property Code which cross-references TRIPS Article 31 safeguards; and 2) enumerating only certain safeguards while specifically excluding other Article 31 safeguards.

Parallel Importation

Under the Act, all government agencies and third parties now can authorize parallel importation of patented drugs and medicines. This broad authority heightens serious concerns related to the lack of adequate infrastructure and monitoring mechanisms in the Philippines to ensure the safety of parallel imports and prevent the importation of counterfeits, as well as concerns over mishandling (which can lead to contamination of the drugs). PhRMA’s member companies have raised their concerns with the Government of the Philippines regarding the risk of an increased flow of counterfeit drugs into (and out of) the Philippines due to an inadequate monitoring process.

Patent Linkage

PhRMA urges the Government of the Philippines to return to a system of patent linkage that 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 been forced to pursue legal remedies that are both costly and lengthy in order to protect patented products from facing generic competition prior to the expiration of a patent term. The Government of the Philippines could remedy this situation, and thus free up legal resources for more pressing matters, by reinstalling a patent linkage system within

the agency of BFAD and thus ensure that marketing authorization is not granted for pharmaceutical products that are already under patent protection.

Counterfeit Drug Enforcement Activity

PhRMA and its member companies commend the Philippine Government on improvements in its anti-counterfeiting efforts. The Philippine Government has conducted a number of high-profile activities, including partnering with PhRMA member companies to raise awareness of the dangers associated with counterfeit drugs; increasing law enforcement raids of counterfeit drug sites; and successfully prosecuting a drug counterfeiter, resulting in a substantial prison sentence. While these efforts are extremely positive, it is critical for the Government to continue activities to eliminate counterfeit drugs. These positive efforts may be rendered ineffective unless the Philippine Government implements the necessary safeguards, monitoring and control mechanisms for parallel imports as discussed above.

Consistent with the concern over counterfeit drugs and the need to ensure patient health and safety, PhRMA member companies are also concerned about a provision in the Act that would allow non-prescription products to be sold in "small quantities, not in their original containers" in retail outlets. This provision, together with lax monitoring of parallel imports, can increase health safety risks through mislabeling and mishandling of medicines.

Market Access Barriers

Concerns Related to the Cheaper Medicines Act Maximum Drug Retail Price Mechanism (MDRP)

By September 15, 2009, all pharmaceutical retailers were required to implement a government-mandated 50% price cut on five pharmaceutical products that were recommended by the Department of Health (DOH). This was the result of Executive Order 821, issued under Republic Act No. 9502: Universally Accessible Cheaper and Quality Medicines Act of 2008 ("the Act"). Compliance by retailers has been generally good. On January 6, 2010, PhRMA members were asked to undertake a second round of voluntary price cuts targeting high-value innovative drugs with little or no generic competition. PhRMA and its member companies have and continue to fully support the objective of ensuring that Philippine patients have access to life-saving pharmaceutical products, but question whether the MDRP as currently designed is the most effective means for accomplishing this goal. Until a thorough investigation of the MDRP process is conducted and a full review of the factors that impede the most economically disadvantaged citizens from accessing medicines occurs, PhRMA requests that the MDRP mechanism not be utilized. In addition, PhRMA is concerned that the initial MDRP list was drafted without proper stakeholder input and urges the Government of the Philippines to develop a more transparent process for utilizing the MDRP mechanism in the future.

PhRMA believes that many salient barriers to access must also be explored outside the scope of pharmaceuticals to successfully expand access to healthcare for the entire Philippine population. PhRMA stands ready to work with the Government of the Philippines to address this complex challenge.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

CANADA

CANADA

PhRMA and its member companies operating in Canada remain concerned that Canada's intellectual property environment continues to be characterized by uncertainty and instability for innovators. Canada's intellectual property regime lags behind that of other G-7 nations in several significant respects, including the absence of a workable right of appeal under its linkage system and the fact that Canada is the only G-7 nation without any form of Patent Term Restoration (PTR).

Key Issues of Concern:

- Weak enforcement of patents
- Increased patent disclosure requirements
- Lack of patent term restoration
- Legal challenges to data protection

For these reasons, PhRMA requests that Canada remain on the **Priority Watch List** for the 2010 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

Enforcement (Linkage and Patent Infringement Actions)

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.

A number of issues have arisen over the years regarding the PM (NOC) Regulations. The Canadian Government took a modest step and remedied one issue with respect to its linkage regime in 2008. Amendments had been implemented in 2006 to implement a strict form of a relevance requirement, further defining the rules for eligibility of listing patents on the Patent Register. These 2006 amendments were intended to apply the "relevance requirement" prospectively, to newly listed patents. However, Canadian courts, in a decision of the Supreme Court of Canada in November 2006 (after the amendments) imposed a "relevance requirement" on patents listed under the pre-October 2006 amendments. This judicial interpretation³⁵ was destabilizing for innovators and negatively impacted their ability to adequately protect and enforce intellectual property rights. In June 2008, the Canadian Government implemented a regulatory change to effectively reverse the decision, and to restore the original intent of the October 2006 amendments.

³⁵ Ratiopharm v. Wyeth, 2007 FCA 264.

Despite this positive step, serious and systemic deficiencies remain with the *PM (NOC) Regulations*. There is ample evidence that they do not reliably provide “expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements,” as required under TRIPS and NAFTA. For example:

1. No Effective Right of Appeal

The patentee does not always have an effective right of appeal if it is not successful in the first instance under the summary proceeding (which differs from an infringement proceeding) under the *PM (NOC) Regulations*. This is because the generic product may be approved for marketing following a decision by the Court under the *PM (NOC) Regulations* in favor of the generic producer; once the NOC issues, an appeal filed by the patentee becomes moot.³⁶ The patentee is then left with no alternative but to start another proceeding (an action for patent infringement) once the generic enters the market. This essentially requires the patentee to restart a case it had already spent up to two years litigating. In contrast, a right of appeal is available to the generic if it is the patentee who initially prevails in a summary proceeding under the *PM (NOC) Regulations*. The deficiencies in the summary proceeding described above, particularly the absence of an effective right of appeal for the patentee, constitute a serious lack of due process as required under TRIPS Article 42 and NAFTA Article 1715.1(d). The disparity between the innovator and generic rights of appeal under the Canadian linkage system is highly inequitable. As this issue continues to create instability and unpredictability in the business environment, PhRMA member companies urge the U.S. Government to encourage Canadian authorities to address this fundamental imbalance through effective regulatory changes that will ensure there is an equal right of appeal.

2. Limitation on the Listing of Valid Patents

Patent owners are 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 U.S. 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.

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

³⁶ Eli Lilly Canada Inc. v. Novopharm Limited 2007 FCA 359.

the generic drug is stayed for a maximum period of up to 24 months pending judicial review.

In the U.S., such a challenge to an allegation of non-infringement or patent invalidity proceeds as a full action for infringement on the merits. Under the Canadian *PM (NOC) Regulations*, however, 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, can make it difficult for the patentee to prove its case.

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 motions rarely succeed in Canada even if there is compelling evidence of infringement.

Additionally, it takes 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.

Increased Patent Disclosure Requirements for Inventions

A line of decisions from the Federal Court of Canada over the last two years is re-defining Canadian patent law by raising the patent disclosure requirements for inventions in biopharmaceuticals. In a recent decision, the Federal Court invalidated a pharmaceutical patent by effectively requiring the patentee to have conducted conclusive human clinical trials before filing its patent application and to have disclosed such results in their patent application. Traditionally, a patentee has not been required to have conducted conclusive clinical trials nor has it been required to disclose such results in a patent application. The emerging testing and disclosure requirements in Canada represent a significant departure from United States’ interpretations of patent law and may be contrary to Canada’s international obligations. The requirements take Canada out of step with its international trading partners.

Canadian federal authorities should be encouraged by the United States Government to take immediate and effective measures to amend the current linkage regime to address the serious inequities and deficiencies set out above.

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. Many other countries, 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.

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 WTO Members would otherwise be bound in issuing compulsory licenses. Canada was one of the first countries to enact domestic legislation to permit its companies in Canada 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", given there is no compelling evidence that any further changes were needed. Despite complaints from some non-governmental organizations and the generic industry that Canada's system is unworkable, in September 2007 an authorization to export was issued under the legislation to a Canadian generic company within 60 days of the original request, demonstrating that the statutory mechanism is both efficient and functional. More recently, in September 2009 the same generic company was able to extend its original two-year license under CAMR for an additional two year period; the renewal issued within one week of the renewal application being filed with the Commissioner, demonstrating once again that CAMR is workable.

The Canadian Government continues to receive unwarranted and inaccurate criticism related to the operation of CAMR. In 2009, two bills were introduced in the House of Commons and in the Canadian Senate that would eliminate important intellectual property safeguards from the regime. The Senate Bill, S-232, is currently subject to a Committee review process, while the House Bill, C-393, will be examined by a Committee in 2010. It is concerning that the bills have received support from members of several Canadian federal political parties. The Canadian Government

should be encouraged to maintain its stated position that the existing legislative model does not require further disruptive and unnecessary changes.

Data Protection

For many years, PhRMA members expressed serious concern over the failure of Canadian regulatory authorities to provide effective data protection, to prevent unfair commercial use of regulatory data, as required by TRIPS Article 39.3 and NAFTA Article 1711(5) and (6). PhRMA member companies appreciated Canada's publication, on October 18, 2006, of regulations implementing eight years of data protection, thereby preventing unauthorized parties from gaining unfair commercial benefit during the period of exclusivity through reliance on the clinical dossier of others. This was an important step in improving Canada's intellectual property regime.

However, our members still have concerns about the potential loss of data protection under the new regulations if the innovator drug is not being marketed in Canada. Additionally, PhRMA notes that the new Canadian data protection regime is now subject to two legal challenges by the generic industry, which were heard together at the Federal Court in December 2008. On July 17, 2009, the Federal Court dismissed these challenges, but the generic industry has appealed the decision.³⁷ It is anticipated that the appeal decision will be rendered in 2010.

PhRMA member companies urge the U.S. Government to request that Canadian authorities continue to vigorously defend the 2006 amendments to the data protection regime.

Market Access Barriers

Patented Medicine Prices Review Board (PMPRB)

In Canada, 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 regardless of whether generic alternatives are available. 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,³⁸ 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 three years, the PMPRB has commenced numerous investigations and

³⁷ *Canadian Generic Pharmaceutical Association v. The Minister of Health et al. (A-360-09/T-1976-06) Apotex Inc. v. The Minister of Health et al. (A-352-09/T-2047-06)*

³⁸ Patent Act (R.S.C, 1985, c. P-4).

hearings, alleging excessive pricing by individual drug companies, including a number of U.S.-based companies.³⁹

The PMPRB issued new Guidelines in June 2009. 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.

The PMPRB had issued a Communiqué on August 18, 2008, requiring all patentees to report all benefits “connected” to sales transactions, including rebates/payments to third parties. This requirement was scheduled to take effect in January 2010. In September 2008, the Canadian innovative industry association, together with 17 member companies, filed a notice of application for judicial review with the Federal Court of Canada challenging the PMPRB’s jurisdiction to impose the requirement to report third party benefits, as set out in the Communiqué. On July 10, 2009, the Federal Court ruled in favor of the innovative industry association and its members,⁴⁰ finding that no third party benefits are reportable. However, it remains to be seen how PMPRB will implement the remainder of the reporting requirements of the Communiqué, creating significant uncertainty in the meantime for patentees. PhRMA member companies hope to continue working with the PMPRB to find mutually agreeable policy solutions to these challenges.

Common Drug Review (CDR)

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 was 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 and cooperation initiated with the pharmaceutical industry, the CDR has not been transparent in its operations and has rejected 44 percent of the products reviewed. Furthermore, given that the CDR can only provide listing recommendations rather than decisions, the F/P/T drug plans who manage the formularies can either discount or accept its advice without providing clear reasons to manufacturers either way.

In early 2007, the Standing Committee on Health (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 Committee’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 Committee’s recommendations, no progress has been made to date.

³⁹ PMPRB Annual Report of 2008, <http://www.pmprb-cepmb.gc.ca/English/View.asp?x=1211&mp=91>

⁴⁰ *Pfizer Canada Inc. v. Canada (AG)*, 2009 FC 719.

The Rx&D International Report on Access to Medicines – 2008 – 2009 examined public drug plans in 25 OECD countries and compared 82 new approved drugs common to all jurisdictions. It found that Canada ranked 20th out of the 25 countries and is comparable with Iceland, Slovakia and Turkey with the CDR recommending only 56% of drugs for public reimbursement, far less than the 73% average for the other countries.

PhRMA member companies request that the United States Government urge the Canadian Government to implement the Standing Committee on Health's recommendations.

Joint Oncology Drug Review

In order to provide a separate national review of oncology products, an interim process was set up by the provinces to observe the Ontario drug review process for one year and determine if the process should be adopted as a national review process. Initially, this was to be done over one year but timelines have slipped and the assessment of the process has yet to be finalized.

At the inception of this project, Ontario had one of the lowest listing rates for oncology drugs. During the first part of the process, only seven out of 19 drugs had been recommended to the provinces for listing. Provinces that have traditionally covered more drugs have continued to do so.

The uncertainty of what the final process will look like creates an unpredictable environment and falls short of meeting the goal of ensuring that all Canadians have access to the therapies they need.

PhRMA member companies therefore request that oncology drugs be assessed outside of the CDR and that a new approach be developed that is evidence-based and focused on achieving appropriate health outcomes for patients.

Subsequent Entry Biologics (SEBs)

On January 30, 2008, Health Canada issued a Draft Guidance Document, *Information and Submission Requirements for Subsequent Entry Biologics (SEBs)*, addressing issues that would arise in the context of considering SEB submissions for regulatory approval. One of the key issues not clearly addressed by the initial version of the Draft Guidance is the protection of intellectual property for innovative biologic products. While a further draft released on March 30, 2009, along with proposed changes to guidances relating to the *Patented Medicines (Notice of Compliance) Regulations (PM(NOC) Regulations)* and the *Food and Drug Regulations – Data Protection* contained significant improvements and clarifications, it remains unclear how these intellectual property protections will be provided to biologics approved in Canada. For example, the March 2009 draft 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 which may also practically erode intellectual property protection for innovative biologics.

In addition, the Guidance Document in question is an administrative document as opposed to a binding statutory or regulatory instrument. As such, PhRMA member companies are concerned that even if the eventual final version is satisfactory, there may be administrative exceptions made to its contents in practice, and therefore innovators may be confronted by significant uncertainty and litigation with respect to future Health Canada approvals of SEBs. 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, including a requirement that all SEB applications submitted in Canada be based upon comparison to a Canadian reference product. It is expected that Health Canada will issue a final version of the SEB guidance document in early 2010.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

Overview: The European Union

PhRMA member companies are facing a variety of government restrictions in the European Union (EU) that undermine the ability of PhRMA member companies to enjoy the full benefits of their patents and that predominantly affect innovative products relative to their generic counterparts.

First, government price controls 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. Economic progress is built on the good health of citizens, so it is very concerning that increased cuts to the prices of pharmaceuticals imposed by national governments are slowing the rate of delivery of new medicines to Europeans.

A second concern arises from a common situation, *e.g.*, when a generic product is launched and remains on the market until infringement is proved in patent litigation, unquantifiable harm may be caused to the patent owner which cannot be compensated through damage awards.⁴¹ Data show that interim injunctions to prevent accused products from remaining on the market until trial are granted in less than half the relevant cases.⁴² This failure to provide effective remedies fundamentally undermines the exclusive rights conferred by a patent.

A mechanism to resolve legitimate disputes before marketing approval would alleviate this problem. It would also help prevent wasteful litigation regarding the amount of damages and problems associated with removing an infringing generic product.

It is important to have dependable mechanisms for companies, both innovators and generics, to create legal certainty by resolving potential patent infringement issues before generic product launch.⁴³

Currently there are three mechanisms available to generic companies to “clear the path” of patents that may be obstacles to launch and marketing.⁴⁴

⁴¹ This is acknowledged in a number of English cases dealing with pre-trial interim injunctions *e.g.* Leo Pharma –v- Sandoz, [2008] EWHC 541 and Novartis –v- Dexcel -Pharma [2008] FSR 31 and is often a reason contributing to the decision to grant such an injunction by the English, but not all, EU courts.

⁴² Cite to para 641 Final Report

⁴³ EFPIA, SUBMISSION TO THE EUROPEAN COMMISSION IN RELATION TO THE PHARMACEUTICAL SECTOR INQUIRY. 13 June 2008
<http://www.efpia.org/content/default.asp?PageID=559&DocID=4892>

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. And, as noted above, it takes several years to bring such disputes to trial, and achieve resolution.

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 finance 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.

A mechanism which allows innovators as well as generics to obtain early resolution of patent disputes would be very helpful in Europe. It would give innovators security in knowing that their efforts in creating a new drug will be respected for the duration of the patent period.

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 “early resolution” mechanism to the European Commission and PhRMA supports this approach in Europe.

Third, 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 to avoid subjecting products not reimbursed by the Member State to price controls, as recommended by G10.

A fourth 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.

⁴⁴ 1. Opposition in the European Patent Office 2. Revocation/nullity action in individual Member States 3. Application for declaration of non-infringement in individual Member States This is similar to an application for declaratory judgment in the US

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 it's member concerns.

CZECH REPUBLIC

PhRMA and its member companies operating in the Czech Republic are concerned regarding the government system for determining pricing and reimbursement levels for pharmaceutical products. The current system constitutes a significant and discriminatory barrier to U.S. products. This and other market access barriers in the Czech system restrict access to advanced life-saving medical treatments for Czech patients.

Key Issues of Concern:

- The “therapeutic reference pricing” system is the main issue of concern for PhRMA member companies. The Government continues to link patented and non-patented products in its reimbursement mechanism.
- The Czech Government artificially suppresses demand for pharmaceuticals, specifically 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. This has had an adverse effect on PhRMA member companies.

For these reasons, PhRMA requests that the Czech Republic be placed on the **Priority Watch List** for the 2010 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

A range of market access barriers imposed by the Czech Government deny innovative, patent-protected pharmaceuticals full access to the Czech market. The barrier of greatest concern to the pharmaceutical industry is the Czech Government’s use of “therapeutic reference pricing,” which links reimbursement for patented and non-patented products. Other components of the Czech health care reimbursement system – such as positive lists, prescribing limitations, and individual physician prescribing budgets – also directly or indirectly limit access for innovative pharmaceuticals to the Czech market.

2008 Changes in Government Pricing and Reimbursement

In the 2008 version of paragraph 39 of Law 48, dealing with pricing and reimbursement, both processes are concentrated in one regulatory body – the State's Institute for Drugs' Control (SUKL). SUKL is responsible for all three steps required for drugs to reach the market, including the medical evaluation of their efficacy and safety, and setting of the prices and reimbursement rates.

Although the Law contains some strictly-defined and verifiable criteria for both government pricing and reimbursement decisions, it continues to restrict market access for pharmaceuticals. For example, with respect to government price setting, the Law establishes a strict comparison with the average of five traditionally low-price EU countries (Spain, Portugal, Greece, Italy and France). With respect to government reimbursement, the lowest price for the final customer of a specific product in any EU country is the basis for the reimbursement of the same product in the Czech Republic. Law 48 sets pricing and reimbursement levels across broadly-created reference groups and clusters.

