Brian Toohey
VICE PRESIDENT
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PhRMA

February 11, 2008

Ms. Jennifer Choe Groves
Director for Intellectual Property
Office of the United States Trade Representative
600 17th Street, N.W., Room 301
Washington, D.C. 20508

Re: Request for Public Comment: Identification of Countries under Section 182 ("Special 301") of the Trade Act of 1974, as amended, 73 Federal Register No. 11 (January 16, 2008)

Dear Ms. Choe Groves:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) member companies, I am pleased to submit our comments identifying countries that deny adequate and effective protection of intellectual property rights and/or deny market access to U.S. persons who rely on intellectual property protection (IP). PhRMA members place a high priority on addressing the harm caused by inadequate IP protection and market access barriers put in place by some U.S. trading partners. PhRMA members appreciate the continuing efforts underway at all levels by USTR, the Departments of State and Commerce, and the effective advocacy of U.S. overseas missions to promote compliance with international obligations.

Our submission this year also emphasizes in an "Overview" section and in some individual country chapters counterfeiting problems that present public health concerns in the United States and elsewhere in the world. Our member companies are actively engaged in seeking solutions to these problems with the U.S. Government, governments mentioned in this submission, allied industry associations, the World Health Organization and concerned health professionals and patient groups. The focus on counterfeit issues in this submission reflects a stepped-up engagement by PhRMA and its members to address the public health risks and other public interests that are compromised by those who traffic in counterfeit medicines.

The pharmaceutical industry is one of the largest and most important knowledge-intensive sectors in the United States economy. Diseases and debilitating conditions that defied effective remedies for centuries are increasingly treated with satisfying results achieved through applications of scientific advances led by pharmaceutical companies. Cutting edge science, particularly biotechnology, is a driving force in today's pharmaceutical research and product development efforts. As a result, members of PhRMA are key components of the biopharmaceutical industrial sector which has extraordinary research demands and extraordinary research promise. This industry's

research and development efforts contribute significantly to the health of the U.S. economy and to the health of individual patients our member companies serve. In economic terms, the U.S. biopharmaceutical industry employed 406,700 people in 2003, contributing $63.9 billion in total real output to the U.S. economy.

In health terms, bringing new life-saving and life-improving products to people is the central role of our member companies. Biopharmaceutical firms invest between 10 to 20 percent of sales in research and development, a high proportion compared to other industries. In 2006, PhRMA member companies invested more than 42 billion dollars in research worldwide to develop and bring to market new medicines. The research work of PhRMA members includes efforts individually and through public private partnerships to develop new or improved drug products for diseases that disproportionately affect poor countries.

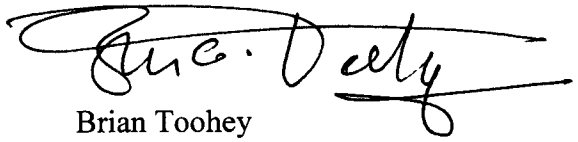
In addition to making new products available through the discovery, development and regulatory processes, our companies are committed to improving access to medicines in the United States and developing countries. Member companies participate in over 126 health partnerships and have donated medicines, vaccines, equipment, education and manpower, that have helped treat millions of people around the world.

Strong protection of intellectual property covering our newest innovative products in the United States and outside the United States is an important component of the legal and economic conditions needed to ensure the continued economic vitality of this industrial sector and development of additional innovative products to solve today's disease challenges and disease challenges of the future. Market access barriers erected by some trading partners subvert intellectual property protection, constrain patient access to innovative products made by PhRMA member companies and distort international trade in pharmaceuticals. Weak intellectual property protection and market access barriers described in this year's submission thus have negative ramifications for patients and workers in the United States and around the world.

The "Special 301" process continues to be a significant tool for United States trade policy. PhRMA members believe that the "Special 301" review process can be a particularly useful trade tool for addressing both intellectual property issues and the use of price controls and other market access barriers in priority markets.

Please do not hesitate to contact me for any further information on any of the countries mentioned in our submission.

Sincerely,



Brian Toohey

Attachment

cc: Ambassador Susan C. Schwab, United States Trade Representative

Ambassador Peter Allgeier, Deputy U. S. Trade Representative

Ambassador John K. Veroneau, Deputy U. S. Trade Representative

Warren H. Maruyama . General Counsel

Daniel Brinza, AUSTR Monitoring and Enforcement

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Christopher Padilla, Under Secretary for International Trade, Department of Commerce

Jon Dudas, Acting Under Secretary for Intellectual Property and Acting Director of the U.S. Patent and Trademark Office, Department of Commerce

Josette Shiner, Under Secretary, Economic Business, and Agricultural Affairs, Department of State

E. Anthony Wayne, Assistant Secretary, Economic and Business Affairs, Department of State

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) SPECIAL 301 SUBMISSION 2008

TABLE OF CONTENTS

PhRMA SPECIAL 301 SUBMISSION 2008 OVERVIEW 4

PRIORITY FOREIGN COUNTRIES 26
Philippines 28
Thailand 32

SECTION 306 MONITORING 42
Paraguay 44
The People's Republic of China 48

PRIORITY WATCH LIST COUNTRIES 56

ASIA-PACIFIC 58
Australia 60
India (with OCR) 64
Indonesia 72
Korea 76
New Zealand 82

EUROPE 88
European Union 90
Czech Republic 92
Germany 98
Hungary 104
Italy 108
Poland 112
Russia 116
Turkey 120

LATIN AMERICA 126
Argentina 128
Brazil 132
Chile 138
Costa Rica 144
Venezuela 148

MIDDLE EAST/ AFRICA/ SOUTH ASIA 154
Israel 156
Lebanon 164
Pakistan 168
Saudi Arabia 170

WATCH LIST COUNTRIES 174

ASIA-PACIFIC 176
Malaysia 178
Taiwan 182
Vietnam 190

CANADA 198
Canada 200

EUROPE 206
Austria 208
France 210
Norway 216
Romania 218
Slovak Republic 220
Slovenia 222
Spain 226
Ukraine 230

LATIN AMERICA 232
Colombia 234
Dominican Republic 240
Ecuador 242
El Salvador 246
Guatemala 248
Honduras 250
Mexico 252
Nicaragua 256
Peru 258

MIDDLE EAST/ AFRICA/SOUTH ASIA 262
Algeria 264

Undesignated Countries 268
Egypt 270

PhRMA SPECIAL 301 SUBMISSION 2008 OVERVIEW

PhRMA SPECIAL 301 SUBMISSION 2008 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 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 Agreement was to provide developing countries with a number of extended transition periods to implement the Agreement. The developing country WTO Members were given a five-year grace period to implement most of their obligations, while the least developed WTO Members were given an eleven-year transition period. Additional concessions were made to developing countries to allow delay of product patent protection for pharmaceutical products, and more recently to least developed countries to allow a further transition for patent protection until the year 2016. The first of these transition periods ended on January 1, 2000, and as of January 1, 2005, all but the least developed countries are 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 pharmaceutical sector – because they have not provided effective intellectual property systems.

Despite the end of the transition period on January 1, 2005, for the full implementation of the TRIPS Agreement by most WTO member countries, 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 to pharmaceutical products. The actual protection and enforcement of intellectual property rights on the ground in those countries fall 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 on data exclusivity. PhRMA members 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 data.

An important area of concern is counterfeit drugs. Weak 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 implementation of FTA obligations is an increasing need. The 301 process is an important tool in ensuring that these important agreements are complied with.

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, level the playing field 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. 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 counterfeit drugs.

The World Health Organization defines a "counterfeit medicine" as "one which is deliberately and fraudulently mislabeled with respect to identity and/or source." [1] This definition recognizes that any deceptively labeled pharmaceutical poses a significant danger to consumers, regardless of whether the product bears a counterfeit trademark or is substandard in any respect. Of course, many counterfeit medicines are of inferior quality or even toxic, evidencing a complete disregard for drug safety standards; and most counterfeit drugs violate important intellectual property rights. But the essential characteristic of a counterfeit medicine is deception as to identity or source, no matter what form that deception may take.

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. According to a recent PhRMA survey of drug counterfeiting regimes in China, India, Russia, Brazil and Mexico (i.e., markets where pharmaceutical counterfeiting is believed to be a growing threat), several

[1] See the World Health Organization definition of "counterfeit medicines" at http://www.who.int/medicines/services/counterfeit/overview/en.

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 at home 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 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. Government Price and Access Controls Undermine IP Rights, Innovation and Health Care

In addition to seeking improvements in IP protection around the globe, it is important for the U.S. Government to address other foreign market access barriers like government price controls which, in effect, burden U.S. citizens and allow foreign governments to free-ride on American innovation. 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 government price controls and other market access barriers in priority markets.

Despite significant academic and government research outlining the dangers of government-imposed price and access controls on pharmaceuticals, this damaging practice continues largely unchecked throughout foreign markets. Without U.S. Government action, price and access controls will threaten innovation, delay and deny market access and diminish U.S. intellectual property rights.

These concerns have been underscored in high profile studies and hearings in recent years, including an important speech given by Deputy Secretary of Health and Human Services (HHS), Alex Azar, in November 2005, where he aptly summed up the situation: "My message is simple. Government actions affect prices, prices affect investment, investment affects innovation, and innovation affects health. The more free competition there is in the pharmaceuticals and medical devices market, the more innovation the world will enjoy."

These words echo the points made in a February 2005 Senate Health, Education, Labor and Pensions Committee hearing on Prescription Drug Safety. In that hearing, Committee Chairman Michael Enzi (R-WY) argued that price controls, "…could endanger the future of drug innovation by limiting the financial resources available for drug research and development." Chairman Enzi's comments represent growing concern in Congress about the effects of foreign price controls on American consumers and industry. A 2004 Commerce Department Report ("The Commerce Report" or "Report") , *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation,* supported Chairman Enzi's assertion by stating "To encourage the continued development of new drugs, economic incentives are essential…without such incentives, private corporations, which bring to market the vast majority of new drugs, would be less able to assume the risks and costs necessary to continue their research and development (R&D)."

The risks inherent in pharmaceutical innovation are staggering. 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. The Commerce Report provides evidence that foreign price controls 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 30 new drugs from 2000 to 2003, a reduction of four new drugs in a year (or more than 50% of those approved by FDA in that period) is a significant setback in innovation and potential patient care. The Report also points out that U.S. consumers could benefit over time from the elimination of price controls abroad through the enhancement of global price competition.

The Commerce Report addresses the serious detrimental effects of price and access controls in the countries using them. Ironically, these measures suppress the use of generic medicines and generic prices are on average much higher than those in the United States. According to the Report, altering these policies could result in a savings of $5 to $30 billion annually depending on the country, which could significantly or fully offset the effects of allowing market-based pricing for innovative medicines. The Report also states that government price controls and related measures impede in-country R&D and patient access to the most effective medicines.

USTR's 2007 Special 301 annual report correctly connected the protection of intellectual property rights and financial incentives to innovation:

> The United States is firmly of the conviction that intellectual property protection, including for pharmaceutical patents, is critical to the long term viability of a health care system capable of developing new and

> innovative lifesaving medicines. Intellectual property rights are necessary to encourage rapid innovation, development, and commercialization of effective and safe drug therapies. Financial incentives are needed to develop new medications; no one benefits if research on such products is discouraged.

PhRMA welcomes the Administration's view of the dangers inherent in foreign government price and access controls and looks to the Administration and USTR specifically to take action by continuing to develop its strategy to address such practices. Such a move would be consistent with congressional directives found in the Medicare Modernization Act and the Trade Promotion Authority Act.

The conference report accompanying the Medicare Modernization Act of 2003 recognized the negative impact of price and market access controls 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 has called and continues to call on the Administration to use the Special 301 process to advance a multi-front strategy. First, as recognized in USTR's 2006 Special 301 Report, bilateral consultations should be pursued to promote sustainable innovation by addressing government price controls and related measures. The 2007 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.

USTR, HHS, the Commerce Department and other agencies should 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. PhRMA has placed Germany in the priority foreign country category in prior years to

highlight its significance for our members. While Germany remains one of our highest priorities, we agree with the Administration's view that the best way to make progress in this area is through an effective bilateral dialogue. For that reason, for this year's submission, 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 to structure and implement such talks.

Bilateral consultations should also be pursued in other OECD countries (such as France, Italy, and Canada) to address government-imposed price and access controls and other trade distorting measures. Similar to the situation in Germany, the market access barriers maintained in these developed countries undermine intellectual property rights and deny patients access to the most innovative medicines.

Second, the Administration should use ongoing and new bilateral and multilateral trade negotiations to pursue a positive agenda on pharmaceutical pricing and 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 reimbursment decisions, which is intended to enhance the accountability of the process.

Third, the Administration should ensure that U.S. trading partners are abiding by national and international commitments in the area of pharmaceuticals. PhRMA commends USTR's work thus far to ensure that countries adhere to Article III of the GATT 1994, as well as the TRIPs and TBT agreements. In recent years, USTR invoked paragraph 9 of Article III in requesting in the context of the WTO Trade Policy Review of the European Union that the EU identify the steps being taken at the supra-national and member-state levels to ensure their price control regimes "avoid to the fullest practicable extent effects prejudicial to the United States," as required by Article III. PhRMA strongly encourages USTR to remain vigilant in pressing the EU and its member states to fully comply with WTO rules and the EU's transparency directive, neither of which have been fully followed in key EU markets. Similarly, countries in other regions that do not abide by their international obligations should be held accountable.

Special 301 Covers Market Access Barriers

The Special 301 statute requires USTR to address in its review foreign country practices that deny fair and equitable market access to U.S. persons that rely upon intellectual property protection. A country cannot be said to adequately and effectively protect intellectual property rights within the meaning of the trade statutes if that country puts in place regulations that effectively nullify the value of the patent rights granted. A patent gives the patent holder the exclusive right to sell his invention in a market, but that right can be undermined by government polices which reduce the price down toward the marginal cost of production.

In these circumstances, the Special 301 statute calls upon USTR to designate a trading partner as a priority foreign country *even if* there were no apparent clear-cut violations of the country's TRIPS Agreement obligations in the operation or enforcement of its intellectual property rights laws. Section 182(b)(4) of the Trade Act of 1974, as amended, requires USTR, in making a PFC designation, to take into account whether a country is providing "adequate and effective protection . . . of intellectual property rights." A country that maintains IPR laws on the books but eviscerates the value of patented inventions through other regulations cannot be said to provide "adequate and effective protection." This is further reinforced in section 301(d)(3)(F)(ii) of the Trade Act of 1974, as amended, which "includes restrictions on market access related to the use, exploitation, or enjoyment of commercial benefits derived from exercising intellectual property rights . . . ."

Foreign Price and Access Controls Diminish 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, which government monopsonist purchasers have an incentive to drive down toward a product's marginal cost of production – which, in effect, totally 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 a scheme is put in place, a patent holder loses the ability to gain a reasonable, market-based return on investment for the risks assumed in the course of innovation. Moreover, a country that utilizes such pricing 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 price and access

control policies that effectively deny or delay the rights of companies and workers to benefit from their intellectual property.

For at least the past 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 allow free-riding through other means -- *i.e.*, price and volume controls -- equally diminish the value of U.S. intellectual property rights and hurt U.S. exporters that rely on intellectual property protection.

One of the most egregious measures used by foreign governments is "reference pricing," which is the indexing of innovative drug prices to older, related medicines that are often off-patent. These systems are designed to pay the same price for innovative products, usually developed by foreign companies, as generic products that are often produced by domestic companies. For example, many countries use "therapeutic reference pricing", which links reimbursement rates for patented and non-patented products within a defined therapeutic class. The effect of such practices is to undermine the value of pharmaceutical patents in that market and to push risk and costs of R&D on to the backs of American consumers, where market prices are not artificially constrained.

Foreign Government Price and Access Controls on Pharmaceuticals Serve as a Barrier to Trade

Price and market access control mechanisms imposed by foreign governments deny pharmaceutical companies the ability to market or sell their products in many countries. Those control mechanisms usually delay or deny the availability of new products to patients, often in favor of generic drugs produced domestically. Given that national health insurance schemes typically dominate country markets for pharmaceuticals, a product effectively cannot be marketed in a country until the national authorities have determined its reimbursement price, a process which can be cleverly used to delay a drug's market entrance for years. Moreover, because governments know that developers of new drugs face a ticking patent clock, they routinely confront them with the Hobson's choice of either a lower price (see above) or a delay in launch. In short, market access delays are often the other side of the price control coin.

The price control entity in almost every country is a highly opaque bureaucracy and the process of obtaining a government-approved price can be lengthy. Sometimes these delays become so lengthy that they become effective denials of market access. Governments often delay adding new products to national reimbursement lists merely to avoid the cost of providing those treatment options to patients or to benefit domestic generic drug makers. It is not

uncommon for some foreign governments to make a policy decision to close reimbursement lists altogether, to innovative pharmaceuticals.

These processes operate to delay market access (and to diminish the effective patent term) for many U.S. medicines. The Commerce Department Report evaluated 11 OECD countries and determined that bureaucratic obstacles prevent companies from "charging a market-based price" for pharmaceuticals. The Report also noted that these price and market access control methods "tend to be nontransparent, as the criteria and rationale for certain pharmaceutical prices or reimbursement amounts are not fully disclosed even to the pharmaceutical companies seeking to market their drugs."

Lack of Transparency and Procedural Fairness Present Significant Hurdles to Access

Recent experience has revealed significant issues relating to the procedural fairness and transparency of systems governing pricing and reimbursement of pharmaceuticals in many countries. These deficiencies can undermine the factual basis for decisions by excluding key stakeholders from effective participation in the decision-making process.

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

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

The need for effective rights of participation and transparency has been recognized in international agreements. For example, Article III.9 of GATT acknowledges that "internal maximum price control measures . . . can have effects prejudicial to the interests of contracting parties supplying imported products." For that reason, Article III.9 provides that "contracting parties applying such measures shall take account of the interests of exporting contracting parties

with a view to avoiding to fullest practicable extent such prejudicial effects." Such a requirement underscores the essential nature of providing importers adequate rights of participation and taking into account those interests when a government is administering a price control system and any related measures.

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

While the EU has adopted a Transparency Directive (Council Directive 89/105/EEC) designed to ensure the transparency and procedural fairness of member state pharmaceutical price and reimbursement regulations, the Directive has not lived up to its important objective. Many member states do not fully comply with the Directive, and manufacturers and sellers often find that key stages of the decision-making process are not transparent. The Directive also does not go far enough in addressing the core problems, such as lack of a meaningful and independent review mechanism.

As detailed further in the country chapters that follow, transparency and procedural fairness concerns course throughout a broad range of countries administering pharmaceutical price and reimbursement controls. U.S. government advocacy in this area would, therefore, address 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.

Foreign Price Control Systems Often Discriminate against Imports and/or Foreign Innovative Producers

Foreign governments often use price and access controls on 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 price controls 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.

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

The country chapters of PhRMA's 2008 submission provide numerous examples of the above pricing and reimbursement policies and practices.

Americans Continue to Pay the Price for Foreign Price and Access Controls

As academic and government research mounts against price and access controls, American consumers continue to carry the burden of funding the vast majority of the world's research and development costs for pharmaceuticals. Moreover, research indicates that the world's R&D investment is lower than it would otherwise be without foreign price controls, leading to the development and distribution of fewer lifesaving and life-enhancing medicines. Additionally,

economic literature explains that U.S. prices may be higher because of the absence of these new drugs, many of which could increase market competition thereby driving down prices in many therapeutic classes of medicines. Put more simply, basic economy theory points to the fact that Americans are effectively subsidizing other countries' health systems through higher prices, while having fewer medicines from which to choose.

While the negative effects of these controls on American patients are significant, the long-term and negative effect on the U.S. economy may be just as bad in the form of reduced exports, less employment and direct harm to the American pharmaceutical industry and its stakeholders. The pharmaceutical industry is a cornerstone of America's high-tech economy and depends on continued innovation and market access for growth. Moreover, pharmaceutical companies continue to be the most research-intensive industry in the U.S. having invested nearly $55.2 billion in discovering and developing new medicines in 2006 alone.[2] In fact, nearly one in five dollars in U.S. sales goes toward R&D, while the risks of pharmaceutical innovation continue to be highly significant.[3] Government price controls provide a disincentive for stakeholders to put resources into pharmaceutical companies and the innovation they foster, which is distorting markets and hurting patient care.

In 2003, the biopharmaceutical industry directly employed 406,689 people in the U.S. For each job directly created by biopharmaceutical companies, an additional 5.7 jobs were created in the overall economy – substantially above the average for all industries. That means the biopharmaceutical industry was responsible for creating over 2.7 million jobs in the U.S., which represents 2.1 percent of total U.S. employment. Jobs in the biopharmaceutical industry are high quality, and well paying with an average annual wage of $72,600 in 2003. The biopharmaceutical industry was directly responsible for $63.9 billion in real output in 2003 and a total output of over $172 billion when the economic multiplier effect is consider.[4] The value of medicinal and pharmaceutical product exports from the U.S. exceeded $16 billion in 2002, while biopharmaceutical exports increased almost four and a half times from $3.7 billion in 1989 to approximately $16.2 billion in 2002.[5]

Americans continue to bear an unfair burden in the form of higher drug costs, fewer jobs and less innovation in medicines, because foreign governments impose price and access controls on U.S.-produced pharmaceuticals. PhRMA strongly urges the Administration and USTR to utilize the Special 301 process to

[2] PhRMA 2007 Industry Profile

[3] Ibid

[4] "Biopharmaceutical Industry Contributions to State and U.S. Economies," The Milken Institute, October 2004, available at: www.milkeninstitute.org.

[5] Bureau of the Census: HS-Based Schedule B, Annual Historical U.S. Domestic Trade Data.

address the trade distorting aspects of these foreign government price and access controls.

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 Thailand and the Philippines be designated Priority Foreign Countries under "Special 301" for 2008 and The Peoples Republic of China and Paraguay continue to be designated under Section 306, in accordance with relevant provisions of the Trade Act of 1974, as amended:

- **Philippines:** PhRMA members conducting business in the Philippines are concerned that despite the improvement of the country's Special 301 status in early 2006, the Philippine Government, including the Philippines' Congress, continues to pursue measures that would seriously weaken intellectual property rights for the pharmaceutical industry. Recent developments are of particular concern to the research-based companies operating in the Philippines. These include the passage of Senate Bill 1658 and House Bill 2844, both of which include proposals to amend the IP Code of the Philippines with TRIPS-inconsistent discriminatory provisions, such as limiting the patentability of new forms and uses of drugs and medicines. Both bills would also authorize the parallel importation of drugs and medicines without adequate infrastructure to ensure the safety of parallel imports and prevent the flow of counterfeit drugs. The House Bill would also preclude the prescribing of brand name drugs, by mandating the prescribing of generics only. If signed into law, these measures would unfairly discriminate against U.S. pharmaceutical manufacturers, severely curtail market access for innovative pharmaceuticals, serve as impediments to U.S. trade, and foster an environment that devalues investment in the Philippines. PhRMA members conducting business in the Philippines are also concerned with the absence of patent linkage, distortion of the market from parallel importation, and poor enforcement four counterfeits. Given these concerns, we recommend that the Philippines be designated as a **Priority Foreign Country** in the 2008 Special 301 report.

- **Thailand:** The business and investment environment in Thailand has deteriorated as a result of the Health Ministry's decision to issue compulsory licenses on six innovative medicines. The policy was initiated in December 2006 with the compulsory licensing of two HIV-AIDS medications, followed in January 2007 when the Thai government compelled a license for a leading cardiovascular medicine. The most recent action by the outgoing Health Minister to declare the government's intention to issue compulsory licenses for three sophisticated cancer therapies seriously undermines the value of pharmaceutical research and development. The former Health Minister's policy calls into question the government's respect for innovation and creates an environment marked by an extreme level of uncertainty and risk for foreign investors in R&D based industries. This policy and other significant existing and emerging concerns including counterfeiting, the absence of effective patent linkage, weak data exclusivity, patent delays, and other market access barriers are addressed in the chapter. The newly elected Thai government could assuage lingering doubts about Thailand's desire to foster a technologically advanced society by strengthening and upholding intellectual property rights for all industry sectors. However, in view of the recent decisions to expand the compulsory licensing policy in Thailand, the innovative pharmaceutical industry calls on the US Government to designate Thailand as a **Priority Foreign Country** under Section 182 of the Trade Act of 1974 (as amended). Should Thailand reverse its policy with regard to compulsory licensing and continue the collaborative dialogue with industry established through the Joint Committee under the Ministry of Health, we would encourage the US Government to revisit Thailand's status pursuant to the 2008 Special 301 review.

Section 306 Monitoring

- **Paraguay:**. PhRMA members are concerned that Paraguay has not provided effective protection for certain pharmaceutical test and other data as required by TRIPS Article 39.3 and has not provided a link between the patent system and the system for granting marketing approval to pharmaceutical products. In March 2006, the Director of the Industrial Property Department started to cancel patents of confirmation covering pharmaceutical products. These cancellations follow the earlier Resolution 577/04 by the Director that declared these patents were invalid but did not provide a rationale for their invalidity. For these reasons, PhRMA recommends that Paraguay remain as a country under a **Section 306** Review and monitoring in 2008.

- **The Peoples Republic of China:** The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in China recognize the efforts of the Chinese government to improve the business and investment environment for innovative pharmaceutical companies. However, systemic issues related to insufficient healthcare funding, prescribing and dispensing practices, hospital bidding procedures, and government pricing and reimbursement policies hamper growth in this sector and do not serve the best interests of Chinese patients. In addition, China's policies with respect to data protection do not conform with international best practice. Pharmaceutical counterfeiting remains a serious concern. For these reasons, PhRMA requests that China remain in its current status under **Section 306** monitoring for 2008 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 2008 Priority Watch List. PhRMA urges USTR to take aggressive action to remedy these violations, including the consideration of WTO dispute settlement, as necessary. The following paragraphs provide snapshot-summaries of issues in selected countries in this category.

For the Asia-Pacific Region:

- Australia
- India
- Indonesia
- Korea
- New Zealand

For Europe:

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

For the Latin America Region:

- Argentina
- Brazil
- Chile
- Costa Rica
- Venezuela

For the Middle East/Africa Region:

- Israel
- Lebanon
- Pakistan
- Saudi Arabia

Watch List Countries

The PhRMA submission identifies 22 countries which we believe should be included on the "Special 301" Watch List in 2008. 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 very real political barriers to legal reforms needed to provide rule-of-law protections such as data exclusivity. Successful precedents only take

root with repetition and this requires a commitment from the U.S. Government to promote the truth and the success of the WTO TRIPS Agreement.

For the Asia-Pacific Region:

- Malaysia
- Taiwan
- Vietnam

Canada

For Europe:

- Austria
- France
- Norway
- Romania
- Slovakia
- Slovenia
- Spain
- Ukraine

For the Latin America Region:

- Colombia
- Dominican Republic
- Ecuador
- El Salvador
- Guatemala
- Honduras
- Mexico
- Nicaragua

- Peru

For the Middle East/Africa Region:

- Algeria

Undesignated Countries

Recognizing the positive developments in Egypt, PhRMA does not recommend that USTR include Egypt in its Special 301 Report. However, because there are still concerns related to data exclusivity, government pricing, patents, and registration, PhRMA is submitting this chapter to encourage continued engagement by the U.S. Government with its Egyptian counterparts.

PRIORITY FOREIGN COUNTRIES

PHILIPPINES

PhRMA members conducting business in the Philippines are concerned that despite the improvement of the country's Special 301 status in early 2006, the Philippine Government, including the Philippines' Congress, continues to pursue measures that would seriously weaken intellectual property rights for the pharmaceutical industry. Recent developments are of particular concern to the research-based companies operating in the Philippines. These include the passage of Senate Bill 1658 and House Bill 2844, both of which include proposals to amend the IP Code of the Philippines with TRIPS-inconsistent discriminatory provisions, such as limiting the patentability of new forms and uses of drugs and medicines. Both bills would also authorize the parallel importation of drugs and medicines without adequate infrastructure to ensure the safety of parallel imports and prevent the flow of counterfeit drugs. The House Bill would also preclude the prescribing of brand name drugs, by mandating the prescribing of generics only. If signed into law, these measures would unfairly discriminate against U.S. pharmaceutical manufacturers, severely curtail market access for innovative pharmaceuticals and serve as impediments to U.S. trade and an environment that encourages investment in the Philippines. Given these concerns, we recommend that the Philippines be designated as a **Priority Foreign Country** in the 2008 Special 301 report.

Intellectual Property Rights

TRIPS-Related Concerns

Of significant concern to the U.S. innovative pharmaceutical industry are IP-related provisions in Senate Bill 1658 and House Bill 2844. Both the House and Senate Bills would amend the current Philippines Intellectual Property Code to severely limit the patentability of new forms and uses of drugs and medicines. This limitation on patentability would only apply 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.

House Bill 2844 would create 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." If implemented, this new ground for compulsory licensing is applicable only to drugs and medicines and, therefore, is inconsistent with the non-discrimination requirements of Article 27.1 in TRIPS. In addition, when this new ground is utilized, the amendment under the House Bill 2844 would waive the requirement under the existing IP Code (and the TRIPS Agreement) that a compulsory license can only be granted after the petitioner

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. Therefore, this amendment, if implemented in its current state, would be inconsistent with Article 31 of TRIPS. In addition, the final version of House Bill 2844 increases concern that all of the obligations and safeguards related to compulsory licenses required by TRIPS Article 31 would not be preserved if this bill is enacted.

Absence of Patent Linkage

Two years ago, the Philippine Government, through a Department of Health Administrative Order (A.O. No. 2005-0001) removed the patent linkage system and intellectual property protection, in general, from the responsibilities of the Bureau of Food and Drug Administration (BFAD). The Administrative Order permits 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 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 consequence of this policy, the only available option to companies is to pursue legal remedies without recourse to injunctive relief 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.

A transparent patent linkage system would enhance the environment for pharmaceutical development by: (1) providing transparency and predictability to the process for both the pioneer and the generic company; (2) helping PhRMA member companies make better and more efficient investment decisions; and (3) ensuring timely redress of genuine disputes. In principle, an environment in which there are better-informed and more efficient investment decisions correlates with product introduction and development of life saving inventions and better healthcare.

Parallel Importation

The Philippine pharmaceutical market is being unfairly distorted through the Government's administrative order permitting the Philippine International Trading Corporation (PITC) to import pharmaceuticals from India and Pakistan. Products that enter the country through parallel importation carry health risks associated with counterfeits, and improper handling and packaging. These risks include sub-standard drug efficacy, such that the product may not contain an active ingredient, may not have enough active ingredient to be effective, or may

contain an improper ingredient. Additionally, as it is established in the Philippines, pharmaceutical manufacturers cannot guarantee the safety of a product that is purchased from a third-party distributor as the manufacturer cannot control the conditions under which the product is shipped or stored. Moreover, there is no way of ensuring that a third party attempting to benefit from price arbitrage between markets will take adequate precautions to handle pharmaceutical products appropriately.

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. It also permits an expedited review for pharmaceutical registration. This A.O. provides 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. The Philippine Government must also address inconsistencies between parallel importation and established Philippine law. Sections 72 and 72.1 of the Philippine IP Law reference Section 71 which enumerates the rights of a patent holder. These rights include the right to restrain authorized parties from making, using, offering for sale, selling or importing a patented product.

Both the Senate Bill 1658 and House Bill 2844 would allow the importation of patented drugs and medicines. In addition, the House Bill would broaden the authority for parallel imports to all government agencies and duly authorized third parties. However, neither bill addresses the current serious concerns over the lack of proper infrastructure and monitoring mechanisms to ensure the safety of parallel imports.

Counterfeit Drug Enforcement

PhRMA and its member companies commend the Philippine government on improvements in anti-counterfeiting activities. The Philippine Government has conducted a number of high-profile activities, including partnering with the industry to raise awareness of the dangers associated with counterfeit drugs; increased law enforcement raids of counterfeit drug sites; and, the successful prosecution of a drug counterfeiter resulting in a substantial prison sentence. While these efforts are extremely positive, it is critical for the Philippine Government to continue activities to eliminate counterfeit drugs to ensure patients' health and safety are not compromised. These positive efforts may be rendered ineffective by encouraging (through the pending legislation) parallel importation without the necessary safeguards and monitoring and control mechanisms.

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 House Bill 2844 which, if implemented, would allow non-

prescription products to be sold in "small quantities, not in their original containers" in retail outlets. Together with legalized parallel importation, this provision can further add to health safety risks, mislabeling and mishandling of medicines in the country.

Market Access Barriers

Proposal to Regulate Drug Prices

The proposals under House Bill 2844 to establish a price control regime and provide expanded and virtually unfettered powers to a proposed Drug Regulation Board pose serious transparency concerns. House Bill 2844 proposes to regulate drug prices through the creation of a Drug Prices Regulation Board with extensive powers and the following functions:

- establishing maximum retail prices of medicines on the regulated drug list;
- power to include other pharmaceutical products in the list subject to price regulation;
- power to implement cost-containment and other measures; and
- power to impose administrative fines and penalties.

The Board is given wide discretion to act on its own or under “public interest” (not defined). Determination criteria and process for pricing are not addressed and overall the system and process is not transparent. Because of the lack of criteria and definition the Board has broad and apparently unchecked authority to determine “fair prices”. The Board also has broad authority to add at will to the list of drugs subject to price controls. Adding to the concern about the lack of transparency and due process in the proposed price control regime is the fact that the bill denies the pharmaceutical industry and others in the health care sector representation on the proposed Board. Article III.9 of GATT requires that any member which applies maximum price control measures must take into account the interests of exporting contracting parties.

Other provisions in the House Bill such as labeling and reporting requirements would place an unfair burden on the industry and further hinder market access.

Senate Bill 1658 provides the President of the Philippines authority to impose drug price ceilings in times of true calamity, public health emergencies and illegal price manipulation. These powers are also provided to the President of the Philippines in “other instances of unreasonable drug price increases,” which remain undefined in the Bill and would lead to a lack of transparency in how and when this element would be applied.

