

**PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF
AMERICA (PhRMA)
SPECIAL 301 SUBMISSION 2009**

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PhRMA SPECIAL 301
SUBMISSION 2009
OVERVIEW

PhRMA SPECIAL 301 SUBMISSION 2009 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 biopharmaceutical 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 2004, the Milken Institute released a study entitled Biopharmaceutical Industry Contributions to State and U.S. Economies, which

underscores the importance of advocacy on behalf of one of America's leading edge high-technology industries. According to this study, in 2003 America's biopharmaceutical companies are responsible for creating over 2.7 million jobs across the United States and \$172 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.

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. 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.

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.¹ 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 ingredient.

The World Health Organization defines a "counterfeit medicine" as "one which is deliberately and fraudulently mislabeled with respect to identity and/or source."² 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

¹ The World Health Organization. IMPACT. www.who.org 2008.

² See the World Health Organization definition of "counterfeit medicines" at <http://www.who.int/medicines/services/counterfeit/overview/en>.

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 IMPACT are taking important steps to better understand and address the threat of counterfeits. PhRMA's member companies support the work of IMPACT.

In a recent study, U.S. Customs announced the following statistics on seizures of goods entering the U.S.:

- China is the country of origin for 80% of all counterfeit goods seized while entering the US.³
- Seizures of pharmaceuticals increased more than 100% in domestic value in FY 2008 over FY 2007.
- Pharmaceuticals, the top safety commodity, products seized due to safety concerns, seized in FY 2008, accounted for almost 45% of all safety and security IPR seizures by value.
- India's \$16.2M in seized value makes it the second most significant trading partner by value for IPR seizures.
- Pharmaceuticals accounted for 99% of the total domestic value of IPR seizures from India.

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. 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.

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

³ *Intellectual Property Rights, Seizures and Statistic FY 2008*. U.S. Customs and Boarder Protection Published January 2009.

criminal law enforcement officials, who often lack the expertise, resources and commitment to prosecute such offenses.

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. Moreover, they ignore 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 -- an inexplicable omission that obviously facilitates counterfeiting activity.

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. 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 China and 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. Nor is there any meaningful effort in China or other key source countries to more effectively regulate exports of bulk chemicals and prevent counterfeit medicines, whether at the border or through the Internet.

To address these deficiencies, a comprehensive regulatory and enforcement framework is needed, 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. 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, 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 and undermining sustainable innovation.

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 pharmaceutical industry. The pharmaceutical industry is a cornerstone of America's high-tech economy, and depends on continued innovation and market access for growth.

The biopharmaceutical industry is a major contributor to U.S. economic growth. Activity of the industry encompasses research, development, manufacturing, and more.

- Total economic impact of industry = \$172B⁴
- Total industry exports = \$29B⁵
- Industry expands the U.S. GDP by at least \$27 billion annually, on a permanent basis, for every one-time R&D investment of \$15 billion⁶

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 sales than other industries.⁷ In 2007 alone, the biopharmaceutical industry spent \$58.8

⁴ Milken Institute, "Biopharmaceutical Industry Contributions to State and US Economies" (October 2004).

⁵ U.S. Department of Commerce, Bureau of the Census. Foreign Trade Division, Trade Stats Express, 2008 [Computer File].

⁶ R. Shapiro, et al., Economic Effects of Intellectual Property-Intensive Manufacturing in the United States, July 2007.

⁷ Ibid

billion in discovering and developing new medicines.⁸ In fact, nearly one in five dollars in U.S. sales goes toward R&D.⁹

Although the economic downturn affects 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.

The biopharmaceutical sector comprises an extensive and diverse group of companies that research, develop, and manufacture medicines. These companies range in size from small 10-person firms to large multi-billion dollar, multi-national corporations. According to a study by the Milken Institute¹⁰, together they directly offer more than 400,000 Americans well-paying jobs with benefits. According to the study, total sector employment, including direct, indirect, and induced jobs, was 2.7 million, which means that for each direct job an additional 5.7 jobs were created in the overall economy including healthcare, retail, wholesale trade, real estate, and many more.

Market Access Barriers Abroad Undermine Sustainable Innovation

The risks inherent in pharmaceutical innovation are staggering and access barriers abroad exacerbate the intensity around 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 costs¹¹.

A Report by the U.S. Department of Commerce¹² 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. Given that the FDA approved only 18 new drugs in 2007, a reduction of four new drugs in a year (or more than 20% of those approved by FDA that year) is a significant setback in innovation and potential patient care.

Despite the risks of R&D, PhRMA's member companies have made tremendous strides in research and development to date, enhancing the quality and quantity of life, enhancing productivity of workers, and reducing the need for other health services. Some key examples are as follows:

⁸ PhRMA 2008 Industry Profile

⁹ Ibid

¹⁰ Milken Institute, "Biopharmaceutical Industry Contributions to State and US Economies" (October 2004).

¹¹ Pharmaceutical Research and Manufacturers of America, New Drug Approval Reports, 1997–2006.

¹² U.S. Department of Commerce, "Price Controls in OECD Countries," (2004)

- 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 1975¹³.
- 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 levels¹⁴.
- 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/AIDS¹⁵.
- 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 home¹⁶.

Nevertheless, there continue to be considerable unmet needs which pharmaceutical companies are working tirelessly and committing tremendous resources to solve. In 2008, the U.S. biopharmaceutical pipeline contained 2888 medicines in clinical trials or awaiting regulatory review¹⁷. The U.S. biopharmaceutical industry has consistently had more compounds in development than the rest of the world combined in recent years. Among the compounds in the pipeline 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 fibrosis
- 750 possible treatments for cancers, particularly lung cancer and breast cancer
- 277 new approaches for heart disease and stroke

¹³ F. Lichtenberg, "The Expanding Pharmaceutical Arsenal in the War on Cancer," NBER Working Paper 10328, February, 2004.

¹⁴ W. Dunham, "Progress Seen in Heart Disease, Stroke Deaths, However, Obesity Epidemic May Offset Decline in Deaths this Decade," *Reuters*, 15 December 2008.

¹⁵ CDC, National Center for Health Statistics, *Health, United States, 2006 With Chartbook on Trends in the Health of Americans*, 2006.

¹⁶ O.L. Lopez et al., "Alteration of a Clinically Meaningful Outcome in the Natural History of Alzheimer's Disease by Cholinesterase Inhibition," *Journal of the American Geriatric Society*, 2005.

¹⁷ Adis R&D Insight database, November 2008

- 109 new treatments to fight and prevent HIV/AIDS¹⁸

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 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 Delays Abroad are a Barrier to Trade

Policies that impose market access barriers by foreign governments adversely affect research-based pharmaceutical companies' ability to market or sell their products in many countries. These barriers 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 entry 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 government entities responsible for pricing and reimbursement 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 act as effective denials of market access. Governments often delay adding new products to national reimbursement lists merely to avoid the cost of providing 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 close reimbursement lists altogether to

¹⁸ Pharmaceutical Research and Manufacturers of America, "Medicines in Development for HIV/AIDS," December 2008, <http://www.phrma.org/files/New%20Meds%20for%20HIV-AIDS%20report.pdf> (accessed 12 January 2009).

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.

It should be further noted that policies creating market access barriers 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 of those pharmaceuticals above what they would be in free market. Indeed, many foreign systems actually mandate high prices for generics products, requiring that they 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 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 abroad¹⁹.”

The country chapters of PhRMA’s 2009 submission provide numerous examples of the above government pricing and reimbursement policies and practices.

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.

¹⁹ U.S. Department of Commerce, “Price Controls in OECD Countries,” (2004)

Most countries afford manufacturers or sellers some right of participation when making pricing or reimbursement decisions, but there are significant disparities in the openness and accessibility of the decision-making process. In many countries (such as China, Brazil, and India) governments obtain information from manufacturers or sellers that forms part of the basis for a pricing or reimbursement decision, 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 pharmaceutical manufacturers adequate rights of participation and taking into account those interests when a government is administering a price control system or 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 constraints 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 certain 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 fertile 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 that 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 effectively undermined by over-burdensome and discriminatory market access restrictions.

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 Priority Foreign Country 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 monopsonist 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. Such a scheme takes value away from the patent and is 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. Market access barriers that discriminate in favor of domestic manufacturers can also harm patent holders that import their products. Moreover, a country that utilizes such schemes cannot be said to adequately and effectively protect 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 and workers 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 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 2008 Special 301 Report, bilateral consultations should be pursued to promote sustainable innovation by addressing market access barriers abroad. The 2008 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 Germany, and is seeking to establish ones with other countries. It also has established a dialogue on pharmaceutical issues with China.²⁰

We would like to see the USTR, HHS, the Commerce Department and other agencies move rapidly to advance the bilateral dialogue with Germany, one of PhRMA’s highest priority countries. As detailed in our submission, Germany’s approach to regulating innovative products represents a substantial impediment to innovation in one of the biggest and most developed pharmaceutical markets in the world. For that reason, we have included Germany 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 France, Italy, and Canada) to address government-imposed market access barriers and other trade distorting measures. Similar to the situation in Germany, the market access barriers maintained in these developed countries undermine intellectual property rights, deny patients access to the most innovative medicines, and undermine sustainable innovation.

²⁰ United States Trade Representative Special 301 Report 2008.

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 Agreement and the WTO Agreement on Technical Barriers to Trade (TBT). 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 that government price control regimes “avoid to the fullest practicable extent effects prejudicial to the United States,” as required by GATT Article III. PhRMA strongly encourages USTR to remain vigilant in pressing the EU and its Member States to fully comply with WTO commitments and the EU’s Transparency Directive, none 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 for the failure to do so.

IV. Summary of Selected Countries and Issues

To emphasize priorities of PhRMA members for this collaboration, we provide in the following paragraphs summaries of the issues in selected countries from our more detailed reports.

Priority Foreign Countries

PhRMA recommends that the Philippines and Thailand be designated Priority Foreign Countries under "Special 301" for 2009 and The Peoples Republic of China continue to be designated under Section 306, in accordance with relevant provisions of the Trade Act of 1974, as amended:

Philippines: PhRMA and its member companies operating in the Philippines are increasingly 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 addition, PhRMA's member companies continue to face numerous issues related to patent linkage, parallel importation, data protection, counterfeit drug enforcement, regulation of drug prices, and the labeling of unbranded generics. For these reasons, PhRMA requests that the Philippines be designated as a **Priority Foreign Country** for the 2009 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Thailand: PhRMA and its member companies operating in Thailand are very concerned that Thailand has made no progress in addressing PhRMA's concerns over the past year, and fear that the Government is backsliding in its protection of intellectual property rights. Despite previous assurances by the Thai Government that a constructive healthcare dialogue between PhRMA's member companies and Thailand Government officials would be convened, numerous good faith attempts by member companies to start this process have been rebuffed. Specifically, PhRMA's member companies continue to have major concerns related to counterfeit medicines, patent linkage, data exclusivity, patent delays, government procurement, and safety monitoring period requirements. For these reasons, PhRMA requests that Thailand be designated a **Priority Foreign Country** for the 2009 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Section 306 Monitoring

China: PhRMA and its member companies operating in the People's Republic of China remain concerned over inadequate intellectual property protections, including a lack of effective data protection and poor enforcement against counterfeit pharmaceuticals. Likewise, PhRMA is concerned about several market access barriers, including: (1) a deteriorating government pricing policy for innovative products; (2) an absence of update of drug reimbursement list for over four years; and (3) a lengthy requirement for clinical trial applications. For these reasons, PhRMA requests that the People's Republic of China remain under **Section 306** monitoring for the 2009 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Priority Watch List Countries

PhRMA believes that 21 countries should be included in the 2009 Priority Watch List. PhRMA urges USTR to take aggressive action to remedy these violations which undermine IP rights, including the consideration of WTO dispute settlement, as necessary. The following paragraphs provide summaries of issues in selected countries in this category.

ASIA-PACIFIC

- Australia
- India (with OCR)
- Indonesia
- Korea
- New Zealand

EUROPE

- Czech Republic
- Germany
- Hungary
- Italy
- Poland
- Russia
- Turkey

LATIN AMERICA

- Argentina
- Brazil
- Chile
- Venezuela

MIDDLE EAST/ AFRICA/ SOUTH ASIA

- Algeria
- Israel
- Lebanon
- Pakistan
- Saudi Arabia

Watch List Countries

The PhRMA submission identifies 19 countries which we believe should be included on the Special 301 Watch List in 2009. 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 IP standards including the WTO TRIPS Agreement and FTA provisions.

ASIA-PACIFIC

- Malaysia
- Taiwan
- Vietnam

CANADA

- Canada

EUROPE

- Finland
- France
- Norway
- Slovenia
- Spain
- Sweden

LATIN AMERICA

- Colombia
- Costa Rica
- Dominican Republic
- El Salvador
- Guatemala
- Honduras
- Mexico
- Nicaragua
- Peru

PRIORITY FOREIGN **COUNTRIES**

PHILIPPINES

PhRMA and its member companies operating in the Philippines are increasingly 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 addition, PhRMA's member companies continue to face numerous issues related to patent linkage, parallel importation, data protection, counterfeit drug enforcement, regulation of drug prices, and the labeling of unbranded generics.

For these reasons, PhRMA requests that the Philippines be designated as a **Priority Foreign Country** for the 2009 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

TRIPS-Related Concerns

Of significant concern to PhRMA member companies are IP-related provisions in the Act that amend the Philippines Intellectual Property Code to severely limit the patentability of new forms and uses of drugs and medicines. This limitation on patentability only applies to new forms and uses related to drugs and medicines, and therefore is 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 drugs and medicines and, therefore, is also inconsistent with the non-discrimination requirements of Article 27.1 in TRIPS. In addition, if this new ground is utilized, the Act waives the requirement under the IP 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; 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 IP Code which cross-references TRIPS Article 31 safeguards; and 2) enumerating only certain safeguards while specifically excluding other Article 31 safeguards.

Patent Linkage

Three years ago, the Philippine Government, through a DOH Administrative Order (A.O. No. 2005-0001) removed the patent linkage system and intellectual property protection, in general, from the responsibilities of the BFAD. The Administrative Order permits the BFAD to accept and process applications for product registration without the need to verify whether or not the pharmaceutical being submitted for registration is under patent protection. Moreover, even if the BFAD is made aware of a valid patent, it is “exempted” from honoring such patent and can grant approval for marketing of the infringing product. As a result, the only available option for PhRMA member companies is to pursue legal remedies to protect their product patents, which in the current legal system can result in great expense, long delays and economic injury before a decision is made. This is especially troubling, as the Philippine courts/judges are hesitant to issue preliminary injunctions to stop the infringing activity. The elimination of this linkage and the subsequent adoption of a Bolar-type exception as provided by the Act may result in more injuries to patent owners, which may not be easily remedied by court actions.

Parallel Importation

Under the new Act, all government agencies and third parties now have the authority to parallel import 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). In addition, PhRMA’s member companies have raised concerns regarding the risk of an increased flow of counterfeit drugs into (and out of) the Philippines due to an inadequate monitoring process.

The Act fails to address these concerns, which are exacerbated by an administrative order permitting the Philippine International Trading Corporation (PITC) to import pharmaceuticals from India and Pakistan using “substitute requirements” and via a “priority lane”. Administrative Order (A.O.) No. 85 enables the Government, through the PITC, to import branded, off-patent medicines and exempts the PITC from complying with standard regulatory requirements, potentially compromising patients’ safety. It also permits an expedited review for pharmaceutical registration. A.O. No. 85 grants an unfair advantage to PITC, which directly competes with U.S. pharmaceutical companies, by permitting PITC to import and sell medicines to the public without complying with strict registration and testing requirements required of innovative pharmaceutical companies. If this procedure continues, and if private parallel importers are granted the same benefit, foreign drug manufacturers and suppliers will face even greater discrimination in the Philippine market.

Provisions related to parallel imports in the final IRRs of the Act also raise concerns. Rule 9(i) of the final IRRs broadens the scope of drug and medicines that can be brought into the Philippines as non-infringing parallel imports by establishing international exhaustion of the patent holder’s exclusive rights at the point that the drug or medicine has been sold or offered anywhere else in the world, even without the authorization or permission of the patent holder. This opens the possibility that drugs and medicines first introduced by an unauthorized sale, or subject to a compulsory license, could be brought into the Philippines as a non-infringing parallel import.

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; increase law enforcement raids of counterfeit drug sites; and successfully prosecuting a drug counterfeiter resulted 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 (discussed above).

Consistent with the concern over counterfeit drugs and the need to ensure patients’ 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 Maximum Government Price Control System and “Cost-Containment Measures”

The government price control regime implemented under the Act poses serious transparency concerns. Under the Act, the President of the Philippines has the power to impose maximum retail prices upon the recommendation of the Secretary of the Department of Health (“Secretary”). The Act provides the President of the Philippines authority to impose drug price ceilings in times of true calamity, public health emergencies and illegal price manipulation. The President can also impose maximum retail prices (MRPs) in “other instances of unreasonable drug price increases,” which remain undefined in the law.

The Secretary is given expansive and relatively unfettered powers to establish a price monitoring and regulation system, as well as other broad “cost containment measures.” The Secretary is required to consider several factors in setting a maximum price for the President’s approval, including foreign price referencing. While there is a mandate to consider these circumstances when setting a MRP, the Secretary is not required to conduct hearings or take into account stakeholder comments to ensure the reasonableness of a proposed MRP. There is a non-exhaustive list of the types of drugs and medicines that are subject to governmental price regulation. The Secretary has unfettered discretion to add any additional drugs or medicines to the list.

Despite the fact that the Act authorizes the DOH to establish advisory bodies and councils to facilitate stakeholder input for the MRP system, the final IRRs do not provide for an established mechanism to facilitate stakeholder input, or to ensure that stakeholder input will be taken into account.

GATT Article III paragraph 9 states that members implementing maximum price control measures “*shall* take into account the interests of exporting contracting parties.” The final IRRs only provide the DOH the *discretion* to create advisory bodies and consultative councils for the implementation of the MRP system. Given the significant impact that the MRP system will have on all pharmaceutical manufacturers and other key stakeholders such as patients and health care providers, PhRMA and its member companies recommend that the DOH be required to establish and utilize advisory bodies and consultative councils in order to facilitate and ensure stakeholder input, and to ensure that stakeholders are separately and adequately represented on those advisory bodies and councils.

The Act also contains provisions that place additional burdens on research-based pharmaceutical companies in the Philippines. These include: (1) specific labeling requirements, including maximum retail price and notification

that medications are subject to government price regulation; (2) a requirement to issue a price list for drugs and medicines to distributors, wholesalers, retailers and the Secretary, indicating retail prices, MRPs, "and such other information as may be required by the Secretary"; and 3) a requirement that every manufacturer, importer, trader, distributor, wholesaler, or retailer of a drug or medicine provide to the Secretary within 30 days from the effective date of the Act, and then by December 31 in subsequent years, a list of the corresponding prices and inventories of all drugs or medicines it manufactures, imports, trades, distributes, wholesales, or retails, and "any and all necessary information that Secretary may require."

Labeling/Unbranded Generics

The Act amended the Generics Act to require that the following statement appear prominently on generic drug labels: "This product has the same therapeutic efficacy as any other generic product of the same name. Signed: BFAD." This requirement raises serious public health concerns because the BFAD is currently unable to test for the bioequivalence of products. The Act also requires drug manufacturing companies to make an "unbranded generic counterpart of their branded product widely" available to the general public. The scope and implementation of this provision remains unclear.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

THAILAND

PhRMA and its member companies operating in Thailand are very concerned that Thailand has made no progress in addressing PhRMA's concerns over the past year, and fear that the Government is backsliding in its protection of intellectual property rights. Despite previous assurances by the Thai Government that a constructive healthcare dialogue between PhRMA's member companies and Thailand Government officials would be convened, numerous good faith attempts by member companies to start this process have been rebuffed. Specifically, PhRMA's member companies continue to have major concerns related to counterfeit medicines, patent linkage, data exclusivity, patent delays, government procurement, and safety monitoring period requirements.

For these reasons, PhRMA requests that Thailand be designated a **Priority Foreign Country** for the 2009 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Compulsory Licenses

As noted in our 2008 Special 301 submission, in no instance has Thailand cited a national emergency or a situation of extreme urgency as its justification for issuing compulsory licenses. In addition, the Thai Government's actions ascribed to "public non-commercial use" remain poorly defined.

PhRMA member companies regarded Thailand as an emerging leader in innovation and a developing center of excellence in life sciences in the region. Opportunities existed to work with Thailand's medical scientists, healthcare professionals, and science and health policy experts to foster an environment that would support development of a vibrant life sciences sector in Thailand. The deterioration of intellectual property rights has undermined these opportunities.

Thailand's use of compulsory licenses raises concerns within the broader Thailand business community. As noted during a meeting between U.S. business leaders and the Prime Minister during the APEC Summit in September 2007, and subsequently at a US-ASEAN Business Council discussion in New York City, PhRMA member companies believe that the Government's policies have resulted in a very unpredictable business environment for investors and have created a situation that may ultimately work to disadvantage Thai citizens.

In November 2008, Thailand's press widely reported on the Ministry of Public Health's intention to issue additional compulsory licenses. At no point in this process has Thailand consulted with PhRMA, PReMA or individual member

companies that might be affected by these actions. Also, statements made by the Minister of Public Health in recent weeks and reported by the press indicate that the Government has pursued a compulsory licensing policy primarily as a cost-cutting measure and not as a response to national emergencies.

PhRMA urges the new Government to adopt holistic healthcare reforms that address issues related to overall healthcare expenditure, government distribution of medical care and pharmaceuticals, taxes and tariffs on medicines, public hospital management and expenses, private contributions for healthcare products and services, and patient education and knowledge on disease and preventive care. PhRMA member companies would welcome the opportunity to engage in a constructive public-private dialogue that includes all stakeholders to discuss sustainable ways in which broader access to innovative medicines could be achieved and how to develop a quality healthcare system in Thailand.

Pharmaceutical Counterfeiters

The growth in availability of counterfeit medicines has become a serious problem in Thailand. Counterfeit pharmaceuticals are readily available in most drug stores and pharmacies. Counterfeit medicines pose a major health risk to patients in Thailand and across the world.

The resources currently allocated by the Thai Government to deal with the volume of counterfeit medicines are insufficient. In addition, the relevant law enforcement agencies do not aggressively pursue traffickers in counterfeit pharmaceuticals. Real, practical deterrence is an issue because there is often a failure to pursue criminal charges and, when charges are brought, the penalties for counterfeiting are insignificant relative to the profits made from the supply of fake medicines and the resulting harm to human health. Further, the lengthy process required to take administrative action, such as revoking the license of a pharmacy found to be selling counterfeit pharmaceuticals, makes this action ineffective. Historical tolerance towards counterfeit products impedes progress, due in large part to a lack of understanding or awareness among the general public and enforcement officials as to the severity and dangers of the problem.

PhRMA member companies have organized numerous workshops and training seminars to raise awareness among officials, healthcare providers and consumers as to the availability and dangers of counterfeit pharmaceuticals, and how to recognize a genuine from a counterfeit product. However, these efforts have been hindered by overly-restrictive interpretations of drug advertising laws by Thai FDA officials. Such restrictive interpretations have greatly curtailed the ability of pharmaceutical companies to effectively warn patients and pharmacists of the availability and dangers of counterfeit medicines.

PhRMA is pleased that the Thai Government has welcomed, supported and assisted various efforts of pharmaceutical companies to educate officials and

the general public; however, the Thai legislature should implement laws with stricter penalties for pharmaceutical counterfeiters. The Thai FDA and law enforcement leadership should provide adequate resources to train and equip Thai enforcement agencies to deal with counterfeiting. Where offenders are convicted, the Thai judiciary should impose significant prison terms in order to create practical deterrence. We look forward to working with the new Government on the realization of an initiative begun in mid-2007 that is memorialized in a Memorandum of Understanding between key agencies in the Thai Government and private sector representatives to facilitate improved enforcement of IP rights and suppress counterfeiting.

Patent Linkage

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 that would have otherwise been denied regulatory approval, results in a significant and unnecessary burden on PhRMA member companies as well as on the Thai court system.

PhRMA and its member companies are concerned that the producers of innovative products are not receiving appropriate notice of generic firms attempting to register and release products that are under patent protection. Patent litigation in Thailand is time consuming and patent holders face significant costs and losses during the period of litigation. Moreover, preliminary injunctions are rarely granted and damages awards generally do not capture the true extent of economic loss to the patent holders. Unfortunately, litigation is often the only available option.

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.

Data Exclusivity

TRIPS requires WTO Members to prohibit unfair commercial use of, or reliance on, regulatory data. The widely accepted mechanism for complying with this obligation is a data exclusivity regime which prevents regulatory authorities from prematurely allowing generic producers to rely on or otherwise use the originator's proprietary data to gain approval of copies of the originator's drug. To date, Thailand has not implemented an effective system for preventing unfair reliance on the originator's underlying data to obtain regulatory approval.

The development and introduction of a new drug requires the originator to conduct extensive chemical, pharmacological, toxicological and clinical research and testing, at is a hugely expensive and time-consuming process. The data

generated to prove safety and efficacy is proprietary to the originator and enormously valuable.

The Thai Parliament passed a Trade Secrets Act in April 2002 (the "Act"). Chapter 3, Section 15 of the Act provides for the "Preservation of Trade Secrets by Government Entity." It is the legislative vehicle through which Thailand seeks to meet its obligation to enact data protection consistent with TRIPS Article 39.3.

Although the Act was passed in 2002, the Thai FDA, which is in charge of implementation and enforcement of the Act, did not issue implementing Ministerial regulations until January 30, 2007. A further 16 months is expected before the Ministry of Public Health (MoPH) regulation takes effect. Furthermore, while it protects physical disclosure of confidential information, the official regulation fails to expressly 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.

Under the new MoPH regulations, protection applies only to data related to new chemical substances (not to new dosage forms, new indications, composition, etc.) that are qualified as trade secrets under Section 3 of the Trade Secrets Act and have never been approved to be registered in Thailand. The term of this physical protection is only five years starting from the date of recordation, not the date of marketing approval as in the laws of other countries. This means that any benefit of the protection is dependent on the efficiency of review by the Thai FDA.

PhRMA believes strongly that these interpretations of Thailand's obligations will further harm the interests of PhRMA members by, among others, restricting their ability to recoup their investment and fund further R&D. This could result in fewer new medicines being introduced in Thailand and elsewhere in the world.