Reimbursement Criteria

The Czech Government uses a therapeutic reference pricing (TRP) system 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 GATT as well as potential TBT concerns.

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. However, 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 not only the branded counterpart to the generic, but also 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 the generic competitors to imported patented 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.

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.⁴⁵ These limits severely suppress demand and restrict access to innovative medicines, lack any medical basis, and are applied in a discriminatory fashion. The Government typically removes all prescribing restrictions on a drug when the patent expires on an imported drug, and a generic product (almost always domestically produced) enters the market.⁴⁶

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, since imported innovative drugs are generally more expensive than domestically produced generics, they 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.

⁴⁵ Czech pharmaceutical law number 48 in effect as of January 1, 2008

⁴⁶ Ibid.

ISRAEL

The following chapter is an expression of PhRMA and its member's views on February 16, 2010. PhRMA and its member companies note that the level of pharmaceutical intellectual property 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 been systematically eroded. This deterioration has resulted, among other things, in the nullification of patent extension terms, slow and ineffective review of patent applications (which is subject to the abuse of pre-grant opposition procedures and delays in the publication of patent applications), and ineffective protection of innovators' clinical data.

PhRMA recognizes and supports the ongoing negotiations between the Office of the U.S. Trade Representative and the Government of Israel to resolve certain key outstanding IP concerns. PhRMA believes that these negotiations can lead to a long-standing improvement in the market access environment for innovative medicines in Israel.

Key Issues of Concern:

- Nullification of Patent Term Extensions (PTE).⁴⁷ The nullification has limited PTE 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.
- Pre-grant opposition to patent grants (Art. 30 of the Patent Act).
- Serious delays in the registration of innovative products in Israel.
- Israel's IP policies in the pharmaceutical field are explicitly aimed at providing local generic exporters with an unfair commercial advantage in major markets in the U.S. and in the EU.
- The Government's practices and inefficiencies with regard to the registration of innovative pharmaceutical products, which currently also result in a shortening of data protection periods, and which create a hostile and unstable environment for the commercial interests of U.S.-based companies.

For these reasons, PhRMA recommends that Israel be designated as a **Priority Watch List** country in the course of the 2010 Special 301 Review Process.

Intellectual Property Protection

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

⁴⁷ Amendment no. 7, to Article 64, December 19th 2005

unfair outcomes created by linking data protection and patent term extension terms to the terms provided by other governments; 2) The 2005 amendment to the Patents Act that considerably shortens the patent extension term and that would possibly nullify it completely; 3) Inadequate protection of regulatory registration data (data protection); 4) Substantial delays in the grant of patents (unnecessarily burdensome system of pre-grant patent opposition) and the publication of patent applications; and (5) Significant delays in the registration of new drugs in Israel which, among other things, shortens the effective period of data protection of these products.

Substandard Data Protection

Under the Israeli Patents Act and the Pharmacist Ordinance, patent extension and regulatory data protection periods are linked to the earliest date of product approval in any of the Recognized Countries.⁴⁸ As a result, the *de-facto* exclusivity periods of patent extensions and regulatory data protection in Israel are considerably shorter than is stated in their respective laws. This leads to situations whereby U.S. innovators are unable to obtain meaningful protection in Israel.

The Government of Israel often argues that the rationale for this mechanism is to encourage multinational companies to expedite local submission of their innovation. Yet the damaging combination of substandard data protection with the current inefficiencies of pharmaceutical registration in Israel (described below) compromises the interests of patients by slowing delivery of new products to Israel in a timely manner, as well as eliminating valuable data protection time needed by the innovator to receive a legitimate return on its investment.

Simultaneously, circumvention of the principle of national territoriality provides local generic companies with an unfair commercial advantage when exporting their generic products to the major markets in the U.S. and Europe. Israel therefore creates an unacceptable situation, in which the interests of US research-based companies are being jeopardized both in Israel and globally. While the data protection periods of U.S. innovators are being subject to intentional eroding policies by the Government of Israel, local Israeli innovators enjoy the full term of protection provided in the United States.

Patent Term Extension - Amendment no. 7, to Article 64 (entered into force – January 2006)

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 the "Recognized Countries."

48. The list of "Recognized Countries" includes: the United States, EU-15, Switzerland, Norway, Iceland, Japan and Australia.

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 U.S. 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 interest 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 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 (entered into force – April 2005)

As a member of the World Trade Organization, Israel was required to fully implement 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 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 Ministry of Health to rely on the innovator's data to register generic products during the exclusivity period. More importantly, the Ministry of Health 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 EU 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 stipulated by the Pharmacists Ordinance), whichever is shorter.⁴⁹ 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 Ministry of Health between 15 and 18 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 in the EU 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 suggest that it takes between 4 and 6 years on average until the examination of an application for a pharmaceutical or biotechnological patent is completed in Israel.⁵⁰ 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 was aggravated in September 2006 when the Government of Israel (via the Attorney General Office, Ministry of Justice) expressed its position that IP owners should be denied the right to use the principle of Unjust Enrichment in legal disputes that concern proprietary pharmaceutical products.

⁴⁹. Under the Pharmacist Ordinance, the list of Recognized Counties includes: the United States, EU-15, Switzerland, Norway, Iceland, Japan, Australia, Canada and New Zealand.

⁵⁰. <http://www.justice.gov.il/MOJHeb/RashamHaptentim/Ptentim/application+for+fast+examination.htm>

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 U.S. 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 U.S. 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.

Market Access Barriers

PhRMA member companies continue to face government market access barriers in Israel that delay the launch of new medicines.

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.
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 lasts.

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 U.S. or in the EU (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 15 to 18 months in 2009.

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, without any foreseeable improvement in the near future. Currently there are more than 200 - 230 medicines in Israel waiting for approval.

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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

ITALY

PhRMA and its member companies operating in Italy remain concerned about certain policies of the Italian Government and Regional Authorities which have had a detrimental effect on the innovative pharmaceutical industry in Italy and pharmaceutical research and innovation worldwide.

Key Issues of Concern:

- During 2001 through 2007, Italy has adopted various cost-containment measures through several laws which have severely hit the pharmaceutical sector. Chief of these measures is Law 222/2007, which provides that the Italian Drug Agency (AIFA) has to establish a fixed-sales budget for each company operating in Italy. Furthermore, the law requires companies, pharmacists, and wholesalers to refund 100 percent of the value of all additional sales made through the retail sector once public pharmaceutical retail expenditures exceed 14 percent of the National Healthcare Fund (NHF)
- In 2009, the NHF's budget ceiling was reduced by Law 77/2009 (to reflect the earthquake in the Abruzzo Region) and Law 102/2009 (which was used as a cost saving measure in response to the economic crisis). These two Laws effectively combined to reduce the public pharmaceutical ceiling from 14% to 13.3% in 2010, 2011 and 2012.
- Regional governments are introducing measures to limit, delay or deny access for innovative and patented drugs in the retail and the hospital markets by fragmenting the regulatory environment and the Italian market into 21 different systems.

For these reasons, PhRMA requests that Italy be placed on the **Priority Watch List** for the 2010 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

Company Budget Restrictions

Law 222/2007 empowered AIFA to establish individual company budgets in 2008 based on volumes and pricing data for mature and generic products for the previous 12 months. This unprecedented measure created noncompetitive market conditions that discriminate against innovative products. In late 2007, the Italian Anti-trust Authority (IAA), expressed strong reservations about the Law's effect on competition in the Italian market. Specifically, the IAA noted that basing a company's market share on the previous year's sales could potentially limit competition in the Italian market.

The recent cuts applied to the public pharmaceutical ceiling in 2009 will increase the risk that PhRMA members will be asked to pay a refund to the state budget.

Government Pricing and Restrictive Reimbursement Policies

Pursuant to Law 222/2007, the pharmaceutical sector must refund 100 percent of overspending in the retail pharmacy sector (representing about 83 percent of the overall public pharmaceutical expenditure) once public pharmaceutical retail expenditures exceed 14 percent of the National Healthcare Fund. For hospital sales, pharmaceutical companies are not asked to refund any overspending, but the cap is set to 2.4 percent of the NHF (excluding the drugs sold through third-party distribution). Excess expenditures in the hospital sector are the responsibility of the regions, which, as a result, are introducing a variety of schemes designed to find cost-savings, including by limiting patient access to innovative medicines.

In addition, in 2007, AIFA introduced a system for evaluating innovation, to be used in pricing and reimbursement decisions for new drugs. Under this system:

- To date, no new drugs have been classified as “innovative” by the AIFA; and
- Very few drugs have been classified as “potentially innovative.” This classification requires additional procedures for monitoring the usage of those drugs that discourage patients’ compliance and creates a bureaucratic burden for innovative pharmaceutical companies.

In addition, AIFA is increasingly using negotiating tools called “risk sharing” and “payment by results,” that limit the reimbursement of innovative drugs.

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

The Italian Government’s focus on controlling pharmaceutical expenditures is unique relative to other expenditures within Italy’s NHS. Pharmaceutical expenditures were capped at 14 percent (retail) (now 13.6% in 2009 and 13.3% in 2010-2012) and 2.4 percent (hospital) of the NHF, while no other category of healthcare expenditures faced similar budgetary restraints or limitations. As a result of this policy, in the last five years the public pharmaceutical expenditure grew only 5.7 percent, while, by contrast, the other health care costs registered an average growth of 41.2 percent.⁵¹

In addition, the two laws adopted in 2009 introduced further cost containment measures only for pharmaceuticals, but not for the other costs and expenses of the National Healthcare System.

⁵¹ Law Decree 78.2009 passed on June 26, 2009

Regulatory Approval, Market Access Delays and Limitations

As documented in the IMS 2008 study, “Patients W.A.I.T”, the average time of marketing delays for products with marketing approvals between 2003-2006 in Italy was 335 days, with the minimum being 48 days and the maximum delay being 817 days.⁵² While the creation of AIFA in 2004 reduced these delays, they remain far above the EU average.

Moreover, several regions have introduced regulations, quantitative objectives and budgets that limit the freedom of physicians to prescribe innovative pharmaceuticals, requiring them to almost exclusively prescribe generics in therapeutic classes that include patented drugs without considering patients’ needs. In addition, some regions require co-payment for each pack prescribed (if reimbursed) for branded drugs only, thereby penalizing patented drugs and branded off-patent drugs.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

⁵² Source: <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=3658>

POLAND

PhRMA and its member companies operating in Poland remain concerned that insufficient transparency continues to undermine the reimbursement process, while weak intellectual property protection and discriminatory policies continue to block access to the market.

Key Issues of Concern:

- The presence of “ghost” drugs on the Polish market.
- The failure to effectively implement 8/2/1 term of data protection.
- The significant backlog of drugs waiting for reimbursement decisions.
- Non-transparent government pricing policies.
- Restrictive rules governing interaction between pharmaceutical companies and physicians and pharmacists.
- Unwillingness of the Polish Ministry of Health to engage in meaningful dialogue with the innovative pharmaceutical industry.
- Policies that discriminate against foreign pharmaceutical investors.

For these reasons, PhRMA requests that Poland be placed on the **Priority Watch List** for the 2010 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 in order to benefit from a derogation period allowed for compliance with certain regulations. As confirmed in 2008 by individual court rulings, Polish law does not recognize “conditional” authorizations in this situation, which is inconsistent with EU rules and Polish pre-accession obligations. Unfortunately, additional conditional authorizations have been issued with retrospective grant dates preceding the date of EU accession and supposedly brought within the derogation by way of published amendments to the original list so that the list now covers over 1000 drugs. Poland should remove the wrongfully approved products from the Polish market.

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. Continued engagement on this issue by the U.S. Government and its EU counterparts is needed to ensure effective implementation.

Market Access Barriers

Significant Reimbursement Backlog for Innovative Medicines

Poland continues to pose the most difficult market access situation for innovative medicines of all 27 EU Member States. Following an almost ten-year period where no new innovative medicines were added to the reimbursement list, in the last two years a small number of new molecules were granted reimbursement status.⁵³ However, there are approximately 100 new molecules still waiting for inclusion on the reimbursement list. As of March 2009, 43 of the applications for reimbursement submitted between 1998-2009 by the companies that comprise the Local Area Working Group in Poland had still not received any official reply from the Ministry of Health.

In the most recent update to the reimbursement list (October 2009), only two innovative medicines were added: Dabigatran and Valganciclovirum.⁵⁴ By contrast, 110 new generics were added to the essential medicine and supplementary list and 123 new generics were added to the list of chronic diseases.⁵⁵ In addition, the MoH regularly reduces the price of the innovative medicines included in the reimbursement list. To date, MoH has failed to provide reasoned justifications for products that were denied reimbursement, disapprovals, an appeals process, or a clear timeline for reimbursement decision-making.

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

⁵³ “Analysis of Access to Modern Drug Therapies – Comparison Between EU countries,” Higher School of Business, National-Louis University

⁵⁴ Regulation of Ministry of Health on official list of wholesale and retail prices of drugs and medical devices - it still has draft status; draft dated 2.09.2009

⁵⁵ Ministry of Health Regulation on the list of essential and complementary medicines and the amount of payment for complementary medicines; Regulation on the list of diseases and the list of medicines and medical devices, which, due to these diseases are prescribed free of charge – flat partial or full payment – it still has draft status – draft dated 2.09.2009

Poland's obligations under the EU Transparency Directive, including the requirement that it issue individual decisions within 90 days.

The AOTM's role and procedures could be made clearer via updates to the Healthcare Law, the legislative implementation of which is currently being completed. The updates contain new mechanisms for creating guaranteed and nonguaranteed 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 proposed significantly increased prices 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.

An example of discriminatory government pricing activities which affect U.S. and other innovative pharmaceutical companies is the planned amendment to the Pricing Act of the Pharmaceutical Law, which would formally define selling price and fixed margins.⁵⁶ Industry analyses indicate that if such an amendment came into force as drafted, it could have a negative impact on the pharmaceutical industry by considerably restricting freedom of business operations for pharmaceutical manufacturers.⁵⁷

Poland continues to employ a therapeutic reference pricing (TRP) system for setting reimbursement rates where patented and non-patented products are grouped together based on therapeutic class and the reference price is set at the level of the cheapest generic product in the class. In many cases, the therapeutic classes are set by MoH contrary to WHO guidelines, which state that "therapeutic reference pricing and other pricing decisions on Anatomical Therapeutic Chemical (ATC)/Defined Daily Dose (DDD) classification are a misuse of the system."⁵⁸

⁵⁶ The Ministry of Health is currently preparing a Reimbursement Act, in which the inclusion of a regulation on fixed prices and margins is being considered (Source: Ministry of Health)

⁵⁷ Pharma expert and IMS Health, September 2009.

⁵⁸ Guidelines from the WHO's Center for Drug Statistics. Methodology Concerning ATC/DDD use for Pricing (2004)

The Polish Government has yet to repeal its 2006 discriminatory 13% price cut on imported medical products, raising concerns under various provisions of the GATT and the U.S. Poland Bilateral Investment Treaty. In 2007, the Polish Government extended the 13% price cut to imported components of locally-manufactured products as well, deepening the discriminatory effects of the price cut. In 2007 the EU Commission presented a reasoned opinion that this price cut creates impediments to market access and constitutes a measure having equivalent effect to a quantitative restriction (Complaint 2006/4725/PL).

Limitation in Access to Physicians and Pharmacists

Another regulation was adopted on December 1, 2008, which has had a 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 in practice, 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, in the absence of 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, claiming that time constraints make it impossible to meet. This means that our members' position and proposals on how to increase transparency and introduce workable solutions are never taken into account during the preparation of legislative and systemic changes 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 (or financial planning) 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, thereby violating legal standards of the legislative process in Poland.

Discrimination Against Foreign Companies

Discriminatory measures against foreign companies continue, including a striking example of non-inclusion of long lasting analogues of human insulin into the draft reimbursement list presented for public consultation in September 2009.⁵⁹ Despite the fact that these products met all regulatory requirements and received all the necessary recommendations from expert bodies, they were not included in the draft regulation by MoH – a decision which was neither explained nor justified. This unexplained failure to include human insulin analogues not only raises serious concerns under the Transparency Directive, but also distorts competition on the insulin market. The situation clearly protects the interests of Polish producers of human insulin against competition from international companies offering innovative long-lasting insulin to Polish patients – *therapy that is reimbursed in all of the EU countries except for Poland.*

The Government of Poland is also 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 2009 attributable to trade barriers related to intellectual property protection and market access.

⁵⁹ Draft Regulation of Ministry of Health on official list of wholesale and retail prices of drugs and medical devices (September 2, 2009)

RUSSIA

PhRMA and its member companies operating in Russia continue to be concerned about Russia's commitment to strong intellectual property, both in terms of its international obligations and its existing statutes. Ongoing problems with transparency and administrative burden also continue to affect PhRMA member companies operating in Russia. A new government pricing policy is expected to be particularly challenging in 2010.

Key Issues of Concern:

- Regulatory Data Protection
- State Support for Infringement of Patent-Protected Drugs
- Trademarks/Counterfeiting
- Government Pricing Regulation
- Other Market Access Issues

For these reasons, PhRMA requests that Russia be placed on the **Priority Watch List** for the 2010 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 (RDP)

Russia has not yet enacted Regulatory Data Protection (RDP) legislation, despite its international commitments to do so. The United States-Russia Bilateral IPR Agreement of November 19, 2006 obligated Russia to provide at least six years of RDP as part of its World Trade Organization accession. The Agreement stated that the Government of Russia commits to work with the Duma to enact legislation and implementing regulations providing that undisclosed information submitted to obtain marketing approval, *i.e.*, registration of pharmaceutical products, would be protected against unfair commercial use for a period of at least six years starting from the date of grant of marketing approval in the Russian Federation.

In July 2009, the Ministry of Health (MoH) placed on its official website a new draft bill "On turnover of medicines", envisaging cardinal changes in regulatory issues like registration processes, marketing authorization, clinical trials, etc. The new bill proposes to replace the current statute, FZ 86 "On Medicines." Article 29 of the bill would allow generics seeking marketing authorization for their copies to rely on published data or bioequivalence studies for approval. The publications relied upon contain summaries of underlying data that remain undisclosed. Reliance on such publications is therefore reliance on undisclosed data.

The latest version of the bill, approved by the Duma in its first reading on January 29, 2010, however, does not contain any provisions for RDP. The bill should be amended to prohibit registration, for six years from the marketing authorization of the originator, of any application that relies on innovator data (published or otherwise) or making reference to an original product through a bioequivalence study.

State Support for Domestic Production of Patent-Protected Drugs

The Russian President has presented a list of 15 essential drugs that the Russian Government wants to be produced domestically. Nine of these are patent-protected drugs, several of which are produced by PhRMA member companies. Domestic companies have submitted plans to start producing five of the drugs (of which four still have patent protection), and the plans for domestic production of these were presented to the Russian Minister of Industry and Trade. The originator companies whose products were involved were not consulted on the inclusion of their drugs on this list prior to release of the list. Domestic companies involved in the production of these drugs stand to gain significant subsidies from the state to develop these medicines domestically. State financial support for the infringement of patent-protected medicines constitutes an egregious failure to live up to commitments in the market access and intellectual property rights areas.

Trademarks / Counterfeiting

The Government of Russia provides weak enforcement against counterfeit medicine producers. There is no formal statistic or estimate of counterfeit products on the market; however, the vast majority of counterfeit products are produced by local manufacturers.