PhRMA member companies recognize the Government’s desire to ensure

affordable healthcare. If the legislation is passed, however, the Government will have the power to indiscriminately set the prices of medicines, potentially removing the ability of pharmaceutical companies to recoup the costs associated with marketing a pharmaceutical and creating an environment of significant uncertainty for U.S. pharmaceutical companies conducting business in the Philippines. Government price controls unfairly discriminate against research-based pharmaceutical companies who continue to incur research and development costs to discover new treatments and bring them to market.

Mandating the Prescription of Generics

House Bill 2844 would remove a medical practitioner's discretion to prescribe a brand name drug by mandating that prescriptions be written for generic drugs only. This provision if implemented would severely affect market access for innovative brand name drugs and importantly, would take away a doctor's ability to prescribe a possibly more effective brand name drug which can be detrimental to a patient's welfare. The current law is more than adequate in promoting the prescription of generic drugs, while still allowing the medical practitioner the discretion to include a brand name drug as well.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

THAILAND

The business and investment environment in Thailand has deteriorated as a result of the Health Ministry's decision to issue compulsory licenses on six innovative medicines. The policy was initiated in December 2006 with the compulsory licensing of two HIV-AIDS medications, followed in January 2007 when the Thai government compelled a license for a leading cardiovascular medicine. The most recent action by the outgoing Health Minister to declare the government's intention to issue compulsory licenses for three sophisticated cancer therapies seriously undermines the value of pharmaceutical research and development. The Health Minister's policy calls into question the government's respect for innovation and creates an environment marked by an extreme level of uncertainty and risk for foreign investors in R&D based industries. This policy and other significant existing and emerging market access concerns are addressed in the following sections.

The newly elected Thai government could assuage lingering doubts about Thailand's desire to foster a technologically advanced society by strengthening and upholding intellectual property rights for all industry sectors. However, in view of the recent decisions to expand the compulsory licensing policy in Thailand, the innovative pharmaceutical industry calls on the US Government to designate Thailand as a **Priority Foreign Country** under Section 182 of the Trade Act of 1974 (as amended). Should Thailand reverse its policy with regard to compulsory licensing and continue the collaborative dialogue with industry established through the Joint Committee under the Ministry of Health, we would encourage the US Government to revisit Thailand's status pursuant to the 2008 Special 301 review.

Intellectual Property Protection

Compulsory Licenses

As noted in our previous Special 301 submission, in no instance has Thailand cited a national emergency, nor a situation of extreme urgency, as its justification for issuing compulsory licenses. Actions ascribed to public non-commercial use remain poorly defined.

Thailand had previously been regarded as an emerging leader in innovation in the region and a developing center of excellence in life sciences in the region. Opportunities existed for the research-based pharmaceutical industry 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 life sciences sector in Thailand. However, this situation has

been undermined by the deterioration of intellectual property rights has undermined these efforts.

Thailand's compulsory licensing action has raised concern within the broader business community. As noted during the US business leaders meeting with the Prime Minister during the APEC Summit in September, 2007 and subsequently at the US-ASEAN Business Council discussion with the Prime Minister in New York city, industry feels that the government's policies have resulted in it is working in a very unpredictable environment that is broadly seen as harmful to international investors and which will ultimately work to disadvantage Thai citizens.

The innovative pharmaceutical industry 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, and private contributions for healthcare products and services. PhRMA member companies would welcome an opportunity through the Joint Committee to discuss ways in which broader access to innovative medicines could be achieved in a sustainable way through working constructively with all stakeholders in the health sector to develop a quality healthcare system for Thailand.

Pharmaceutical Counterfeiters

The growth in availability of counterfeit medicines has become a serious problem in Thailand[6]. Counterfeit pharmaceuticals, particularly Erectile Dysfunction (ED) medicines are readily available in most drug stores and pharmacies, particularly those in tourist areas. Counterfeit medicines pose a major health risk to patients in Thailand and across the world.

Further, the problem is far greater than the resources currently allocated by the Thai Government to tackle it. Real, practical deterrence is an issue, since there is often a failure to pursue criminal charges in many instances and when charges are brought[7], the penalties for counterfeiting are insignificant relative to the profits made from the supply of fake medicines. 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 fake and counterfeit products impedes progress, in particular as there is a lack of understanding amongst the general

[6] According to the FDA, between January 2007 and June 2007, the Thai FDA seized 340,600 suspected counterfeit or illegal medicines in Thailand. During this same period the Thai FDA with the assistance of the Police conducted 33 raids. In 2006, 285 raids were conducted and only 74,500 alleged counterfeit or illegal drugs were seized.

[7] The Department of Intellectual Property website does not provide updated information on the number of cases brought to the Intellectual Property and International Trade Court in 2007.

public and general enforcement officials as to the severity and dangers of the problem.

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

The Thai legislature should implement laws with stricter penalties on medicine counterfeiters. The FDA and law enforcement leadership should provide adequate resources to train and equip its enforcement agencies to deal with counterfeiting. Where offenders are convicted, the Thai judiciary should impose significant prison terms in order to create a level of practical deterrence. On a positive note, the Thai government has welcomed, supported and assisted where possible the efforts of drug companies to educate officials and the general public. We look forward to working with the new Government on the achievement of an initiative begun in mid-2007 through the conclusion of a Memorandum of Understanding between key agencies in the Thai government and private sector representatives in order 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 accelerated regulatory approval of generic versions of pharmaceuticals that are still covered by a valid patent. In recent years, there has been a marked increase in the number of generic products receiving Thai FDA approval while the original product is still under patent protection. This imposes a significant threat to PhRMA member companies as a result of the accelerated launch of generic products. We have not been able to find publicly available statistics disclosing the number of generic drugs receiving FDA approval while patented comparator medicines remain within patent protection.

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[8]. 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. Members of the judiciary and regulatory authorities have expressed a need for more training on pharmaceutical IP issues.

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 regulatory data for a fixed period of time. The widely accepted mechanism for complying with this obligation is a data exclusivity regime which prevents regulatory authorities from prematurely allowing generics producers to rely on or otherwise use the originator's proprietary data to gain approval of copies of the drug. To date, Thailand has not implemented an effective system for preventing unfair reliance on the underlying data of originator companies 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 an average cost of US $800 million or more. Research and testing generally takes 10 to 15 years to complete. 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. Chapter 3, Section 15 of the Trade Secrets 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 legislation, did not issue implementing Ministerial regulations until January 30, 2007. A further 16 months is expected before the FDA regulation takes effect. Furthermore, while it protects physical disclosure of confidential information, the official regulation fails to provide an express prohibition to prevent unfair commercial use of regulatory data by generic firms, by providing a fixed period in which the data cannot be used or relied on for the approval of generic products.

[8] The Intellectual Property and International Trade Court does not provide the number of cases relating to infringement of patented drugs by generic companies.

Under the new MOPH regulations, protection applies only to data related to new chemical substances (not to 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. Additional public statements made by Thai FDA officials suggest that they consider that they only are obliged to refrain from disclosing an originator's data to third parties and that they believe that approving a generic drug based upon an originator's application is not "unfair commercial use".

PhRMA believes strongly that these interpretations of Thailand's obligations will further harm the interests of PhRMA members and the development of the healthcare sector in Thailand.

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 subsequent approval of similar pharmaceutical products during the designated period of exclusivity. The protected data may include, but should not be limited to, the originator's laboratory, pre-clinical and clinical data, such as information regarding product indications, efficacy, tolerability and safety, pharmacokinetics, drug interactions, side effects, contra-indications, precautions, warnings, adverse effects, dosage and product administration.

In addition, the regulations should not differentiate between whether or not the product in question is patented under Thai law. The regulations should require state 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 similar 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 this delay are available, DIP has not made any substantive progress in remedying the delay, unlike other countries in the region that have used outsourcing relationships to maintain reasonable patent prosecution timelines.

PhRMA encourages Thailand to join the Patent Cooperation Treaty (PCT), which has been adopted by 138 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 will 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

Thailand is one of a small number of countries that still places a tariff barrier on pharmaceuticals. This tariff is contrary to Thailand's stated healthcare objectives of supplying medicines at the lowest possible price point. In addition, as the tariff's biggest nominal impact is on high value medicines that are under patent (and hence unavailable for local production) the tax regime's ability to foster the development of a viable domestic industry is very questionable. The tariff is currently 10% and is applied to all pharmaceuticals excluding vaccines and therapies for HIV, malaria and thallassaemia. This tariff restricts PhRMA member companies' access to the Thai market.

In addition, non-tariff barriers in the Thai pharmaceutical market, described below, raise serious National Treatment issues.

Government Procurement

The Thai Government's procurement regulations (Article 60 and 61) require government hospitals to give the Government Pharmaceutical Organization (GPO) preference in purchasing medicines, even at higher prices for the same generic, chemical ingredient. This organization, established by the Royal 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 Drugs (NLED). The GPO is also exempt from prohibitions against anti-competitive practices in 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 healthcare market. Moreover, the GPO has on occasion unilaterally refused to distribute products that contain the same basic compound as those of PhRMA member companies, albeit under a different formulation which is documented to offer benefits to Thai patients. These regulations should be revoked to create a

level playing field for all pharmaceutical producers.

Safety Monitoring Period (SMP)

All new chemical entities registered and approved for marketing in Thailand must undergo a mandatory Safety Monitoring Period from 2 to 4 years. During the SMP, only doctors in hospitals and clinics can prescribe the product and only hospital and clinic pharmacies can dispense it. In addition, the product cannot be sold in drug stores and cannot be included in the NLED during the SMP. This last requirement prevents sales of a subject drug from being reimbursed under the government-subsidized medical benefit schemes, such as the Universal Coverage (UC-Free services), Social Security Scheme (SSS) and Civil Servant Medical Benefit Scheme (CSMBS). Once the Thai FDA has granted marketing approval there are no legitimate safety reasons for restricting distribution. Because the products under SMP are not reimbursed by the government, they are rarely prescribed by doctors for public sector patients. This policy severely restricts PhRMA member companies' access to the Thai market and access of Thai patients to the newest therapies.

New Draft Drug Bill

The Thai FDA has demonstrated its intention to request, as part of the marketing approval process, information related to whether the product is patented and also seeks disclosure of the product's cost structure at the time of submission of the new drug application. PhRMA members believe the Thai FDA may unnecessarily and inappropriately use this information to narrow the criteria for new drug registration focusing on patent and cost considerations over safety and efficacy. The language of the draft bill is vague and ambiguous and would result in arbitrary rejections of new drug applications because authorization would be granted to the Drug Regulatory Agency (DRA) not to approve any application, if that patented product has a subjectively "improper cost structure". If this new regulation passes, it will become the most serious trade barrier to the PhRMA member companies and restrict access to new innovative medicines to Thai patients.

PhRMA strongly recommends that the Thai FDA removes such provisions from the draft regulation so as to promote free trade, efficient introduction of new drug products into the market and ensure the Thai patients can get access to safe, effective, high-quality innovative drugs and the newest therapies.

Product Liability Bill

The Draft Product Liability Act is currently under consideration by the National Legislative Assembly. The pharmaceutical industry has not been guaranteed any opportunity to submit comments on certain draft provisions that could have wide ranging effects on liability risks applicable to producers of medicines in Thailand. The Bill has been sent to the National Legislative Assembly for the second and third readings before its adoption. This draft does not apply only to the pharmaceutical industries, but could have a chilling effect because of the uncertainties created by liability risks arising from application of this draft law.

Trade Competition Act

There are signs that the Trade Competition Committee appears to be taking a direction that suggests that the Committee views the enforcement of patent rights as incompatible with Trade Competition laws. Because of the lack of jurisprudence on this issue, there is uncertainty in the pharmaceutical industry with respect to how far the Trade Competition Committee will go in reconfiguring the traditional balance between a robust patent enforcement system and laws designed to prevent abuse of monopoly powers in the Thai market. The issue is also problematic since the Thai Government Pharmaceutical Organization ("GPO") is a state enterprise with leading market share in the Thai pharmaceutical market, yet is exempt from application of Trade Competition rules.

Moreover, the Thai Department of Intellectual Property has organized a study with Chulalongkorn University in order to look at the possibility of reconfiguring the balance that has historically allowed vigorous enforcement of IP rights in many industries in coexistence with laws designed to prevent abuses and anti-competitive practices by market dominant firms This legal risk may curtail the ability of patent owners to enforce IP rights and result in other market access barriers.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

SECTION 306 MONITORING

PARAGUAY

Paraguay has not provided effective protection for certain pharmaceutical test and other data as required by TRIPS Article 39.3 and has not provided a link between the patent system and the system for granting marketing approval to pharmaceutical products. In March 2006, the Director of the Industrial Property Department started to cancel patents of confirmation covering pharmaceutical products. These cancellations follow the earlier Resolution 577/04 by the Director that declared these patents were invalid but did not provide a rationale for their invalidity.

For these reasons, PhRMA recommends that Paraguay remain as a country under a **Section 306** Review and monitoring in 2008.

Intellectual Property Protection

Data Exclusivity

Paraguay does not protect undisclosed pharmaceutical test and other data as required by TRIPS Article 39.3. Although Paraguay approved Law 3283 on Data Protection in September 2007, the law does not adequately protect pharmaceutical test data. The law is a copy of the 1996 Argentine law that was the subject of WTO dispute resolution with the United States on grounds that it was inadequate.

Furthermore, the promulgated law was proposed by CIFARMA (association of local generic laboratories) and it allows the use by the sanitary authorities of the information provided by the originator for the unfair benefit of those producing copies.

Article 9 of the law states that protection of clinical test data is dependent on a request for authorization of the new chemical entity being filed in Paraguay before approval in any other country. This requirement is nearly impossible to fulfill since pharmaceutical products using new chemical entities are usually first authorized by the FDA and the EMEA.

Revocation of Confirmation Patents

Background

Until 2001, Paraguay maintained a system of “confirmation” patents under Decree No. 32,611 of 1929 (Articles 32 to 34). Confirmation patents were patents granted to inventions claimed in foreign patents without examination in Paraguay and without imposing the novelty requirement or the exclusion for

pharmaceutical products. The term of protection was limited to the term of the foreign patent upon which the confirmation was based. (Confirmation patents were available in many countries in the region until 20 years ago.) Paraguay also maintained a system of "patents of invention" under Patents of Invention Law 773 of 1925. Applications for patents of invention were independent of foreign patents, were examined, and could only claim inventions that were new. The term of protection was not limited by a foreign patent. Patents of invention, however, were not available for "pharmaceutical compositions or medicines of all kinds" under Article 3(3). Consequently, PhRMA members relied on confirmation patents to obtain protection in Paraguay.

Change in Law

Article 90 of the Patents Law No. 1,630 of 2000 provided that patents of invention would be available in Paraguay on 1 January 2003. This Law was amended by Law 2,047 on 29 December 2002 to postpone the availability of patents of invention for pharmaceutical products to 1 January 2005. The Director of Industrial Property implemented transition provisions in accordance with provisions of Article 65 of the TRIPS Agreement and Law No. 1630/00 for requests for patents of invention for pharmaceutical products filed between 2003 and 2004. There were no transitional provisions for the confirmation patents claiming pharmaceutical products and the Director continued to grant confirmation patents in 2003 and 2004. Fees to maintain these patents in force during this period were accepted.

Confirmation patents granted during 2003 and 2004 drew complaints by local laboratories. On 27 December 2004, the Director approved Resolution 577/04 that provided, without any rationale, that patents for pharmaceutical products granted up to that date by the Directorate of Industrial Property were not valid. PhRMA members understand that the Director, however, does not have the authority to invalidate a patent. Under the Paraguayan legal code, only a court has authority to declare a patent invalid. .In March 2006, the Director started to invalidate confirmation patents claiming pharmaceutical products.

Currently, the Exchequer Court has confirmed the invalidation of confirmation patents claiming pharmaceutical products. The owners of said confirmation patents, as a last instance, might appeal the Exchequer Court Decisions before the Supreme Court. These developments leave PhRMA members without protection as a practical matter.

Also, there appear to be other inconsistencies with Paraguayan law including Constitutional issues.

Patent Law Issues

On 17 June 2005, Law No. 2,593 of 2005 further amended several Articles of the Patents Law. There are a number of troubling amendments which PhRMA members believe will deny them adequate and effective intellectual property protection.

Amended Article 25 gives the Ministry of Public Health and Social Welfare the authority to conduct patent examinations. However, the Ministry of Public Health lacks the technical capacity required to conduct technical examinations of patents. This measure is inconsistent with the anti-discrimination clause of TRIPS Article 27.1 because it discriminates against patent applications in the pharmaceutical field of technology by imposing burdens (additional reviews and delays) that are not imposed on applications in other technological fields.

Amended Article 48 establishes that when a competitor is granted a sanitary registration for a pharmaceutical product and has traded that product or taken steps to introduce that product into the market, patent authorities must grant the competitor a compulsory license to any Paraguayan patent that covers the product. This appears to establish a license of right that is inconsistent with TRIPS Article 31(a).

Also, the Patents Law fails to comply with several obligations in the TRIPS Agreement. Exclusive marketing rights are jeopardized by language allowing unauthorized third parties to block those rights via the local health regulatory authorities. However, it does require those who receive a patent compulsory license to remunerate the patent owner adequately as required by TRIPS Article 31(h).

More than two years after promulgation, the Ministry of Industry and Commerce has still not developed appropriate regulations. As a result, the Department of Public Health lacks established time limits for action on pharmaceutical patent applications which further increases delays in the concession of these patents.

Counterfeit Medicines

The quantity of counterfeit medicines seized by law enforcement, primarily from China, has increased during 2007.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

THE PEOPLE'S REPUBLIC OF CHINA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies operating in China recognize the efforts of the Chinese government to improve the business and investment environment for innovative pharmaceutical companies. However, systemic issues related to insufficient healthcare funding, prescribing and dispensing practices, hospital bidding procedures and government pricing and reimbursement policies hamper growth in this sector and do not serve the best interests of Chinese patients. In addition, China's policies with respect to data protection do not conform with international best practice. Pharmaceutical counterfeiting remains a serious concern. The following sections address these issues.

For these reasons, PhRMA requests that China remain in its current status under **Section 306** monitoring for 2008 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 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. Loopholes 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 is the organization in China responsible for upholding this law. Unfortunately, the current law is ambiguous as to how data exclusivity (DE) is implemented. For example, certain key concepts such as "new chemical ingredient" and "unfair commercial use" are undefined.

China's regulatory procedures permit the State Food and Drug Administration (SFDA) to grant marketing approval to products that have previously been approved outside of China. 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. The 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 companies because non-originator companies do not incur the cost of generating their own clinical data.

In practice, the SFDA receives numerous applications for marketing approval of a compound once it is approved in the United States or Europe. The originator's application may or may not be the first application SFDA receives. SFDA has interpreted the data protection provision of the Drug Registration Regulation to apply after marketing authorization is granted in China. Marketing authorization can take up to four years. During this period additional applications from Chinese companies can be submitted to the SFDA. Any company that receives authorization to begin clinical trials before marketing approval is granted to the first company is permitted to complete the regulatory process. This can result in multiple companies entering the market with the same product – and no effective data exclusivity for the originator.

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 basic patent linkage provisions are provided for in Articles 18 and 19 of China's recently updated *Drug Registration Regulation*, the regulation does not explicitly address the circumstances in which disputes over the patent status of a new product will be resolved.

In the past, Chinese courts would not accept a patent infringement case until the generic producer had received marketing approval from the State Food and Drug Administration and had begun manufacturing and is selling product in the marketplace. As a result, there were multiple infringement lawsuits ongoing in Chinese courts while both the innovator and generic competitors continued to sell their products. Chinese courts have been reluctant to issue preliminary injunctions to suspend sales until a final judgment is issued in the lawsuit.

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 and regulations do not address this issue. To avoid costly patent litigation and to increase market predictability, Chinese authorities should implement a form of automatic postponement of drug

registration approval for at least 30 months, or until resolution of the dispute, upon initiation of a patent infringement case, similar to U.S. practice.
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Counterfeit Pharmaceuticals

While 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 first and foremost a drug safety violation. Thus, the adequacy of China's response to pharmaceutical counterfeiting must be measured against the framework of laws that regulate the various links in the drug manufacturing and supply chain. In that regard, China has yet to enact laws that address all aspects of drug counterfeiting activity or to provide the kind of enforcement 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 harm, a statutory requirement that requires evidence of a serious defect in quality. This burdensome and excessive evidentiary requirement all but precludes criminal prosecution against counterfeiters under China's drug laws.

To help resolve these issues, China could amend its drug laws to prohibit and criminalize the manufacture, distribution, import or export of any pharmaceutical that is deliberately mislabeled as 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 create 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 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.

In that regard, another important factor contributing to the pervasiveness of drug counterfeiting is that Chinese chemical manufacturers are producing bulk active pharmaceutical ingredients (API) which are being used in the manufacture of counterfeit drugs.

The SFDA recognizes the importance of patient health and safety by regulating chemicals that will be used in finished pharmaceuticals goods. However, clear evidence exists that chemical companies are ignoring SFDA requirements by advertising their API products on commercial websites in bulk form under the category of "(for) medicinal use" while not adhering to SFDA GMP regulations. Chemical manufacturers are freely 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 Chinese regulations that would bring them under the oversight of the SFDA. These unregulated and unethical practices by chemical companies contribute significantly to, and, in some cases, aid and abet the counterfeit drug trade.[9] More troubling is that the unregulated distribution of API exposes patients to serious and significant health risks as well as degrades consumer confidence in the global medicinal supply chain.

The recent Memorandum of Understanding between the US Department of Health and Human Services and China's State Food and Drug Administration is a positive step toward reducing the volume of counterfeit API that is exported from China, but it does not address the prevalence of counterfeit API distributed within China.

Market Access Barriers

Healthcare Funding

China contributes a relatively small percentage of its GDP to healthcare compared to other countries of comparable economic development. The majority of Chinese patients pay most of their healthcare expenses out-of-pocket. PhRMA supports the Chinese Government's effort to expand public health insurance and encourage greater uptake of private health insurance. Comprehensive reform of the healthcare sector will improve the quality and accessibility of medical care in China. PhRMA hopes to work with the Chinese Government to develop long-term 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. Approximately 80 percent of total pharmaceutical products are sold through hospital pharmacies. This practice allows doctors and hospitals to profit from the medicines they prescribe. As a result, doctors have a financial motivation to prescribe products for which they can make the greatest return (for themselves and the hospitals that employ them) as opposed to prescribing products solely on the basis of medical need. The problem is exacerbated by inadequate funding for hospital and physician

[9] 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 knowingly involved in the illegal activity, be charged with a conspiracy to commit that offense, 18 U.S.C. 371. In addition, the supplier who knowingly helps its customers in violating the counterfeit prohibition could be charged for aiding and abetting a violation of a U.S. federal statute, 18 U.S.C. 2.

services. Because patient fees for medical services are low, doctors and hospitals supplement their income by charging large mark-ups on medicines.

Revenue available to hospitals and medical professionals from linking prescribing and dispensing practices significantly distort Chinese pharmaceutical prescriptions by promoting sales of products for which they can make the largest profits.

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 with the implementation of hospital bidding, the National Development and Reform Commission (NRDC) 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 medicine drives the government to cut prices, but until recently, very little was done by the government to address the disparity between ex-factory and retail prices. In June 2006, the NDRC imposed a cap of 15 percent on hospital pharmaceutical mark-ups. Although NDRC has conducted a few hospital audits and has established a hotline to report excessive mark-ups, it is unclear how the government intends to ensure compliance over the long term. Unfortunately, the 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. As noted above, over-prescribing has serious health consequences.

Medical Representatives

The medical representative is used internationally in almost all markets and is recognized as the best way to educate healthcare professionals about new medicines. The medical representative fulfills many important functions, such as:

- Ensuring that prescribing physicians are fully informed on the proper use of medications;

- Obtaining key information on the use and adverse events of medicines post-launch; and

- Keeping the physician informed on the latest advances and developments in key therapeutic fields.

Although there had been increasing acceptance by Chinese officials of the important role of medical representatives in the last decade, as part of the anti-commercial bribery effort, some local government agencies and hospitals recently took measures to curb corruption by banning medical representatives from certain hospitals. PhRMA companies support the government's desire to improve the operating environment in China, but are concerned that the policy does not sufficiently consider the long-term interest of the physician and the patient in China, and may actually decrease transparency by making abusive practices in the system more difficult to detect. To ensure responsible behavior among multinational companies, the innovative pharmaceutical industry in China adopted a "Code of Conduct" which all companies sign and adhere to, and which is used to guide the sales and marketing practices of international pharmaceutical companies in China.

PhRMA encourages the Chinese government to endorse the innovative industry's code of conduct and extend it to the entire pharmaceutical industry in China. We would like to work with the Ministry of Health to promote such an effort and are willing to assist in the requisite training that would be required for successful implementation.

Government Pricing and Reimbursement Policies

Pharmaceutical products are considered special commodities in China and thus many are subject to price controls. In 1997, pharmaceutical price jurisdiction was vested in the National Development and Reform Commission (NRDC). The NDRC maintains tiered pricing for patented, innovative and generic products. PhRMA encourages the Chinese Government to closely collaborate with America's pharmaceutical companies to evaluating and implementing government pricing policy for innovative products.

The Ministry of Labor and Social Security 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. PhRMA encourages MOLSS to update the national drug reimbursement list to ensure Chinese patients have access to the latest, most advanced treatment options.

Clinical Trial Application Approval

Although recently improved, China's clinical trial application (CTA) submission requirements are unduly burdensome. They include comparatively extensive pre-clinical, clinical and CMC requirements, the inability to supplement

the application as new information is discovered or made available, and repeated use of the same procedures to every clinical protocol with no abbreviated process. Taken together, these requirements make it extremely difficult to integrate Chinese patients into regional or global trials intended to expedite the availability of meaningful new therapies in China. In order to mitigate some of these arduous requirements, PhRMA recommends that SFDA develop new practices that are in line with internationally accepted requirements.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 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:

- Actions during the ongoing implementation of the U.S.-Australia Free Trade Agreement (FTA) have weakened intellectual property provisions; and
- 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 pharmaceuticals.

Patient access to medicines is an area of key priority for PhRMA which has been progressed through the implementation of several measures articulated in the FTA. We believe, however, that there is still much to be done by the government to achieve the intention of delivering access to new and innovative medicines. We are aware of the changes to the Pharmaceutical Benefits Scheme (PBS) that the Australian Government has recently commenced implementing. In spite of these positive changes, it is noted that the industry in Australia has largely welcomed the proposed changes though remains concerned to work through a range of important issues with the Australian Government.

We continue to emphasize the importance of government policies, including those PBS reforms being implemented through to 2012, to adequately recognize and reward innovation.

Due to these concerns, we recommend that Australia be placed on the 2008 Special 301 **Priority Watch List.**

Intellectual Property Protection

Australia traditionally has maintained a strong intellectual property regime for protecting innovative biomedical discoveries, including patent term restoration. Accordingly, 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.

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 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 agreement. The good faith implementation of these assurances is critical to ensuring that Australia's intellectual property regime remains strong, and that the agreement is implemented as originally negotiated.

Amendments to the Bill implementing the FTA that were passed by the Australian Parliament weaken patent enforcement for pharmaceuticals and appear to 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. We are disappointed that the previous Australian Government, which itself expressed strong concern with these very amendments when they had been introduced, did not take action to revise or repeal them. As these amendments were initiated by the Labor Party, albeit under a different leader, it would seem that the new Australian Government under Labor is even less likely to take action on this issue.

In addition, PhRMA would like to note that data exclusivity provisions provided for in Australia are weak and do not compare to those available in the US and EU. Currently, a new active component receives a 5 year period of data exclusivity which is granted upon the date of marketing approval, but there is no data exclusivity provided for new uses or formulations. The lack of adequate data exclusivity is of particular importance in the light of recent 'springboarding' amendments to the Patents Act that enable the registration of generic competitors at any time during the life of a patent.

Market Access Barriers

Under Australia's national health care system, the PBS accounts for over 90 percent of Australia's sales of prescription medicines. Accordingly, the PBS effectively controls access to the Australian pharmaceutical market. In the Pharmaceuticals Annex to the FTA, the U.S. and Australia agreed on breakthrough provisions for increased transparency and accountability and enhanced consultation in the operation of Australia's PBS. Annex 2-C of the FTA establishes four basic obligations.

1. The Agreement establishes agreed principles concerning biomedical innovation and research and development, including:

- Recognition of the role of innovative pharmaceuticals in high-quality health care;
- Recognition of the importance of pharmaceutical research and development;
- Recognition of the need to support timely and affordable access through transparent, expeditious, and accountable procedures; and
- Recognition of the need to value innovative pharmaceuticals through operation of markets or procedures which objectively value therapeutic significance.

2. In Annex 2C and an Exchange of Letters regarding the PBS, Australia agreed to improve the transparency of the PBS as follows:

   - Disclosure of procedural rules, methods, principles, and guidelines;
   - Timely opportunity for applicants to provide comments; and
   - Detailed written information regarding recommendations or determinations for the listing of new pharmaceuticals or reimbursement amount.

3. Australia agreed to establish an Independent Review Process that may be invoked by an applicant directly affected by a recommendation or determination.

4. The Parties agreed to establish a bilateral Medicines Working Group to discuss issues relating to Annex 2C, including the importance of pharmaceutical research and development.

PhRMA considers that the work done to date in implementation of the above has been significant and is welcome, and looks forward to seeing constructive outcomes from the work of the Medicines Working Group. We must also note however that there are still substantive and important initiatives needed to improve access to new medicines.

PhRMA acknowledges that industry was consulted in relation to the PBS reform package. We understand that the reform process is ongoing and anticipate that this occurs in close consultation with the industry 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 is also concerned about previous government price-cutting mechanisms which were arbitrarily applied across patented medicines. The new PBS reform measures alter this practice although we note that some patented medicines will continue to be subjected to price reductions, due to being affected

by arbitrary government-imposed price cuts in some broad therapeutic classes. In addition, the previous government has left the door open to the creation of new therapeutic groups affecting the pricing of patented medicines.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

INDIA

PhRMA and its member companies remain concerned about deteriorating intellectual property protection and significant market access barriers in India.

India did not implement provisions in 2007 to protect pharmaceutical test and other data, as required by TRIPS Article 39.3. This is a significant problem.

The backlog of patent applications awaiting examination and the patent pendency period grew in 2007. While India has proposed investing capital in the Indian Patent Office to modernize the Patent Office in order to reduce the backlog, the Government needs to increase the staff of the Patent Office and needs to eliminate inefficient practices stemming from pre-grant oppositions. Moreover, standards for patentability need to be amended to conform to the obligations in the TRIPS Agreement as well as prevailing international practice. For example, the law discriminates between patents on inventions specifically relating to chemical compounds and other technology areas by adding an additional hurdle requiring the demonstration of enhanced efficacy in the case of chemical inventions. Further, restrictions on patents for "new uses" of known inventions should be repealed.

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. This is first and foremost a safety issue for patients that should be resolved through the system for regulating the local distribution of pharmaceutical products. PhRMA members are also concerned about proposals to increase the scope of the government price control system in India significantly in a manner that discriminates against imported products that are protected by intellectual property.

To address these serious challenges to market access and patent and data protection for pharmaceuticals in India, the U.S. Government should pursue a high-level dialogue to promote compliance with WTO disciplines 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 be designated as a **Priority Watch List** country in 2008 and that the U.S. Government conduct an **Out-of-Cycle review** on the deteriorating intellectual property environment.

Intellectual Property Protection

Data Protection

India was 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 only. 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. An inter-ministerial committee has examined issues related to protecting this data and has submitted its report after more than three years of deliberations.

However, while the recently released Reddy Report has recommended 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), for pharmaceuticals it has proposed a differential treatment and a calibrated approach. For the time being, the Report has recommended a 'minimum standard of Data Protection under TRIPS Article 39.3 i.e., prevention of unauthorized disclosure and unauthorized use through explicit legal provisions in Drugs and Cosmetics Act, 1940'. Thereafter, it recommends that, after an unspecified transitional period, higher standards of Data Protection can be considered: 5 years of non-reliance by the Drug Controller General of India (hereinafter DCGI) on data submitted by the originator for obtaining marketing approval for a new drug which is a new chemical entity and is actually relied upon by the Drug regulator for that approval. This differential treatment is indeed discriminatory.

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. It would be much easier to design and institute such a system while the number of patents to be linked is small.

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 28,882 in 2006-2007. 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, has inadequate resources, and has inefficient substantive rules. For example, the Office received 17,466 applications in 2004 but only granted patents on 2,317 applications.[10] Presently, the total number of applications pending Examination is 22,008 and the average pendency period is 2-3 years. According to an article in the Economic Times from January 4, 2008, "Revenues generated by the intellectual property office has gone up eight-fold in the last 3 years. This is 10 times more than the expenditure on these offices." Despite this substantial increase in funding, the backlog of applications has not decreased.

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 undertake "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 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 are being 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

[10] Some applications are abandoned because the inventions claimed in the application are not patentable or are no longer considered commercially viable. Nevertheless, the rate of patent grants to abandoned applications is usually 2:1 in most developed countries. Consequently, it is estimated that well over 10,000 applications are added to the backlog each year in India.

expense of the applicant without any accompanying benefit to society and create an opportunity for competitors to abuse the patent system. PhRMA members understand 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 of 2005 creates additional and unnecessary obstacles for pharmaceutical patents to be granted. This provision imparts discretionary powers upon the individual patent controllers and is more often than not interpreted in a subjective and inconsistent manner. 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. First, Article 27 of the TRIPS agreement provides a non-extendable list of the types of subject-matter that can be excluded from patent coverage. This list does not include "new forms of known substances lacking enhanced efficacy", as excluded by Section 3(d) of the Indian law. Therefore, Section 3(d) 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. In addition, the concepts in Section 3(d) are nebulous and potentially have a broad 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”. 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.

Patent Compulsory Licenses

One of the most damaging provisions of the Indian Patent Law is the Mandatory Compulsory Licensing for Mail Box Patents (See Section 11 A and Section 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, and 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, despite India's change to the product patent regime envisioned by TRIPS Article 70.8 and 70.9. By negating the market exclusivity required by these TRIPS articles, the amendment is clearly contrary to India's TRIPS obligations.