PhRMA encourages Thailand to implement new regulations that do not permit a generics producer to rely on the originator's data, unless consent has been provided by the originator, for the approval of generic pharmaceutical products during the designated period of exclusivity.

In addition, the regulations should not differentiate between patented and unpatented products. The regulations should require the 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. The regulations should impose liability for state officials who receive the information and disclose it to third parties or the public.

Patent Delays

It currently takes an average of 8 to 10 years or more to obtain grant of a pharmaceutical patent in Thailand. When combined with regulatory approval delays this negatively impacts the effective patent term available for innovative medicines in Thailand. If undue delays ensue, the patent holder should be compensated with an appropriate extension of the patent term. PhRMA members are concerned that while effective solutions to help maintain reasonable patent prosecution timelines, such as outsourcing, are available, the Thai Department of Intellectual Property (DIP) has not made any substantive progress in remedying the delay.

PhRMA encourages Thailand to join the Patent Cooperation Treaty (PCT), which has been adopted by more than 130 countries. The PCT, enacted in 1970, offers advantages to patent applicants, national patent offices, and the public in the countries that have joined the system, and would be of enormous benefit to Thai inventors. Instead of filing separate national patent applications with the office of each country in which a patent is sought, the PCT allows an inventor/applicant to file one "international" application in one language and to seek protection simultaneously in all its member states. The PCT helps reduce the burden on the patent office substantially as the system offers centralized and detailed, high-value information on which approval decisions can be made without having to locally duplicate the information gathering and evaluation process.

Market Access Barriers

Government Procurement

The Thai Government's procurement regulations (Articles 60 and 61) require government hospitals to give the pharmaceuticals manufactured by the Government Pharmaceutical Organization (GPO) preference when purchasing medicines. This organization, established by the Thai Government to manufacture medicines in the Government's name, has rights to an exclusive position in supplying government hospitals with products on the National List of Essential Medicines (NLEM). The GPO, as a state enterprise, is also exempt from prohibitions against anti-competitive practices under Thailand's Trade Competition Act. PhRMA believes the government procurement regulations give GPO an unfair advantage, and prevent research-based pharmaceutical companies from competing on quality and value in the largest sector of the Thai healthcare market. Moreover, the GPO has on occasion unilaterally refused to distribute products that contain the same basic compound as products manufactured by PhRMA member companies, albeit under a different formulation, even though the products have been documented to offer benefits to

Thai patients. These regulations should be revoked because they discriminate against foreign pharmaceutical producers.

Safety Monitoring Program (SMP)

All new chemical entities registered and approved for marketing in Thailand must undergo a mandatory Safety Monitoring Program (SMP) of approximately two years and in some cases up to four years. During the SMP, only doctors in hospitals and clinics can prescribe the medicines, and only hospital and clinic pharmacies can dispense them. In addition, the medicines cannot be sold in drug stores and cannot be included in the NLEM. This last requirement prevents sales of a subject medicine from being reimbursed under the government-subsidized medical benefit schemes, such as the Universal Coverage (UC-Free services), Social Security Scheme and Civil Servant Medical Benefit Scheme. Once the Thai FDA has granted marketing approval there are no legitimate safety reasons for restricting distribution. Because the medicines under SMP are not reimbursed by the Government, they are rarely prescribed by doctors for public sector patients. Indeed, by restricting distribution, and therefore the medicine's use in patients, this policy diminishes the benefit and the intent of SMP, which is to monitor the safety profile of the medicine in a larger population. In addition, this policy severely restricts PhRMA member companies' access to the Thai market and restricts Thai patients' access to the newest therapies.

New Draft Drugs Bill

The Thai FDA has demonstrated its intention to request, as part of the marketing approval process under the new draft Drugs Bill, information related to the medicine's patent status and its price structure. PhRMA members believe that the Thai FDA may unnecessarily and inappropriately use this information to narrow the criteria for new drug registration by focusing on patent and cost considerations over safety and efficacy. The language of the draft Bill is vague and ambiguous, and could result in arbitrary rejections of new drug applications because of a subjectively "improper or unworthy price structure". If this new Bill passes, it could become a serious trade barrier to PhRMA member companies and restrict Thai patients' access to new innovative medicines.

PhRMA strongly recommends that the Thai FDA remove such provisions from the draft Bill to promote free trade and the efficient introduction of new medicines into the market, as well as to ensure that Thai patients have access to safe, effective, high-quality innovative medicines.

Product Liability Act

The Product Liability Act was rapidly passed by the National Legislative Assembly in December 2007, and will become effective on 20 February 2009. As it stands, the Thai Government enforcement body has stated that it will

consider drugs and medicines being tested in clinical trials in Thailand as potentially liable under the Product Liability Act, which could create a disincentive for companies to enter the market and conduct trials in Thailand.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

SECTION 306 **MONITORING**

THE PEOPLE'S REPUBLIC OF CHINA

PhRMA and its member companies operating in the People's Republic of China remain concerned over inadequate intellectual property protections, including a lack of effective data protection and poor enforcement against counterfeit pharmaceuticals. Likewise, PhRMA is concerned about several market access barriers, including: (1) a deteriorating government pricing policy for innovative products; (2) an absence of update of drug reimbursement list for over four years; and (3) a lengthy requirement for clinical trial applications.

For these reasons, PhRMA requests that the People's Republic of China remain under **Section 306** monitoring for the 2009 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

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

The Implementation Regulation of the Drug Administration Law and the Drug Registration Regulation establish a 6-year period of protection for test data of products containing a new chemical ingredient against unfair commercial use. The State Food and Drug Administration (SFDA) is 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 clinical data developed by originator companies. The published data alone are usually insufficient to prove the safety and efficacy of a product. Published data merely summarize the data

included in the original filing. 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 conveys an unfair commercial advantage to non-originator/non-patent holder companies because non-originator companies do not incur the cost of generating their own clinical data to prove safety and efficacy. Such reliance can also create significant safety concerns around products introduced into China via this drug registration pathway.

A recent not yet published independent study, focused on the period January 1, 2003 to June 30, 2008, demonstrating the inadequacy of data protection in China was shared with both the US and the Chinese government. The study shows that since the beginning of 2003 and shortly after China officially incorporated the data protection provision of TRIPS in its laws, forty-nine (49) pharmaceutical products containing new chemical entities (“NCE”) (as defined in the United States²¹) have been brought to the China market by twenty-one (21) multinational pharmaceutical companies. As many as eighteen (18) of these NCE products are severely impacted by domestically manufactured products, which are essentially the same as the original NCE product but were all approved as “New Drugs” in China. The number of non-original manufacturers producing the equivalent of an NCE product is overall significant, and the time of the generic approval was either before or shortly after that of the NCE product. These facts show that China has yet to provide meaningful data protection to NCE originator companies.

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 require there to be sales in the market place 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 patent products from infringement as long as it is “for

²¹ A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination. <http://www.fda.gov/cder/orange/supplement/cspreface.htm>

the purpose of submitting information necessary for an administrative approval". As a result, PhRMA member companies cannot seek to enjoin the marketing approval of an infringing product and are thus presented a higher practical barrier to market in China.

To avoid costly patent litigation and to increase market predictability, China should allow patent holder companies to file patent infringement suits before marketing authorization is granted to non-patent holders and 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 requirement all but precludes effective criminal prosecution against counterfeiters under China's drug laws.

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 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, and 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 chemical companies are able to ignore SFDA requirements by advertising their API products (which do not satisfy SFDA GMP requirements) for medicinal use. Chemical manufacturers are selling and shipping 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.²² 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 as appropriate. Those requirements should be enforced by SFDA. Additionally, the SFDA should require documentation to support that API intermediates or API are being exported only to pharmaceutical firms who have approved applications (or IND/CTA)

²² 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.

The Memorandum of Agreement on the Safety of Drugs and Medical Devices (MOA) signed in December 2007 between the U.S. Department of Health and Human Services and China's SFDA is a positive step toward reducing the volume of unregulated API that is exported from China, but it does not adequately address the prevalence of the unregulated supply of API to drug counterfeiters within and outside of China. In addition, the implementation of the MOA has been very slow and, thus far, unsatisfactory. Moreover, the specific items listed in the MOA should be reviewed on a regular basis to reflect the pharmaceutical products and APIs that are being counterfeited in large quantities in China.

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 product to the global market. China should strengthen its efforts to control exports and increase its international and multi-lateral 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.

Market Access Barriers

Healthcare Funding

The Chinese Government 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 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 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.

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 and Reimbursement Policies

Pharmaceutical products are subject to government price controls in China. 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 with America's pharmaceutical companies when it evaluates and implements a government pricing policy for innovative products generally, or when proposed changes are being considered.

The Ministry of Human Resources and Social Security (MoHRSS) maintains the national drug reimbursement list. In accordance with Chinese law, the list is to be updated every two years. However, the current list has not been updated since 2004. As a result many new, innovative products have received marketing approval in China, but are not widely available to patients because they remain ineligible for reimbursement. PhRMA encourages MoHRSS to update the national drug reimbursement list to ensure that Chinese patients have access to the latest, most advanced treatment options. China's commitment through the Joint Committee on Commerce and Trade in September 2008 to update the national and regional reimbursement lists every two years is a very positive development on this issue.

Clinical Trial Application Approval

Although recently slightly improved, China's clinical trial application (CTA) submission requirements remain burdensome relative to other countries' drug regulatory procedures. China maintains comparatively extensive chemistry manufacturing and controls (CMC), pre-clinical, and clinical requirements. Moreover, applicants are unable to supplement applications as new information is discovered or made available, and must repeat the same procedures for every change to an approved 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 develop new, science and risk-based practices that are in line with international best practices, including formal processes for sponsor/agency interaction.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

PRIORITY WATCH LIST

ASIA-PACIFIC

AUSTRALIA

Australia traditionally has maintained a strong intellectual property regime. However, PhRMA and its member companies are concerned that:

- (1) Actions during the ongoing implementation of the U.S.-Australia Free Trade Agreement (FTA) have weakened intellectual property provisions; and
- (2) Existing and emerging issues affecting patient access to new medicines have not yet been adequately addressed.

While PhRMA believes that the FTA represents an important step forward in creating conditions which make Australia a more attractive destination for life sciences investment and research, PhRMA remains concerned with the apparent backsliding on intellectual property protection for innovative pharmaceuticals.

Patient access to medicines is a key priority for PhRMA, and several measures articulated in the FTA address and are intended to increase access. However, there is still much to be done to achieve the goal of providing access to new and innovative medicines. The recent reforms to Australia's Pharmaceutical Benefit Scheme (PBS) were largely welcomed, but PhRMA member companies and their Australian affiliates 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.

Due to these concerns, we recommend that Australia be placed on the 2009 Special 301 **Priority Watch List**.

Intellectual Property Protection

Patent Protection

Australia traditionally has maintained a strong intellectual property regime for protecting innovative biomedical discoveries, including patent term restoration. However, PhRMA continues to be deeply concerned by actions taken by the Australian Parliament after the negotiation of the FTA which weaken and undermine intellectual property provisions that were agreed to during the negotiations. These actions concern (1) notice of approvals given to generic products covered by patents and (2) discriminatory treatment of pharmaceutical patent enforcement actions.

PhRMA understands 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 FTA. Token notice provisions have been implemented but, in the majority of cases, they only require notification of the Therapeutic Goods Administration (TGA), not the patent holder. The good faith implementation of these assurances is critical to ensuring that Australia's intellectual property regime remains strong, and that the FTA is implemented as originally negotiated.

During a 2007 briefing by the USTR's office after the second meeting of the Australia-U.S. Medicines Working Group, the US Government indicated that amendments to Australian law weakening patent protection for pharmaceuticals, passed by Australia after the FTA was completed, are unjustifiable, counterproductive, and violate Australia's international obligations. More specifically, the potentially heavy penalties under the amendments that would apply only to holders of pharmaceutical patents who seek to enforce their patent rights appear to discriminate against a field of technology in violation of Australia's WTO TRIPS Article 27.1 obligations. Such penalties are not applicable to patent enforcement actions involving non-pharmaceutical products. PhRMA is disappointed that the Australian Government, which itself expressed strong concern with these very amendments when they were introduced, is not taking action to revise or repeal them. The Australian Government itself has said these amendments are unnecessary and undermine Australia's patent laws.

Finally, we are also aware of a possibility that the Australian *Patents Act 1990* will be amended to allow the manufacture of medicines that are generic copies of innovator medicines that currently benefit from Australian patent term extensions, for export to international markets where relevant patents have expired. If implemented, this measure would:

- undermine the legitimate and exclusive rights of patentees in Australia to exploit their inventions;
- contravene Australia's obligations under TRIPS and the FTA;
- create a dangerous precedent for other nations, which may, in the first instance, provoke a chain reaction of retaliatory trade policy measures, and ultimately undermine international efforts to implement global standards of IP protection; and
- hamper efforts to improve access to innovative medicines.

In addition, the data exclusivity provisions provided for in Australia are weak and do not compare to those available in the US and EU. The lack of adequate data exclusivity is of particular importance in the light of a proposed 'spring-boarding' amendment to the Patents Act, introduced March 2006 by

Australian Ministry of Industry, Tourism, and Resources, that would have enabled the registration of generic competitors at any time during the life of a patent.

Market Access Barriers

PhRMA appreciates the fact that its member companies were consulted in relation to elements of the PBS reform package. We also understand that the reform process is ongoing and we expect that this will occur in close consultation with PhRMA's member companies, and in a manner that avoids any unintended consequences which would be contrary to the principles of the FTA, particularly with respect to the value of patent-protected medicines, transparency and patient access to innovative medicines.

PhRMA notes that there is some disagreement between PhRMA member companies and the Australian Government regarding the likely impact of statutory price reductions on the listing of new, innovative medicines on the PBS, identified in a recent report to the Minister for Health and Ageing from the separate joint Government-Industry Access to Medicines Working Group which was created as part of the PBS reform process.²³ PhRMA encourages the Australian Government to pursue policy solutions which will ensure that innovative medicines are not adversely affected by the PBS reforms.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

²³ "The Access to Medicines Working Group Interim Report to Government: Executive Summary", p. 4, July 2008, <http://www.medicinesaustralia.com.au/pages/images/Exec-AMWG-Interim-Report-Gov-210708-merged.pdf>, and Medicines Australia Press Release, "New era for PBS but Australians' access to medicines not yet assured," 1 August 2008, <http://www.medicinesaustralia.com.au/pages/images/MR%20Aug%200108%20New%20era%20for%20PBS.pdf>.

INDIA

PhRMA and its member companies remain concerned about deteriorating intellectual property protection and significant market access barriers in India. In 2008, India failed to implement provisions to protect pharmaceutical test and other data, as required by TRIPS Article 39.3, and the backlog of patent applications awaiting examination and the patent pendency period grew. Standards for patentability need to be amended to conform to India's obligations under the TRIPS Agreement as well as prevailing international practice. Also, India is an increasingly significant source of counterfeit pharmaceutical products and is believed to be a major channel for the export of counterfeits to consumers worldwide. Finally, PhRMA members are concerned about proposals to increase the scope of India's government price control system such that it would discriminate against imported products.

To address these serious challenges to market access and patent and data protection for innovative pharmaceuticals in India, the U.S. Government should pursue a high-level dialogue to promote compliance with India's WTO obligations across the board, including intellectual property. At the same time, PhRMA supports expansion of international assistance opportunities for the training of patent examiners along with other technical cooperation to prepare India to meet its TRIPS obligations.

In view of all the circumstances, PhRMA recommends that India remain a **Priority Watch List** country in 2009 and that the U.S. Government conduct an **Out-of-Cycle Review** on the deteriorating intellectual property environment in India.

Intellectual Property Protection

Data Protection

India is and has been required by TRIPS Article 39.3 to provide protection for certain pharmaceutical test and other data, but has yet to do so. To obtain marketing approval of a pharmaceutical product that was granted marketing approval in some other country, applicants for marketing approval in India must prove that the product was approved and marketed in another country and must provide confirmatory test and other data from clinical studies on 100 Indian patients. By requiring proof of approval in other countries that require the submission of such test and other data, India, in effect, uses those countries as its agents and effectively relies on test data submitted by originators to another country. TRIPS requires that submitted data should be protected against reliance as well as against disclosure.

Over the course of three years, an inter-ministerial committee examined issues related to protecting these data and submitted its report in May 2007. To date, no formal decision has been made by the Indian Government. While the report recommended instituting data protection, including protection from unfair commercial use by third parties by way of non-reliance on data submitted by the originator for agro-chemicals (three years) and “traditional medicines” (five years), it proposed a differential treatment for pharmaceuticals. The report recommended during an initial “transition period”²⁴ only prevention of unauthorized disclosure and unauthorized use through explicit legal provisions in India’s Drugs and Cosmetics Act, 1940. The report also recommended that after the transition period, there be consideration of five years of non-reliance by the Drugs Controller-General of India (DCGI) on data that are submitted by the originator for obtaining marketing approval for a new drug which is a new chemical entity and that are actually relied upon by the DCGI for that approval. This differential treatment from other forms of protected data discriminates against innovative pharmaceuticals and the absence of data protection that prevents unfair commercial use is a direct violation of 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. Implementation of 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 recently been granted patents in India. This is a great disadvantage for research-based companies because the courts offer limited protection to holders of patents. Patent enforcement mechanisms are severely lacking and penalties for patent infringement are extremely weak which undermines patent holders in their efforts to seek a legal remedy in instances of (often blatant) patent infringement.

Backlog of Unexamined Patent Applications/Pre-grant Opposition to the Grant of Patents

According to publicly available data, in anticipation of the improvements required by the TRIPS Agreement, the number of patent applications filed in India increased dramatically from 4,800 in 1994 (before entry into force of the TRIPS Agreement) to 35,000 in 2007-2008.²⁵ Moreover, the technological complexity of these applications increased with the extension of patent protection to pharmaceutical products and other complex technological fields. Unfortunately, the Indian Patent Office has not been able to examine these applications in a timely fashion because it only has about 135 patent examiners,

²⁴ The transitional period is unclear in that no date was suggested as to when the transition period should begin and no formal decision on the report has been made.

²⁵ Answer to Parliamentary Question raised in the Rajya Sabha on October 24, 2008

inadequate training programs for existing staff, inadequate resources, and inefficient substantive rules. Presently, according to figures published in the Indian Patent Office Journal, the total number of applications pending examination is around 44,000 (an increase of 22,000 over the previous year) and the average pendency period is 2-3 years.

PhRMA members understand that the Government of India has allocated an amount of \$US 75 million in the 11th Five-Year Plans to improve facilities and modernize the Patent Office. This is a significant step in the right direction. It appears that hiring a significant number of additional examiners and training current patent examiners will be necessary to cope with both the increased number of patent applications received each year and the increasing complexity of technology in these applications. PhRMA members request the U.S. Government to expand its “technical cooperation” to the Indian Patent Office and also urge international intergovernmental organizations to assist the Office. An MOU signed between USPTO and the Indian Government in December 2006 is a very positive development toward providing much needed technical assistance.

Modern facilities and additional examiners will not be sufficient to reduce the increasing backlog in a timely manner, however. The Government of India must also eliminate statutory and administrative practices that hinder the efficient examination of patent applications. For example, the Indian Patents law currently permits “pre-grant” oppositions to the grant of patent applications – that is, members of the public, including competitors and NGOs, are permitted to object to the grant of a patent any time after publication and anytime before the grant of Patent. It has been observed that multiple pre-grant oppositions have been filed sequentially by different competitors for the same patent application, thereby causing a substantial delay in issuing a decision, which in turn delays the grant of a patent. No procedures exist for quickly dismissing frivolous oppositions filed by competitors, and regulations requiring patent officials to conclude these oppositions in a timely manner are thwarted given the open-ended timeline. These oppositions and procedures create a significant amount of “unnecessary” work for patent officials and increased costs for the Patent Office and the patent applicant. Multiple pre-grant oppositions delay the grant of patents at the expense of the applicant without any accompanying benefit to society and create an opportunity for generic competitors and NGOs to manipulate and abuse the patent system. Reviews of Indian Patent Office Journals indicate that there are currently 200 pre-grant oppositions pending in the Patent Office, most of which relate to applications for pharmaceutical products, that may not be resolved in a timely manner. Frequent and extended delays under this system of pre-grant opposition deprive patent owners of a substantial portion of their patent term, which is inconsistent with obligations under TRIPS Articles 62.2 and 62.4.

Standards for Patentability

Some of the standards for patentability, as amended by the Patents (Amendment) Act of 2005, in India are inconsistent with the TRIPS Agreement, depart from the mainstream of practice internationally, or are not transparent. For example, the current Indian law does not allow second use and method of treatment patents.

Further, Section 3(d) of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005 creates additional hurdles for pharmaceutical patents. Under this provision, salts, esters, ethers, polymorphs, and other derivatives of known substances are considered the same substance and 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.

Section 3(d) is contrary to TRIPS in 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) goes beyond 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. The concepts in Section 3(d) are nebulous and potentially have a broad negative impact, thus undermining incentives for innovation.

The application of the criteria for patentability under Section 3(d) is not consistent or transparent because of the lack of clear guidelines for applying concepts the provision uses in determining patentability, such as "inventive step", "technical advance", and "economic significance". The draft Manual of Patent Practice and Procedure (MPPP) formulated by the Patent Office too does not provide any clear guideline to impart transparency in the application of Section 3(d) by the Patent Offices. Such guidelines, if promulgated, would provide consistency and transparency, as well as promote efficiency by reducing the number of issues that would have to be considered during the examination of applications.

Also, Section 3(i) of the Patents Act provides that "any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products" is not an invention. While WTO Members are permitted to exclude "diagnostic, therapeutic, or surgical methods" from patentable subject matter under TRIPS Article 27.3, they are nonetheless considered inventions. More importantly, the

invention and use of these methods can be extremely beneficial to society and should be encouraged by the patent system, not discouraged by their exclusion from the patent system.

Mandatory Compulsory Licenses for Mail Box Patents

One of the most damaging provisions of the Indian Patent Law is the Mandatory Compulsory Licensing for Mail Box Patents (Section 11 A and 5 (2)), which does not permit holders of patents that issue from mail box applications the ability to remove from the market generic copies already present in the country prior to January 1, 2005, or even after the date on which the patent was granted. In such a situation, the patent holder is only entitled to receive a reasonable royalty. This will allow generics already on the Indian market to continue with business as usual, denying the marketing exclusivity required by TRIPS Article 70.

India must ensure that the provision for Mandatory Compulsory Licensing for Mail Box Patents reflects its TRIPS obligations. Moreover, India should ensure that other aspects of its compulsory licensing (CL) provisions comply with TRIPS by:

- Clarifying that importation satisfies the “working” requirement (TRIPS Article 27.1);
- Eliminating mention of price as a trigger for a CL; and,
- In cases of compulsory license for exports, India should ensure that proper anti-diversion measures are taken and that the compulsory license itself is limited to humanitarian, non-commercial use.

Counterfeiting

India is an increasingly significant source of counterfeit pharmaceutical products and is believed to be a major channel for the export of counterfeits to consumers worldwide.²⁶ 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 import and export control.

²⁶ Cockburn R, Newton PN, Agyarko EK, Akunyili D, White NJ (2005) “The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers.” *PLoS Med* 2(4): e100 doi:10.1371/journal.pmed.0020100

Beyond these trademark-related deficiencies, weaknesses in India's drug regulatory regime contribute to the proliferation of counterfeit pharmaceuticals and the global export of these dangerous products. Even though pharmaceutical counterfeiting is first and foremost a drug safety violation, India has yet to enact drug laws that expressly address all aspects of drug counterfeiting activity, or to provide the kinds of remedies and enforcement resources necessary to combat this growing problem.²⁷ Of particular concern is the fact that India's drug laws do not define the term "counterfeit". In India, criminal liability appears to be conditioned upon proof of adulteration or harm. This burdensome evidentiary requirement not only precludes criminal prosecution of many counterfeiters, it fails to acknowledge the inherent dangers of deceptively mislabeled drugs. Anti-counterfeiting enforcement is further undermined by poor inter-agency coordination and India's failure to provide administrative remedies for drug safety violations.

Also of concern is India's failure to regulate the bulk active pharmaceutical ingredients (APIs) and other chemicals used to manufacture pharmaceutical products, including counterfeits. There are no laws that specifically regulate bulk chemicals or APIs; instead, such chemicals are regulated under the same laws that govern pharmaceuticals and are not subject to adequate protection to prevent their inclusion in counterfeit drugs. At a minimum, India's Government should clarify that all such bulk APIs are regulated pharmaceuticals subject to drug safety laws. Similarly, the Government should introduce additional safeguards to prevent wholesale and retail distribution of counterfeits via online pharmacies and traditional channels.

Market Access Barriers

Government Price Controls

PhRMA member companies are extremely concerned about the requirement, under the Proposed National Pharmaceutical Policy 2006, to extend current government price controls to patented medicines specifically. The proposed National Pharmaceutical Policy 2006 contains several provisions which favor domestic manufacturers over multinational companies. For example, it contains several provisions, such as designation of "Gold Standard Companies" and incentives for "indigenous innovations," which exempt local producers from government price controls.²⁸

²⁷ Legislation currently pending in the Indian Parliament would amend the Drugs and Cosmetics Act by increasing the level of penalties for "spurious and adulterated" drugs, but does not address other aspects of counterfeiting, such as a legal definition of "counterfeit." Furthermore, there is considerable uncertainty how this legislation, if enacted, would be implemented.

²⁸Draft National Pharmaceuticals Policy, 2006, Part A, p. 24,
http://pib.nic.in/archieve/others/2005/documents2005dec/documents2005dec_chemfert.pdf

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

Import Policies

PhRMA member companies operating in India face high effective import duties for active ingredients and finished products. Though the basic import duties for pharmaceutical products average about 10%, additional duties commensurate with excise duties applicable on the same or similar products, even when no such products are manufactured in India, as well as other assessments, bring effective import duties up to approximately 30%. Moreover, excessive duties on the reagents and equipment imported for use in R&D and the manufacture of biotech products make biotech operations difficult to sustain. Compared to other countries in the region in similar stages of development, effective import duties in India are indeed very high. These duties should be brought down to enable the pharmaceutical sector to realize its potential and for the benefit of patients. PhRMA urges U.S. Government officials to advocate that pharmaceutical duties be brought down to zero, the level of many WTO signatories.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

INDONESIA

PhRMA and its member companies operating in Indonesia remain concerned that the Indonesian Government has made little progress in improving the intellectual property and market access environment in the past year, and continues to pursue extreme measures that are preventing PhRMA member companies from providing timely access to essential medicines for Indonesian patients. Of immediate concern is a November 2008 Decree published by the Ministry of Health that severely restricts operations of multinational pharmaceutical companies that do not own a factory in Indonesia. Other important concerns to PhRMA and its member companies include insufficient anti-counterfeiting efforts, data exclusivity, patent linkage, the negative investment list, government controls on pharmaceutical pricing, bioequivalence requirements, and tax treatments.

