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PRIORITY FOREIGN COUNTRIES

Immediate WTO Case

ARGENTINA

Argentina remains the worst expropriator of the intellectual property of the research-based pharmaceutical industry in the Western Hemisphere, and one of the worst in the world. It intentionally permits the local industry to copy innovative pharmaceutical products immediately, without permission of the innovator and without having to expend resources for research and development to prove safety and efficacy. The government actively facilitates local company appropriation of the core of PhRMA member competitiveness in both the Argentine and the extended regional market. In addition, Argentina has signaled its intent to dilute existing commitments, create onerous compulsory licensing requirements (including for local working), and to unfairly encumber the grant of exclusive marketing rights. The U.S. Government has initiated formal World Trade Organization (WTO) consultations with Argentina as the first step in a dispute resolution process as a result of Argentina's failure to implement commitments undertaken through the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). In the same light, PhRMA requests that U.S. Trade Representative designate Argentina as a Priority Foreign Country (PFC) through the 2001 "Special 301" review process.

Intellectual Property Protection

Patent Law: On March 22, 1996, Argentina approved a new patent regime through Decree 260. The law came into force in October 2000. Although the industrial property office (INPI) began issuing pharmaceutical patents – for the first time in Argentine history – on October 24, 2000, most of the patents issued thus far have not been for commercially significant products. Moreover, due to the lack of protection for medicines in development (pipeline) and other severe deficiencies, effective pharmaceutical product protection cannot be expected to take place even after the year 2001.

Because of its numerous deficiencies, ambiguities and contradictions, the law does not adequately protect intellectual property, is not compliant with TRIPS, and is the basis of the U.S. WTO case filed against Argentina in 2000. These omissions and shortcomings are not accidental. They were introduced deliberately into the Argentine legal regime to limit the protection available for innovative products and to limit the enforceability of rights when they are granted. The above deficiencies also enable Argentine companies to export copycat products to other countries in Latin America.

The law fails to comply with TRIPS in several areas:

- It does not provide patent protection for products made using patented processes.

- It does not implement the transitional measures properly, e.g., it does not extend the term of existing patents and does not permit the conversion of process patent applications in some instances.

- It does not provide patent protection for certain biotechnological inventions.

- It does not implement required safeguards on compulsory licensing included in TRIPS Article 31.

- It does not provide for preliminary injunctive relief and/or reversal of burden of proof during trials for patent infringement.

Argentine practices exert a substantial negative impact on the ability of the U.S. research-based pharmaceutical industry to compete in the Argentine market and more generally in the Western Hemisphere. The Argentine regime directly and adversely affects PhRMA members as follows:

- Under Argentine law, an applicant whose application for a process patent was pending on January 1, 2000, is not permitted to amend the application to include product claims. This denies effective product patent protection in Argentina for products that are patentable under the TRIPS Agreement.

- Further, the absence of exclusive rights in products made by patented processes, a loophole closed by the TRIPS Agreement, allows competitors to avoid liability for infringement of patented processes.

- The growing number of products across therapeutic classes that rely on biotech inventions remain unprotected under Argentine law.

- The overly broad definition of anti-competitive practices allows for the issuance of a compulsory license when, for example, the manufacturer prices its product above market prices for legitimate commercial reasons, or when it rationalizes its operations in a way that results in a slowing of marketing of production activities. This is a clear violation of TRIPS Article 31.

- The granting of compulsory licenses to produce products for export markets violates TRIPS requirements that compulsory licenses be limited to allow use predominantly for the supply of the domestic market. The Argentine system allows compulsory licensees to export patented inventions when the license was granted due to a national emergency in Argentina.

- Argentine law dramatically and unjustifiably magnifies the scope of a compulsory license by automatically granting compulsory licenses for patents on any technology that is necessary to work the patent that was the subject of a compulsory license.

- The failure to provide preliminary injunctions in patent cases allows competitors to continue to infringe a patent until the litigation is concluded, which irrevocably erodes the market share and the reputation of the patent owner. The TRIPS Agreement requires that judicial authorities be given the authority to halt this type of unauthorized exploitation during the litigation.

- TRIPS requires that the defendant bear the burden of proof in an infringement action, even if the product was new prior to January 1, 2000. However, Argentina has reversed this, forcing the plaintiff to bear the impossible burden of proving that an identical product resulting from a patented process was made by the defendant using an infringing process.

  Data Protection: A separate law was enacted to regulate the disclosure and protection of test data used in connection with applications for marketing approval of pharmaceutical and agricultural chemical products. Instead of protecting this data from "unfair commercial use" as required by TRIPS Article 39.3, it permits competitors to rely on the test data prepared at great expense and submitted by the developer of the product. As a consequence, any competitor can begin to market the innovator's product no later than 120 days after a request to market without having to undertake the expense of proving that the product is safe and effective.

Argentina's data exclusivity law legitimizes the use by other companies of confidential test data and other commercially valuable data submitted for registration purposes after only four months. The data exclusivity law runs counter to TRIPS Article 39, and to established practice in the U.S., Europe, and many other countries. There is no acceptable remedy to this legislation, other than wholesale changes. However, requiring that "second applicants" affirmatively demonstrate that their application does not violate either a product or process patent might provide some amelioration of a very poor IP situation.

Argentina has failed repeatedly to respond to efforts by the research-based industry and the U.S. Government to identify specific administrative actions that would serve to at least partially address the deficiencies in its patent regime. The approval by the Argentine Congress of this unacceptable regime is the result of the Argentine domestic laboratories' pressure to maintain barriers to U.S. trade and investments, and maintain Argentina's deficient industrial property regime well beyond the timeframe stipulated by the WTO. The De la Rua Administration has not advocated any changes to the current regime. Given its past history, the Argentine Congress is unlikely to enact legislation to enhance the protection of intellectual property rights in Argentina.

Difficulties in effectively implementing a precedent-setting decision by the National Institute of Industrial Property (INPI) and the health agency (ANMAT) to honor exclusive marketing rights (EMR) led the U.S. Government to initiate a WTO dispute

settlement case against Argentina in 1999. Argentina, flouting terms of Article 70.9 of TRIPS, has effectively precluded the enjoyment of the rights, delayed new approvals, and more recently, rejected on questionable grounds an application that had earlier received every assurance that it complied with all eligibility requirements. The U.S. Government has continued to pursue these violations in the broader WTO case initiated in mid-2000. The Argentine Congress responded by proposing legislation to force companies to produce patented products locally and mandating compulsory licensing of products with Exclusive Marketing Rights.

Only a decision by the WTO dispute settlement panel will induce change in Argentina and we urge the U.S. Government to proceed expeditiously to the panel phase of its WTO dispute settlement case.

Damage Estimate

PhRMA is in the process of establishing methodology for estimating damages in the Argentine market. Argentina is widely recognized as the worst expropriator of U.S. pharmaceutical inventions in the Western Hemisphere, as local firms dominate over 50% of the pharmaceutical market currently estimated at almost U.S.$ 4.1 billion. Substantial and continuing loss of market share, in the range of hundreds of millions of dollars, is directly attributable to Argentina's defective intellectual property regime.

INDIA

Measured by any standard, India fails to provide adequate and effective protection for intellectual property rights or fair market access for products or corporations dependent on intellectual property protection. The Indian Government is fully aware of its obligations under the WTO TRIPS Agreement, but is unprepared to meet its current obligations. Accordingly, PhRMA urges the U.S. Trade Representative to designate India as a Priority Foreign Country (PFC) through the 2001 "Special 301" review process and to initiate a dispute settlement action in the WTO against the Government of India on the basis of its failure to meet current WTO TRIPS obligations.

PhRMA member companies believe it is imperative that the U.S. Government initiate dispute settlement proceedings against the Government of India as the first step towards reforming their fundamentally deficient regime. The Indian regime has become a "model system" for opponents of strong intellectual property protection systems. Those who cite the "benefits" of the Indian regime tend to be those who support weakening the disciplines of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). In other areas of its trade regime, India continues to resist U.S. requests for improved market access and other needed reforms. Furthermore, India continues to block the international consensus that is needed to continue market access and other trade reforms sought by the United States in new multilateral trade negotiations in the WTO. Initiation of a trade dispute would at a minimum preserve the ability of the United States to protect its rights under the WTO, and discourage other countries from taking the Indian path, which has proven to be a developmental cul-de-sac.[*]

Intellectual Property Protection

India has missed multiple deadlines for compliance with current WTO TRIPS obligations applying to developing countries. Notwithstanding that India has elected to delay full patent protection until 2005, India remains seriously out of compliance with current obligations.