India should rectify the provision for Mandatory Compulsory Licensing for Mail Box Patents, which does not allow the patent holder of a mail box patent to preclude generic manufacturers from manufacturing the patented product.

It should also ensure that the compulsory licensing (CL) provisions comply with TRIPS by:

- Clarifying that importation satisfies the "working" requirement (TRIPS Article 27.1);

- Either eliminating mention of price as a trigger to CL or clarifying what is meant by 'reasonably affordable price' (Section 84(1)(a)(b) provides for compulsory license if the patented invention is not available to the public at a "reasonably affordable price").

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

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

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 pernicious 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 kind of remedies and enforcement resources necessary to combat this growing problem. 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 any deceptively mislabeled drug. 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 and other chemicals (APIs) 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, including pedigree requirements.

Market Access Barriers

Government Price Controls

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

Further, the draft policy contravenes the Government's stated goal of liberalizing the pharmaceutical sector by reducing Government control over the

pricing of pharmaceutical products in India. The proposed policy could bring 354 pharmaceutical products under price control in addition to the 74 products now subject to price controls. This expands coverage from the 2002 drug policy (now mired in litigation), which envisaged only 37 drugs to be under price control.

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 pricing policy itself is marked by 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 12.5%, additional duties commensurate with the excise duty applicable on the same or similar product, even when there is no such product manufactured in India as well as other assessments, bring the effective import duty up to 38% (approximately). Moreover, excessive duties (up to 68 percent) on the reagents and equipment imported for use in R&D and manufacture of biotech products make biotech operations difficult to sustain. Compared to the other Asian countries in similar stages of development, import duties in India are indeed very high. The import duties need to be brought down to enable this sector to realize its potential and for the benefit of patients. The Government of India has stated its intention to progressively lower import duties on pharmaceuticals. In 1996, duties were brought down to 85 percent with plans to further decrease rates to 25 percent by the end of 1999. Progress has been slow however and import duties remain unreasonably high. PhRMA urges U.S. officials to insist 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 2007 attributable to trade barriers related to intellectual property protection and market access.

INDONESIA

PhRMA member companies face significant market access barriers in Indonesia and poor intellectual property protection. A new foreign investment law fails to promote a competitive market environment. A proposed trademark rule raises national treatment concerns, as it appears to favor domestic generic companies over branded multinational companies. In addition, a lack of data exclusivity, inadequate enforcement against counterfeit medicines, cumbersome customs procedures and a lack of transparency with respect to recently issued ministerial decrees unfairly discriminate against PhRMA member companies.

Given these concerns, we recommend that Indonesia be returned to the 2008 "Special 301" **Priority Watch List**.

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. IPMG estimates that approximately 25% of drugs on the market in Indonesia are counterfeit. While we welcome Indonesia's recent attention to the problem of counterfeit medicines (for example, hosting the recent conference on counterfeit medicines with ASEAN, China, WHO and Interpol), PhRMA considers that there is an urgent need to expand enforcement efforts nationally 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 gathered by innovative companies to secure marketing approval. To date, Indonesia has not passed a data exclusivity law.

Generic Labeling

The Ministry of Health (MOH) issued Ministerial Decree No. 314/Menkes/SK/V/2006 which was an evolved amendment to Ministerial Decree No. 988/Menkes/SK/VIII/2004, which requires any pharmaceutical product manufactured and distributed in Indonesia to state on the label its generic name with its trade name. The generic name must be placed exactly below the trade name with letter size at least 80% of the size of the trade name, and must use the same font and color as the tradename. This policy creates confusion as to the source and quality of the product. The color and font requirements make it

more difficult for consumers to distinguish the branded product from the generic. Because the requirement to conduct bioequivalence and bioavailability studies by independent and international credible sources is not consistently enforced in Indonesia, generic products are often not produced to the same quality standards as the branded products produced by multinational companies.

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 prevent BPOM from issuing marketing authorization to a generic for a product that would infringe on existing patents in Indonesia.

In addition, implementation of the Bolar provision by BPOM is not clear. While the Bolar Provision under the Patent Law applies to certain activities undertaken for 2 years before the Patent Expires (Art. 135.b Patent Law), BPOM has no clear provision requiring the recognition of patent status of the innovator.

Market Access Barriers

Marketing Practices- Lack of Level Playing Field

In an effort to curb local corruption, the Government of Indonesia mandated that all pharmaceutical companies, both multinational and local, adhere to the Code of Conduct of Pharmaceutical Marketing Practices of Ethical Products. Unfortunately the code is not followed by many local companies, and the Indonesian Government is not seriously enforcing or monitoring the practices of local companies. For example, the contracting of doctors and cash rewards for prescriptions is a common practice amongst local companies. These discriminatory practices impose significant losses on our industry, and also lead to over-prescription of medicines to the public. PhRMA is concerned that the current situation does not offer a level playing field for MNCs.

We would like to seek the support and commitment of the Agency for Drug and Food Control (BPOM) in enforcing the laws pertaining to its scope of authority and Code of Ethics.

Government Controls on Pharmaceutical Pricing

Despite having the largest economy in Southeast Asia, Indonesia spends less per capita on healthcare than many countries in the region. The Government of Indonesia does not currently reimburse patients for pharmaceutical expenses – nor is reasonably widespread private healthcare insurance available. Most patients pay 100 percent out-of-pocket for pharmaceutical products.

Although Indonesia does not currently impose price controls on all pharmaceutical products, PhRMA members are concerned with a lack of transparency regarding the government's development of pharmaceutical pricing policies that could directly impact the industry. We welcome an opportunity to discuss with MOH options for promoting affordable, quality healthcare in a competitive market environment.

Bioequivalence Requirement

BPOM recently established bioequivalence requirements for generic applicants seeking marketing approval. Today there are approximately 5 laboratories that have the technical capacity to carry out bioavailability/bioequivalence (BA/BE) studies. PhRMA is concerned that the other testing facilities in Indonesia used to assess the bioequivalence of the generic product may not be adequate as there are more than 170 local companies producing a wide array of generic products in plants that do not meet international good manufacturing standards. This poses a serious public health risk.

Negative Investment List

The new Presidential Regulations No. 76/2007 and No. 77/2007 concerning restrictions on foreign direct investment (FDI) were issued this year. PhRMA member companies are concerned about their effect on the environment for investment and distribution by pharmaceutical companies. Presidential Regulation No. 77/2007 limits distribution rights for foreign owned companies.

The regulations also seem to require that any change in shareholding capital of a pharmaceutical company, would trigger the requirement for foreign ownership in that company to be (reduced to) no more than 75%, meaning that a suitable local partner would need to be found to take up the 25% interest. Even if a suitable local partner was found, the 25% ceiling would limit the expansion ability of the company. It also would render ineffective any buy-out mechanism if the relationship did not work. Finally, this law's impact on ongoing or about to be completed negotiations with local firms is unclear. The Government of Indonesia has indicated to business associations that there could be grand-fathering of existing operations. PhRMA requests that Indonesia clarify its policy with respect to the grand-fathering of existing companies. Overall we see the new law as having the effect of limiting a competitive market environment.

Marketing Authorization

Article 37 of the Decree of the Head of the National Agency of Drug & Food Control on Criteria and Procedure of Drug Registration, HK.00.05.3.1950, dated 14 May 2003 stipulates that marketing authorization would be granted for a period of 5 years. However, recent approvals have been provided with a 2 year marketing authorization. Letters asking for 5 years consistent with the decree have been met with no response.

Tax Treatments

Varying implementation approaches by the tax office regarding tax levies discriminate against multinational companies and present many obstacles to overcome. One example that illustrates the unfair treatment to MNCs is the inadequate time given by tax auditors for company members to fulfill their long list of queries. This causes unnecessary cost and delays. An inefficient judicial system hinders fast tax return processes. Additionally, 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.

Government Procurement

Presidential Regulation no. 94/2007 empowers the Minister of Health to directly appoint a supplier without a tender process for drugs listed in the National Essential Drugs List and in the health program, for the supply of drugs at a price fixed by the Minister of Health. There are confusing provisions regarding compensation in the event of a loss by the supplier.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

KOREA

On June 30, 2007, the U.S. and Korean Governments signed the landmark U.S.-Korea ("KORUS" FTA). PhRMA strongly supports the passage of this FTA and 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 FTA provisions that help to tear down market access barriers and shore up protection and enforcement of intellectual property rights in Korea 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 Korea is in the process of adopting a patent linkage system in the KFDA's drug approval system, and an independent appeal review process in the drug pricing and reimbursement system, in line with the KORUS FTA commitments. We support this process and efforts of the Korean Government. Korea's actions prior to enactment of the KORUS FTA will send an important signal on whether Korea will follow the intentions of the agreement by regulating pharmaceuticals in a transparent, predictable and non-discriminatory manner consistent with accepted international practice.

Despite these recent advances, we remain concerned with many elements of the new system as detailed below. Given these concerns, we recommend that Korea be placed on the 2008 Special 301 **Priority Watch List**.

Long-Standing Issues in Korea

The operating environment in Korea has for many years presented numerous challenges for PhRMA's member companies. Given that Korea has a single payer system, access to the national healthcare system is critical to having any meaningful right to participate in the Korean market. Innovative products, which are mainly imported into Korea by U.S. and other multinational producers, only gained access to Korea's national healthcare system in August 1999. Since then, U.S. and other multinationals have continued to face a range of market access impediments, including shifting standards of review for having new innovative products listed on the national reimbursement list and lax enforcement of intellectual property rights. Korea's policies have also long favored the domestic industry, which has a disproportionately large share of the Korean market. Adding to the existing market access issues, on May 3rd, 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 takes several strides forward in addressing these issues and ensuring that U.S. pharmaceutical companies have fair and non-discriminatory access to this important market.

Key Elements of the KORUS FTA

Key features of the FTA are:

1. A set of agreed general principles: These underscore the importance of: 1) adequate access to pharmaceutical products; 2) economic incentives for the development of pharmaceutical products; and 3) government support for research and development and intellectual property protections and other incentives for innovation.

2. An article focused on access to innovation: This spells out that rules for pricing and reimbursement must be fair, reasonable and non-discriminatory and must appropriately recognize the value of patented products.

3. Forward-leaning, extensive transparency provisions: Lack of transparency in Korea's reimbursement and listing decisions has been a key impediment to fair market access in Korea. As such, PhRMA has been especially pleased with the specific provisions on transparency in the Pharmaceuticals and Medical Devices chapter of the agreement which ensure that all stakeholders have a meaningful opportunity to participate in the development of rules and regulations in this sector. One key element of the agreement which will enhance the transparency of the Korean system is the creation of an independent review process – something the industry has long called for in Korea.

4. A precedent-setting article on ethical business practices: The provisions in this article commit both countries to ensuring that appropriate measures are in place to prohibit improper inducements by generic or innovative pharmaceutical manufacturers to healthcare professionals or institutions, and to enforce such measures.

5. A Medicines and Medical Devices Committee: The agreement creates a joint Committee whose mandate is to monitor and support implementation of the FTA provisions and to promote discussion of issues related to the Pharmaceutical and Medical Devices FTA chapter. PhRMA looks forward to working with the U.S. Government through this Committee to ensuring that future changes to Korea's health care system are done in a manner fully consistent with the FTA provisions.

6. Important provisions related to intellectual property rights: These include, especially: 1) agreement by Korea to establish a patent-linkage system to help prevent patent-infringing products from gaining access to the market; 2) provision of at least a five-year period of data exclusivity or its equivalent; and 3) providing that the term of a patent can be adjusted to compensate for unreasonable delays that occur in the patent and marketing application processes.

   As intellectual property is the life blood of the pharmaceutical industry, provisions such as these are essential to ensuring that an environment attractive to making investments is needed for the U.S. innovative pharmaceutical industry to continue to provide new and life-saving drugs to U.S., Korean and other patients around the world. Further, Korea's forward-leaning stance in support of increased domestic protection and enforcement of intellectual property rights shows that Korean leaders fully understand that these measures will be highly beneficial to domestic as well as foreign firms and consumers in a wide variety of sectors as well as to Korea's goal of enhancing its life sciences industry.

Continued Engagement on Issues of Concern is Necessary

Korea's efforts to reform its healthcare system are ongoing, and many specific elements of Korea's new pricing and reimbursement system which was implemented on January 1, 2007, remain vague. In fact, at the writing of this submission, there are a number of new developments that are of concern to PhRMA. These include:

1) Korean pilot projects to re-evaluate currently listed drugs: Korea has conducted these pilot projects in a non-transparent manner. Stakeholders were not involved in discussions to identify which drugs would be included in the pilot projects. Stakeholders, including innovative pharmaceutical companies, have not been given basic information as to how products are being evaluated under the pilot projects. PhRMA is concerned that Korean officials intend to adopt the procedures and methodologies employed in the pilot projects system-wide without fully involving stakeholders or giving sufficient time to fully analyze what elements were successful and what elements need improvement.

2) In the new government pricing and reimbursement system under the new Drug Expenditure Rationalization Plan, lack of clear and verifiable criteria for decision making has posed a critical issue for new innovative pharmaceuticals in the Korean market. The Ministry of Health and Welfare (MHW) had correctly acknowledged the issue of lack of predictability in the new listing process in its press statement in July 2007. Although this statement refers only to the lack of predictability from the

viewpoint of the producers of incrementally modified drugs, which are mostly local pharmaceutical companies, it will be important to recognize the lack of predictability and transparency from the KORUS FTA commitment perspectives. The need for improved transparency, and support for enhanced access to innovation in government pricing and reimbursement should be duly recognized, and appropriate corrective measures should be adopted in consultation with stakeholders including industry.

3) The Korean Fair Trade Commission (KFTC) has been conducting an investigation with respect to pharmaceutical companies since September 2006, in which both multinational and local companies have been engaged. We fully endorse the spirit of the KFTC's efforts to improve transparency and ethical business practices in the pharmaceutical market, and ask that this momentum become the springboard for Korea's systematic approach to improvement in this arena. It is essential that Korea conduct evaluations of the issues and problems in this arena in a fair and non-discriminatory manner, and that the Korea's rules and guidelines in the pharmaceutical market should be consistent with globally accepted standards and practices.

4) Requirements to prescribe under active ingredient names: MHW announced last year that they would be launching a pilot project under which doctors would be required to prescribe by identifying active ingredients rather than specific pharmaceutical names. To date, MHW has not entered into any meaningful dialogue with stakeholders on this process, and PhRMA is concerned that a new system could be implemented without consultation with industry or other interested stakeholders.

PhRMA urges the U.S. Government to work with the Korean Government to address industry concerns in these and other areas. As Korea continues to implement elements of its new pharmaceutical pricing and reimbursement system even before the anticipated ratification of the FTA, it will be critical to ensure that new policies are developed and implemented in a way that is fully consistent with the FTA principles.

Early and Full Implementation is Essential

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

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

PhRMA looks forward to working closely with the U.S. and Korean Governments in the coming months to ensure that the KORUS FTA is ratified in an early timeframe, that new and lingering industry concerns are addressed, and that the 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 2007 attributable to trade barriers related to intellectual property protection and market access.

NEW ZEALAND

The Government of New Zealand remains the primary funder of pharmaceuticals in New Zealand. Pharmaceutical Management Agency (PHARMAC) continues to operate stringent cost containment strategies[11], and issues of transparency, predictability and accountability remain unresolved. New Zealand has created a hostile environment for innovative medicines.

In October 2005, the United Future Party announced that it had secured an agreement from the Labour Party to develop a national medicines strategy as part of Labour's coalition negotiations to form a Government. This had the potential to review the Government's pharmaceutical policy. The terms of reference, released in April 2006, focused the strategy review on three areas: Access to Medicines; Quality Use of Medicines; and the Rational Use of Medicines. But a full review of PHARMAC was explicitly ruled out.

The consultation document, "Towards a New Zealand Medicines Strategy", was released through the Ministry of Health in December 2006. It was a broad statement of principles, primarily focused on the rational use of medicines. The New Zealand government subsequently developed policies to effectuate the national medicines review. These policies, however, fail to reform the government's procurement procedures for medicine, and fall short of improving access to innovative therapies. Due to these concerns, we recommend that New Zealand be placed on the 2008 Special 301 **Priority Watch List.**

Intellectual Property Protection

In 2000, the Government initiated a review of the Patents Act of 1953. Although a draft Bill was released in early 2005 for consultation, it has yet to have its first reading in the legislature. The stated purpose of the Bill is to ensure that New Zealand's patent regime takes account of international developments.

One such development is the international trend for countries to strengthen intellectual property protection through patent term restoration. On average, the regulatory approval processes for new drugs in New Zealand takes about 3 years after the date of approval in the country of first launch. This delay is exacerbated by the uncertainty and timeliness of PHARMAC funding which is necessary for effective market access. Many countries, including the U.S., Australia, and the EU, have established mechanisms to restore patent terms for pharmaceutical products to recover time lost due to the regulatory approval

[11] Reference pricing and parity pricing; cross-therapeutic deals; tendering, sole supply, price/volume contracts; special authority and restricted indications; delayed listing (on average 3 times longer than Australia)

process. The research-based industry urges the New Zealand legislature to amend the current bill to include patent term restoration in keeping with international best practices.

The research-based industry supports the 2003 recommendations of the Government's Biotechnology Taskforce to ensure that matters of intellectual property protection, effective patent life and the value of innovation, are addressed in the review of medicines policies and PHARMAC.

Market Access Issues

Government Pricing and Reimbursement

Though not explicitly stated, PHARMAC's reimbursement decisions suggest a pharmaceutical must achieve a cost per QALY (quality adjusted life year) of about NZ$10,000 to NZ$15,000 to be considered cost effective. This approach, combined with the need to stay within a capped budget, means that many effective medicines are not available to New Zealand patients. Recent analysis[12] has found that of the 83 innovative new prescription-only medicines listed on the PBS in Australia between May 2000 and October 2006, only 22 are currently reimbursed in New Zealand. Many of these 22 products have restricted reimbursement, such as reimbursement for limited indications.

The innovative pharmaceutical industry is advocating for the following key policy reforms in New Zealand:

1. **Patient Outcomes -** The National Medicines Strategy (NMS) must ensure the provision of quality medicines in a way that is responsive to people's needs and achieves optimal health outcomes.

2. **Comparable Access** - The NMS must ensure that New Zealanders should have at least comparable access to medicines as do citizens in other OECD countries.

3. **A Core Health Strategy** - Medicines play a vital role in the prevention, amelioration and treatment of disease and as such the NMS is integral to the achievement of all national health strategies and should have equal standing and priority.

4. **Integrity and Public Confidence** - The current bundling of clinical assessment and procurement decisions creates incentives to subordinate

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

clinical judgment to budget imperative. For these decisions to have integrity and improve public confidence in the system, determinations about which medicines are cost effective and are of clinical merit must be conducted independently before being used to form decisions about which products can be funded.

5. **Transparency and Rigor of Processes and Decision Making** - Public confidence will be enhanced if decision making processes are underpinned by openness, fairness, timeliness and high standards of consultation and review. All stakeholders must be able to understand the true basis of decisions and rationing should be explicit. What is considered 'value for money' should be comparable to other OECD countries and meet WHO recommendations. Health Technology Assessment (HTA) methodologies must be rigorous and up to world standards.

6. **Recognition of the Value of Innovation** - The NMS should recognize the value of innovation and innovative pharmaceuticals through the adoption of procedures that appropriately value the objectively demonstrated therapeutic significance of the pharmaceuticals.

7. **Responsive Budget Management** - The pharmaceutical budget should be determined by need and access benchmarks. Rather than conduct health technology assessments (HTA) of products after the capped budget has been set, thus simply creating a priority list of new products competing for the limited funding available, horizon scanning and HTA should be used to establish budget estimates on an annual basis. The capped budget is a concern as there has been little to no growth (a total of 9.5% over the last 10 years) and savings from year to year are not accrued into the following year's budget.

8. **Partnership** - The achievement of timely access to medicines, quality use of medicines and other NMS objectives is greatly enhanced by the maintenance of a responsible and viable industry environment in New Zealand. Coordination of health and industry policies and a consistent and more welcoming environment will better enable the industry to effectively partner the government and other stakeholders to achieve improved health and economic outcomes.

9. **Whole of System** - The NMS must be a whole of system approach. Meaningful and sustainable improvements will only be achieved by a comprehensive, system wide, review. Selecting and pursing only a limited range of issues will not meet public expectations for reform and would negatively impact the relevance and effectiveness of the National Medicines Strategy.

Regulatory Issues

The establishment of a joint regulatory agency with Australia that would allow a single point of entry for both markets with a dual country product license failed to gain parliamentary support this year. The Labour Government has postponed any action in this regard and the Therapeutic Products and Medicines Bill has been put aside indefinitely. In a September 2007 policy discussion paper the Opposition National Party indicated that it favored adopting the Singaporean model, relying primarily on other jurisdictions. PhRMA supports moves to enhance regulatory processes to increase efficiency.

Biotechnology Taskforce Recommendations

The Government's Biotechnology Taskforce made recommendations in 2003 to enhance the Government's relationship with the pharmaceutical industry and stimulate research investment:

- Introduce certainty and predictability into PHARMAC's funding by setting on-going three-year funding rather than year-to-year funding.
- Develop an action agenda for the industry on public policy issues building on the local industry association's report "Bio-pharmaceuticals - A Pathway to Economic Growth"; and
- Review the channels through which the Government engages with the pharmaceutical industry.

The first recommendation was achieved initially with an announcement in September 2004 of annual budgets through 2007. Unfortunately this has now been rescinded with indicative forecasts no longer published. It should, however, be noted that each annual budget is discrete, i.e., savings from one year cannot be carried over to the next, nor can out-year funding be accessed for current year expenditure. District Health Boards and the Minister of Health can also review and adjust budgets part way through the year as happened during the 2003/04 financial year when the budget was reduced from NZ$566 million to NZ$541 million.

To date, the Government has made no move to implement the second and third recommendations beyond the interdepartmental "Pharmaceuticals Overview Paper" that was undertaken during 2003. While this paper examined a number of the public policy issues affecting the pharmaceutical industry, it did not recommend any changes to the current public policy framework, nor did it support a whole-of-government approach to the industry.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

EUROPEAN UNION

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

First, government price controls have harmful effects on patients and innovation. EU legislation requires transparent processes for national pricing and reimbursement decisions, but these principles need to be applied more rigorously with broader controls of national practices. Since the U.S. research-based industry is the world leader in the development of new medicines, PhRMA members and their innovative products disproportionately bear the brunt of these policies. Restricting the availability of state-of-the-art medicines limits patient access to new drugs and risks undermining the financial incentive for privately sponsored research and development. Economic progress is built on the good health of citizens. It is therefore very concerning that increased cuts to the prices of pharmaceuticals or indeed access to innovation, imposed by national governments are slowing the rate of delivery of new medicines to Europeans. In some cases this is being justified by the use of relative effectiveness evaluations of medicines more heavily weighted to reduce costs than ensure patient benefits.

Second, PhRMA members continue to suffer economic losses as a result of policies which allow extensive parallel trading of medicines within the EU. The gains benefit mainly the parallel traders themselves, and provide minimal benefit to national social security budgets.

Third, the EU's ban on patient information bars patients from making informed choices and has a disproportionate impact on new and more effective innovative medicines, medicines increasingly developed in the United States.

Finally, the general regulatory environment should be improved with regard to reliability, transparency and accountability to deliver centrally approved innovative medicines to the market without delays.

Market Access Barriers

Government Pricing and Reimbursement Controls

The industry is confronted by increasing restrictions on effective market access because of national pricing and reimbursement rules. EU legislation provides for basic procedural guarantees for national pricing and reimbursement

decisions in the Transparency Directive 89/105.[13] However, these guarantees, especially those with regard to time limits and the application of objective and verifiable criteria, are not consistently enforced throughout the EU. These include the right to have a decision within ninety days and the right to a statement of reasons in the case of a negative decision. If a decision on price is not taken by the end of the time-limit of 180 days, the applicant shall have the right to market the product at the priced he proposed. The Directive also obliges Member States to inform an applicant of available appeal mechanisms in case of a negative decision. Member States were supposed to comply with the Directive by December 31, 1989.

EU Member States that have joined the EU since that date have to comply with the Directive at the date of their accession to the EU. Member States have previously been condemned by the European Court of Justice for failure to comply with the Directive, for instance by not providing judicial remedies. Yet, significant violations of the Directive can be found in both old and new Member States. In Member States such as Italy, EMEA approved medicines must go through an additional national approval process. Austria, Belgium, France, Hungary, Slovakia, Italy and the Czech Republic have market access delays of over 300 days.

Beyond the significant problems associated with delays, PhRMA members share a number of other transparency and procedural concerns. In some Member States, decisions relating to reimbursement are taken by parliamentary decree. This raises questions relating to the applicant's right to access to judicial review since a parliamentary decree is not subject to full judicial review. Other problems include national legislation not providing for the right to market the product at the proposed price if the authority fails to respect the deadlines for giving its decision. There are several transparency cases brought by the industry already pending with the European Commission (EC), including a case against Italy, the Czech Republic, Poland, Slovakia, and Slovenia. It is imperative that the EC act on these cases quickly to demonstrate that Members States must strictly comply with the specific terms of the Directive.

Lack of a Single Market in Medicines

As a result of widely diverging national pricing and reimbursement policies among the EU Member States, there is no real single market for medicines in the EU. The EU Internal Market Council in its Conclusions on the Single Market in Pharmaceuticals (May 1998) stated that "the development of the single market requires Member States to take account of European Union dimensions … and that ways need to be found within the Treaty to address the question of the price

[13] Council Directive 89/105/EEC, of 21 December 1988, relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems.

differentials between Member States and the issue of parallel trade in this sub-sector."

In keeping with the Council's instructions, the Commission's Communication on the Single Market in Pharmaceuticals [Com (98) 588 final (Nov. 25, 1998)] stated that Member States when controlling their public health expenditures are expected to adopt measures that do not distort the operation of the market leading to a reduction in the competitiveness of this sector in a global context. Member states have not adhered to this mandate, and distorting regulations remain in place generating opportunities for arbitrage among parallel traders.

Ban on Information to Patients

Additional barriers to market access exist in prohibitions on informing patients about prescription medicines in the EU. A European Union directive adopted in 1992 (Article 88 of European Parliament and Council Directive 2001/83/EC) requires 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.

EU member states have adopted basic restrictions on advertising, including the dissemination of non-promotional information, although the exact approach taken by each country varies significantly. An EU-wide ban on such helpful information has many 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 patients at a huge disadvantage because they can not obtain valuable information in their own language.

Regulatory Environment

The regulatory environment for the pharmaceutical industry is increasingly determined by EU rules and EU decisions in contrast to efforts in the past that attempted to harmonize national approaches. This shift in focus took effect in 1995, concurrent with implementation of a new EU regulatory system. The Commission now issues new rules (in the form of regulations) that are directly applicable to the Member States and mandatory EU decisions (in the form of community-wide marketing authorizations, decisions on withdrawals and labeling changes, etc.). While conceptually attractive, this highly centralized EU system

does not yet offer the same level of reliability, consistency, and accountability that has traditionally been built into national systems over the years, and it remains uncertain whether it ever will, given the delicate balance and authority that exists on healthcare issues between the EU and Member States. Yet, such clarity, consistency and accountability are exactly what industry most desires.

There are only limited principles of administrative procedure expressed in EU law, so that the mode of operation of institutions is not predictable. There is a need for a general EU Administrative Procedure Code, especially in light of the increasing degree of discretion bestowed on the regulators under the revised legislation. In addition, there is a trend by EU drug regulators, as well as EU competition authorities, to consider drug approvals as public tools that are to be managed in the general interest, disregarding the principle that they are key commercial assets of pharmaceutical companies.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

CZECH REPUBLIC

Market access barriers are the area of greatest concern for PhRMA members operating in the Czech Republic. The Czech system for determining pricing and reimbursement levels for pharmaceutical products constitutes a significant and discriminatory barrier to imported biomedical innovation, particularly innovation 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 developed by U.S. companies.

In light of these measures and others discussed below, PhRMA members recommend that US government agencies identify the Czech Republic as a **Priority Watch List** country in the 2008 "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 the pharmaceutical industry is the Czech government's use of "therapeutic reference pricing," which links reimbursement for patented and non-patented products. Other choices made in 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.

Newest Changes in the Government Price and Reimbursement Setting

In the newly-created paragraph 39 of Law 48 of 2007 dealing with pricing and reimbursement, both processes will be concentrated in the regulatory body – the State's Institute for Drugs' Control (SUKL). This law makes SUKL responsible for all 3 steps of the access of drugs to the market: starting with the medical evaluation of their efficacy and safety and continuing with pricing and reimbursement setting.

Although this law establishes strictly defined verifiable criteria for both pricing and reimbursement setting, it is still a very restrictive act. For example in the field of price setting it establishes a strict comparison with the average of 5 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 this product in the Czech Republic and, what is even worse, bill 48 fixes for the future the above-described therapeutic referencing within and also across broadly-created reference groups and clusters.

Reimbursement Criteria

The Czech Government uses a therapeutic reference pricing (TRP) system for setting reimbursement rates for medicines. This system discriminates against imports in violation of Czech obligations under Article III: 4 of GATT 1994, as well as Articles 2.1 and 2.2 of the WTO Agreement on Technical Barriers to Trade (TBT). More specifically, this regulation represents an unnecessary and unjustified barrier to international trade because it functions as an obstacle to innovative products, all of which are imported (the Czech Republic produces none), and is without scientific or technical justification.

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) no matter whether the product is patented, off-patent or an infringing copy. In rare cases, the government does award a reimbursement premium to a patented molecule. However, any reimbursement cut for the generic molecules nearly always triggers corresponding reimbursement cuts for the branded molecule.

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 inherently and negatively 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 prices for imported patented products towards those of domestically produced generics. Such linkage undermines the value of pharmaceutical patents in that market segment. Through the operation of this regulation, the Ministry of Health (MOH) and the insurance funds are effectively operating a purchasing cartel and are jointly fixing a maximum price that aims to prevent, restrict or distort competition. At the same time, it heavily favors the local generic manufacturers, who almost always are producing the generic competitors to imported patented drugs. An effective remedy against this is denied to manufacturers at the local level (see below) and whether a remedy may be available under European law is subject to a referral to the European Court of Justice.

The reimbursement regulation provides more favorable treatment to generic manufactured products (which are overwhelmingly domestically produced) than patented products (which are exclusively imported). Thus, it represents a violation of the requirements of GATT Article III:4 and Article 2.1 of

the WTO TBT Agreement that imported pharmaceuticals be treated no less favorably than Czech-origin products. In addition, the reimbursement regulation is in violation of the requirements of Article 2.2 of the WTO TBT Agreement that the Czech Republic ensure that its technical regulations (which this clearly is because it regulates products based on their characteristics) "are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade."

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 suppress 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 on an imported drug, and a generic product (almost always domestically produced) enters the market. 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 the local manufacturers launched generic versions, the government immediately removed all prescribing limitations on antidepressants. The same type of discriminatory changes happened with sartans.

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. While 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 2007 attributable to trade barriers related to intellectual property protection and market access

GERMANY

Market access barriers that undermine the value and benefit of pharmaceutical patents are the greatest concern for PhRMA members operating in Germany. 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 IPR protections. Among other things, these measures relate to: (1) the cost-benefit analyses performed by the Institute for Quality and Economic Efficiency in the Healthcare System (IQWiG), (2) limitation of reimbursement prices for pharmaceutical products by fixed reference prices and reimbursement ceilings, (3) and 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. PhRMA is encouraged by actions taken by the German Ministry of Health in terms of moving towards greater transparency in IQWiG's operations, as well as greater patient access to information. However, these actions have led to few concrete improvements in the German market. To demonstrate the importance that PhRMA continues to place on resolving these outstanding market access barriers, PhRMA requests that Germany be placed on the **Priority Watch List** for the 2008 Special 301 Report.

Market Access Barriers

2007 Healthcare Reform

On April 1, 2007, the German Government implemented a new law governing the healthcare sector. Although this law includes some improvements, major threats remain, including:

- Implementation of reimbursement ceilings for reimbursement of innovative products.
- Cost benefit evaluations (i.e., Health Technology Assessments (HTAs)) will be implemented and executed by the existing Institute for Quality and Economic Efficiency in the Healthcare System (IQWiG). Recent decision making by IQWiG has shown extremely poor performance due to lack of transparency of process and no recognition of international health technology assessment protocol or studies developed by companies. The April 1 law, however, calls for increased transparency in IQWiGs decision-making, the adoption of international standards for HTAs, and the early involvement of industry and other stakeholders.

- Before prescribing for innovative chronic disease treatment with very high costs or special clinical profiles (i.e. cancer, anti-inflammatory diseases), doctors will be required to obtain a second opinion from a specialist.

There are other parts of the legislation that call for more regulation and less liberalization of the market, but the points mentioned above are the most serious. The Pharmaceutical Local Area Working Group (an association of innovative pharmaceutical companies) is actively monitoring the implementation of the new law and is working with political leaders at the national and regional levels to support public policy improvements in relation to the provision of healthcare services, including pharmaceutical products.

Reimbursement Ceilings – IQWiG Drug benefit and Cost Benefit evaluations

IQWiG conducts benefit and cost/benefit assessment of drugs, as well as issues recommendations to the Joint Committee (see below) and Sick Funds. The criteria for making these evaluations are non-transparent and arbitrary, and there is little opportunity for input by the pharmaceutical industry as a whole or by individual manufacturers of the drugs that are under assessment. While the new law implemented on April 1, 2007 should improve the process to some degree, it has not been implemented and IQWiG is still in the process of revising its methodology.

Reimbursement ceilings, which were introduced with the healthcare reform of April 1, 2007, form a new major threat for innovative pharmaceuticals. Like reference prices, they limit the reimbursement 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 as well, the Federal Association of Sick Funds may set a fixed reimbursement ceiling. The law neither defines how the pharmaceutical industry 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 the industry have to be taken into account; it does not describe how this is to be done. It remains unclear whether this regulation may discriminate against international companies whose R&D costs incur mainly outside of Germany.