For these reasons, PhRMA requests that Indonesia be placed on the **Priority Watch List** for the 2009 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

Anti-counterfeiting

Despite the establishment of a National Anti-counterfeiting Task Force, and efforts by Indonesia to stop piracy activities in certain sectors (e.g., optical disks), counterfeit medicines continue to be a significant problem in Indonesia. The International Pharmaceutical Manufacturers Group (IPMG) estimates that as many as 25% of drugs on the market in Indonesia are counterfeit. While we welcome 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 pharmaceutical products.

Data Exclusivity

As a Member of the WTO, Indonesia is required by Article 39.3 of TRIPS to prevent unfair commercial use of valuable test data generated by innovative companies to secure marketing approval. To date, Indonesia has not passed a data exclusivity law to fulfill that obligation.

Patent Linkage

The current process for determining and verifying the patent status of a product prior to marketing authorization is insufficient to protect the intellectual

property rights of the patent holder. A mechanism is needed to inform BPOM not to issue marketing authorization to a generic for a product that would infringe on existing patents in Indonesia.

Market Access Barriers

Ministerial Decree No. 1010/MENKES/PER/XI/2008

In November 2008, BPOM issued a Decree that severely hinders the ability of many PhRMA member companies to conduct business in Indonesia by placing excessive penalties on companies that do not own production facilities in Indonesia. This Decree has reclassified such companies as wholesalers/distributors (PBFs) and blocks such companies from renewing registrations and registering new pharmaceutical products in Indonesia in the future. While the Decree is a major market access barrier, it also represents a serious erosion of intellectual property rights of the affected pharmaceutical companies by forcing the transfer of intellectual property to local manufacturers. The Decree could ultimately reduce Indonesian patients' access to innovative medicines. PhRMA and its member companies ask that an immediate standstill be placed on Ministerial Decree No. 1010/MENKES/PER/XI/2008 until a solution is reached between PhRMA's member companies and the Indonesian Government.

Negative Investment List

In 2007, Indonesia issued Presidential Regulation Nos. 76/2007 and 77/2007, outlining a series of restrictions on foreign direct investment (FDI). Among other things, these Regulations establish a negative investment list that sets equity caps on the amount of foreign investment allowed in the pharmaceutical sector and discriminates against certain business models. Regulation 77/2007 requires that any change in shareholding capital of a pharmaceutical company triggers a requirement for foreign ownership in that company to be (reduced to) no more than 75% of the new investment, meaning that a suitable local partner needs to be found to take up the remaining 25% interest. Even if a suitable local partner can be found, the 25% ceiling limits the expansion ability of the company. It also renders ineffective any buy-out mechanism if the relationship does not work.

Regulation 77/2007 has also affected pharmaceutical companies that operate in Indonesia without a local manufacturing presence. Under the Regulation, these companies are currently, and improperly, classified and operating as wholesalers/distributors. Foreign ownership is not allowed in the wholesaler/distribution area, with an exception for existing wholesalers/distributors. Although Article 5 of the Regulation, as amended in Regulation No.111/2007, states that "the provisions of this Perpres 77/111 2007

shall not apply to investments in certain business fields that have been approved prior to the issuance of this Presidential Regulation,” companies that operated as wholesalers/distributors prior to the new investment law and that obtained this “grandfathering” approval in accordance with the provision have routinely seen applications rejected or delayed. Furthermore, the above referenced Ministry of Health Decree No. 1010/MENKES/PER/XI/2008 has effectively denied these companies a grandfathered status.

Given this situation, some imported products might no longer be available in Indonesia within the next two years. This number could increase over time because all registration licenses kept by companies operating with wholesaler licenses must be renewed every two years. Numerous U.S.-based pharmaceutical companies will be affected by this requirement unless this issue is addressed immediately.

Despite attempts to engage with the relevant authorities, there remains a disturbing lack of clarity and transparency surrounding the implementation of the Regulations. We understand that the negative list was reviewed in June 2008, and that this review has been completed. However, the results of the review have not been made public, causing continuing uncertainty for PhRMA’s member companies.

Article 3 of Indonesia’s Investment Law states that the “principle of transparency” is one of receptiveness to the right of the public to have access to true, honest, and non-discriminatory information on investment activities. This principle has not been followed in this case, as calls for clarity have gone unanswered and applications are rejected or delayed without explanation. Article 3 of the Investment Law also states that “principles of equal treatment and non-discrimination on country of origin” apply to both domestic and foreign investors, and between investors of one foreign country and another. The spirit of Presidential Regulation Nos. 76/2007 and 77/2007 directly contradicts this assurance of non-discrimination and national treatment, as foreign firms are put at a severe disadvantage with respect to local and certain foreign firms.

In addition to the financial implications of the Regulations, the health consequences for the Indonesian public may also be significant. By forcing foreign pharmaceutical companies without a domestic manufacturing presence to hand control over product distribution to a third party, these companies cannot ensure the integrity of the supply chain. This could exacerbate the already serious counterfeit drug problem that plagues the Indonesian market.

Bioequivalence Requirement

BPOM has established bioequivalence requirements for generic applicants seeking marketing approval. Today, there are approximately five laboratories that have the technical capacity to carry out

bioavailability/bioequivalence (BA/BE) studies in Indonesia. PhRMA is concerned that the other testing facilities in Indonesia used to assess the bioequivalence of generic products may not be adequate.

Tax Treatments

Varying implementation approaches by the tax office regarding tax levies appear to unfairly target multinational companies (MNCs) and present many obstacles. Ambiguous tax laws and inconsistent interpretation of transactions result in higher tax burdens for MNCs. These problems are normally not applicable to local companies or are avoided by local companies through mechanisms not available to MNCs. Additionally, tax auditors provide little opportunity for companies to respond adequately to inquiries.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 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. These provisions will: improve PhRMA members' access to the Korean market; further improve the transparency and accountability of the National Health Insurance (NHI) system; and secure better and lasting recognition of the value of innovative American biomedical discoveries, thereby enhancing Korean patients' access to the most innovative medicines.

We recognize that, in line with its FTA commitments, Korea has started work toward the establishment of a patent linkage system in the Korean Food and Drug Administration's (KFDA) drug approval system, and an independent appeal review process in the government drug pricing and reimbursement system. We support efforts of the Korean Government to fulfill these commitments, and encourage Korea to implement these new systems as soon as possible. Doing so will send an important signal to the world that Korea puts a priority on protecting and enforcing intellectual property rights and ensuring that its government pharmaceutical pricing and reimbursement system operates in a transparent, predictable and non-discriminatory manner consistent with accepted international practice.

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 2009 Special 301 **Priority Watch List**.

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 health insurance system is critical to having any meaningful ability to participate in the Korean market. Only since August 1999 have innovative products, which are mainly imported into Korea by U.S. and other multinational producers, gained access to Korea's national healthcare system. Despite that initial opening, U.S. and other multinational

companies 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. Korea's policies have also long favored the domestic industry, which has a disproportionately large share of the Korean market. Moreover, on May 3, 2006, the Korean Government proposed an entirely new pricing and reimbursement system for pharmaceuticals, which Korean authorities are continuing to work to implement. The KORUS FTA, when implemented, would take several strides forward in addressing these issues and ensuring that U.S. pharmaceutical companies have fair and non-discriminatory access to this important 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 government pricing and reimbursement system, known as the Drug Expenditure Rationalization Plan (DERP), which was implemented on December 29, 2006, remain vague and, in some cases, appear to run contrary to the commitments Korea made under the KORUS FTA. There are a number of new developments that are of priority concern to PhRMA. These include:

- 1) Under 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 regulations be 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.
- 2) Under 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 stakeholders, including PhRMA member companies.
- 3) There have been many flaws in the Korean pilot project to re-evaluate currently listed drugs. Of note, Korean authorities conducted the pilot project in a non-transparent manner, and stakeholders were not given basic information as to how products were evaluated under the project until after the project was essentially completed. Revised results for the pilot project on hyperlipidemia drugs were decided (but not made public) in mid-November. PhRMA member companies are currently appealing these results because they were not developed in a fair and transparent manner and that was in line with international norms. PhRMA believes it

is essential that Korean authorities provide assurances that, in the future, all drugs subject to re-evaluation will be reviewed in a fair and transparent manner consistent with international norms.

- 4) The Korean Fair Trade Commission (KFTC) has been conducting an investigation of the conduct of both domestic and innovative pharmaceutical companies in the market. On October 31, 2007, the KFTC issued corrective orders and fines on 10 pharmaceutical companies, only one of which was a PhRMA member company²⁹. On January 15, 2009, the KFTC issued a second sanction on seven pharmaceutical companies, five of which are PhRMA member companies. While details of this second round of sanctions have not been made available, it appears that the sanctions have been levied on a number of activities which are normally consistent with globally-accepted standard and practices.³⁰ We fully endorse the spirit of the KFTC's efforts to improve transparency and ethical business practices in the pharmaceutical market, and we believe that it is important that the Korean Government put a high priority on this issue in 2009 and beyond. With a growing number of "blockbuster" generics and incrementally modified drugs being brought to market in Korea, competition to gain access to institutions' formularies is fierce. As such, it appears that use of unethical business practices in this sector, such as providing payment and/or gifts in return for access to a formulary or agreement to prescribe specific drugs, is growing.³¹ It is essential that Korea actively enforce its laws in this area and conduct its evaluations in a fair and non-discriminatory manner. It is also important that Korea ensure that its rules and guidelines in the pharmaceutical market are consistent with globally-accepted standards and practices.

- 5) 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 point. 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, several price-cutting mechanisms are built into the DERP such that an innovative drug's price can be significantly reduced by the Government within just a few years of introduction in the Korean market. Of key concern is the use of "Price-Volume Agreements" (PVAs). Under PVAs, if a drug is more popular than originally estimated 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 contradicts

²⁹ KFTC Newsletter, Issue 5, Dec 28, 2007, p. 6.

http://eng.ftc.go.kr/bbs.do?command=getList&type_cd=10

³⁰ KFTC Press Release, "KFTC Orders 7 Pharmaceutical Companies to Correct Illegal Inducement of Customers and Retain of Resale Prices," January 15, 2009.

³¹ KFTC Press Release, January 15, 2009.

Korea's FTA commitment to adequately reward innovation, and we believe that PVAs should be eliminated from the DERP system.

PhRMA urges the U.S. Government to work with the Korean Government to address concerns in these and other areas. Even though the KORUS FTA has yet to be ratified, it is critical that Korea ensure that its government pricing and reimbursement policies are developed and implemented in a way that is fully consistent with its obligations under the Agreement.

Early and Full Implementation of the KORUS FTA is Essential

PhRMA urges Korean authorities to move to implement commitments under the KORUS FTA, including the establishment of a patent linkage system and an independent appeals mechanism, as quickly 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.

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 KORUS FTA commitments are implemented fully.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

NEW ZEALAND

PhRMA and its member companies operating in New Zealand remain concerned over the government procurement system employed by New Zealand. The Government of New Zealand remains the primary purchaser of pharmaceuticals in New Zealand. New Zealand's Pharmaceutical Management Agency (PHARMAC) continues to impose stringent cost containment strategies, and operate in a non-transparent, unpredictable manner, creating an unfavorable environment for innovative medicines.

For these reasons, PhRMA requests that New Zealand be placed on the **Priority Watch List** for the 2009 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

The Patents Bill, Government Bill 235—1 of 2008 was introduced to the New Zealand Parliament in July 2008 and is intended to amend the Patents Act of 1953. The draft legislation would put in place a new procedure for challenging the grant of a patent. This overbroad administrative revocation procedure would allow third parties to apply to the commissioner of patents to seek a revocation at any time during the term of the original patent.

One notable omission from the proposed amendment is patent term restoration. Many countries, including the U.S., Australia, and in the EU, have established mechanisms to restore patent terms for pharmaceutical products to recover effective patent life lost due to the regulatory approval process. PhRMA's members urge the New Zealand legislature to amend the current bill to include patent term restoration in keeping with international best practices. It is anticipated that a select committee will consider the bill during 2009 and call for public submissions. PhRMA and its member companies will advocate for the application of international best practice at this time.

Market Access Barriers

Government Reference Pricing

Government Reference pricing mechanisms have been introduced in several countries, including Germany, the Netherlands, Denmark, New Zealand and British Columbia.

Under reference pricing, medicines are grouped into clusters with therapeutically similar properties. The funder sets a single reimbursement price for all products in a cluster.

In New Zealand, in order for a product to receive a subsidy, the price of the product must equal the subsidy; thus PHARMAC effectively dictates the price.

In theory, where already funded products have their subsidy reduced as a result of reference pricing, the supplier is free to charge a price above the reference price. In practice, this rarely takes place as patients are generally unwilling to pay the difference as an excess out of pocket charge.

Under reference pricing, when a supplier introduces a new product with enhanced safety or efficacy attributes, there is no payment recognition for the superior product, even when the benefits of the new medicine are significant. PHARMAC's aggressive reference pricing models thus erodes the intellectual property rights of innovative medicine suppliers. For example, market exclusivity is protected by the patent, but the commercial value of the patent is significantly undermined by reference pricing to competing off-patent products, effectively diminishing the patent holders' economic return on investment.

Government Pricing and Reimbursement

Though not explicitly stated, PHARMAC's reimbursement decisions suggest that 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 narrow approach, combined with the need to stay within a capped budget, means that many of the most effective medicines are not made available to New Zealand's patients. Recent analysis has found that of the 78 innovative new prescription-only medicines listed on the Pharmaceutical Benefit Scheme in Australia between May 2000 and October 2006, only 20 are currently reimbursed in New Zealand. Many of these 20 products have restricted reimbursement, such as reimbursement for limited indications.³²

Incorporating the Biotechnology Taskforce Recommendations

The Government's Biotechnology Taskforce made the following recommendations in 2003 to enhance the Government's relationship with PhRMA's member companies and stimulate research investment:

³² *Access by patients in New Zealand to innovative new prescription-only medicines, how have they been faring in recent times in relation to their trans-Tasman counterparts*" Michael Wonder, Senior Health Economist, at Novartis Pharmaceuticals Australia.

- 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".

The first recommendation was achieved initially with an announcement in September 2004 of annual budgets through 2007. Unfortunately this policy was rescinded, and the subsequent budget for 2008-2010 was not published. To date, the Government has not implemented the second recommendation.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

CZECH REPUBLIC

The Czech system for determining government pricing and reimbursement levels for pharmaceutical products constitutes a significant barrier to imported innovative pharmaceuticals, particularly of U.S. origin. This and other market access barriers in the Czech system restrict access by Czech patients to advanced life-saving medical treatments. In light of these measures and others discussed below, PhRMA recommends that the U.S. Government identify the Czech Republic as a **Priority Watch List** country in the 2009 Special 301 Report.

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 pharmaceutical companies is the Czech Government's use of "therapeutic reference pricing," which links reimbursement for patented and non-patented products. Other aspects 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.

Recent Changes in the Government Pricing and Reimbursement Setting

In the newly-created paragraph 39 of Law 48 of 2007 dealing with government pricing and reimbursement, both processes will be concentrated in a single regulatory body – the State's Institute for Drugs' Control (SUKL). The Law makes SUKL responsible for all three steps necessary for the access of drugs to the market, starting with the medical evaluation of their efficacy and safety, and continuing with government pricing and reimbursement.

Although the Law establishes strictly-defined verifiable criteria for both government pricing and reimbursement, it is very restrictive. For example, in the field of 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). In the field of reimbursement the lowest price for the final customer of a specific product in any EU country is the basis for the reimbursement of the product in the Czech Republic and, worse still, fixes for the future the above-described therapeutic referencing within and across broadly-created reference groups and clusters.

The Czech Government is expected to review and propose amendments to Law 48 in the first quarter of 2009. The Czech Government should be urged to amend Law 48 to ensure that patented products are not included in reference

groups with non-patented products, thereby ensuring that innovative pharmaceutical companies can effectively exercise their patent rights.

Reimbursement Criteria

The Czech Government uses a therapeutic reference pricing (TRP) system for setting reimbursement rates for medicines. 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 will award a reimbursement premium to a patented molecule. However, any reimbursement cut for a generic molecule nearly always triggers corresponding reimbursement cuts for the branded molecule. By grouping patented and non-patented products together in pricing groups, the Czech Government significantly diminishes the benefits of patents and fails to protect adequately the intellectual property rights of innovative pharmaceutical companies.

If the Government cuts the reimbursement for a drug below the market price, patients must make up any difference out of their own pockets. Whenever reimbursement cuts target innovative drugs for significant co-payments, these co-payments target imported drugs, as the innovative U.S. company is either forced to lose its market to low-priced generic competitors, or to meet the price of the cheapest generic in the group. 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 other products still protected by patents.

Grouping patented products with generics and linking reimbursement for patented and generic products forces government-reimbursed prices for imported patented products towards those of domestically-produced generics. This undermines the value of pharmaceutical patents in that market segment. Through the operation of this policy, the Ministry of Health (MOH) and the insurance funds are effectively operating a purchasing cartel and are jointly fixing a maximum reimbursement price that restricts competition. At the same time, the Government's policy heavily favors local generic manufacturers, who almost always produce the generic competitors to imported patented drugs. An effective remedy against 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, limiting

which medical specialties may prescribe certain medications. These limits severely affect demand for the products they restrict, 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, and a generic product (almost always domestically produced) enters the market. For example, for many years, general practitioners were only permitted to prescribe the generic antidepressant fluoxetine, and all imported patent-protected antidepressants could only be prescribed by psychiatrists. As soon as the patents on the other antidepressants expired and local manufacturers launched generic versions, the Government immediately removed all prescribing limitations on antidepressants. The same type of discriminatory changes took place with sartans, a class of medicines.

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 serves as a brake on demand, particularly for higher-priced drugs, because the budget is based on the price of drugs, not on the volume of drugs prescribed. Although this system affects demand for all pharmaceuticals, because imported innovative drugs are generally more expensive than domestically produced generics, they are disproportionately affected.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

GERMANY

PhRMA and its member companies operating in Germany remain concerned that Germany maintains several measures that discriminate against innovative pharmaceutical products as compared to generic products, thereby denying fair and equitable market access to U.S. interests that rely on intellectual property protections in the German market. Among other things, these measures relate to: (1) the cost-benefit analyses being developed by the Institute for Quality and Efficiency in the Healthcare System (IQWiG); (2) the limitation of government reimbursement prices for pharmaceutical products resulting from fixed reference prices and reimbursement ceilings; and (3) restrictions on patient access to information about innovative pharmaceutical products.

In light of these adverse measures, Germany remains one of our highest priority countries for this Special 301 submission. To demonstrate the importance that PhRMA continues to place on resolving the following outstanding market access barriers, PhRMA requests that Germany be placed on the **Priority Watch List** for the 2009 Special 301 Report.

Market Access Barriers

2007 Healthcare Reform and IQWiG

Germany is in the course of implementing the Healthcare Reform Act of April 1st, 2007 (“GKV-WSG” - Act for the Enhancement of Competition in Statutory Health Insurance). Although the Act has led to some improvements to the German healthcare system, significant market access barriers remain for innovative pharmaceutical companies. One of the most significant relates to the operation of IQWiG. In addition to other tasks, IQWiG provides pharmaceutical benefit analyses and, based on the Act, will perform cost/benefit analyses for the Joint Federal Committee (GBA) and/or the Ministry of Health, particularly for new pharmaceutical products introduced in Germany. IQWiG’s determinations, in turn, are the basis for reimbursement decisions of the GBA, the top decision-making body in the German statutory health insurance system. While the GBA can issue reimbursement restrictions (reference prices, therapeutic guidelines, etc.) independent of IQWiG assessments, IQWiG’s decisions have significant influence on GBA’s positions. In addition, the setting of uniform maximum reimbursement amounts for all sick funds, a new cost-containment measure introduced pursuant to the Act, requires a negative cost/benefit assessment by IQWiG.

Health insurance is provided to the vast majority of German citizens through one of 238 sick funds (i.e., legally chartered not-for-profit insurance providers). The reimbursement decisions of the GBA are binding for all 238 statutory sick funds. Thus, a single decision by the GBA (which as noted above,

relies heavily on IQWiG's analysis) sets a single reimbursement rate for a pharmaceutical in virtually the entire German market.

Research-based pharmaceutical companies have a number of concerns regarding how assessments and decisions are made by IQWiG and the GBA.

- **Value of Innovation:** IQWiG and GBA have inadequately taken into account the value of innovative pharmaceuticals, considering only limited data to substantiate the value brought to patients and payers by new medicines.
- **Transparency and Opportunities for Engagement:** There is no mechanism that ensures sufficient interaction and exchange of information between pharmaceutical manufacturers and IQWiG during the evaluation process. Similarly, patients and physicians have limited opportunities to provide their perspectives to decision makers. Companies' participation in the evaluation process is limited to only providing comments on the report plans and on the preliminary reports, which PhRMA has done on two occasions.
- **Lack of Appeals:** There is no ability to appeal an IQWiG assessment or a decision made by GBA, except by going outside the process to the German legal system and the social courts. (Social courts represent one of the five branches of the German legal system, and have in their jurisdiction matters involving the statutory health insurance system.) However, these legal challenges take years, and during the process there is no injunctive or other relief from a negative GBA decision.

The 2007 Healthcare Reform Act has clarified some of the requirements for transparency and participation in the IQWiG appraisal process, and requires IQWiG's adherence to international standards of evidence-based medicine and pharmaco-economics. PhRMA and its member companies welcome these amendments, although we note that there are still many issues where consensus on "international standards", to which IQWiG is required to adhere, has not yet been achieved.

Reimbursement Ceilings

Reimbursement ceilings introduced by the Law negatively effect market access for innovative pharmaceuticals. Like government reference prices, they limit reimbursements for all statutory sick funds, but unlike reference prices, they may be fixed in the absence of other, pharmacologically-comparable drugs. If a cost-benefit assessment by the IQWiG determines that a new product is not cost-effective compared to other therapeutic options, which may include non-drug therapies, the Federal Association of Sick Funds may set a fixed reimbursement ceiling. The Law neither defines how PhRMA member companies can

participate in this decision-making process, nor describes the criteria for increasing the transparency of the process. The only stated requirement is that R&D costs of pharmaceutical manufacturers have to be taken into account, though the Law does not describe how this is to be done. It remains unclear whether this requirement may discriminate against international companies whose R&D costs are incurred mainly outside of Germany.

Reimbursement ceilings are particularly problematic due to the lack of: (1) transparency of the process; (2) clearly defined guidelines for stakeholder input; (3) adherence by IQWiG to international standards in the drug assessment process; and (4) concrete steps to implement the improvements required by the healthcare reform.

Government Reference Pricing – Jumbo Groups, “Additional Therapeutic Value”

Through its Therapeutic Reference Price (TRP) system for determining the reimbursement of new medicines, the GBA (see below), groups patented products together with older generic drugs in reference groups. The establishment of these reference or “Jumbo Groups” undermines product patents and the ability to capture the relative value of products in the marketplace.

The German law that established the FRP system has a procedure by which “novel” patented products may be excluded from the system if manufacturers are able to demonstrate “added therapeutic value.” However, to date, the German Government has not issued objective and verifiable scientific criteria for excluding novel products, leaving companies uncertain about what information is required to obtain an exemption, raising concerns about the basis upon which decisions are being made, and resulting in market access barriers. Those whose applications have been denied may appeal a decision, but the lack of transparency may discourage them from doing so.

Joint Federal Committee (GBA) – Process and Transparency

Reimbursement decisions for pharmaceuticals under Statutory Health Insurance are made by the GBA. Voting members of the GBA are named by the federal associations of physicians and sick funds; patient representatives are non-voting members. The GBA commissions IQWiG drug benefit and cost-benefit assessments in setting reimbursement restrictions. It may, however, issue therapy advice or reimbursement restrictions without an IQWiG assessment. In the TRP fixing process, the Committee determines product groupings, as well as whether patented products should be excluded from the TRP. In addition, the GBA defines which drugs require a second opinion for prescription within the Statutory Health Insurance System. The GBA’s decision-making procedures are flawed in the following ways:

- The GBA lacks transparency. It is not clear what a party needs to provide in order to demonstrate “added therapeutic value” and be exempted from the TRP system, or what criteria the GBA applies in its decisions on reimbursement restrictions;
- Its procedures do not allow for a meaningful dialogue between the developer of a new drug and the individual who evaluates it, denying any discussion of the science behind an evaluation of its innovative therapeutic value;
- There is no effective legal protection or control over the implementation of the FRP or reimbursement restrictions. Any actions relating to this system must be brought to the social courts, which apply very strict requirements for summary proceedings and pharmaceutical injunctions. Additionally, these legal challenges last for years, and during the process there is no relief from a negative GBA decision. If a research-based manufacturer loses years of market exclusivity during a lawsuit, any eventual favourable decision likely will be meaningless.

Like the IQWiG, the GBA is reluctant to implement the transparency requirements of the 2007 healthcare reform in a timely and robust manner, particularly as regards granting improved participation rights to pharmaceutical manufacturers.

Because German Sick Funds provide healthcare to approximately 90 percent of the German population (10 percent are privately insured), the impact of the FRP system on research-based pharmaceutical companies has been, and will continue to be considerable. This government pricing system has created an environment that discourages research and development.

Ban on Information to Patients

Like other EU Member States, Germany has transposed strict prohibitions on the marketing and advertising of innovative medicines from European to German law. Specifically, Article 88 of European Parliament and Council Directive 2001/83/EC require EU Member States to prohibit all advertising of prescription medicinal products to the general public. Under a strict interpretation of the Directive, pharmaceutical company web sites directed to the general public may contain only unedited copies of the labeling and assessment reports produced by government agencies, without any product-specific information from the company itself, no matter how accurate, up-to-date and balanced that information may be. Such key product information also cannot be available through other mechanisms, such as print media. In contrast, patients are permitted to receive information about over-the-counter medications.