As explored more fully in Appendix A, India's industrial property system was designed to allow local Indian industries to free ride on the innovations of inventors and companies from developed countries like the United States. Their patent system denies rights for pharmaceutical and other chemical product inventions and makes procurement and enforcement of patent rights virtually impossible. Most U.S. companies do not even attempt to obtain patents in India because of the difficulties

[*] See Appendix A for fuller discussion of the negative ramifications for development of India's failure to protect pharmaceutical patents.

they face in obtaining, licensing and enforcing rights, and the inherent weakness of the rights available in the status quo.

Moreover, India has refused to take the difficult steps needed to reform its fundamentally flawed industrial property system. India declined the opportunity to use the five-year transition period under the TRIPS Agreement to bring about the legislative and regulatory reforms to comply with its obligations. India chose instead to fight the U.S. and European Union on a simple transitional measure it had failed to implement, and has led political attacks on the TRIPS Agreement in the WTO that have increased in virulence and scope in recent months[*1]. Now, more than one year after India was obligated to have its reforms in place, the situation in India remains bleak for industrial property reform.

The Deficient Patent Regime of India

The Indian industrial property system, particularly its patent law, has been designed to punish importers of patented technology into India, and to coerce local production and distribution of products. As described in past "Special 301" submissions, the current Indian patent regime contains many inconsistencies with the TRIPS Agreement:

- The Indian patent system curtails or eliminates rights for foreign-originated technology or importers of patented products in a wide variety of ways. Sanctions under the Indian regime include disqualification of standing to obtain patents, special compulsory licensing penalties for those who import patented products and those who do not manufacture patented products in India.

- The Indian patent system also denies eligibility to a wide range of technologies that are within the core of the U.S. industrial base, including not only pharmaceutical and agricultural chemicals, but also other types of chemical products, glass products, and semiconductors.

- The term of protection for pharmaceutical process patents in India is only seven years under the existing Patent Act of 1970. As of January 1, 2000, India has been obligated by TRIPS Article 33 to provide a minimum term of at least twenty years from the filing date of the patent application.

[*] In light of its complete abrogation of TRIPS obligations and the certainty that it would lose in the WTO if and when challenged, the Indian Government has embarked on a campaign to demonize and delegitimize the WTO and the available dispute settlement processes. The WTO has provided improved access to dispute settlement panels of benefit to developing countries. Nonetheless, Indian officials consistently attack both the WTO TRIPS Agreement and the panel process as evil tools of developed countries to vanquish competitors in developing countries, e.g. "the WTO is a satanic force, depriving the 'human development' of India." See IDMA Bulletin XXXI (25) 7th July 2000, pp. 577 - 580, as well as subsequent IDMA Bulletin XXXI (28) 31st July 2000 pp. 634 - 637, XXXI (29), 7th August 2000 pp. 672 - 675XXXI (33) 7th September 2000 pp. 767 - 769.

- The Indian compulsory licensing system, with its infamous practice of "licenses of right" and unbridled government use authority, does not contain the safeguards required by TRIPS Article 31 and targets and penalizes U.S. inventors, particularly those that do not manufacture their inventions within India.

- The numerous deficiencies of the Indian patent system have resulted in very weak and ineffective patent protection in India. The experience of PhRMA member companies has been so negative with regard to the Indian system that most companies have abandoned efforts to obtain or enforce patents in India.

The Draft Patent Legislation

The Government of India and its Parliament are currently considering patent reform. We are discouraged that India waited until mid-November, 2000, less than two months before the deadline for TRIPS implementation, to *start* the legislative process to amend its patent law. In and of itself, this is evidence of India's overall bad faith with respect to TRIPS obligations. More recently, the Parliamentary Patent Select Committee charged with preparing the legislation has engaged in tactical delays to prevent introduction of the overdue patent reform bill. The most recent example is further delay in a planned six-country visit to ostensibly research the TRIPS implementation efforts of Argentina, Brazil, China, Japan and Korea with a report to follow prior to discussion of the patent law before its formal consideration in the Parliament. PhRMA believes that the date for introduction and substantive debate of the legislation will slide well into the year 2001.

The proposed legislation does improve certain features of the Indian system. These improvements, however, build on a fundamentally flawed regime. Unfortunately, the draft legislation is also regressive in a number of areas. In fact, the legislation introduces several new provisions that are inconsistent with TRIPS and fails to remove many of the most offensive inconsistencies noted above.

- The draft law, if enacted, would continue to discriminate against foreign patent owners who manufacture products outside of India. The new law retains sanctions, including compulsory licenses, for patent owners who do not "work" their patented inventions within India. Local working as a requirement for full enjoyment of patent rights without the recognition that the obligation may be satisfied through importation is prohibited under Article 27.1 of the TRIPS Agreement.

- Some improvements would be made to the existing compulsory licensing regime in Indian law. However, an extensive amount of authority would continue to be available to the Indian Government to use patented technology without the consent of the patent owner and in a manner inconsistent with Articles 27 and 31

of the TRIPS Agreement.

- Competitors would continue to have the right to harass and challenge patent applicants and patent owners. Numerous grounds will continue to be available under the law to oppose, cancel and revoke patents on grounds not permitted under the TRIPS Agreement. For example, the Indian system of pre-grant opposition would be altered to provide two new grounds for opposing patent grants that are not allowed under Article 29 of TRIPS. Combined with the backlog of more than 30,000 applications pending in India and the dearth of qualified examiners, the opposition proceedings would easily allow competitors of patent applicants to delay the issuance of a patent until the expiration of the term. This would effectively eliminate patent protection for important inventions.

- The draft law, in contravention to Article 28.1 of the TRIPS Agreement would exclude product-by-process protection for certain types of products that are now denied full product patent protection under Indian law. This exclusion also violates Article 27.1 of the TRIPS Agreement, which forbids discrimination as to the field of technology of the invention. In addition, the product-by-process protection would only be available to patents issued on applications filed after January 1, 2000, in contravention of the transition provisions contained in Article 70.2.

As noted above, the Indian patent regime currently, and will continue to, falls far short of India's obligations under the TRIPS Agreement. More troubling is the apparent lack of political will and commitment to the establishment of a modern patent system that delivers the patent exclusivity, which is a necessary precondition to significant investments in India by our industry.

We are also disappointed that India's greatest efforts have been reserved for Geneva, where, rather than sincerely attempting to meet its own obligations, it has sought the support of other WTO Members for weakening the industrial property standards now found in the TRIPS Agreement. From this we can only conclude that the Indian Government is fully aware of its obligations under the TRIPS Agreement, but is unprepared to meet its current obligations. In the summer of 2000, India tabled a proposal in Geneva recommending that the TRIPS Agreement be amended to serve as a lever for technology transfer to developing countries and to eliminate binding obligations in the area of industrial property.

Exclusive Marketing Rights; Absence of Data Exclusivity

India is particularly hostile to intellectual property rights that would interfere with the commercial strength of its domestic pharmaceutical and chemical industries. This explains India's essentially non-functional patent system and the decision of the Government of India to refuse to grant exclusive marketing rights (EMR) or rights in

data used to obtain marketing approval for pharmaceutical and other chemical products.

India fought against implementing its obligations under Articles 70.8 (“mailbox”) and 70.9 (exclusive marketing rights) until the complete WTO dispute settlement process had been completed. It made substantial commitments to the United States to settle the dispute. These commitments were to have resulted in establishment of an efficient process for granting exclusive marketing rights. However, since that settlement, the Indian regulations passed to implement the agreement have been challenged in two courts, and the Indian Government has made no effort to prevent third parties from obtaining marketing approval for covered products. India thus has ignored its obligations to settle the mailbox/EMR disputes to the detriment of U.S. interests.

India has also elected to ignore its obligations under Article 39.3 of the TRIPS Agreement. Neither the Indian Government nor the Indian Parliament has even raised the idea of implementing legislation that would provide protection for test data submitted by innovators to obtain marketing approval for their new products. The absence of such pro

modernization efforts at the administrative and legislative level to make it possible to operate a modern patent office in India.

Market Access Barriers

The Indian Government's liberalization and economic reforms have not yet been fully extended to the pharmaceutical industry. The industry is unable to attract fresh investment and the research-based pharmaceutical industry is either withdrawing from India or not expanding operations. In the area of drug pricing, India imposes some of the most stringent price controls in the world under the rigid provisions of the Drug Price Control Order (DPCO). In the eyes of many research-based company managers in India, this strict pricing regime – combined with the lack of any meaningful patent protection – make India virtually non-viable for research-based companies from a commercial standpoint, particularly if those companies were to consider placing the latest and best innovative drugs on the Indian market. Foreign companies also experience arbitrary BICP (Bureau of Industrial Cost and Pricing) pricing norms.