Russian law does not specifically criminalize pharmaceutical counterfeiting, and injunction measures are not applied. A definition of a “pharmaceutical counterfeit” was introduced in the Law on Medicines in August 2004; however, no related prosecution articles have been added in the criminal and civil legislation. There is no procedure for evidence gathering and acceptance by courts to facilitate court proceedings in counterfeit cases.

The main article of Russian legislation currently applicable in cases of pharmaceutical counterfeits is one that addresses trademark infringement. However, the Criminal Code applies only in cases of numerous violations or significant damages, and even in cases where the Criminal Code applies, the penalties are inadequate (\$5000 to \$8000 maximum). The penalty set in the Administrative Violations Code is even lower (\$1400 maximum).

The Russian parliament has been debating a potential increase in criminal and administrative liabilities for several years, but to date, no action has been taken. Penalties for trademarks infringements (Art. 180 of the RF Criminal Code) vary from a

fine in the amount of up to 200,000 RUR or participation in obligatory work programs. Some Duma Members are planning to introduce a bill to impose criminal liability for the production and sale of counterfeit pharmaceuticals.

Market Access Barriers

Proposed Clinical Trial Requirements

The Duma on January 29, 2010 passed the first reading of the draft Law on the Circulation of Medicines ("Draft Law"). The Draft Law currently could require an innovator company to re-conduct locally a full cycle of clinical studies, regardless of whether there are existing results from clinical trials that have already taken place elsewhere. This provision would not reflect the international trend towards regulatory harmonization and greater transparency. The Draft Law does not clarify the decision-making process and responsibilities for pre-registration clinical trials, and therefore the duration of clinical trials required in Russia for an applicant may last 3 to 10 years. During this period of delay, Russian patients will not have access to life-saving medicines that have already been proven safe and effective elsewhere.

Government Price Regulation

In August 2009, the Government issued Resolution #654 to regulate prices for essential medical products, and to create regulations governing maximum margins for all transactions throughout the supply chain. The corresponding draft governmental price control methodologies introduce separate regulations for producer price, wholesaler and pharmacy mark-ups. As the draft methodologies differ considerably from current world-wide practices, their implementation without substantial modifications could be counterproductive for development of Russia's pharmaceutical market.

Reimbursement Procedures

The Government of Russia instituted a federal drug reimbursement program in 2004, which went into operation in 2005. Regrettably, reimbursement decisions are not based on objective and verifiable criteria. Mechanisms for purchases of reimbursed drugs and tenders are not transparent. Foreign firms are often discriminated against in both the federal reimbursement system for pharmaceuticals (DLO) and other tender processes, and no appeal procedures for reimbursement decisions are provided.

The MoH issued a regulation in 2006⁶⁰ in an attempt to regulate the reimbursement process, but this regulation fails to provide clear and transparent criteria for determining which products are included in the reimbursement program, timelines for decision-making, or appeals processes. At present, the processes remain opaque for development of an Essential Drugs List. The recent revision of the Essential Drugs List

⁶⁰ Order of the Ministry of Health and Social Development # 93 as of February 15, 2006.

excludes almost all innovative INNs that are not manufactured in Russia. This decision discriminates against foreign firms and will limit patient access to modern treatments of important diseases.

Marketing Approval

The marketing approval process in Russia continues to be lengthy, unpredictable, and non-transparent. The approval process and corresponding fee collection are the responsibility of the Federal Government Establishment or FGU, a semi-state subsidiary structure (actually functioning on a commercial basis) of the Federal Health Service (Roszdravnadzor).

A recently-published draft law (posted on the MoH website in December 2009), entitled "On Medicines Circulation," introduces a new accelerated procedure for state registration of medical goods in no more than 60 days (see Article 27 "Accelerated Procedure for State Expert Appraisal of Medicinal goods"). This procedure would apply to generic products, but would not be applied to immunobiologicals (vaccines), insulins, and products which are registered for the first time in the Russian Federation. The last category generally encompasses imported innovative products. While efforts to decrease regulatory delays are laudable because they would improve access for Russian patients, the application of this new procedure is clearly discriminatory, as it favors some categories of medicine over others, and disproportionately affects foreign manufacturers of innovative medicines.

Import Procedures

On January 1, 2007, the Government of Russia replaced the prior system of import procedures, which required the mandatory certification of medicines imported into Russia, with a new system that mandates that manufacturers produce a Declaration of Conformity. A manufacturer's declaration is based on evidence from the applicant (manufacturer's certificate of conformance) as well as evidence obtained from a third party testing organization (visual and laboratory inspection of 10 to 20 samples from each product batch). This procedure is not consistent with international practice.

The new procedure also discriminates against importers by requiring them to provide a Declaration of Conformity for each batch of medicines, while Russian manufacturers are permitted to provide a declaration for a full series. The Government of Russia claimed that the new procedures were introduced to prevent counterfeit products from reaching the market, but the impact on companies has been to increase costs and time to market with little apparent impact on the counterfeiting problem. The Moscow-based Association of Innovative Pharmaceutical Manufacturers estimated in 2006 that the certification procedure cost the industry \$200 million. Based on the higher costs for individual testing, the total costs for the new system could likely be double that of its predecessor.

In addition, the Government of Russia collects an import license fee in the amount of 0.05% of the contract price. This fee constitutes a significant additional cost for importers. The process is also time-consuming; it takes at least 36 working days and requires approval of two governmental bodies: the Roszdravnadzor (Federal Service for Healthcare Surveillance) and the Ministry of Economic Development.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access. We do confirm, however, that due to tremendous unmet medical needs, consumer and patient demand is growing for innovative medicines and vaccines in Russia. The removal of artificial market access barriers and modernizing IPR will enable these medicines to reach the patients who need them, resulting in improved health and a more favorable environment for investment.

TURKEY

Over the last decade, Turkey has undertaken reforms to modernize its economy and expand its healthcare system in many positive ways for PhRMA member companies and Turkish patients. A general lack of transparency in decision-making, however, has contributed to unclear policies that undermine Turkey's investment climate and damage market access for PhRMA member companies. Key issues of concern relate to the government reimbursement and pricing policies, as well as the intellectual property framework.

Key Issues of Concern:

- Intellectual Property Protection
 - Patent Protection
 - Data Protection

- Market Access Barriers
 - GMP Inspection
 - Reimbursement
 - Reference Pricing

For these reasons, PhRMA requests that Turkey be placed on the **Priority Watch List** for the 2010 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 regulatory data protection (RDP) relating to pharmaceuticals have been officially recognized in Turkey since 1995 and 2005, respectively, but there remain significant areas needing regulatory and legislative improvement. Of particular concern, there have been attempts to amend the current patent law with provisions weakening the current level of protection. While the innovative pharmaceutical industry has viewed the draft patent law as an opportunity to upgrade the intellectual property policy environment as part of Turkey's drive to become more globally competitive, some parties have seen this process as an opportunity to reduce existing protections.

Patent Protection

- During the recent past, the local generics industry has undertaken extensive lobbying activities designed to introduce radical amendments to the current Patent Law. These amendments include provisions to weaken the current protection of original innovative pharmaceuticals. They also aim to discriminate against foreign innovators and include proposals such as:

- A proposal by a Parliamentary Member to nullify the validity of patents where the product is not manufactured locally.
- A proposal drafted by Turkish Patent Institute includes provisions for expanding compulsory licensing, weakening infringement penalties and loosening customs procedures.

PhRMA members urge the U.S. Government to monitor these initiatives and encourage the Government of Turkey to consider the adverse consequences of such policy directions.

Of additional concern, Turkey today does not offer an effective patent linkage system between patents and marketing approvals by the health regulatory authorities. In the past, generic copies have been registered in the country while the patents on the original product are still in force. This development is particularly alarming to PhRMA member companies. A functioning patent linkage system would help eliminate this problem because withholding final approval of generic registrations would provide a period sufficient to allow resolution of patent issues.

In addition, supplementary patent protection has not been recognized in Turkey to date. To be able to create an effective patent environment, it will be necessary to accept the ability to obtain up to five (5) years additional protection for patented products with the adoption of the Council Regulation No 1768/92 of 18 June 1992 concerning the Creation of a Supplementary Protection Certificate for Medicinal Products and EC Regulation No 1902/2006. Furthermore, there is 6 months additional protection for pediatric products in the EU. It would be also beneficial to recognize this pediatric supplementary protection with the adoption of Pediatric Use and Amending EC Regulation No 1768/92 in the Turkish legislation.

Data Protection

With respect to pharmaceuticals, particular problems persist in the interpretation and implementation of the regulatory data protection (RDP) regime. These concerns include the start date of the protection period; Turkey's refusal to confirm RDP protection for products with RDP in Europe; and the limitation of the RDP period to the period of patent protection.

In 2005, the Government of Turkey took positive steps toward establishing protection for the commercially valuable data generated by innovator companies and now provides for RDP for a minimum period of six years for products registered in the EU. The period of RDP currently begins on the first date of marketing authorization in any country of the European Customs Union (ECU). The Health Ministry has said that products first registered in any country of the ECU between 1 January 2001 and 31 December 2004 would benefit from the RDP regulation *if there were no generic or generic application of that product in Turkey prior to 31 December 2004.*

The EU Commission has inquired on multiple occasions how this regulation applies to up to 55 medicines registered in the EU and Turkey between 2001-2005, but to our knowledge, it has not received a clear and firm explanation from the Government. The lack of a clear response has been a major concern to the EU Commission, which has insisted that Turkey should provide RDP for all products registered in the EU after 2001, consistent with its European Customs Union and WTO/TRIPS obligations.

While even a minimum six-year period is a welcome step, the implementation in Turkey is problematic because the six-year protection period commences from the date when a product first gains registration in any country of the ECU. Inefficiencies of the regulatory system in Turkey also have the effect of significantly diminishing RDP in Turkey. Inefficient regulatory procedures that do not fully comply today with the EU Transparency Directive erode the period of protection for new medicines by delaying market access. Effective RDP is reduced to as little as two to three years in some cases, resulting in an environment where incentives for innovators to undertake risky and expensive research are undermined.

Application of RDP today in Turkey is clearly out of step with European standards and must be amended to commence upon registration in Turkey.

Furthermore, Turkey does not today provide RDP for combination products. However, Directive 2004/27/EC article 10 /bis recognizes RDP for combination products. The European Commission's NOTICE TO APPLICANTS, VOLUME 2A, Procedures for Marketing Authorisation, CHAPTER 1, MARKETING AUTHORISATION dated November 2005, section 5.5 gives guidance on the implementation of Article 10(b) in relation to combination products. Turkey's refusal to apply RDP to combination products is thus counter to established practice in Europe today. In addition, it is unclear how Turkey will harmonize its six-year RDP term to meet the requirements of the system established in the EU, which allows an effective data protection period of up to 11 years from the time of the first registration in the EU. Turkey has stated its aspiration to join the EU as a full member sometime after 2015. In this case, Turkey's trading partners, led by the EU but also with the engagement of U.S. trade negotiators, should inquire how Turkey plans to harmonize its current regime to allow protection of up to 11 years (8/2/1).

Finally, the current regulation inappropriately ties the term of RDP to patents relating to the product. For patented products, the protection period cannot extend beyond the period granted for patents in Turkey, an exception not consistent with RDP in the ECU today.

Market Access Barriers

GMP Inspections

In response to GMP certificates issued by the Turkish Ministry of Health (MoH) for pharmaceutical manufacturing sites in Turkey being regarded as invalid by EU

member states and by a number of other countries, the MoH introduced a requirement for inspection of manufacturing sites for imported medicinal products by the Turkish Ministry of Health. The MoH, however, has stopped issuing marketing authorization certificates for such products.

Notably, the problem with mutual inspections could be resolved through Turkey's participation in the Pharmaceutical Inspection Convention PIC, to which Turkey made an application for membership in 1989. The European Federation of Pharmaceutical Industries and Associations (EFPIA) was notified by its member companies and asked to support accelerating the Turkish Ministry of Health's participation in the PIC or suggest a solution to the mutual recognition scheme.

However, while the participation procedure in the PIC/S is expected to take 4 to 7 years, the marketing authorization granting procedure of imported products has been frozen for a number of reasons, including: GMP certificates currently not being accepted for outstanding applications, applicants being required to undergo manufacturing site inspections, and lack of an adequate number of personnel to perform such inspections. Because of this practice, there are existing marketed products, which are manufactured at the same manufacturing sites as products for which marketing authorization procedures have been halted

Recently, as a result of GMP certificates not being recognized, the application dossiers of some imported products were rejected, and then admission of applications started again on condition that manufacturing site inspections must be completed. However, the authorization procedure of products has been halted until completion of manufacturing site inspections. As a result of the sudden change in the requirements regarding the GMP certificate, the approval for new marketing authorizations will be significantly delayed. Furthermore, the supply of specific medicines could be interrupted because the flexibility to switch between production sites has been significantly reduced.

Moreover, MoH officials have informed the AIFD that the objectives of the Decree are to encourage local manufacturing and meet budgetary targets. Neither of these objectives, nor the imposition of a ban to achieve them, would likely pass muster under international rules, including the WTO Agreements on Technical Barriers to Trade and Trade-Related Investment Measures.

It is therefore strongly recommended that the Turkish Government sets a realistic time schedule for the implementation of the new GMP certificate requirement, and develops an interim procedure which will allow companies to obtain marketing authorization for new products as well as approval for production site changes for existing products, within a reasonable time frame.

Reimbursement

Turkey has established two committees at the Social Security Institute (SSI) to oversee transitions in the state reimbursement program. In an effort to improve efficiency, transparency, and standards for evaluation and stakeholder involvement, Turkey published the list of the Committee for Medical and Financial Evaluation & Payment Committee members, committee working principles and also submission requirements. Challenges remain, including compliance with the established meeting schedules; frequent delays are the norm. PhRMA member companies are also concerned that SSI fails to provide sufficient rationale for its decision-making. Furthermore, the Institute also fails to provide adequate information about the participants in the technical committees charged with evaluating new products, whom report to the Committee for Medical and Financial Evaluation.

In the absence of publicly available reliable and complete data, PhRMA member companies believe that the new requirements are likely to complicate reimbursement procedures and add to delays in patient access to new medicines. In an effort to determine a practical and balanced approach, innovative companies should be able to collaborate with the SSI to define realistic criteria for the reimbursement of new medicines.

Under the conditions of the global economic crisis, increasing health expenditures and budgetary discipline of Turkish Government, SSI recently imposed additional discounts for pharmaceuticals.. In December 2009, the Social Security Institute determined the following additional discounts for pharmaceuticals:

- Original products without generics will be purchased by the government with an additional 12% discount (on top of the existing 11% base discount for a 23% total).
- 20-year-old products having a retail price higher than 10 Turkish Lira and without generic competition will be purchased by the government with an additional 12% discount (on top of the existing 11% base discount for a 23% total) till they will be subject to reference pricing system in 01.01.2010 (see details in Reference Pricing section).

Reference Pricing

The Turkish Government applies a reference price system for pharmaceuticals. Under the pricing legislation that went into effect in 2004, February 14, the reference price of an original product is determined according to the lowest price among five countries from an established list of up to ten EU reference countries. The list may be subjected to alteration. The five reference countries are France, Spain, Italy, Portugal, and Greece. Countries where product is released and shipped also serve as references. According to the 2004 legislation, the original product sets the reference price while its

generic can take 80% of the reference price at most; 20 year old products are exempted from the reference price decreases.

On September 18, the Turkish Government published a new pricing decree (amended December 3rd), which outlines strict cost containment measures. The measures include changes in the reference pricing scheme for original products which have generic competition. Original products with generics will have a reference price of up to 66% of the lowest price among reference EU countries; the generic competitors will also receive the 66% reference price. 20 year old products (only above 10 TL) will be subjected to the reference price system after January 2010, but the rest of 20 year old products (below 10 TL) are still kept out reference price system. Correcting government pricing levels to match exchange rate changes has been made harder with the introduction of a currency band, which does not require the Government to update prices unless there has been a 10% fluctuation in the value of the Euro – and at least 90 days of a 5% fluctuation. Moreover, the new legislation for reimbursement brings additional discounts for public purchases as stated under *Reimbursement* section.

The newly-published decree amending pricing provisions will have a disproportionate impact on the innovative pharmaceutical industry (approximately 70% of savings according to the local innovative pharmaceutical association AIFD). These targeted savings can be achieved by alternative and more balanced policy solutions through a process that brings the industry and government together to solve the problem..

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

LATIN AMERICA

ARGENTINA

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 of the most important issues for PhRMA's member companies: protection for undisclosed test and other data required by the TRIPS Agreement, and "linkage" between patents and the system for approving pharmaceutical products.

Efforts to decrease the patent application backlog, which showed a significant improvement in 2005, 2006 and the first half of 2007, seem to have come to a halt. The number of incoming applications exceeds the number of processed applications. 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.

In addition, there has been a setback in IP rights protection since the Argentine House of Representatives and Senate passed legislation eliminating the previous amendment to the customs code related to border measures for enforcing trademark rights and copyrights. The new legislation excludes other IP rights, such as patents, from this provision.

For these reasons, PhRMA requests that Argentina remain on the **Priority Watch List** because it continues to deny "adequate and effective protection of intellectual property rights" and "fair and equitable market access", 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. Law No. 24,766 permits 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 are 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 (such as term of protection) to provide a sound legal basis for protection, under the TRIPS Article 39.3, even if the provision requiring reliance was deleted.

If data are 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 Resolutions 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 headcount at INPI increased over the past two years and 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. The current backlog in all areas amounts to 18,000 applications with full examination fees paid, while the total backlog amounts to 32,000 applications. In 2008, submissions of patent applications exceeded output of processed applications by 2,800 applications.

Along with the delays, there is also growing concern over the increasingly restrictive patentability criteria being applied by INPI with regards to pharmaceutical applications, particularly in the evaluation of “inventive step”. Such restrictions would affect patents involving polymorphic entities, 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 135 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.

Patent Linkage

Argentina does not provide any link between the patent system and the system for approving the marketing of pharmaceutical products, including generics and other kinds of copies. This is a significant problem in view of obstacles to enforcing patents.

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 2009 attributable to trade barriers related to intellectual property protection and market access.

BRAZIL

PhRMA and its member companies operating in Brazil remain concerned by the Government of Brazil's failure to make progress on extremely important issues for PhRMA's research-intensive member companies. Several of these concerns have been raised in prior years with little apparent impact.

Key Issues of Concern:

- Brazil's health regulatory agency's (ANVISA) inappropriate role in the patent application process;
- Lack of clarity regarding the decree that authorizes the Minister of Health to issue compulsory licenses;
- Continued concerns regarding the patent backlog despite some efforts by the patent office (INPI) to improve its operations;
- Government price control mechanisms that discourage innovation while not addressing the stated goal of improving access to medicines;
- The unhelpful, and often antagonistic, positions supported by Brazil in numerous multilateral fora that would, if successful, undermine the international patent system and thereby diminish incentives for critical R&D worldwide.

For these reasons, PhRMA recommends that Brazil be placed on the **Priority Watch List** because it continues to deny "adequate and effective protection of intellectual property rights" and "fair and equitable market access."

Intellectual Property Protection

Examination by ANVISA

PhRMA and its member companies have previously cited the problems created by the examination of patent applications claiming pharmaceutical products by officials of ANVISA, the Brazilian agency that regulates the marketing of pharmaceutical products. The "dual" examination authority remains a major obstacle to adequate and effective protection for inventions associated with pharmaceutical products in Brazil that has severe, long-term adverse effects for PhRMA's member companies.