A ban on such helpful information has many potential adverse consequences: it prevents patients from making informed choices; it impedes market access of new innovative medicines that are least familiar to patients in

terms of their beneficial properties (and which often are imported); and it puts non-English speaking German patients at a huge disadvantage because they can not obtain valuable information in their own language.

Additional Market Access Barriers

Other German healthcare cost-containment measures exist that, taken collectively, further undermine German patient care, discriminate against healthcare innovation, and raise barriers to trade for innovative pharmaceutical companies. These include:

- Strict monetary dispensing guidelines for physicians and pharmacists on patient, speciality, region and yearly bases. Due to the potential for legally mandated audits and personal fines, physicians are forced to base prescribing not solely on the health conditions of their patients, but on other externalities that influences which prescriptions should be written. As a result, generic medicines are often prescribed, even when patented products would provide the best result for the patient's condition.
- A quota that pharmacists must meet for dispensing "parallel imports" – mostly patented products from outside the country that are imported and sold at a minimum discount of €15 (or 15 percent, whichever is less) within Germany.
- Mandatory rebates that manufacturers have to pay to the statutory sick funds were introduced in 2003 and are still in effect. A 6% rebate for all drugs without reference prices particularly impacts innovative drugs.

Finally, while PhRMA was pleased to see the April 1, 2007, Law passed and believes that it can lead to the reduction of market access barriers for innovative pharmaceutical companies, it is critical that the Law be implemented fully and transparently.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

HUNGARY

A variety of severe cost-containment measures 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. For these reasons, PhRMA requests that Hungary be placed on the Special 301 **Priority Watch List** for 2009.

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. Instead of passing legislation to establish this protection, the Hungarian Government submitted a derogation request that was refused in 2004 by the EU. The European Commission reiterated the need for full implementation of 8/2/1 data protection in 2008.

Market Access Barriers

Transparency and Cost Containment Measures in Government Reimbursement

The Government of Hungary provides health care to its citizens through the National Health Insurance Fund (NHIF).

In order to fulfill the EU Maastricht criteria, a wide-ranging reform of the government reimbursement system was introduced as part of a broad program to curb public spending in order to achieve convergence with the fiscal criteria required to join the euro-zone. Effective January 2007, pharmaceutical legislation established certain new tax burden elements and created new barriers to patients' access to pharmaceutical products. These include the following:

- A 12% tax for retail reimbursed sales.
- The introduction of a \$25,000 tax for each sales representative operating in Hungary, roughly doubling the cost of hiring sales representatives. After a judicial review of this policy by the Constitutional Court, the sales representative tax was abolished, effective June 18, 2008. However, the Government intends to re-introduce the tax in a form that it believes complies with the Constitution.
- A general reduction in the level of reimbursement, resulting in an increase in co-payments for approximately half of reimbursed drugs by 50%.

- The NHIF is not transparent about how it uses pharmacoeconomic data for decision-making.
- Reimbursement is only available for a limited number of indications.
- Reimbursement approvals are subject to an overly-lengthy publication process, requiring a ministerial decree, and thus are incompatible with EU Directive 89/105/EC.
- The formulation process of Type 2 government reference pricing groups is not transparent.
- A claw-back system under which growing companies will become financially accountable for all of the overspending in the retail pharmaceutical budget.
- Restricting patient access to prescriptions for specialty medicines to a limited number of centers.
- Three year reimbursement volume contract obligation for all drugs reimbursed at 100%.
- Quarterly electronic bidding in reference priced groups, with delisting.

The budget-cutting system imposed by the 2007 law is not sustainable in the long run. 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 Sick Fund financial exposure. In certain circumstances, this limitation increases pressure for increased funding of reimbursement by creating additional incentives to increase sales volume.

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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

ITALY

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

Between 2001-2007, Italy adopted 18 different cost-containment measures through several laws and decrees affecting the pharmaceutical sector, including Law 222/2007 (enacted on November 29, 2007), which is linked to the provisions of the 2008 Financial Act. As a result of these measures, Italy's pharmaceutical market is moving further away from a free market system.

Although the Government has engaged in a positive dialogue with PhRMA member companies, measures imposed pursuant to Law 222/2007 contain new rules that could further restrict the market and do not conform with declared intentions to improve access to new pharmaceutical products. Pursuant to the Law, the Italian Drug Agency (AIFA) has established a fixed-sales budget for each company operating in Italy. This unprecedented measure has created non-competitive market conditions. In addition, Law 222/2007 requires companies, pharmacists, and wholesalers to refund 100 percent of the value of all additional sales made through the retail sector if public pharmaceutical retail expenditures exceed 14 percent of the National Healthcare Fund (NHF).

Despite these problematic provisions, it is important to acknowledge that Law 222/2007 does, for the first time, implicitly recognize the importance of innovation by limiting the effect of budget caps to products older than three years. In addition, the Law limits the ability of Italy's regions to implement additional cost-containment measures without the approval of AIFA, and requires the regions, not pharmaceutical manufacturers, to cover any overspending in the hospital sector.

At the same time, regional governments are continuously and autonomously introducing measures and burdens that limit, delay or deny access for innovative and patented drugs in the retail and the hospital channel, fragmenting the regulatory scenario and the Italian market into 21 different systems.

To demonstrate the importance that PhRMA continues to place on resolving the outstanding market access barriers in Italy, PhRMA requests that Italy be placed on the **Priority Watch List** for the 2009 Special 301 Report.

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 is creating non-competitive market conditions that restrict growth and Italian patients' access to the most innovative products. To this end, the Italian Antitrust Authority (IAA), on October 25, 2007, 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.

Government Pricing and Restrictive Reimbursement Policies

Pursuant to Law 222/2007, the pharmaceutical sector must now refund 100 percent of overspending in the retail pharmacy sector (representing about 83 percent of the overall public pharmaceutical expenditure). For hospital sales, pharmaceutical companies will no longer be asked to refund any overspending, but the cap has been reduced from 3 to 2.4 percent of the NHF (excluding the drugs sold through third-party distribution). Excess expenditures will be the responsibility of the regions, which likely will lead to the introduction of cost-containment measures targeted at healthcare expenses, including pharmaceuticals.

In addition, in 2007, AIFA introduced a system for evaluating innovation, to be used in government 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 these drugs. These procedures may discourage patients' compliance and create bureaucratic burdens for innovative pharmaceutical companies.

Drug Formulary Revision

In 2002, 2004, and 2006, the Government introduced revisions to the National Formulary for all drugs reimbursed by the National Healthcare System (NHS). The first revision, introduced in 2002, established a limit to reimbursement levels inside several therapeutic classes, adversely affecting higher-priced innovative drugs. A second and third revision affected drugs that registered a sales increase higher than the industry's average growth.

Medicines, particularly innovative pharmaceuticals, bore additional government-controlled price cuts of up to ten percent.

Health Care System

The Italian Government's focus on controlling pharmaceutical expenditures is unique relative to other expenditures within Italy's NHS. Pharmaceutical expenditures are capped at 14 percent (retail) and 2.4 percent (hospital) of the NHF, while no other category of healthcare expenditures faces 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, other health care costs registered an average growth of 41.2 percent.³³

Regulatory Approval, Market Access Delays and Limitations

As documented in the IMS 2008 study, "Patients W.A.I.T", the average marketing delay 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. While the creation of AIFA in 2004 reduced these delays, they remain far above the EU average.

At the local level, in the vast majority of the regions, it takes, on average, an additional 230 days (from the date the drugs are approved by the AIFA) for H-class drugs (those limited to distribution within hospitals) to be approved.

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.

PhRMA Complaint Against the Government of Italy Under EU Law

In late 2002, PhRMA filed a complaint with the EU concerning an Italian decree that, among other things, imposed a 5% reduction on sales prices of medicinal products, including pharmaceuticals, a 50% reduction in spending on scientific conferences held outside of Italy, and new labeling requirements for the outer packaging of medicinal products. These measures contravened a variety of EU laws, including EU rules on transparency and non-discrimination against imports. PhRMA has updated its complaint over the years to reflect new infringing measures, including Law 222. PhRMA member companies believe

³³ Government of Italy. Ministero del Lavoro, della Salute e delle Politiche Sociali, 2008.

that it is important for the EU to take appropriate action to ensure that Member States, including Italy, are acting consistently with EU rules.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

POLAND

In Poland, transparency concerns continue to undermine the reimbursement process, while weak intellectual property and discriminatory policies continue to block access to the market. PhRMA therefore recommends that Poland be placed on the Special 301 **Priority Watch List** for 2009.

Intellectual Property Protection

TRIPS Article 41 requires Poland to provide for fair and equitable enforcement of intellectual property rights. Enforcement of intellectual property rights is extremely insufficient in Poland:

- There are considerable procedural barriers to obtaining preliminary injunctions against patent infringement. The Industrial Property Law does not contain discovery rules (provided in Copyright Law for instance), which would facilitate establishment of patent infringement.
- The current damages awarded for intellectual property rights violations are inadequate compensation for infringements, as the right holder is rarely permitted to recover its profits. This clearly fails to comply with TRIPS Article 45.

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 is obligated 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 of Poland 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 some individual court rulings, Polish law does not recognize “conditionality” in this situation. In addition, this was wholly inconsistent with EU rules and Polish pre-accession regulations. Furthermore, additional conditional authorizations have been issued with retrospective grant dates preceding the date of EU accession in 2004.

PhRMA member companies are concerned that MoH may use a similar approach in 2008 to issue conditional re-registrations for older generics when the transitional period allowed for upgrading of old dossiers comes to an end. The violations of the transitional provisions are the subject of an EU infringement procedure, which has been referred to the European Court of Justice.

Failure to Implement Data Exclusivity Rule

Poland was required to provide innovative pharmaceuticals the European “8/2/1” term of data exclusivity 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.

Market Access Barriers

Reimbursement Backlog

Despite incremental steps in addressing the backlog of innovative applications for reimbursement, the government reimbursement list has only been updated once, in July 2008, following a 3-month delay. No new substances, meaning no new innovative medicines, have been added to the list. Meanwhile, the MoH posted a reduction in the prices of 85 drugs already within the government’s reimbursement system. The updated list contains 15 new generic drugs, while 79 drugs have been removed from the list (at the request of their producers). Approximately 100 new molecules are still waiting for inclusion or other decision by the MoH.

To date, MoH has failed to provide reasoned justifications for (dis)approvals, an appeals process, or a clear timeline for reimbursement decision-making. Moreover, no improvements are expected in 2009 because the National Health Fund has planned a 1.5% decrease in drug reimbursement.

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 entirely clear. Current provisions do not meet the appropriate standards of transparency (e.g., a clear appeals procedure) and would make the decision-making process lengthier. Moreover, the review of recommendations by the AOTM in no way mitigates the need for Poland to meet the requirements of the EU Transparency Directive and to issue individual decisions within 90 days.

The AOTM could become better defined as a result of proposed updates to the Healthcare Law, which are currently being reviewed by Parliament. The proposed updates contain new mechanisms for creating guaranteed and non-guaranteed medical services – a Basic Benefit Package, and the role of Health Technology Assessment in the reimbursement process. These amendments leave many gaps regarding transparency in the government pricing and reimbursement system. Moreover, the proposed updates still do not provide

objective and verifiable criteria, justification of decisions, or a comprehensive appeals procedure. Under the amendments, 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.

Government Pricing Policies

Similar to reimbursement decisions, government pricing decisions also are made by regulation, *i.e.*, an act which cannot be appealed to or reviewed by an independent court.

An example of a discriminatory government pricing activity which affects U.S. and other foreign pharmaceutical companies is the planned amendment to the Pricing Act of the Pharmaceutical Law, which would formally define selling price and fixed margins. If such an amendment came into force as drafted, it would likely restrict the freedom of business operations for pharmaceutical manufacturers.

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."³⁴

The Polish Government has yet to repeal its 2006 discriminatory 13% price cut on imported medical products, raising WTO national treatment concerns. 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 (*Regulation by the Minister of Health on advertising medicinal products*, published 28 October 2008) was put into force on December 1, 2008, which is having a significant impact on U.S. pharmaceutical companies

³⁴ Guidelines from the WHO's Center for Drug Statistics. Methodology Concerning ATC/DDD use for Pricing (2004).

doing business in Poland. The regulation limits access to physicians 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 extremely short implementation time did not allow pharmaceutical companies to adapt their practices and activities to the new requirements, and the impact of this sudden but significant limitation of operations is still being assessed as pharmaceutical companies monitor the first weeks of compliance with this regulation.

Moreover, this year the MoH set up a new transparency contact policy for pharmaceutical companies. Anyone wishing to meet a MoH representative must do so by formal request, with an attached, binding agenda. At the meeting, at least three MoH representatives must be present, and the meeting will be either recorded or documented with minutes. The new policy has made it much more difficult (near impossible) to plan a calendar of meetings with the Ministry, as meetings will be held in the order in which meeting requests are submitted by the companies and approved by the Ministry.

Discrimination Against Imported Pharmaceuticals

Recently, the Government has been working on a new strategy for the pharmaceutical sector, with a view to facilitating domestic drug manufacturing. According to the Deputy Prime Minister, a string of takeovers of domestic drug makers by foreign rivals in recent years has had a “paradoxical effect” of turning Poland – traditionally a major producer and exporter of generic drugs – into a net importer of pharmaceuticals, with an annual negative balance of €2bn.

The Government of Poland is also discriminating against the United States and multinational innovation-based pharmaceutical companies by retroactively fining companies large sums of money for imports made under previously-accepted procedures. To date, civil damage claims have been filed by Poland’s National Health Fund against 31 pharmaceutical companies (including many U.S. companies doing business in Poland).

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

RUSSIA

As Russia prepares to develop its own innovative pharmaceutical industry, major market access barriers remain. Russia still has no data exclusivity (DE), despite commitments to the U.S. Government to implement six years of DE by May, 2007. Moreover, non-transparent market conditions are compounded by new signals that some Russian officials want to use healthcare reform to promote discriminatory policies that further impair market access for PhRMA member companies.

Though Russia made significant commitments in the 2006 U.S.-Russia WTO Accession bilateral on intellectual property rights (IPR), the Russian Government has not taken steps to fulfill these commitments. In the meantime, PhRMA member companies continue to face non-transparent market conditions. In light of this situation, PhRMA requests that Russia remain on the Special 301 **Priority Watch List** for 2009.

Intellectual Property Protection

Data Protection

Russia has not yet enacted data exclusivity 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 data exclusivity as part of its World Trade Organization (WTO) accession. The agreement stated that the Government of Russia has 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 for a period of at least 6 years against unfair commercial use starting from the date of grant of marketing approval in the Russian Federation.

In cooperation with the Ministry of Health and Social Development (MoH), the Ministry of Economic Development (MED) has introduced a draft to the Governmental secretariat, which may be subsequently introduced by the Government to the Duma. This bill attempts to meet obligations taken on by Russia during WTO negotiations, including data exclusivity.

The Ministry of Health and Social Development has also prepared a more thorough revision of amendments to the Law on Medicines. These amendments address issues raised by local manufacturers and could introduce cardinal changes in regulatory issues like registration processes (marketing authorization) and clinical trials, with potential implications for the functioning of future data exclusivity policies.

Implementation of the data exclusivity commitment must remain a prerequisite for Russia's accession to the WTO.

Trademarks / Counterfeiting

The Government of Russia provides weak enforcement against counterfeit medicine producers. There is no formal statistic to estimate counterfeit products on the market; however, the vast majority of identified 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 to the criminal and civil legislation. Moreover, there is no procedure for evidence gathering or acceptance by Russian courts to facilitate court proceedings in counterfeit cases.

The main article of Russian legislation currently applicable to pharmaceutical counterfeits, set out in the Criminal Code, addresses trademark infringement. However, the legislation applies only in cases of numerous violations or significant damages and imposes inadequate penalties (\$5000 to \$8000 maximum).³⁵ The penalty set in the Administrative Violations Code is even lower (\$1400 maximum).³⁶ The Russian Parliament has been debating a potential increase in criminal and administrative liabilities for several years but nothing has been done so far.

Some Duma Members are planning to introduce a bill to impose criminal liability for production and sales of counterfeit pharmaceuticals.

Market Access Barriers

Marketing Approval

The marketing approval process in Russia continues to be lengthy, unpredictable, and nontransparent. The approval process and corresponding fee collection are the responsibility of the Federal Government Establishment or FGU, a non-commercial subsidiary of the Federal Health Service (Roszdravnadzor). Although Roszdravnadzor officially collects a fee (set by the Russian Tax Code) of 2000 rubles (\$80.00) per product application, the FGU charges roughly \$19,000 per product application.

³⁵ RF Criminal Code, art.180

³⁶ RF Code on Administrative Violations, art.14.10

Reimbursement Procedures

The Government of Russia instituted a federal drug reimbursement program in 2004, which went into operation in 2005. Unfortunately, reimbursement decisions are not based on objective or verifiable criteria. Mechanisms for purchases of reimbursed drugs and tenders are non-transparent. Foreign firms are often discriminated against in both the federal reimbursement system for pharmaceuticals (DLO) and other comparable systems at the regional/state level, and no appeal procedures for reimbursement decisions are provided.

The Ministry of Health (MoH) issued a regulation in 2006³⁷ 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 for development of Essential Drug Lists remain opaque. The number of products included in the lists has not increased compared to previous years, resulting in inadequate reimbursement for innovative products.

The changing nature of the government pricing and reimbursement system in Russia presents an opportunity for the U.S. Government to engage in a dialogue with government officials at all levels in Russia.

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 for each batch of imported pharmaceuticals.³⁸ 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 discriminates against importers by requiring that they provide a Declaration of Conformity for each batch of medicines, whereas Russian manufacturers are permitted to provide a declaration for a full series. The Government of Russia has claimed that the new procedures were introduced to prevent counterfeit products from reaching the market, but the impact on

³⁷ Order of the Ministry of Health and Social Development No. 93 as of February 15, 2006

³⁸ Governmental Resolution No. 72, as of February 10, 2004

⁵ MoH Decree No. 8543, dated November 30, 2006 – Administrative Regulation enforcement

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 pharmaceutical manufacturers \$200 million. Based on the higher costs for individual testing, the total costs for the new system could 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 2008 attributable to trade barriers related to intellectual property protection and market access.

TURKEY

Over the last five years, Turkey's pharmaceutical sector has been undergoing an important transition period. There have been important reforms and changes affecting intellectual property rights (IPR), government reimbursement, pricing and registration. Challenges related to implementation contribute to transparency and predictability problems for pharmaceutical companies operating in Turkey.

PhRMA therefore requests that Turkey be placed on the **Priority Watch List** for 2009.

Intellectual Property Rights

Patents and data exclusivity relating to pharmaceuticals have been officially recognized in Turkey since 1995 and 2005, respectively, but there remain significant needs for regulatory and legislative improvement. Of particular concern, there have been attempts in past years and in 2008 to amend the current patent law with provisions weakening the current level of protection. While PhRMA member companies have viewed the draft patent law as an opportunity to upgrade IPR as part of Turkey's drive to become more globally competitive in innovative medicines, some parties have seen this process as an opportunity to reduce existing protections.

Patent Protection

During 2008, the local generics industry undertook extensive lobbying activities designed to introduce radical amendments to the current Patent Law. These amendments would have included provisions to weaken the current protection of original innovative pharmaceuticals. They also would have aimed to discriminate against foreign innovators and would have included 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, which would have expanded compulsory licensing, weakened infringement penalties and loosened customs procedures.

Of additional concern to innovators and investors, Turkey today does not offer an effective patent linkage system between patents and marketing approvals by the health regulatory authorities. Generic copies have been registered in the country while the patents on the original product are still in force. A functioning patent linkage system would help eliminate this problem because

withholding final approval of generic registrations would allow for a period sufficient to allow resolution of patent issues.

Data Exclusivity

With respect to pharmaceuticals, particular problems persist in the interpretation and implementation of the data exclusivity (DE) regime. 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 DE for a minimum period of six years for products registered in the EU.

The concerns include the start date of the protection period for the data. There is also continuing concern that products granted DE status in Europe are not recognized as eligible for protection in Turkey. There is also concern about tying the term of DE to the remaining term of product patents, which is not consistent with international norms.

The period of DE 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 DE 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 has not received a clear and firm explanation. The lack of a coherent, consistent response has been a major concern to the EU Commission and European trading partners, which insist that Turkey should provide DE for all products registered in the EU after 2001, consistent with its European Customs Union and WTO/TRIPS obligations.

While even a minimum 6-year period of DE is a welcome step, the implementation in Turkey is problematic because the six-year protection period commences when a product first gains registration in any country of the ECU. Given that the period starts prior to approval in Turkey, the inefficiencies of the regulatory system in Turkey have the effect of significantly diminishing the effective DE period in Turkey. Inefficient regulatory procedures that do not fully comply today with the EU Transparency Directive erode the period of DE for new medicines by delaying market access. Effective DE is reduced to as little as 2-3 years in some cases, resulting in an environment where incentives for innovators are undermined. Application of DE today in Turkey is clearly out of step with European standards and must be amended to begin the DE period when local approval is obtained in Turkey.

Furthermore, Turkey does not provide DE for combination products or vaccines. Most recently, the Health Ministry on January 16, 2009 published a government-approved pricing list, including a generic combination product that infringes the DE rights for a PhRMA member-company-developed combination product that was registered in Europe after January 2005.³⁹ On 2 February, the Social Security Institute published a government reimbursement list with the generic combination product referenced above.⁴⁰ This decision for government reimbursement was made despite a prior written request from the local industry association that the generic combination product was infringing regulatory data protection of a PhRMA member company.

In addition, it is unclear how Turkey will harmonize its 6-year DE 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 US trade negotiators, should inquire how Turkey plans to harmonize its current regime to allow a DE period of up to 11 years (8/2/1).

Finally, the current regulation ties the term of DE to patents relating to the product. This also is not consistent with DE in the ECU today or the fundamental purpose of DE.

Market Access Barriers

Reimbursement

Turkey has established a committee 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 committee members, committee working principles and also submission requirements. Challenges remain, however, including the SSI's compliance with the established meeting schedules (frequent delays). Innovative pharmaceutical companies are also concerned that SSI fails to provide sufficient rationale for its decision-making.

The Turkish Government also fails to provide adequate information about the decision makers in the technical committees charged with evaluating new products.

³⁹ Pricing list available at:

http://www.iegm.gov.tr/fiyatlandirma/Documents/16_OCAK_2009_TUM_ILAC_FIYAT_LISTESI.xls

S.

⁴⁰ See the 02.02.09 entry at <http://www.sgk.gov.tr/wps/portal/ESGK/GSS/GSSSUTEki>.

Moreover, the appeal procedure for government reimbursement decisions is not clearly defined. The appeal process should be undertaken by an independent body that reviews the application, the analysis and the resulting decision. Because the same body that conducted the initial assessment is used to review the appeals assessment, changes to the initial decision are very rare, negating the purpose and objective of an appeal.

In addition, in certain instances, innovative products have been grouped as equivalent with much older and dissimilar technologies for state reimbursement purposes. This creates a maximum reimbursement limit for all products in the group. Patients pay for any costs over the limit and therefore have a harder time accessing innovative treatments.

PhRMA member companies believe that, in the absence of publicly available reliable and complete data, 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 are advocating that the SSI define realistic criteria for the reimbursement of new medicines. This work is expected to continue through 2009.

Government Reference Pricing

The Turkish Government applies a reference price system for pharmaceuticals.

Under the new government pricing legislation that went into effect in 2007, 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 altered every year. Currently, the five reference countries are France, Spain, Italy, Portugal, and Greece. Countries where product is released and shipped also serve as references.

A budget crisis that erupted in the Turkish pharmacy sector in 2008 has led to Government demands on biotechnology and research-based pharmaceutical companies to provide additional discounts. The discount system that had been established by regulation in 2004 to allow for more predictability and stability, and recognize the value of innovative medicines was eliminated. Innovator companies were ultimately compelled by the Government to increase their discounts to the state from 4% to 11% in late 2008.

Moreover, the Turkish Government has failed to effectively apply currency rules and mechanisms that account for significant changes for the Turkish lira against the Euro. The Government has failed to implement adjustments in accordance with its Pricing Decree, leading to a situation where, during a

substantial period of 2008, companies had to conduct their daily commercial interactions at a Euro exchange rate that is higher than the officially-announced rate, leaving companies to make up for foreign-exchange losses.

Registration

There appears to be modest movement toward harmonizing pharmaceutical regulations with EU standards and requirements. In January 2005, the Government took an important first step toward making the regulatory system more efficient and transparent, introducing the "Regulation on the Registration of Medicinal Products for Human Use".

However, a recent industry survey of 37 biotechnology and research-based pharmaceutical companies revealed that in the area of cancer, for example, the average new medicine approval time was 871 days with approximately 600-700 days spent in registration.⁴¹ This amounts to 2-3 times the period set forth in the registration regulation and far longer than the time it takes to register a new medicine in EU countries following EMEA approval.

During the registration process, an economic evaluation is sometimes required by the Health Ministry's Clinical Committee as part of the scientific review, effectively halting review of the product because it is not possible to submit the economic evaluation for a new product if government reference prices are unavailable.

In addition, even routine applications to amend products in line with approvals in reference countries (*e.g.*, Europe's EMEA or the U.S. FDA), such as adding new indications, can take many months, whereas in other countries these amendments are processed very efficiently.

Moreover, the Turkish Ministry of Health has published biosimilar guidelines, which do not meet EU standards on DE implementation.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

⁴¹ AIFD Reimbursement Survey Nov 2008.

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 addressed in order "to avoid unwarranted curtailment of the period of protection" for patents, as required by the TRIPS Agreement.

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 to 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 Agreement, even if the provision requiring reliance were 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 countries⁴² as their review. Thus, the requirement to submit data in these countries is functionally a requirement to submit data for use by Argentine officials. Thus, 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 over the past three years 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 372 of January, 2004, (under which companies had to declare interest in their application, or they would be considered abandoned,) and 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, productivity has dropped.

In spite of 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 key examiners who are recruited by the private sector. The current backlog in all areas amounts to 16,000 applications with full examination fees paid, while the total backlog amounts to 30,000 applications. In 2007, input of patent applications exceeded output by 1,200 applications.