The present pricing regime is more than five years old. Recognizing that the pricing regime needs change, the government constituted a committee to propose a new pricing policy. The committee's report was subjected to the review of a special task force, yet no meaningful new price control regimen has been established. There is no system allowing automatic increase of prices to offset cost increases and inflation. Individual research-based firms have held good faith discussions with the Government of India for provision of needed drugs at preferential rates in return for market-based reforms. Our industry would urge any new government in India to consider seriously abolition of the DPCO. The DPCO is neither in the interest of the Indian economy nor of the Indian pharmaceutical industry, nor – and most importantly – in the interests of the Indian healthcare consumer.

PhRMA and its member companies desire that:

- The Government of India remove the anomalies in the present Price Control Order.

- The Government of India takes measures to adopt a system of market-based pricing in India in the near-term.

<u>Import Policies</u>

PhRMA member companies operating in India also face high 44% effective import duty for active ingredients and 66% for the finished products import and complex import procedures. The Government of India has stated its intention to progressively lower import tariffs on pharmaceuticals. Duty rates, however, remain unacceptably high. In 1996, tariffs were brought down to 85% with plans to further decrease rates to 25% by the end of 1999. Progress has been slow and tariff rates are currently high.

PhRMA urges U.S. negotiators to insist that tariffs be brought down to zero, the goal for GATT signatories.

Standards, Testing, Labeling, etc.

Except for the problem of trademarks and the regulations concerning the size and placement of the generic name on medicines in India, there currently are no discriminatory regulations for pharmaceutical multinationals. PhRMA member companies operating in India have reported experiencing arbitrary local FDA decisions.

Damage Estimate

PhRMA is currently studying methodology for estimating damages caused by absence of intellectual property protection in India. The damage caused by the inadequate protection of intellectual property rights in India reaches beyond direct losses caused by displaced sales in India. Indian bulk pharmaceutical companies aggressively export their products to third countries where intellectual property laws are similarly lax. The damage caused to U.S. pharmaceutical manufacturers due to the deficiencies of the Indian patent regime thus goes beyond displaced sales in the Indian market, and reaches to the ability of U.S. companies to compete in other significant markets, especially in the Asia-Pacific and Middle East regions. PhRMA estimates the losses attributable to the deficiencies in the Indian intellectual property system to be approximately $500 million per year.

ISRAEL

In early 2001, in the absence of any public health crisis, and despite ongoing Supreme Court litigation, the Government of Israel became the first industrialized country to go forward with parallel importation. Israel has also failed to date to adopt protection for confidential data as required by TRIPS Article 39.3, and has also recently implemented price controls in an already monopsynistic market. For these reasons, PhRMA requests that the U.S. Trade Representative designate Israel as a Priority Foreign Country (PFC) under the "Special 301" review process for the year 2001. PhRMA further requests that the U.S. Government initiate formal consultations with the Government of Israel under the auspices of the WTO in Geneva to provide a forum for discussion of these and other related issues.

Intellectual Property Protection

Israel's treatment of the pharmaceutical industry contrasts sharply with the situation fo

In its answer to the Israel Supreme Court filed on August 30, the State stated that the Ministry of Health was not yet prepared to implement the regulations, and accordingly that there was no immediate risk of parallel importation.[2] Although, the Supreme Court petition had a temporary chilling effect on potential importers, the Ministry of Health ultimately went forward with parallel importation, despite the clear concern of the Supreme Court, which did not dismiss the Petitioners' claim as requested by the State.

The Petition has improved the environment for the pharmaceutical industry in Israel in that the Ministry of Justice is now considering legislative proposals for data protection of pharmaceutical tests and other commercially valuable data. While we are encouraged by Ministry of Justice statements that the GOI may consider legislative proposals to provide data protection, PhRMA believes that unless patented pharmaceuticals products are explicitly eliminated from the jurisdiction of the law, the parallel import program will: (1) facilitate patent infringement by importation by non-right holders; and (2) violate Israel's WTO TRIPS obligations, particularly in the area of data exclusivity and effective enforcement measures. PhRMA appreciates the strong USG support that has, coupled with the ongoing litigation, thus far prevented actual parallel importation, and will continue to work closely with all parties to ensure that the final result does not weaken patent protection in Israel.

Lack of Patent Restoration

In 1998, the GOI amended the patent law to allow local companies that are not patent owners or licensees to manufacture patented material prior to expiration in order to submit registration data to health authorities in Israel, and other countries that allow similar pre-expiration activities, for marketing approval. Implementation of this law allows Israeli manufacturers who do not have any rights to the patent to conduct large-scale manufacturing in Israel during the life of the originator's patent. Although the law is designed to permit the manufacture and export of patented medications for the limited purpose of applying for marketing approval, because the Israeli Government has not established any effective enforcement mechanisms to prevent abuse of this provision, companies may manufacture and export large quantities of pharmaceutical products during the period of patent protection.

The law has, in effect, significantly shortened the period of patent protection for pharmaceutical products (which discriminates between technologies and so may violate TRIPS), and so reduces patent protection in Israel. The effective period of patent protection in Israel is now approximately five years, the shortest patent terms in any developed country except Canada.

[2] The State's response also acknowledged that the parallel importation program would infringe patents held by the research-based pharmaceutical industry in Israel, but argued that civil remedies protect the petitioners, and the State is not obligated to provide data protection. (But note that Ministry of Justice officials are now exploring legislative proposals to add data protection for pharmaceutical test and other data.)

Data Exclusivity

The GOI's Health Ministry allows reliance by local pharmaceutical firms on the confidential data that it receives from pioneer pharmaceutical applicants, arguing that as long as it refrains from active dissemination of confidential data from pharmaceutical

Israel has implemented price controls for pharmaceutical products effective June 1, 2001. The new Israeli price regime is based on the Dutch model (i.e. the average price in the Belgium, France, Germany and the UK) plus 1.2%. Higher prices will go down, lower prices will come up. The decree applies only to pharmacy prices (3-5% of the market). There should be no legal impact on prices to the sick funds (90% of the market), which are determined by negotiations between the pharmaceutical companies and the sick funds. Indirectly, pharmacy prices are a point of reference for these negotiations, and so prices to the sick funds might also be affected. It should be noted that the sick fund prices are already substantially lower than the pharmacy prices. When the decree comes into effect on June 1, price convergence will take place in three stages bringing the current prices to the "target prices" in a process that will end on June 1, 2003.

Damage Estimate

Research on assessing damage to industry due to absence of data protection is currently underway, and will be provided as soon as practicable. Damage to the industry from lack of protection for confidential data, given that the threat of parallel importation on patented pharmaceutical products is not in place, is difficult to estimate. However, based on experiences in other markets, parallel importation would have a domino effect on the whole market and would not be limited to a specific product. Parallel importation could seriously damage the Israeli healthcare system, and the Israeli pharmaceutical and related sectors. Given that the threat of parallel importation on patented pharmaceutical products is not in place, it is difficult to estimate potential damages. But based on experiences in other markets, parallel importation would have a domino effect on the whole market and would not be limited to a specific product. Parallel importation could seriously damage the Israeli healthcare system, and the Israeli pharmaceutical and related sectors.

The Israeli pharmaceutical market totals some U.S. $690 million (1998). Sales of patented imported products were approximately U.S. $450 million (most sales are by the multinational pharmaceutical companies). Sick funds represent 90% of the market, i.e., U.S. $400 million in patented imported products. Members of the research-based pharmaceutical industry in Israel currently employ 700 people; many may lose their jobs. International research-based firms invest U.S. $80 million per annum in clinical trials conducted by Israeli medical institutions and physicians. If parallel importation of patented pharmaceutical products were to be implemented, many of these research initiatives could be moved out of Israel.

In sum, parallel importation brings with it the attendant risk of significant job losses in Israel, curtailed participation by Israeli doctors and scientists in clinical trials, and reduced incentives for new biotech investment by foreign firms. All of the foregoing could have adverse impacts on public health and safety outcomes. Good medicine relies on the availability of skilled personnel and resources. For illustration of

possible harm to the Israeli market, consider the following: The Israeli pharmaceutical market totals some U.S. $690 million (1998). Sales of patented imported products were approximately U.S. $450 million (most sales are by the multinational pharmaceutical companies). Sick funds represent 90% of the market, i.e., U.S. $400 million in patented imported products. International research-based firms invest U.S. $80 million per annum in clinical trials conducted by Israeli medical institutions and physicians.

TAIWAN

Taiwan is the 20th largest pharmaceutical market internationally, with 1999 sales of approximately U.S. $2.5 billion. International pharmaceutical firms have about 70% market share with U.S. share being around 25%. Over the past year, through close and constant communication and engagement with the government, some progress has been made in regulatory affairs, but much remains to be resolved through mutual discussion and cooperation, notably in the areas of intellectual property protection and reimbursement pricing. Ta

limited patents to a term of "fifteen years from the date of publication of the application."[4]

In amending its law, however, Taiwan specifically excluded certain patents from the new 20-year term required by TRIPS. Article 134:2 of the revised Patent Law provides:

> For patent cases that have been allowed and published before the revision of this Law, the computation of the terms of the patent rights thereof shall be effected in accordance with the provisions in force prior to the present revision of this Law.