This measure is particularly threatening due to the current lack of: (1) transparency of the process, (2) clearly defined guidelines for industry 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"

In January 2004, the German Government formally established a new Fixed Reference Price (FRP) system for determining the reimbursement of new medicines. The system grouped or "referenced" together patented products with older generic drugs. The establishment of these reference or "Jumbo Groups" undermines product patents, and the ability of companies to harness marketplace forces to capture the relative value of their products to consumers.

The German healthcare reform law that established the FRP system permits a procedure for "novel" patented products to be excluded from the system by demonstrating "added therapeutic value." The process for proving such value is so seriously flawed, however, that it constitutes a market access barrier for U.S. developers of innovative products. For example, objective and verifiable scientific criteria for excluding novel products have not been issued to date, leaving companies uncertain about what information is required to obtain an exemption and raising concerns about the basis upon which decisions are being made. Those that have been denied may appeal a decision, but the lack of transparency may discourage them from doing so.

In effect, German Sick Funds are operating a purchasing cartel and are jointly fixing an upper reimbursement limit through the reimbursement ceilings and the FRP system that distorts competition. An effective remedy against this was denied to manufacturers by the German Supreme Court and a similar view was shared by the European Court of Justice.

Joint Federal Committee – Process and Transparency

Reimbursement decisions for pharmaceuticals in the Statutory Health Insurance are made by the Joint Federal Committee. Voting members of the Committee are named by the federal associations of physicians and of sick funds; patient representatives are Committee members without voting rights. The Committee commissions the IQWiG with drug beneft and cost-benefit assessments, and it decides on the implementation of reimbursement restrictions based on the aforementioned assessments. It may issue therapy advices or reimbursement restrictions even without an IQWiG assessment. In the FRP fixing process, the Committee determines the product groupings, as well as whether patented products should be excluded from the FRP. Additionally, the Committee defines which drugs require a second opinion for prescription within the Statutory Health Insurance System. The Committee's procedures for making these determinations are flawed in the following ways:

- The Committee lacks transparency. It is not clear what a party needs to provide in order to demonstrate "added therapeutic value" to be

exempted from the FRP system, or what criteria the Committee applies for their decision on reimbursement restrictions;

- Its procedures do not allow for a meaningful dialogue between the developer of a new drug and individual who evaluates it, to discuss the science behind an evaluation of its innovative therapeutic value;
- The Ministry of Health is not exercising its authority to effectively control compliance of the Committee with transparent decision-making procedures.
- There is no effective legal protection or control over the implementation of the FRP or of reimbursement restrictions. Any actions relating to this system must be brought in the Social Security Courts, which apply very strict requirements for summary proceedings or 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 substantial way, particularly in those aspects granting improved participation rights to pharmaceutical manufacturers.

Since 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 has serious consequences for PhRMA members as 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 requires 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. On the other hand, patients are permitted to receive information about over-the-counter medications, but they are not supposed to know about prescription-only alternatives.

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 U.S. pharmaceutical companies in the country. They include:

- Establishing strict monetary dispensing guidelines for physicians and pharmacists on a patient, speciality, region and yearly basis. Physicians who might otherwise prescribe a patented product are instead encouraged to prescribe a generic product or face possible review, and pharmacists are required to dispense one of the cheapest generic products..
- Establishing 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 affects innovative drugs.

Finally, while the innovative pharmaceutical industry was pleased to see the April 1, 2007 law passed and believes that it can lead to the reduction of market access barriers for the industry, it is critical that the law be implemented fully 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 2007 attributable to trade barriers related to intellectual property protection and market access.

HUNGARY

The Government of Hungary does not provide fully effective intellectual property protection for pharmaceutical products and manufacturing processes. In particular, Hungary does not adequately protect data exclusivity or enforce intellectual property rights in administrative and judicial procedures. Hungary also imposes market access restrictions on innovative pharmaceutical imports through its procedures for setting reimbursement levels, listing products for reimbursement, and taxing reimbursements, and by the excessive fees it imposes on pharmaceutical sales representatives. The sheer number and severity of these measures operate to make Hungary one of the worst environments for pharmaceutical investment and operations in Europe.

These measures undermine the value of PhRMA member companies' intellectual property and deny U.S. intellectual property rights owners adequate access to the Hungarian market. For these reasons, PhRMA requests that Hungary be placed on the Special 301 **Priority Watch List** for 2008.

Intellectual Property

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 Hungarian Government still has not implemented the full European term of data protection, in spite of the refusal of the derogation request. Current Hungarian legislation still contains only 6 years, causing Hungary's protection of data to fall well behind the standard in other European countries.

Market Access Barriers

Transparency in Government Reimbursement

The Government of Hungary provides health care to its citizens through the National Health Insurance fund (NHIF). Decisions regarding which pharmaceutical products will be reimbursed lack predictability and transparency. Hungarian law provides neither timelines nor justifications for decisions. In fact, the law gives NHIF the option to suspend reimbursement for 365 days upon issuance of a positive decision. There is no appeal process for negative decisions. The NHIF makes unclear use of pharmaco-economic data.

Cost-containment Issues

In order to fulfill the EU Maastricht criteria, a wide-ranging reform of the government pricing and 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, a new Drug Act contains new fiscal (tax-like) burden elements and further barriers to new products' access.

Key elements of the reforms include:

- A requirement that all companies pay a 12% rebate to the government for reimbursed sales.

- The introduction of a fee of approximately $25,000, required for each sales representative operating in Hungary, roughly doubling the cost of hiring sales representatives.,

- A general reduction in the level of reimbursement, resulting in an increase in co-payments of approximately half of reimbursed drugs by 50%.

- A claw-back system under which companies will become financially accountable for any overspend in the state budget for the reimbursement of pharmaceuticals.

In addition to these measures, the Ministry of Health routinely sets the annual budget for pharmaceuticals at 20 to 25% lower than the actual expenditures in the prior year, a clearly unrealistic target. Taken together these reforms aimed to sharply contain the reimbursement budget in the short-term, with apparent success in 2007 in this regard. As a result of the restrictions included in the legislation, the "claw-back" mechanism was not triggered in 2007, despite the recent history of double-digit annual increases in the reimbursement budget.

The system imposed by the Drug Act is not sustainable in the long run. First, the concept of baseline budgets is very problematic for a number of reasons, since it institutionalizes existing practice without regard to the needs of patients. The system provides a fixed upper limit on sick fund financial exposure. However, it also creates an environment containing very strong incentives for market operators to increase sales volumes under certain circumstances. In normal circumstances, this will in turn increase pressure for increased funding of reimbursement.

The clawback system creates an environment which 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 innovative products with high product costs.

Taken as a whole, the Drug Act attempts to make pharmaceutical companies individually accountable for any overspending on the part of the Government of Hungary and shifts the responsibility for funding patient care to US companies.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

ITALY

PhRMA members are concerned about the regulation of pharmaceuticals in Italy and the effect of these regulations on innovative pharmaceutical products, including those which are dependent on intellectual property rights. Italian government policies and the environment they create could have a long-term detrimental effect on the development of the innovative pharmaceutical industry, potentially eroding the quality and quantity of pharmaceutical research and innovation worldwide.

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

Although the Central Government, which was elected in 2006, has engaged with the industry in a positive dialogue, the measures adopted in Law 222/2007 contain new rules that could further restrict the market and do not conform with their declared intentions to improve access to new pharmaceutical products. In fact, according to this new decree, the Italian Drug Agency (AIFA) will establish a fixed budget for each company on its sales in Italy. This unprecedented measure will create non-competitive market conditions that restrict growth and the ability of the Italian patient to receive the best and most innovative products. In addition, Law 222/2007 requires companies, pharmacist, 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 provisions, it is important to acknowledge that Law 222 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 industry, to cover any overspending in the hospital sector.

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 2008 Special 301 Report.

Market Access Barriers

Company Budget Restrictions

Law 222/2007, passed on November 29, 2007, empowers AIFA to established individual company budgets for 2008, based on volumes and pricing data for mature and generic products for the previous 12 months. PhRMA believes this unprecedented measure will create non-competitive market conditions that restrict growth and the ability of the Italian patient to receive the best and most innovative products. PhRMA's view is supported by the Italian Anti-trust Authority (IAA), which, on October 25, 2007, issued an opinion expressing strong reservations about the new 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

Until last year, the pharmaceutical sector (including pharmacists, and wholesalers) was asked to refund 60 percent of total pharmaceutical overspending in the retail pharmacy sector. Now, according to Law 222/2007 (passed on November 29, 2007), the pharmaceutical sector must refund 100 percent of the overspending in the retail channel (that represents about 83 percent of the overall public pharmaceutical expenditure). For hospital sales, pharmaceutical companies will be no longer formally asked to refund the overspendings, but the cap has been reduced from three to 2.4 percent of the NHF (but now excluding the drugs sold through the third-party distribution). Excess expenditures will now be the responsibility of the regions, which will lead to the introduction of cost-containment measures targeted at healthcare expenses, including pharmaceuticals.

In addition, AIFA recently introduced a new system for the evaluation of innovation, to be used in pricing and reimbursement decisions for new drugs. The pharmaceutical companies provided input into the design and definition of the new system and AIFA agreed on some proposals of amendment of the original document. However, it is not clear how it will be applied and to what extent it will delay further the ability of new drugs to enter the Italian market.

Drug Formulary Revision

In 2002, 2004, and 2006, the Italian Government introduced revisions to the National Formulary for all drugs reimbursed by that National Healthcare system. The first revision, introduced in 2002, established a limit to the reimbursement levels inside several therapeutic classes, damaging generally

higher-priced innovative drugs. The second and the last revisions affected those drugs that registered a sales increase higher than the industry's average growth.

Those fast growing medicines bore additional government controlled price cuts (on top of the mandatory discounts and the overall price cuts, introduced for the pay back) by up to 10 percent. This measure particularly damages the most innovative drugs under this criterion.

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

The Italian Government's focus on controlling pharmaceutical expenditures is unique relative to other expenditures within Italy's National Healthcare System (NHS). While pharmaceutical expenditures are capped at 14 percent (retail) and 2.4 percent (hospital) of the NHF, 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, in the same period, the other health care costs registered an average growth of 41.2 percent.

Regulatory Approval and Market Access Delays

As was documented in IMS 2007 study, "Patients W.A.I.T," which compared the time to market for all new medicines with marketing authorization from 1 July 2002 to 30 June 2006 (61 in total for Italy), the average time to market in Italy was 356 days, with a minimum of 28 days and a maximum of 841 days. While the creation of AIFA in 2004 reduced these delays, they still remain far above the EU average. In addition, it can take an additional six months (from the date the drugs are approved by the European Agency for the Evaluation of Medical Products (EMEA)) for H-class drugs to be approved (those limited to distribution within hospitals).

Industry 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 in the selling prices of all medicinal products, 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, enacted on November29, 2007. The EU authorities have pursued this complaint, and issued a reasoned opinion letter in 2007 identifying a number of Transparency Directive Infringements. A persistent pattern of violations continues unabated in Italy. PhRMA members remain concerned about Italy's practices in regulating pharmaceuticals and believe it is important for the

EU to take appropriate action to ensure its members 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 2007 attributable to trade barriers related to intellectual property protection and market access.

POLAND

U.S. and multinational research-based pharmaceutical companies face many policies that hinder a fair and transparent business environment in Poland. Though the Polish government has made initial steps toward reviewing the backlog of innovative products, transparency concerns continue to undermine the reimbursement process, while weak intellectual property and discriminatory policies continue to block access to the market. PhRMA members to recommend that Poland be designated **Priority Watch List** for 2008.

Intellectual Property

Patent Enforcement

Patent protection in Poland has been weakened by a growing trend of generic products being launched before patent expiration and Polish regulations make it difficult for innovative companies to defend their patents. Where there is a case for a legal dispute over patent infringement, as is the case in EU Member States generally, the generic authorization is not suspended to allow the parties' time to resolve the issue. As a result, of this growing trend of generic products launched before patent expiration, market access is being reduced even with a valid patent.

Data Protection

Poland was required to provide innovative pharmaceuticals the European "8+2+1" term of data protection prior to its 2004 accession. Instead of passing legislation to establish this protection, the Polish Government submitted a derogation request that was refused in 2004 by the EU. The Polish Government still has not implemented the full European term of data protection, in spite of the refusal of the derogation request. Current Polish legislation still contains only 6 years, causing Poland's protection of data to fall well behind the standard in other European countries.

Market Access Barriers

Marketing Authorization Delays

Innovative companies also face significant obstacles in the market authorization process, which undermines their intellectual property rights. Timelines established in Polish law are routinely ignored, and the lack of transparency in the process often tends to result in discriminatory action towards foreign companies. For example, the registration process for Merck's ***Fosamax*** took 15 months (instead of 6) and was substantially delayed by continuous

actions by the MOH and its dependent agencies that complicated that process without any clear reason. In the same period, two generic copies of ***Fosamax 10*** were registered in just 3 months.

Reimbursement Backlog

Between December 1999 and December 2003, the Government of Poland granted marketing approval to 111 new molecules, but none were included on the list for reimbursement under the Polish health system. In 2007, the Polish government took incremental steps toward addressing the backlog of innovator applications for reimbursement. Eighteen new innovative molecules were added to the state reimbursement system in updates from March and December. These steps, however, were not accompanied by a plan to address the remainder of the backlog. Furthermore, the updating process lacks reasoned justifications for (dis)approvals, an appeals process, and a clear timeline for decision-making.

Lack of Transparency

A key barrier to trade for U.S. companies is that the Polish government's registration, reimbursement and pricing systems lack transparency and undermine equitable market access to foreign products and manufacturers in favor of locally-produced copies. Reimbursement is currently determined by the Ministry of Health (MOH) based upon a recommendation from the Drug Management Committee, which includes three representatives from each of the MOH, Ministry of Finance, Ministry of Economy and non-obligatory representation of the Health Insurance Funds. The roles of each of these representatives are unclear. Under the law, the decision process cannot take longer than 90 days from a price submission or 180 days if both pricing and reimbursement submissions are made. Nevertheless, these timeframes are not adhered to by the Ministry, the decision criteria are not transparent, and the appeal system is inadequate.

A recent update of the Healthcare Law which came into effect on October 1 leaves many gaps in the transparency of the pricing and reimbursement system. The current regulations still do not provide: objective and verifiable criteria, individual decisions (absence of individual decisions provides no basis for appeal) justifications of decisions, or a comprehensive appeals procedure

A newer category of non-transparent processes concerns Health Technology Assessments (HTA) for innovative products. Innovative companies are not officially informed about any assessments of their own products and have no official recourse to present their opinions or supplementary information in the process of developing the assessment. HTAs thus can be used as an excuse to

keep innovative products out of the reimbursement system without justifiable criteria and open processes.

Similar to reimbursement decisions, government pricing decisions also are taken formally in the form of a regulation, i.e., an act which cannot be appealed to or reviewed by an independent court.

Discriminatory 13% Price Cut

On July 1, 2006, the Government of Poland implemented an average 13% price cut for imported medical products, clearly discriminating against multinational companies. The Regulation did not target official prices for drugs produced in Poland, and even chemically identical products manufactured in Poland are exempt from the reduction. The Polish Government seeks to justify the regulation by linking it to changes in the dollar/euro exchange rate, even though reimbursement is made in Polish currency and therefore is unaffected by exchange rates. The price cut is discriminatory because it only affects imported products; the price of local products is unaffected. The price cut violates Poland's obligation under GATT Art. III:4 (national treatment), which requires that imported products be treated no less favorably than domestic products. The price cut also violates Poland's obligations under the U.S.-Poland Bilateral Investment Treaty (entered into force August 6, 1994) to accord non-discriminatory (Article II:1) and fair and equitable (Article II:6) treatment to Polish affiliates of U.S. nationals. In 2007, the Polish government extended the 13% price cut to imported components of locally-manufactured products as well. This move deepens the discriminatory effects of the price cut.

Therapeutic Reference Pricing

Another key barrier is the Polish government's use of 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".

The Polish government's use of a TRP system for setting reimbursement rates for medicines discriminates against imports in violation of Polish obligations under Article III:4 of GATT 1994. More specifically, this regulation represents an unnecessary and unjustified barrier to international trade because it discriminates against and functions as an obstacle to innovative products, the vast majority of which are imported, and is without scientific or technical justification. The TRP system also violates Articles 2.1 and 2.2 of the WTO Agreement on Technical Barriers to Trade. The system is a "technical regulation" under the TBT

Agreement because it is set forth in a "document" (*i.e.*, statute and regulation), which "lays down product characteristics" (*e.g.*, ingredients and therapeutic effects) with which "compliance is mandatory" (*i.e.*, reimbursement are fixed and binding for all products in same category).

Ghost products

Prior to EU Accession there was an accelerated registration of generic, mostly domestic products with incomplete dossiers, in order to maximize the opportunity provided by the EC Treaty annex to register products according to the former regulatory standards which were lower than EU standards. These products were given conditional registration for which there was no normative provision and there was no mechanism to check if the conditions were satisfied. Some of the products registered in this way were used for reference pricing purposes by the government thus undermining prices of the innovative originals. Other copy products were registered despite the original innovator product having centralized EU registration. These products continue to be present on the Polish market. The concern is that a similar approach may be used by the Ministry of Health 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, and a "Reasoned Opinion" was recently communicated to the Polish Government.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

RUSSIA

Trade in the Russian pharmaceutical sector continues to be impeded by the government's failure to protect commercially valuable test data and poor enforcement of intellectual property rights. Though Russia made significant commitments in the 2006 U.S.-Russia WTO Accession bilateral on 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 be included on the "Special 301" **Priority Watch List** for 2008, pending the results of the 2007 Out-of-Cycle Review.

Intellectual Property

Data Protection

Russia currently does not provide data exclusivity. Russia's legal regime fails to ensure a period during which no person may, without the permission of the originator, rely on test data generated by the originator in support of an application for product approval. This lack of data exclusivity has left the U.S. research-based pharmaceutical industry vulnerable to premature copying by domestic and foreign generic companies.

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 accession. Specifically, the Government of the Russia Federation committed to "work actively with the Duma to secure enactment of" data exclusivity legislation "by June 1, 2007." Unfortunately, not only has the Russian Government failed to meet the agreement's deadline of June 1, 2007, for enacting data exclusivity legislation, it has failed to take any steps to fulfill this obligation.

To date, the Russian Ministry of Economic Development and Trade (MEDT) has not introduced draft legislation to the Duma to fulfill this obligation. Furthermore, official draft legislation has not been produced for public comment.

Implementation of the data exclusivity commitment must be a prerequisite for Russia's accession to the World Trade Organization.

Trademarks / Counterfeiting

The Government of Russia provides weak enforcement against counterfeit medicine producers. Counterfeit products currently represent a negligible portion of the market, the vast majority of which is produced by local manufacturers.

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

The main article of Russian legislation currently applicable in cases of pharmaceutical counterfeits is the one that addresses trademark infringement. However, the Criminal Code applies only in cases of numerous violations or involving significant damages, and even in those cases where the Criminal Code applies, the penalties are inadequate. ($5000 to $8000 maximum)[14]. The penalty set in the Administrative Violations Code is even lower ($1400 maximum)[15]. The Russian parliament has been debating a potential increase in criminal and administrative liabilities for several years but nothing has been done so far.

Part IV of the Russian Civil Code, dedicated to intellectual property rights, will come into force on January 1, 2008. It does not envisage specific provisions regarding medicines, but may contribute to overall enforcement of IPR protection, which definitely remains a problem.

Market Access Barriers

Marketing Approval

Pharmaceutical products are required to obtain marketing approval in Russia, as is required in the United States. Unfortunately, the marketing approval process in Russia is lengthy, unpredictable, and nontransparent. The approval process and the corresponding fee collection are the responsibility of the Federal Government Establishment or FGU, a non-commercial subsidiary to 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.

Reimbursement Procedures

The Government of Russia instituted a federal drug reimbursement program in 2004, which began operations in 2005. Unfortunately, reimbursement decisions are not made based on objective and 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

[14] RF Criminal Code, art.180
[15] RF Code on Administrative Violations, art.14.10

for pharmaceuticals (DLO) and other tender processes. No appeal procedures for reimbursement decisions are provided.

The Ministry of Health issued a regulation in 2006[16] 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.

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[17]. 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 delivered. This procedure is not consistent with international practice.

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

In addition, the Government of Russia collects a payment for granting the relevant import license at the amount of 0.05% of the contract price. This fee constitutes a significant additional cost for importers.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

[16] Order of the Ministry of Health and Social Development # 93 as of February 15, 2006
[17] Governmental Resolution # 72 as of February 10, 2004
[5] MoH Decree № 8543 dated November 30, 2006 – Administrative Regulation enforcement

TURKEY

Turkey continues to face a number of significant challenges in providing appropriate intellectual property rights and developing regulatory policies that allow innovator pharmaceutical companies to use those rights fully. Concerns linger about the government's interpretation and implementation of regulations relating to data exclusivity in view of TRIPS and European Customs Union obligations. Moreover, Turkey still does not provide adequate patent linkage to prevent marketing approval of copies of medicines that are under patent. While in some areas there has been limited progress since 2006, lengthening regulatory delays and barriers indicate overall deterioration in market access.

PhRMA therefore requests that Turkey remain on the **Priority Watch List** for 2008.

Intellectual Property Rights

Although there has been notable improvement in recent years, Turkey's intellectual property rights (IPR) regime does not meet the standards of globally competitive countries in this sector. In April 2007, the US Trade Representative maintained Turkey as a "Priority Watch Country," in large part due to IPR concerns. Particular problems include an inadequate data exclusivity regime and the lack of a patent linkage system.

Data Exclusivity

With respect to pharmaceuticals, particular problems persist to interpretation and implementation of the data exclusivity (DE) regime. These concerns include the start date of the protection period for commercially valuable clinical and testing data, and the lack of a mechanism to restore time lost due to mandated regulatory processes. There is 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 the product patent, which is not consistent with international obligations.

The Government of Turkey has taken positive steps toward establishing protection for the commercially valuable data generated by innovator companies. Turkey now provides for Data Exclusivity (DE) for the minimum period of six years for products registered in the EU. 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 is a welcome step, the implementation in Turkey is problematic, because the six-year protection period commences from when a product first gains registration in any country of the ECU.

The inefficiencies have the effect of significantly diminishing DE in Turkey. Inefficient regulatory procedures that do not fully comply today with the EU Transparency Directive erode the period of DE for new medicines. Effective DE is reduced to as little as 2-3 years in some cases, resulting in an environment where incentives for innovators to undertake risky and expensive research are undermined. Application of data exclusivity today in Turkey is clearly out of step with European standards and must be amended to include restoration for time lost in the regulatory process by starting the period of DE when approval is obtained in Turkey. Furthermore, Turkey does not provide DE for combination products. This is counter to established practice in Europe today.

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. 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 protection of up to 11 years (8+2+1), thereby avoiding a situation of dis-harmonization among EU members upon Turkey's accession.

There is also the related problem specific to patented medicines. The current regulation is not consistent with Turkey's international obligations, as it ties the term of DE to patents relating to the product. For patented products, the protection period cannot extend beyond the period granted for patents in Turkey, an exception not consistent with DE in the ECU today.

Patent Linkage

Providing patent protection for pharmaceuticals is a relatively new regime in Turkey. Patent legislation was first introduced in 1995. In accordance with the 1995 patent law and Turkey's agreement with the EU, patent protection for pharmaceuticals began on 1 January 1999. Turkey has been accepting patent

applications since 1996, in compliance with the TRIPS agreement, and has significantly upgraded the capabilities of the Turkish Patent Institute in Ankara.

Turkey today does not offer an effective patent linkage system between patents and marketing approvals by the health regulators. As a result, there are a number of registrations for generic versions of patented drugs that are pending approval. This has meant that generic drugs have been registered in the country while the patents on the original product are still valid. This development is particularly alarming to innovator biotechnology and research-based pharmaceutical companies. A functioning patent linkage system would help eliminate this problem because final approval of generic registrations would be postponed for some period sufficient to allow resolution of patent issues.

Market Access Barriers

Although some regulations (registration, reimbursement, pricing) have been revised in recent years, in practice the regulatory system represents the main barrier to market access, as it inhibits the timely and efficient uptake of new medical technologies that extend, improve and save lives.

The regulatory system works, in effect, as a barrier to the rapid diffusion of new medical products and technologies that could offset exploding costs in non-pharmaceutical healthcare. It also creates an environment which may hinder investment in the innovative medicines sector, and represents the main obstacle to efficient market access today in the Turkish medicines market.

The current regulatory system, while in many ways superior to the opaque and cumbersome system it replaced in 2004-2005, can take up to 3 years or longer to complete procedures relating to registration, pricing and reimbursement.

Registration

Generally, significant regulatory barriers remain to health improvement and investment, and the Government may only be in the early stages of realizing the important positive impact that an efficient, transparent regulatory system can have on health and investment. The main issue is the length and complicated nature of the system, which delays the introduction of new medicines for on average 2-3 years, or more, according to industry experience.

On the positive side, there does appear 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 a new “Regulation on the Registration of Medicinal Products for Human Use".

The regulation limited the registration appraisal time for new drugs to 210 days, and after a long discussion about working vs. calendar days, the Government announced that it would count only calendar days to align Turkey to EU implementation.

Currently, biotechnology and research-based pharmaceutical companies are engaged in a process to determine for advocacy purposes the impact of this regulatory clarification. The general impression is that due to frequent work stoppages, registration of promising new medicines approved in Europe (EMA) or the USA (FDA) can still take up to 18-24 months in Turkey, well past the nominal 210 day review period.

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

Companies note that even routine applications to amend products in line with approvals in reference countries (e.g., EMA in Europe or the FDA in the USA), such as adding new indications, can take many months, whereas in other countries these are acknowledged and licensed very efficiently.

Reimbursement

During the past two years, the Government appears to have become increasingly aware of the length of time that it takes to register and reimburse new medicines. Public opinion polls have shown that consumers want immediate access to promising new medicines, and are not content to wait up to 2-3 years for access through the Health Security Institution (SGK), which provides health insurance to a majority of citizens.

To address this, the Government recently approved reimbursement procedure reforms ostensibly designed to make it more responsive, transparent and efficient. While there are a number of promising amendments, PhRMA member companies are very concerned about new requirements that cannot be met given the lack of reliable and comprehensive cost, epidemiology and disease prevalence data in Turkey.

The Government appears to share the concerns of industry, as it has requested industry’s help in devising practicable criteria for assessing new medicines.

In the meantime, the assessment of PhRMA member companies is that in the absence of publicly available data, the new requirements are likely in the short to medium term to complicate reimbursement procedures and add to delays in market access for new medicines.

In the short term, PhRMA member companies are concerned that the reimbursement system appears to be focused on implementing cost containment tools that may carry long term consequences for patients and the quality of care and treatment.

Government Imposed Price Controls

The Turkish government exerts strict control over pricing in the pharmaceutical sector through the implementation of a reference price system.

In September 2007, new pricing legislation was published, a refinement of changes implemented in 2004. Under the new rules, the reference price of an original product is determined according to the lowest price among 5 countries from an established list of up to 10 EU reference countries. The list may be updated every year, with certain countries rotated in or out.

Following publication, the current 5 reference countries, France, Spain, Italy, Portugal, Greece, were retained as reference countries (the production country and export country can also serve as references).

Turkey's pharmaceutical pricing policy will continue an environment with conditions that undermine incentives to market entry and investment by the private sector. As is the case in any system where government price controls govern, distortions and unforeseen consequences inevitably crop up.

Summary

In summary, the lack of a world class, highly efficient and transparent regulatory system, lingering IP issues regarding data exclusivity and lack of patent linkage, and the heavy hand of government price controls lead to avoidable delays in the flow and diffusion of promising new medicines and technology to Turkish patients, adding to market access barriers and higher costs in the healthcare system.

Working with the support of the major trading partners, including the US Government and EU Commission, PhRMA members will continue to support market access and investment policies that move Turkey toward its full potential for better health and a more globally competitive position in the life sciences.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access

LATIN AMERICA

ARGENTINA

The Government of Argentina did not make any progress during the last year in resolving two of the most important issues for the research-intensive pharmaceutical industry: protection for undisclosed test and other data required by the TRIPS Agreement and "linkage" between patents and the system for approving pharmaceutical products. Efforts by the Argentine Patent Office (INPI) to decrease the backlog of applications awaiting examination continued last year. PhRMA members are pleased with the efforts and look forward to continued improvements in the patent backlog and patent approval times. In this context, the Economy Ministry needs to ensure that there are adequate financial and human resources over the long term "to avoid unwarranted curtailment of the period of protection" for patents, as prohibited by the TRIPS Agreement. However, there has been a set back in IP rights protection since the Argentine House of Representatives passed legislation eliminating the previous amendment to the customs code to comply with Section 4 of Part III of TRIPS Agreement related to border measures for enforcing trademark rights and copyrights. The new legislation, pending a Senate vote, excludes other IP rights, such as patents, from this provision.

As a result, PhRMA recommends 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."

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 for 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, as required by 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 countries as their review. Thus, the requirement to submit data in these countries is essentially 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 to reduce the backlog of patent applications awaiting examination over the past 3 years. The Ministry increased the budget of the INPI. As a result, an additional thirty examiners and eleven administrative officials were hired and more applications are examined each year than are received by INPI.

To further reduce the backlog, INPI issued Resolution 372 in 2004, whereby companies had to indicate that they were still interested in obtaining an examination in Argentina for each of their applications filed before 1 January 2004. If a company did not indicate an interest in examination, an application was abandoned. This resulted in a large one-time reduction in the backlog. On 11 December 2006, INPI issued Resolution 350, establishing a procedure whereby companies could change the order of examination of their applications so that the more important applications could be examined first. A similar resolution (Nº162) – enabling companies to change the order of their applications - was issued on June 20th, 2007. 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. 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). These terms were intended to provide effective and fast measures for patent owners in Argentina to obtain relief from infringement before the conclusion of an infringement trial in special circumstances. Unfortunately, these terms, when implemented in the Argentine legal system, have not had the effect intended as a practical matter.

Customs Code Reform

The Argentine Congress enacted legislation, Law No. 25.986 in 2005, to amend Article 46 of Customs Code (Title III – Foreign Trade/Counterfeited goods) to comply with Section 4 of Part III of the TRIPS Agreement. The Executive Branch never implemented the regulations to make the law effective. Furthermore, in March of this year, the Executive sent a draft bill to Congress eliminating from the above mentioned legislation the provisions against the infringement of "other intellectual property rights or industrial property rights granted by the national legislation". Under this change, patent infringements would not be protected in compliance with TRIPS. This means that the protection for trademarks and copyrights will remain in place, but patent infringements have been eliminated. The bill was passed by the Lower House on July 18th, and Senate approval is pending.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

BRAZIL

The Government of Brazil has not made any progress on extremely important issues for the research-intensive pharmaceutical industry such as clarifying a decree that currently authorizes the Minister of Health to issue compulsory licenses for patents and to misuse this authorization to control prices. In fact, our concerns were justified in light of the decision to issue a compulsory license for a patented product in May, 2007.

During the last year, the Government of Brazil continued to take steps to decrease the backlog of patent and trademark applications awaiting examination as well as to improve the operations of the National Institute of Industrial Property. It also continued to implement its long-range plans to reduce substantial pendency periods. While these are important steps forward, limited progress has been actually made towards reducing the large backlog of patent applications. The examination of patent applications by ANVISA, the agency that regulates the marketing of pharmaceutical products, contributed to this backlog without providing any significant benefits to the examination process. Although the Government took steps to reduce delays caused by the sequential examination by ANVISA, the examination still discriminates against innovative products in the pharmaceutical field and continues to create uncertainty surrounding the accurate application of patentability criteria.

No progress was made administratively to protect certain pharmaceutical test and other data as required by TRIPS Article 39.3 on 1 January 2000.

Moreover, the Government of Brazil retained price controls that do not fully account for devaluations, inflation, and the cost of doing business in Brazil.

As a result, PhRMA recommends that Brazil remains on the **Priority Watch List** in 2007 because it continues to deny "adequate and effective protection of intellectual property rights" and "fair and equitable market access."

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 the innovative pharmaceutical industry.

When examinations were separate, ANVISA officials overturned patentability determinations by the Brazilian Industrial Property Institute (INPI) by

applying, in industry's opinion, more restrictive patentability standards than were authorized under Brazilian law. More specifically, they unduly restricted the definition of invention, rejected claims drawn to new uses of known products, and imposed higher standards of novelty and inventive step than mandated by Law. While examinations are now conducted in tandem, industry believes ANVISA officials are still applying improper standards. As a result, patents are still not granted on important pharmaceutical inventions although these inventions are patentable 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 haunt 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 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 we noted that these mechanisms appeared to be "safety valves" to be used in extraordinary circumstances when supplies of the patented products were not sufficient to meet 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*" patent compulsory licenses during national emergencies and declared instances in the public interest:

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

Other Concerns

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 is still approximately 10 years as reported by member companies (but the President of INPI estimates that the pendency period is 4.5 years). PhRMA also acknowledges that INPI is significantly reducing the backlog of applications for the registration of trademarks and planned to meet pendency targets by the end of 2007.

Patent Linkage.

Efforts to gain support for legislation that would require a link between the system in ANVISA for approving generic products and the patent system continued. However there were no legislative developments in 2007.

Data Exclusivity.

The Brazilian Government still fails to clearly prohibit Government officials from allowing companies other than innovators to rely for a period of time 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. If these deficiencies persist, Brazil risks becoming a major regional hub 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. As such, it is imperative that drug safety laws provide strong administrative and criminal remedies for any activity that facilitates or directly entails the manufacture, distribution, import and/or export of counterfeit pharmaceutical products. In that regard, Brazil's drug safety regime falls far short in guarding against counterfeit pharmaceutical products. Among other deficiencies, drug regulators lack adequate investigative and enforcement powers, and administrative remedies

require evidence of actual harm - a burdensome statutory requirement that prevents effective enforcement and ignores the inherent dangers of all counterfeit pharmaceutical products. Although pharmaceutical product counterfeiting is subject to criminal remedies and stiff penalties under the Brazilian penal code, criminal enforcement is undermined by inadequate resources and a failure to treat pharmaceutical product counterfeiting as a law enforcement priority.