ANVISA officials have overturned patentability determinations by the Brazilian Industrial Property Institute (INPI) by applying, in the opinion of member companies, more restrictive or different patentability standards than those used by the patent office itself. More specifically, through a more restrictive interpretation of the law, they have unduly restricted the definition of "invention," rejected claims drawn to new uses of known products, and imposed different standards of novelty and inventive steps. As a result, patents have not been granted on some important pharmaceutical inventions even though corresponding patents covering these products have been granted in most developed countries and many developing countries. Given the long development

times for pharmaceutical products, the failure to obtain patents on these inventions today will burden PhRMA's members for several decades in the future even if improper practices are promptly eliminated.

The continued existence of the "dual examination" authority in Brazil for pharmaceutical patents is incompatible with the obligations of Brazil under the "anti-discrimination" provisions of TRIPS Article 27.1.

This controversy has been submitted to the internal settlement bodies of the Government of Brazil. The Federal Attorney General issued a legal opinion in October 2009 stating that ANVISA should limit its role in the examination process to health and safety concerns. Despite this official recommendation, no effective measure has been implemented so far to solve this issue and ANVISA has continued to conduct "dual examinations" on member company patent applications.

Compulsory Licenses

In our 2008 Special 301 submission, we noted that mechanisms were put into place by earlier administrations in Brazil to grant compulsory licenses for patents in "national emergencies" and in the "public interest" and 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 public demand. Concern was expressed that the lack of specificity in the Industrial Property Law and the associated Decree could lead to the provisions being invoked in circumstances that were not extraordinary, for example to remedy a short-term budgetary deficit. We noted that the mechanisms could be invoked to impose *de facto* governmental price controls in a manner that lacked transparency, consistency, and predictability or to usurp the function of patents. Given the 2007 grant of a compulsory license under Article 71 based on claims of public interest, it appears these fears were justified.

PhRMA and its members believe that the Government of Brazil should modify its regime for granting "*ex officio*" compulsory patent licenses during declared instances of "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* governmental price control measure; and
3. To eliminate provisions for the expropriation of privately-held, undisclosed information.

Backlog – INPI.

PhRMA member companies recognize that the efforts to improve patent examining operations at INPI continue. However, the backlog of patent applications is still large and the pendency period, according to the official gazette published on

November 24, 2009, is ten years; unchanged from 2008. PhRMA also acknowledges that INPI is significantly reducing the backlog of applications for the registration of trademarks and continues to pursue more rapid action on such applications. More effective measures need to be taken, however, to reduce the extremely large backlog of patent applications.

Patent Linkage

Efforts to gain support for legislation that would require a link between ANVISA's issuance of marketing approvals and patents continue. However, the chances to improve the situation have been seriously diminished by the Brazilian Senate's recent rejection of a legislative proposal to provide this mechanism. An appeal may be filed against the decision, although it appears that passage of the bill is unlikely.

Data Protection

The Brazilian Government still fails to clearly prohibit Government officials for a period of time from allowing companies other than innovators to rely on test and other data submitted by PhRMA member companies when approving marketing requests submitted by such other companies. Some steps have been taken in a positive direction to prevent inappropriate disclosure of these data held by the Government, but additional efforts are needed to ensure that they are protected fully.

Counterfeiting

Pharmaceutical counterfeiting, which encompasses any deceptively mislabeled pharmaceutical product or packaging, accounts for roughly 20% of the total pharmaceutical market (according to Interpol statistics) in Brazil due to the Government's failure to protect foreign intellectual property and police its domestic drug distribution chain and borders. If these deficiencies persist, Brazil risks becoming an important source for counterfeit pharmaceuticals and a leading exporter to developing as well as developed markets in search of "cheap" medicines.

Pharmaceutical counterfeiting is first and foremost a public health threat. Of particular concern is the failure by drug regulators to police wholesale and retail distribution channels and to enforce regulations governing bulk active pharmaceutical ingredients (APIs). Strong administrative and criminal remedies for any activity that facilitates or directly entails the manufacture, distribution, import and/or export of counterfeit pharmaceutical products should also be considered.

Trademark enforcement is undermined by the absence of administrative remedies and generally weak border enforcement, due in significant part to the Government's failure to establish within customs a trademark recordation system and formal application process.

It is important for Brazil to take immediate steps to strengthen pharmaceutical anti-counterfeiting oversight and enforcement, including through measures that rectify deficiencies in drug safety controls, provide effective administrative and criminal remedies for all pharmaceutical counterfeiting offenses, and elevate pharmaceutical counterfeiting offenses as a law enforcement priority under both drug safety and trademark laws.

PhRMA and its member companies recognize the recent efforts undertaken by the Brazilian Government's CNCP (National Council for Anti-Counterfeit, which is part of the Ministry of Justice) with the participation of various stakeholders (ANVISA, federal and customs police, Itamaraty, Interfarma, the U.S. Chamber of Commerce, and ETCO Institute), as positive steps towards the improvement of the current situation. Hopefully, the measures under discussion, including: the creation of a database, stronger border enforcement, training of Government officials (mainly police), and a mass-media education campaign on how to identify a pharmaceutical counterfeit product, can be successfully implemented in order to avoid the deterioration of the Brazilian market. The public and private sectors have recently entered into an agreement which formalized mutual commitments on projects designed to increase the awareness of the Brazilian population on the mechanisms available to identify illegal copies and, at the same time, encourage Government Officials to act in a more coordinated and effective manner against counterfeit products.

Market Access Barriers

Government Price Freeze and Controls.

A government-mandated price adjustment mechanism, in effect since July 2000, is a major trade barrier to PhRMA's member companies. The arbitrary pricing restrictions were imposed with minimal input from PhRMA members. The restrictions are contrary to free-market principles espoused by Brazil and create an environment that discourages international investment.

The methodology used in the calculations of 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. In March 2009, a price increase of 5.90% was authorized. This rate fails to take into account government-mandated increases in manufacturers' costs, including salary increases.

On top of the price adjustment mechanism described above, Brazil created a reference price regime (Resolution 2) for new patented products in 2003. Under this regime, the final price of a new drug in Brazil cannot exceed the lowest price among nine reference countries.

In March 2007, ANVISA approved a resolution creating a price reduction factor (CAP) of 24.92 percent for government purchases at all levels of government (municipal, state, and federal). The CAP is uniformly applied to the ex-factory price of new products, which is established by an international reference price system. Calculation of the price reduction factor takes into account Brazil's per capita GDP and those of the reference countries.

Despite these controls, the Brazilian Government has not reached its goal of improved access to medicines. While income, a major determining factor in measuring access to medicines, has improved somewhat for poorer segments of the population, unit sales volumes have remained almost flat in the last few years.⁶¹ This suggests that more needs to be done to achieve the goal of improved access.

Progress in Multilateral Negotiations

The Government of Brazil has not supported multilateral efforts 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.

Efforts have been underway within the World Intellectual Property Organization to conclude an agreement that would harmonize significant aspects of patent law. The Government of Brazil has taken every opportunity to prevent early agreement on key harmonization issues and has proposed or supported "dis-harmonization" articles in the draft under discussion.

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, but also in the World Trade Organization, and the World Intellectual Property Organization.

Conclusion

PhRMA member companies believe that the misinterpretation and misapplication of the Brazilian "ex officio" patent compulsory licensing provisions, the improper application of patentability decisions by ANVISA and the other cited problems in Brazil deny adequate and effective intellectual property protection for pharmaceutical products. Moreover, the actions of the Government of Brazil in multilateral arenas are clearly intended to reduce the level of patent protection in all areas of technology. As a result, PhRMA recommends that Brazil be elevated to the Priority Watch List.

⁶¹ GRUPEMEF; CPI dos Medicamentos; MOH/SCTIE/DAF; Folha de S. Paulo; Target; Banco Central; BCG analysis.

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.

CHILE

PhRMA is pleased to acknowledge several advances by the Chilean Government during 2009 in its support for intellectual property rights (IPR) and its compliance with IPR-related obligations included in international agreements – specifically, the establishment in January 2009 of the new Intellectual Property Institute (INAPI) and the ratification in June 2009 of the Patent Cooperation Treaty. In addition, PhRMA and the local innovative biopharmaceutical association (“CIF”) noted a new willingness among certain Chilean Government officials to discuss directly with the innovative biopharmaceutical industry the establishment of an effective patent linkage mechanism, and it welcomed the Health Ministry’s preparation of a draft regulatory decree that would correct certain deficiencies of Chile’s regulatory data protection (RDP) system.

Unfortunately, the Chilean Government has not yet taken concrete action to adopt the regulatory and other changes needed to establish a linkage system 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 (which in December 2009 was under legal review by the General Controller of the Republic or CGR) 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 2009 to address the U.S. Government and innovative biopharmaceutical industry’s concerns regarding the absence of effective linkage and effective 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 TRIPS, the U.S.-Chile Free Trade Agreement, and other bilateral trade agreements. Accordingly, PhRMA recommends Chile’s continued inclusion on USTR’s **Priority Watch List** (PWL) in 2010.

Intellectual Property Protection

Patent Linkage

Notwithstanding the requirement contained in Article 17.10.2 of the U.S.-Chile FTA, Chile has failed to establish a satisfactory mechanism (known as patent linkage) to prevent the Public Health Institute (ISP) from granting sanitary registrations (which in Chile are *de facto* marketing approvals) to patent-infringing pharmaceuticals. That Article requires Chile to “make available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent” and “not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of

the patent owner.” The longstanding position of the Chilean Government has been that (1) the 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.
- All government agencies share the responsibility to uphold the legal obligations undertaken by the Government of Chile as a whole, including those contained in its bilateral free trade agreements. Although the ISP and the patent office have distinct purposes, they are both agencies of the Government of Chile. It stands to reason that they should communicate with each other and cooperate in ensuring compliance with Chilean laws and regulations. It makes little sense for one governmental agency to grant a patent while another agency of the same government fails to respect the protections guaranteed under national law to the patent-holder.
- 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 halt the processing of that request until the competent judicial authority can resolve questions relating to the patent’s validity) 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 a formal administrative mechanism to prevent the grant of a sanitary registration/marketing approval to an infringing product until the patent holder has a reasonable opportunity to defend its rights in court. The linkage requirement is not satisfied by enabling a patent-holder to defend itself, after a third party has requested and received a sanitary registration/marketing approval for an infringing product.

Proposed regulatory modifications contained in the Health Ministry’s draft sanitary decree (*which is intended to replace S.D. 1876*) would make it even more difficult to establish effective linkage during the foreseeable future. The draft regulation does not recognize that the ISP has any obligation to consider patent status in granting sanitary

registrations to pharmaceutical products. Article 19 of the proposed regulation states that “The administrative act of sanitary registration constitutes an activity of preventive control by the Institute acting as the health authority, which has as its exclusive goal the protection of human health, in terms of evaluating favorably the quality, safety, and efficacy of the product... [That evaluation] is entirely independent of the commercial interests or the intellectual or industrial property interests of those who seek or obtain the sanitary registration.” Moreover, although several articles of the proposed regulation refer to the Institute’s role in authorizing the distribution and use of pharmaceuticals in Chile, nowhere does the regulation mention “commercialization” or include “commercial authorization” among the ISP’s responsibilities. The definition of “distribution” cited in the regulation excludes the act of commercialization from the Institute’s sphere of responsibility.⁶²

Representatives of the innovative biopharmaceutical industry met with relevant officials of the Government of Chile during 2009 to discuss the minimum requirements of a linkage system that would be acceptable to both the innovative biopharmaceutical industry and the Government. Although the fact that such discussions are taking place represents an important advance, they have not yet yielded tangible progress toward enactment of the regulatory and/or statutory modifications that would be needed to establish an acceptable linkage system. Moreover, it is not clear whether Chile’s next Government will continue the conversations currently underway.

According to the CIF, Chile’s failure to establish linkage 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. Fully half of those registered copies – 114 different patent-infringing products – have already entered the Chilean market.

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 TRIPS, the EU-Chile Association Agreement, and the US-Chile Free Trade Agreement. Chile’s current regulatory 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 exclusive use of such data 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 current regulations protect pharmaceutical test data primarily against physical disclosure, and do not unambiguously protect them against unfair commercial use, understood as direct or indirect reliance on such data by an unauthorized third party in order to obtain a sanitary registration for a similar product.

⁶² The regulation defines “distribution” as “the delivery of the pharmaceutical product from the manufacturer, importer, or distributor to establishments authorized by the health authority” (Article 5[14]).

- In several cases, the current rules have permitted the ISP to accept sanitary registration applications for pharmaceutical products characterized as “new,” even though the applications relied on test data belonging to a third party that had not authorized such reliance.
- Chile’s data protection system imposes grounds for revocation or denial of the right to exclusive use that are not stated in TRIPS or Chile’s bilateral trade agreements with the EU and the United States. These conditions significantly weaken the applicability and usefulness of the available data protection.

In November 2008, the Health Ministry made available an updated draft of its new data protection regulation (intended to replace Health Decree 153/2005), initially published for public comment the previous April. If approved and enacted, the November 2008 text would have corrected several of the most important deficiencies in Chile’s current regulatory framework for RDP. Specifically, the November 2008 draft would have established that:

- Prior partial data disclosures made by foreign regulatory agencies or international organizations will not negate the “undisclosed” nature of the data.
- Sanitary registration applications for products identified as “new” (as opposed to “similar”) must be supported by complete data dossiers.
- All data submitted that relate to safety or efficacy will receive protection.
- To obtain data protection, the applicant for sanitary registration must provide a sworn statement that it owns the data or has owner’s authorization.
- Data would qualify automatically for protection, provided that they refer to an eligible chemical entity and that the applicant complies with the required formalities – thereby eliminating the ISP’s authority to make case-by-case determinations of whether the data are in fact “undisclosed.”

The new draft regulation did not address the statutory deficiencies regarding RDP contained in Law 19,996, correction of which would require new legislation. The most important deficiencies relate to the overly restrictive definition of what constitutes a “new chemical entity,” and the various TRIPS-inconsistent grounds for denial or revocation of protection.

Unfortunately, several of the elements of the November 2008 draft were weakened significantly in the latest draft, which the Health Ministry sent to the CGR for legal review in September 2009. Specifically, the new text – unlike the previous one – does not state unambiguously that prior partial disclosures of data by foreign regulatory agencies or international organizations cannot be cited to justify denial of data protection in Chile. In addition, the new text would permit the ISP publicly to disclose protected data on broad and vague grounds (“... in order to provide guidance or warnings regarding the appropriate use of the medicine”).

Although the current regulatory text includes some provisions that would modestly strengthen Chile's data protection regime, it would leave untouched or fail adequately to remedy other important deficiencies in the current system. For this

reason, it is PhRMA's position that enactment and implementation of the decree, in its present form, would not suffice to justify Chile's removal from the USTR Priority Watch List.

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 10 imitative pharmaceutical products, relying, without due authorization, on test 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).⁶³ 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.

⁶³ 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

PhRMA and its member companies continue to have intellectual property and market access concerns in Venezuela. In addition to the great number and complexity of regulations and procedures necessary for innovative pharmaceuticals to reach the market in Venezuela, there has been a standstill in the granting of patents for pharmaceutical products.

Key Issues of Concern:

- Withdrawal of Venezuela from the Andean Community has caused a great deal of uncertainty regarding the legal framework in Venezuela, particularly the repeal of Intellectual Property Decision 486. With this decision, the Government of Venezuela has, according to public statements by government officials, reverted to the Industrial Property Law of 1956 which prohibits patents for pharmaceutical products.
- Venezuela has not granted a pharmaceutical patent since 2003.
- Venezuela has not provided data protection since 2002.

For these and other reasons outlined below, PhRMA and its member companies recommend that Venezuela be included on the **Priority Watch List** and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property

In April 2006, Venezuela formally withdrew from the Andean Community ("AC"). As a result of this decision, all rights and obligations for Venezuela, including application of Intellectual Property Decision 486, apparently ceased. 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 WTO TRIPS Agreement and the Paris Convention. The local pharmaceutical R&D 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 is applicable in Venezuela (Andean Decision 486 or IPL).

Regardless of how the legal issues described above are resolved, the legal framework for patents is inadequate and has been for some time. According to the official Industrial Property Bulletin, Venezuela has not granted a single pharmaceutical patent since 2003. It has not granted a patent of any kind since 2005.

Data Protection

Between 1998 and 2001, Venezuela enforced a five-year period of data protection. That changed in 2002, and as a result, Venezuela has not provided effective data protection since February 2002. It has instead granted second regulatory authorizations for “copy” products, by relying on the original data during the period when data protection should have been applied, raising serious concerns under TRIPS Article 39.3. Domestic legal challenges to elimination of data protection and its consequences (detailed below) have been unsuccessful.

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)). Individual research-based pharmaceutical companies filed challenges against the Government in 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), but all claims of unfair competition were dismissed. Claims were also brought by pharmaceutical companies in the Administrative Courts and then to the Supreme Court of Justice. Both courts denied preliminary remedies and continue to process claims with no decision in sight.

On June 6, 2005, CAVEME sued the Venezuelan National Institute of Health 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.

Counterfeit medicines and other illicit activities

According to Direction of Drugs, Medicines and Cosmetics of Health Ministry, Venezuela in 2009 has 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 may 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.

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 to get exemptions from the VAT, 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, both creating 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: (i) be awarded with complete disregard to the Bidding Law, or (ii) be 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/services without satisfying the terms of the Bidding Law.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

MIDDLE EAST/
AFRICA/
SOUTH ASIA

ALGERIA

PhRMA and its member companies operating in Algeria have increased concerns about the lack of intellectual property (IP) rights protection and market barriers which seriously impede access to the Algerian market for innovative pharmaceutical products.

Key Issues of Concern:

- Importation restrictions since January 2009 which unfairly discriminate against multinational pharmaceutical manufacturers.
- The new investments and commercial laws that require a minimum 30% Algerian share of ownership and letters of credit for importation.
- Government mandated reimbursement price and volume controls imposed through an annual import quota for medicines.
- The absence of IP protection for products on the Algerian market before 2003 because of practical and legal changes. In addition, effective judicial remedies are not available.
- The absence of data protection.
- The delay in granting marketing approval for innovative products of PhRMA members due to burdensome new regulatory requirements.

For these reasons, PhRMA recommends that Algeria remain on the **Priority Watch List** for the 2010 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 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.

Market Access Barriers

Importation restrictions

In September 2003, the Ministry of Health issued a Decree called “Instruction #5 for the generalization of generics,” which stipulates that medicines for which local production is sufficient to cover the local demand may no longer be imported.

Algeria’s progress in the WTO accession process and the 2005 ratification of an EU Association Agreement indicated that the Algerian Government was willing and ready to accept foreign investment across most sectors including the pharmaceutical industry. As part of this progress, in late 2005, the Algerian authorities communicated to industry that “Instruction #5” would not be applied anymore. However, it was never officially cancelled.

On October 21 2008, the Algerian Government issued a decision (published in Nov 2008 under the name “Arrêté du 30 novembre 2008 relatif à l’interdiction des produits pharmaceutiques et dispositifs médicaux destinés à la médecine humaine fabriqué en Algérie”) stipulating that, effective January 2009, the importation of pharmaceutical products that are being manufactured locally will again be prohibited. Subsequently, the Ministry of Health has published lists comprising hundreds of branded medicines.