Accordingly, while patents based on applications filed under the new Taiwanese Patent Law are entitled to a 20-year term from date of filing, patents based on applications filed and published before January 23, 1994 are limited to 15 years from the publication date (which occurs between filing and grant), and are subject to an additional cap of 18 years from the date of filing. In short, as a matter of law, products for which patents were filed before January 23, 1994, cannot receive patent protection for twenty years from the filing date of the application.

TRIPS Article 33 specifies that the term of patent protection "shall not end before the expiration of a period of twenty years from the filing date." Moreover, TRIPS Article 70:2 provides that "this Agreement gives rise to obligations in respect of all subject matter existing on the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date. . .." As a result, in applying the Uruguay Round TRIPS Agreement effective January 1, 1996, WTO Members, including the U.S. and European Union, interpreted the transition obligations of Article 70:2 to require application of TRIPS to existing, protected subject matter, including all patents then in existence. This interpretation resulted in changes to a wide variety of national laws and regulations by WTO Members, including the United States.

In *Canada – Term of Patent Protection*, AB-2000-7 (18 Sept. 2000), the WTO struck down a Canadian law that denied a 20-year term to certain existing patents. On October 12, 2000, the WTO's Dispute Settlement Body (DSB) adopted both the Panel and Appellate Body reports, establishing *Canada – Term of Patent Protection* as settled WTO law. Under Section 45 of its Patent Act, Canada, before October 1, 1989, provided a patent term of seventeen years from the date of grant. While the Canadian law was revised to provide a 20-year term for applications filed after October 1, 1989, there was no transition mechanism for pre-October 1, 1989 patents.

In a challenge filed by the United States, the WTO determined that TRIPS Article 33 requires a patent term of "twenty years counted from the date of filing." It

[4] Patent Law of the Republic of China (Taiwan), Chapter I, Article 6 (Promulgated on May 29, 1944; Effective from Jan. 1, 1949; Last revised on Dec. 24, 1986).

concluded that "(1) the reference to 'subject matter. . . which is protected' on the date of application of the TRIPS Agreement in Article 70:2 includes inventions that are currently protected by patents in accordance with Section 45 and that were protected by patents on 1 January 1996, and this is not affected by Article 70:1; and (2) Section 45 of Canada's Patent Act does not make available a term of protection that does not end before 20 years from the date of filing as mandated by Article 33." *Canada – Term of Patent Protection*, WT/DS170 at 7.1.

As a result, the WTO directed Canada to amend its law to provide a full 20-year patent term for inventions that received patent protection in Canada on the date that it applied TRIPS, i.e. January 1, 1996. The Panel and Appellate Body both flatly rejected Canada's claim (now echoed by Taiwan) that Article 70:1 precludes retroactive application of TRIPS. The Appellate Body distinguished Article 70:2, which governs "continuing situations," from Article 70:1, which precludes "retroactive" application of TRIPS to "acts which occurred" before the Agreement entered into force. It determined that an existing patent-protected invention represents a "continuing situation" governed by Article 70.2, not a prior "act" under Article 70.1. As a result, the Appellate Body concluded Canada was required to "apply the obligation contained in Article 33 of the TRIPS Agreement to Old Act patents." *Id*. at 32.

It should be apparent that Taiwan's Patent Law is deficient in ways that are virtually identical to Canada's Old Act. Like Canada, when Taiwan amended its patent law in 1994 to provide a TRIPS-consistent 20-year term, it failed to provide a transition mechanism for patents based on applications predating the new law. Thus, Taiwan's violation of TRIPS Articles 33 and 70:2 falls squarely within the WTO's ruling in *Canada – Term of Patent Protection*. It would be deeply troubling if Taiwan were to refuse to recognize the WTO's ruling in *Canada – Term of Patent Protection,* or were to persist in essentially frivolous arguments which have already been flatly rejected by the WTO, even as it seeks to convince the WTO that it is worthy of membership.

As we understand it, the terms for Taiwan's WTO membership could be finalized shortly, depending on progress in the Chinese accession negotiations. The purpose of a WTO protocol package is to ensure that a new member's laws and regulations conform to WTO rules. Accordingly, Taiwan's protocol represents a key test of whether it is prepared to assume the obligations and responsibilities of WTO membership. WTO membership would represent an important form of international recognition for Taiwan, which unfortunately has been excluded from most international organizations since the 1970s. While Taiwan has not yet formally done so in the draft Working Party report, it has committed to implement and apply TRIPS immediately upon accession to the WTO. Failure to extend a full 20-year term to pre-January 23, 1994, patents immediately upon accession would represent a glaring deficiency in Taiwan's WTO protocol; invite an immediate WTO challenge; and call into serious question Taiwan's commitment to WTO principles. It would also result in severe losses to PhRMA members.

Market Access Barriers

Market access barriers in Taiwan affecting the interests of international pharmaceutical companies fall into two broad categories: pricing and reimbursement and regulatory affairs. The priority issues include discriminatory reference pricing, reimbursement issues, clinical trial requirements, and plant master file requirements -- all key subjects for ongoing priority discussion between U.S. and Taiwan Government officials.

Pricing And Reimbursement Issues

Over the past several years, Taiwan has moved from a half-Government and half-private purchase market for medicines to an approximately 95% Government operated National Health Insurance (NHI) scheme. With insurance introduction, through the Bureau of National Health Insurance (BNHI), a series of price and reimbursement controls have been introduced, which particularly affect the research-based industry.

PhRMA's chief objection to these controls is their discriminatory effect; that is, the favorable position local companies enjoy via the controls' application. The other leading concern is the negative impact these controls create for the introduction of new products, including novel, breakthrough medicines.

Pricing

Taiwan operates a price setting system based on international comparisons. New products without bioequivalent competition are set at the median price of the product as it is listed in ten developed markets. In practice, new products are often reimbursed near the bottom end of the ten countries' market price spectrum due to the current cost containment measures of the BNHI. For locally manufactured bioequivalent generic products, BNHI sets a reimbursement level at close to 100% of the originator's brand. For common generics (i.e. no proven bioequivalent generics), BHNI approves a price near 80% of the originator's price. These discriminatory practices, artificially distort market dynamics, and interfere with free market forces. They also are becoming more prevalent as the BNHI budgetary deficit worsens.

The *de facto* practice of Reference Pricing that appears to have been practiced in recent months seems to be driven by the BNHI's efforts to achieve immediate, short-term savings by primarily targeting foreign and imported medicines for price restrictions. This results in low reimbursement prices for new products and others in that group. This approach also helps avoid the political complications of fixing the "*Black Hole*" (the difference between the selling price and the reimbursement price),

which would be strongly opposed by the local industry, private hospitals who rely on it for revenue, and certain local politicians. A key difficulty in assessing the new Reference Pricing scheme is its fundamental lack of transparency. A New Drug Pricing Committee created by BNHI, administers the system without meaningful Industry participation by U.S. and European companies. To date, no rules, regulations, or guidelines have been issued.

There has been little consultation with industry regarding the impact of the new scheme on access to new innovative medicines by Taiwanese patients. As a result, U.S. and European firms have little idea when the new system was adopted or how it really operates. Instead, Reference Pricing has been implemented on an unpredictable case-by-case basis in one-on-one meetings between BNHI officials and managers of individual U.S. and European firms.

Despite its lack of transparency, PhRMA believes the new system being practiced involves (1) therapeutic grouping (comparing new products with existing ones of same category), and (2) generic grouping (comparing all existing off-patent products with generics of same active ingredients), in addition to (3) the original reimbursement guidelines published by the BNHI in 1995.

PhRMA maintains that the Taiwan Government's policies are unfair and discriminatory for the following reasons:

- Reference Pricing tends to drive down the prices of innovative medicines, which are primarily produced by research-based U.S. and European pharmaceutical companies, while artificially boosting the prices of local generics. In addition, PhRMA is concerned by reports that the "rules" are being applied arbitrarily and inconsistently. U.S. and European companies have been informed by BNHI officials that their reimbursements will be reduced by a specific percentage, referring to unpublished guidelines. Others have been told that applications for reimbursement of new indications of existing medicines will not be approved unless they agree to arbitrary price reductions for other products.

- Taiwan's Reference Pricing system disproportionately burdens medicines of imported origin. To date, the BNHI apparently has only targeted new products from US, European, and Japanese companies. Additionally, BNHI appears to have singled out certain medicines in certain disease categories, e.g., antibiotics, cardiovascular products, hypoglycemics, and hormones, in an effort to cut reimbursement prices for successful international products.