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). All too often, these authorities succumb to pressure to relax oversight of the drug supply chain; in the process, they open the door to increased counterfeiting.

Weaknesses in drug safety controls are exacerbated by inadequate intellectual property remedies and enforcement, particularly criminal trademark remedies. Trademark counterfeiting is not treated as a serious public offense under Brazilian law; as a result, law enforcement authorities lack *ex officio* powers to prosecute trademark counterfeiting crimes, thus forcing right holders to assume the burden of criminal enforcement. For example, right holders often face significant delays in obtaining criminal seizure orders because judges give priority to state-initiated criminal actions; moreover, criminal penalties appear to be infrequently applied against well-financed and politically-connected organized counterfeiting operations.

Trademark enforcement is further 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 deterrent 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.

Government Price Freeze and Controls.

A Government-mandated price adjustment mechanism, in effect since July 2000, is a major trade barrier to the research intensive pharmaceutical industry. The arbitrary pricing restrictions were imposed with minimal input from the pharmaceutical industry. 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 2006, a price increase between 3.64 percent and 5.51 percent was allowed, depending on the percentage of generics in a certain therapeutic class. Another below-the-inflation-rate average price increase is expected for 2007. 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. 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 24.69 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 faction in measuring access to medicines, has improved somewhat for the less favored social classes, unit sales volumes have remained almost flat in the last few years. This suggests that more needs to be done to reach 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. 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 standards 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 remain on 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 2007 attributable to trade barriers related to intellectual property protection and market access.

CHILE

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 patent linkage and to correct important weaknesses in its data exclusivity (DE) regime.

Despite repeated and ongoing efforts by PhRMA and its member companies to work with the authorities to identify mutually acceptable solutions, the Government of Chile has taken no substantive steps during 2007 to address U.S. Government and industry concerns regarding the absence of linkage and acceptable DE.

- Following USTR's announcement in January 2007 that it had placed Chile on the Priority Watch List, due in part to Chile's failure to comply with its FTA obligations regarding linkage and data exclusivity, Economy Minister Alejandro Ferreiro asserted that Chile already respects linkage by enabling patent holders to defend their claims in court. He stated that "our legal structure has not permitted us to establish what they [the U.S.] have asked for, in terms of linking sanitary authorization to commercialize a medicine with elements related to intellectual property protection…To commercialize a medicine, approval is needed from the industrial property agency, and the Chilean Government imposes sanctions through the judicial system, as happens in Chile in any area, on whoever commercializes a medicine without possessing the corresponding patents." [18]
- In August 2007, Ferreiro stated that "…we do not share the positions of the United States regarding Chile's legislation and current practice regarding IP protection," and that "…we have long held that we are in full compliance with the FTA, we have a different interpretation of the obligations imposed by that agreement."[19]
- On October 1, DIRECON director Carlos Furche was quoted as saying that "Chile complies with international standards of IP protection, and fully honored its international commitments, in accordance with mutually agreed principles and time frames…."[20]
- On October 3, Health Minister Soledad Barria published a letter in *La Tercera* stating that "the protection of trademarks and commercial patents depends on their registration with the Department of Industrial Property, which is part of the Economy Ministry. Any attempt to link patent protection [with the work of the ISP, which is responsible solely

[18] "Decisión de Estados Unidos nos resulta decepcionante," *El Mercurio*, 10 Enero 2007.
[19] "Gobierno: Chile Ha Cumplido con EE.UU. en Materia de Propiedad Intelectual," *Estrategia*, 9 Agosto 2007.
[20] "Se cumplen estándares internacionales," *Diario Financiero*, 1 Octubre 2007, p. 34.

> for registering medicines that meet applicable technical criteria] constitutes a conceptual mistake." Demonstrating a misunderstanding of the nature and purpose of linkage, she added that Sanofi-Aventis's recent victory in a patent infringement case against Royal Pharma "shows that Chile respects intellectual property and provides the means by which those who feel themselves injured can act formally and obtain reparations."[21]

In view of the Chilean Government's unwillingness to comply fully with its linkage and DE obligations under TRIPS and the US-Chile Free Trade Agreement, as those obligations are understood by both the U.S. Government and the research pharmaceutical industry, PhRMA recommends that Chile remain on the **Priority Watch List** in 2008.

Intellectual Property Protection

Linkage

Contrary to the requirement contained in Article 17.10.2 of the US-Chile FTA, Chile has failed to establish a formal institutional mechanism (also known as patent linkage) to prevent the *Instituto de Salud Pública* (ISP) from granting sanitary registrations and/or marketing authorizations to pharmaceutical products that infringe already-granted patents. That Article requires Chile to "make available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent" and "not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner." Chilean officials have contended (1) that the ISP grants only sanitary registrations, not marketing approval, and (2) that Chile satisfies its linkage obligation by enabling patent holders to pursue cases of alleged infringement through existing judicial channels.

PhRMA regards both of these arguments as disingenuous. 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 modified Supreme Decree 1876 to eliminate references to "marketing approval." Strictly speaking, 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. Because sanitary registration is therefore equivalent to marketing authorization, PhRMA members contend that Article 17.10.2 of the FTA requires

[21] "Propiedad industrial," *La Tercera*, 3 Octubre 2007, p. 2.

the Government of Chile to deny sanitary registration to products whose sale would infringe patents already granted to others.[22] Nevertheless, the ISP has granted sanitary registrations to such products on numerous occasions.

The Chilean generic pharmaceutical industry and its advocates have argued erroneously that a court judgment in September 2007 finding local generic manufacturer Royal Pharma liable for patent infringement against Sanofi-Aventis undercuts complaints by the U.S. Government and the pharmaceutical industry regarding the absence of linkage in Chile. The Executive Vice President of the generic industry association ASILFA claimed that "…this case demonstrates that the court system works effectively in intellectual property cases. Therefore, efforts by the U.S.-based pharmaceutical industry to establish linkage and impose further restrictions on [the use of] unpublished information [i.e., proprietary test data] are unjustified."[23] Similarly, generic industry lawyer Gabriel Zaliasnik claimed that the verdict "clearly shows that anything having to do with pharmaceutical patent infringement must be adjudicated exclusively in the courts."[24] In fact, the Sanofi-Aventis/Royal Pharma litigation demonstrates precisely the opposite – i.e., that Chile requires a genuine linkage mechanism capable of forestalling prolonged, expensive, and unnecessary patent infringement litigation by preventing patent-infringing medicines from reaching market in the first place.

PhRMA member companies and the local industry trade association (CIF) met with relevant Chilean Government officials – including the Department of Industrial Property director and the director and staff of DIRECON – to explain why linkage is necessary, provide information about the tangible damages caused to PhRMA members by the absence of linkage, and discuss the minimum requirements of a linkage system that would be acceptable to both industry and the Government several times during 2007. DIRECON's responses have ranged from non-committal to outright rejection (e.g., Carlos Furche informed PhRMA in March 2007 that the linkage issue is "closed"). As a practical matter, the Government of Chile has taken no action during 2007 to

[22] This position has been implicitly supported by Minister of the Presidency Paulina Veloso, who stated in an official communication to the Constitutional Court in October 2006 that ISP sanitary registration is required before any pharmaceutical product can be commercialized, imported, or manufactured in Chile (Formula Observaciones a Requerimiento presentado por Paulina Veloso Valenzuela, Ministra Secretaria General de la Presidencia, al Tribunal Constitucional el 27 de Octubre 2006, en relación con el requerimiento presentado por un grupo de diputados en contra de la Resolución Nº 584, del Ministerio de Salud, de 2006, rol 591-2006). In addition, a Chilean civil court ruled in November 2006 that sanitary registration in Chile is equivalent to marketing authorization (Folio 90; 30º Juzgado Civil de Santiago, Rol C-6613-2003; Caratulado Porzio Bozzolo M/Instituto de Salud Pública, 10 de Noviembre 2006). This preliminary ruling is currently under appeal.

[23] "Sentencia por infraccion a Ley de Propiedad Industrial podria marcar precedente en el mercado farmaceutico nacional," *Estrategia*, 9 Septiembre 2007.

[24] "Expertos discrepan sobre avance en el respecto a la propiedad intelectual," *Diario Financiero*, 1 Octubre 2007.

establish linkage, and its officials continue to insist that Chile is already complying fully with the IP chapter of the U.S.-Chile FTA.

Chile's failure to establish linkage has enabled the ISP to grant 38 sanitary registrations to imitative pharmaceutical products in violation of patents already granted to the companies that discovered and developed those products. Fourteen of these linkage violations have occurred since January 8, 2007, when Chile was added to the PWL.

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.
- The current rules permit the ISP to accept sanitary registration applications for pharmaceutical products characterized as "new," even though the applications rely on test data belonging to a third party that had not authorized such reliance.
- Chile's data exclusivity norms impose conditions on the right to exclusive use that are not authorized by TRIPS or Chile's bilateral trade agreements with the EU and the United States. These limitations significantly weaken the applicability and usefulness of the available exclusivity.

In early 2007, PhRMA learned that the Chilean Health Ministry intended to undertake a thorough review of its pharmaceutical regulatory framework, aimed in part at addressing the concerns of industry and the U.S. Government regarding inadequate data exclusivity. PhRMA member companies attempted to contribute constructively to that process by communicating their concerns and recommendations in writing to the Health Minister, and by meeting in person several times with key Health Ministry and ISP officials to discuss needed regulatory changes. Though, the Ministry failed to meet its own July 2007 deadline for publishing new draft regulations for public comment, a draft

regulation was published in December 2007 and is now subject to a 60 day comment period.

In concrete terms, the Government of Chile has done nothing during 2007 to address the concerns of the U.S. Government and the pharmaceutical industry regarding data exclusivity that contributed to USTR's decision to place Chile on the PWL. Since January 1, 2000 (the World Trade Organization's deadline for Chile to subscribe to and implement TRIPS, which requires the establishment of data exclusivity), the ISP has granted sanitary registrations to 8 imitative pharmaceutical products, relying without due authorization on test data belonging to other companies. 5 of these cases have occurred since December 2005, when Chile adopted domestic legislation establishing data exclusivity, and 2 have occurred since January 8, 2007.

Patent Term Restoration

In January 2007 Chile approved new legislation that establishes the possibility of "supplementary protection" for pharmaceutical patents to compensate for unjustified administrative delays in granting patents and sanitary registrations. Although this supplementary protection represents an advance, it falls short of full patent term restoration as required by Chile's bilateral trade agreement with the United States. The legislation gives the regulatory authorities excessive discretion in determining whether or not an unjustified administrative delay has occurred, and it unduly limits what constitutes an unjustified delay in granting a patent or sanitary registration.

Patent Cooperation Treaty

Chile's bilateral trade agreements with the European Union and the United States require Chile to subscribe to the Patent Cooperation Treaty no later than January 1, 2007. As of December 2007, the Chilean Congress had failed to approve the necessary legislation, with the result that Chile is now one year overdue in complying with this important obligation.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

COSTA RICA

Costa Rica has not corrected deficiencies in its intellectual property regime since the last Special 301 review process in 2007. As explained in previous submissions, Costa Rica does not provide test data protection as required by TRIPS Article 39.3. Significant changes to its patent law are required in order to comply with other elements of the TRIPS agreement and the Paris Convention, such as an effective 20-year patent term and elimination of procedures to forfeit a patent for failure to "work" the patent locally. Draft bills proposing amendments to the Patent Law have been submitted to Congress, but none of the proposed amendments address test data protection or the deficiencies described above. These bills are not fully consistent with the TRIPS agreement or the DR-CAFTA. Costa Rica's Patent Office has serious delays in processing patent applications; furthermore, the Office lacks resources to conduct its own patent examinations and relies instead on outside examiners, which may result in conflicts of interest.

PhRMA recommends that Costa Rica be elevated to the **Priority Watch List** because of the Government's continued failure to take steps to fulfill its existing international commitments and those in anticipation of the entry into force of CAFTA.

Intellectual Property Protection

Data Protection

The provisions for the protection of certain pharmaceutical test and other data, contained within the "Undisclosed Information Law", are limited and ineffective. These provisions contain exceptions, limitations and omissions that are inconsistent with the TRIPS Agreement or the DR-CAFTA. 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 and fails to specify a term of protection against unfair commercial use. As no implementing regulations have been promulgated to clarify ambiguities and omissions such as the term of protection, Government authorities argue that data protection cannot be applied and have failed to protect test data. In addition, the Law requires "deposit before a certain authority," of what is considered undisclosed information; failure to deposit this information may result in the denial of protection. This deposit requirement is inconsistent with the TRIPS Agreement.

Linkage

Costa Rica does not provide a system to ensure that the health agency will not approve a sanitary registration to a second applicant for a product that is

claimed in a patent. PhRMA members look forward to Costa Rica implementing the provisions related to linkage in DR-CAFTA promptly.

Patent Issues

Article 17 of Law No. 6,867 (Law on Patents of Inventions, Designs, and Models) does not comply with a 20-year patent term as established by TRIPS Article 33 and Article 4*bis* of the Paris Convention that is incorporated by reference into the TRIPS Agreement. The term begins on the date of filing of the patent application in the country of origin, rather than from the filing date of the application in Costa Rica as required by the TRIPS Agreement and the Paris Convention.

Article 18 of Law No. 6,867 requires patent holders to "work" the patented invention in Costa Rica either by local production or by importation. If the patented invention is not worked sufficiently within the specified periods (three years from grant or four years from filing), competitors may request a compulsory license to work the invention. If the invention is not worked sufficiently within one year of the specified periods, the patent will be forfeited even if a compulsory license was not granted. This forfeiture requirement is inconsistent with Paris Article 5 that prohibits countries of the Paris Union from forfeiting patents unless compulsory licenses do not provide for sufficient working and not before the expiration of two years from the grant of the first compulsory license. The obligations in Paris Article 5 are incorporated into the TRIPS Agreement by TRIPS Article 2.

The Costa Rican patent law provides for any third party to file opposition against a patent filing; a de facto pre-grant cancellation procedure. This procedure may provide the means to delay grant of a patent, since if the opposition is rejected by the patent office, the third party may bring an appeal before the Administrative Tribunal. Until the Tribunal completes its review, the patent office cannot grant the patent.

Inadequate IP Infrastructure and conflict of interest in patent examination

The Intellectual Property Registry has not improved its capabilities regarding patent procedures and serious delays in patent examination and minimal issues of patents remain of concern to the pharmaceutical industry. From 2004 through 2006, more than 1700 filings for patents and utility models have been filed in Costa Rica yet only 34 patents were granted.

Market Access Barriers

The sanitary registration process in Costa Rica is one of the slowest and most bureaucratic among the Central American countries. During 2006, delays arose resulting in substantive delays in the launch of new products and the

renewal of existing ones. New provisions in force require certain documentation from innovators that results in discrimination in comparison to that requested of copiers.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

VENEZUELA

Beginning in 2002, the number of pharmaceutical patents granted by the Venezuelan intellectual property agency, (SAPI), fell dramatically compared to other economic sectors. Beginning in 2005, Venezuela stopped granting patents in all technical fields, in a clear violation of TRIPS Articles 27.1 and 62.2. Furthermore, 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 was never provided. In October 2007, the National Assembly approved an amendment to article 98 of the Constitution, in which intellectual property rights were eliminated, except with respect to copyright. However, this amendment was later rejected, along with the rest of the constitutional reform, by the referendum that took place on December 2, 2007.

For these reasons, PhRMA recommends that Venezuela remain on the **Priority Watch List** in 2008.

Intellectual Property Protection

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 2007, the National Assembly approved an amendment to article 98 of the Constitution, in which intellectual property rights were eliminated, except with respect to copyright. This amendment was rejected as well as the rest of the constitutional reform by the referendum that took place on December 2, 2007.

Venezuela is one of the few countries in the region that has not acceded to the WIPO Patent Cooperation Treaty (PCT) and the WIPO Trademark Treaty. The Venezuelan Intellectual Property Agency (SAPI) does not support the entry of Venezuela into the PCT or subscription to the Trademark Treaty.

Data Exclusivity

In a departure from past practice (1998-2001) when 5 years of data protection was enforced, Venezuela began in 2002 to violate data protection principles by granting second sanitary authorizations through reliance on the

originator's data during the five year period. These actions are not consistent with TRIPS Article 39.3 as unfair commercial use of data is occurring.

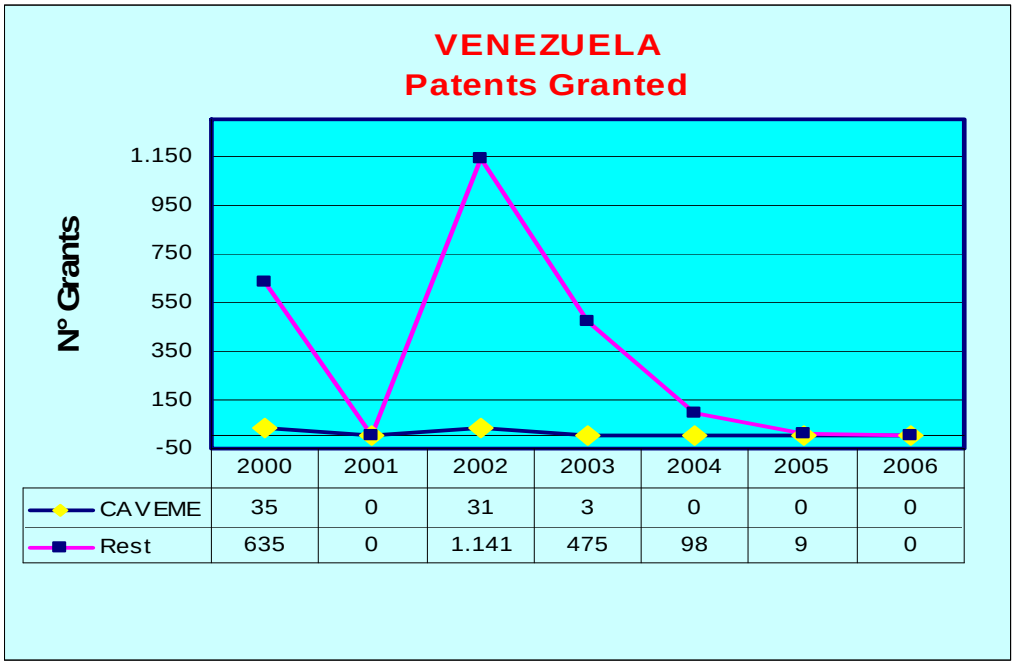
Since 2002, over 20 copies of original medicines obtained a registration from the sanitary authority (Instituto Nacional de Higiene) during the 5 year data protection term of the innovative drug. Research-based company challenges in the courts were unsuccessful. Many companies acted directly against infringers at the Venezuelan Antitrust Agency (Procompetencia), which dismissed all unfair competition claims. Claims were brought by pharmaceutical companies before the Administrative Courts and then before the Supreme Court of Justice, but both denied preliminary remedies and are processing claims with no decision in sight.

The copy products reached the market in 2003 and 2004, causing commercial 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 have aggregate numbers of the present and future losses.

In June 2005, the local 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. In 2006, the claim was accepted by the Court but has not yet been decided.

Patent Slow Down

Between 2001-2005 the average number of patents requested by CAVEME members was 270 per year. Nevertheless, in the same period, the number of patents granted by the government of Venezuela (SAPI) dropped to zero. Effective intellectual property protection is plainly not being provided for pharmaceutical products. Between 2001 and 2004 SAPI continued granting patents in fields other than pharmaceuticals, but since 2005 has ceased granting patents in all technical fields.



	2000	2001	2002	2003	2004	2005	2006
CAVEME	35	0	31	3	0	0	0
Rest	635	0	1.141	475	98	9	0

Source: SAPI; data compiled by CAVEME

Market Access Barriers

On market access issues, Venezuela took helpful steps in 2003 to reduce government intervention, limiting price controls to a list of essential medicines, as defined by the WHO. Although Venezuela has made some limited progress on reducing price controls and foreign currency limitations, additional steps are required. In addition, PhRMA members have serious concerns with preferences given to local manufacturers.

Government price controls

Government price controls for medicines were established in Venezuela in 2003 for Essential Medicines, as defined by WHO. These medicines are approximately one third of the number of medicines marketed in Venezuela. Most of the Essential Medicines are off-patent medicines, and represent nearly 80% of government purchases and no less than 30% of those in the private market. This price control policy continues in effect today (minor price adjustments were made in September 2005) and is expected to continue for the foreseeable future. The prices of Essential Medicines have not been revised sufficiently to take into account the March 2003 – February 2007 accumulated inflation (91,51%) and devaluation (34,8%), adversely impacting companies and distorting the market.

Foreign currency access policy

Rigid and restrictive controls on access to foreign currency were established in 2003 for all economic sectors. Improvements were made in 2004, 2005 and 2006, thus easing access to currency for main industrial and economical needs. Nevertheless, uncertainty persists over the government's potentially inappropriate use of this policy at any time to develop a selective import policy, to control imports (as in the past), to force changing import suppliers, or to audit import prices.

As Venezuela is facing a shortage of various supplies, particularly food supplies, it is expected that the government will take action to allow more imports. In the short term, such actions should improve access to currency for the importation of medicines as well.

Counterfeit medicines and other illicit activities

Venezuela is experiencing increasing numbers of counterfeit medicines (more than 10% of the market) and other illicit activities in pharmaceuticals, such as smuggling, robbery and adulteration. The increase in counterfeiting and other illicit activities involving medicines can be explained by a combination of factors, including the government's lack of awareness of the problem, administrative inefficiency, poor laws, with bad or no enforcement, low penalties and an ineffective judicial system.

VAT

Also of concern is a 2002 law that establishes VAT payments and exemptions. To obtain an exemption, a manufacturer must submit to the government a letter stating that the product is not being manufactured in the country. The government, however, considers that illegal copy products manufactured in the country qualify as local production, burdening imported original medicines with the VAT.

Government Procurement

The Venezuelan Bidding Law (*Ley de Licitaciones*) must be applied to all government procurement, requiring all government entities to open competitive bidding processes for the purchase of all goods and services (including pharmaceutical products). Public entities may only award contracts directly and without a bidding process within certain circumstances, when the requirements set forth in the Bidding Law are met. However, in practice, the Bidding Law is currently not strenuously enforced by Venezuelan authorities. It is very common in Venezuela for (i) public contracts to be awarded with complete disregard to the Bidding Law, or (ii) based on aggressive interpretations of the exceptions set

forth in the Bidding Law, therefore avoiding a competitive bidding process. The lack of enforcement of the Bidding Law results in lack of transparency in government procurement.

The Bidding Law contains local content criteria under which (i) public entities must take the necessary actions in their public bidding processes to ensure the maximum participation of local products and services, provided by small and medium-sized Venezuelan companies, (ii) if the price of competing bids is not different by 5% or more, then the contract must be awarded to the bidder who (a) is a Venezuelan company, and (b) included more local content (employees, goods and services). Public entities may give preference to a local company over a foreign company only if the above conditions are met. However, public entities have shown disregard for such limits and have awarded contracts without complying with the limits included in 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. This represents new and onerous financial loads for companies.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

MIDDLE EAST / AFRICA / SOUTH ASIA

ISRAEL

The level of pharmaceutical intellectual property protection provided by the state of Israel falls considerably short of international standards. Over the last 9 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 ineffective protection of innovators' clinical data.

Israel's IP policies in the pharmaceutical field are based on the violation of the principle of national territoriality, and are explicitly aimed at providing local generic exporters with an unfair commercial advantage in major markets in the US and in the EU.

Also, the Government's practices and inefficiencies with regard to the registration of innovative pharmaceutical products, which currently also leads to the shortening of exclusivity periods, create a hostile and unstable environment for the commercial interests of U.S -based companies.

For these reasons, PhRMA recommends that Israel be designated as a **Priority Watch LIST** country in the course of the 2008 Special 301 Review Process.

Intellectual Property Protection

Over the last 9 years, the protection of pharmaceutical-related IP rights in Israel has been eroding dramatically. Five areas are the focus of the industry's concerns: 1) The circumvention of the principle of national territoriality vis-à-vis the so-called Israeli "Linkage Mechanism"; 2) The 2005 amendment to the Patents Act that considerably shortens the patent extension term and that would possibly nullify it completely; 3) Inadequate protection of regulatory registration data (data exclusivity); 4) Substantial delays in the grant of patents (ineffective system of pre-grant patent opposition); and 5) The government's intention to make void the principle of unjust enrichment with regard to proprietary products.

Circumvention of the principle of national territoriality – the Israeli "Linkage Mechanism"

Under the Israeli Patents Act and the Pharmacist Ordinance, patent extension and regulatory market exclusivity periods are linked to the earliest date of product approval in any of the Recognized Countries[25]. As a result, the de-facto exclusivity periods of patent extensions and regulatory data exclusivity in

25. For the purpose of this amendment the list of Recognized Counties shall include: the US, EU-15, Switzerland, Norway, Iceland, Japan and Australia.

Israel are considerably shorter than is stated in their respective laws. This type of "Linkage Mechanism" leads to situations whereby US innovators are unable to obtain meaningful protection in Israel.

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

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

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

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

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

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

Pharma Israel, the association of the research-based pharmaceutical companies, estimates that this retroactive application will bring about an immediate cumulative reduction of 200 years of patent extension certificates granted in Israel. It is also estimated that the average annual loss from this retroactive enactment is $US 350 Million.[26]

Regulatory Exclusivity – Pharmacist Ordinance, Article 47 (entered into force – April 2005)

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

However, only in March 2005 did Israel enact sub-standard legislation after drawn-out negotiations with the U.S. Government, which ultimately proved fruitless in gaining effective protection for registration files in Israel. The legislation curtailed the period and scope of non-reliance on the data, while at the same time effectively permitting reliance on the originators’ dossiers for export.

In stark contrast to the accepted standards of developed countries, Article 47 D(2) of the Pharmacists Ordinance allows the Ministry of Health to rely on the innovator's data to register generic products during the exclusivity period. More importantly, the Ministry of Health can rely on the registration data to approve the export of generic products to other markets. This sub-standard type of protection ensures that local generic companies would enjoy an unfair competitive advantage over their US and other generic competitors when submitting generic products for registration in other markets.

While the United States affords 5 years of data exclusivity (4 years with a patent challenge)and the EU allows approvals after 10 years (8 years of data exclusivity but the patent cannot be approved before 10 years have passed, Article 47D(b) (2) leads to a protection period significantly shorter than 5 years. It provides either a 5 year exclusivity from the day of product registration in Israel, or 5.5 years of exclusivity period from the day of the earliest registration in any of the ‘Recognized Countries’ (as stipulated by the Pharmacists Ordinance), whichever is shorter.[27] However, as a result the Israeli Linkage Mechanism explained above, the effective term of regulatory market exclusivity in Israel today is less than five years. This is because it currently takes the Ministry of Health between 15 to 18 months on average to approve a new pharmaceutical

[26]. Estimates are based on market size figures of 2006.
[27]. Under the Pharmacist Ordinance, the list of Recognized Counties includes: the US, EU-15, Switzerland, Norway, Iceland, Japan, Australia, Canada and New Zealand

product in Israel, from the day it was registered in a Recognized Country. As such, the regulatory market exclusivity period afforded in Israel to innovative products amounts to a much shorter period.

It should also be noted that in July 2007, the MoH issued a new guideline for the establishment of a set time framework for the registration of pharmaceutical products in Israel according to which a new chemical or biological drug would be registered within 365 days of the date of submission. As such the maximum period of regulatory exclusivity granted to innovators in Israel would by definition be no more than 4.5 years.[28]

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 have been registered in any of the Recognized Countries after July 2005 are eligible for protection. This means that if companies intend to register in Israel new products that are already marketed before July 2005 elsewhere, these products would not be protected. This runs counter to the basic rationale of the legislation, aimed to provide incentives for new medicines.

Substantial delays in the grant of patents – the system of Pre-Grant Opposition

The Israeli Patent System is based on an Examination-system, in which patent applications are thoroughly examined by technically competent examiners. However, current statistics suggest that it takes six years on average until the examination of an application for a pharmaceutical or biotechnological patent is completed in Israel.[29] As a result of this unusually long examination process, U.S. innovators lose a significant part of effective patent life to which they are entitled.

Once an examiner deems that the invention is worthy of patent protection and accepts the application, under Article 30 of the Israeli Patents Act, any competitor may block the patent grant simply by filing an opposition to the patent

[28]. Ministry of Health, Draft Guidelines for the Evaluation of Product Registration (time tables), page 7, 26 November 2006, (translated from Hebrew). According to the Pharmacist Ordinanace the maximum term of exclusivity provided by the is 5.5 years exclusivity from the day of the earliest registration in any of the 'Recognized Countries' (as stipulated by the Pharmacists Ordinance), whichever is shorter (as mentioned above). This in turn means that the built-in delay in the Israel registration system of 360 days will automatically "shave off" a year from the 5.5 years of exclusivity, which brings the maximum de facto term of exclusivity to 4.5

[29].http://www.justice.gov.il/MOJHeb/RashamHaptentim/Ptentim/application+for+fast+examination.htm

application. Resolution of the opposition may take many more years so that the patentee is actually deprived of the remainder of the period of exclusivity to which it is entitled.

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

The combination of the system of pre-grant opposition and the inadequate level of protection provided by the marketing exclusivity legislation essentially denies research-based pharmaceutical companies any meaningful tool to protect their marketed products against the premature and unfair launch of generic products. This problem was aggravated in September 2006 when the Government of Israel (via the Attorney General Office, Ministry of Justice) expressed a position according to which IP owners should be denied the right to use the principle of Unjust Enrichment in legal disputes that concern proprietary pharmaceutical products.

Market Access Barriers

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

Marketing approval (Registration) deficiencies and delays

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

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

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

(3) The inconsistency between the Government of Israel’s statements concerning the time period required for the registration of new

pharmaceutical products in Israel, and the de-facto period that such registration currently lasts.

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

In recent years, there has been a significant prolongation of the registration process of innovative products in Israel. Due to such delays, the average period for the registration of a new drug in Israel, from its date of approval in a Recognized Country, has increased from 6 months in 2003 to the current period of 15-18 months in 2007.

Moreover, current budgetary problems in the Institute for Standardization and Control of Pharmaceuticals of the MOH, as well as other inefficiencies, result in the increasing delay in the examination of products' registration dossiers, without any foreseeable improvement in the near future. Currently there are more than 250 medicines in Israel waiting for approval.

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

In addition, PhRMA member companies continue to be adversely affected by a GATT-inconsistent amendment to Art. 47 of the Pharmacists Ordinance (dated 2002) that allows for a 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. Imported innovative products cannot take advantage of this fast track procedure. This amendment benefits only local generic producers, and thus appears to be inconsistent with GATT Article III obligations relating to National Treatment.

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

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

LEBANON

In 2007, Lebanon continued to deny effective protection for undisclosed pharmaceutical test and other data. Health officials erroneously argue that public summaries and conclusions from innovators related to safety and efficacy of an innovative product are a sufficient basis for the independent approval of copied products. Further, they claim that they do not rely on the data of the innovator when they actually must rely scientifically on the undisclosed data used to generate the summaries. Also, protection (transitional or pipeline) has not been provided to pharmaceutical products that were not covered by the 2000 industrial property law, but that have received protection in other countries. Moreover, counterfeit pharmaceutical products are entering the Lebanese market but steps have not been taken to improve IPR enforcement in an effort to eliminate these counterfeits.

During 2007, industry members met with the Minister of Economy and Trade and had follow-up meetings with his staff. However, no positive developments occurred. Also, the Minister of Health has encouraged and facilitated the marketing approval of several unauthorized copies, while their patents are still valid in the counties of origin. For these reasons, PhRMA recommends that Lebanon remain on the **Priority Watch List** in 2008.

Intellectual Property Protection

Transitional Protection for Inventions

In July 2000, Lebanon enacted a new industrial property law that extended patent protection to pharmaceutical products. Unfortunately, the new law did not provide transitional protection for pharmaceutical products that could not be protected under that new law but that were protected in other countries and not yet marketed in Lebanon. This type of transitional protection is often referred to as "pipeline" protection because it offers incentives to market pharmaceutical products that are the subject of patents but that are still in the development pipeline and yet to be marketed.

Data Exclusivity

Article 47 of the current patent law requires Lebanese authorities to protect certain undisclosed pharmaceutical test and other data from unfair commercial use and disclosure. The Government is supposed to require information on safety and efficacy of all products for which marketing approval is sought in Lebanon. In reality, the Ministry of Health requires complete data from the innovative companies but approves copies of innovative products on the basis of summaries of such data or conclusions drawn from the data published in medical journals or in educational material on the Internet. Officials argue that

they only rely on data supplied by submitters and it is not their responsibility to determine the true source of the data. Thus, they argue that Article 47 is not applicable because they do no rely on the data of others. In the view of PhRMA members, the summary information submitted by copiers is not sufficient to support a scientific conclusion that the copied products are safe and effective without a reference to or reliance on other information. Thus, Ministry officials are still relying indirectly on the data supporting the safety and efficacy determinations associated with the innovative product but are not applying Article 47 as required by Lebanese law. An active dialogue with the Ministry of Economy has not yielded any progress on this front. The Ministry of Health is not considering themselves as a concerned party in this issue.

Parallel Importation

Legislation enacted by Lebanese Parliament in 2002 allows parallel importation of goods. Goods imported directly by the manufacturer must meet all of the Lebanese sanitary and labeling requirements. Goods from the same manufacturer imported by others in parallel do not have to meet the Lebanese sanitary and labeling standards.

Counterfeits

During 2007, industry representatives reported to the government that there was a a considerable expansion of trade in counterfeit pharmaceutical products. These products are often difficult to identify by consumers and pharmacists. We expect that this continuing trade in counterfeits will become one of the significant health hazards in the country due to the absence of effective surveillance by the authorities.

While the law on counterfeiting is clear and stipulates up to three years imprisonment, enforcement is not consistent and fines levied by the Judiciary are too low to deter counterfeiters. Recently, two industry members filed a lawsuit against a hospital for providing counterfeit products. Both cases are still at the police investigation level.