Some molecules were banned despite limited local capacity and very small market share of local players, indicating that MOH issued an import ban without validating sufficient local capacity, which puts the market at risk of serious shortages

Algeria’s reactivation of this policy on the importation of pharmaceuticals unfairly discriminates against multinational pharmaceutical manufacturers, severely curtails

market access for innovative pharmaceuticals, serves as a hurdle to trade, and jeopardizes Algeria's chances of acceding to the WTO in the near future.

Investment & Financial Laws

In December 2008, the Algerian Government declared that any company engaged in foreign trade should have a minimum of 30% of local Algerian shareholders. This decision has been applied to new companies, not to already existing companies.

New measures concerning importers, however, were introduced 26 July 2009. The Government now requires importers to secure letters of credit and set aside 25% to 100% of the import value as a deposit on their purchase. These amendments negatively impact mostly small and medium sized importers who may not be able to satisfy deposit money to fund their imports.

Government Reference Pricing

Algerian law requires that reference pricing be applied only if there is a corresponding generic on the Algerian market. However, in practice, some products that have no generic equivalent on the market have been referenced. In addition, some products have been referenced against a therapeutic class to obtain the lowest possible price.

Article 59-3 of the Law of July 2, 1983, was supplemented by an Inter-ministerial Order fixing reference rates for the reimbursement of pharmaceutical products. Corresponding conditions for application of reference rates under the Order were published on July 21, 2001. The Order limited government reimbursement for a finite list of pharmaceutical products to a price set by referencing the cost of the generic versions of the product. The Order was not implemented until the publication of an Inter-ministerial Order that entered into force on April 15 2006. Since the Order was executed, hundreds of products have been officially added to the list. The 2006 Order sets government reimbursement prices, and is expected to be extended to additional products semi-annually as requested by the Minister of Health. The Government's process for setting the prices is not transparent or reviewable and does not provide for any specific appeal system. A potential solution might be to ensure that any reference price should be linked to the price of at least three corresponding generics available on the market before its application to avoid the risk of stock-outs related to insufficient local manufacturing capabilities.

Volumes Control

Algeria continues to impose an annual import quota for medicines with the requirement that each shipment receive prior clearance from the Ministry of Health. Also, the Government practice is to temporarily block importation as a cost-containment

tool, and the MOH delayed approval of PhRMA member companies' import plans in 2008 and 2009

Under this requirement, the MOH can instruct companies to revise downwards their submitted importation plans (as happened for 2008 quantities) and require that these new importation levels be approved by the Algerian Government.

Regulatory Environment

The registration process remains slow and additional, burdensome requirements for obtaining registration to market pharmaceutical products, especially innovative products, have been issued. These requirements are communicated to pharmaceutical companies in the form of "notes", and present a significant market access barrier for innovative pharmaceutical companies. In some cases, these requirements are also requested for marketing authorization renewals.

From July to September 2009, all submissions at MOH were frozen. 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.

Notably, under Executive Decree No. 92-284, dated July 6, 1992, the approval by the Ministry of Health of a pharmaceutical product for human use is to be granted – or refused – within a 120-day period from the filing date of the scientific and technical application. In exceptional cases, this period can be extended for an additional period of 90 days. In practice, it takes the MOH approximately 18 to 24 months to approve biopharmaceutical product for human use.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

LEBANON

PhRMA and its member companies operating in Lebanon remain concerned about the lack of adequate intellectual property right protections in the Lebanese pharmaceutical market. Market access for innovative pharmaceutical products, however, has improved since the implementation of a new registration and importation process at the Ministry of Health (MOH) in October 2008. PhRMA congratulates the Lebanese Government on taking this important step and improving market access for innovative pharmaceutical products.

Key Issues of Concern:

- Inadequate intellectual property rights protection.
- The absence of criteria to distinguish between innovative and generic medicines.
- The absence of government testing facilities to validate the quality of pharmaceutical products.
- Data protection (DP) provisions in the 2000 Patent Law must be strengthened.
- The Government must take a firm stance against counterfeits.

For these reasons, PhRMA recommends that Lebanon remain on the **Priority Watch List** for the 2010 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

In July 2000, Lebanon passed a new industrial property law, which represented a major improvement over the 1924 law. The 2000 law provides 20 years of product patent protection, as well as incentives for new foreign direct investment and technology transfer, specifically for the pharmaceutical sector. Much of the 2000 law complies with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and improved the environment for innovation.

◆ The law provides a good basis for Lebanon's eventual accession into the WTO. PhRMA supports the Lebanese Government's efforts to implement laws and regulations that are consistent with WTO standards and Lebanon's eventual accession to the organization. WTO membership requirements, and in particular, TRIPS obligations, would address longstanding trademark and patent issues, as well as provide needed clarification in the area of data protection.

In its present form, however, the patent law does not provide any tangible protection for the products of PhRMA member companies due to the lack of pipeline or

transitional patent protection. In addition, since data protection provisions are ambiguous, marketing authorizations to copy products continue to be granted prematurely. Data protection provisions in the 2000 Patent Law still must be strengthened to ensure adequate intellectual property protection for the research-based pharmaceutical industry.

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

Data Protection

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

The new drug registration regime, issued in late October 2008, has incorporated some protections for regulatory test data and patents. No confidential data shall be incorporated in the registration dossier, unless specifically asked for by the committee. In this case, the committee would provide written consent to protect data from disclosure. The applicant is to state that the data submitted pertains to its product, that the applicant owns the data, or that the data was obtained from publicly available sources. Lebanon patent submissions and certificates are to be included in the registration dossier. PhRMA is still awaiting the proper implementation of these provisions.

A comprehensive provision preventing unfair reliance on valuable undisclosed information and data (as it pertains to a regulatory approval requirement), is required in order to protect the intellectual property rights of research-based pharmaceutical companies. PhRMA members have engaged in an active dialogue with the Ministry of Economy and Trade (MOET) over a new Unfair Competition Law. The MOET has taken the position that publication of any data in a medical journal or on the Internet would constitute a disclosure of the data (even though the underlying data are not disclosed), thus permitting the MOH to approve generics at any time after the innovator. An effort was made to inform MOET that publication of preliminary test data and results is ethically sound and helps inform the medical community as early as possible about scientific progress. PhRMA has also explained that publication of results does not substitute for safety and efficacy data submitted in support of product licensing.

To be TRIPS-consistent, MOH should protect regulatory test data from unfair commercial use during the data protection period by refusing marketing approval for pharmaceutical product applications filed by third parties that rely on the same data or conclusions without the consent of the party that produced the data. In addition, MOH

should protect such data from disclosure except where necessary to protect the public health.

Parallel Importation

The new drug registration regime allows for parallel importation of pharmaceuticals through special import licenses granted by the Minister of Health. However, international experience demonstrates that parallel importation presents risks to Lebanese patients by facilitating the importation of counterfeit or uncontrolled pharmaceuticals. It is very hard to police the supply of medicines once the chain of supply from manufacturer to authorized importer is broken. Counterfeit and/or poor quality goods may enter the drug supply once this has occurred. Moreover, in the case of product withdrawal or recall, it may be very difficult for the manufacturer to identify parallel importers to alert them of recall decisions.

Trade in counterfeit pharmaceutical products in Lebanon is an ongoing problem. It is often difficult for consumer to identify these products. This continuing trade in counterfeits may become a significant health issue in Lebanon despite surveillance by the authorities.

In 2009, PhRMA's member companies participated in training government enforcement agencies on counterfeit pharmaceuticals as part of a multi-sector approach that would enhance collaboration among various government bodies in detecting counterfeit pharmaceuticals and protecting patient safety.

Market Access Barriers

Regulatory Barriers

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

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

The new drug registration regime has improved regulatory processes. However, innovative products are subject to more onerous requirements than generics. Local manufacturers of “copy” products and importers of unauthorized copies are able to register with MOH, and sometimes be reimbursed by the Social Security Fund before registration of original products. Products manufactured by local companies enjoy a “fast-track” registration procedure and a significantly reduced list of requirements as compared to products imported from the United States or European countries.

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

During 2009, PhRMA member companies collaborated with the MOH on a seminar aimed at discussing international guidelines on bio-similars, quality and self-medicine.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

PAKISTAN

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:

- No implementation of data protection as required under TRIPS Article 39.3.
- The Ministry of Health (MOH) continues to disregard process patents at the time of registration and the majority of mailbox applications have not been granted or finally acted upon. Copies of molecules filed under mailbox applications continue to be permitted to be marketed, as the original products do not have patent protection in Pakistan.
- The MOH maintains a local manufacturing requirement as a prerequisite for product registration.
- The MOH has placed restrictions on toll manufacturing, where they have given June 30, 2010 as its cut off date.
- The current government pricing system is nontransparent, and government prices of innovative products are set at extremely low and arbitrary levels. Government prices have not been revised since 2001 despite the rapid increase in the inflation rate.

For the reasons stated above, PhRMA member companies recommend that Pakistan remain on the **Priority Watch List** for the 2010 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein will be quickly and effectively resolved.

Intellectual Property Protection

Patents

In January 2001, a new patent ordinance, called the Patent Ordinance 2000, was promulgated and made incomplete, though promising, strides towards recognizing Pakistan's TRIPS obligations as a member of the WTO. To date, no clearly defined rules or regulations have been released implementing this legislation. More troubling than the lack of underlying regulations are changes made to the Patent Act in 2002 that drastically inhibit the ability of U.S.-based pharmaceutical companies to enjoy effective and meaningful patent protection in Pakistan. The change to the Patent Acts, effective from October 2002:

- Eliminates use patents;
- Establishes 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 devalue intellectual property rights in Pakistan and are inconsistent with the spirit and law of Pakistan's current and future TRIPS obligations.

Furthermore, the Ministry of Health (MOH) continues to register generic copies of products patented by U.S. and other multinational pharmaceutical companies. In all practical matters, current and expected patent protection in Pakistan remains inconsistent with Pakistan's WTO obligations and disadvantages U.S. based multinationals.

Mailbox applications

The International Patent Office initially committed to process "mailbox" patent applications within 18 months beginning January 1, 2005. This was a requirement of the Patent Act. However, little has happened since January 2005. The Patent Office extended the period to 27 months, and now has dropped that deadline. 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.

Data Protection

As a WTO member, Pakistan is required to implement TRIPS Article 39.3 to prevent unfair commercial use of regulatory test data. To date, Pakistan does not protect such data against unfair commercial use. Such protection should preclude direct and indirect reliance by MOH on the data package used to support initial marketing approval of the originator product for a period not less than 5 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 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 is leaked after the 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 in the process of notifying a Statutory Regulation Order (SRO) of the draft law that would extend protection to pharmaceutical test data. PhRMA member companies are now waiting for the SRO notification and look forward to working with the Pakistani Government to ensure that this meets Pakistan's international obligations and provides full protection for pharmaceutical intellectual property.

Market Access Barriers

Local and Toll Manufacturing Requirements

Pakistan's MOH maintains a local manufacturing requirement as a prerequisite for product registration. In addition, the MOH has placed restrictions on toll manufacturing, where they have given June 30, 2010 as a cut off date. However, due to the strong advocacy by PhRMA member companies, in collaboration with local companies in Pakistan, the MOH has constituted a Toll Manufacturing Committee comprised of one member from the Pharma Bureau, the PPMA (representing local companies), and an expert from the MOH, with the DG Health personally overseeing this requirement. The Committee will review the current manufacturing situation and give guidelines to ensure continuity of the toll manufacturing.

Government Pricing

The current government pricing system in Pakistan is another major market access barrier. The Government sets the prices of new products at extremely low and arbitrary levels.

There is also a lack of transparent government pricing directives or guidelines. Although the Pakistani Government has considered implementing a policy to adjust government prices to compensate for devaluation and/or exchange rate fluctuations, these changes have not been implemented. Government prices 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. In the latest development, the Supreme Court of Pakistan has asked the MOH to finalize the policy by the end of March 2010, and to submit monthly progress on implementation.

Fast Track Registration

In the past, the MOH has agreed that if a product is registered in two key developed markets (United States, EU, UK, Japan, or Switzerland), the MOH will prepare a list of documentation required for registering the same product in Pakistan. The applicant must guarantee that the product is of the same strength and indications as the product registered in the two developed countries, and provide all marketing materials, indicating how and to whom the product will be marketed. If these conditions are met, the MOH will not send the registration application for expert review. However, as of late, the MOH has been sending such cases for expert review, which has created a barrier by delaying the rate of access for new, innovative drugs to the Pakistani market.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

WATCH LIST

ASIA-PACIFIC

AUSTRALIA

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 still much to be done to achieve the goal of providing access to new and innovative medicines. The 2006 reforms to Australia's Pharmaceutical Benefit Scheme (PBS) were largely welcomed, but PhRMA member companies continue to monitor the implementation of the PBS reforms, 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.

Key Issue of Concern:

- Lack of sufficient advance notice of potentially patent-infringing products in order for patent holders to seek injunctive relief

For the reasons set out below, PhRMA requests that Australia be placed on the **Watch List** for the 2010 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Patent Protection

Australia traditionally has maintained a strong intellectual property regime for protecting innovative biomedical discoveries, including patent term restoration. PhRMA was pleased by a decision of the Australian Government on July 22, 2009, not to adopt a proposal that would have weakened Australian intellectual property laws and undermined the rights of Australian patentees. If taken up, an amendment to Australia's patent laws would have permitted the manufacture of pharmaceutical products for export during the extended patent term in Australia. This would have been contrary to generally permitted practice throughout the rest of the developed world. As the Australian Government itself has said, these amendments were not supportable in light of Australia's commitments on intellectual property and trade.

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 and the PBS would ensure patent-holders received advance notice to enable them to seek injunctive relief prior to patent infringing products entering the market, as required by the Agreement. Notice provisions have not, however, been implemented in a workable

way. 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.

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.⁶⁴ 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 it has been quite some time since the last meeting of the Medicines Working Group and are hopeful that the next meeting will be scheduled soon.

PhRMA is pleased to note that its member companies were consulted in relation to elements of the PBS reform package of 2006, and as well have been able to participate in follow-on dialogue between Government and industry, as part of the Access to Medicines Working Group (AMWG). We look forward to continuing progress via the AMWG.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

⁶⁴ "About the PBS," Australia Dept of Health and Ageing,
<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-aboutus.htm-copy2>

MALAYSIA

PhRMA and its member companies operating in Malaysia hope to remain engaged with the Government of Malaysia as it looks to improve the IP and regulatory environment for the research-based innovative biopharmaceutical industry.

Key Issues of Concern:

- Data Protection
- Patent Protection and Enforcement
- Counterfeits

For these reasons, PhRMA requests that Malaysia be placed on the **Watch List** for the 2010 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 May 2007, the Malaysian Government announced that, by the end of 2007, five years of data protection would be provided for new chemical entities and three years for new indications, starting from the date of approval in the country of origin rather than from the date of approval of the medicine in Malaysia. However, issues related to the implementation of data protection (such as legislative amendments) have yet to be worked out, and the implementation deadline has been delayed. Expediting data protection implementation is in line with the country's aspiration under the Ninth Malaysia Plan to create an enabling environment for biosciences and biomedical research. PhRMA thus urges the Government of Malaysia to ensure data protection is implemented in a timely manner. Because regulatory approval can take up to two years in Malaysia, PhRMA hopes that the Malaysian Government can amend the draft regulation to begin the term for data protection upon regulatory approval in Malaysia.

Patent Protection and Enforcement

The Malaysian National Intellectual Policy (NIPP) is set to harness intellectual property (IP) as a new engine of growth for the enhancement of economic and social prosperity. One of the main objectives of NIPP is to ensure the highest standard of IP protection, i.e., to ensure fast and easy acquisition of rights as well as competent and practical enforcement mechanisms that provide redress for infringements of IP rights and deter the repetition of infringement.

To complement the IP protection system of NIPP, the pharmaceutical research-based companies recommend that a system of patent linkage be incorporated into the current procurement system, especially for pharmaceutical products in Malaysia. This

will further 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.

Counterfeit Medicines

Stronger criminal penalties and improved enforcement efforts are among the most effective means for deterring counterfeits. PhRMA supports close coordination between the U.S. and Malaysian Governments on anti-counterfeit initiatives, including training for regulatory and security officials and the tightening of the legal framework to include an efficient legal process to prosecute counterfeiting crimes. PhRMA commends the Ministry of Health on the recent announcement that a new bill will be introduced soon to curb counterfeit medicines, introducing more severe penalties for criminals caught manufacturing, supplying or selling counterfeits.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

TAIWAN

PhRMA and its member companies support the continuation of the Trade and Investment Framework Agreement (TIFA) discussions between the United States and Taiwan. These discussions provide a platform to discuss health policy reform measures that directly impact the market environment for PhRMA member companies in Taiwan. PhRMA also appreciates the Government's willingness to enter into substantive dialogue with member companies over market access barriers and other concerns. PhRMA and its member companies operating in Taiwan, however, remain concerned over issues related to policies that reward for innovation and intellectual property protection.

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 patent linkage in their regulatory procedures for approving generics.

For these reasons, PhRMA requests that Taiwan be placed on the **Watch List** for the 2010 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 TRIPS Article 39.3. TRIPS Article 39.3 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 only covers new chemical entity products and 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 may not effectively prohibit unfair commercial use.

Patent Linkage

Taiwan has not yet established patent linkage in the regulatory procedures for approving generics, which means that the Taiwan Department of Health and the Bureau of National Health Insurance do not take patent-holders' intellectual property rights into

consideration when issuing drug marketing approvals and granting reimbursement prices. This significantly disadvantages innovator companies, particularly in view of pending proposals to alter regulatory approval procedures. Under a revision four years ago to the Pharmaceutical Affairs Law, the Taiwan Government asks patent-owners to register their patents upon receiving product licenses; thus, data similar to that submitted in the “Orange Book” system in the United States is available. That change in the Taiwanese law is ineffective, however, without a patent linkage system in place.

Furthermore, the Government’s Intellectual Property Office (TIPO) has proposed to amend the Intellectual Property Law in a manner that would appear to broaden the “safe harbor” for tests performed to secure generic marketing approval. While such a safe harbor is acceptable in principle, it should be accompanied by an effective linkage system (as exists in the United States). If Taiwan continues, and particularly if it broadens, the safe harbor which permits testing needed to obtain commercial marketing approval during the term of a valid patent, it should implement an effective linkage system. The current and proposed approach erodes incentives for originators’ to introduce new pharmaceutical products into the Taiwan market and thus jeopardizes patients’ access to new medications.

Market Access Barriers

Reward for Innovation

DOH’s Bureau of National Health Insurance (BNHI) sets pharmaceutical prices for new innovative drugs that are extremely low. According to BNHI data, new product reimbursement prices in Taiwan have dropped from 80% of the A-10 median (based on the prices in 10 benchmark advanced countries) during the 1996-2002 period to only 51% of the A-10 median in 2007-2008. Furthermore, on average, new drugs obtained only 72% of the *lowest* A-10 prices in 2007-2008.⁶⁵

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 the interest of rewarding innovation, development of 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 simply cost-containment objectives.