- The "*Black Hole*" is the core issue precipitating the need for cost/price interventions by the Taiwan Government. PhRMA believes that the potential introduction of a global budgeting system in the future will not solve the

healthcare funding crisis that Taiwan is experiencing. Conversely, it will further entrench the "*Black Hole*".

- In summary, PhRMA supports a ratio between originator, bio-equivalent and common generics that provides appropriate recognition of the value of innovative medicines. Effective competition in the current Taiwan structure cannot be stimulated in the market under the conditions by which the Government of Taiwan currently accords extraordinary and misplaced incentives to bioequivalent and generic products. Greater recognition of innovation is needed, as well as significantly reduced funding for non-BE generics, which are questionably effective medicines (i.e., common generics). This would reduce the burden of generics on the BNHI reimbursement system, and would provide "headroom" for the introduction of innovative, breakthrough medicines.

It is also worth noting that the BNHI reimbursement value of pharmaceuticals for all generics grew from 35% of the total budget in 1995 to around 55% by the close of 1999. This growth is driven not by market competition, but by government sponsored overpricing support for generics, due to government attempts to foster development of the local bioscience industry. This support achieves levels higher than would prevail were market forces in place to stimulate greater price differentials between originator and non-originator, off-patent products.

Reimbursement

Virtually all pharmaceuticals (including many OTCs) are reimbursed by BNHI to hospitals and clinics that dispense them. Pharmacy dispensing is not yet fully developed in Taiwan, despite government intentions to promote it. There are three issues that are of principal concern to PhRMA:

First, Article 49 of the NHI Law states that "drugs, priced medical devices and materials shall be reimbursed at cost." This law is not enforced, as it should be. Current estimates of the amount between invoices and claimed reimbursements by hospitals are approximately U.S. $650 million (i.e., this is the value of the "*Black Hole*"*)*, according to the IRPMA, the international pharmaceutical industry group based in Taiwan. The main reason for this difference is that the current reimbursement system allows health-care providers to profit from the Government's non-enforcement of Article 49.

While the government has tried to more accurately assess this gap by conducting a price/volume survey, the data have not been fully conclusive, because not all hospitals agree to release full information. Implementation of Article 49 (i.e., elimination of the "*Black Hole*") is imperative as a prerequisite for further actions. Otherwise, once reimbursement is cut further, private hospitals will be inclined to

demand ongoing free goods and other bonuses from manufacturers to maintain their profit margins currently derived from drug dispensing. What is needed is a more transparent system of reimbursing hospitals that eliminates questionable discounts and provides higher fees for hospitals for the cost of advanced medical care.

Secondly, hospitals (through government acknowledgement, but not government mandate) in most cases require a formulary-listing trial to be conducted prior to admission to the hospitals' reimbursement list. These trials are not required for products from generic manufacturers. While it is important that hospital pharmaceutical committees have the authority to review product use, delays to patient access to new and innovative therapies need to be minimized.

Third, there is increasing use restriction placed on new drug reimbursement. Almost all new drugs now have effective reimbursement limitations of one kind or another. In many cases, this burden falls disproportionately on innovative U.S. and European medicines, and means the research-based product is effectively prevented from achieving a reasonable return on investment.

PhRMA recommends that, to correct these reimbursement discrepancies:

- Hospitals should be reimbursed at net actual acquisition cost for pharmaceutical purchases, plus a reasonable management (i.e., dispensing/service) fee, that would be a fixed percentage of the purchase price.

- The price of the products from the fee for the transaction of storage, dispensing and record keeping; such a system would eliminate the non-transparent impact of discounts and free goods.

- The BNHI prescribing restriction guidelines limit the doctor's freedom of choice to prescribe what is indeed best for the individual patient. This problem is compounded by a BNHI system of excessive penalties for mis-prescribing (10-100 times the prescription value) that have stimulated a trend to prescribe the cheapest product rather than the one with the best cost-benefit profile.

<u>Regulatory Affairs</u>

While some progress has been made in achieving more rapid registration for certain classes of drugs to treat life-threatening diseases (e.g., AIDS, cancer), Taiwan remains a late registration market by international standards. This fact is driven heavily by a series of technical and regulatory hurdles that continue to prevent rapid market entry for new drugs that have been approved in other industrialized countries. However, recent experiences are demonstrating that significant restrictions are being put on actual utilization of new medicines.

The main issue and its impact on the industry are summarized below.

- Registration Clinical Trials: Currently registration clinical trials must be conducted prior to marketing approval for a drug. These trials serve no scientific purpose, and result in a three to four year delay in launch from first major market. Some progress has been made in this area to reduce this delay. Parallel submission of the registration dossier and the clinical trial (registration trial) protocol is now possible, so that the review occurs concurrently with the registration trial.

  In June 1998, the DoH indicated that registration trials would be phased out over the following two years. Over this time, the DoH conducted a review every three months to waive this requirement for certain groups of drugs based on medical indications. In 1999, the DoH announced that it would implement the ICH E5 guideline on Ethnic Differences in the Acceptability of Foreign Clinical Data in June 2000. While the industry is pleased that the DoH would be implementing internationally harmonized standards in this area, the DoH's interpretation of the ICH guideline would require clinical studies to be conducted in Taiwan for the registration of a pharmaceutical, effectively replacing the registration trial with another clinical trial requirement. This was to become effective in June 2000, but has been postponed due to industry concerns with the DoH's interpretation of the guideline. Industry has been in active dialogue with the DoH on this issue since June 2000. The ICH E5 guideline must not be implemented until the remaining issues on interpretation have been resolved, and an implementation strategy, agreed to with industry, is in place.

- Free Sales Certificates (FSCs): Taiwan recently has decreased from three to two the number of FSCs it requires for registration, so long as one is from the country of origin within a list of ten advanced countries (otherwise three are required). However, company manufacturing strategies may result in a product not being sold in the country of origin. In this case, an FSC from the country of origin will not exist, thus preventing the product being launched in Taiwan. Given that the DoH carries out its own review of the dossier for drug approval, the FSC adds no value, and the requirement should be removed.

- Plant Master Files (PMFs): PMF is a requisite of a new drug registration in Taiwan, and is a requirement seen in few other countries, justified by the DoH on public health grounds. The PMF contains significant quantities of detailed proprietary information about the drug manufacturing process and the site of manufacture, and its submission is of considerable concern to companies at many levels, not least from an intellectual property perspective. The requirement for submission of the PMF has led to drastically increased review times – 60% of dossiers now take more than two years to review, compared to the three months claimed by the DoH. Furthermore, if a company changes a manufacturing site for an approved product, this process has to be repeated at considerable expense and time.

While the DoH is carrying out its mandate in assuring the quality of the products it approves for sale in the Taiwan market, there are other, less onerous, internationally accepted methods by which it could fulfill this mandate. Taiwan has indicated it will replace the PMF requirement with a GMP (Good Manufacturing Practices) Inspection Report once it becomes a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S). These inspection reports are produced by the regulatory authority in the country of origin and address all the technical elements of a PMF, without requiring that information to be compiled and submitted to the agency.

As a prelude to this, Taiwan has concluded an accord with Switzerland, Germany, Spain, Italy, Belgium, and France to use Site Master Files (a short descriptive document, readily prepared by companies, and non-proprietary) and PIC inspection reports instead of PMFs. However, in the case of the United States, this type of agreement is not possible as the U.S. is not a member of PIC/S. However, in an analogous fashion the DoH should accept the U.S. FDA issued Certificate of Pharmaceutical Product (CPP), which is the FDA version of the PIC/S report, and waive the PMF requirement. An agreement on this point must be concluded with the DoH as soon as possible, to bring the Taiwan DoH in line with international practices and reduce the registration time for new pharmaceuticals, as well as new manufacturing sites.

In addition to the PMF issue, in a related area the DoH has recently announced a drug validation scheme that requires companies with imported drugs to provide the same information on drug validation as domestically manufactured drugs. This is an extremely onerous requirement that is being applied to drugs already registered as well as new drugs. This requirement is unnecessary, is unique to Taiwan, and as with the PMF issue, could be fulfilled by the acceptance of GMP certificate, Site Master File, or PIC/S inspection report of CPP from the country of origin. Failure of a company to comply with this requirement will mean de-listing of the product. It is hence critical that this requirement is lifted and replaced with a requirement to supply a GMP certificate (or similar) from the country of origin.

- Repackaging: Taiwan maintains restrictions on the ability of companies to import multi-site source products (bulk medicines) for repackaging in Taiwan pursuant to regulations adopted in April 1998. Taiwan has said it will separate this issue from its accession to the WTO. Taiwan should eliminate this requirement as a good faith sign to eliminate import barriers.