Industry members are trying to address this issue with the help of other stakeholders, including the Pharmacist Syndicate, the American Lebanese Chamber of Commerce, and the Brand Protection Group. Some industry members have launched campaigns to educate pharmacists about the difference between an original and a counterfeit. Another industry member is organizing a two-year comprehensive campaign on counterfeits; outreach has so far targeted the media, physicians and pharmacists. A media campaign launched by the American Lebanese Chamber of Commerce called on consumers to use the original drug to avoid any health hazard. Recognizing the importance of cross-industry alliances in developing effective advocacy strategies, two industry

members joined the Brand Protection Group, an association dedicated to fighting counterfeits in all sectors.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

PAKISTAN

Despite significant efforts by PhRMA members to educate Pakistani officials on the importance of data exclusivity, Pakistan has not implemented protection for certain pharmaceutical test and other data as required by TRIPS Article 39.3. Pakistan also has failed to complete the examination of patent applications (*i.e.*, mailbox applications) filed in accordance with procedures to implement TRIPS Article 70.8. There continues to be no linkage between health authorities and the patent system to prevent the issuance of marketing approvals for patent-infringing products. Hence, through non-transparent methods, the MOH grants marketing authorization to infringing generic products when related patents have either been granted or are in the process of being approved.

For these reasons, PhRMA recommends that Pakistan be placed on the **Priority Watch List** for 2008.

Intellectual Property Protection

Lack of Data Protection

Pakistan does not protect certain pharmaceutical test and other data against unfair commercial use and disclosure as required by TRIPS Article 39.3. Local generic manufacturers continue to use the scientific data of the original, innovative product in their registration applications without authorization, and the MOH relies on innovator data to grant marketing authorization to generic products in violation of TRIPS. PhRMA member companies have actively worked over the last year to promote legislation that includes comprehensive definitions of “new chemical entity” and “undisclosed test or other data” to ensure that all undisclosed innovator data that is submitted to the drug regulatory authority as part of the marketing approval process receives adequate protection. Pakistan’s data protection legislation also should include clear language stating that the Government of Pakistan will protect innovator data against unfair commercial use through non-reliance. While a legislative proposal to protect such test and other data is currently with the Law Ministry, such legislation has yet to be submitted to the President for approval.

Lack of Patent Protection

Patent protection for pharmaceutical products in Pakistan is deficient in several ways. First, there is a significant backlog of patent applications that are not being reviewed in a timely manner. This backlog needs to be eliminated in order to provide effective patent protection to pharmaceutical products. In the meantime, a transitional rule is needed for those pharmaceuticals that have received patent protection in other jurisdictions, yet remain part of the backlog of pending applications in Pakistan. For those patented pharmaceuticals, the MOH

should delay marketing approval of generic products until the Patent Office rules on the pending patent applications. Second, for those products that are protected by patents in Pakistan, there is no formal process to ensure that the MOH does not grant market authorization to patent-infringing products. A linkage system between patents and health authorities, including provisions to give the patent owner notice of the identity of the person requesting marketing approval, would ensure that patent rights are respected.

Compulsory Licenses

Subsections 58(1)(iii) and (iv) of the Patents (Amendment) Ordinance, 2002, respectively, authorize patent compulsory licenses if "the patent holder refuses to grant a license to a third party on reasonable commercial terms and conditions" and if "the patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology." These grounds for granting a compulsory license appear to require the patent owner to license to any and all requesters. This would be inconsistent with the concept of exclusive rights in TRIPS Article 28 and the concept of authorizing compulsory licenses on their "individual merits" under TRIPS Article 31(a).

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

SAUDI ARABIA

The research based pharmaceutical companies are troubled by developments undertaken by the government in Saudi Arabia. Unilateral government pricing policies and lack of effective intellectual property rights protection constitute serious market access barriers for innovative pharmaceutical products. The Saudi patent law created by a Decree in 2004, allows patents for pharmaceutical products, but did not provide for the conversion of patent applications submitted under the old system to patent applications under the new law. Moreover, the Ministry of Health no longer provides administrative protection for inventions claimed in the applications filed under the previous law. Consequently, PhRMA members have been denied protection for many valuable inventions. PhRMA proposed that Saudi Arabia adopt transitional provisions to eliminate this inequity, but Saudi officials took no such action in 2007. Also, the Saudi Ministry of Health unilaterally decided to start the implementation of a "Riyalization" policy that will discriminate against U.S.-origin, innovative products, and to reduce CIF prices for products more than Saudi Riyal (SR) 20 by 1 % annually from the date of regulatory approval, beginning in February 2008.

For these reasons, PhRMA members request that Saudi Arabia be elevated to the **Priority Watch List** in 2008.

Intellectual Property Protection

Until 2004, Saudi patent law allowed inventors to file patent applications for pharmaceutical products patented elsewhere; patents granted on these applications were called "confirmation" patents. While more than 1,500 such applications were filed in Saudi Arabia, Saudi officials never examined the applications. Rather, Ministry of Health officials refrained from granting marketing approval for copies of the pharmaceutical products covered by these patents, until the patents in the country of origin lapsed. In short, PhRMA members relied on a *de facto* form of administrative protection because Saudi officials failed to provide protection under the patent law.

In 2004, the *Patents, Layout Designs of Integrated Circuits, Plant Varieties and Industrial Models Law*, Decree M/27, was promulgated. This Law allowed for the granting of patents for pharmaceutical products that were, among other requirements, innovative. The Law eliminated the procedures relating to the confirmation patents without providing for the conversion of these applications to patents under the new Law. Consequently, the inventions in the applications for confirmation patents could not be protected under the new Decree because they were not novel (they had been disclosed before the date of the new Decree).

In September 2007, the Ministry of Health granted marketing authorization to copies of innovative drugs in an unprecedented move. PhRMA members are alarmed about the MOH's registration of those copies, and now have less intellectual property rights protection for their products than they had prior to Saudi Arabia's accession to the WTO. PhRMA did not envision this result when we strongly supported Saudi Arabia's WTO membership.

To remedy the patent protection difficulties that PhRMA members are facing in Saudi Arabia, PhRMA is still waiting for Saudi Arabia to adopt transitional protection in the form of time-limited exclusive marketing and manufacturing rights for certain U.S. pharmaceutical products. This proposal is limited to only those drugs that have been 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 adoption of the new Saudi law. 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 a particular country. The concept of transitional protection was also recognized in TRIPS.

Although industry members provided the Saudi government with examples of products to be included under the EMR proposal based on their request, the Saudi government position is still unclear. There is at present, however, no reported timetable or process to bring this concept to closure.

Market Access Barriers

The Saudi Ministry of Health is still applying a nontransparent-pricing policy and takes unilateral decisions related to pricing of pharmaceuticals. Recently, the Ministry of Health decided to implement the "Riyalization" policy, *i.e*., converting euros and other European currencies CIF prices to Saudi Riyal-based prices on a theoretical exchange rate, and decided unilaterally to reduce CIF prices for products more than Saudi Riyal (SR) 20 by one percent annually from the date of approval (this will enter into effect on February 1, 2008). They have given an exemption for "life saving products," although the definition of what constitutes "life saving" is not clear.

Currently, when determining prices for pharmaceutical products, the Ministry still reviews information on prices from thirty countries that are not comparable to Saudi Arabia in terms of living standards, income levels, consumer choices, exchange rates, regulatory requirements and/or drug consumption patterns. The Saudi government then bases their price on the lowest price of those thirty countries.

The process for obtaining marketing approval in Saudi Arabia is lengthy (16-24 months) and is not transparent. PhRMA members do not have a clear idea of what documents are needed to obtain marketing approval. While final approval is conditioned on the report of a central laboratory, this report cannot be requested until the grant of "primary approval" although there is no substantive reason for delaying the request until the primary approval is received.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

WATCH LIST

ASIA-PACIFIC

MALAYSIA

The Malaysian market for innovative pharmaceutical products is dynamic and growing. The Malaysian Government has been taking steps to enhance intellectual property protection and thereby fostering a good environment for patients and industry. A significant milestone is the recent announcement by the government that five years of data exclusivity will be provided for new chemical entities and three years for new indications. While this is a positive indication of Malaysia's commitment to intellectual property, legislative changes have yet to be finalized. PhRMA members encourage the Government of Malaysia to adopt patent linkage requirements, aggressively prosecute producers and distributors of counterfeit drugs, and require bioequivalence data and manufacturing process information for all generic applicants.

In 2006, Malaysia and the US announced their intention to enter into a Free Trade Agreement (FTA). Even though the negotiations failed to meet the June 2007 US Trade Promotions Authority expiration period for fast-track approval from the US Congress, talks between both countries are still ongoing. This FTA is significant given that the US is Malaysia's largest trading partner, largest foreign investor, and is a leader in research and development for new cures for the most debilitating and deadly diseases globally, particularly that of tropical countries. PhRMA views the US-Malaysia FTA as an appropriate means in which to to address significant intellectual property and market access concerns for the research-based pharmaceutical industry in Malaysia. Until such intellectual property protection concerns, as laid out in this submission, are remedied, we recommend that Malaysia be placed on the 2008 "Special 301" **Watch List**.

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, all issues related to the implementation of DE such as legislative amendments have yet to be worked out and the implementation deadline has been delayed to early 2008. PhRMA is of the view that 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

and thus, urges the government 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. As a result, PhRMA member companies have encountered instances of generic products being registered and brought to market while patents remain valid. 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 proposed generic product is still in force.

A system of patent linkage has a number of advantages that enhance the environment for pharmaceutical development by: (1) providing transparency and predictability to the process for both the pioneer and the generic company; (2) creating a more predictable environment for investment decisions; and (3) ensuring timely redress of genuine disputes. Conditions that allow better-informed and more efficient investment decisions can encourage product introduction and development of life-saving inventions and better healthcare.

By establishing and ensuring adequate "linkage," the Malaysian Government could contribute significantly to an environment that attracts innovation and encourages growth in the life sciences sector.

Counterfeits

Stronger criminal penalties and improved enforcement efforts are among the most effective means for deterring counterfeits. PhRMA supports close coordination between the U.S. and Malaysian Governments on anti-counterfeit initiatives, including training for regulatory and security officials and the tightening of the legal framework to include an efficient legal process to prosecute counterfeiting crimes. The government has since created a dedicated IP Court and we look forward to more effective and expeditious disposal of counterfeit cases in the future.

Market Access Barriers

Bioequivalence Requirements

Although a requirement for bioequivalence studies for generic was recently put in place, the list of therapeutic areas for which data are required is limited at this time. Only 85 generic drugs are required to provide bioequivalence data. In line with the Ministry of Health's objective to ensure quality, safety and

efficacy of products registered in Malaysia, we recommend that the Government of Malaysia introduce further categories & products to the list to ensure that all generic products available are therapeutically equivalent to the innovator's products and are clinically interchangeable. In practice, demonstration of bioequivalence is generally the most appropriate method of substantiating therapeutic equivalence between drug products.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

TAIWAN

PhRMA members support the continuation of the Trade Investment Framework Agreement (TIFA) between the United States and Taiwan. The TIFA discussions provide a platform to discuss health policy reform measures that directly impact the commercial environment for PhRMA member companies in Taiwan.

During the course of TIFA discussions, PhRMA has recommended that the Government of Taiwan focus on eliminating Taiwan's pharmaceutical price gap, otherwise known as the "Black Hole." The Black Hole seriously distorts trade by creating a financial incentive for Taiwanese hospitals and medical practitioners to favor the prescribing and dispensing of domestically-produced generic medicines over high-quality imported medicines that embody the latest biomedical advances.

More importantly, the Black Hole jeopardizes the health and well-being of Taiwanese patients by encouraging inappropriate prescribing, promoting massive over-prescribing, and increasing the potential for risks of adverse drug interactions. Because addressing the Black Hole would require structural reforms of the Taiwanese pharmaceutical pricing and reimbursement system, including an effective policy to regulate both healthcare providers and suppliers, separation of dispensing and prescribing (SDP) and actual transaction pricing (ATP), it will require a sustained effort over time. Accordingly, 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 2006 TIFA talks yielded agreement to form two joint working groups to work towards certain system reforms in Taiwan: one on actual transaction pricing (including the separation of prescribing and dispensing); the other on a standard drug purchasing contract for use by hospitals. PhRMA members are concerned that there has been little progress made in relation to formation, meetings, actions and Industry engagement by the working groups.

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 members remain willing to assist in this regard. Just prior to the 2007 TIFA talks a range of pricing proposals were announced by the Government of Taiwan. Some of these are very concerning to PhRMA members and it is understood that a commitment to consult with Industry on those proposals was provided by the Government of Taiwan. This is a crucial commitment for PhRMA members who have been concerned by the Government of Taiwan's lack of overall consultation on policy reforms. On other issues, the

2007 TIFA talks deferred to the two working groups and it is clear that these urgently need to be constituted and focused on a work program.

Because of the 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 2008 "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 gathered 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 outlined to the Government of Taiwan cases in which the absence of patent linkage has seen local generic products proceed to market (including hospital listing and procurement) following the granting of licensing approval and NHI price but in infringement of and during the valid term of an innovative medicine's patent. We believe that the Taiwanese Government should adopt a patent linkage system that is similar to that of the U.S. and that it include the following: (1) notification to the originator (by the generic manufacturer or the

government) when a generic company files an application for a product with the same active ingredient and (2) a requirement that the regulatory agency suspend the approval of a generic application that the originator feels violates its IPR for a reasonable period of time (30 months in the U.S.) if the originator of the medicine decides to initiate legal action against the applicant *before* the generic goes on the market.

Market Access Barriers

Violation of National Treatment

Article 49 of the National Health Insurance law mandates reimbursement of healthcare providers at actual transaction cost. This law is not enforced. Producers of generic drugs, with little or no research and development costs to recoup, offer significant discounts to cash-strapped healthcare providers due to the reimbursement policy that sets high prices for generics (80% of the originator price). Industry supports strong enforcement of Article 49 by the Government, so that product bonuses, discounts and other forms of promotion are accurately captured.

At present, periodic Price-Volume Surveys (PVS) are conducted by the Government with the intent of clawing back these monies “provided” by drug suppliers. These surveys lead to reductions in reimbursement prices that provide an immediate savings to government, but fail to resolve the underlying financing shortfall. These surveys, with other policy measures in Taiwan, have seen the prices of innovative pharmaceuticals set by the government spiral down significantly in recent years and at the same time have delivered no substantive improvements to the system.

The Black Hole (hospital or clinic margins) can not be resolved through the PVS process; it distorts the nature and magnitude of payments by Government, influences unusual and unethical prescribing patterns, and puts patient welfare at 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 substantive reform. Price-volume surveys aimed at clawing back margins from health providers through drug discounts from industry do little to address the root of the problem, but rather foster an environment that rewards local generic manufacturers, stifles innovation, and places patients at risk.

PhRMA continues to be disappointed that the Government of Taiwan has failed to provide a clear and strong implementation of Article 49 that prohibits 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. PhRMA notes the strengthened measures incorporated in the 5th PVS re-check.

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. A cumbersome regulatory system that imposes costs and conditions discriminatory to foreign companies, high generic pricing (up to 80% of innovative drug prices), innovative drug pricing far below international median levels and close to the lowest in the world, and a non-transparent system in which high-price and high-margin generics provide a financing solution to healthcare providers benefits a local generic industry that has its sights set upon a government-aided biotech future. PhRMA believes these practices are in violation of WTO national treatment principles. We are concerned at the lack of real action and reform flowing from the TIFA talks to date. Substantive reform is much needed, and greater Industry consultation would help, to bring the Taiwanese healthcare system to a fair and transparent operation in support of better quality healthcare.

Reward for 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) in the last two years.

Drug reimbursement guidelines contravene internationally accepted norms by severely restricting the use of innovative medicines and disregarding many innovative products' approved indications.

Clear, detailed, and objective written criteria and timelines are needed for government pricing decisions and should take account of appropriate reward for innovation. These criteria should be developed and implemented in a fair, open and transparent process into which all stakeholders have a meaningful opportunity to 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 in Taiwan is an official requirement but one which is not enforced, in part due to a lack of political will and to a powerful hospital lobbying force. Separating prescribing and dispensing functions would effectively remove the profit incentive from the selection of appropriate treatments or therapies. As long as hospital revenue and physician

remuneration is dependent on margins provided by the drug manufacturers, patient welfare is compromised by this conflict of interest, i.e. profits over people.

While Taiwan has attempted to argue that local law does, in fact, require a separation of the two functions, the reality is anything but segregation. Outpatient pharmacies continue operating within all hospitals; clinics meet the separation criteria by "hiring" a pharmacist license and continue dispensing medicine in the same office.

One initial step toward achieving SDP would be to regulate the repeated chronic disease prescriptions in the hospitals, which are already subject to special prescribing practices under the NHI reimbursement, by requiring that they be filled by independent pharmacies instead of refilled within hospital pharmacies. Under current BNHI regulations, Taiwanese patients are not required to visit a doctor to refill a prescription for a chronic disease, e.g. asthma, hypertension, diabetes etc, 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.

This regulation would encourage SDP and could be regulated through new DOH/BNHI guidelines.

Until recently, BNHI provided Taiwanese physicians a special incentive for off-loading prescriptions to a private pharmacy, instead of requiring the prescriptions to 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 the BNHI to carefully monitor implementation of the new guidelines and consider reinstituting an incentive structure.

Hospitals account for 80 percent of the pharmaceutical market in Taiwan. SDP could be achieved in phases by implementing it initially in public hospitals, which are under greater government control. As some of the most advanced Taiwanese medical institutions, these hospitals could offer a useful model for the transition. In order to approach this, Taiwan could begin by utilizing the recommendation above of requiring chronic disease prescriptions to be filled by independent pharmacies. This would be a good first step towards SDP.

Actual Transaction Price

Article 49 of the National Health Insurance Law states that: "Drugs, 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. This step created the Black Hole; BNHI should resume reimbursing at actual transaction price 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

NDA Guideline

DOH proposed regulations in December 2006 which allow for expedited approval of generic products through an abbreviated new drug application (ANDA) or as it is referred to in Taiwan an gNDA (Global New Drug Application) or tNCE (Taiwan New Chemical Entity). The proposed regulations stipulate that if the originator does not submit an NDA to the Taiwan authorities within five-years of registration in certain major international markets that other manufacturers can submit a gNDA that will be reviewed through simplified registration requirements which rely on the originator's published papers to gain approval. However, the guidelines do not allow, in any circumstances, for the originator to submit a gNDA. This leads to two different NCE assessment systems. Industry regards this proposal as discriminatory treatment that would contravene international practice and be totally inconsistent with effective IPR protection.

Industry asks that the Government of Taiwan adopt an equal standard of new product registration regulations and eliminate the proposed dual way for non-originator's simplified NDA (g NCE) procedures, which violates the IPR and fair trade.

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 the companies to provide 2 Certificates of Pharmaceutical Product (CPP) from the A10 countries. However, U.S. FDA and Health Canada do not always issue CPPs where the products are manufactured outside the U.S. or Canada. This results in substantial delay to the review of new drug applications.

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

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

VIETNAM

On behalf of the U.S. research-based pharmaceutical companies, PhRMA welcomes Vietnam's accession to the WTO. Vietnam's WTO accession protocol enhances market access for U.S. firms and improves intellectual property protection.

Notwithstanding new laws and regulations passed in anticipation of WTO accession, market access barriers and intellectual property concerns remain. We welcome recent indications that the Vice Minister of Health is open to a dialogue on many of these issues, which are described in full below. Given these concerns, we recommend that Vietnam be placed on the 2008 "Special 301" **Watch List**.

Intellectual Property Protection

PhRMA commends the Vietnamese Government for issuing the Law on Intellectual Property Protection and the adoption of its WTO obligations under TRIPS. However, intellectual property enforcement remains an issue and there is no clear requirement or administrative process that facilitates establishing that a generic drug registration submission does not violate any patents issued by the National Office of Intellectual Property (NOIP) prior to regulatory approval. Currently the burden is on the patent holder to monitor the marketplace and alert the relevant authorities of intellectual property violations after they have occurred. PhRMA requests that the Vietnamese Government establish a clear mechanism to proactively protect intellectual property. This would further demonstrate the Government's clear commitment to enforce intellectual property protection and establish a strong intellectual property regime in Vietnam.

Data Exclusivity

Vietnam's Law on Intellectual Property protection includes a provision for five years of data exclusivity as part of implementing Vietnam's obligations under TRIPS. We welcome this provision and look forward to working with the Ministry of Health in building capacity in the implementation of data exclusivity. Included in Vietnam's new draft data exclusivity legislation is a requirement that a manufacturer must apply for data exclusivity. Vietnam would be the only country in the world to require this extra step. Countries that provide for data exclusivity should automatically provide data exclusivity upon approval of a drug. PhRMA requests that the Vietnamese Government put in place procedures that would provide for the automatic granting of data exclusivity upon approval of a drug.

Parallel Importation

On May 28, 2004, MOH issued Decision 1906/2004/QD-BYT, authorizing the parallel importation of medicines for the prevention and treatment of human disease. In the case of patented pharmaceutical products, importation by a non-patent holder from a third country violates the rights of the patent holder. Accordingly, the decision undermines the rights of innovators and should be addressed in the ongoing monitoring of Vietnam's accession commitments.

Enforcement

While the Vietnamese Government is making efforts to strengthen the system for enforcing intellectual property rights (patents, trademarks, copyrights), significant improvement is necessary. These rights are enforced by a range of different government authorities with varying degrees of resources and expertise, and with different procedures and powers. This ineffective collage of enforcement procedures is exacerbated by the fact that many of these authorities have discretion on whether or not to take action and can avoid doing so by referring complaints to another agency. The Vietnamese courts have little or no experience in interpreting or enforcing intellectual property rights. Moreover, it is difficult for courts to enforce their own judgments. Vietnam needs to engage in a comprehensive strengthening of its intellectual property rights enforcement regime, including proper enforcement of its newly created IP Law.

Regarding the Vietnam IP law and its decree on Dealing with Infringement of IP rights through Administrative remedies (Decree no. 106/2006/ND-CP, dated on 22 Sep 06), we would suggest the Vietnamese Government impose a fine for violation of intellectual property based on the value of sales of authentic goods to the rights-holder, not the value of infringing products. The value of such infringing products is too low to be an effective deterrent to infringers. Vietnam should accept the principle of imposing a fine according to the value of authentic goods, and only when the value of authentic goods cannot be determined, should the fine be based on the value of the copy product.

Infringement of Registered Pharmaceutical Trademarks

Although the new Civil Code and associated implementing legislation provide a clear legal basis for protecting registered intellectual property rights in Vietnam, infringement of registered trademarks is systematic and widespread, causing substantial financial losses to PhRMA member companies. State-owned pharmaceutical companies under the jurisdiction of MOH, and manufacturers and distributors from foreign countries figure prominently in infringement of the registered trademarks of PhRMA member companies.

In the absence of a formal administrative mechanism for enforcing registered intellectual property, a mechanism has evolved in practice to which

infringement victims primarily turn when they are unable to settle cases through informal discussions with the infringer. This involves petitioning the NOIP for a decision of infringement. While the NOIP has issued decisions of infringement in a responsible and timely manner, victims of infringement have encountered difficulties enforcing NOIP decisions through the de facto administrative mechanism for a number of reasons. These reasons include refusal of state-owned manufacturers and importers of pharmaceutical products to comply with the NOIP decisions, lack of clarity and/or cooperation between NOIP and MOH. PhRMA is hopeful that through implementation of the intellectual property law, that these issues will be addressed.

PhRMA urges Vietnam to improve its procedures for enforcing registered trademarks, particularly with regard to ensuring compliance with NOIP decisions by manufacturers, distributors, and administrative enforcement bodies.

Trade Dress

Vietnam has discriminatory loopholes in the current legal framework for protection of “trade dress”. This loophole allows companies to mimic or copy the product packaging of other companies, thereby trading unfairly on the hard-earned goodwill associated with the product’s “trade dress”. Vietnam should amend its intellectual property rights legislation to provide protection for both foreign and local companies from this type of unfair competition.

Counterfeiting

In Vietnam a high percentage of branded goods available on the market are believed to be counterfeited, placing the public at risk of consuming medicines of questionable or unknown quality. In addition to endangering human health, counterfeited medicines undermine confidence in legitimate medicines and waste limited healthcare resources. While the incidence of counterfeited consumer goods available on the market is understood to be high, the percentage of counterfeited pharmaceuticals in distribution in Vietnam is not quantified at this point. However, increasing vigilance and improved enforcement efforts regarding this important aspect of public health are required. This requires the adoption of additional enforcement measures and the allocation of additional resources to intellectual property rights enforcement in order to prevent widespread counterfeiting.

Local Working Requirement

To render the Vietnamese law consistent with obligations of Articles 27 and 31 of TRIPS (which are incorporated in the U.S.-Vietnam BTA), Vietnam needs to adopt measures that specify that importation of a patented product will be legally equivalent to manufacturing the product in Vietnam, and as a

consequence, be sufficient to block the grant of a compulsory license based on non-use or inadequate use.

Market Access Barriers

Governmental Trade Restrictions

Trading and Distribution Rights: The Vietnamese Government's Investment Law and the Commercial Law, and a clarification Decree No. 72, coupled with the WTO accession timeline present significant market access barriers for the research-based pharmaceutical industry. Under the WTO accession agreement a foreign pharmaceutical company can not incorporate in Vietnam until January 1, 2009 unless they establish local manufacturing or a joint venture with a Vietnamese company. In order to operate as representative offices in Vietnam foreign pharmaceutical companies can only establish representative offices and work through third parties. As a result, companies must engage a Vietnamese company to import, distribute or market their products.

This restriction has serious implications for the U.S. research-based pharmaceutical industry, physicians and patients. The barrier established between the pharmaceutical industry and healthcare providers raises a critical issue for patient safety. Multinational companies, by law, are not able to conduct information dissemination activities, limiting their control over the quality of information presented to physicians. This restriction may limit physicians' ability to provide the most appropriate medical care for their patients. Without direct interaction with healthcare providers, multinational companies may not receive complete information on adverse events related to the use of their products. PhRMA member companies are obligated to ensure that any health risks to Vietnamese patients are accurately monitored or addressed. For the benefit of the overall public health system in Vietnam, it is critical that research-based pharmaceutical manufacturers be permitted to provide scientific information about their medicines, including appropriate use, and potential side effects directly to prescribers.

PhRMA welcomes the opportunity to work with the Government of Vietnam on the implementing regulations to ensure that these issues are addressed.

Tariffs/Zero-for-Zero: Import duties on pharmaceutical products are quite high. The tariff rate is often not known until the products are imported and can vary by point of entry. Elimination of these import duties would help address these discrepancies and promote patient access to medicines.

The Government's Use of Reference Pricing

The Vietnamese Government recently announced changes to pharmaceutical pricing regulations under Circular 11/2007/TTLT-BYT-BTC-BCT that effectively implements a reference pricing scheme for PhRMA member companies, as well as other multinational firms prohibited from establishing legal entities in Vietnam.

At a time when the Vietnamese Government is making significant progress in implementing its WTO obligations in many areas, this reference pricing policy deviates from that goal. Under current Vietnamese Law this Circular would disproportionately discriminate against PhRMA member companies, inconsistent with GATT Article III, by explicitly exempting all products manufactured by domestic companies from key aspects of this pricing policy. The Circular stipulates that the price of imported medicine must be based on a company's cost, insurance and freight (CIF) price, which is referenced to the real average CIF prices in Myanmar, Cambodia, Laos and Indonesia. Under current Vietnamese law PhRMA member companies can not directly import products and must rely on third party arrangements, while the majority of the listed countries do not have such import restrictions. The difference in these legal requirements necessarily gives rise to differing commercial considerations and a different pricing environment. Therefore, the CIF price of pharmaceuticals in Vietnam should not be considered directly comparable to the real average CIF price in "neighboring countries." This form of reference pricing particularly impacts PhRMA member companies unable to establish full legal entities in Vietnam.

PhRMA requests that the Vietnamese Government halt the implementation of Circular 11/2007/TTLT-BYT-BTC-BCT and establish a forum for the research-based industry to provide meaningful input into the government's pharmaceutical pricing policies.

Product Registration

PhRMA believes that Vietnam's product registration regime, which is inconsistent with international standards and practices, should be reviewed in respect of the following issues:

a) *Discriminatory Enforcement of Product Registration Requirements:* At the same time that the Ministry of Health (MOH) is issuing more stringent product registration requirements, state-owned importers of pharmaceutical products under the jurisdiction of MOH continue to import and/or distribute products from companies that have not registered their products. Many of the unregistered pharmaceutical products infringe the registered trademark rights of others or violate applicable quotas.

b) *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 each government to confirm that a product has been licensed for sale within their country. However, the country of manufacturing/packaging may not be the country where the product is marketed. These requirements may result in a significant hurdle in applying for registration which has an administrative and commercial impact on PhRMA 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.

c) *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 still need to comply.

d) *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 that the generic product has the same therapeutic and chemical equivalence as the original innovative medicine. This policy exempts local generic manufacturers from important testing requirements fulfilled by research-based manufacturers. It is critical that Vietnamese companies conduct these studies to ensure that patients are receiving safe, effective and high quality medicines

e) *Requirements of Zone IV stability data:* The Vietnamese regulatory authorities announced that they would apply the requirements of climatic zone IV (35°C±2°C, 75%±5% RH) stability data to be submitted for product registration by January 2007, which is not in line with the ASEAN timeline (by January 2009) and may block the access of several innovative and hi-tech medicines. Many of these medicines are produced by multinational companies and tested in other than zone IV climatic conditions. This new timeline for the application of zone IV stability requirements does not provide industry with sufficient time to deploy new facilities to meet these new test conditions. We would request that the Vietnam requirements be implemented in January 2009, as is consistent with the ASEAN timeline stability. Furthermore, the requirement should not be applied to renewal applications for very

long stable and established products.

The objective of product registration, in PhRMA's view, should be to record necessary information about pharmaceutical products being sold in Vietnam and ensure product quality. Currently there are no clear guidelines or objectives to provide consistency in the registration process.

Requirement that Clinical Trials of Medicines Be Conducted in Vietnam

The Pharmaceutical Law 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 is unnecessary, as PhRMA member companies that develop and manufacture medicines 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), regarding the conduct of safety and efficacy trials before introducing their medicines to Vietnam. The duplication of clinical trials already conducted outside of Vietnam results in significant cost to the manufacturer and unnecessary delay in access to medicines for Vietnamese physicians and patients. PhRMA manufacturers conducting clinical trials outside of Vietnam in accordance with FDA or other ICH standards should be exempt from the requirement that local clinical trials be conducted in Vietnam.

Import Quotas

All state companies wishing to import foreign pharmaceutical products are required to apply for annual quotas. Under the U.S.-Vietnam Bilateral Trade Agreement (U.S.-Vietnam BTA), such import quotas are to be phased out.

Requirement That Pharmaceutical Raw Materials Be Imported Within Six Months of Manufacture

Circular 06/2006/TT-BYT requires that all pharmaceutical raw materials be imported into Vietnam within six (6) months of the date of manufacture of an end product. This requirement lacks scientific justification and is discriminatory against manufacturers who must: i) produce buffer stocks of such raw materials at least five months in advance of delivery in order to meet fluctuating demand and ii) produce in large quantities. This also results in inefficiencies in the production and delivery of pharmaceuticals. Vietnam should extend the period within which pharmaceutical raw materials must be imported into Vietnam after their manufacture to up to 12 months or no later than six (6) months before the date of expiration of their shelf-life.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

CANADA

CANADA

For the reasons summarized below and that are described in more detail in the sections that follow, PhRMA requests that Canada be designated as a Special 301 **Watch List** country in 2008. Despite some recent positive regulatory changes and policy announcements by the Canadian government, PhRMA requests that the 2008 Report specifically note the matters set out here and that the USTR take the actions suggested below to secure further changes to the Canadian intellectual property regime.

In October 2006, the Government of Canada published new data exclusivity regulations granting 8 years of data protection, with an additional 6-month period for pediatric studies. This represented a positive step for improving the business environment for PhRMA member companies operating in Canada. However, the regulations implementing data protection were published at the same time as changes to Canada's linkage regulations, and the industry remains concerned that these latter changes may negatively impact innovation.

It is also commendable that the present Canadian government has made positive statements regarding the importance of intellectual property rights, notably the recent commitment that "Our Government will improve the protection of cultural and intellectual property rights in Canada" in the October 16, 2007 Speech from the Throne outlining its major objectives. However, despite such statements and the improvement to its data protection regime, Canada's intellectual property environment continues to be characterized by uncertainty and instability for patentees. In addition, Canada's intellectual property regime lags behind that of other G-7 nations in several significant respects. PhRMA members believe that the United States should strongly encourage the Canadian government to address the identified intellectual property issues.

Intellectual Property Protection

Data Protection

For many years, PhRMA members had 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 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 is an important step in improving Canada's intellectual property regime. However, the industry still has concerns about the potential loss of data

protection under the new regulations if a drug is not being marketed in Canada by the originator. Additionally, PhRMA notes that the new Canadian data protection regime is now subject to two legal challenges by the generic industry. PhRMA members urge the U.S. government to request that Canadian authorities vigorously defend the 2006 amendments to the data protection regime.

Enforcement (Linkage)

Under both TRIPS and NAFTA, Canada is required to ensure effective enforcement of the standards of patent protection provided in those Agreements. In particular, Article 28 of TRIPS and Article 1709 of NAFTA require Canada to confer on patent owners the exclusive right to prevent third parties not having the owner's consent from making, using or selling the product or process that is the subject of the patent. Additionally, Article 41 and the related Articles of TRIPS, and Article 1714 and the related Articles of NAFTA, require Canada to "ensure that enforcement procedures are available under its law so as to permit effective action against any act of infringement of intellectual property rights … including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements."

In 1993, Canada implemented an early working regime in the pharmaceutical sector based on the U.S. Hatch-Waxman Act. An early working exception similar to that contained in Hatch-Waxman was enacted under Section 55.2(1) of the Canadian *Patent Act*. The *Patented Medicines (Notice of Compliance) Regulations* (the *PM (NOC) Regulations*) were then promulgated for the stated purpose of preventing the infringement of patents by the premature market entry of generic drugs as a result of the early working exception.