⁴² As per Decrees 150 and 176.

Also, Argentina should accede to the Patent Cooperation Treaty because that would facilitate the filing and examination of patent applications in Argentina as it does now in 135 Contracting Parties.

Linkage

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

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.

Customs Code Reform

The Argentine Congress enacted Law No. 25.986 in 2005, to amend Article 46 of Customs Code (Title III – Foreign Trade/Counterfeited goods); however, the Executive Branch never implemented the regulations implementing the law. Furthermore, in March of 2007, the Executive sent a draft bill to Congress eliminating from the above mentioned legislation the provisions barring the infringement of “other intellectual property rights or industrial property rights granted by the national legislation”. Protection for trademarks and copyrights will remain in place, but protections against patent infringements have been eliminated. The bill eliminating protections was passed by the Lower House on July 18, 2007, and by the Senate on December 10, 2008.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

BRAZIL

PhRMA's 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:

- 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.

As a result, 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 patents 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 patentability standards than those used by the patent office itself. More specifically, through a more restrictive interpretation of the law, they 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 the industry 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.

Compulsory Licenses

In our 2007 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. We feared 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 recent 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* government 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 18, 2008, is ten years; unchanged from 2007 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 to reduce the extremely large backlog of patent applications.

Patent Linkage

Efforts to gain support for legislation that would require a link between the system in ANVISA for approving generic products and patents continue. However, there were no legislative developments in 2008.

Data Exclusivity

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 against non-reliance, as well as unauthorized disclosure and use.

Counterfeiting

Pharmaceutical counterfeiting, which encompasses any deceptively mislabeled pharmaceutical product or packaging, is on the rise 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 provider for counterfeit pharmaceuticals and a leading exporter to developing as well as developed markets in search of "cheap" medicines.

Although pharmaceutical counterfeiting often violates intellectual property rights, this pernicious activity 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.

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 2008, a price increase between 4.61 percent and 2.52 percent was allowed, depending on the percentage of generics in a particular therapeutic class. These rates fail 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, the regulatory Health Agency (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. This suggests that more needs to be done to achieve the goal of improved access. (Source: GRUPEMEF; CPI dos Medicamentos; MOH/SCTIE/DAF; Folha de S. Paulo; Target; Banco Central; BCG analysis).

Progress in Multilateral Negotiations

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

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 an 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 and the U.N. Food and Agricultural Organization, but also in the World Trade Organization, the World Intellectual Property Organization, and the World Health Organization.

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 in 2008.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

CHILE

PhRMA and its member companies operating in Chile remain concerned that Chile's protection of the intellectual property rights of research-based pharmaceutical companies fails to comply fully with the country's obligations under TRIPS and its free trade agreements with the United States and the European Union. The most serious deficiencies involve Chile's failure to establish effective patent linkage and to correct important weaknesses in its data exclusivity (DE) regime.

Unfortunately, the Government of Chile has taken no definitive steps during 2008 to address U.S. Government and PhRMA member companies' concerns regarding the absence of effective linkage and effective DE. A new sanitary decree issued by the Health Ministry for public comment in April 2008 would, if enacted, definitively foreclose linkage by stating explicitly that the Public Health Institute lacks authority to consider intellectual property— or any other criterion apart from safety and efficacy – in granting sanitary registrations. A new draft executive decree on DE also released for public comment in April would, if enacted, correct certain deficiencies in the current DE regulations. However, it would leave other serious problems uncorrected, while failing to address any of the underlying DE-related deficiencies in Chile's intellectual property law (Law 19,996).

Although CIF (the Chilean Pharmaceutical association for the pharmaceutical R&D industry) continues to communicate frequently with the Chilean authorities in the hope of finding mutually acceptable solutions to both of these problems, it believes that continued active involvement by the U.S. Government is vital in encouraging Chile's full implementation of its intellectual property obligations under TRIPS and the U.S.-Chile Free Trade Agreement. Therefore, PhRMA recommends that Chile remain on the **Priority Watch List**.

Intellectual Property Protection

Chilean Government Reaction to PWL Announcement

The Government of Chile issued no formal response to USTR's announcement on April 25, 2008, that it would maintain Chile on the PWL for a second year. The few officials who offered public comments dismissed USTR's action as insignificant in practical terms and as driven almost entirely by pressure from PhRMA member companies.

- In comments to *El Mercurio* on April 25, Economy Minister Hugo Lavados noted that the Government was "... not happy about being on this list," but added that "... we've seen recently that views within the United States on this subject aren't as strong as they were awhile ago.

The topics on which some disagreement exists between both governments are very specific, and in Chile they are highly concentrated in the area of pharmaceutical trademarks and patents and marketing authorizations. It's a topic that has us busy, but we don't think that it's very serious."

- In comments made to *Radio Cooperativa* on April 26, Patent Office director Bernardita Escobar stated that Chile had made tremendous efforts to protect intellectual property, as shown by its establishment of a special police unit to prosecute economic crimes, and that the government did not have further obligations on the matter. She also told the Italian press agency ANSA that USTR's decision was "... unilateral, and I cannot make myself responsible for the feelings of third parties, much less for third parties in other countries."
- Christian Democrat legislator Mariano Ruiz Esquide, a member of the Education Committee of the Chamber of Deputies, made the following comment to the Chinese news agency Xinhua: "I would be concerned if Chile were given a low ranking by international or global institutions. But I'm not concerned when it's the United States that is making these characterizations."
- On April 26 *El Mercurio* reported that according to prominent generic industry lawyer Gabriel Zaliasnik, "... the [PWL] is elaborated by a private lobby group with the aim of supporting the interests of private U.S. companies. I believe that this is very far from the reality of Chilean-U.S. trade relations." According to Zaliasnik, the PWL has no practical relevance for the multilateral trade organizations to which Chile and the U.S. belong, nor is it among the mechanisms established under the free trade agreements [for resolution of trade disputes]."

Linkage

Contrary to the requirement contained in Article 17.10.2 of the U.S.-Chile FTA, Chile has failed to establish a 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. Article 17.10.2 requires Chile to "make available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent" and "not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner." Chilean officials have contended 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, since 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 regards each of these arguments as disingenuous for the following reasons:

- When the Free Trade Agreement came into force in January 2004, the ISP was responsible for granting both sanitary registrations and marketing approval for new pharmaceutical products. In July of that year, the government amended Supreme Decree 1876 (which establishes the responsibilities of the ISP) 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 required in order to sell a pharmaceutical product in Chile. Sanitary registration is therefore marketing approval in Chile – a view confirmed by a preliminary Chilean civil court ruling in November 2006.⁴³
- In any state governed by the rule of law, all governmental agencies share the responsibility to ensure that the government as a whole complies with its legal obligations – in this case, 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, and 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 ignores the protections guaranteed under national law to the patent-holder.
- The obligation contained in Article 17.10.2 (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 Article 17.10.2, Chile must establish a formal administrative mechanism to prevent the granting 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 only after a third party has violated its rights by requesting and receiving a sanitary registration/marketing approval for an infringing product.

The CIF has met frequently during 2008 with relevant officials of the Economy Ministry (which has lead responsibility for industrial/intellectual property protection)

⁴³ Folio 90; 30° Juzgado Civil de Santiago, Rol C-6613-2003; Caratulado Porzio Bozzolo M/Instituto de Salud Publica, 10 November 2006. This preliminary ruling is currently under appeal.

and the Foreign Ministry (which is responsible for negotiating and implementing Chile's international agreements) to discuss the minimum requirements of a linkage system that would be acceptable to both research-based pharmaceutical companies and the Government. Unfortunately, those conversations have not yielded any tangible progress, or even any shared recognition that a problem exists. Government officials continue to maintain publicly and privately that Chile is complying with the IP chapter of the U.S.-Chile FTA.

Recently proposed regulatory modifications would make it even more difficult to establish linkage in the foreseeable future. On April 23 the Health Ministry posted for public comment a new draft sanitary regulation which goes beyond the existing code by explicitly denying 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.⁴⁴

Data Exclusivity

Chile has failed to establish an adequate system to protect proprietary pharmaceutical test data against unfair commercial use as required by TRIPS, the EU-Chile Association Agreement, and the US-Chile Free Trade Agreement. Chile's current data exclusivity system is deficient for the following reasons:

- Because Chile's existing norms (contained in Law 19.996 and Supreme Decree 153) 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 that inevitably take place during the regulatory review process.
- 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.

⁴⁴ 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 exclusivity norms impose grounds for revocation of the right to exclusive use that are not authorized by TRIPS or Chile’s bilateral trade agreements with the EU and the United States. For example, Law Article 91 provides grounds for not allowing protection for products, including that data exclusivity is not available for any product receiving a sanitary registration in Chile more than twelve months after the date of a sanitary registration in another country. These grounds for revocation significantly weaken the applicability and usefulness of the available exclusivity.

On April 23, 2008, the Health Ministry released for public comment a new draft regulation relating to data exclusivity. Although the new decree would correct several deficiencies in Chile’s current regulatory framework for DE, it would leave a number of other major problems unresolved. Moreover, most of the DE-related deficiencies that contributed to Chile’s inclusion on the PWL are statutory and thus cannot be corrected by executive decree.

On the positive side, the draft regulation would prevent national laboratories from basing sanitary registration applications for products characterized as “new” upon partial or incomplete test data. It also states that prior data disclosures made by foreign regulatory agencies or “international organizations” will not negate the “undisclosed” nature of data for which protection is sought, and it ostensibly eliminates the ISP’s authority to make case-by-case determinations of whether or not particular data for which protection is sought are in fact “undisclosed.”

Conversely, the draft regulation requires, contrary to TRIPS and the FTA, that an innovator file an application for data exclusivity (containing copies of all data for which protection is sought) and certify that the data in question are “not of general knowledge.” The regulation requires the publication of resolutions granting data protection and allows legal challenges to those decisions, which would potentially enable the ISP to continue exercising its discretion in deciding the eligibility of particular data for protection. It could be interpreted in a manner which would limit the protection offered to data against disclosure to the same five-year term available for protection against unfair commercial use. The regulation authorizes the full or partial disclosure of protected data on grounds of “public health” (not further defined). Finally, it reproduces the various TRIPS-noncompliant grounds for revocation of data protection that are stated in Article 91 of Law 19,039.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

VENEZUELA

PhRMA and its member companies operating in Venezuela remain concerned that since 2002, Venezuela's Trademark and Patent Office (SAPI) has not granted a single pharmaceutical patent. By 2005, Venezuela stopped granting patents in all technical fields, in breach of its obligations under TRIPS Articles 27.1 and 62.2. Further, since February 2002, Venezuela stopped protecting data from clinical trials, in contravention of TRIPS Article 39.3. A link between the patent status of products and the sanitary registration system has yet to be provided.

For these reasons, and others outlined below, PhRMA recommends that Venezuela remain on the Special 301 **Priority Watch List** in 2009 and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property

Since 2001, the Government of Venezuela has promoted an industrial property bill that would lower protection below thresholds set by TRIPS. The intellectual property bill would reduce owner rights, create international exhaustion of rights, facilitate compulsory licensing in ways not permitted by TRIPS, and eliminate data protection. In October 2007, the National Assembly approved an amendment to article 98 of the Constitution, in which intellectual property rights were eliminated from the Constitutional text, except with respect to copyright, further underscoring the government's stance on Intellectual Property. However, this amendment was later rejected, along with the rest of the constitutional reform, by the referendum that took place on December 2, 2007. In September 2008, SAPI published an official notice informing that pursuant to the withdrawal of Venezuela from the Cartagena Agreement, the Venezuelan Industrial Property Law of 1955 ("IPL") would be applicable instead of the Andean regulations. PhRMA's concern is that product patents for pharmaceutical products are prohibited under article 15(1) of the IPL, and thus it would not be possible to grant product patents for pharmaceutical products in Venezuela.

Venezuela is one of the few countries in the region that has not acceded to the Patent Cooperation Treaty (PCT) and the Trademark and Patent treaties. The SAPI does not support the entry of Venezuela into the PCT or accession to the other mentioned treaties.

Data exclusivity

In a departure from past practice (1998-2001) when a 5 year period of data protection was enforced, Venezuela has not provided effective data protection since February 2002. It has instead granted second regulatory

authorizations and relied on the original data during the period when data exclusivity should be applied. These actions are not consistent with TRIPS Article 39.3.

Since 2002, over 20 “copy” products corresponding to original medicines that should have each been covered under a 5 year term of data protection, obtained registration from the health authorities (Venezuelan National Institute of Health). As a result, individual research based pharmaceutical companies initially filed challenges against the government in the courts to enforce data exclusivity, with no results to date. Many companies acted directly against marketers of the copy products at the Venezuelan Antitrust Agency (Procompetencia), which dismissed all unfair competition claims. Claims were brought by pharmaceutical companies to the Administrative Courts and then to the Supreme Court of Justice, but both courts denied preliminary remedies and are processing claims with no decision in sight.

It is believed that copies of these products reached the market in 2003 and 2004, causing substantial harm and significant legal costs to the companies involved. Because of the different nature of the products involved and the different administrative and legal procedures initiated by each company, it is not yet possible to aggregate numbers of the present and future losses.

On June 6, 2005, the local pharmaceutical R&D association, Cámara Venezolana del Medicamento (CAVEME) sued the Venezuelan National Institute of Health for not granting the data protection stipulated by TRIPS Article 39.3 and other treaties mentioned above. The claim was accepted by the Court in 2006, but has not yet been decided.

Patent Slow Down

Since 2002, the SAPI has not granted a single pharmaceutical patent. This denies effective intellectual property protection required by TRIPS.

Market Access Barriers

Government price controls of Essential Medicines

Since 2003, Venezuela has imposed price controls for Essential Medicines (following WHO criteria) comprising close to one-third of the medicines marketed in-country. Venezuela maintained this government price control policy from 2004 to 2008 (with minor adjustments of prices made in September 2005), but it is unclear whether it will be maintained in the near future. To date, prices of Essential Medicines have not been revised to take into account accumulated inflation (172%) in the period between March 2003 – August 2008, or devaluation

(34.4%), thereby adversely impacting pharmaceutical companies and distorting the market.

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 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.

Counterfeit medicines and other illicit activities

Venezuela 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 can be explained by 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.

VAT

Venezuela continues to enforce a problematic 2002 value added tax (VAT) law to imported medicines. In order to obtain an exemption from the VAT, a manufacturer must submit a letter to the Government stating that the product is not manufactured in the country or manufactured in insufficient quantities. Discriminatory use of the VAT may reward domestic manufacturers, including manufacturers of illegal copies of products, by increasing the burden on imported, innovative products.

Government Procurement

The Venezuelan Bidding Law (*Ley de Licitaciones*) 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 aggressive interpretations of the exceptions set forth in the Bidding Law in order to avoid a competitive bidding process. The lack of enforcement of 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.

Legal labor framework

The legal framework for private companies, in general, is changing with the modification of some labor laws in a framework that not only regulates the worker-employer relationship, but establishes contribution and penalization schemes. These represent new and onerous financial burdens for companies. The cost of labor has increased considerably because of new social charges such as the 1% tax of net utilities to finance government anti-drug programs and the 0.5% tax of gross income to finance government science and technology activities.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 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 remain concerned that a lack of intellectual property rights protection and market access barriers seriously impede access to the Algerian market for innovative pharmaceutical products. Specifically, PhRMA is concerned that:

- The 2003 Algerian patent law, which was promoted as a means to ensure protection for pharmaceutical intellectual property, removed the administrative protections for patented inventions upon which PhRMA members relied.
- Algeria does not protect certain pharmaceutical test and other data from unfair commercial use or disclosure.
- Algeria introduced government reimbursement price controls and volume controls through the imposition of an annual import quota for medicines.
- Each batch of imported product is subject to testing by the National Control Laboratory, the state laboratory responsible for monitoring the quality of the products under registration and imported to the country
- It appears that Algeria continues to delay the granting of marketing approval for patented products of PhRMA members (due to burdensome requirements) while granting faster marketing approval for copies. Generics are exempted from the clinical committee review which usually happens 1-2 times/year.
- Member companies have found that Algeria is granting marketing approval for copies of products that are not yet marketed in Algeria
- In October 2008, the Government issued a decision to ban the importation of products that are also being manufactured locally. This provision entered into effect in January 2009.

For these reasons, PhRMA recommends that Algeria be placed on the **Priority Watch List** for the 2009 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/Transitional 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 generics 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. 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.

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.

Data Exclusivity

Algeria does not protect certain pharmaceutical test and other data from unfair commercial use and disclosure. Such protection, however, is a requirement for accession to the World Trade Organization.

Standstill Agreement

PhRMA members appreciate that Algeria will need to amend its intellectual property laws to accede to the World Trade Organization, including the enactment of a statute to protect certain pharmaceutical test and other data as required by Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These amendments should apply to all existing subject matter at the time of the entry into force of the amendments, along the lines of the extension of protection to existing subject matter in TRIPS Article 70.2. Marketing approvals that are pending on the date of entry into force of the legislation, and that are conditioned on the submission of test and other data, should result in data being protected by the new law.

Market Access Barriers

Government Reference Pricing

Market access for innovative pharmaceuticals is hindered by the Algerian Government's reference pricing system. Algerian law requires that reference pricing be applied only if there is a corresponding generic on the Algerian market.

However, in practice, products have been referenced that have no generic equivalent on the market. 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 generic versions of the product. The Order was not implemented until the April 15, 2006, publication of an additional Inter-ministerial Order ("2006 Order"). A new group of 300 products was officially added to the list on October 1, 2008.

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.

Regulatory Approval Delays

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. Between 2000 and 2004, approval of registration requests stalled, with only ten new product registrations being granted for special medical needs or other specific reasons (such as a plant opening). Since late 2005, however, there have been signs that the Ministry has begun to examine the backlogged pending requests. The process remains slow and, since Decree No. 92-984 exempts generic medicines from clinical committee review, generics enter the market much faster than patented medicines.

Another issue that has emerged recently is the Ministry of Health's creation of additional, burdensome requirements for obtaining registration to market pharmaceutical products, especially innovative products. These requirements are communicated to pharmaceutical companies in the form of "notes," and they impose excessive requirements and present a significant market access barrier for innovative pharmaceutical companies. In some cases, these requirements are also requested for marketing authorization renewals.

Preferential Treatment / Importation of Pharmaceutical Products

On September 7, 2003, the Ministry of Health issued a Decree, "Instruction #5 for the generalization of generics," which discriminates against foreign pharmaceutical companies and appears to breach numerous Algerian intellectual property-related and other trade-related obligations. The Decree stipulates that medicines for which local production is sufficient to cover local demand may no longer be imported (since 2004, this has been applied to 128 products). Moreover, the Ministry offers assistance to local generic manufacturers for priority registration and production process approval. Imported branded products can only be registered if there are no generics of the same molecule already registered on the Algerian market and if the proposed price for the branded product is within a certain range that will be determined by the Government.

In October 2008, the Government issued a decision reinforcing the application of the Decree.⁴⁵ The Decision stated that, effective January 2009, the importation of products already being manufactured locally would be restricted and that foreign companies desiring to operate in Algeria must invest to be able to do so. No clear guidance on the level/type of required investments has been communicated by the Government to date.

The Ministry of Health is developing the list of products that would be banned from importation under the decision. The final list is expected to include around 600 pharmaceutical products, including even those packaged locally and priced in alignment with generics (due to the use by the Government of reference prices). The decision unfairly discriminates against foreign pharmaceutical companies and could negatively impact access to innovative pharmaceutical products for Algerian patients. Moreover, the decision potentially jeopardizes Algeria's chances of acceding to the WTO in the near future and may violate commitments under the EU – Algeria Association Agreement.

PhRMA requests that the U.S. Government urge the Algerian Government to reverse the implementation of these discriminatory rules. PhRMA members are willing to partner with the Algerian Government to discuss alternative options that are in the best interest of all affected parties, will ensure the safety of the drug supply chain, bolster the investment environment, and, most importantly, provide Algerian patients with access to innovative medicines.

Volume Controls

Algeria continues to apply trade distorting volume controls, including: (1) the imposition of an annual import quota for medicines with the requirement that each shipment receive clearance from the Ministry of Health ('déclaration

⁴⁵ Decree of November 30, 2008, relating to the prohibition of the medicinal products and medical devices intended for human medicine.

statistique'), and (2) temporarily blocking importation as a cost-containment tool. Pursuant to these controls, at the end of December 2007, companies were instructed to revise downwards by 30 to 50% their submitted importation plans for 2008, with the requirement that these new importation levels be approved by the Algerian Government.

Damage Estimate

At the time of reporting, PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

ISRAEL

PhRMA and its member companies operating in Israel remain concerned that the level of pharmaceutical intellectual property protection provided by the state of Israel falls considerably short of international standards. Over the last nine years, the protection of pharmaceutical-related IP rights in Israel has eroded dramatically. 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. However, until the negotiations result in concrete improvements in Israel, PhRMA will continue to recommend that Israel be designated as a **Priority Watch List** country in the Special 301 Report, including in the 2009 process.

Intellectual Property Protection

Over the last nine years, the protection of intellectual property rights in Israel has been eroding dramatically. Three areas are the focus of PhRMA's concerns: (1) a law amending the Patents Act that will considerably shorten the patent term extension period and possibly nullify it completely; (2) inadequate protection of regulatory registration data (data exclusivity); and (3) substantial delays in the grant of patents because of pre-grant patent opposition.

Patent Term Extension - Amendment No. 7, to Article 64 (December 19th 2005)

In December 2005, the Government of Israel introduced a new amendment to the Patents Act that significantly reduces the effective patent extension term in Israel. It requires that the patent term extension in Israel be aligned with the shortest of the extension periods granted in any of a number of Recognized Countries⁴⁶ (the "Israeli Linkage Mechanism").

The amendment adds new and 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 US and in at least one EU member country that is considered a Recognized Country.

⁴⁶ Under the amendment, the list of Recognized Counties includes: the US, EU-15, Switzerland, Norway, Iceland, Japan and Australia.

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 based on the assumption that a meaningful extension will be granted.

Regulatory Market Exclusivity – Pharmacist Ordinance, Article 47 (2003)

As a member of the World Trade Organization (WTO), Israel was required to fully implement TRIPS, no later than January 1, 2000. TRIPS Article 39.3 obligates WTO members to protect the registration files of innovative pharmaceutical companies against unfair commercial use. This protection is known as “data exclusivity”.

However, it was not before March 2005 that the Israeli Government enacted new marketing exclusivity provisions via Article 47 of the Pharmacists Ordinance new subsection D(2). Unfortunately, the marketing exclusivity provisions fall short of acceptable standards in this field.

Article 47 D(2) provides a Marketing Exclusivity type of protection rather than data exclusivity, insofar that MOH is still able to rely on the innovator’s data to register generic products during the exclusivity period, and more importantly rely on the registration data to approve the export of these products to other markets.

While the U.S. essentially affords 5 years of data exclusivity and the EU allows for 10 years (8 years of data exclusivity plus 2 years of marketing exclusivity), Article 47D(b)(2) stipulates a protection period significantly shorter than 5 years. Article 47D(b)(2) of the Pharmacist Ordinance provides for 5 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’, whichever is shorter.

However, as a result of linking exclusivity to the day of earliest registration in a Recognized Country, the effective term of regulatory market exclusivity in Israel today is less than four years. This is because, according to Israeli Government data, it currently takes the MOH 13-16 months to approve a new pharmaceutical product in Israel, from the day it was registered in a Recognized Country. As such, the regulatory marketing exclusivity period afforded in Israel to innovative products amounts to less than four years in a best-case scenario.

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.

Finally, only products that are registered in any of the Recognized Countries after July 2005 will be eligible for protection. This means that if companies intend to register in Israel new products that are already marketed elsewhere, these products would not be protected. This runs counter to the basic rationale of the legislation, aimed to increase public access to new medicines.

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

Under Israeli law, patents are thoroughly examined by technically competent examiners. It currently takes six years until the examination of a pharmaceutical patent is completed. As a result of this unusually long examination process, the patentee “loses” a significant part of the period of exclusivity to which it is entitled (without the opportunity for patent term adjustment).

One would have assumed that once the examiner deems that the invention is worthy of patent protection and accepts the application, the patent will finally be granted. However, under Article 30 of the Israeli Patents Act, any competitor may block a patent grant simply by filing an opposition to the patent application. The 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 situation in Israel is diametrically opposed to the legal situation in other developed countries. In most developed countries, any opposition proceedings are conducted post registration and it is not possible to block the registration of the patent. The deeply flawed pre-grant opposition system applicable under Israeli law has been rejected in the vast majority of developed countries, including in the EU and the U.S.

Third parties can be given an opportunity to challenge the validity of the patent, but as recognized elsewhere, any such action should be done post-grant. Indeed, the Patents Act already provides a system for post-grant challenge. Additionally, a potential infringer is also entitled to challenge validity in infringement proceedings. However, a system of pre-grant oppositions that blocks patent grant for many years actually nullifies patent protection.

Publication of Patent Applications

Israel allows third parties to file oppositions during the examination of the patent application. This is based on the patent application being published and the file being made available to the public during examination. Indeed, in the US and Europe applications are generally authorized to be published 18 months after their priority date.

Under the Israeli Patents Act, the 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 US and Europe. Consequently, these applications are published in other jurisdictions well before the examination of the Israeli application has been completed. This renders the strict "confidentiality" prevailing over the Israeli applications redundant. It also reduces the ability of the patent holder to claim retroactive damages.

Local generic companies in Israel have used 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 US applications generally are published 18 months after their priority date) to exploit the patent without being accused of breaching the confidentiality of the Israeli patent application. In other words, in Israel, generic companies have automatically opposed patent applications in Israel, thereby delaying entry of patents into force, and at the same time have exploited the patent subject matter.

Other Deficiencies

It should also be mentioned that Israel suffers from many other IP deficiencies, most notably: the absence of Orphan Drugs legislation (such as in the US and the EU); the fact the Israel permits the parallel importation of patented medicines; and the Government's review of new proposals seeking to cancel the principles of unjust enrichment with regard to proprietary patented products.