- Zero Tariffs: Taiwan committed to achieve zero tariffs for pharmaceuticals by 2002. Companies currently face on average a 12.5% import duty on finished products. This level of tariff barrier is hard to justify in a country as internationally competitive as Taiwan. Faster implementation of the zero tariff accord would be a welcome sign

of cooperation by Taiwan. Moreover, Taiwan should abolish tariffs on all categories of pharmaceuticals recognized by other nations that have implemented this exercise. There is particular opportunity for this upon Taiwan's' accession to WTO.

- Relief Fund for Victims of Side Effects: The Department of Health in 1998 created a relief fund to compensate patients and their families harmed through use of approved medicines. The fund will initially cover damage caused by Western drugs (as opposed to Traditional Chinese Medicines). Most manufacturers have joined the fund through a voluntary contribution of 0.1% sales revenue of pharmaceuticals, and companies are represented on the management committee of the fund. Industry's major concern remains that Traditional Chinese Medicines and health foods likewise be included in the fund, in order to eliminate any discriminatory treatment.

Damage Estimate

If Taiwan fails to convert its patent term length from 15 to 20 years for all patents, PhRMA member companies will face losses of U.S.$ 330 million for this issue alone, due to lost effective patent terms on 39 separate products. PhRMA is currently studying methodology but estimates that total losses in Taiwan can be conservatively estimated at U.S.$ 730 million.

PRIORITY WATCH LIST COUNTRIES

Possible Future WTO Cases or Bilateral Action

ASIA-PACIFIC

CHINA

The Pharmaceutical Research and Manufacturers of America (PhRMA) member companies operating in China continue to face significant challenges and problems as China finalizes its negotiations with World Trade Organization (WTO) member countries to prepare for WTO accession. The major challenges may be found in the broad areas of intellectual property protection, the pricing and reimbursement of medicines and the technical regulation governing the approval of medicines for human use. Some improvements have been made in the operating environment for PhRMA member companies in China since China enacted intellectual property laws in 1993, but significant problems remain. In particular, inadequate intellectual property laws and the poor implementation of China's "Administrative Protection" program (i.e., pipeline protection) for pharmaceuticals pose a serious public health risk, and serve to undermine the competitive advantage that innovative companies gain from their substantial investments in research and development.

For these reasons, PhRMA requests that China be included in the 2001 "Special 301" Priority Watch List, and that the U.S. Government continue to seek assurances that the problems described herein are resolved prior to China's accession to the WTO.

Intellectual Property Protection

Administrative Protection

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While the State Drug Administration has promulgated an administrative sanctions law and established a small anti-counterfeiting office, few resources have been allocated for anti-counterfeiting efforts. We urge the Chinese government to:

- allocate more resources to anti-counterfeit pharmaceutical initiatives;
- commit to random, unannounced searches of pharmaceutical operations; and,
- enact mandatory criminal prosecution and jail time for convicted counterfeiters.

Patents

After a foreign company receives patent protection on a pharmaceutical compound in China, it is all too common to find that the SDA has allowed local companies to conduct clinical trials on the patented compound. These clinical trials are conducted without the permission of the patent holder, and thus constitute patent infringement.

When a patent is issued in China, it should be the responsibility of all ministries and agencies in the Chinese government to uphold and enforce the rights of the patent holder. With regard to pharmaceuticals, clinical trial authority should be denied if the compound is under patent and the applicant prior to conducting clinical trials has not first obtained the express written permission of the patent holder.

Market Access Barriers

Price and Profit Controls/Protectionism

Pharmaceutical products are considered special commodities in China and thus subject to price controls. In 1997, pharmaceutical price jurisdiction was vested in the State Development and Planning Commission (SDPC). Since that time, the SDPC policy or guidelines for establishing pharmaceutical prices have been in a continuous state of change and has become an area of great concern and unpredictability for pharmaceutical companies. Experience has proven that pharmaceutical price controls discourage innovation and high quality manufacturing, and often result in unintended consequences such as discouraging the timely introduction of innovative products in the marketplace, and maintaining artificially high prices in the generic pharmaceutical sector.

SDPC pricing policy has changed significantly in the past two years and reflects some of the recommendations advocated by the international industry. While the SDPC originally intended to set rigid margin controls at each stage of the distribution chain, a policy change implemented last year focused on the *end retail price* while

continuing to monitor margins at the distributor and hospital level. In the event that the SDPC found distributor and hospital margins to be excessive, it reserved the right to cut the product's retail price.

In July 2000, the SDPC promulgated the *Guidelines for Drug Price Administration.* This new policy is encouraging as it immediately allows free market pricing for some products and implies that use of the free market will be gradually expanded. This policy raises new concerns, however, as the SDPC has abrogated a substantial share of its pricing authority to the provincial and local governments. Further, these new regulations set forth the following principles for consideration in establishing pharmaceutical prices:

- innovative v. generic; GMP v. non-GMP; and brand v. non-brand,

- imported drug prices should be referenced to locally manufactured drug prices or to the prices in countries at roughly the same level of economic development as China.

This new policy will result in a number of unanticipated and unintended consequences, not least of which are higher operating costs for companies as new pricing departments and personnel are added in order to negotiate with the many regional government-pricing authorities. Additionally, as the SDPC reserves the right to order a price cut, a company may be discouraged from offering higher volume discounts as this could result in an across-the-board price cut for the company's product nationwide. Finally, this new policy theoretically allows provincial and local governments to maintain higher government-established prices for locally produced products. This could exacerbate provincial and local protectionism, which would contradict one of the key policy goals of the central government as China pursues entry into the World Trade Organization (WTO).

Damage Estimate

PhRMA is currently studying methodology for estimating damages caused by absence of intellectual property protection in China. It has been difficult to measure precisely the size of China's pharmaceutical market, and the shares held in that market by foreign and domestic pharmaceutical companies. Today, there are 12 PhRMA member affiliates in China, which PhRMA estimates enjoy approximately a 12% share of the Chinese pharmaceutical market of U.S. $6 billion (for finished formulations of western medicines) or around U.S. $720 million in annual sales.

It also is difficult to determine whether the total number of pirated products (as a percentage of all products on the market in China) has fallen substantially in the last five years, a result of the enactment of improved intellectual property protection or improved enforcement of these "IP" laws. PhRMA member companies in China

estimate that a substantial part of the market still is dominated by pirated or counterfeit products, and that market share could rise from 12% to 25%, or roughly double current sales, if problems in China were rectified. It is thus estimated that lost sales are in the area of U.S. $780 million.

KOREA

Over the past twelve months, through close and constant communication and positive engagement with the Government of Korea and with assistance of the U.S Embassy in Seoul, some significant progress was made in various areas. There remain certain key issues to be resolved through mutual discussion and cooperation, particularly relating to intellectual property protection and new drug registration. Resolution of these issues would substantially enhance access to medicine and patient welfare in Korea. For the reasons described herein, PhRMA requests that Korea be included in the 2001 "Special 301" Priority Watch List.

Market Access Barriers

At the beginning of 2001, PhRMA discovered that the Korean Medical Association had sent a letter to over 30,000 doctors nationwide recommending that they prescribe Korean medicines and avoid prescribing "foreign" medicines. The Korean Pharmaceutical Manufacturers Association (KPMA) sent out a similar letter. PhRMA is very concerned with this latest "buy/prescribe Korea" campaign, as it appears that the government of Korea is doing little to discourage this discriminatory activity.

More broadly, the pharmaceutical regulatory and pricing systems under the control of the Ministry of Health and Welfare (MoHW) have been in serious need of deregulation, trade liberalization and harmonization with the international community for many years. Some important steps, such as the listing of imported pharmaceuticals on the national reimbursement schedule, and elimination of illegal hospital dispensing margins related to reimbursement pricing, were made in 1999. However, any moderate progress on market access, non-discrimination and transparency is being targeted for reversal by local interest groups set on causing derailment of important reforms. In addition, new problems continue to develop, and barriers to market access for innovative pharmaceuticals remain in place. Discriminatory, non-transparent reimbursement pricing methodologies and protectionism in favor of the local industry make Korea an exceptionally difficult market for the industry compared to other major pharmaceutical markets worldwide.

Industry has been working collaboratively with the American Chamber of Commerce (AmCham), the Korean Research-based Pharmaceutical Industry Association (KRPIA), and the U.S. Embassy and the U.S. Trade Representative , in efforts to resolve Industry issues. In addition, a WTO level trade action has been initiated by the European Commission, and the U.S. industry is now requesting the initiation of a Super 301 investigation of Korea's policies, practices and acts related to the pharmaceutical sector.