⁶⁵ 2009 White Paper, American Chamber of Commerce in Taiwan (ACCT), Taipei, Taiwan.
http://www.amcham.com.tw/component/option,com_docman/task,doc_download/gid,298/Itemid,/

National Treatment Concerns

Article 49 of the National Health Insurance Law mandates reimbursement of healthcare providers at actual transaction cost; however, this law is not enforced. Producers of generic drugs offer significant discounts to cash-strapped healthcare providers due to the fact that the reimbursement system sets high prices for generics (85% of the originator price).⁶⁶ PhRMA member companies support strong enforcement of Article 49 by the Government so that product bonuses, discounts and other forms of promotion are accurately captured.

Until March 31, 1997, BNHI treated the official reimbursement price as a “ceiling price” and reimbursed at actual transaction price in accordance with the National Health Insurance Law. Thereafter, BNHI unified prices for all healthcare providers and began reimbursing for pharmaceuticals at the official price, regardless of actual transaction price, thereby creating a pharmaceutical price gap, otherwise known as the “Black Hole.” BNHI should resume reimbursing at actual transaction prices and require medical providers to submit the real transaction prices for reimbursement at the time of their service claims, as required by Article 49.

The Black Hole also exists because of inadequate hospital and physician fees. Hospitals and physicians have come to depend on revenues from the Black Hole.⁶⁷ A direct and transparent system for financing healthcare and adequately compensating hospitals and physicians, including increasing medical service fees to replace lost revenues, is urgently needed.

At present, periodic Price-Volume Surveys (PVS) are conducted by the Government with the intent of clawing back discounts “provided” by drug suppliers; the 6th PVS was recently completed in 2009. These surveys lead to reductions in reimbursement prices that provide an immediate savings to the Government, but fail to resolve the underlying financing shortfall. The price reductions announced in 2009 were particularly severe.⁶⁸

These price reductions, in the Government’s view, are necessitated by Taiwan’s price gap. The Black Hole seriously distorts trade by creating a financial incentive for Taiwanese hospitals and medical practitioners to favor the prescribing and dispensing of domestically-produced generic medicines over high-quality imported medicines that embody the latest biomedical advances. PhRMA has developed and communicated to BNHI, both directly and through the TIFA process, a series of recommendations aimed at achieving our core goal of eliminating the Black Hole as expeditiously as possible.

⁶⁶ 2009 White Paper, ACCT

⁶⁷ 2009 White Paper, ACCT

⁶⁸ *Apple Daily*, July 18, 2009. “The Bureau of National Health Insurance announced that prices of over 7,500 kinds of health care medicines (for about 47% of total health care medicines) will be reduced, commenced on September 1st. It is estimated to save near NT\$10 billion in medical expenses.”

However, the PVS process will not be able to resolve the long-term issue of the pharmaceutical price gap. The price gap distorts the pharmaceutical budget, encourages unusual and unethical prescribing practices by physicians, and puts patient welfare at a frighteningly-low priority. Resolution of the Black Hole in Taiwan by requiring transparent funding of healthcare expenses in all sectors, implementation of actual transaction pricing and, most importantly, and a real separation of prescribing and dispensing of pharmaceuticals is essential. PVS aimed at clawing back margins from healthcare providers through drug discounts from pharmaceutical manufacturers do little to address the root of the problem, and instead foster an environment that rewards local generic manufacturers, stifles innovation, and may place patients at risk.

PhRMA continues to be disappointed that the Government of Taiwan has failed to effectively implement Article 49 in a manner that would prohibit these transactions. As the exclusive benefit provider in the country, the Government wields considerable leverage over private and public institutions reliant upon reimbursement income as the primary source of revenue.

In the past, DOH and BNHI have been reluctant to initiate substantive reform in the healthcare arena. Taiwan's cumbersome pricing and reimbursement system, which imposes costs and conditions discriminatory to foreign companies, permits high generic pricing that favors domestic producers, sets innovative drug pricing far below international median levels and close to the lowest in the world, and is maintained in a non-transparent manner.

Separation of Prescribing and Dispensing

The separation of prescribing and dispensing (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. SDP would effectively remove profit incentive from the selection of appropriate treatments or therapies. As long as hospital revenue and physician remuneration is dependent on mark-ups on pharmaceutical products, patient welfare is compromised by this conflict of interest.

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 reinstating an incentive structure. Hospitals account for 80 percent of the pharmaceutical market in Taiwan, and are under significant government control.⁶⁹ A transition to SDP could be achieved in phases by first implementing it in public hospitals.

⁶⁹ 2009 White Paper, ACCT.

Regulatory Issues

In the discussion at the recent National Drug Policy Conference, one key focus was how to ensure drug quality. Taiwan has already established a good foundation on drug manufacturing standards through implementing GMP and cGMP standards, and a bioequivalence requirement has been in place for products with a higher reimbursement price. Due to differences in the active ingredients and excipients (inactive ingredients used as carriers), however, these measures are not sufficient to ensure the quality and efficacy of generic drugs. To assure patient access to quality medicines, it is essential to strengthen local regulatory requirements to bring them in line with international standards.

PhRMA's member companies seek continuous improvements in the regulatory system so as to expedite the launch of innovative products in Taiwan. In 2006, DOH substantially raised the new-drug-registration review fee, while committing to speed up the approval process. But product license approvals are still being significantly delayed due to the time-consuming requirement that companies submit three Certificates of Pharmaceutical Product (or two CPPs if the sourcing country is on the A10 list of 10 advanced countries) and have them notarized by a Taiwan representative office in the country in question. Additionally, it is not always feasible to obtain a CPP from the sourcing country because products may not be sold in the sourcing country.

BOPA should reduce these unnecessary delays by recognizing official approval letters from A10 countries that are certified by company officials, and should require only one CPP from any A10 country.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

VIETNAM

PhRMA and its member companies operating in Vietnam are concerned that despite the Government of Vietnam's taking steps in 2009 to address some of PhRMA's members' policy concerns, progress has been limited. Also, many of the reforms proposed by the Government of Vietnam in 2009 would not put Vietnam in line with international and regional standards. 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:

- Draft regulations on data protection
- New proposed regulations on clinical trials
- Investment restrictions

For these reasons, PhRMA requests that Vietnam be placed on the **Watch List** for the 2010 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 August 2009, the Drug Administration of Vietnam (DAV) issued a set of draft regulations on data protection for comment. PhRMA and its member companies offered views on the draft regulations, but there has not been any follow-up by the DAV to date. PhRMA believes that the regulations, as they were originally drafted, fall short of making meaningful improvements to the existing regime for protecting pharmaceutical test and other data in Vietnam. In PhRMA's submission to the DAV commenting on the draft regulations, PhRMA proposed the following changes: 1) resolve the misconception that data protection applies only when there are patents; and 2) require that government authorities check the status of previously approved products at issue and delay the grant of marketing approval for a generic product if there is an applicable data protection period.

Market Access Barriers

Clinical Trials

PhRMA is concerned that new regulations issued in September 2009 on clinical trial requirements could impose onerous barriers to innovative pharmaceutical companies supplying Vietnam's market. Article 4 of the draft regulations suggests that

Vietnam would require all new “western drug” applications to include a full set of clinical trials conducted in Vietnam in order to gain marketing approval. In Article 5, additional guidance is necessary to determine which phases of clinical trials would be exempted. It currently suggests that registration of a new indication for a pharmaceutical product already registered in Vietnam will require a local clinical study. This would likely apply both to major variations (i.e., a change in formulation, route of administration, etc.) as well as minor variations (i.e., change in excipients/preservatives). If this is the case, this regulation would not be in line with the regulations of other countries in the region, which allow regulatory officials to accept overseas data. PhRMA requests additional clarification from DAV on these points and ultimately amendment of the regulations, as appropriate, before they are finalized and go into effect.

Investment Restrictions

On January 1, 2009, in accordance with Vietnam’s WTO commitments, 100% foreign-owned entities were granted the right to import unrestricted pharmaceutical products into Vietnam. The pharmaceutical industry now awaits guidance from Vietnam’s Ministry of Health 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 Ministry of Health does not require further changes to the current supply chain, which allows companies to contract with foreign-owned storage and logistical services companies that have been licensed by the Ministry of Health 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 importers of record. Therefore, PhRMA recommends that the Ministry of Health allow importing entities (foreign or domestically owned) to assign storage of their products to approved service providers.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

FINLAND

PhRMA and its member companies operating in Finland remain concerned with the lack of protection for process patent protected products and, in particular, the impact of the implementation of the Finnish Medicines Act (of 2008) on innovative medicines. This Act established a new generic reference pricing scheme and repealed an important amendment to the Finnish Medicines Act (of 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 process patent protected products
- Inadequate intellectual property protection erodes government pricing

For these reasons, PhRMA requests that Finland be maintained on the Watch List for the 2010 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 Finnish Medicines Act (of 2008) came into force on 1 April 2009, and it has 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 does not recognize pharmaceutical product claims filed prior to 1 January 1995. However, Finland did recognize product claims in applications filed after that date. On 1 January 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 1 January 1995, and for which Finland did not accept pharmaceutical product claims;
- Patents, for which applications were filed on or after 1 January 1995, and for which Finland accepted pharmaceutical product claims; and
- Patent applications that were pending from before 1 January 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 1 January 1995 to pharmaceutical product patents, no later than 1 January 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 1 January 1996. Finland, however, did not do so. As a result, PhRMA and its member companies believe that, after data exclusivity 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. That the reversed burden does not apply in any such circumstances has been confirmed in a Court of Appeals proceeding to which the Supreme Court has not granted leave for appeal.⁷⁰

Finland was one of the last (if not the last) countries to accept product patent protection for pharmaceuticals. Therefore, most of the top-selling products on the Finnish market are still protected only with analogous process patents⁷¹.

As a consequence of this inferior patent protection, regulatory reforms, such as mandatory substitution and reference pricing, have had severe adverse effects for PhRMA member companies.⁷²

Mandatory generic substitution was introduced in Finland in April 2003. It was soon observed that products protected by analogous process patents (and product patents in most other EU countries) could be subject to mandatory substitution.

This was corrected by an amendment to the Finnish Medicines Act (of 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. On 18 November 2008, the Parliament of Finland passed the Government Bill on the reference price system that removed this amendment, that is: the Finnish Medicines Act (of 2008).

Instead, the approved Finnish Medicines Act (of 2008) extends the mandatory generic substitution and reference price system to products protected by analogous process patents, which should have been excluded from mandatory generic substitution until the expiry of their patent protection by virtue of the amendment of the Medicines Act enforced as of February 2006.

Prior to implementation of the Finnish Medicines Act (of 2008), even though an original product was not eligible for inclusion in the substitution list, and thus in the reference group, it was nevertheless possible for its reimbursement status to be

⁷⁰ Helsinki Court of Appeals' decision No. 1446, in case *Zeneca Inc. and AstraZeneca Oy v. Orion Oyj and Fermion Oy*, 23 May 2008, Docket No. S08/361; Supreme Court Decision No. 2484 of 14 November 2008, Docket No. S2008/581

⁷¹ Sources for patent related information (2008): data from member companies, IMS, National Board of Patents and Registration of Finland and National Agency for medicines (for data exclusivity), compiled by PIF. Source for sales statistic (2008): Pharmaceutical Data Ltd, compiled by PIF.

⁷² Source: Sales statistics company Pharmaceutical Data Ltd, 2010

impacted 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 Act), 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. This practice has been recently applied to products where there is no generic equivalent in the therapeutic area, but simply a generic in a “similar” therapeutic area. A number of currently reimbursed innovative products have lost or are losing reimbursement as this policy is applied.

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

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

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

PhRMA and its member companies encourage the U.S. Government to start a dialogue with the Government of Finland regarding the uneven implementation of the

WTO TRIPS Agreement in Finland and its economic consequences for U.S. pharmaceutical patent holders in the country.

Market Access Barriers

Despite the significant savings realized by the Government through the weakening of IP protections in Finland, very few new and innovative products have been added to the reimbursement list in 2009, further eroding the value of innovative companies' IP protections in Finland. Finnish pharmaceutical prices are some of the lowest in the EU and the current practice of the PPB essentially requires companies to introduce new products at close to the price of generic products in "similar" therapeutic categories to secure reimbursement.

These measures are in addition to the existing PPB's "2-year rule" where products need to be at a base reimbursement level for 2-years prior to being considered for special reimbursement in applicable therapeutic areas. For the moment, health outcomes and pharmacoeconomic data seem to carry little weight with the PPB. Additionally, there is currently no meaningful way for innovators to appeal PPB decisions to a third-party for evaluation of the content or substance, as the High Administrative Court only has jurisdiction over whether the process was followed.

The unfavorable IP and reimbursement environment in Finland has resulted in significant job losses in the pharmaceutical sector and significant restrictions on patient access to new and innovative treatments.

In addition to the request for an IP dialogue, PhRMA and its member companies request the U.S. Government also engage the Government of Finland to discuss the many market access challenges that the innovative industry faces.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

FRANCE

PhRMA and its member companies operating in France are concerned by numerous cost-containment mechanisms impacting pharmaceutical products. Budgetary pressures for pharmaceutical expenditures create an unpredictable environment which, consequently, impacts the return on investment for PhRMA members in France and fails to adequately recognize innovation.

PhRMA is encouraged that the French Government has taken steps to create a better environment for R&D and production in life sciences, especially through the Strategic Council for Health Industries now led by the French President. However, new cost-containment measures targeting research-based pharmaceutical companies (including government price cuts and intensive promotion of generic drugs by the government) have raised concerns regarding the impact of these measures on both French patients and research-based pharmaceutical companies.

Key Issues of Concern:

- The French Government has implemented numerous cost-containment measures, including strong price controls, frequent price and reimbursement cuts, and greater pressure on prescriptions.
- French Government drug evaluations have become increasingly stringent, making it increasingly challenging to prove an adequate level of innovation.
- Increasing pressure by the French Government for the prescription of generic products, sometimes at the expense of patent protection.

For these reasons, PhRMA requests that France be placed on the **Watch List** for the 2010 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Despite a generally positive environment for intellectual property in France, particularly with respect to government efforts to stem the distribution of counterfeit medicines, PhRMA members are concerned by some specific measures and trends that could erode intellectual property protection.

No checking of the intellectual property status by public authorities before approving generic marketing applications.

Passage of the 2004 Social Security Financing Law put in place mechanisms to speed up the entry of generic products into the market. Under that law, the French Agency for the Safety of Health Products (AFSSAPS), which provides marketing approvals, is no longer required to verify patent expiration before authorizing a generic drug. However, the generic manufacturer is required to inform the patent owner when it

applies for marketing approval. Despite this requirement, this notification does not always occur, and there have been situations in which generic manufacturers appeared to use the elimination of the patent verification requirement to introduce products prior to expiration of the innovator's product patent.

In January 2007, the Addendum to the Framework Agreement between the French State and Pharmaceutical Industry set up a process to reinforce patent protection, under the control of the Economic Drug Committee (CEPS). The Committee now warns the brand name manufacturer when it has to examine a pricing file for a product more than six months before the patent ends. It thus provides the brand name manufacturer both the information and the possibility to prepare a court case. The French Government should be urged to enforce these mechanisms.

Market Access Barriers

Unrealistic Healthcare Budgets

The French global healthcare budget is set annually by the Government and the Parliament at unrealistically low levels. As a result, a significant part of the cost of budget overruns is routinely passed on to pharmaceutical manufacturers. This means that PhRMA member companies fund a significant portion of the Social Security deficits. More specifically, for several years, the target for retail drug turnover growth, and now for a large part of hospital products, has been capped at very low levels: 1% for 2005, 2006 and 2007; 1.4% for 2008 and 2009; and return to 1% for 2010. The French MOH has even publicly announced a negative target for drug reimbursement for some years (e.g.: -4% in 2006).

In addition to the foregoing, the French Government maintains a turnover tax from 0.6 to 1 percent, despite the fact that the tax was considered "exceptional" in 2005.

Finally, the French Government regularly employs additional cost-containment measures to fill its "ambitious" objectives within now traditional mid-year saving plans, including price cuts for products with high sales. The French Health Minister has also asked the CEPS to pursue a system of "Dynamic Price Management" for certain therapeutic categories. This will mean government-imposed price cuts on products that are currently on the market for a few years upon generic entry in their therapeutic group.

As a consequence of these multiple pressures, the growth of the reimbursed retail pharmaceutical market in France was only 0.9% in 2006, 3.6 % in 2007 and 1% in 2008.⁷³ This is inadequate for a dynamic, innovative and high-value industry.

Industries operating in France are also particularly concerned about the ability of the French Health Body (HAS) to release medico-economic guidelines. This disposition, adopted in the Social Security Financing Bill for 2008 and now under implementation

⁷³ DREES - «Dépenses de médicaments remboursables en 2007 » - May 2008

(starting with statins) threatens to reinforce budgetary considerations, as opposed to medical ones.

Government Price Controls

Government imposed price controls fail to recognize and reward innovation, in turn eroding intellectual property protections for pharmaceutical products. In France, prices of reimbursed pharmaceuticals are decided by the CEPS after negotiations with individual companies. To be reimbursed by the national health insurance fund, reimbursement status must be granted by the Minister of Health and the public sick-funds based on a Transparency Committee (Commission de la Transparence) assessment.

All registered pharmaceuticals are subject to an Evaluation of Therapeutic Benefit (Service Médical Rendu, or SMR), which drives the level of public reimbursement. In parallel, Therapeutic Benefit Improvement (Amélioration du Service Médical Rendu, or ASMR) serves as a basis for individual company negotiations with the CEPS. The Transparency Committee assesses the efficacy and the safety of a product. This evaluation is based on the judgment of experts and is exclusively based on clinical criteria. While this evaluation is rarely contested, innovative pharmaceutical manufacturers often dispute the ASMR classification made as a result of the data analysis. PhRMA believes that this evaluation has become more and more restrictive and unpredictable; making it more difficult to ensure that innovation is recognized.

Only a limited number of patented pharmaceutical products fall under the most favorable ASMRs, with most products falling instead under the ASMR IV or V categories. Medicines receiving the ASMR I, II, and now III, or even ASMR IV (under certain conditions), can benefit from a fast-track procedure, and the first three categories have the potential to get a European average price and to maintain it for five years. PhRMA member companies believe that this process should be extended beyond five years to ensure an adequate return on investment for innovative products.

While the details remain unclear, the request by the French Government to CEPS to introduce Dynamic Price Management to certain therapeutic categories is an issue of serious concern for innovative pharmaceutical manufacturers. Although the Health Minister has stated that there will be no “jumbo group” reference pricing in France, and despite the fact that the current system is much more targeted, a system that ties prices of innovative products to those of generics would constitute movement towards government reference pricing for products still under patent. Therapeutic reference pricing would undermine the value of the intellectual property of innovative pharmaceutical companies.

Additional Market Access Hurdles

The national sick funds at times have imposed reduction targets for some drug categories (e.g.: antibiotics, statins, anxiolytics, proton pump inhibitors) without clear scientific bases. In many cases, this may pose a direct threat to human health, particularly in areas where a large cross section of society may gain a preventative health benefit from access to medicines. Statins are an important example of this. Volume constraints should be based on medically justifiable quantities (number of patients eligible to be treated for approved indications) and not on financially affordable quantities.

Moreover, since 2009, individual prescription contracts can be signed between public sick funds and doctors leading to financial bonuses. This will lead to significant pressures on some prescriptions and could be particularly harmful for recent and patented products. These contracts have been launched in 2009 and have already attracted nearly 10,000 physicians.