However, systemic deficiencies in the *PM (NOC) Regulations,* their administration, and their judicial interpretation have led to frequent failures to achieve this purpose. There is ample evidence that the *PM (NOC) Regulations* do not reliably provide "expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements," as required under TRIPS and NAFTA.

For example:

- 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 under Hatch-Waxman. 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.

- 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. Recently, Canadian case law now developed to require that the "relevance requirement" with respect to the listing of patents by innovators applies not only to the current (October 2006 amendments) system, but must also apply retroactively to patents listed under the pre-October 2006 amendments, despite the fact that this is clearly contrary to the intention expressed in the amendments. This judicial interpretation is highly destabilizing for innovators and will negatively impact on the ability to adequately protect and enforce intellectual property rights. [30] PhRMA members urge the U.S. government to engage the Canadian government to implement amendments immediately to redress this situation.

- The system under Hatch-Waxman is similar to the Canadian system up to the point of having a mandatory stay. In the U.S., however, a challenge to an allegation of non-infringement or patent invalidity proceeds as a full action for infringement. Under the Canadian scheme, 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, however, 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.

- The patentee does not always have a right of appeal if it is not successful in the first instance. This is because the generic product may be approved following a decision by the Court in favor of the generic producer.[31] The patentee is then left with no alternative but to commence 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

[30] Ratiopharm v. Wyeth, 2007 FCA 264.
[31] Eli Lilly Canada Inc. v. Novopharm Limited 2007 FCA 359.

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 and the absence of a consistent right of appeal for the patentee constitute a lack of due process requirements 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, and PhRMA members urge the U.S. Government to encourage Canadian authorities to address this fundamental imbalance through regulatory changes that will ensure there is an equal right of appeal.

- In the event a patentee must pursue an action for infringement, it may apply for an interlocutory injunction to maintain its rights and, in particular, to prevent the market entry of the generic product or to seek its withdrawal from the market. These applications, however, rarely succeed in Canada even if there is compelling evidence of infringement.

- Finally, it generally takes four to six years before an action for patent infringement is tried. By then the innovative company's market share has been severely eroded. 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 authorities should be encouraged to take measures to amend the current linkage regime to address the 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 lengthy delays caused by 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 members believe Canada should consider supporting innovation by adopting a PTR or other policies or practices to ameliorate the effects of delays caused by its regulatory process.

Market Access Barriers

In Canada, the Patented Medicines Prices Review Board (PMPRB) has been mandated to remedy excessive pricing. In doing so, administrative Guidelines of the Board, as administered by Board Staff, calculate a maximum average factory gate price that a manufacturer can charge for a patented medicine. If a patentee charges above this price, it is, on an administrative level, held to be charging an excessive price.

The jurisdiction of the PMPRB is established under the Patent Act. The PMPRB has authority to regulate the prices of only patented medicines sold in Canada and has the power to issue remedial orders requiring a manufacturer to reduce the price of a patented drug. From 1987 to 2006, very few investigations or hearings into the pricing of drugs were commenced. However, in the past two years, the PMPRB has initiated several investigations into the pricing activities of drug companies, including a number of U.S.-based companies, and has commenced an unprecedented number of hearings.

PhRMA is concerned that Canadian price controls nullify and impair the benefits that U.S. drug manufacturers expected to derive from the TRIPS Agreement and NAFTA by depriving patent holders of the economic benefits associated with the period of market exclusivity conferred under those agreements. The policy of patent law is to provide patent holders with a period of exclusivity during which they can exploit the subject matter of the patent for commercial gain in order to recoup their investment in innovation. Given the apparently expanding downward pressure from the government on prices, to an increasing extent PhRMA member companies cannot take effective advantage of the economic benefit intended to be conferred by the period of market exclusivity. In addition, given significant market access barriers, the value of patents is at times materially diluted.

Canadian price controls are also arguably contrary to TRIPS and NAFTA obligations to ensure that patent rights are enjoyable without discrimination as to the field of technology. The PMPRB's jurisdiction is limited in law and in fact to patented medicines. Canadian price controls violate the non-discrimination obligations of TRIPS and NAFTA to the detriment of PhRMA member companies.

Cross-Border Trade

Over the past several years, prescription drugs intended for Canadian patients have been diverted to the United States through the cross-border trade in pharmaceuticals. These shipments have occurred even while current U.S. law 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 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 U.S. even though the drug may be legal to sell in the originating country.

In addition to the quality and safety questions triggered by cross-border trade in pharmaceuticals, PhRMA members believe there are significant intellectual property issues. Two legislative initiatives to address the cross border issue in recent years were initiated but neither passed into Canadian law. Given that the Canadian government has not introduced legislative or regulatory mechanisms to prevent the diversion of supplies intended for Canadian patients to U.S. buyers, there is no way of assuring that the products shipped from Canada are compliant with the U.S. intellectual property legislation**.** This is particularly a problem for generic products which benefit from earlier patent expiries in Canada. PhRMA members believe the Canadian government should be encouraged to address cross-border trade in a proactive and effective manner.

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

On November 6, 2003, Canada introduced legislation to implement the WTO Decision, which is effectively a waiver of a number of TRIPS obligations to which member nations would otherwise be bound in issuing compulsory licenses. Canada was one of the first countries to seek enactment of domestic legislation to permit its generic manufacturers to export under the compulsory license provisions of the WTO Decision. The implementation bill received Royal Assent on May 14, 2004. The bill and related regulations, now known as Canada's Access to Medicines Regime (CAMR), came into force on May 14, 2005.

The Canadian legislation was reviewed in 2007, as required by the Patent Act. PhRMA applauds the Canadian government's decision to leave CAMR "as-is", given there is no compelling evidence that any further changes are needed. Despite complaints from non-governmental organizations and the generic industry that Canada's system is unworkable, in September 2007 an authorization to export was issued under the legislation to a Canadian generic within 60 days of the original request, demonstrating that the statutory mechanism is both efficient and functional.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

EUROPE

AUSTRIA

PhRMA member companies working in Austria face barriers to full intellectual property protection on account of the inability of reimbursement and regulatory authorities to check patent status. This problem is closely related to general transparency concerns in the reimbursement system which blocks market access. As a result of these concerns, PhRMA recommends **Watch List** for Austria for the 2008 Special 301 report.

Intellectual Property Rights

Patent Protection

Patent protection in Austria has been weakened by a growing trend of generic products being launched before patent expiration.

Companies that try to defend their patents in court can still be deprived of patent protection during court proceedings. Court proceedings on intellectual property issues are long and costly, with a very low probability of securing injunctive relief. While proceedings are underway, manufacturers of original products have to reduce the price of their products to generic's levels to stay within the reimbursement program. If a price cut is not possible, the original product is even removed from the reimbursement list. As a result, of this growing trend of generic products being launched before patent expiration, market access is being reduced even with a valid patent.

Market Access Barriers

Government Pricing & Reimbursement

A pharmaceutical firm seeking to include a product on the list of reimbursable drugs in Austria must first obtain the approval of the umbrella organization of social insurance funds (Hauptverband/HVB). The approval is needed in order to provide consumers with immediate access to products. As virtually all inhabitants are covered by a mandatory social insurance scheme and pharmaceuticals not approved for reimbursement have higher out-of-pocket costs, effective market access for a prescription drug is dependent on favorable reimbursement by the HVB.

According to many U.S. and European pharmaceutical companies, the HVB approval process (particularly the long delay in securing HVB decisions) limits market access for innovative pharmaceutical products. The problem is

compounded by relatively quick HVB approvals of generic competitor products even before patents for the innovative products have expired.

Reform of the Austrian healthcare system was meant to provide an opportunity to come closer to European norms in pharmaceutical pricing and reimbursement. Nevertheless, these reforms did not materialize as desired and Austrian patients still lack rapid access to innovative pharmaceutical products. Within Europe, Austria regularly shows one of the longest time lags before innovative products get reimbursement status.

Transparency

Bilateral Informal Commercial Exchange (ICE) talks between the United States and Austria have led to expanded opportunities for innovative pharmaceutical companies to provide input into healthcare policies instituted by the Austrian Government that affect them, and an Austrian Government commitment to speedier and more transparent approvals. Due to the self-governance system of Austrian social insurance funds, substantial progress has not been achieved so far.

In 2007 the non-transparent HVB approval process - particularly the long delay in securing HVB- decisions forced the European Commission to file a suit against Austria for violating EU-Transparency Directive.

PhRMA welcomes the support of the U.S. Government in addressing these market barriers to innovative medicines, and in closely monitoring implementation of the reforms.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 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 that create market access hurdles harming all products, including those which are dependent on intellectual property rights. French policies could have a long-term detrimental effect on the development of the innovative pharmaceutical industry, eroding the quality and quantity of pharmaceutical research and innovation worldwide.

Specifically, the numerous cost containment tools and strict budgetary limits for pharmaceutical expenditures create an environment which substantially impacts research and development incentives in France. Delays in access to market for innovative medicines still represent a weakness of the French pharmaceutical pricing and reimbursement scheme, which further penalizes the research-based industry, despite some progress through the creation of the "depot de prix" system and its recent enlargement. Innovation is inadequately recognized by the French authorities leading to deterioration in the value of the intellectual property of PhRMA member companies. Furthermore, repeated changes in the rules and the addition of new oversight bodies governing the commercial aspects of the pharmaceutical market create an environment that is unpredictable and unstable.

Despite the ability to advertise for OTC products, communicate on pathologies, and conduct patient education programs, the EU ban on pharmaceutical advertising has a direct impact on new and more effective innovative medicines, which increasingly are being developed outside of France.

PhRMA member companies are also concerned about recent developments in intellectual property where some generic products have been introduced before patent expiry. The industry will pay close attention to the application of the January 2007 Addendum to the Government/Industry Framework Agreement, which has set up information obligations for generic companies, under the control of the Drug Economic Committee (CEPS).

PhRMA is encouraged that the French Government has taken small steps to reform its healthcare system and to improve French competitiveness. However, new cost-containment measures targeting the industry following the Alert Committee[32] warning (government price cuts, aggressive generic promotion…), despite several years of already draconian measures, has the industry concerned about the impact of these measures on both French patients and the industry as a whole. We recommend that the U.S. Government place France on the 2008 Special 301 **Watch List** and elevate these issues in the bilateral commercial

[32] Independent body in charge of appealing to the Government and public sick funds to implement saving measures in case of excessive health expenses.

agenda with France to achieve measurable progress in advancing U.S. commercial priorities.

Intellectual Property

Since the passage of the 2003 Social Security Financing Law, which put in place mechanisms to speed up generic access to market, there have been several instances of generic products being approved by the French government and entering the market before expiration of the originator's patent. The French Agency for the Safety of Health Products (AFSSAPS), which approves products, no longer has the responsibility to verify patent expiration, and since the passage of the 2003 Social Security Financing Law, some generic manufacturers have taken advantage of this regulatory change to introduce products prematurely. The relative difficulty of obtaining an injunction, and delays in the French legal system, hamper the ability of PhRMA member companies to seek legal recourse for these infringements. In January 2007, the Addendum to the Framework Agreement between the French State and the Industry set up a process to reinforce patent protection, under the control of the Drug Economic Committee (CEPS). We urge USTR to encourage the French government to follow and reinforce this initiative in order to be sure to avoid erosion of intellectual property protection.

Market Access Barriers

Unrealistic Healthcare Budgets

The French global healthcare budget, which is set annually by the Government, consistently fails to reflect actual expenditures based on realistically assessed needs. Because the budget is set at unrealistically low levels, it is exceeded every year, and the cost of budget overruns is routinely passed on to industry. Application of this policy means that PhRMA members are required to fund a significant part the Government of France's regular and expected health care expenditures on a recurring basis. More specifically, as part of the healthcare reform law that passed in August of 2004, the target for retail drug turnover growth has been capped for 3 years at 1 percent. The French MOH has even fixed a negative target for drug reimbursement for the last 2 years (-4% in 2006). As a consequence of these multiple pressures, the growth of the reimbursed retail pharmaceutical market in France was only 0.6% in 2006 (€ 18.1 billion). This is inadequate for a dynamic, productive and high-value industry.

In addition to the foregoing, the French Government has maintained an "exceptional" increase in the turnover tax from 0.6 to 1 percent in the French

2007 Social Security Financing Bill. The goal for 2008 is to bring this rate to its standard level.

Finally, there are additional cost-containment measures outlined in the July 2007 saving plan law proposals including government price cuts for products with high sales, limits on sales of certain products and increased therapeutic substitution of innovative products. As well, the French Health Minister has asked the French Reimbursement Authority to consider a new system of Dynamic Price Management for certain therapeutic categories. This means price cuts on all products in a group upon generic entry or price decreases with two new measures particularly impacting PhRMA members:

- Government price cuts on patented drugs up to € 160 million and medical devices up to € 60 million. This measure is linked with the Dynamic Price Management set up by the previous Government in 2006. This policy creates some real threats for intellectual property as it considers generic prices for some on-patent products.
- Extension of the obligation for patients to pay at the pharmacy before being reimbursed when they refuse generic substitution. This measure is particularly harmful for brand-named drugs because it will lead pharmacists to deliver only generics in practice.

Economic constraints and considerations could be still reinforced as the Social security spending should now be mainly managed by the Ministry of Budget.

PhRMA members ask that the U.S. Government raise these issues as a commercial priority in bilateral consultations.

Government Price Controls

Government-imposed price controls fail to recognize and reward innovation and constitute an additional market access barrier which harms pharmaceutical products dependent upon intellectual property protection. In France, prices of reimbursable pharmaceuticals are fixed by the state. To be reimbursed by the national health insurance fund, reimbursement status must be granted by the Transparency Committee (Commission de Transparence), and a reimbursement price must be negotiated with the Economic Committee for Health Products (CEPS).

All registered pharmaceuticals are subjected to Evaluation of Therapeutic Benefit (“Service Médical Rendu”: SMR) which determines the level of Government reimbursement for the product. In parallel, Therapeutic Benefit Improvement (“ Amélioration du Service Médical Rendu”: ASMR) constitutes a basis to negotiate the price with the CEPS. The Transparency Committee has

the competence in assessing the efficacy and the safety of a product; the evaluation is based on the expert judgment, itself exclusively based on clinical criteria. While this evaluation is rarely contested, the industry often disputes the ASMR classification made as a result of the data analysis. Currently, several relevant elements are not taken into account such as the social utility, overall public health interest, and the impact on the health care system.

PhRMA members believe that the evaluation process should include more innovative products to provide reward for innovation. For example, under the present system, only a limited number of patented pharmaceutical products fall under the favorable ASMRs and most products instead fall under the undesirable ASMR IV or V categories which does not provide premiums for innovation. The criteria used to limit the number of products included in ASMR I and II should be relaxed to better reflect innovation – including incremental ones - broaden the number of relevant parties in the review process and provide effective due process, including an appeal process. Medicines receiving the ASMR I , II and III , even for ASMR IV under certain conditions, can benefit from the fast-track procedure with an engagement for the first 3 categories to get an European average price. PhRMA members 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 its pricing authority (CEPS) to introduce Dynamic Price Management to certain therapeutic categories is an issue of serious concern for the innovative industry. While the Health Minister has stated that there will be no jumbo group reference pricing in France, a system that ties the price of innovative products to those of generics appears to the industry as a movement towards reference pricing such as that found in Germany. Therapeutic reference pricing seriously undermines the value of the intellectual property of innovative pharmaceutical companies. We urge USTR to address this issue in bilateral discussions with the French government.

<u>European Ban on Advertising to Patients</u>

Like other EU Member States, France had to transpose prohibitions on the marketing and advertising of innovative medicines from European to French law. Specifically, Article 88 of European Parliament and Council Directive 2001/83/EC requires 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 delivered by pharmaceutical firms through other mechanisms, such as print media. Nevertheless, French

transposition has avoided a complete and strict ban for information. And allows several opportunities to communicate to patients (OTC, pathologies, patient programs…).

Restrictions on such helpful information have many potential adverse consequences: they 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 put non-English speaking patients in France at a huge disadvantage because they can not obtain valuable information in their own language.

Discussions are in progress at the European level on the ban. Despite a favorable position for information to patients, France has expressed some reservations to opening the possibility for industry to directly communicate to patients on prescribed products.

Additional Market Access Hurdles

The Government of France at times has imposed reduction targets for some drug categories (e.g.: antibiotics, statins, anxyolitics, proton pump inhibitors…). In many cases, this may pose a direct threat to human health, particularly in areas where a large cross section of society may gain a preventative health benefit from access to medicines. Statins are an important example of this. Volume constraints should be based on medically justifiable quantities (number of patients eligible to be treated for approved indications) and not on financially affordable quantities.

In addition, in the past few years the French Government has set up measures to help the development of the generic market (incentives on margins for pharmacists, rewards to reach substitution targets…). Regarding the current situation, these measures are no longer necessary but continue to create an unbalanced situation, unfavorable to the brand-name products.

French authorities should also strive to eliminate delays in providing market access for PhRMA members' new, most innovative products. These approvals take an average of 360 days, far beyond the EU statutory limit of 180 days.

Overall, PhRMA members request that the U.S. Government engage in dialogue on all of the above issues, and urge that the Government of France not adopt policies that would worsen the existing situation through measures such as:

- The introduction of jumbo group reference pricing,

- Additional prescription constraints,
- Pushing more products to ASMR IV and V. and,
- Making existing price/volume constraints on hospital sales more restrictive.

Finally, it could be helpful to have the support of the French Government on the necessity to increase abilities to inform European patients.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

NORWAY

Norway's pharmaceutical patent protection lags behind most of Europe and other developed countries. Norway fails to provide pharmaceutical product patents for nearly 75% of the products currently on the Norwegian market. Norway should make changes either to their patent law or to their regulations to ensure that drugs with current patents – including specifically analogous process patents where Norway did not permit product patents – are not included on the Norwegian Medicines Agency's list of interchangeable drugs. As one of the richest countries in the world, Norway has, as public information shows, some of the lowest drug prices in Europe. By failing to provide adequate levels of intellectual property protection, Norway is free-riding on the research and innovation provided by U.S. companies and paid for by the rest of the developed world. Because Norway has failed to uphold basic patent rights, PhRMA recommends that Norway be placed on the Special 301 **Watch List** in 2008.

Intellectual Property

Norway has provided for pharmaceutical product patents since 1992, before the Trade-Related Aspects of Intellectual Property Rights Agreement ("TRIPS") entered into force. The problem the industry faces in Norway relates to pharmaceutical products disclosed in Norwegian patents granted or pending prior to 1992, which account for nearly 75% of the Norwegian market. This failure to provide product patent protection places Norway well behind the overwhelming majority of developed countries in terms of adequate IP protection.

In addition, with respect to at least some of the products at issue, Norway's failure to provide product patent protection violates the TRIPS Agreement. Under TRIPS Article 27, Norway has an obligation to provide protection to "any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application[.]" Under TRIPS Article 70.7, Norway was required to provide for the addition of product claims to any applications for those process patents that were still pending on January 1, 1996, but it has failed to do so.

This issue has tremendous financial significance for U.S. innovative pharmaceutical companies. In Norway, according to public sources, up to 60% of an innovative company's total revenues are at risk as a result of this problem. However, at the time of reporting PhRMA is unable to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

Potential Fix: Addressing the commercial impact of this issue would not require Norway to make major changes to its patent system. European countries

where this issue has existed in the past have taken provisional remedial measures. Finland, for example, resolved the issue in early 2006 by prohibiting products with process patent protection in Finland (and product patent protection in at least five EU countries) from being put on the generic substitution list. A similar fix is feasible in Norway.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

ROMANIA

The Government of Romania has managed to a substantial extent to align national pharmaceutical legislation with European Union standards. However it continues to fall short of fully providing transparency especially in the area of reimbursement process. PhRMA members continue to suffer from market access barriers including the setting of maximum prices by the Ministry of Health and ceilings per prescriptions and per pharmacies. Accordingly, PhRMA recommends that Romania be placed on the Watch List for the 2008 Special 301 Report.

Market Access Barriers

Government Pricing of Pharmaceuticals

The Government of Romania lacks transparency in its pricing of pharmaceuticals in a manner that restricts the ability of U.S. pharmaceutical companies the opportunity to enjoy their intellectual property rights. On June 15th, 2007, MoH posted on its official internet site the new proposal for Pricing Regulation. Instead of a three-country basket for reference price calculation, the regulation states that Romania will apply the minimum reference price out of 12 countries (Czech Republic, Bulgaria, Hungary, Greece, Slovak, Austria, Belgium, Italy, Denmark, Germany, UK, Switzerland).

Under the future pricing legislation, the prices of all products (new on the market, as well as those already registered, regardless of whether they are reimbursed under the government-sponsored health system) cannot be higher than the minimum level in the 12 comparison markets. As the draft is written, the MoH has the possibility to add countries to the basket of comparator countries without providing notice. The new proposed pricing regulation also provides that producers refusing to accept price reductions will be prohibited selling the product in Romania.

Reimbursement System – Transparency Commissions and NHIH levels

Romania took an important step forward regarding transparency in the listing and delisting of products for inclusion in the health system in 2005 when the MOH published an order containing the new listing/delisting criteria and methodology. This order fixed many of the outstanding issues on the transparency of the process, including objective and verifiable reimbursement criteria, time limits of 90 days for reimbursement decisions, explanations for adverse decisions, and the ability to appeal. The system establishes three sub-lists: A) one for patent expired molecules and generics; B) one for innovative,

branded molecules; C) and one for drugs for chronic diseases; for National programs; and for children and pregnant women.

While the order theoretically provides greater transparency, implementation has been lacking. Timelines established in the order are not observed. In fact, no new products have been added to lists A and B since April, 2005 and applications for reimbursement on these lists have not received responses.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

SLOVAK REPUBLIC

The innovative pharmaceutical industry and PhRMA members in the Slovak Republic face significant market access barriers from a new Healthcare Act that decreases transparency in the government's pricing and reimbursement system rather than enhancing it. Furthermore, new provisions in the Act could effectively undermine the patent linkage system that the Slovak Government had made great efforts to implement. In light of these, PhRMA recommends **Watch List** status for the Slovak Republic.

Intellectual Property

Patent Linkage and Government Pricing & Reimbursement

The newly amended *Act 577/2004 on the Scope of Healthcare Provided on the Base of Health Insurance* (Reimbursement Act) passed the Chamber of Deputies on December 5, 2007 and entered into effect on January 1, 2008.

The amended Reimbursement Act contains a provision on patent linkage that provides important intellectual property protection while the original product is still under patent. However, the amended Act creates a situation whereby the patent linkage provision could in effect become meaningless. While an innovative product can only receive pricing and reimbursement from the government after marketing authorization, the generic may receive a pricing and reimbursement decision while the patent of the original drug is still in place and even before the generic marketing authorization has entered into force. PhRMA member companies are concerned by this development given the overwhelming commitment by the Slovak Government to remedy this issue in the past when Slovakia had been consistently listed by USTR on the Special 301 Watch List.

The provision on price regulation also states that high financial demands of a treatment can be considered as a reason not to include or even exclude the drug on reimbursement list without any requirements to specify the criteria for determining "high" financial demands.

PhRMA member companies have been further impacted because a new original drug cannot be put on the list of reimbursed drugs unless the original producer shows at least 6 reference prices from the EU countries. This requirement will significantly delay launch of innovative medicines, but does not apply for generic drugs.

In March 2007, the MOH imposed a provision on maximum import prices. The provision strictly limits import prices while giving wholesalers and

pharmacists the opportunity to use up the distribution margin to the full extent. This provision took away any potential pricing flexibility of the original producer.

Transparency

The decision to put drugs on the reimbursement list is still a non-transparent, one-way process run by the Ministry of Health.

The Slovak Ministry of Health decree (No. 723/2004), which went into effect on October 15, 2005, as well as the newly amended Act 577/2004, further reduced the transparency of government decisions regarding pricing and reimbursement decisions for medicines prescribed by national health insurance. The new 577/2004 Act does not specify criteria under which drugs will be evaluated, nor an established appeals process. The Ministry of Health holds wide discretion to decide on the amount of reimbursement without a clear set of guidelines for such decisions. Since these decisions fall outside the Slovak Administrative Code, there is no formal process for the decisions to be appealed by the companies. The new decree thus has increased the subjectivity of the Board's decision-making powers, thereby minimizing the predictability and transparency of the process.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

SLOVENIA

The Government of Slovenia has managed, to a substantial extent, to align national pharmaceutical legislation with the EU standards. However, it is still not completely aligned with EU transparency directive guidelines especially in the critical areas of possibility to appeal, clear deadlines and criteria for reimbursement decisions. Furthermore, major gaps exist in intellectual property protection. For these reasons, PhRMA recommends that Slovenia be placed on the **Watch List** for 2008.

Intellectual Property Protection

Enforcement

There are significant roadblocks in IP enforcement.

Attempts to enforce existing process patents in the Slovenian courts have been largely unsuccessful. The Slovenian courts have repeatedly denied TRIPS enforcement measures such as preliminary injunctions. Several cases on intellectual property against domestic pharmaceutical companies have been pending in Slovenian courts for four to seven years, due to inaction by the courts or inappropriate delays. This results in a de facto failure to provide expeditious remedies and a denial of fair and equitable enforcement of intellectual property rights as required by Article 41 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

In addition, current damages for intellectual property rights violations are not adequate to compensate for injuries, and it is also rare that the infringer is ordered to pay the right holder's expenses associated with the defense of its intellectual property rights, or ordered to pay profits. These problems are especially acute in pharmaceutical IP litigation due to the strength of local producers. Slovenia should be required to act in compliance with TRIPS Article 45.

Practices in Slovenian courts limit the choice of experts (pharmaceutical, chemical or other), whose opinion is often decisive for the outcome of the litigation, to experts from Slovenia. Overall, the enforcement system inherently favors local companies and obviates fair enforcement of intellectual property rights against local infringers.

Lack of Pipeline Protection

Product patent protection became available in 1993, but there is no pipeline protection in Slovenia. In the past**,** the majority of currently marketed pharmaceutical products were protected in Slovenia only by a process patent,

and therefore were exposed to easy copying by local companies. Slovenia as a new EU member is now obliged to follow EU patent protection. However it will not be until 2013-2018 (20 years from introduction of product protection plus up to five years patent term restoration) that the full product portfolio of research and development companies will enjoy the same level of protection available today in most of the EU. This will cause Slovenia to fall behind the standard of intellectual property rights provided in the majority of European countries.

Market Access Barriers

The EU transparency directive regulates the transparency of measures for pricing of medicines. Its goal is to establish a standard over the national pricing policies and assure clear access for all market players, which is not always the case in Slovenia.

Government Pricing

A government pricing regulation was published and implemented in April 2007. The regulation discriminates against the innovative industry relative to generic companies. The major changes are:

- Changes the list of reference countries to include the European countries that provide some of the lowest prices (Germany, France, Austria);
- Changes the level of price regulation from wholesaler price to manufacturer price; and
- Introduces discrimination between the calculation of prices for innovative and generic prices by providing the lowest price for innovative products and the average for generics.

Slovenia represents a small market and is used as a reference country for other (bigger) countries (e.g., Austria, Greece, Hungary), so the ramifications of changes to Slovenian law extend beyond Slovenia itself.

Reimbursement

The Government of Slovenia fails to provide a transparent and predictable system for the reimbursement of pharmaceutical products, which severely restricts the ability of U.S. pharmaceutical companies to enjoy their intellectual property. The system does not provide objective and verifiable criteria for reimbursement decisions; no explanations are given; timelines are not respected;

the minutes of the reimbursement committee meeting are not available as a public document; and there is no independent body of appeal.

The Interchangeable Drug List (IDL), which was introduced in November 2003, serves as a reference for reimbursement of the "interchangeable" drugs in their group. Physicians are obliged to prescribe the cheapest drugs on the list. The Sick Fund completely reimburses drugs with the lowest price in their group on the IDL. In cases in which a patient wishes treatment with a drug that does not have the lowest price on the interchangeable drug list, he or she must fully co-pay the difference between prices. In cases in which a physician prescribes an original drug which is priced higher than the lowest-priced drug from the interchangeable group, pharmacists are obliged to switch it for the cheaper generic or copy drug, if the patient does not want to co-pay. The IDL is expanding every six months to new groups of products. Criteria of expansion are not defined transparently. Despite the fact that the IDL list has failed to meet its primary objective of significant savings to be used for funding new R&D medicines. Additionally continuous attempts are made to implement therapeutic class referencing (TRP), that would favor generics and would limit the access to adequate therapy for patients.

In addition to the problems described above, the Sick Fund is misusing its position in the market and putting pressures on the companies to lower prices of their products. For example, the cheapest Defined Daily Dose (DDD) is taken as the price ceiling for reimbursement for other products in the cluster. With such conduct, WHO guidelines are not followed and the Anatomical Therapeutic Chemical (ATC)/DDD system is misused. The Sick Fund is also increasingly adopting behaviors and policies directed toward physicians. In order to avoid open legal or political confrontations, these activities are declared as "recommendations" or educational programs. The Sick Fund denies the free flow of information to healthcare professionals by prohibiting visits by professional sales representatives during working hours. The Sick Fund's one-sided doctrine of instructions place Sick Fund savings over patients' needs.

These policies have resulted in serious damages to international - particularly U.S. based – research and development pharmaceutical companies. These policies contribute to an environment that could discourage research and development investment in Slovenia.

Summary

The Government is again considering policies to implement new pricing regulation and therapeutic / class reference pricing, that might compound the damage to U.S. innovative pharmaceutical companies, and which will favor generic companies. Additionally we are still facing breaches of Transparency Directive in the reimbursement process:

No independent body of appeal
Timelines not respected
No chance for hearing
No objective and verifiable criteria – no explanation given on reimbursement decisions
Minutes of the reimbursement committee meeting are not available as a public document

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

SPAIN

PhRMA member companies face market access barriers for patented products in Spain arising from the Government's failure to provide the full patent protections that most developed countries provide innovative pharmaceutical products. Spain needs to make changes to their patent law or to their regulations to ensure that innovative pharmaceutical products with process patents issued prior to 1992 receive the full patent protection accorded product patents now issued by the Government, thereby creating a policy which prevents generic products from entering the market in Spain earlier than they would throughout the rest of Europe. PhRMA requests that Spain be placed on the Special 301 **Watch List** for 2008.

Intellectual Property Protection

A lack of patent harmonization exists in Spain due to the fact that, under the terms of its accession to the EU, Spain was not required to recognize pharmaceutical product claims that had been made in European patent applications prior to October 7, 1992. However, Spain did recognize European product patent claims in applications filed after that date. On January 1, 1995, the date on which the TRIPS Agreement took effect in Spain, the following types of patents existed in Spain:

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

Under the subject matter and the transition rules of the WTO TRIPS Agreement (Articles 70.2 and 27.1), PhRMA believes that Spain was required to essentially convert the process patents for which applications had been filed before October 7, 1992 to pharmaceutical product patents, no later than January 1, 1995. Similarly, under TRIPS Article 70.7, Spain was required to provide for the addition of product claims to any applications for those process patents that were still pending on January 1, 1995. Spain, however, did not do so. As a result, PhRMA believes that, for more than 10 years, holders of such pharmaceutical process patents have had poorer patent protection than is required by the TRIPS Agreement.

Potential Fix: Addressing the commercial impact of this issue would not require Spain to make major changes to its patent system. European countries

where this issue has existed in the past have taken provisional remedial measures. Finland, for example, resolved the issue in early 2006 by prohibiting products with process patent protection in Finland (and product patent protection in at least five EU countries) from being put on the generic substitution list. A similar fix is feasible in Spain.

Market Access Barriers

Spain has made significant advances in modernizing its IP laws in the last two decades. Still, the current lack of harmonization between IP protection in Spain and the European Union results in a situation where generic versions of patent protected molecules can be introduced in Spain, while those same molecules receive full patent protection throughout most of the EU by way of product patent, as noted above.

Lack of harmonized patent protection has significant consequences for PhRMA member companies in Spain.

- **Faster inclusion of innovative products in the Spanish reference pricing system.** The reference pricing system recently adopted in Spain requires that a 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 when they are allowed to enter the Spanish market early.

- **Price erosion in other European countries**: Spain's prices are referenced by many other European countries. As a result, generic products introduced early in Spain not only can lead to the creation of a therapeutic reference price group that lowers the Spanish price, but also to a situation that reduces prices set by other governments throughout Europe.

- **Parallel Trade**: The increase of parallel trade within Europe compounds the problems affecting innovative pharmaceutical companies in Europe resulting from the lack of patent harmonization in Spain.

PhRMA encourages the U.S. Government to elevate its ongoing dialogue with the Government of Spain regarding the uneven implementation of TRIPS in Spain and its economic consequences to 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 2007 attributable to trade barriers related to intellectual property protection and market access.

UKRAINE

In 2007, the government of Ukraine passed legislation to institute data exclusivity, which has been partially implemented. PhRMA commends the government of Ukraine for this important step to enhance intellectual property protection. Despite this progress, crucial implementation and enforcement issues remain. In light of the current situation, PhRMA requests that Ukraine be placed on the "Special 301" **Watch List** for 2008.

Intellectual Property Protection

Implementation of Data Exclusivity

PhRMA commends the government of Ukraine for this important step to enhance intellectual property protection. However, the Ukrainian Ministry of Health in September 2007 accepted amendments proposed by the Ukrainian State Pharma Center to change the procedures regarding data protection in the drug registration process under Regulation 426. This process has resulted in vague definitions as well as transparency and enforcement gaps that need to be addressed before Ukraine will provide meaningful IPR protection connected to its WTO accession obligations.

The local industry association (APRAD) has not received feedback from the government on its advocacy regarding issues related to the implementation of data exclusivity, despite the Pharma Center's claims of openness and the readiness for dialogue.

Enforcement Concerns

If a generic product is submitted for registration while the patent of the original product is still valid, the Pharma Centre has no right under Ukrainian law to refuse the registration for patent violation reasons. So the owner of the patent can challenge the violating company only when commercial activities start. The registration process, including product samples, is not regarded as a commercial activity, subject to patent enforcement in Ukraine. In fact, under current law, the Pharma Centre may be sued for lost sales by a patent-violating company if it refuses to admit for registration a patent-violating product. Legislation needs to be put in place to remedy these deficiencies.