The barriers to market access for patented pharmaceutical products include:

Pricing And Reimbursement Issues – Actual Transaction Price (ATP)

In November 1999, the Korean Government eliminated discriminatory hospital dispensing margins ("kickbacks") applied on pharmaceuticals, through the implementation of a system for reimbursement at Actual Transaction Price (ATP).[5] Under the ATP system, the reimbursement price would be the same as the ex-manufacturer price to medical institutions (hospitals, pharmacies and clinics).

Implementation of ATP would require documentation (receipts) for all transactions related to the dispensing of medicines, either through hospitals, pharmacies or clinics.

Shortly after the Korean Government implemented ATP, local interest groups stepped up their opposition to full application and enforcement of ATP. At this point, PhRMA's major concern with ATP is enforcement and the need for additional measures to prevent corrupt practices that translate into market advantages for companies that engage in illegal discounting. Also, the ATP system should include a mechanism to address foreign exchange fluctuation, thus countering the negative effects of major currency devaluation.

These implementation and enforcement problems, in turn, cause older, multi-source products (generics), marketed mostly by the local companies, to be priced at artificially high levels compared with like or similar medicines in other world markets. Industry expects that the lack of enforcement of ATP and corresponding practice of extra margins and other incentives to hospitals, may have the ironic effect of encouraging excessive dispensing of older, less effective products, versus new, innovative, more cost-efficient (albeit foreign) research-based medicines. Moreover, the Korean Government is itself providing hospitals with financial incentives to use a list of generic "essential drugs". Additionally, prescribing for profit continues under such system. Likewise, the prices of innovative pharmaceuticals are, in contrast to generic prices, relatively low compared to world prices, and the revised new pricing system, enacted by the MoHW from 2000, is seriously flawed.

Notwithstanding that the new pricing system (April 2000) allows a "significantly improved new drug" (in terms of therapeutic efficacy or cost-benefit) to obtain the average price of advanced seven countries, there is no transparent guideline on the definition of "significantly improved new drug." Additionally, the system still contains a mechanism for therapeutic category comparison that can be applied in a discriminatory

[5] ATP refers to a process by which medicines would be reimbursed at their Actual Transfer Price, with some consideration given within a mechanism to take account of changes in currency fluctuations.

fashion when a company fails to prove "significant improvement" even if the new product is patented.

PhRMA requests the continued support of the U.S. Government for full implementation and enforcement of the Korean Government's commitments to fair and equal treatment of foreign products within the reimbursement pricing mechanism.

Separation Of Dispensing And Prescribing (SPD) Including National Treatment (Pharmacy)

The Government of Korea now provides WTO-inconsistent preferences for dispensing of local products compared with imported patented products. The Korean National Assembly has passed into law arrangements planned for the separation of prescribing and dispensing (SPD) in Korea. These include permission for pharmacists, within strict certain limits and conditions (i.e., of the same substance, strength and dosage form), to substitute alternate generics for brand-name medicines prescribed by the doctor (consent). PhRMA is concerned that this practice is a clear effort to promote the use of domestic generic drugs over brand-name foreign products in a WTO-inconsistent manner. Furthermore, in the absence of rigorous generic bio-availability testing in Korea, public health issues could ensue.

Citizens groups publicly have demanded the retesting of all generic substitutes. However, the Korean Food and Drug Administration (KFDA) plans only limited testing of the "B" List from the U.S. Pharmacopoeia Drug Information (PDI) (i.e., 321 products, 31 different ingredients) and considers that there are not enough institutions available to do more extensive testing before the planned separation in July 2000. PhRMA seeks more rigorous and extensive bioequivalence testing for generics, to help assure a more equitable situation and fairer competition.

Concern for the lack of proven bioequivalence of generics is exacerbated by a lack of assured integrity in the Korean regulatory system. A manufacturer can present for review a product that is represented by physical samples and data obtained under special conditions (e.g., laboratory manufacture by highly qualified scientists using specially purified chemicals) or from the public domain (e.g., journal publications relating to the originator's brand). These subjects do not necessarily relate one to the other. Furthermore, the samples may not bear any relation to the final product that the manufacturer will eventually produce on a large scale.

It would seem that these practices do not generally follow internationally accepted Good Manufacturing Practices (GMP) aimed at assuring reliable quality, e.g. process validation. Importantly, there is a concern that KFDA's approval of a product is thus obtained with respect to materials/data that may not be representative of the product made later on a manufacturing scale and distributed generally to the public.

Such practices may well offer local generic manufacturers the opportunity for unfair flexibility in pricing and competitiveness.

KFDA asserts that they test 3,000 products every year and that this is the upper limit of their testing capability. They also assert that standards and testing methods for manufactured products are reviewed before approval and after manufacturing samples are collected and retested and failure rate is only 1.2%. However, PhRMA believes that, given the Korean Government's current plan with regard to generic products, in the interest of public health, all generic products to be used in place of innovative products need to be able to produce up-to-

important step to resolving these differences in interpretation would be the introduction of early, binding consultations between the KFDA and the sponsor. PhRMA and the KRPIA are seeking a dialogue with KFDA to resolve these differences in interpretation in a timely manner. Improvements in regulatory approval procedures would benefit Korean patients by accelerating access to innovative U.S. and European medicines.

Local Testing of Pharmaceuticals, Vaccines and Biologics

KFDA requires that complete local test data for three lots (manufacturing batches) of imported pharmaceutical, vaccines and biologics be submitted with the dossier for product registration. This requirement is both onerous and unnecessary, requiring the transfer of complex proprietary analytical techniques to local testing facilities, often resulting in delays to product registration. Furthermore, once registered every lot of the drug product imported into Korea for commercial purposes must be tested. This is scientifically unnecessary, leading to both additional costs and delays, and may be regarded as a non-tariff trade barrier. The requirements could easily be fulfilled without compromising public safety, by the company supplying the Certificate of Analysis (CoA) from the releasing manufacturing site, and the KFDA should be pressed to accept this proposal.

Free Sales Certificates (FSCs)

Currently the KFDA requires a Free Sales Certificate to be provided with a New Drug Application (NDA) at the time of submission to the KFDA. The FSC (or Certificate of Pharmaceutical Product – CPP) indicates that the drug has been approved for sale in a country (and hence these are typically first available from markets such as the United States, where drugs are typically launched first). This requirement to supply the FSC at the time of submission typically ends up delaying submission in Korea until the drug is approved in another market and the certification available. The KFDA should alter this requirement to require an FSC at time of *approval* in Korea, hence removing the delays to market. The assurance that the KFDA seeks, i.e. that a major agency such as the FDA has approved a drug, could be provided by a simple listing of submission status in other countries. In many countries, such as the USA and EU, there is an early review of the dossier to determine acceptability, and hence a continued review would indicate that a dossier is of a high quality. This would give the KFDA the assurance it is seeking.

Intellectual Property Protection

Data Protection

As a Member of the World Trade Organization (WTO), Korea is obligated to

provided the level of protection against "unfair commercial use" as required by TRIPS. Instead, it relies on limitations on copying drugs that arose from requirements that the innovator reexamine safety and efficacy of drugs at a specified time after marketing. These reexamination requirements were rendered ineffective in 1997, and the Korean Food and Drug Administration (KFDA) began to approve products of copy products based on the test data submitted by the innovator, a practice that is inconsistent with Article 39.3. Since then, the Korean Government has reinstated the reexamination requirement, but it will not withdraw approvals given to competitors after 1997 despite the fact the approvals were granted inconsistently with the TRIPS Agreement.

The KFDA has a clear obligation to ensure that data provided to it in pursuit of regulatory review are secure from being accessed/misused by third parties. TRIPS prohibits reliance directly or indirectly on undisclosed test or other confidential protected data. Unfortunately, there are instances in which the originator's technical data allegedly has been used by local competitors of the file sponsor to gain registration. The KFDA relied indirectly upon the undisclosed confidential test data in the underlying unpublished clinical studies. In their defense, the KFDA claims that the TRIPS protection prevents use of publicly disclosed data for "commercial purposes," not new drug registrations. PhRMA and its member companies in Korea, however, note that registration is for a commercial purpose.

TRIPS Article 39.3 also requires that Members protect certain test data from disclosure. The KFDA has proposed an amendment to stipulate the protection of data from disclosure by government officials, other than in public interest. This amendment is pending before the National Assembly. Under the amendment, companies are supposed to request the protection of this data when they submit the data to KFDA. While PhRMA appreciates any measure by KFDA to improve this aspect of data protection, this amendment does not automatically provide data protection against unfair commercial use. PhRMA believes that further measures to implement that aspect of the TRIPS Agreement are necessary.