Market Access Barriers

Marketing Approval (Registration) Deficiencies and Delays

The process of examining and granting marketing approval for new pharmaceutical products in Israel suffers from a wide range of deficiencies, including:

- (1) A Ministry of Health (MOH) requirement that new products be registered and marketed in a "Recognized Country" prior to being examined by Israeli health authorities;
- (2) A lack of clear, transparent and non-discriminatory timeframes for the examination, approval (or rejection) and registration of new pharmaceutical products in Israel; and

(3) Inconsistencies between statements made by the Government concerning the time period required for the registration of new pharmaceutical products in Israel, and the actual time period required for product registration.

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

In recent years, the registration process for innovative pharmaceutical products has suffered from increasing delays. According to Israeli Government data, the average period for the registration of a new drug in Israel from its date of approval in a Recognized Country increased from approximately six months in 2003 to a period of between approximately 18 to 24 months in 2007. PhRMA member companies' public policy advocacy activities succeeded in shortening the period to 13-15 months during 2008. However, many issues remain in the Institute for Standardization and Control of Pharmaceuticals (ISCP) at the MOH. Current budgetary problems in ISCP, as well as other procedural inefficiencies, result in increasing delays in the examination of product registration dossiers, without any foreseeable improvement in the near future.

Furthermore, due to the problematic Israeli Linkage Mechanism (explained above), which links the terms of intellectual property exclusivity in Israel to the earliest date of product registration in Recognized Countries, the ongoing regulatory delays and procedural inefficiencies negatively effect the exclusivity period provided to U.S. innovators in Israel.

In addition, PhRMA member companies continue to be adversely affected by the amendment to Article 47 of the Pharmacists Ordinance (of 2002), which allows fast-track registration of generic products based on FDA or EMEA approval. Generic products approved by these authorities are granted an automatic marketing authorization unless the MOH objects to their registration within 70 days. Innovative products are not provided a similar opportunity. Because the amendment primarily benefits local generic products over imported innovative products, it raises GATT national treatment concerns.

Reimbursement and Government Pricing

The Israeli pharmaceutical market is highly centralized, insofar as 95% of the market is controlled by four HMOs (Sick-Funds).

All new pharmaceutical products registered in Israel enter the official government reference price system. This system sets the maximum prescription drug retail prices in Israel at the lower of retail prices in the Netherlands or the average of retail prices in the UK, Germany, France, Belgium, Spain, Portugal

and Hungary. As a result, the prices of pharmaceutical products in Israel correspond with the lowest price levels in Europe.

As of 2006, products that are reimbursed by the Government (via the Health Services Basket) are now subject to an additional price reduction.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

LEBANON

PhRMA and its member companies operating in Lebanon remain concerned that significant market access barriers and a lack of adequate intellectual property right protections characterize the Lebanese pharmaceutical market. In late October 2008, the Council of Ministers approved implementing regulations for a 2003 Law that established a new process for registering and importing pharmaceuticals into Lebanon, including new intellectual property criteria. Since these regulations have not yet been implemented, registration procedures still fail to satisfy international norms.

In addition, data exclusivity (DE) provisions in the 2000 Patent Law must be strengthened to ensure adequate intellectual property protection for research-based pharmaceutical companies. The Ministry of Health (MOH) is still granting market authorization to copy products prematurely. The Ministry of Economy and Trade has not adequately weighed-in on this issue. Also, the Government must take a firm stance against substandard parallel imports.

During 2008, PhRMA member companies met with the Minister of Economy and Trade and his staff to discuss many of these issues, with no tangible results to date. For these reasons, PhRMA recommends that Lebanon be placed on the **Priority Watch List** for the 2009 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 represents 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 improves compliance with TRIPS and the environment for innovation.

The law provides a good basis for Lebanon's eventual accession into the World Trade Organization (WTO), but more must be done to strengthen the law, especially with respect to the clauses related to pharmaceutical intellectual property. 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, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) obligations, would address longstanding trademark and patent issues, as well as provide needed clarification in the area of data exclusivity.

In its present form, 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, the data exclusivity provisions are ambiguous.

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 Exclusivity

As a WTO applicant, Lebanon will be required to adopt adequate 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.

Until the new registration regime is implemented, PhRMA and its members remain concerned that the MOH will limit protection to undisclosed or secret data and would rely on innovator's data to approve generics at any time after innovator approval. A comprehensive provision preventing unfair reliance on confidential information during a set period, as it pertains to a regulatory approval requirement, is required in order to protect PhRMA member companies' proprietary information from unfair commercial use.

PhRMA member companies have engaged in an active dialogue with the Ministry of Economy and Trade (MOET) over the 2008 Unfair Competition Law and expressed concern about language in the bill that would limit data exclusivity protection to undisclosed or secret data. The MOET has taken the position that publication of any data in a medical journal or on the Internet permits the MOH to approve generics at any time. The MOH accepts filing and registration of unauthorized copies on the basis of the innovator's data, and without requiring the applicant to submit its own tests and experiments performed on its own product that is the subject of its application for registration. This ignores the reliance that is being placed on the fact of regulatory approval elsewhere and on the data that was the basis of that approval.

To be TRIPS-consistent, MOH should protect regulatory test data from unfair commercial use during the data exclusivity 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 draft implementing regulations for the new drug registration regime described above have the potential to dramatically improve efforts to stem the parallel importation of counterfeit drugs into Lebanon. However, until these regulations are actually implemented, and unless they prove to be effective, PhRMA continues to have serious concerns about the Lebanese parallel importation system. Legislation passed by the Lebanese Parliament in 2002 allows for the parallel importation of goods without taking into consideration the special nature of pharmaceuticals or a proper analysis of the effect of parallel importation on drug supply safety. Parallel importation of pharmaceuticals has been justified as a "cost containment" measure by the Lebanese Government. However, international experience demonstrates that parallel importation fails to produce any savings for patients, while at the same time presenting possible risks by allowing the importation of counterfeit or uncontrolled pharmaceuticals.

Senior Lebanese health officials recognize that parallel importation puts the drug supply at risk, but have failed to stop the practice. PhRMA has explained that 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 and alert parallel importers.

In addition, the draft implementation regulations permit parallel importation after one year from marketing approval of original drugs in Lebanon, while holding the originator liable for the quality of all product batches available on the market.

Trade in counterfeit pharmaceutical products in Lebanon may become a significant health issue in Lebanon due to the absence of effective surveillance by the authorities. In 2008, PhRMA's member companies supported an awareness campaign to enhance public vigilance against counterfeit drugs.

Market Access Barriers

Regulatory Barriers

The delay in the issuance of implementing regulations for Regulatory Law 530, enacted in July 2003, has resulted in fewer new products or line extensions entering the Lebanese market. In late October 2008, however, the Council of Ministers finally approved implementing regulations for Law 530, which establish a new process for registering and importing pharmaceuticals. The MOH did not take into account the comments of PhRMA member companies in developing the content of the implementing regulations.

The MOH has not incorporated PhRMA's recommendation that it rely on U.S. FDA and EMEA determinations in approving new drugs. This would have: (1) facilitated the registration of new chemical entities and their associated line extensions; and (2) ensured that the quality, safety and efficacy of pharmaceuticals entering the Lebanese market would meet the expectations of Lebanese patients and healthcare providers. Lebanon would benefit from the extensive assessment undertaken by these regulatory bodies.

At present, the Lebanese drug registration system lacks criteria to distinguish between innovative and generic medicines, and several of Lebanon's regulatory practices are not optimal. For example:

- There is no central lab to review and validate the quality of pharmaceuticals.
- The drug registration committee's assessment of registration files is merely a checklist to ensure that all sections required are included. The review is not necessarily based on a validation, analysis, quality or reliability of the content.
- There is no insistence that the data submitted belong to the applicant.
- There is no system for site inspection according to international standards.
- There is no pharmacovigilance system in place to track post-marketing adverse events or quality complaints.
- Bioequivalence is "the criteria" for registering generics, but there is no system in place to monitor/confirm bioequivalence studies submitted (i.e., lab analysis, validation methods, analysis equipment, reference standards, qualified personnel).

The MOH has failed to provide clear guidance regarding the registration process, which can take up to three years. Moreover, innovative products appear to be subject to more onerous requirements than generics. It is our understanding that the registration of innovative products manufactured by multinational companies and involving multiple manufacturing sites is subject to delays while 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.

The recently adopted implementing regulations for the registration and importation of pharmaceutical drugs (mentioned above), incorporates international definitions and sets conditions that are more compatible with current drug development and manufacturing trends. Once the new system is implemented, many more life saving drugs can be registered.

As a result of the new system:

- Pharmaceuticals that are manufactured, marketed, and/or licensed for the Lebanese market by different companies can be sold in Lebanon (previously, all of these processes had to be undertaken by a single company).
- Pharmaceuticals that have different trade names and pack sizes from the product marketed in the country of origin may be registered in Lebanon.
- More effective requirements governing the parallel importation of pharmaceuticals into Lebanon have been adopted.
- It will be easier to maintain products on the Lebanese market and avoid product shortages due to:
 - Greater acceptance of changes in the source of products, trade name changes, and other minor changes;
 - Willingness to view line extensions as variations with minimum additional requirements; and
 - Flexibility in the design of pack materials, reducing the need to have specific packs for small volumes.

PhRMA strongly believes that once these regulations are implemented, Lebanese patients will have greater access to some of the world’s most effective and advanced medicines. PhRMA congratulates the Lebanese Government on taking this important step and encourages the new regulations to be implemented as soon as possible.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 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 significant market access barriers.

PhRMA's member companies remain concerned by inadequate trademark policies and the failure of the Government to provide data protection as required under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), specifically TRIPS Article 39.3. However, PhRMA notes that the Government of Pakistan appears to understand that a sound intellectual property (IP) regime is a prerequisite for developing the national economy and for attracting foreign investment. The establishment of the Intellectual Property Office (IPO) is a good start to this effort, but has yet to have a positive impact on the overall IP environment in Pakistan. Many steps still are needed to bring IP protection in Pakistan up to international standards.

The Ministry of Health (MOH) continues to disregard process patents at the time of registration and a majority of mailbox applications still do not receive patent protection. Copies of molecules filed under mailbox applications continue to be permitted to be marketed, as the original products do not have patent protection.

In the context of the U.S. Government's focus on South Asia and the Government of Pakistan's stated willingness to improve its IP environment, PhRMA supports allocating U.S. foreign assistance resources for capacity building in Pakistan, with the goal of providing technical assistance and training to ensure Pakistan's adoption and/or implementation of its TRIPS obligations. Efforts should also focus on developing patent examination capacity and implementation of effective data exclusivity. For the reasons stated above, PhRMA recommends that Pakistan remain on the **Priority Watch List** for the 2009 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

In January 2001, a new patent ordinance was promulgated which made incomplete, though promising, strides towards recognizing Pakistan's TRIPS obligations. To date, no clearly defined rules or regulations have been released on this legislation. More troubling than the non-issuance of underlying regulations are changes made to the Act in 2002 that drastically inhibit the ability of U.S.-

based pharmaceutical companies to enjoy effective and meaningful patent protection in Pakistan. The amendment to the Patent Act, effective from October 2002:

- Eliminates use patents;
- Restricts patent filings to single chemical entities for pharmaceutical and agrochemical inventions;
- Restricts the protection for derivatives or salts;
- Introduces onerous barriers to patenting biotechnology based inventions, and
- 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 patented products of 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 was 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 Exclusivity

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 made 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 discussing a draft law that would extend protection to pharmaceutical test data. PhRMA member companies are encouraged by these discussions and look forward to working with the Pakistani Government to ensure that the new law meets Pakistan's international obligations and provides full protection for pharmaceutical intellectual property.

Market Access Barriers

Local Manufacturing Requirement

Pakistan's MOH maintains a local manufacturing requirement as a prerequisite for product registration. In addition, the MOH has placed restrictions on toll manufacturing. The result of these restrictions is that registration of new chemical entities is often denied.

Pakistan's local manufacturing restriction raises yet another issue. Certain products are manufactured in Pakistan, but as a result of Environmental, Health, and Safety (EHS) compliance, companies must restrict manufacturing to a small number of sites making continued manufacture in Pakistan exceptionally difficult.

Government Pricing

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

There is also a lack of transparent government pricing directives or guidelines. Although the Government has considered implementing a policy to adjust prices in order 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 65%.

Fast Track Registration

In a positive development, 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. This should increase 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 2008 attributable to trade barriers related to intellectual property protection and market access.

SAUDI ARABIA

PhRMA and its member companies operating in Saudi Arabia remain concerned that deficiencies in intellectual property right protections and other market access barriers limit the ability of PhRMA member companies to effectively compete in the Saudi market. PhRMA's member companies are specifically concerned that, as a result of the application of the July 2004 patent law, innovative pharmaceutical products do not enjoy effective IP protection in Saudi Arabia. In addition, pharmaceutical products did not enjoy effective data exclusivity protections and faced significant and arbitrary government price cuts in 2008.

For these reasons, PhRMA requests that Saudi Arabia be elevated to the **Priority Watch List** for the 2009 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

PhRMA member companies encourage Saudi authorities to support a strong intellectual property rights (IPR) regime, including patent protection for all innovative pharmaceutical products, exclusive marketing rights where appropriate, and data protection for clinical and other test data developed as part of the research and development process.

Retroactive Application of Patent Law

Under Saudi Arabia's old patent law, pharmaceutical companies could secure patent protection in Saudi Arabia by relying on the fact that a patent had been granted for the same product in a foreign country (Confirmation Patents). An absolute novelty requirement was not applied in practice. From 1990 to 2004, – however, The Saudi Patent Office did not act upon confirmation patent applications, resulting in a significant patent backlog. In practice, however, Saudi Arabia, through an informal system, also did not grant marketing approval to copy products for which a patent application was pending in Saudi Arabia. In reliance upon the old system, PhRMA member companies brought numerous products to market in Saudi Arabia.

The current Saudi patent law contains an absolute novelty requirement. Saudi Arabia had accumulated a significant backlog of pending patent applications when it passed a new patent law in July 2004. There is a backlog of pending patent applications that have been waiting for review in Saudi Arabia for years after the inventions were first made public through filings in other countries. As part of its agreement with the United States for accession to the World Trade Organization (WTO), Saudi Arabia committed to reducing the backlog of pending

patent applications. The Patent Office of Saudi Arabia, known as the King Abdul Aziz City for Science and Technology (KACST), began applying the new patent law retroactively to applications pending prior to July 2004. That has resulted in unwarranted rejection of patent applications that were properly filed in reliance upon the old formal and informal Saudi patent system.

The new law is being relied upon by KACST to inappropriately reject those applications for failing to meet the new novelty standard. If the improper retroactive application of the new law persists, it could result in the rejection of over 1,500 patent applications, many of which cover innovative pharmaceutical products that enjoy patent protection in the US and the EU. PhRMA member companies reasonably expected that such products would receive intellectual property protection in Saudi Arabia, as was the case under the informal system that existed under the old law. At the time of Saudi Arabia's WTO accession, it was clearly not contemplated that the patent application backlog would be resolved by simply rejecting the applications filed under the old system on the grounds that the inventions are no longer novel.

Retroactive application of Saudi Arabia's new patent law is an unfair method of dealing with the Kingdom's patent backlog. It imposes new criteria for providing patent rights on products that were brought to market in Saudi Arabia in reliance upon a completely different system. The retroactive application of the new patent law essentially harms applicants twice – first, by delaying the examination process in the first place, and second, by now determining the product in question is no longer novel. PhRMA member companies now find themselves in the situation of having a lower standard of protection for their products currently on the market in Saudi Arabia than they did prior to the Kingdom's accession to the WTO. PhRMA members clearly did not envision this result when they strongly supported Saudi Arabia's WTO membership.

Exclusive Marketing Rights

To remedy the patent protection difficulties that PhRMA members are facing in Saudi Arabia, PhRMA has proposed that Saudi Arabia adopt transitional protection in the form of time-limited exclusive marketing and manufacturing rights for certain pharmaceutical products, which enjoy patent protection in the United States and/or the EU and are also caught between the old and new Saudi patent systems. Granting exclusive marketing and manufacturing rights to these products would provide companies with the benefit of their innovations that they reasonably expected to receive when they entered the Saudi market and were largely continuing to receive until the entry into force of the new Saudi patent law. Accordingly, the term of the exclusive marketing and manufacturing rights would expire at the same time as the term of the protection in the United States or in the European Union.

A number of other countries in bilateral agreements with the United States have recognized the need for transitional protection in the form of exclusive

marketing rights when the legal system surrounding patents is changing in the particular country. The concept of transitional protection was also recognized in WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Saudi officials have indicated an interest in considering adoption of the concept of exclusive marketing rights as a means of resolving the current problems. There is at present, however, no timetable or process to bring the Saudi Government's consideration of this concept to closure. We request that the United States Government continue to press the Saudi Governments' to ensure that PhRMA member companies do not receive less protection for their products on the market as a result of Saudi Arabia's WTO accession.

Data Exclusivity

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 member companies are concerned by the MOH's 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.

PhRMA member companies are troubled by the registration of unauthorized copies of innovative and patented pharmaceutical products during the products period of data exclusivity protection. The Ministry of Health is not enforcing 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 information about confidential tests or other data, obtained as a result of substantial efforts, for the approval of the marketing of drugs or agricultural products, which utilize a new chemical entity, shall be protected by the competent authority against unfair commercial use for at least five years from the approval date.

As data exclusivity is a commitment from the Saudi government during their accession to WTO, but is not being implemented, the Ministry of Health has not complied with its regulation and WTO commitments. The Kingdom of Saudi Arabia, under its protocol of Accession to the WTO, acknowledged that

"These Regulations provided for protection of undisclosed test 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 exclusivity regulations. Authorities insist they are not sharing the content of the drug registration file of the innovator product. However, since only bioequivalence is required to gain approval for a copy product, authorities appear to be relying on the data of innovator drugs to approve local copies and ensure bioequivalence. An effective data exclusivity provision 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 exclusivity should be provided to innovative pharmaceutical products whether or not they are patented in Saudi Arabia. Data exclusivity is commercially important to products that may not be patentable. Saudi regulatory authorities should have the responsibility for keeping generic copies of pioneer drugs off the market during the period of data exclusivity. Since KACST is not registering patents, then they need to protect the data submitted to health authorities per decree number 50. However, in the absence of a registered patent, a copy may still receive marketing approval during the data exclusivity period, provided its manufacturer conducts its own pre-clinical and clinical trials and independently seeks marketing authorization from regulatory authorities.

Market Access Barriers

Recent Changes to Government Pricing Policies

On February 1, 2008, the Saudi Ministry of Health implemented an across-the-board price cut for pharmaceutical products. Unless products had been on the market less than five years or were deemed to be “life saving” (which was not defined), government-imposed prices were cut by one percent for every year the product was on the market. This government price cut was implemented with no input from pharmaceutical manufacturers, contrary to Saudi Arabia’s WTO accession commitments.

Also in February, the Ministry of Health converted all Euro-based CIF (cost, insurance and freight) prices for imported pharmaceuticals into Riyals. The Saudi Government chose two different exchange rates, based on the price of the

product (the rates were not disclosed, nor was the rationale for choosing the rates).

To further complicate the Government's pricing policy, the Saudi Government issued a new draft pricing regime in June 2008. While the Government's efforts to seek stakeholder input on the draft policy is commendable, and the result of U.S. Government advocacy for Saudi Arabia to meet its WTO accession commitments, input from research-based pharmaceutical companies was not taken into account..

PhRMA's member companies are concerned that that the proposed government pricing policy does not focus on market-based principles that promote competitiveness and reward innovation. 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 incurred by innovative pharmaceutical companies in the development of these medicines.

PhRMA member companies have communicated to the Saudi Food and Drug Agency (SFDA) specific concerns pertaining to the proposed government pricing policy, mainly regarding the mechanism and frequency of price changes and the need for price adjustments to reflect exchange rate fluctuations. As shown by the systems of Lebanon and Jordan that reference Saudi Arabia, prices of pharmaceuticals in the Kingdom are already among the lowest in the region.[CITE] Under the SFDA plan, 11 additional countries would be added to the price reference basket, mainly countries that do not enjoy a level of development or per capita income equivalent to that of the Kingdom.

Regulatory Environment

In 2008, the SFDA initiated a dialogue with PhRMA member companies over a draft regulatory framework for drug approvals. PhRMA members look forward to working with the Saudi Government to develop a transparent and predictable regulatory framework that will expedite patients' access to innovative medicines.

The registration process for new medicines is lengthy (16-24 months) due to different reasons, including delays caused by the central lab, which is taking 6-8 months to release results of samples examined. Moreover, the central lab process takes place after the primary committee provides its initial approval to register the products, thereby causing further delays. To mitigate these delays, the primary committee tasks should take place simultaneously with central lab tasks. In addition, the draft regulatory framework suffers from a lack of transparency, failing to provide guidance to companies regarding what they must submit to start the approval process.

In addition, the current investment law allows 100% ownership of companies by foreign investors, provided that they establish a manufacturing site in Saudi Arabia. In the absence of domestic manufacturing, PhRMA member companies can only be represented by a Saudi agent and their ownership share may only be 51% during the first year, reaching a maximum of 75% ownership in the third year.

The SFDA is expected to take over responsibilities from the Ministry of Health, effective early-2009. PhRMA's member companies look forward to working with the Saudi Government to develop transparent and predictable healthcare policies that respect market-based principles, promote competitiveness, and ensure quality healthcare for the Saudi people.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

WATCH LIST

ASIA-PACIFIC

MALAYSIA

PhRMA and its member companies operating in Malaysia continue to face significant obstacles relating to data exclusivity, patent linkage, and bioequivalence requirements.

For these reasons, PhRMA requests that Malaysia be placed on the **Watch List** for the 2009 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 Exclusivity

In May 2007, the Malaysian government announced that five years of Data Exclusivity (DE) will be provided for new chemical entities and three years for new indications from the date of approval in the country of origin, rather than from the date of approval of the drug in Malaysia. This is not consistent with international practice, where DE is provided from the date of approval in the end-market (e.g. Malaysia). DE was to be implemented by the end of 2007. However, issues related to the implementation of DE such as legislative amendments have yet to be worked out, and the implementation deadline has been delayed. Expediting DE 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 DE is implemented in a timely manner and in a way that is consistent with usual international practice.

Patent Linkage

Malaysia does not currently have a patent linkage system. Patent linkage describes the "linkage" between patents in a country and the drug approval process for products potentially covered by those patents. This mechanism prevents the registration of a generic form of a patented medicine while a patent covering the proposed generic product is still in force.

A system of patent linkage has a number of advantages that enhance the business environment for pharmaceutical research-based companies: (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. By establishing and ensuring adequate "linkage," the Malaysian Government could foster an environment that is more favorable to innovation and growth in the life sciences sector.

Market Access Barriers

Bioequivalence Requirements

Although Malaysia put in place a requirement for bioequivalence studies for generics in 1999, the list of therapeutic areas for which data are required remains very limited. Only a select minority of generic drugs are currently subject to a requirement that applicants provide bioequivalence data. In line with the Ministry of Health's objective to ensure the quality, safety and efficacy of products registered in Malaysia, we recommend that the Government introduce further categories and products to the list to ensure that all generic products available on the market are therapeutically equivalent to the innovator's products, and are clinically interchangeable.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 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 commercial environment for PhRMA member companies in Taiwan.

The 2006 TIFA talks yielded agreement to form two joint working groups to address certain system reforms in Taiwan: one group that would focus on the related issues of the price gap between the government reimbursement price paid to providers and the actual price paid by providers and the separation of prescribing and dispensing; the other group that would focus on a government-mandated standard drug purchasing contract for use by hospitals and drug manufacturers. The 2007 TIFA talks yielded a firm commitment to implement the standard contract on a mandatory basis. This is commendable, and it is important that a timetable and process for implementation soon be provided by the Government of Taiwan. PhRMA member companies hope that the 2009 high-level TIFA meetings will emphasize the need to fulfill past commitments and broaden the dialogue to include discussions on new government drug pricing and reimbursement policies developed in late 2008.

Because of long-standing intellectual property issues related to data exclusivity implementation, the absence of patent linkage, and significant market access concerns, we recommend that Taiwan be placed on the 2009 Special 301 **Watch List**.

Intellectual Property Protection

Data Exclusivity

In January 2005, Taiwan passed data exclusivity legislation to implement TRIPS Article 39.3. TRIPS Article 39.3 requires Governments to prevent unfair commercial use of valuable test data generated by innovative companies to secure marketing approval.

Although the revised Pharmaceutical Affairs Law provides for five years of data exclusivity, it only covers new chemical entity products and does not cover new indications. In addition, the current law limits the applicability of data exclusivity 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 exclusivity in Taiwan to the date of any other market launch is not consistent with the objectives of data exclusivity rights and does not effectively prohibit unfair commercial use.

Patent Linkage

Taiwan has not yet established patent linkage in the regulatory procedures for approving generics. This significantly disadvantages innovator companies, particularly in view of pending proposals to alter regulatory approval procedures. Patent Linkage describes the “linkage” between patents in a country and the new drug approval process for products potentially covered by those patents. This mechanism prevents the registration of a generic form of a patented medicine while a patent covering the original product is still valid, thereby preventing unnecessary litigation and confusion.

PhRMA has provided to the Government of Taiwan example cases in which the absence of patent linkage has resulted in local generic products proceeding to market (including hospital listing and procurement) following grants of licensing approval and NHI price determinations, notwithstanding a valid patent. We believe that the Taiwanese Government should adopt a patent linkage system that includes: (1) notification to the originator (by the generic manufacturer or the government) when a generic company files an application for marketing a product with the same active ingredient as in the innovator product which the innovator has an approval on, and (2) a requirement that the regulatory agency not grant final marketing approval for a product alleged to violate patent rights until the patent expires or for a reasonable period of time needed to resolve patent dispute.

Market Access Barriers

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 while the Pharmaceutical Benefits Scheme sets reimbursement prices for generics at 80% of the originator price. 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.

Instead of adequate enforcement of Article 49, periodic Price-Volume Surveys (PVS) are conducted by the Government with the intent of capturing discounts provided by drug suppliers. These surveys lead to reductions in reimbursement prices that provide an immediate savings to the Government, but fail to resolve the underlying financing shortfall.

During the course of previous TIFA discussions, PhRMA recommended that the Government of Taiwan focus on eliminating Taiwan’s pharmaceutical

price gap, otherwise known as the “Black Hole.” The Black Hole 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 through the TIFA process a series of recommendations aimed at achieving our core goal of eliminating the Black Hole as expeditiously as possible.