In addition, in the past few years, the French Government has set up measures to help the development of the generic market, including incentives on margins for pharmacists and rewards for reaching substitution targets. These measures are no longer necessary and continue to create an unbalanced situation that is unfavorable to patented products.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

HUNGARY

PhRMA and its member companies operating in Hungary are concerned about a variety of severe cost-containment measures that make Hungary a highly challenging environment for pharmaceutical investment, undermine the value of PhRMA member companies' intellectual property and deny U.S. intellectual property right holders adequate access to the Hungarian market.

Key Issues of Concern:

- slow implementation of data protection
- undue tax burdens

For these reasons, PhRMA requests that Hungary remain on the Special 301 **Watch List** for 2010.

Intellectual Property Protection

Data Protection

Hungary was required to provide innovative pharmaceuticals the European "8/2/1" term of data protection prior to its 2004 accession. The legislation in Hungary to establish this protection was finally published in 2009. PhRMA encourages the U.S. 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:

- 12% tax on all reimbursed products;
- A claw-back system under which growing companies will become financially accountable for all of the overspending in the retail pharmaceutical budget;
- A sales representative tax of approximately USD \$25,000 per year, per representative;
- Three-year, non-transparent reimbursement-volume contracts designed to reduce volumes regardless of the real (epidemiology based) patient demand;
- Prolonging the 90 day process of reimbursement approvals for new-in-class products, reimbursement adjustments on therapeutic or other changes, and

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.

- Lack of clear use of pharmaco-economic data;
- Restrictions on reimbursement, limiting the number of indications, the number of centers, and specific prescribers;
- Quarterly government reference pricing with de-listing (electronic bidding system) for Type 1 (generic) and Type 2 (so-called "jumbo") reimbursement groups;
- Non-transparent formulation of Type 2 reference pricing groups;
- Cross-country referencing that incorporates the lowest European price at launch; and
- Prescription directive for physicians.

Hungary's health care budget-cutting efforts do not appear to be sustainable in the long run and are ultimately detrimental to its patients. First, 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 containing very strong incentives for 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.

The only positive, fairly significant measure is the introduction of a R&D tax incentive in mid 2009. From the taxes listed above, pharmaceutical companies are granted a maximum 20% tax break based on their total R&D spending in 2009.

As of 2010, this tax incentive has been increased to 100%. Thus, as of 2010 every pharmaceutical producer will have the opportunity to exempt its R&D expenditures in Hungary from the Sales Representative Tax and the 12% additional reimbursement tax, up to 100% of these taxes.

There is, however, an entry threshold, which is rather high (especially for multinationals). The tax incentive may only be taken advantage of if the pharmaceutical producer spends an amount on R&D in Hungary which is equal to at a minimum, 20% of the reimbursement amounts paid out by the state to its residents.

PhRMA is very concerned by legislation approved by the Hungarian Parliament on December 14, 2009. According to this legislation, innovative pharmaceutical

products, even following a positive evaluation by Hungary's health technology assessment body, might not be placed on Hungary's reimbursement list unless the manufacturers agree to outcome and/or patient compliance-based agreements for the specific product. It is unclear how these agreements will be developed, implemented, and tracked, and how they will impact the Government's reimbursement decisions. PhRMA believes that requiring such agreements further impedes market access for innovative pharmaceutical products in Hungary.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

THE NETHERLANDS

PhRMA and its member companies operating in The Netherlands are concerned that the Dutch authorities have maintained existing and introduced additional measures that discriminate against innovative pharmaceutical products. These policies deny fair and equitable market access to U.S. interests that rely on intellectual property protections in the Dutch market.

Key Issues of Concern:

- **Slower Reimbursement of Innovative Pharmaceuticals:** The duration of the reimbursement procedure for innovative pharmaceuticals is increasing, particularly the assessment of therapeutic superiority which is substantially longer than the 90 days outlined in the EU Transparency Directive;
- **Additional Hurdles for Innovative Products:** Innovative products face difficulty getting full reimbursement for all registered indications. Increasingly, limitations/restrictions in use have been implemented;
- **Slow Access to Expensive Hospital Drugs:** The special regulation for expensive hospital drugs through which hospitals receive financial compensation of 80% of net drug costs is not meeting its goal of rapid access because of delays in the listing process;
- **Market Uncertainty:** In September 2007, the Government, pharmaceutical companies, and a wide range of other stakeholders agreed on a Transitional Agreement on Pharmaceutical Care 2008-2009 (TAPC). This agreement contained a government pledge to reduce some aspects of price regulation, while retaining certain cost-containment measures, including reference pricing, as part of the system. PhRMA member companies are concerned that when the TAPC expires at the end of 2009, the MOH may not continue these commitments;
- **Downward Pressure on Prices:** One issue of increasing concern in the Netherlands and other European countries that reference the United Kingdom (UK) is the effect of exchange rates on pharmaceutical prices. This is in combination with other cost-containment measures that the Government has instituted.

For these reasons, PhRMA requests that The Netherlands be placed on the **Watch List** for the 2010 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

Reimbursement of Pharmaceuticals

Two pharmaceutical government price control systems are in place in the Netherlands: the GVS (Geneesmiddelen Vergoedings Systeem) and the WGP (Wet Geneesmiddelen Prijzen). The GVS reference price system introduced in 1991 sets fixed reimbursement ceilings for generic and innovative medicines regarded as being equivalent. The GVS has helped to limit Dutch pharmaceutical costs, but has also contributed to high generic prices and slow access for Dutch patient to new medicines.

New medicines that are assessed to have therapeutic superiority are listed separately in the GVS system, and may be permitted a price premium. These medicines account for approximately one-third of all outpatient pharmaceutical use by value.⁷⁴ Health economic studies are mandatory in the reimbursement decision process and for high-cost medicines used in hospitals.

Additional Hurdles for Innovative Products

Innovative products face difficulty getting full reimbursement for all registered indications. Increasingly limitations/restrictions in use are implemented. This is a major hurdle for fast uptake of new products. Physician guidelines often are out of date with little room for prescribing innovative medicines.

Slow Access to Hospital Drugs

In 2002, the Dutch Health Authority introduced a special regulation for expensive hospital drugs pursuant to which hospitals receive financial compensation up to 80% of net drug costs. In 2006, the regulation was adapted and includes conditions for temporary financial compensation such as a minimum total turnover of each drug per indication and collection of data on real world utilization, effectiveness and cost effectiveness with a reassessment after three years.

The 1996 Medicines Pricing Act introduced further controls (the WGP system). This sets the maximum pharmacy purchase price of medicines in The Netherlands. Dutch pharmacy purchase prices are based on the averages of prices in Belgium, France, Germany and the UK.

In 2005, health insurance companies started with preference policies for two classes, namely statins and omeprazoles.

Market Uncertainty

⁷⁴ Ministry of Health and Sports 2009

In September 2007, the Government, pharmaceutical companies, and a wide range of other stakeholders agreed on a Transitional Agreement on Pharmaceutical Care 2008-2009 (TAPC). The TAPC aimed at reducing government regulation and bureaucracy regarding pharmaceutical pricing and reimbursement. The Agreement contains a government pledge to reduce some aspects of price regulation, while retaining certain cost-containment measures, including reference pricing, as part of the system. PhRMA member companies are concerned that when the TAPC terminates at the end of 2009, the MOH might not continue to address these measures, including reference pricing.

The savings which followed from the TAPC were the following:

	<u>Agreed</u>	<u>Realized</u>
2004:	€ 622mio	€ 576mio
2005:	€ 685mio	€ 691mio
2006:	€ 843mio	€ 879mio
2007:	€ 971mio	€ 1.300mio
2008:	€ 1.311mio	€ 1.600mio
2009:	€ 1.427mio	€ 1.427mio

Source: Ministry of Health and Sports 2009

Government Pricing

As mentioned above, the maximum pharmacy purchase price of medicines in the Netherlands is set by the Medicines Pricing Act (WGP). Dutch maximum wholesale prices are based on the average of prices in Belgium, France, Germany and the UK.

Under the TAPC, Dutch pharmaceutical companies may not increase the government price of existing pharmaceutical products, with some exceptions allowed. When a patent expires for a pharmaceutical product (provided that generic equivalents have been introduced in the Dutch market), there will be a list-price reduction (either of that product or of other products as long as it provides the same savings). Effective in 2008, the average price of the existing off-patent products would decrease by at least 10% and for new multi-source products (with generic versions on the market) by at least 50%.

Under the TAPC, the Government undertook (1) not to implement the proposed measures regarding reductions of the reimbursement prices (i.e., they would not implement therapeutic reference pricing), (2) to refrain from extending the WGP to injectables and infusion products, and (3) not to apply any new or strengthen any existing regulations regarding new pharmaceutical products. The TAPC expired at the end of 2009; meanwhile the Government has announced that the WGP will be extended to at least a portion of injectable and infusion products.

In January 2008, the Government indicated that, after the expiration of the current TAPC, it would abolish reimbursement limits on pharmaceutical product clusters, thus opening the way for free price negotiations between individual pharmaceutical companies and insurers. Product clusters will be retained for negotiating purposes. It is critical for PhRMA member companies that innovative products are guaranteed their own separate categories.

One issue that is of increasing concern in The Netherlands and other European countries, which reference the United Kingdom (UK), is the effect of exchange rates on pharmaceutical prices. Due to the decline in value of the UK pound (GBP), government prices in the Netherlands are effectively being reduced, simply because the GBP to Euro rate is decreasing.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

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 the same as drugs covered by product patents in Norway.

Key Issues of Concern:

- Lack of adequate product patent protection

For this reason, PhRMA requests that Norway remain on the **Watch List** for the 2010 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

Norway has provided for compound patents for pharmaceutical products since 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. These products are believed to account for nearly half of the products on the current Norwegian market. This old legislation places Norway well behind the overwhelming majority of developed countries in terms of intellectual property protection.

In the 2009 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 before 1995. 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 2009 attributable to trade barriers related to intellectual property protection and market access.

LATIN AMERICA

COLOMBIA

PhRMA and its member companies operating in Colombia remain concerned that Colombia's enforcement of IP rights is diminishing and new risks threaten ongoing protection. Therefore, PhRMA and its member companies recommend that Colombia be included on the **Watch List** and that the U.S. Government continue to engage on these issues to ensure that the problems described herein are quickly and effectively resolved.

Obstacles to obtaining and enforcing patent rights persist. The Colombian Patent Office (CPO) continues to deny patent applications for innovative products (including those corresponding to patents that have been granted in other countries), negatively impacting PhRMA member companies. Additionally, current procedural norms prevent patent-holders from efficiently seeking effective remedies (preliminary injunctions) against infringing products prior to market launch. Also, the current patent application backlog is generating, on average, an unacceptable delay of seven years for pharmaceutical patents.

Trademark rights have also been seriously eroded by Colombia's Regulatory Authority, INVIMA, which has allowed a copy company to use the registered trademark of a PhRMA member company without authorization. This has tarnished the image of the trademark as well as the company, and allowed the copy company to take unfair commercial advantage of the trademark's reputation.

Intellectual Property Protection

Patent Linkage

PhRMA's member companies continue to be detrimentally affected by the Government's failure to provide a patent linkage mechanism. Such a mechanism would remedy the situation which currently prevents a titleholder from seeking effective enforcement of its patent prior to the commercial launch of a potentially infringing product. With an efficient linkage 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 investments, that may eventually be declared infringing after market launch. To date, patent owners, proceeding diligently 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 are: (i) lack of adequate notice regarding the impending approval by the INVIMA of a potentially infringing product; (ii) lack of legal standing to pursue infringement based solely on a health registration or an application; and (iii) lack of a time period during which market approval is automatically suspended until the patent infringement issue is adjudicated.

Colombian court procedures do not provide adequate due process guarantees to effectively litigate patent enforcement. Additionally, litigation delays can be unreasonably long, with decisions in these types of cases often taking more than eight years. Simply put, if a preliminary injunction is not granted, a patent-holder must stand by idly for almost a decade until a decision is handed down. Colombia has a number of solutions at hand which it could implement to solve these problems, for example, the model of an autonomous intellectual property court. This type of model could be a starting point to offer effective, expeditious and competent adjudication mechanisms for patent infringement issues.

Patents for Improvements of Known Molecules (e.g., polymorphs, isomers)

PhRMA continues to be very concerned that the Colombian Patent Office (CPO) continues to apply standards for patentable inventions that make it unjustifiably difficult to obtain patents for improvements in Colombia, which are otherwise patentable in the rest of the world. In the past four years, the CPO has been consistently applying 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, which appears to single out the research-based pharmaceutical companies. These standards may constitute a technical sector-specific protectionist barrier, as they clearly benefit the local generic industry. This would violate Article 27 of the TRIPS Agreement, which prevents WTO Members 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 13 August 2009), reversing a Patent Office determination denying the patentability of a polymorph case, this decision comes 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.

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 to deny second use patents and honor Andean Community obligations, or ignore their TRIPS obligations. The failure to provide patents for second uses particularly affects PhRMA's members, who make significant research investments to evaluate 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.

Patents for Biotechnology

Article 15 of Andean Community Decision 486 excludes a great part of all biotech innovation from patent protection, 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 exclusion is a violation of TRIPS Article 27 as it is not one of the acceptable exceptions to patentability.

Unreasonable Delays in Patent Grant

Delays in patent prosecution are serious. On average, pharmaceutical patent applications suffer up to a nine year delay before a first instance decision is taken, and until late 2006, there was an upward trend. In an effort to reverse this, 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 has yet to take 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, the possibility has been prohibited by recent modifications to the Andean IP Decision, which expressly exclude pharmaceutical patents from any possibility to obtain term restoration.

Trademarks

Colombia's Regulatory Authority, INVIMA, issued in 2003 an authorization allowing 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 owner 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 internal law. To date, this case have 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

Regulatory Delays

Colombian regulatory law and practice require the Colombian health regulatory agency, INVIMA, to review clinical studies regarding the safety and efficacy of a new molecule before it can be authorized for marketing. In the majority of cases, INVIMA is satisfied with a review of the clinical studies generated and submitted by the applicant. INVIMA has significantly increased the average delay in approving new medications by increasing the frequency of times it has required the presentation of published articles. During 2007, INVIMA requested published studies in 33 percent of all applications submitted during the year (three out of nine).⁷⁵

² INVIMA Medicament Review Commission

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 may discriminate against patented pharmaceutical products. Pursuant to the policy established in Circular No. 04, all medicines must be classified in one of the following three regimes established by Law 81 of 1988: (i) Supervised Freedom Regime; (ii) Regulated Freedom Regime; or (iii) Direct Control Regime.

The National Commission on Pricing of Medications fixes the maximum public sale price of the medicines included in the Direct Control Regime, according to the reference price obtained as an average of the three lowest prices of at least four of the following reference countries: Colombia, Argentina, Brazil, Chile, Colombia, Ecuador, Mexico, Panama, Peru and Venezuela.

Public messages delivered by the Government of Colombia suggest that the government price control measures were implemented as a counterbalance to IP provisions like the ones established in Decree 2085 and those envisioned in future CTPA obligations. Beyond simply creating a business climate that deteriorates competitiveness, these measures serve to undercut the underpinnings of an effective IP system.

PhRMA member companies are closely monitoring the expected implementation of Circular 04, as further regulation is required for defining its scope and impact on market access for pharmaceuticals. Improper implementation and a lack of transparency in both the implementation and application of Circular 04 could negatively impact PhRMA's member companies.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

COSTA RICA

PhRMA and its member companies operating in Costa Rica remain concerned that Costa Rica's obligations under the CAFTA-DR have still not been implemented. Considering the facts expressed in this paper and experiences in Costa Rica, during which effective implementation of patent and test data protection have been delayed, PhRMA recommends that Costa Rica remain on the **Watch List**.

Intellectual Property Protection

Data Protection

The "Undisclosed Information Law" ("the Law") still contains exceptions or limitations that are inconsistent with the TRIPS Agreement or the CAFTA-DR. For example, the Law allows for disclosure of clinical test data under situations and/or conditions which are not consistent with obligations in those Agreements. Furthermore, there is an absence of a period of at least 5 years of data protection and the definition of a new chemical entity is unduly restrictive.

Patent Linkage

Although the amendments to the Patent Law introduced Patent Linkage, the law's text is limited to reproducing the CAFTA-DR linkage provision without providing details for effective implementation. To date, Costa Rica has not introduced a linkage system which implements the Agreement.

Patent Issues

CAFTA-DR allows countries to revoke or cancel a patent only under specified circumstances, none of which includes failure to work the patent locally. Nonetheless, amended Article 18 of Law No. 6,867, which requires patent holders to "work" the patented invention in Costa Rica either by local production or by importation, establishes that if the patented invention is not worked sufficiently within the specified periods, competitors may request a compulsory license to work the invention and that the patent may be cancelled. The wording of amended Article 18 establishes terms that evidently will enable cancellation of pharmaceutical patents in Costa Rica, and fails to take into consideration the inability of pharmaceutical companies to "work" a patent without corresponding market approval.

Patent Backlog

The Intellectual Property Registry has not improved its capabilities regarding patent procedures, and serious delays in patent examination continue to concern PhRMA's member companies. As of 2009, more than 1000 filings for patents and utility models remain pending.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

DOMINICAN REPUBLIC

PhRMA and its member companies operating in the Dominican Republic continue to face a difficult commercial 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" (the Agreement entered into force in March 2007). However, internal regulations, which must be adopted for the Dominican Republic to comply with test data protection and patent linkage 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.

In light of these developments, PhRMA recommends that the Dominican Republic remain on the **Watch List** for the 2010 Special 301 Report due to its failure to effectively protect IP rights.

Intellectual Property Protection

Pending Regulations for Implementation of CAFTA-DR Test Data and Linkage Provisions

Among other matters, Chapter 15 of the CAFTA-DR and Dominican Law 424-06 for the Implementation of CAFTA-DR provides for the protection of pharmaceutical test data from unfair commercial use, as well as prohibiting health authorities (for example, the Secretary of Health) from granting regulatory approvals for the sale of pharmaceuticals subject to patent protection through a "linkage" mechanism. Nevertheless, the implementation of test data protection and the "linkage" provisions are still pending because Dominican authorities have not issued the necessary regulations for application of these provisions.

Fulfillment of the commitments agreed in the CAFTA-DR is increasingly important for the protection of IP rights. For example, under the current legal framework in the Dominican Republic, patent infringement cases constitute civil infractions subject to insignificant monetary compensation. This fails to adequately address violations of patent rights.

Patent Term Restoration and Patent Backlog

Although provisions for patent term restoration (PTR) entered into Dominican law on March 1, 2008, the first application did not occur until November 2009. This is the case despite the existence of a significant and persistent backlog in the issuance of patent certificates by the National Office of Industrial Property ("ONAPI").

Currently, there are 976 patent applications pending at ONAPI; out of which 698 are pharmaceutical patent applications.⁷⁶ In 2009, only one pharmaceutical patent was issued. It should be noted that a new General Director was appointed in the past six months, and we look forward to improvements being made in the system in the year to come.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

⁷⁶ In accordance with certification issued by ONAPI's Office of Access to Public Information on December 14, 2009.