In addition, notice of potentially patent-infringing applications is inadequate. Until June 2007, the State Pharma Center published on its website a list of applicants for registration, so that innovative companies could keep track of potential infringements. In June, this list inexplicably disappeared. Following a November 2007 meeting with the U.S. Embassy and the Ukraine State

Department of Intellectual Property, the web-based list was restored. Still, some major gaps need to be addressed:

a) The list should state all active ingredients in the products. Now it is unclear what ingredients are contained in combination products.

b) The list should state the manufacturer of the product (since the applicant and the manufacturer are not always the same).

c) The information for the period Jun 07 – Nov 07 needs to be restored.

The failure to protect patent enforcement is compounded by the inadequacies of the Ukrainian justice system. Implementation and application of Ukrainian law by state bodies differs from the letter of the law. PhRMA believes that Ukraine could benefit from dedicated courts for intellectual property rights-related cases and training.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

LATIN AMERICA

COLOMBIA

The research-based pharmaceutical industry recommends that Colombia remains on the **Watch List** for the 2007 "Special 301" Report for three principal reasons.

First, obstacles to obtain and enforce patent rights continue to exist. The Colombian Patent Office (CPO) continues to deny patent applications for innovative products, such as polymorphs and salts, despite the fact that such patents fulfill the patentability criteria established by the TRIPS Agreement and such products have often been granted patents in other countries, generating significant commercial impact on PhRMA members. Also, the current patent application backlog has caused an unacceptable 7 year delay for pharmaceutical patents. If a patent is granted, current procedural norms prevent patent holders from effectively seeking effective remedies such as preliminary injunctions against a presumably infringing product prior to market launch.

Second, trademark rights have also been seriously eroded by Colombia's Regulatory Authority, INVIMA, which has allowed copy companies to use registered trademarks 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 owner's reputation.

Additionally, the Government of Colombia issued in early September 2006 Circular 04/06 which establishes the new price policy regime for pharmaceutical products. This policy is of great concern since it is regressive, undermines basic free market principles, and generates legal instability.

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", an obligation under TRIPS Article 39.3. 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 fifty (50) molecules have been protected by Decree 2085. Of these, eleven (11) have already lost protection due to lawful expiration.[33]

Although to date, the Government of Colombia has shown political will to continue respecting DE principles, the R&D industry is concerned by recent public statements made by the government before Congress, and posted on the Ministry of Trade's website, which suggest that the revised text of the intellectual

[33] Source: INVIMA

property protocol of the Colombia Trade Promotion Agreement (CTPA) between the US and Colombia provides authorities the flexibility to bypass data exclusivity protection if a generic manufacturer files bioavailability or bioequivalence studies.[34] In particular, the Ministry of Trade interprets the language of the CTPA[35] to mean that, if a third party requests marketing approval for a generic version of a product covered by data protection, it only needs to file bioequivalence studies in order to avoid the data protection term. This is an incorrect interpretation of the CTPA obligations and completely eviscerates the very spirit of test data protection. Moreover, this is not an innocuous interpretation; in fact, if not rectified, it has the ability to become a legal precedent to undermine any future data exclusivity obligations.

Linkage

The Industry continues to be detrimentally affected by the government's failure to provide a linkage mechanism. 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 to conduct that may eventually be declared illegal 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). There are reasons for this: (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, most importantly, (iii) lack of a time period during which market approval is automatically suspended until the patent infringement issue is adjudicated.

Additionally, Colombian procedure does not provide adequate due process guarantees to effectively litigate patent enforcement. For one, judges have inadequate training to effectively deal with patent and technical issues. Additionally, litigation delays can be extensive, 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 simply stand by idly for almost a decade before a decision is handed down. Colombia has a number of solutions at hand which it could implement to solve these problems, such as the model of an autonomous intellectual property institute. This type of model could be a starting point to offer

[34] http://www.mincomercio.gov.co/eContent/newsdetail.asp?id=5916&idcompany=1, and also, http://www.mincomercio.gov.co/eContent/newsdetail.asp?id=5912&idcompany=1 (accessed 22 October 2007).
[35] Colombia Trade Promotion Agreement (2007), currently pending approval.

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 suggesting that the CPO is applying unreasonable standards for inventive level, making it extremely difficult to obtain patents for improvements, which are otherwise patentable in other countries. Moreover, in the past three 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 single out the pharmaceutical R&D industry. These standards also constitute a technical sector-specific protectionist barrier, as they clearly benefit the local generic industry, which can gratuitously exploit the improvement in Colombia. This is a violation of 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. 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 the pharmaceutical industry, which has dedicated substantial 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.

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

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, this 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 is yet to be seen.

Trademarks

Colombia's Regulatory Authority, INVIMA, issued an authorization allowing a copier to use the registered trademark of a U.S. pharmaceutical company 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 (a "knock-off") 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 Delay

INVIMA delays for approval of sanitary registrations of new products have increased. During the past 18 months, the Medicines Review Commission has issued a new requirement that arbitrarily forces the applicant to include published clinical studies covering the molecule in order to complete the application dossier. Out of all approval requests submitted for purposes of NCEs from April 2006 to the present date, the Review Commission has issued eight (8) specific requirements, requesting delivery of published clinical studies. The above is equivalent to less than 20% of all approvals requested. The difficulty, and sometimes impossibility, of complying with these requirements results in delays in the approval process. In essence, since the molecule is new, there is typically little, if any, published information covering the molecule.

Government Price Control

With the issuance of Circular No. 04 by the National Commission for Pharmaceutical Prices in 2006, the Government of Colombia created a price reference regime for pharmaceutical products in a way that could potentially unfairly limit free trade competition and may discriminate against products enjoying intellectual property protection. In particular, the decree applies price controls to products for which there is no substitute product on the market. If the term "substitute product" is defined as a product with the same active ingredient, all new pharmaceutical products would be subject to direct price control without exception (this interpretation is held by certain regulators in the government). Likewise, if the classification applied by the GoC (Relevant Therapeutic Classification) does not correspond to universal standards relating to substitution

terms, the GoC would be creating false market conditions (this interpretation has also been expressed by regulators). In both cases we would have artificially controlled prices that ignore the real existence of market competitors, and instead rely on theoretical assumptions.

Finally, the application and standardization of reference prices will be critical. In effect, if the regulator ignores market reality, foreign exchange fluctuations, level of development, subsidies, taxes, state sponsorship, etc., in order to ensure reference prices are comparable, prices in Colombia would be based on comparisons between non-analogous elements, which would artificially reduce market prices for Colombia. Similarly, the Industry does not know how prices from each reference country will be compared, especially since there is no mechanism (not even IMS) that stores standardized information for each country that will allow a comparison between normalized variables and at the same stage of the distribution chain.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

DOMINICAN REPUBLIC

The Dominican Republic's industrial property law system remains problematic. An amendment to the industrial property law approved in November 2006 fails to bring the Dominican Republic into compliance with the DR-CAFTA. Moreover, it seriously diminishes patent protection through the elimination of penal sanctions applicable to patent violators (civil sanctions do not act as a deterrent to violators in the Dominican Republic due to the length of legal actions and judges' reluctance to impose significant civil sanctions). Additionally, although the Health Department has not enacted regulations for the application of DR-CAFTA provisions, the draft regulation seems to be geared to limiting the cases where data protection is to be granted to those where "undisclosed" data is filed. PhRMA recommends that the Dominican Republic be placed on the **Watch List** due to its well-documented, persistent failure to adequately protect intellectual property rights. We ask that the U.S. Government address these issues in the context of the implementation of the DR-CAFTA by the Dominican Republic.

Intellectual Property Protection

PhRMA members operating in the Dominican Republic face a difficult commercial climate due to the Government's failure to provide adequate IP protection. On 14 November 2006, the Dominican Congress passed a law for the implementation of the DR-CAFTA ("DR-CAFTA Implementation Law"), which was used as an instrument for the elimination of penal sanctions applicable to patent violators since 1911. Penal courts are now remitting all patent violation cases to the civil courts, where minimal indemnifications are awarded, therefore failing to curb violations of this nature.

Data Protection

The DR-CAFTA Implementation Law includes the protection of test data from unfair commercial use as established by TRIPS Article 39.3 and more by Article 15.10 of the DR-CAFTA. Nevertheless, it still lacks a regulation for its application.

The Health Department is currently proposing a draft regulation which would eliminate the requirement to file clinical and preclinical tests in the applications for health registrations for all products. Additionally, proposed flow charts designed for the implementation of data protection provisions of the DR-CAFTA include a requirement that the applicant clearly distinguish between "disclosed" and "undisclosed data," within the data submitted to the health

authorities. Both the proposed regulation and the flow charts for their application seem to be more an effort to circumvent the provisions of DR-CAFTA than an effort to comply with the agreement. To our knowledge, data protection has not been granted for any product since DR-CAFTA entered into force.

Conclusion

Although increasing levels of patent approvals constitute a welcome improvement, progress remains modest in a number of areas. Should the encouraging, albeit limited, improvements prove temporary, sufficient grounds exist which would justify PhRMA recommending that the Dominican Republic be elevated to the Priority Watch List in the future.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

ECUADOR

Ecuador did not make any progress in 2007 toward providing an effective system for protecting test and other data or in establishing a mechanism for linking the patent system and the system for approving sanitary permits.

Patents are still not available for "second uses" and for "isolations" of naturally occurring materials. In addition, the lack of experienced judges to settle disputes related to patents has made the enforcement of patents problematic. However, there were positive actions towards reducing the backlog of patent applications awaiting examination during 2007.

Ecuador maintained a government price control system that has not adjusted for increased costs of doing business or inflation in Ecuador.

For these reasons, PhRMA recommends that Ecuador should remain on the **Watch List** in 2008.

Intellectual Property Protection

Patent Backlog***:***

According to the Ecuadorian Institute for Intellectual Property (IEPI), the backlog of patent applications decreased in 2007 and patent examination productivity increased by 300% over a recent 6 month period. Although IEPI has autonomy and charges for its services, legal constraints such as the Executive Decree for Public Expenses Rationalization (2005) limit IEPI's ability to retain and use these revenues to improve its operations. Despite this, and given that a new President of IEPI was appointed in May 2007, additional resources were obtained and some initiatives were developed in order to reduce the backlog, hire additional personnel, and provide better service.

On the other hand, Ecuador permits members of the public to oppose the grant of a patent, a procedure that is called a "pre-grant opposition". The number of pre-grant oppositions increases each year, but most of these oppositions have been found to lack a sound technical or legal basis. Consequently, these oppositions delay the grant of patents unnecessarily and they use resources that could be used to examine patents. Unfortunately, current Ecuadorian law does not provide any mechanism for promptly terminating actions that do not have a sound basis. The substitution of effective post-grant cancellation procedures would provide a more effective mechanism to encourage meritorious challenges to the validity of patents while discouraging frivolous challenges that delay grants and waste valuable resources.

Intellectual Property Court:

Section 294 of the Law on Intellectual Property, No. 83 of 1998, required the creation of specialized intellectual property courts. To date, these courts have not been established. As a consequence, patent infringement actions are tried before courts that lack expertise in the subject matter and appear unwilling to enforce intellectual property laws.

Data Protection:

Article 191 of the Law on Intellectual Property provides for the protection of undisclosed pharmaceutical test and other data along the lines of Article 39.3 of the TRIPS Agreement and Article 266 of Andean Decision 486. The Law Article does not provide details on the nature and duration of the required protection. As a consequence, sanitary authorities in Ecuador rely on the data submitted to obtain approval of innovative products, in order to approve copied products usually within three months of the approval of the innovative product. PhRMA members have initiated actions in the Ecuadorian courts to obtain effective data protection and are awaiting decisions in these actions.

Linkage*:*

There is no procedure in Ecuador for linking the patent system and the system for granting sanitary approvals. Sanitary authorities have approved copies for all the innovative products that are covered by patents in Ecuador.

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. 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 the pharmaceutical industry, which has dedicated substantial 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.

Patents for Biotechnology*:*

Article 15 of Andean Community Decision 486 excludes a large part of biotechnological innovation from patentable subject matter by providing that "biological material … able to be separated [from their natural state], including

the genome or germ plasma of any living thing" is not an invention. Such isolations of materials are clearly the products of human intervention that are not found in the same form in nature. Thus, they constitute inventions as the term is used in TRIPS Article 27.

Market Access Barriers

Government Price Controls*:*

Ecuadorian Government has a rigid government price control system established by Law No. 152 of 1992 and Law 2000-12 and recently confirmed by the new Health Law enacted on December 2006. It covers all presentations of pharmaceutical products and discriminates against innovative pharmaceutical products by setting a maximum 25 percent profit for generic copy drugs and 20 percent profit for innovative drugs. Moreover, prices of pharmaceutical products have not been reviewed by the government since March 2003, despite a general inflation rate of more than 10 percent for the period.

Additional regulations required to facilitate the enforcement of the 2006 Health Law will be developed by the Minister of Health, and may present further market access barriers.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

EL SALVADOR

Despite the enthusiasm displayed by El Salvador to ratify the DR-CAFTA and pass implementing legislation, almost two years after the entry into force of the agreement no substantial changes have been achieved regarding data protection and patent linkage notwithstanding technical assistance provided by industry.

As of December 2007, El Salvador had not passed implementing regulations for the application of test data protection and patent linkage. A draft proposal has been circulated which includes limiting language that generates uncertainty as to how the norms could effectively be applied. This raises concern because the implementing legislation on test data includes wording that, absent further regulations, may be applied in a way that circumvents protection against unfair commercial use of test data. Our industry has actively called for effective implementation and followed up on the Government's regulatory projects; unfortunately, this effort does not provide confidence that effective implementation will occur.

PhRMA members recommend that El Salvador be placed on the **Watch List** to promote implementation of CAFTA compliant regulations for patent linkage and data protection.

Intellectual Property Protection

Data Protection

The health authority (the Consejo Superior de Salud Pública –CSSP-) has not enforced data protection and has failed to provide R&D companies with assurances that it will observe the DR-CAFTA and the implementing legislation. The CSSP has raised the burden of documentation and requirements to R&D companies when filing for market approval of new products, without providing effective protection. The Ministry of Economy and the CSSP have been reviewing data protection regulations for more than a year but, as of January 2007, the regulations have not been implemented. In addition, the draft regulations, when reviewed in early December by the R&D industry, showed inconsistencies with the DR-CAFTA and the domestic implementing legislation, such as allowing for the CSSP to grant market approval to third parties while test data protection is still in force but withhold permission to commercialize the product until the expiration of the five year term, and confusing wording regarding protection in El Salvador when original approval was obtained in another country.

Linkage

The CSSP is not enforcing patent linkage. A sworn declaration stating that the generic product for which approval is requested does not infringe a valid patent in El Salvador is required by the implementing legislation; however, the CSSP is not requiring that this declaration be provided. Therefore, El Salvador fails to comply with its commitment and own domestic legislation regarding linkage.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

GUATEMALA

In 2007, Guatemala suspended two regulations, issued by the Health Authority in December, 2006, that limited patent linkage and threatened test data protection. Despite entry into force of the DR-CAFTA, patent linkage has not yet been fully implemented. Regrettably, implementation has been delayed by the Ministry of Economy's failure to act upon proposals developed by the Ministry of Health. Regarding market access, Guatemala has not corrected the tax discrimination caused by Decree 16-2003 against R&D products that has been in force for more than four years.

For these reasons, PhRMA members recommend that Guatemala remain on the **Watch List** in 2008, and strongly recommend that Guatemala be subject to out-of-cycle review if an effective linkage system is not provided promptly or if the level of data protection decreases.

Intellectual Property Protection

Patent Linkage

Local producers of copied products are advocating against application of Government Accord 351-2006 before Ministry of Health and Ministry of Economy officials at both the political and technical levels. This Accord provides patent linkage and requires prospective registrants to provide sworn statements regarding their authorization to market the product. The Ministry of Health, during the second half of 2007, proposed language and procedures to provide clarity and simplify application of the Accord. However, local manufacturers opposed the proposal and sought the involvement of the Ministry of Economy, which in turn has delayed discussions and prevented full implementation of the patent linkage provisions by the Ministry of Health. The Ministry of Economy's intervention calls into question whether the patent linkage system will be effectively enforced.

Market Access Barriers and Tax Discrimination

PhRMA member companies believe that Decree 16-2003 discriminates against innovative pharmaceutical products by establishing value-added tax exemptions and other benefits for "generic" and "natural" medicines and to "salts" used in the manufacture of such products. This discriminates between products that depend on intellectual property and originate in the United States and copied products of domestic or foreign origin. The decree provides advantages to "generic" and "natural" products in government tenders, calling for the Government to favor those products over innovative products. The decree also discriminates against innovative pharmaceutical products by requiring government health entities to favor the prescription of generic products. R&D

companies have presented the President of the Republic and the Ministry of Economy with proposals aimed at eliminating discrimination; 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 2007 attributable to trade barriers related to intellectual property protection and market access.

HONDURAS

The Honduran Government has failed to effectively implement test data protection and patent linkage. Health authorities have not been involved in the implementation of the DR-CAFTA and the very limited level of awareness of the specific commitments that apply both to linkage and test data protection is clearly a serious threat to the rights of the innovative pharmaceutical industry in that country. The implementing legislation poses several questions regarding implementation of test data protection and patent linkage as a result of inconsistent and unclear wording throughout the text.

PhRMA members recommend that Honduras be placed on the **Watch List**.

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. In August 2007, draft regulations, including two that refer to undisclosed information and test data, were published for public consultation. The drafts under consideration did not address test data protection or patent linkage appropriately. Rather, the drafts contain numerous inconsistencies with the DR-CAFTA. Because the process, as of the end of December 2007, has not resulted in revised draft regulations that would address these deficiencies, PhRMA and its member companies are concerned that the Government may enact provisions with limiting wording that will result in ineffective protection. The draft amendment regarding undisclosed information introduces language that confuses test data with trade secrets and allows for disclosure beyond exceptions agreed to under the DR-CAFTA. The proposed draft bylaw, at this time, includes wording that will allow third parties, without having developed their own test data or without proper authorization, to seek and obtain marketing approval even within the 5-year protection period. This wording needs to be appropriately revised to prevent such an outcome.

Limited coordination between the Industry and Commerce Ministry and the Health Ministry regarding the DR-CAFTA implementation process is evident; lack of information at the Health Ministry on its obligations under the treaty, in addition to 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 2007 attributable to trade barriers related to intellectual property protection and market access.

MEXICO

Mexico has been a regional leader in the improvement of IPR. For example, a 2003 decree linking patents of pharmaceuticals and health registrations (Linkage Decree) represented significant progress. While that initiative was welcome, the following concerns remain: (1) the Linkage Decree has not been properly implemented due to ambiguous guidelines, lack of government action, and interpretations which undermine the Decree's objectives; (2) data protection provisions established by NAFTA have not been fully implemented; and (3) government actions to contain counterfeit drugs have been insufficient. Due to this it is strongly recommended to maintain Mexico on the **Watch List**.

Intellectual Property Rights

Linkage

The application of the Linkage Decree remains a concern for patent holders as the Health Regulatory Agency (COFEPRIS) has not revoked all those registrations improperly granted to copy products. And, while there have been no additional violations this year, this situation remains a serious concern for the industry.

Without adequate implementation of the linkage system, the patent holder's rights are under serious threat due to the lack of an effective enforcement system to quickly stop attempts to infringe patents. The weak enforcement of the Linkage Decree represents potentially significant commercial losses and a clear violation of the legal framework of IP protection, not only derived from direct erosion of market share, but also from resources wasted on costly and lengthy legal actions.

COFEPRIS and the Mexican Institute of Industrial Property (IMPI) fail to provide linkage for the full range of patents that protect pharmaceutical products. The 2003 Linkage Decree has been incorrectly interpreted to be limited to the linking of patents on active ingredients per se, and not to the full range of patents that protect pharmaceutical products.

The only patents that arguably should be excluded from the linkage process according to the Linkage Decree are those that claim manufacturing and formulation processes. In the second-to-last paragraph of Article 47 bis of the Industrial Property Law Regulations, the reference to "process patents" should not affect the inclusion of "second use" and "formulation" patents regarding pharmaceutical products. Thus, based on the above, we believe that the list of products described in Article 47 bis ought to include any patent granted with respect to a drug that is not referred to as a process patent, and should include

patents that claim pharmaceutical formulations and the use of a specific pharmaceutical product or formulation.

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

It is recommended that the Mexican and the U.S. governments initiate a dialogue to ensure that (1) IMPI incorporates the full range of patents (active ingredient, formulation and use) that protect pharmaceutical products into the existing linkage system, preferably, through a law (rather than regulations), to avoid patent owners having to resort to costly litigation proceedings before the Mexican Courts to secure the rights stemming from their patents and (2) COFEPRIS abides by the Linkage system objective of preventing patent infringement and that it reverses all the health registrations granted in violation of the Linkage Decree.

Data Protection

The Government of Mexico is required to protect certain test and other data associated with pharmaceutical products under paragraph 3 of TRIPS Article 39 and paragraphs 5 through 7 of NAFTA Article 1711. The TRIPS Article requires WTO Members to protect data:

(1) against “unfair commercial use”; and
(2) against disclosure

if the data were submitted to the government as a condition of obtaining marketing approval, if the data were related to a product containing a “new chemical entity”, and if the data were generated through considerable efforts. NAFTA Article 1711 more explicitly requires parties to prohibit “reliance” by competitors for a period of five-years in normal circumstances.

Article 86*bis* of the Industrial Property Law states generally that information associated with pharmaceutical products should be protected in accordance with treaties to which Mexico is a party. The last paragraph of Article 167*bis* of the Health Inputs Regulation echoes Article 86*bis*. Notwithstanding these Articles, however, there is no clear national legislation or implementing regulations to protect data. Consequently, there is no clear delegation of authority or responsibility for protection to any official of the Government of Mexico. There is no clear indication of which data are to be protected, precisely how the data are to be protected within the framework of the laws and regulations of Mexico, or the duration of protection. In our view, the failure to

delegate authority expressly and failure to indicate the scope of protection clearly translates into a failure to establish a legal mechanism that provides sound basis for protection of test and other data in contradiction to the obligations undertaken by the Government of Mexico in the TRIPS Agreement and NAFTA.

To fulfill its obligations effectively, we suggest that the Government of Mexico amend the General Health Law (*Ley General de Salud*) and/or its implementing regulations to integrate the procedures for protecting data (including delegation of responsibility and indication of scope and term of protection) with the existing procedures for registering pharmaceutical products. We believe that such amendments would go a long way towards eliminating uncertainties in the level of protection -- which create significant risks for PhRMA Members -- and would ensure that copies of pharmaceutical products associated with data that are entitled to protection under the TRIPS Agreement and the NAFTA are not approved in the future.

Counterfeit Drugs

In recent years there has been a significant increase of counterfeit products that are being marketed openly and without effective controls, especially along the Mexican border with the United States.

Government actions regarding these illegal activities have not been sufficient and this represents an increasing risk to the health of the population. Members of PhRMA urge the government to take corrective steps.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

NICARAGUA

The Nicaraguan Government has failed in 2007 to effectively implement test data protection and patent linkage. Though the health authorities have shown some level of awareness of the CAFTA-DR commitment 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 if the country applies a reliance system.

PhRMA members recommend that Nicaragua be placed on the **Watch List**.

Intellectual Property Protection

Data Protection

During 2006 and 2007, PhRMA member companies 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 2007, 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 2007 attributable to trade barriers related to intellectual property protection and market access.

PERU

On April 12, 2006, the United States and Peru signed the U.S.– Peru Trade Promotion Agreement (PTPA) that provides effective protection for pharmaceutical test and other data, a pre-launch legal system that will provide the opportunity for patent holders to prevent the marketing of an infringing product and a stronger intellectual property framework. Regrettably, some of these effective provisions were subsequently modified in a manner that reduces the legal protection. Now that the ratification process has been completed in both the United States and Peru, PhRMA will closely monitor implementation of that Agreement and assess improvements in the intellectual property regime. Notwithstanding our commitment to monitor implementation, PhRMA and its members do not consider the PTPA a model for future trade agreements given its failure to provide strong incentives for innovation.

In addition to the current lack of effective data protection and linkage, problems in infringement action procedures, such as the difficulty in obtaining preliminary injunctions against patent infringers, persist.

For these reasons, PhRMA recommends that Peru remain on the **Watch List** for 2008.

Intellectual Property Protection

Patent Enforcement

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

No relationship exists in Peru between the patent status of products and grants of sanitary registrations to copies of patented products. 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. With respect to the latter, INDECOPI has interpreted the regulations to require a preliminary injunction be lifted after 120 days regardless of whether the technical analysis needed to resolve the patent challenge has been completed. Since the technical analysis for pharmaceuticals is often complex, this automatic lifting of the injunctions has a uniquely harmful impact on the pharmaceutical industry.

With this exception, however, INDECOPI has made certain efforts to lower process barriers. Examples of such progress are the continuous 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 counterfeited 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 the pharmaceutical industry, which dedicates many of its 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 at the level required by the TRIPS Agreement. On April 12, 2006, however Peru and the United States signed the United States-Peru Trade Promotion Agreement. The obligations in the IP chapter require Peru, on the date of entry into force of the Agreement, to prevent reliance on safety and efficacy information for a reasonable period of normally five years related to pharmaceutical products whether the information is submitted to Peruvian officials or submitted to officials in other countries upon whom Peruvian officials rely.

Patents and the Regulatory System

Peru fails to relate the patent system with the system for granting marketing approval of pharmaceutical products. Under the terms of the PTPA Peru must now adopt a system in line with the agreement. PhRMA will monitor this effort closely.

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 of the innovative pharmaceutical product. This practice is both dangerous to public health and discriminates *de facto* against United States 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 2007 attributable to trade barriers related to intellectual property protection and market access.

MIDDLE EAST / AFRICA / SOUTH ASIA

ALGERIA

The 2003 Algerian patent law, which was promoted as a means to ensure protection for pharmaceutical intellectual property, revoked administrative protection for patentable inventions upon which PhRMA members relied. Algeria does not protect certain pharmaceutical test and other data from unfair commercial use and from disclosure. In addition, Algeria introduced reimbursement price controls and volume controls through the imposition of an annual import quota for medicines, and continues to delay the grant of marketing approval to patentable products of PhRMA members (due to burdensome requirements) while granting faster marketing approval for copies. Also, in 2007, an infringing copy of a product granted patent protection in Algeria, was approved. For these reasons, PhRMA recommends that Algeria be placed on the **Watch List** in 2008.

Intellectual Property Protection

Patents/Transitional Protection

Pharmaceutical products were not eligible for patents until the promulgation of Ordinance No. 03-07 on 19 July 2003. Before that date, however, the Algerian authorities would not administratively authorize the marketing of generics of pharmaceutical products covered by patents in force 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 patentable subject matter 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 take advantage of the extension of patent protection in the Ordinance. In 2005, however, Algerian health authorities abandoned the practice of providing 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.

Under current law, the government may approve a copy of a product covered by an Algerian patent and permit access to the market while the original patent is still in effect. The absence of effective judicial remedies for preventing the infringement of basic patent rights and 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.

It is important that Algeria enforce the linkage between granted patents and the registration of generic products. This should include, for instance, requiring the generic to prove in a legal proceeding (which allows the originator to defend its patent) that the originator patent is invalid before the generic is granted access to the market. Also, transitional rights to products that relied on the earlier practice of the Algerian Government should be re-established to prevent further copying until the patents in the country of origin elapse.

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 understand that it will be necessary for Algeria 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 TRIPS Article 39.3. 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 have the submitted data protected by the new law.

Market Access Barriers

Government Reference Pricing

Article 59-3 of the Law of 2 July 1983 was supplemented by an inter-ministerial order fixing the reference rates for the reimbursement of pharmaceutical products and the conditions for their enforcement published on 21 July 2001. This order limited Government reimbursement for a certain list of pharmaceutical products to a price set by reference to the cost of generic versions of the product, but this order was not implemented until the publication of the Inter-ministerial Order that entered into force on 15 April 2006. The implemented order set reimbursement prices with respect to 116 products 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. The prices, however, appear to be set to favor local and generic products over patentable products of U.S. enterprises.

Regulatory Approval Delays

Under Executive Decree No. 92-284, dated 6 July, 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 came to a standstill, with only 10 new product registrations being granted for special medical needs or other specific reasons (such as a plant opening) and with an estimated backlog of 1,000 requests. Since late 2005, however, there have been signs that the Ministry has begun to examine the backlogged pending requests. The process is still slow and the Algerian health authorities are registering generic products at a faster pace than patented products offered by U.S. enterprises.

Another issue that has emerged recently is the Ministry of Health's creation of additional, burdensome requirements for obtaining the registration to market pharmaceutical products, especially innovative products. These requirements are communicated to pharmaceutical companies in the form of "notes" and impose excessive requirements. These excessive requirements are even requested for marketing authorization renewals, and collectively represent a market access hurdle.

Preferential Treatment

On September 7, 2003, the Ministry of Health issued a Decree, "Instruction #5 for the generalization of generics," which violates numerous Algerian intellectual property-related obligations and fair trade rules and restricts access to the Algerian market in a discriminatory way. This decree stipulates that medicines for which local production is sufficient to cover the local demand may no longer be imported (since 2004, this has been applied to 128 products already). The Ministry offers assistance to local generic manufacturers for priority registration and production process approval. Branded products for importation can only be registered, if there are no generics of the same molecule already registered and if the proposed price for the branded product is within a certain range (application unclear).

In late 2005, health authorities have been responding to PhRMA member companies inquiries regarding Instruction # 5, that it will not be applied anymore; however, it has not been officially cancelled.

PhRMA requests that the U.S. Government urge the Algerian government to end this discriminatory market access barrier by officially canceling "Instruction #5".

Volume Controls

Additional market access barriers include: (1) the imposition of an annual import quota for medicines with the requirement that each shipment receives clearance from the Ministry of Health ('déclaration statistique'), and (2) the government practice of temporarily blocking importation as a cost-containment tool. In a related measure, 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 levels be approved by the Algerian Government.

PhRMA members are also concerned about current government plans to negotiate medicine by medicine the prices and volumes for the annual import quota and to deny the importation of medicines considered by an anonymous MOH commission as non-essential medicines.

The Algerian Government needs to end these actual and planned discriminatory market access barriers by canceling the above mentioned import control mechanisms.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

UNDESIGNATED COUNTRIES

EGYPT

Egypt has made significant efforts to improve its protection and enforcement of intellectual property in 2007. Areas of improvement included: training of judges and patent examiners, modernizing the infrastructure of its patent office, and the appointment of new personnel in key functions including the head of the patent office in the Ministry of Higher Education & Scientific Research.

In line with its TRIPS obligation, Egypt continued to process its black box patent applications, initiating technical and legal examination of these applications for the third year in a row. In 2007, the pace of granting patents quickened, as most of the pending patent applications were reviewed by the Patent Office and the Ministry of Health. This was a significant improvement compared to 2006, when only one patent was issued.

The Minister of Health has made some progress in terms of granting adjustments of prices to compensate for devaluation; however, the pricing system is still not transparent. The Minister of Health also has issued the Ministerial Decree 370 for 2006 to facilitate fast track registration of new innovative medicines, but full implementation of this decree has not been completed. PhRMA also still has concerns about the Egyptian Government's view of data exclusivity and the lack of protection that it currently affords confidential test data. During his November 2007 visit to the United States, the Minister confirmed to PhRMA that he will undertake a comprehensive reform of Egypt's healthcare sector, including a reorganization of his Ministry, in order to improve services provided to all stakeholders.

Recognizing the positive developments in Egypt, **PhRMA does not recommend that USTR include Egypt in its Special 301 Report.** However, because there are still concerns related to data exclusivity, government pricing, patents, and registration, PhRMA is submitting this chapter to encourage continued engagement by the U.S. Government with its Egyptian counterparts.

Intellectual Property Protection

Data Protection

In theory, Articles 56 through 62 of the Intellectual Property Law, No. 82 of 2002, require protection in Egypt for certain undisclosed pharmaceutical test and other data from unfair commercial use and disclosure. Article 56, however, is interpreted by Egyptian government officials to limit protection to five years from the date of submission of the application for marketing approval, rather than from

the date the application receives marketing approval. WTO member states, however, should not place a time limit on protection against disclosure.

Moreover, protection against unfair commercial use (non-reliance) should lapse only after five years from the approval of the underlying product. As an intermediary step to providing full protection for data from the time of marketing authorization, PhRMA appreciates the Ministry of Health's efforts to approve medicines for marketing 120 days after the same molecule is approved by the FDA or the EMEA.

Patent Protection

Egypt only began granting patents for pharmaceutical products in 2005. However, since 1995, Egypt provided a "mail-box" for applications, which was opened on January 1, 2005, when the official review of the applications commenced. In 2007, the Patent Office and the Ministry of Health reviewed most of the outstanding patent applications; all of the applications are expected to be completed by the beginning of 2008.

Market Access Barriers

Government Price Controls

The Minister of Health has granted price adjustments for some pharmaceutical products, to compensate for the devaluation of the Egyptian currency. However, all affected products have not been addressed. In addition, the pricing system is still not transparent. To remedy this, the Minister of Health commissioned a committee to review the current pricing system; some members of this committee represent PhRMA member companies. This committee will recommend a system that will be consistent with Decree 314/1991 in order to address changes in exchange rates.

Regulatory Barriers

The current regulatory system implemented by the Ministry of Health (MOH) creates serious problems for PhRMA members and discriminates against PhRMA members in favor of local companies. Recently, the MOH announced a new system in Ministerial Decree 370/2006 that would simplify the registration of pharmaceutical products and grant approvals for products within 120 days from their approval by the U.S. Food and Drug Administration and/or the European Medicines Agency (EMEA). This Decree was scheduled to be implemented on January 1, 2007 but was not, due to opposition from local companies. The pharmaceutical industry looks forward to the implementation of the new system in the Decree which will facilitate access to innovative medicines.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.