The Black Hole cannot be resolved through the PVS process; it distorts the nature and magnitude of payments by the Government, encourages unusual and unethical prescribing patterns, and sets patient welfare as a frighteningly-low priority. Resolution of the Black Hole in Taiwan – requiring transparent funding of healthcare expenses in all sectors, implementation of actual transaction pricing and, most importantly, a real separation of prescribing and dispensing of pharmaceuticals – lies at the core of needed substantive reform. 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. The recent 5th PVS re-check has confirmed perceptions of significant under-reporting of discounts by local generic manufacturers.⁴⁷

In the past, the Department of Health (DOH) and the Bureau of National Health Insurance (BNHI) have been reluctant to initiate substantive reform in the healthcare arena. Taiwan’s cumbersome regulatory 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.

Government Pricing Should Reward Innovation

BNHI prices for new innovative drugs are extremely low, currently averaging only 60% of the average A-10 prices (the prices in 10 benchmark advanced countries) over the last three years.

BNHI’s drug reimbursement guidelines contravene internationally-accepted norms by severely restricting the use of innovative medicines and disregarding many innovative products’ approved indications.

⁴⁷ Bureau of National Health Insurance Press Release, dated September 28, 2006.

Clear, detailed, and objective written criteria and timelines are needed for government pricing decisions, and should appropriately reward innovation. These criteria should be developed and implemented in a fair, open and transparent process in which all stakeholders have a meaningful opportunity to provide input. They should be published in the Government gazette and on an easily accessible part of BNHI's website.

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 powerful hospital lobbying interests. Proper implementation of SDP would effectively remove profit incentives from the selection of appropriate treatments or therapies. As long as hospital revenue and physician remuneration are dependent on mark-ups on pharmaceutical products, patient welfare is compromised by this conflict of interest.

One initial step toward achieving SDP would be to regulate repeated chronic disease prescriptions in hospitals, which are already subject to special prescribing practices under the BNHI reimbursement guidelines. BNHI should require that these types of prescriptions be filled by independent pharmacies instead of refilled within hospital pharmacies. Under current BNHI guidelines, Taiwanese patients are not required to visit a doctor to refill a prescription for a chronic disease (e.g., asthma, hypertension, or diabetes) if they receive a three-month prescription from a doctor. However, the prescribing physician usually requires a patient to come back to pick up medicine from a designated hospital pharmacy, allowing the hospitals to capture the profit from illicit Black Hole discounts.

Until recently, BNHI provided Taiwanese physicians a special incentive for off-loading prescriptions to a private pharmacy instead of requiring that prescriptions be filled by an affiliated pharmacy. If a doctor directed more than 70 percent of his or her prescriptions to a single pharmacy, he/she became ineligible for the incentive. BNHI guidelines, effective July 1, 2006, revised this policy to address certain corruption concerns. PhRMA supports the Government's initiative, but encourages an incentive structure that favors SDP. We have urged BNHI to monitor implementation of the new guidelines and consider reinstating an incentive structure.

Government hospitals in Taiwan account for 80 percent of the pharmaceutical market in Taiwan, and thus are under significant Department of Health control. A transition to SDP could be achieved in phases by first implementing it in government hospitals.

Actual Transaction Price

Article 49 of the National Health Insurance Law states that: “[d]rugs, priced medical devices and materials should be reimbursed at cost.” Until March 31, 1997, BNHI treated the official reimbursement price as a “ceiling price” and reimbursed at actual transaction price in accordance with the 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 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 Taiwan’s inadequate hospital and physician fees. As a result, hospitals and physicians have come to depend on revenues from the Black Hole. 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.

Regulatory Issues

Certificate of Pharmaceutical Product (CPP)

To grant a license for a new drug or line extension of existing drugs, the Bureau of Pharmaceutical Affairs (BOPA) requires that companies provide two Certificates of Pharmaceutical Product (CPP) from A10 countries. However, the U.S. FDA and Health Canada do not always issue CPPs where the products are manufactured outside the United States or Canada. This results in substantial delay in the review of new drug applications in Taiwan.

BOPA should reduce these unnecessary delays by recognizing official approval letters from A10 countries that are certified by company officials, and should require, at most, 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 2008 attributable to trade barriers related to intellectual property protection and market access.

VIETNAM

PhRMA and its member companies operating in Vietnam acknowledge the efforts of the Vietnam Government to address existing intellectual property and market access barriers. However, PhRMA members still face real challenges in the Vietnam market with regard to intellectual property protection and market access barriers. Even with the significant reforms Vietnam has undertaken in recent years, there are still several areas which are of great concern to PhRMA, namely weak intellectual property protection, the absence of data exclusivity, patent linkage legislation, overly-stringent product registration and clinical trial requirements, a lack of legal status, and government reference pricing.

For these reasons, PhRMA requests that Vietnam be placed on the **Watch List** for the 2009 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

Vietnam needs to implement a number of reforms to its legal system before effective and efficient IP protection in Vietnam will be a reality. This process will likely take years, and PhRMA and its member companies believe that significant steps are needed to initiate this process.

To this end, PhRMA has been working with Vietnam's National Office of Intellectual Property (NOIP) this year to open a dialogue on the serious deficiencies that remain with Vietnam's intellectual property protection regime. However, we have yet to see any significant changes to the regime. PhRMA also supports capacity building to help Vietnam implement its WTO accession commitments and commitments under the Bilateral Trade Agreement.

Data Exclusivity

Vietnam is obligated to prevent unfair commercial use of non-disclosed test and other data developed by PhRMA's member companies in obtaining marketing approval for new medicines. Despite the requirement under TRIPS Article 39.3 and paragraphs 5 and 6 of Article 9 of Chapter II of the U.S.-Vietnam Agreement on Trade Relations, Vietnam has not implemented data exclusivity to fulfill this obligation. Data exclusivity is a simple mechanism for providing that protection. While Vietnam's Law on Intellectual Property Protection provides for a period of 5 years of data exclusivity, it is our understanding that no company has been granted this protection to date. In addition, the Vietnamese authorities require pharmaceutical companies to request data exclusivity in the application for marketing approval. Protection of the data, however, is an explicit obligation of the Government under both the cited agreements. To impose "procedures and

formalities” as a condition of extending a period of data exclusivity is not consistent with Vietnam’s obligations under either TRIPS or the Bilateral Trade Agreement, nor is it consistent with international norms.

PhRMA and its members companies request that Vietnam make its timetable explicit for full implementation of data exclusivity that is consistent with international norms. Any conditions applied to such protection, such as requiring the submitting party to request the protection, should be eliminated. Data exclusivity should be automatic and comprehensive.

Patent Linkage

Vietnam currently does not have a system in place for “linking” the drug registration system with the patent system. Vietnam argues that it is not appropriate to inject patent enforcement procedures into regulatory procedures, and that it is impossible to issue administrative rules or procedures to administrative agencies to enforce patents.

PhRMA and its member companies believe that the adoption of patent linkage is good public policy and the experience of countries that have adopted linkage is that it is relatively easy to implement. When an agency approves the marketing of a product that is covered by a patent without the permission of the owner of the patent, in effect it enables infringement. Linkage can prevent this from occurring.

Intellectual Property Enforcement Action Plan

PhRMA and its member companies were encouraged by the adoption of an enforcement action plan for intellectual property by the Government of Vietnam in 2008. We remain concerned, however, that certain aspects of the plan are deficient. Specifically, the level of fines that may be imposed to deter future infringements by the infringer or others is too low. Limited administrative proceedings are often the only path for obtaining relief.

TRIPS Article 41 requires that WTO members have in place procedures to prevent infringements and adequate remedies to deter future infringements. Vietnam does not currently have in place either effective administrative or effective judicial procedures, as a result leaving little deterrent against future infringements. At a minimum, using the administrative proceeding as a means of imposing higher fines based on the value of “lost” sales would be a valuable step toward fulfilling Vietnam’s obligation to deter future infringements.

Market Access Barriers

Certificate of Pharmaceutical Product

A Certificate of Pharmaceutical Product (CPP) or a Free Sales Certificate (FSC) and Good Manufacturing Practices (GMP) certification from the country of manufacturing or packaging is mandatory as part of the marketing authorization process for all imported pharmaceutical products. These documents are issued by a government to confirm that a product has been licensed for sale within its territory. However, the country of manufacturing/packaging may not be the country where the product is ultimately marketed, meaning that products may not always have a CPP or FSC from the country of manufacture. Vietnam's CPP requirement may therefore result in a significant hurdle in applying for registration for PhRMA's member companies, and could delay the availability of innovative medicines in Vietnam. PhRMA maintains that a CPP from any country should be acceptable to comply with the regulation.

Quality tests of vaccines and biological products

The Vietnamese Government requires quality tests for all new batches of vaccines and biological products before they are imported into the country. These "batch tests" are scientifically unnecessary and time-consuming, resulting in an undue burden on manufacturers and delaying the availability of vaccines to Vietnam's citizens. In addition, biological products are not manufactured in batches but must nevertheless comply with testing requirements. PhRMA and its member companies request that these quality tests no longer be required.

Lack of bioequivalence study requirements

Generic medicines are exempted from clinical trials, including the requirement for generic producers to conduct bioequivalence studies before applying for regulatory approval. Bioequivalence studies are designed to ensure generic products have the same therapeutic and chemical equivalence as original, innovative medicines. Vietnam's policy exempts local generic manufacturers from this important testing requirement, which is imposed on research-based manufacturers. It is critical that these studies are conducted for all products to avoid discriminating against innovative products and to ensure that patients are receiving safe, effective and high-quality medicines. These very low requirements for registration of local generic products are inconsistent with the very strict requirements for clinical trials for registration of new products (see above) and are not in the interest of patient safety. PhRMA and its member companies request that the registration requirements for generic products be increased to a level similar to the requirements for original, innovative products.

Requirement that clinical trials be conducted in Vietnam

Vietnam's Law on Pharmaceuticals, passed in June 2005, requires that multinational companies conduct local clinical trials prior to registration of medicines (if the product has not been available in the country of origin for five years or more). This requirement is unnecessary, because PhRMA member companies are already subject to very stringent rules and rigorous protocols required by the U.S. Food and Drug Administration and/or other internationally-recognized regulatory bodies (such as the International Conference on Harmonization (ICH) and European Medicines Agency (EMA)) regarding the conduct of safety and efficacy trials before introducing their medicines into Vietnam. The duplication of clinical trials already conducted outside of Vietnam results in significant costs to manufacturers and unnecessary delays in access to medicines for Vietnamese physicians and patients.

PhRMA and its member companies request that companies conducting clinical trials outside of Vietnam in accordance with FDA or other ICH standards be exempted from this overly-burdensome requirement.

Investment restrictions/Legal status

Vietnam modified its regulations for foreign representative and branch offices in Decree No. 72/2006/ND-CP of July 25, 2006. The Decree spells-out procedures for applying for and renewing applications for representative and branch offices. The Decree is not sector-specific.

Vietnam agreed, as part of its WTO accession commitments, to extend trading rights (the right to import and export independent of government-approved channels) to pharmaceuticals, effective January 1, 2009. The Ministry of Trade is responsible for developing the regulations implementing this obligation. However, to date, no clear guidelines or procedures have been put in place to allow effective implementation of this WTO commitment. The January 2009 deadline has now passed with no signal from Vietnam as to how it will implement its accession commitments. Clear implementing guidelines and procedures must be developed quickly, and in a transparent manner.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

CANADA

CANADA

The intellectual property environment for PhRMA member companies operating in Canada continues to be very challenging and 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 because Canada is the only G-7 nation without any form of Patent Term Restoration (PTR).

For these reason, PhRMA requests that Canada be placed on the 2009 Special 301 **Watch List**.

Intellectual Property Protection

Data Protection

For many years, PhRMA members expressed serious concern over the failure of Canadian regulatory authorities to provide effective data exclusivity to prevent unfair commercial use of regulatory data, as required by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Article 39.3 and NAFTA Article 1711(5) and (6). PhRMA member companies appreciated Canada's recognition, through the publication on October 18, 2006 of regulations implementing 8 years of data protection, that it is inappropriate for unauthorized parties to gain commercial benefit during the period of exclusivity by gaining marketing authorization in reliance on the clinical dossier of others. This was an important step in improving Canada's intellectual property regime.

However, PhRMA 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.

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

Enforcement (Linkage)

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 in respect of 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 relevance requirement, further defining the rules for eligibility of listing patents on the Patent Register. These amendments would have meant that the “relevance requirement” only applied prospectively. However, Canadian courts developed case law that applied the “relevance requirement” not only to patents listed under the current (October 2006 amendments) system, but also to patents listed under the pre-October 2006 systems, despite the fact that this was contrary to the intention expressed in the amendments. This judicial interpretation⁴⁸ 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 reverse this case law requirement and to restore the original prospective intent of this element of the October 2006 amendments.

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 Right of Appeal

The patentee does not always have a 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, upon which any filed appeal will become moot.⁴⁹ The patentee is then left with no alternative but to start another proceeding, commencing an action for infringement once the generic enters the market, essentially having 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 a consistent 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. 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.

⁴⁸ *Ratiopharm v. Wyeth*, 2007 FCA 264.

⁴⁹ *Eli Lilly Canada Inc. v. Novopharm Limited* 2007 FCA 359.

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. Moreover, on October 18, 2006, the Canadian Government published amendments to the *PM (NOC) Regulations* that further limit the listing of valid patents. The effect of these amendments 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 the generic drug is stayed for a maximum period of up to 24 months pending judicial review.

In the U.S., a challenge to an allegation of non-infringement or patent invalidity proceeds as a full action for infringement. Under the Canadian scheme, however, a challenge proceeds by way of 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.

Although a patentee 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 applications rarely succeed in Canada even if there is compelling evidence of infringement.

Finally, patent infringement actions involve multi-year and complex litigation processes, and it often takes several years before such actions reach the Federal Court for trial. By then the innovative company’s market share can be severely eroded by the marketing of the generic product. Provincial policies mandating the substitution of generics for brand-name products guarantee rapid market loss.

These various deficiencies frequently result in violations of the patent rights of PhRMA member companies with attendant economic losses. These losses are serious and of growing concern.

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 or other policies or practices to ameliorate the effects of delays caused by its regulatory processes, which can significantly erode the duration of the intellectual property rights of innovators.

Cross-Border Trade

Over the past several years, prescription drugs intended for Canadian patients have been diverted to the United States. These cross-border shipments have occurred despite the fact that U.S. law generally prohibits imports from Canada. It is illegal under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to import an unapproved drug into this country. The U.S. Food and Drug Administration (FDA) maintains that it is illegal for anyone, including a foreign pharmacy, to import prescription drugs that are not approved by FDA into the United States even though the drugs may be legal to sell in the originating country.

In addition to the quality and safety questions raised by cross-border trade in pharmaceuticals, PhRMA member companies believe that cross-border trade causes significant intellectual property issues as well. Two legislative initiatives to address the cross-border issue were initiated in recent years, but neither passed into law.

PhRMA member companies believe that the U.S. Government should request that the Canadian Government move to address cross-border trade issues.

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 Draft Guidance is the protection of intellectual property for innovative biologic products. The Draft Guidance merely notes “all the laws, patent, and intellectual property principles....are applicable to SEBs”. It should be made clear that all appropriate intellectual property protections will be provided to biologics approved in Canada.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

FINLAND

PhRMA and its member companies operating in Finland are concerned about the recent passage of a Government Bill establishing a new generic reference pricing scheme. Upon implementation, the Bill will repeal 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 would not be included on the interchangeable drug list. The deterioration of the regulatory environment has enhanced the negative effects of inferior patent protection for pharmaceutical products.

For this reason, PhRMA requests that Finland be placed on the 2009 Special 301 **Watch List**.

Intellectual Property Protection

A lack of patent harmonization exists in Finland due to the fact that Finland has not recognized pharmaceutical product claims that have been 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 WTO TRIPS Agreement (Articles 70.2 and 27.1), PhRMA believes 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 believes that, after Data Exclusivity expiration (6 to 10 years), holders of such pharmaceutical process patents have had poorer patent protection than is required by the TRIPS Agreement.

In addition to the poor patent protection, Finnish Courts have not applied the reversed burden of proof provided for by Article 34 of the TRIPS Agreement in preliminary injunction proceedings. This has expressly been confirmed as a

requirement in a Court of Appeals proceeding to which the Supreme Court has not granted leave for appeal.⁵⁰

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 an analogous process patent.

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

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

This was corrected by an amendment to the Finnish Medicines Act (of 2006) stating that an original and respective generic drug 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 November 18, 2008, the Parliament of Finland passed the Government Bill on the reference price system that will remove this amendment.

The approved Government Bill includes an extension of the generic substitution system pursuant to which the generic substitution and reference price system would encompass products protected by analogous process patents, which should have been excluded from generic substitution until the expiry of their patent protection by virtue of the amendment of the Medicines Act enforced as of February 2006.

The Government Bill was submitted to the Parliament on September 9, 2008. The reporting committee, the Committee for Social Affairs and Health (CSAH), held hearings during the weeks of October 13 and October 20. Despite strong concerns regarding the broader implications of the Bill from the Foreign Affairs Committee and the Commerce Committee as well as the Ministry of Foreign Affairs, the CSAH proceeded without modification to the Government Bill on November 6. The Parliament approved the bill on November 18, 2008 and the legislation will take effect April 1, 2009.

Prior to implementation of the bill, even though an original product would not be eligible for inclusion in the substitution list and thus to the reference group,

⁵⁰ 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.

it was nevertheless possible for its reimbursement status to be deteriorated by other measures, *e.g.*, by the Finnish authorities cancelling the reimbursement during the reimbursement period. According to the reimbursement provisions of the Finnish Sickness Insurance Act (1224/2004) (the 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.

Due to the increased deterioration of the Finnish IP environment, PhRMA and its member companies request that the US Government include Finland in the 2009 Special 301 Watch List for failure to provide protection for patent protected products.

Market Access Barriers

The current lack of harmonization between IP protection in Finland and the rest of the EU continues to result 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 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 therapeutic 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 encourages 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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

FRANCE

France's healthcare system employs an increasing number of government-created cost-containment mechanisms impacting pharmaceutical products. The numerous cost containment tools and 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.

The government pricing and reimbursement mechanism for new medicines is still very time-consuming, despite the "ATU" mechanism (temporary pre-authorization) and some progress through the creation and recent enlargement of the "depot de prix" system (fast-track).

Moreover, since 2004, French national authorities are no longer required to check the possible applicability of patents before granting marketing authorization ("MA") for generics, raising serious intellectual property protection concerns. PhRMA member companies will therefore pay close attention to the application of the January 2007 Addendum to the State/Industry Framework Agreement, which has given the Drug Economic Committee (CEPS) control over information obligations for generic companies.

PhRMA is encouraged that the French Government has taken small steps to reform its healthcare system. However, new cost-containment measures targeting research-based pharmaceutical companies (including government price cuts and aggressive generic promotion), despite several years of already draconian measures, have raised concerns regarding the impact of these measures on both French patients and research-based pharmaceutical companies.

We therefore recommend that the U.S. Government place France on the 2009 Special 301 **Watch List** and elevate these issues in the bilateral commercial agenda with France.

Market Access Barriers

Unrealistic Healthcare Budgets

The French global healthcare budget is set annually by the Government 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 has been capped at very low levels (1% (2005, 2006 and 2007); 1.4% (2008 and already planned at this level for 2009, 2010 and 2011)). Moreover, the

French Ministry of Health (MOH) has decided a negative target for public drug reimbursement in the last few years (e.g.: -4% for 2007; -5% for 2006).

In addition to the foregoing, the French Parliament decided through the 2009 Social Security Financing Bill to maintain a turnover tax from 0.6 to 1 percent for 2009, 2010 and 2011.

Finally, the French Government regularly employs additional cost-containment measures within now traditional mid-year saving plans, including government 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 could mean government-imposed price cuts on products that have only been on the market for a short time upon generic entry in their therapeutic group.

PhRMA remains concerned about two aspects of the Social Security Financing Bill of 2008:

- The authority given to the French Health Body (HAS) to release medico-economic guidelines which could reinforce budgetary issues as opposed to medical ones and the recognition of innovation; and
- The inclusion of individual prescription contracts signed between public sick funds and doctors (private sick funds consulted) leading to financial incentives which could include HAS guidelines and could lead to significant pressures on some prescriptions.

In addition, the Social Security Financing Bill of 2009 raises several new concerns, including:

- Enlargement of the generic drug list⁵¹ to include modified-release tablet specialities
- Introduction of the notion of “therapeutic moiety”⁵² to enlarge the generic drug list beyond the strict definition of a generic
- An obligation to prescribe an INN when a product has some generic competitors

Government Price Controls

Government-imposed price controls fail to recognize and reward innovation and erode intellectual property protections for pharmaceutical products. In France, prices of reimbursable 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

⁵¹ « Répertoire des Génériques » (Generic Drug Directory) which rules the options for the pharmacists to substitute, beyond the definition of a “generic”

⁵² Considered as the therapeutic active entities in the molecule

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, 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. PhRMA member companies believe that this process should be extended beyond five years to ensure an adequate return on investments in 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 very 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 Public Sick-Funds (UNCAM) have on occasion negotiated with doctors reduction targets concerning some retail drug categories (e.g., antibiotics, statins, anxyolitics, proton pump inhibitors) and planned incentives to prescribe more generics. Statins are an important example of this. Any volume constraints should therefore be based on medically-justifiable quantities (number of patients eligible to be treated for approved indications) and not on affordability.

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 brand name products.

French authorities should also strive to eliminate delays in providing market access for the newest, most innovative pharmaceutical products. These approvals take, on average, 256 days for new products,⁵³ far beyond the EU statutory limit of 180 days.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

⁵³ Drug Economic Committee (CEPS) 2007 Report – July 2008

NORWAY

Norway does not provide 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.

Because Norway does not provide protection for products covered by analogous process patents, PhRMA recommends that Norway remain on the Special 301 **Watch List** in 2009.

Intellectual Property

Norway has provided for compound patents for pharmaceutical products since 1992. The problem PhRMA members 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 2008 Special 301 Report, Norway was singled out as one of only 37 “Watch List” countries that “deny adequate and effective protection” for intellectual property rights. Norway was included because, as described above, it fails to provide robust product patent protection to about half of the pharmaceutical products currently on the Norwegian market. 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 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 2008 attributable to trade barriers related to intellectual property protection and market access.

SLOVENIA

Constant changes in government pricing and reimbursement regulation create a highly unpredictable market for innovative pharmaceuticals. PhRMA therefore recommends that Slovenia be placed on the **Watch List** for 2009.

Market Access Barriers

Lack of Transparency of Government Pricing and Reimbursement

Slovenia was required to implement the provisions of the European Union's Transparency Directive governing pricing and reimbursement of pharmaceuticals regulation by the end of June 2008, but has failed to do so. As a result, innovative pharmaceutical companies face significant challenges in the Slovenian market.

Government Pricing Policies

Slovenian government pricing regulations have changed, on average, every 18 months. The current pricing regulation was published and implemented in April 2007. It established reference pricing, using Germany, France, and Austria as comparators. The maximum ex-factory price of these three markets is set as the maximum price for Slovenia. A new draft pricing regulation was recently prepared, but has neither been officially adopted by the Minister of Health (MoH), nor published in the Official Gazette.

The new pricing regulation could pose a number of significant problems, particularly with respect to a new proposal under consideration to set the maximum Slovenian price as a fraction of reference countries' prices as opposed to full prices. This could have a cascade effect by creating a new low European price that would impact other European countries with reference price systems. PhRMA is also concerned that the process to obtain exceptions to this policy would be extremely arduous and could delay product entry.

Government Reimbursement Programs

The Interchangeable Drug List (IDL), which was introduced in November 2003, serves as a reference for reimbursement of "interchangeable" drugs in a designated group. Physicians are obligated to prescribe the cheapest drugs on the list. The Sick Fund completely reimburses drugs up to the maximum acknowledged price, *i.e.*, the lowest price in a particular group on the IDL. In cases in which a patient seeks treatment with a drug that costs more than the lowest price on the IDL, he or she must cover the difference in prices. In the event a physician prescribes an innovative pharmaceutical that is priced higher than the lowest-priced drug, pharmacists are obligated to switch the innovative

product for the cheaper generic if the patient does not want to cover the price difference. Slovenia has expanded the IDL every six months to new groups of products, and criteria for expansion are not transparently defined. Reimbursed prices are sometimes based on the lowest generic price, even if the generic product is not available on the Slovenian market.

Further, the Government has attempted on several occasions to implement therapeutic class referencing (TRP) that would discriminate against innovative pharmaceutical companies and could limit access to adequate therapy for patients.

In addition to the problems described above, the Sick Fund misuses its position in the market and fails to abide by World Health Organization (WHO) guidelines. For example, under the Sick Funds, the cheapest Defined Daily Dose (DDD) is taken as the price ceiling for reimbursement for other products in a given cluster. In sum, the Sick Fund's one-sided, cost-saving approach places Sick Fund savings over patients' needs.

These policies are compounded by a general lack of transparency and predictable timeframes for government reimbursement-related decisions. Moreover, the Sick Fund impedes the free flow of information to healthcare professionals by limiting visits by professional sales representatives during working hours.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

SPAIN

PhRMA and its member companies operating in Spain are not able to obtain patent protection for certain “un-translated” pharmaceutical product claims in pre-1992 European patents. This discrimination between “un-translated” and “translated” claims is unfair and extremely burdensome for PhRMA’s member companies. Spain must change its patent regime to ensure that these “un-translated” claims can be protected. PhRMA requests that Spain remain on the Special 301 **Watch List** for 2009.

Intellectual Property Protection

Failure to Recognize Pharmaceutical Product Claims in Certain Patents

Background

PhRMA member companies protect most of their inventions in Spain through European patents granted by the European Patent Office (EPO) established by the European Patent Convention (EPC). To obtain this protection, a member company must file an application with the EPO. If EPO officials grant a European patent based on that application, the member company must also file with Spanish patent authorities a translation of that patent in the Spanish language to make that patent enforceable in Spain.

However, when Spain acceded to the EPC, the Spanish Government took advantage of the right to reserve with respect to the EPC obligation to protect pharmaceutical product claims.⁵⁴ As a result, Spain did not give effect to these claims even though they were included in a European patent. The reservation ceased to have effect on 7 October 1992. Since then, Spain has provided protection for pharmaceutical product claims in European patents based on European applications filed on and after 7 October 1992 (post-1992 patents).