EL SALVADOR

PhRMA and its member companies recommend that El Salvador be included on the **Watch List** 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 and Patent Linkage

On July 7, 2008, El Salvador's Ministry of Health issued Decree No. 65, which contains the "Regulation for Test Data Exclusivity of New Pharmaceutical Products." The approval of Decree 65 in December 2008 was considered an important advance toward express recognition of test data protection and patent linkage.

Although the Health Regulatory Agency (Consejo Superior de Salud Pública – CSSP) has taken steps to grant and apply data protection, operational and other limitations at the CSSP jeopardize effective enforcement. In addition, the decree contains confusing language on the scope of protection, resulting in restrictive coverage.

At present, the Patent Data Base for purposes of patent linkage has yet to be completed. Although Decree 65 mandates the CSSP to provide such a data base, the CSSP has been reluctant to do it, arguing that such a data base should be established by the Salvadorian Patent Office (CNR). Without the data base, there is no effective way to implement patent linkage at the CSSP level; which deprives PhRMA member companies the protections detailed in the CAFTA-DR Agreement.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

HONDURAS

PhRMA and its member companies operating in Honduras remain concerned that despite offers by the Honduran Government (prior to the current political situation in Honduras) to develop implementing and clarifying regulations for test data protection and patent linkage, it has not done so as of December 2009. In 2008, draft regulations on such matters were made publicly available for consultation. However, one year later, the Government has failed to produce implementing regulations.

PhRMA members strongly recommend that Honduras be included on the **Watch List** 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 and Patent Linkage

Despite repeated efforts by PhRMA member companies to discuss test data protection and patent linkage implementation with Honduran health authorities and with the Industry and Commerce Ministry, no progress has been made through 2009 toward effective implementation of these matters. After publication of draft regulations, no further action has been taken by the Honduran Government. Because the process, as of December 2009, has not resulted in revised draft regulations that would (i) address current deficiencies and (ii) orient the regulatory agency responsibilities, both regarding test data protection and patent linkage, PhRMA and its member companies recommend that Honduras be included within the Watch List.

Limited coordination between the Industry and Commerce Ministry and the Health Ministry regarding the CAFTA-DR implementation process is evident. Meanwhile, a lack of information at the Health Ministry on its obligations under the treaty, in addition to the presence of confusing and technically limited language in the implementing legislation, generate great uncertainty regarding data protection.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

MEXICO

PhRMA and its member companies operating in Mexico note that Mexico's continued efforts to improve intellectual property (IP) standards have been emphatically confirmed during unprecedented bilateral meetings held in 2009 between heads of the most relevant government agencies and senior representatives of PhRMA and member companies. These unprecedented high level discussions underscore the strong commitment of the Mexican Government to listen to and address the concerns of the innovative pharmaceutical sector. For example, for the first time since the enactment of NAFTA and TRIPS, Mexico engaged in a serious analysis of possible reforms to more effectively implement data protection for dossiers of innovative pharmaceutical products. Preserving these meetings will be the driver for additional important improvements in 2010. Moreover, on a different important IP front, unprecedented Mexican Government actions to contain counterfeit drugs were adopted. In addition, the Mexican Government effectively managed the H1N1 flu pandemic crisis and ensured the health and safety of its people without resorting to compulsory licenses despite considerable pressure to do so.

Key Issues of Concern:

- Inconsistent implementation of the patent Linkage Decree continues to undermine the Decree's objectives;
- Despite IMPI's laudable decisions on patent infringement cases, the Mexican IP system is not effectively enforcing patent rights in a reasonable manner; and
- Increasingly, unreasonable anti-IP bills are considered in Congress, which threaten current IP standards.
- Concerning Data Protection implementation

For these reasons, PhRMA recommends that Mexico remain on the **Watch List** pending favorable Data Protection reform, a definitive solution to patent linkage problems and determined actions to improve the IP system in a way that is strongly supportive of innovation.

Intellectual Property Protection

Patent Linkage

PhRMA member companies recognize COFEPRIS' efforts in 2009 to revoke approvals for copies of several patented products that were previously approved in violation of patent linkage provisions. However, the application of the Linkage Decree remains a concern for patent holders because:

1. Despite overwhelming court precedents ordering the listing of a broad range of patents related to medicines, such as formulation and use type patents in addition to those for active ingredients, the interpretation of the Linkage Decree by IMPI and COFEPRIS remains a concern for patentees. The failure to provide linkage for these types of patents requires patentees to pursue lengthy and costly litigation to ensure their patents are protected from improperly registered copy products;
2. Special concern exists with regard to COFEPRIS' approval of copies of products for which patents are listed in the linkage gazette. The Linkage system objective is to prevent patent infringement and without adequate implementation, patentee's rights are vulnerable and can be irreparably damaged.

Both of Mexico's NAFTA partners apply linkage in connection with product, formulation and use patents. It would therefore be inappropriate for Mexico to restrict its linkage regulation to only patents on active chemical substances. Furthermore, the intent of the linkage system is to prevent the granting of marketing approvals to generic or copy pharmaceuticals whenever there is a patent right related to a specific product until patent disputes can be resolved.

An inter-ministerial working group on linkage should be promptly convened as this issue is of great significance to PhRMA's member companies. PhRMA encourages the inter-ministerial working group to reach uniform criteria consistent with court precedents ordering the listing of use and formulation patents in the Linkage gazette.

Data Protection

The Mexican Government's commitment to analyze the need for data protection reform is deeply appreciated. PhRMA's member companies encourage the Mexican authorities to evaluate developed data protection systems and replicate in Mexico practices from advanced models that may provide good references as a result of their evolution.

Mexico should take conclusive actions towards reforming data protection in a manner that guarantees alignment with NAFTA and meets its TRIPS obligations. Prompt conclusion of those actions still under development is anticipated by PhRMA members.

Counterfeit Drugs

PhRMA members recognize important achievements on the anti-counterfeiting front this year resulting in unprecedented closure of pharmacies selling counterfeit medicines, under coordinated efforts of COFEPRIS, IMPI, PGR and PFP.

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

IP Enforcement

PhRMA members encourage IMPI to expedite patent infringement proceedings; use all available legal mechanisms to enforce its decisions and effectively prevent infringers from persistent violation of IP rights; and implement all necessary actions to guarantee effective preliminary injunctions. Persistent violations of pharmaceutical patent rights cause irreparable damage to patentees.

Anti - IP Congress Bills

PhRMA members reported this year the growing threats against IP rights resulting from Congressional bills of reforms to the IP Law, which aim to diminish IP rights important to pharmaceutical innovation. PhRMA members and the executive branch of the Mexican Government should partner to protect the IP system from unreasonable bills of reforms and inform congressmen on the importance of maintaining a legislative environment respectful of innovation. PhRMA members are especially concerned regarding an amendment relating to pre-grant patent opposition currently under discussion at the Senate and look forward to continued engagement with the Government on this proposal.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

NICARAGUA

PhRMA and its member companies operating in Nicaragua are concerned that the Nicaraguan Government has failed in 2009 to implement its data protection and patent linkage commitments. Though the health authorities have shown some level of awareness of the CAFTA-DR obligations on these topics, they have not yet implemented regulations to comply with these obligations.

PhRMA members recommend that Nicaragua be placed on the Special 301 **Watch List** in 2010 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 and Patent Linkage

Since 2006, PhRMA member companies have requested that the Nicaraguan health authorities explain how test data protection and patent linkage will be enforced, but have received no meaningful response. Further, the Ministry of Industry and Trade has not coordinated implementation with the Health Authorities.

As of the date these comments were prepared, no draft proposal for effective enforcement of patent linkage or test data protection were known to exist.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

PANAMA

PhRMA member companies operating in Panama face a difficult commercial climate due to the Panamanian Government's failure to provide adequate intellectual property (IP) protection. PhRMA recommends that Panama be placed on the Special 301 **Watch List** in 2010 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

Data protection was provided for through a presidential decree in 2003. However, implementation of test data protection is still pending because Panamanian authorities have not issued the necessary regulations for application of the decree.

Patent Linkage

Panama does not provide any link between the patent system and the system for approving the marketing of pharmaceutical products, including generics and other kinds of copies.

Other Issues

In October 2009, a regulation was approved by the Panamanian Ministry of Health that eliminates the need to submit bioequivalency studies to obtain an interchangeability certificate, which is a prerequisite for participation in Social Security tenders. The regulation applies to more than forty active ingredients. Until this regulation went into effect, Panama had been a model country in the region regarding drug quality and safety requirements. However, this change increases the possibility of counterfeit and otherwise harmful products entering Panama.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

PERU

PhRMA and its member companies operating in Peru are concerned with the current state of intellectual property protection in Peru. PhRMA recommends that Peru be placed on the Special 301 **Watch List** in 2010 and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

The U.S. – Peru Trade Promotion Agreement (USPTPA or TPA Agreement), which entered into force in February 2009, sets out obligations to protect pharmaceutical test and other data and to provide for an intellectual property enforcement framework. Although PhRMA and its members do not consider the USPTPA and its Peruvian implementation a model for future trade negotiations, PhRMA supports close monitoring and enforcement of implementing regulations.

PhRMA has noted and raised to both the Peruvian and U.S. Governments the failure by the Peruvian Government to provide data protection for all pharmaceutical products. This is most apparent in Peru's discriminatory regulations that exclude biotechnological pharmaceuticals from data protection.

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 an additional four years on average and discourages patent owners from enforcing their patents.

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 to deny second use patents and honor Andean Community obligations, or ignore their TRIPS obligations. The failure to provide patents for second uses particularly affects pharmaceutical companies, who make significant investments to evaluate 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.

Data Protection

The Government of Peru still fails to protect undisclosed pharmaceutical test and other data as required by the TRIPS Agreement. Article 16.10 of the USPTPA requires Peru to prevent reliance on safety and efficacy information related to pharmaceutical products for a “Reasonable period”, defined in the TPA Agreement as normally five years whether the information is submitted to Peruvian officials or submitted to officials in other countries upon whose approval Peruvian officials rely.

Peru has approved Legislative Decree 1072 and Supreme Decree 02-2009-SA, providing for 5 years of data protection. Nevertheless, the following deficiencies remain a concern:

- Exclusion by the Government of Peru of biotechnological pharmaceuticals as products eligible for data protection. DIGEMID does not grant data protection to biotechnological pharmaceuticals. Its theory is the USPTPA does not obligate the parties to protect these kinds of products because, according to its interpretation; they do not contain chemical entities. This is a false distinction from both technical and legal perspectives. PhRMA believes that excluding products of biological origin from the scope of data protection violates the obligation contained in Article 16.10 of the USPTPA, as well as LD 1072 and its implementing regulation. Biotechnological pharmaceutical products also require safety and efficacy studies and, as such, merit test data protection, as for non-biotechnological pharmaceuticals.
- DIGEMID has approved a Sanitary Registration Form that encloses an affidavit of non-disclosure of the data on the safety and efficacy of the product. If the affidavit is not executed, no protection will be granted. Months ago, officials had orally warned that no protection will be granted if a single part, abstract or conclusion of the studies is disclosed. Fortunately, the health authority stated more recently that as long as a single piece of information is still undisclosed, it will protect the product for the 5-year period. Nevertheless, uncertainty remains, and PhRMA requests that the U.S. Government closely monitor this implementation issue.

Market Access Barriers

The Government of Peru is not enforcing the requirement that a parallel importer comply with the same sanitary regulations as the title-holder of the sanitary registration for an innovative pharmaceutical product. This practice is both dangerous to public health and discriminates against U.S. manufacturers of innovative pharmaceutical products covered by patents.

The Government of Peru discriminates against foreign manufacturers by granting a 20% bonus, or bidding preference, to domestic manufacturers participating in a public

“competitive” bidding process. This benefit, granted to companies offering goods manufactured in Peru, discriminates against foreign manufacturers and fails to satisfy the Andean Trade Preference Act eligibility requirement that beneficiaries ensure the “application of transparent and non-discriminating policies in government procurement.”

Additionally, Law 29459 (Pharmaceutical Products’ Law), which was recently enacted, discriminates against imported pharmaceuticals by providing that the quality testing of a recently approved or renewed pharmaceutical product has to be performed in Peru.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

MIDDLE EAST

SAUDI ARABIA

PhRMA and its member companies operating in Saudi Arabia are encouraged by the signing of a Royal decree on Exclusive Marketing Rights (EMR). Once implemented, this decree is expected to resolve outstanding patent protection concerns for a limited number of pharmaceutical products not covered by the 2004 patent law. PhRMA congratulates the Saudi Government for taking this important step.

PhRMA also greatly appreciates initial indications that the Saudi Government is committed to properly enforcing strong data protection for pharmaceutical test data. PhRMA and its member companies are committed to working with the Kingdom of Saudi Arabia to ensure proper enforcement of this important WTO commitment.

As an indication of PhRMA's recognition of improved intellectual property enforcement, PhRMA members request that Saudi Arabia be placed on the **Watch List** for the 2010 Special 301 Report. In addition, since PhRMA recognizes that the Saudi Government will continue to make advances in intellectual property (IP) protection in 2010, specifically related to data protection, PhRMA encourages the U.S. Government to undertake an Out of Cycle Review of Saudi Arabia, prior to the 2011 Special 301 Report. This would ensure immediate recognition of further improvements to pharmaceutical IP protection in Saudi Arabia.

Intellectual Property Protection

Exclusive Marketing Rights Royal Decree Signed

To remedy the patent protection difficulties that PhRMA members are facing in Saudi Arabia, Saudi authorities signed a Royal Decree that would grant transitional protection to a limited number of pharmaceutical products caught between the pre-2004 and new Saudi patent systems. In principle, the EMR would provide for those products exclusive marketing and manufacturing rights until the U.S. patent on the product expires.

The General Directorate of Industrial Property of KACST had started to accept applications for protection under EMR. Member companies are awaiting responses from KACST.

PhRMA would like to thank the U.S. Government (USTR, Department of Commerce, Department of State, and the U.S. Embassy in Riyadh) for its tireless work on the EMR agreement.

Data Protection

Saudi Arabia is not enforcing its regulations to protect against unfair commercial use of undisclosed test and other data submitted to obtain the approval of a

pharmaceutical product. PhRMA members are troubled by the registration of unauthorized copies of innovative and patented pharmaceutical products.

PhRMA member companies are concerned by the authorities failure to provide effective data exclusivity for a period of at least five years from the date of marketing authorization of the innovator product in Saudi Arabia. SFDA should enforce Article 5 of a Council of Ministers' Trade Secrets Protection Regulation (decision number 50, dated 25/2/1426 H, April 4, 2005). Pursuant to Article 5, the submission of undisclosed test or other data, obtained as a result of substantial efforts, needed for marketing approval of drugs or agricultural products, shall be protected by the competent authority against unfair commercial use for at least five years from the approval date.

The Kingdom of Saudi Arabia has not shown compliance with its regulations (and WTO commitments). Under its protocol of Accession to the WTO, authorities acknowledged that "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 data protection regulations. Authorities insist they are not sharing the content of the drug registration file of the innovator product. However, they may be relying on the data of innovator drugs to approve local copies. An effective system of pharmaceutical data protection requires "non-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. Saudi regulatory authorities should keep generic copies of pioneer drugs off the market during the period of data exclusivity. In the absence of a registered patent, a copy may, of course, 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.

In 2009, PhRMA sponsored a day-long training program focused on pharmaceutical data protection. USPTO and a representative from the EU participated in the event. Officials from the Saudi Food and Drug Agency and the Ministries of Economy and Health also participated in the event.

Market Access Barriers

Volatile Government Pricing Policies

PhRMA member companies are concerned by the volatility of Saudi Arabia's government pricing regime. The Saudi 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 the result of U.S. Government advocacy for Saudi Arabia to live up to its WTO accession commitments.

PhRMA member companies are concerned that the proposed government pricing policy does not focus on market-based principles that promote competitiveness. Instead, it appears to put in place a system for automatic reductions in the prices of 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 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 from 30 referenced countries to 41 countries; (4) Government prices are revised too frequently; (5) the categories of products that are subject to the price cut are unknown, (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 issue of exchange rate is still not resolved.

Since July 2009, the Saudi SFDA has taken over responsibilities from the Ministry of Health. PhRMA hopes that the SFDA will engage with pharmaceutical companies to discuss the real implications of the proposed policy.

Drug Formularies

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

The Saudi Government has established a National Unified Purchase Company (NUPCO) which is expected to procure pharmaceuticals on behalf of all government agencies. In the past, each agency procured its pharmaceuticals independently on the basis of its own formulary. PhRMA has learned that NUPCO is in the process of developing a unified formulary.

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

Regulatory Environment

The registration process for new medicines is lengthy (16-24 months) for several reasons, including, in particular, the central lab requirement that depends on a primary technical approval. In light of the fact that companies cannot submit files until getting such approval, the introduction of new medicines is delayed.

SFDA has also implemented a new fee structure that is exorbitant. New product registration jumped from USD 266 in the old system to 25,000 in the new fee structure. The fee might go up to USD 115,000 for products sourced from the US and requiring site inspection by Saudi officials.

In 2008, the SFDA initiated 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. The framework, not yet implemented by SFDA, would expedite patient access to innovative medication, ensure public safety and develop new modalities to address public hazards. It is also expected to speed up registration to a maximum number of 290 working days. PhRMA looks forward to the implementation of the framework.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2009 attributable to trade barriers related to intellectual property protection and market access.

COUNTRIES OF NOTE
WITHOUT DESIGNATION

GERMANY

PhRMA and its member companies operating in Germany have enthusiastically welcomed the approach that the new German Government has announced regarding the pharmaceutical industry in Germany. Of particular note is the open dialogue on innovation issues, and the strong support expressed in the October 24, 2009, Coalition Agreement. Germany is the cradle of the modern pharmaceutical industry and the new policy direction announced is an encouraging first step in reestablishing and reinforcing Germany's competitiveness as a destination for life sciences investment.

Key Issues Addressed in the Coalition Agreement:

The Coalition Agreement outlines a number of key policy directions that respond to many of the concerns expressed by PhRMA and its member companies in past Special 301 submissions and through direct contact between the German Government, VfA, and the German Local Area Working Group, comprised of pharmaceutical companies operating in Germany.

Initiatives outlined in the Coalition Agreement include:

- Deregulation of the pharmaceutical market to increase competition and efficiency.
- Improved utilization of innovative pharmaceutical products.
- Improvements at the Institute for Quality and Efficiency in Health Care (IQWiG) leading to:
 - A) cost-benefit assessments that are conducted under clear and unambiguous criteria, with greater transparency for patients;
 - B) greater transparency and earlier involvement for stakeholders, including patients, providers and manufacturers. The examination will also review the procedures which IQWiG follows to ensure that the procedures are transparent in order to improve the reception of IQWiG's decisions, not only for patients but also for service providers and manufacturers.
- A renewed commitment to R&D in "future-oriented technologies" including biotechnology.
- Support for preventative health research as an opportunity for expanding overall health care research in Germany.
- Promotion of intellectual property rights by strengthening the legal framework in Germany.
- Proactive efforts to ensure fair market conditions for manufacturers in European and Global markets.

While other outstanding issues remain in the German market, PhRMA sees this new environment as very encouraging and an excellent basis for policy dialogue with the Government. While we encourage the U.S. Government to continue ongoing bilateral discussions on these issues with Germany, PhRMA recommends that Germany not be listed on the 2010 Special 301 for the reasons outlined above. We look forward to working with the new Government and appreciate their willingness to address long-standing industry concerns.