The situation with respect to pharmaceutical product claims in European patents based on applications filed before that date (pre-1992 patents) is more complicated. Owners of European patents with these product claims have attempted to enforce product claims in Spanish courts. If the patent owner filed a Spanish-language translation of the product claims with Spanish patent authorities, Spanish courts are enforcing the product claims based on the EPO article authorizing the reservation, TRIPS Article 27.1 related to patentable subject matter, and paragraphs 2 and 7 (when applicable) of TRIPS Article 70

⁵⁴ EPC Article 167(2)(a) allowed Spain to hold pharmaceutical product claims in European patents ineffective or revocable. EPC Article 167 was rescinded when its terms were no longer applicable.

related to “existing subject matter”.⁵⁵ Many owners of patents that are not within the scope of TRIPS Article 70.7 did not file Spanish-language translations of the product claims based on the advice of EPO officials. Courts have yet to enforce “un-translated” claims and Spanish patent authorities have yet to allow owners of European patent to amend their translations to include the product claims.

Failure to Recognize Claims

Recognition by Spain of pharmaceutical product claims in pre-1992 patents as a practical matter is conditioned on the completion of an “administrative” or “clerical” act – translation of these claims. It appears that the EPC would allow for correction of the translations by adding product claims, but Spanish authorities do not permit such corrections.

Failure to recognize these product claims discriminates between patents with translated claims and patents with un-translated claims. Patents with un-translated claims are treated differently from those with translated claims and places manufacturers with un-translated claims at a great disadvantage. For example, owners of patents with un-translated claims face competition in Spain immediately by copiers that manufacture product with a different process whereas owners of patents with translated claims do not. Moreover, reference prices are heavily influenced by prices charged by copiers who do not undertake the expenses in developing the product and its market in Spain. Thus, reference prices for products covered by un-translated claims are lower than those with translated claims. There is no compelling public policy reason that justifies this level of discrimination based on the failure to complete the administrative act of translation, especially given that full descriptions of the products were and are readily available in the Spanish language and given the ease in obtaining the claims in one of three other languages used in Europe.

The disadvantages to the owners of un-translated claims go beyond the Spanish market and flow to other countries, especially European Union (Union) Member States. When establishing their reference prices, some countries consider reference prices for pharmaceutical products in countries with similar market conditions. More specifically, some Member States that enforce all pre-1992 product claims consider prices charged in Spain for pharmaceutical products but do not distinguish between pre-1992 and post-1992 products when determining the reference price in their countries. But market conditions in Spain for pre-1992 products are very different from the market conditions in those Member States because of the discrimination in Spain between translated and

⁵⁵ These rulings are: a March 31, 2008 ruling in favor of Pfizer issued by the Commercial Court number 4 of Barcelona; August 7, 2007 and December 7, 2007 rulings issued by the Commercial Court Number 1 of Barcelona in favor of Eli Lilly (these rulings were confirmed on July 31, 2008); a July 30, 2008 injunction in favor of Janssen Cilag, and rulings by Commercial Court number 3 of Barcelona (October 2007) and Commercial Court number 6 of Madrid (November 2007) in favor of Merck Sharp and Dohme.

un-translated claims that does not exist in those other Member States. Consequently, the reference prices in those Member States are set unfairly low for their respective market conditions for many pre-1992 products.

Furthermore, the Union assumes that the regulatory framework is significantly identical in all Member States and, thus, requires the free movement of goods between Member States. This free movement principle is interpreted to exempt from patent infringement the importation into or use or sale in one Member State a product made or sold legally in another Member State. That is, copies of products subject to un-translated claims in Spain may be made, used, or sold in Spain. These copies then may be imported into another Member State and used or sold there even though the copy is subject to product patent claims in that Member State and the patent owner objects to the importation. But since the regulatory framework for pre-1992 European patents is not significantly identical in Spain to other Member States that enforce all product claims in European patents the application of the free movement principle is unjustified because the same regulatory framework was not and is not available to patent owners in Spain.

To end this discrimination and its adverse affects on PhRMA member companies, the Spanish Patent Office (attached to the Ministry of Industry) should allow the translation and publication of product claims in pre-1992 European patents. Then, it would be easier for Spanish courts to apply the same jurisprudence involving the EPC and the TRIPS Agreement to claims that were not translated initially.

Damage Estimate

At the time of reporting, PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

SWEDEN

PhRMA and its member companies are deeply concerned about a recent development in Sweden. We understand that the Government is considering a proposal to unilaterally reduce prices of patented pharmaceuticals on the Swedish market with the express aim to finance the redesign of the pharmacy system. This Government-imposed price cut would not only contravene Swedish and EU law (EU Transparency Directive and EU Treaty), it would exclusively target patented pharmaceuticals and would undermine the Government-mandated value-based pricing system in Sweden.

For this reason, PhRMA requests that Sweden be placed on the 2009 Special 301 **Watch List**.

Sweden has a state-owned chain of pharmacies. Over the course of the last year-and-a-half, the Swedish Government has been working to develop a proposal on deregulation of the pharmacy monopoly which would allow both horizontal and vertical integration of pharmacy chains. It is expected that the new proposal will lead to the emergence of a few chains owned by large international wholesalers. In order to secure availability of pharmacies in remote and sparsely populated areas of Sweden, the Government intends to sell 50% of the current pharmacies in clusters. Each cluster of three to four pharmacies would likely include pharmacies both in urban and rural areas.

The Government is considering a proposal that would establish an increased dispensing fee for the new pharmacy owners, which would be offset by lowering the government-set pharmacy purchase prices of patented pharmaceuticals. The TLV, the agency responsible for pricing of reimbursed pharmaceuticals in Sweden, will be charged with implementing this price cut. The mandate of TLV is to review new medicines and set the reimbursed price for medicines based on data submitted by the patent holder. These prices are based on the value of the product reflecting the societal perspective, i.e. when cost and benefit of medicines are evaluated, the effects outside the health care system are considered, e.g. effect on sick leave, productivity, and longevity. Lowering these prices would be inconsistent with the value-based pricing system in Sweden, and by targeting patented pharmaceuticals (not generic or over-the-counter products), would discriminate against them and diminish the value of intellectual property for these products.

PhRMA member companies expect that the Government will release its report on this proposed plan by February 24. We remain deeply concerned by this proposal as it will not only disadvantage PhRMA's member companies operating in Sweden, it will also specifically impact innovative products in countries that reference Sweden in government price control models. There is a

direct effect on prices in Austria, Greece, Norway and Spain. In addition, there is an indirect effect on prices in Canada, Finland and Spain. An additional number of countries, e.g. Turkey, base the price on the lowest three in a region (e.g. EU). If Swedish prices are among the lowest three, which is not unlikely through the combined effect of a price cut and the depreciation of the Swedish currency, prices in more countries will be affected.⁵⁶ In addition, we are concerned that if this proposal is implemented in Sweden it would set a negative precedent that other countries may follow.

PhRMA member companies request that the U.S. Government monitor this situation very closely over the coming weeks.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

⁵⁶ Source IMS Health, 2008

LATIN AMERICA

COLOMBIA

PhRMA and its member companies operating in Colombia remain concerned that Colombia's enforcement of IP rights is diminishing. PhRMA therefore recommends that Colombia remain on the Special 301 **Watch List**.

Obstacles to obtaining and enforcing patent rights persist. The Colombian Patent Office (CPO) continues to deny patent applications for innovative products, particularly those corresponding to patents that have been granted in other countries, negatively impacting PhRMA member companies.⁵⁷ 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.⁵⁸

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 U.S. pharmaceutical company without authorization. This has tarnished the image of the trademark and allowed the copy company to take unfair commercial advantage of the trademark's reputation.

Intellectual Property Protection

Data Exclusivity

Decree 2085 provides the domestic legal basis for proper implementation of Andean Decision 486 that protects test data from "unfair commercial use." Decree 2085 establishes a five-year data exclusivity period during which no third party may obtain a health registration for a pharmaceutical product relying on safety and efficacy studies filed by the innovator. To date, sixty eight (68) molecules have been protected by Decree 2085. Of these, seventeen (17) have already lost protection due to lawful expiration.⁵⁹

Litigation

PhRMA's member companies continue to be detrimentally affected by the GOC'S failure to provide a linkage mechanism, which currently prevents a titleholder from seeking effective enforcement of its patent prior to the

⁵⁷ The problem that remains is the irregular, inconsistent and discriminatory standard for inventive level as applied by the CPO, concerning patents in the pharmaceutical field.

⁵⁸ The government refuses to grant compensatory measures such as patent term adjustment to allow patent holders to effectively enjoy their rights. In fact, said possibility has been prohibited by recent modifications to the Andean IP Decision, which expressly exclude pharmaceutical patents from any possibility to obtain term restoration.

⁵⁹ Source: INVIMA

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 an act that may eventually be declared infringing after market launch. To date, patent owners, proceeding diligently under Colombian law and with a certain degree of luck, have only been able to obtain injunctive remedies after commercial acts have taken place (*i.e.* the product has been launched, the active ingredient imported or commercial offers have been made). The reasons for this have been: (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 procedure does not provide adequate due process guarantees to effectively litigate patent enforcement. Additionally, litigation delays can be glacial, with decisions in these types of cases often taking more than 8 years. These delays are completely detached from the reality of the market. 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, processes)

PhRMA continues to be very concerned over an ongoing trend that the Colombian Patent Office (CPO) is applying 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. Moreover, in the past four years, the CPO has been 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 signatory countries from discriminating against inventions as to their field of technology.

Patents for Second Uses

The Andean Court of Justice (ACJ) issued several legal opinions (89-AI-2000, 01-AI-2001 and 34-AI-2001) forcing Andean Community members to refuse recognition of patents for second uses, in violation of TRIPS Article 27.1,

and contrary to long-standing precedents. Andean member countries have either been compelled by the ACJ not to grant second use patents or chosen to honor Andean Community obligations, while ignoring their TRIPS obligations. The failure to provide patents for second uses particularly affects PhRMA's members, which dedicates many of its research investments to evaluating additional therapeutic benefits of known molecules (second uses) in order to provide effective solutions for unsatisfied medical needs. The ACJ position is dispositive on the issue and no further domestic appeals/remedies are possible.

Patents for Biotechnology

Article 15 of Andean Community Decision 486 excludes a great part of all biotech innovation, by considering that "all or part of living beings as they are found in nature ... existing biological material or that which can be isolated" is not considered an invention. This exclusion is in clear violation of TRIPS Article 27 as it is not one of the acceptable patentability exceptions.

Unreasonable Delays in Patent Grant

Finally, delays in patent prosecution are serious. On average, pharmaceutical patent applications suffer a 7-year delay before a first instance decision is taken, and until late 2006, there was an upward trend. In an effort to reverse this momentum, the SIC hired additional examiners during the first semester of 2007 with the promise to show positive results by year end. However, to date, the impact of these measures has yet to take effect.

Trademarks

Colombia's Regulatory Authority, INVIMA, issued 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 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.

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).⁶⁰ This new trend significantly delays launch of new products in the Colombian market.

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 medications 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 medications included in the Direct Control Regime, according to the reference price obtained as an average of the three lowest prices in the following reference countries: 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 very 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 the research-based pharmaceutical industry.

⁶⁰ INVIMA Commission

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 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.

Although several amendments appear to have improved the existing patent law, there are provisions, such as a pre-grant opposition process, that will result in delaying the grant of patents because oppositions could be filed without any sustainable argument or specification of the basis for challenge (i.e., novelty, obviousness, etc). In addition, there is a provision that refers to patent linkage, but does not provide details as to how it will be implemented; therefore, implementing regulations will be required to ensure its effective application. The procedures to forfeit a patent for failure to "work" the patent locally do not yet comply with the Paris Convention and thus represent a serious threat to patent rights in Costa Rica. Finally, Costa Rica's Patent Office has experienced serious delays in processing patent applications.

PhRMA recommends that, considering the facts expressed in this paper and prior experiences in Costa Rica over more than ten years, which have delayed effective implementation of patent and test data protection, Costa Rica remain on the **Watch List**.

Intellectual Property Protection

Data Exclusivity

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.

In addition, the Law requires a "deposit before a certain authority," of data that is considered "undisclosed information," and failure to deposit such information may result in the denial of protection. This creates particular uncertainty because it disregards the reality that some of the data may inevitably become public during regulatory review. Such a deposit requirement is clearly not a condition for data exclusivity under the TRIPS Agreement. An amendment to article 8 of the "Undisclosed Information Law" introduced language that reiterated certain exceptions to test data protection that are not allowed under the TRIPS Agreement nor under the CAFTA-DR, considering the confusion between undisclosed information and data exclusivity, the absence of the 5-year period of protection for data exclusivity, and the recent attempt to introduce a restricted definition for new product by the Costa Rican Government.

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. In late December 2008, Decree 34925 was published. The decree includes some regulations on linkage, however based on initial review they do not appear to properly implement the provision on linkage called for in CAFTA-DR. PhRMA will monitor this closely.

Patent Issues

The twenty year patent term in Costa Rica remains uncertain. Amended Article 17 of Law No. 6,867 (Law on Patents of Inventions, Designs, and Models) introduced confusing language to define the patent term, which may result, as did the prior existing provision, in failure to provide the internationally agreed upon 20-year patent term.

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.

Inadequate IP Infrastructure

The Intellectual Property Registry has not improved its capabilities regarding patent procedures, and serious delays in patent examination remain of concern to the pharmaceutical industry. As of 2008 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 2008 attributable to trade barriers related to intellectual property protection and market access.

DOMINICAN REPUBLIC

PhRMA 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 ("IP") 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. A bill to reform the Dominican Constitution, proposed by the President and currently being reviewed by the Dominican Congress, would eliminate the express Constitutional provisions regarding the protection of IP and the right of IP holders to prevent third parties from infringing such rights for a term defined by law.

In light of these developments, PhRMA recommends that the Dominican Republic remain on the **Watch List** for the 2009 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 provide for the protection of pharmaceutical test data from unfair commercial use, as well as a prohibition for health authorities (for example, the Secretary of Health) to grant regulatory approvals for the sale of pharmaceuticals subject to patent protection through a "linkage" between said health authorities and the patent status of the product. 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.

Backlog of Issuance of Patents

There is a significant backlog of patent applications according to the most recent information from ONAPI. While there are more than 1,300 patent applications pending at ONAPI as of the end of 2008, only 16 patents have been issued pursuant to the Dominican IP Law 20-00. Of the 16 patents issued, only 6 were pharmaceuticals

ONAPI would benefit from capacity building so that its patent examiners could evaluate patent applications received by the office in a timelier manner and mitigate the current backlog.

Conclusion

Although certain laws may represent, in theory, increasing levels of patent protection, such as the CAFTA-DR text itself or the implementing legislation, progress remains modest. PhRMA and its member companies underscore the need for the Government of the Dominican Republic to fully implement the CAFTA-DR, including provisions related to data protection and patent linkage, in an expeditious manner.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

EL SALVADOR

PhRMA and its member companies recommend that El Salvador be placed 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.

On July 7, 2008, El Salvador's Ministry of Health issued Decree No. 65, which contains the so called "Regulation for Test Data Protection of New Pharmaceutical Products." Despite the enthusiasm displayed by El Salvador to ratify the CAFTA-DR and pass implementing legislation, it took the Administration more than two years after entry into force of the agreement to pass this regulation. Moreover, the decree still contains confusing language, which in addition to operational limitations at the Health Regulatory Agency, doesn't provide effective enforcement of data protection and patent linkage.

PhRMA's member companies have actively called for effective implementation of the CAFTA-DR and have monitored the El Salvadorian Government's regulatory projects regarding Decree 65. Consultations have been requested with the Regulatory Agency in order to review the interpretation and further application of the Decree. This process is not an expeditious one. Meanwhile, PhRMA is monitoring the Agency's action in order to identify potential and actual cases of lack of enforcement on data protection and patent linkage.

Until recently, the Higher Council for Public Health ("CSSP") was only enforcing patent linkage with regard to research-based companies; that is, sworn declarations stating that the product for which approval was being sought were only being requested by the government from petitioners for "new products" and not "generic" products. After several consultations and submission of technical papers by research-based pharmaceutical companies, the CSSP authorities acknowledged, orally, that they were obliged, by law, to request the sworn declaration, for patent linkage purposes, also from applicants for "generic" products. With the enactment of Decree 65, monitoring of CSSP's work is advisable, considering past enforcement practices. Additionally, the language of the Decree is not clear in certain areas, which may further hamper the patent linkage system.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.

GUATEMALA

PhRMA and its member companies operating in Guatemala recommend that Guatemala remain on the Special 301 **Watch List** in 2009 and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Patent Linkage

In January 2008, the Ministry of Health issued Norm 55-2008, which established a patent information data base consisting of data submitted by the patent owners or their representatives. This information could be used by marketing approval petitioners to prepare the sworn declaration required under Accord 351-2006. The Ministry's officials have diligently requested such sworn declarations from research-based pharmaceutical companies, but there is still uncertainty as to whether this policy is being fully enforced with respect to registrants of generics or copy products. PhRMA and its member companies will continue to monitor the implementation of the patent information data base closely.

Market Access Barriers

Decree 16-2003 discriminates against innovative pharmaceutical products by establishing value-added tax exemptions and other benefits for "generic" and "natural" medicines and for "salts" used in the manufacture of such products. In addition, the Decree provides advantages to "generic" and "natural" products in government tenders, requiring the Government to favor these products over innovative products based on cost. PhRMA's member companies have presented the Government with proposals aimed at eliminating these discriminatory measures; however, these proposals have not been acted upon.

Damage Estimate

At the time of reporting, PhRMA is not able to provide a specific estimate of the damages incurred in 2008 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 to develop implementing and clarifying regulations to test data and patent linkage norms, it has not done so as of December 2008. In 2007, two draft regulations on such matters were made publicly available for consultation. PhRMA member companies submitted comments under the established procedures and explained to the competent authorities the comments prepared for such consultations. After almost a year, the Government has not completed the process and has not passed final regulations. Health authorities have not been involved in the implementation of the CAFTA-DR and the very limited level of awareness of the specific commitments to linkage and test data protection remains a serious threat to the rights of innovative pharmaceutical companies in Honduras. The implementing legislation poses several questions regarding test data protection and patent linkage, in part due to inconsistent and unclear wording throughout the text.

PhRMA members recommend that Honduras be placed 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, no progress has been made in the past year toward full and effective implementation of these commitments. After publication in August 2007 of draft regulations, including two that referred to undisclosed information and test data, no further action has been taken in Honduras. The drafts under consideration did not address test data protection or patent linkage appropriately. Rather, the drafts contained numerous inconsistencies with the CAFTA-DR. Because the process, as of December 2008, has not resulted in revised draft regulations that would (i) address current deficiencies and (ii) orient the regulatory agency responsibilities, both regarding test data and patent linkage, PhRMA and its member companies feel that Honduras should 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 2008 attributable to trade barriers related to intellectual property protection and market access.

MEXICO

PhRMA and its member companies operating in Mexico note that while IPR statutory protection in Mexico is among the best within Latin America, nevertheless there are important issues, described below, on which Mexico has not made adequate progress and has, in some cases, regressed.

Key Issues:

- Continued failure to develop and implement regulations to ensure compliance with Mexico's obligations under NAFTA and TRIPS to provide test data protection;
- Violations of the 2003 linkage decree that remain unresolved;
- Insufficient and ineffective mechanisms to defend patent rights, namely in the area of injunctive relief; and
- Congressional consideration of legislation that diminishes current IP standards.

In light of the failure of the Mexican Government to address ongoing concerns, PhRMA recommends that Mexico be elevated to 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 Exclusivity

PhRMA and its member companies have raised the need to provide adequate protection against unfair commercial use for test or other data generated to obtain marketing approval for pharmaceutical products on numerous occasions through its annual submission for the Special 301 Report and through direct advocacy with Mexican and U.S. Government officials. Nevertheless, regulations to guarantee (1) the recognition of the right for exclusive exploitation of this data by the generator for a reasonable time; and (2) the prevention of direct and indirect reliance on this data during this reasonable time period; have yet to be implemented. As a result, Mexico remains non-compliant with its NAFTA and TRIPS obligations.

The Mexican Government fails to clearly prohibit for a reasonable time Government officials from relying on test and other data submitted by our member companies to prove safety and efficacy when approving marketing requests submitted by other companies. Some minimal steps have been taken by the Government in a positive direction to prevent inappropriate disclosure of these data held by the Government, but additional measures to guarantee against improper disclosure and prevent unfair commercial use are needed. PhRMA and its member companies are concerned that the lack of such a

mechanism, and importantly continued reliance on originator data, could potentially facilitate violations.

Linkage

Despite continued requests for improved enforcement, COFEPRIS has not revoked all of the registrations it previously and improperly granted for infringing copies. This situation has become one of extreme concern for those patentees affected in view of the irreparable harm caused to date.

The weak enforcement of the 2003 Linkage Decree represents a clear violation of the legal framework of IP protection and harm to the IP environment in Mexico, not only from direct erosion of market share due to improper approval of infringing copies, but also from resources expended on costly and lengthy legal actions.

Furthermore, despite judicial orders requiring publication of all pharmaceutical patents claiming protection for new indications for existing compounds or new formulations, IMPI and COFEPRIS continue to limit recognition of the linkage benefits to compound patents only.

In addition, generic products with marketing authorizations granted by COFEPRIS prior to the 2003 promulgation of the Linkage Decree are appearing on the market with increasing frequency. COFEPRIS has refused to revoke such registrations, arguing that it did not have a legal obligation to respect patent rights prior to 2003. COFEPRIS' issuance of marketing authorizations for patent infringing products further underscores the difficulty in enforcing patents and the generally inadequate protection of IP rights in Mexico. PhRMA member companies note that Mexico has both international treaty obligations and domestic Constitutional obligations to protect the rights of patent holders.

In light of these inconsistencies, PhRMA calls for the enforcement of the true spirit of the Linkage Decree (1) by ex-officio revocation of approval of all copies erroneously approved by COFEPRIS and (2) by acting with respect to the full range of patents (active ingredient, formulation and use) through administrative means instead of costly litigation.

Enforcement of Pharmaceutical Patents

Patentees suffer irreparable damage to their patent rights when infringers profit from the lack of forceful actions to effectively stop infringing activities.

Because IMPI decisions regarding patent infringement cases are subsequently contestable before Courts, obtaining a final decision on patent infringement takes many years. Even if a favorable result is obtained, patentees still have to undertake civil actions to recover damages. The lengthy and unpredictable process causes PhRMA members undue cost and harm and call into question Mexico's commitment to the rule of law.

Congressional Consideration of IP-related Legislation

A considerable number of members of the Mexican Congress (in both houses) seem to be insufficiently informed on the importance of IP and inaccurately believe that pharmaceutical IP rights are a barrier to access to medicines in Mexico. This lack of understanding leads to the continued submission of bills that seek to undermine IP for pharmaceuticals in Mexico. This trend has manifested itself on issues including: compulsory licensing and pre-grant opposition on patent applications.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 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 2008 to effectively implement its test data protection and patent linkage commitments. Though the health authorities have shown some level of awareness of the CAFTA-DR obligations to do so, they have not yet implemented regulations to comply with these obligations. Implementing legislation fails to address patent linkage and does not clearly develop protection against unfair commercial use of test data.

PhRMA members recommend that Nicaragua be placed on the Special 301 **Watch List** in 2009 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 Linkage

From 2006 through September 2008, 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 response. Further, the Ministry of Industry and Trade has not coordinated implementation with the Health Authorities. As of December 2008, no draft proposal for effective enforcement of patent linkage or test data protection is known to exist.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 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 protections in Peru.

In light of the reasons outlined below, PhRMA requests that Peru remain on the **Watch List** for the 2009 Special 301 Report.

Intellectual Property Protection

The United States and Peru signed the U.S. – Peru Trade Promotion Agreement (USPTPA), which sets out obligations to protect pharmaceutical test and other data and to provide a stronger intellectual property enforcement framework (which PhRMA believes should include establishing a pre-launch patent enforcement system (linkage) that will provide the opportunity for patent holders to prevent the marketing of an infringing product). Currently, entry into force (EIF) of the Agreement is being negotiated. Although PhRMA and its members do not consider the USPTPA a model for future trade agreements, PhRMA is committed to closely monitoring implementation of that Agreement.

Patent Enforcement

The Peruvian system for enforcing patents is a two-step, sequential process: (1) an administrative process for determining infringement within the Institute for Defense of Competition and Intellectual Property (INDECOPI) that takes two years on average; and (2) a judicial action in a civil court to recover damages, which can commence only after the administrative process is exhausted. This judicial action takes four years on average and discourages patent owners from enforcing their patents.

No relationship exists in Peru between the patent protection status of pharmaceutical products and grants of sanitary registrations to copies of patented products (linkage). Additionally, preliminary injunctions have been lifted without resolution when the infringer challenged the validity of the patent by filing a nullification action, or after a 120-day preliminary injunction period elapsed. This last problem (the automatic lifting of preliminary injunctions) might be solved by Legislative Decree 1075, but enforceability is conditioned to the entry into force of the USPTPA. Furthermore, Articles 16.10.4 and 5 of the Agreement require Peru to provide patent holders with an opportunity to seek injunctive relief if marketing approval is requested by an unauthorized manufacturer of a patented product. Until now, no bill or draft regulation has been shared with the private sector aimed at complying with this obligation. PhRMA will monitor this effort closely.

With this exception, however, INDECOPI has made good efforts to lower procedural barriers. Examples of such progress are the frequent IP Training for judges and prosecutors as well as National Campaigns to promote original products acquisition by consumers and celebration of the IP Week, which includes destruction of pirated and counterfeit products (250,000 illegal products).

Second Use Patents

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

Data Exclusivity

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 of 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 such that it will be in effect by EIF of the Agreement. Without proper implementing regulations (which to date have not been released), Decree 1072 is insufficient to provide effective data protection, since it only prevents the use of proprietary confidential documents to obtain a copy registration. Regulations should define that for a certain period of time which shall be normally 5 years from the grant of registration to a new chemical entity, no copy registration should be granted to a product that contains such protected chemical entity.

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.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2008 attributable to trade barriers related to intellectual property protection and market access.