Enforcement of TRIPS Obligations

Given past decisions, PhRMA has little faith in the ability of Korean courts to interpret the intellectual property laws accurately, to apply them to the facts in dispute correctly, and to conclude the proceedings in a timely manner. Furthermore, the courts lack the ability to grant injunction relief or provisional measures as required by TRIPS Article 50. This hampers the ability of the courts to provide effective remedies to the patent owner. As such, the injured party is disinclined to pursue legal proceedings against the KFDA since the company must rely on KFDA officials for the issuance of other product licenses.

Absence of Linkage Between Patent Office, Regulatory Authorities and Enforcement Agencies

The absence of any direct linkage between KFDA and Korean Industrial Patent Office (KIPO) is another area of concern. KFDA, while assuming responsibility for safety and efficacy review, apparently has abdicated any responsibility for ensuring that competitors do not market products covered by patents through linkage to KIPO. Thus, instead of taking the opportunity during the marketing approval process to prevent infringement and unnecessary litigation, the Government of Korea forces patent owners – foreign and domestic – to resort to the court system after infringement has occurred. This practice is in sharp contrast to the more effective system in the United States. In the U.S., those seeking marketing approval must certify that products involved do not infringe patents in force, and the health authorities refuse to approve products whose marketing would infringe a patent. The Korean Government is in the process of discussing the possible establishment of such linkage, but remains non-committal to near term implementation of such a system.

Damage Estimate

PhRMA is currently studying methodology for estimating damages caused by the aforementioned trade barriers in Korea to member company affiliates in Korea. At the present time, PhRMA believes that its member company affiliates in Korea could maintain an additional 25% share of the current U.S. $2 billion Korean ethical pharmaceutical market were it not for the current market barriers there. Currently, the PhRMA member company affiliates have a 20% share of the ethical pharmaceuticals market in Korea but the normal range is over 50% in developed countries, save Japan. Thus, the estimated losses due to market access barriers and the problems in the industrial property regime to PhRMA member company affiliates in Korea are in the area of U.S. $500 million.

The above information signifies that the market for pharmaceutical products in Korea falls far short of providing conditions for free and fair trading. Local manufacturers appear to be favored in matters related to trade. Furthermore, the environment is not as yet open and transparent to the degree expected of a trading partner that is a member of the World Trade Organization. The U.S. pharmaceutical industry has serious concerns about the degree of commitment of the Korean Government to implementing (even sometimes agreed upon) reforms.

NEW ZEALAND

Through the imposition of regulatory measures that strip value from pharmaceutical goods protected by patents and trademarks, New Zealand continues to deny adequate and effective protection for intellectual property and for market access for companies and/or products reliant upon intellectual property rights. For the reasons explained below, PhRMA requests that New Zealand be included among the 2001 "Special 301" Priority Watch Countries.

Market Access Barriers

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member company affiliates in New Zealand believe that the policies of the New Zealand Government agencies that set the reimbursement price of medicines, largely deny market access for the American research-based pharmaceutical industry to the New Zealand market. As such, the U.S. research-based pharmaceutical industry is not able to take full advantage of the intellectual property protection that is promised to it by New Zealand law.

Once regulatory approval has been obtained from the New Zealand Ministry of Health, market access is effectively determined by entry to the Government Pharmaceutical Schedule (PS). Access to the PS is determined by the Pharmaceutical Management Agency (PHARMAC) currently a wholly owned subsidiary of the Health Funding Authority (HFA).

As part of wider health sector reforms, the New Zealand Government has introduced a bill that will establish PHARMAC as a stand-alone crown entity structured as a statutory corporation. PHARMAC will manage the PS alongside 21 proposed district health boards, and the Ministry of Health. The Pharmaceutical Schedule (PS) lists the medicines that attract a Government reimbursement for patients and specifies the ex-manufacturer reimbursement level that will be paid for each listed medicine. The PS also defines the supply conditions by restricting prescriptions of a product when it decides to reimburse a product.

Since the New Zealand Government has instituted a socialized health insurance system, PHARMAC functions as a monopsonistic power in the market by controlling the level of and entitlement to reimbursement. PHARMAC's monopsonistic position allows it to control market access for new medicines and exploit the negative impact of reimbursement premiums to control prices for currently reimbursed medicines. PHARMAC also controls supplier or prescriber restrictions, which further restrict the true or potential market for pharmaceuticals in New Zealand.

Due to PHARMAC's practices, and the nature of a socialized health insurance system, significant sales of most medicines in New Zealand are not possible unless the medicine is reimbursed on the Pharmaceutical Schedule. Moreover, all private medical insurers in New Zealand reimburse claims only for medicines that are included on the Pharmaceutical Schedule; this means that no one will underwrite a premium or co-payment for the cost of a medicine unless it is "acceptable" to PHARMAC. The absence of a PS listing also severely limits the in-hospital use of some medicines. Hospital doctors often prefer to initiate treatment with medicines that are reimbursed so that the medicine does not have to be changed when the patient is discharged.

PHARMAC's management of the PS creates barriers to market access by denying or conditioning the listing of new medicines on the willingness of manufacturers to accept discriminatory pricing and reimbursement policies. PHARMAC applies its discriminatory policies in the following manner:

1. Grouping together of patented products with generics for reference pricing -- PHARMAC's use of reference pricing differs significantly from that used in other countries, by including patented products in therapeutic reference groups with generic products. This policy erodes the value of intellectual property accrued through innovation.

2. Denying a PS listing when PHARMAC subjectively considers that "sufficient" products are available to meet patients' needs.

3. Denying or conditioning PS listing upon the manufacturer's acceptance of a reimbursement level that is less than or equal to the current PHARMAC-imposed reimbursement level of existing medicines. This effectively limits the Government-allowed reimbursement price of new medicines to the price of older medicines.

4. Denying or conditioning PS listing upon the manufacturers' agreement to set the introductory market price at the reimbursement level, in effect, imposing a maximum price control at the time of listing.

5. Denying or conditioning PS listing upon the manufacturer's agreement to Government-mandated cross therapeutic reference pricing which requires a major price reduction on one or more other medicines, often in a completely unrelated therapeutic class.

6. Delisting of medicines based on the award of a single tender or "preferred provider" status. All competing suppliers not awarded, including those currently on the Pharmaceutical Schedule, have had reimbursement denied, restricted, or have had their products removed from the PS.

7. Lack of transparency in reference pricing methodology -- methodology is capriciously applied to different therapeutic sub-groups. Clinical evidence and therapeutic differences, as well as the views of physicians, are ignored in favor of products with lower reimbursement levels.

PHARMAC Exemption from Commerce Act

PHARMAC has been able to institute these policies through its statutory exemption from the anti-trust provisions of the New Zealand Commerce Act. Thus, while pharmaceutical companies are bound by normal commercial competition law, a government agency has the right to act in such a way as to lessen competition significantly in the market without legal redress by affected companies.

The New Zealand Government continues to retain the exemption from Part II of the New Zealand Commerce Act 1986, dealing with restrictive trade practices in favor of the PHARMAC. This issue is currently before the New Zealand Parliament in the form of clause 46 of the New Zealand Public Health and Disability (NZPHD) Bill. This clause proposes to maintain the broad exemption from Part II of the New Zealand Commerce Act for any agreement to which PHARMAC is a party that relates to publicly reimbursed pharmaceuticals. The industry has pursued the removal of PHARMAC's exemption with the New Zealand Government and this has been rejected.

PhRMA member company affiliates in New Zealand have openly acknowledged that some limited form of exemption is appropriate to ensure that PHARMAC's centralized purchasing role can continue under the new health system. Indeed, in its submission to the Health Select Committee on the NZPHD Bill, the industry, through the Researched Medicines Industry (RMI) Association, drafted an appropriate form of limited exemption that would cover PHARMAC's purchasing role on behalf of the new District Health Boards.

The only exemption that is required for this purpose relates to the dealings between PHARMAC and the proposed District Health Boards. The current form of exemption is much wider than is necessary and immunizes from normal anti-trust scrutiny all supply arrangements entered into by PHARMAC. The effect is to give PHARMAC effective "carte blanche" in its commercial dealings, without the need to comply at all with the NZ Commerce Act, which is part of the true foundation of New Zealand's economic policy.

PhRMA believes, with the RMI of New Zealand, that the whole purpose of the New Zealand Commerce Act is to avoid inefficiency and maximize the most efficient use of New Zealand's resources, through an appropriate level of competition. However, the continued retention of the broad exemption from Part II of the Act in favor of PHARMAC is quite inconsistent with this, as it is entrenches PHARMAC's monopsony power and creates no incentive for PHARMAC to act in a normal commercial manner in its dealings with pharmaceutical suppliers.

At the time of the health reforms in 1993, PHARMAC enjoyed a broad exemption from Part II of the Act. The rationale for this exemption was to enable PHARMAC, as agent for the then four Regional Health Authorities, to manage and operate the Pharmaceutical Schedule and the reimbursement regime for medicines. It was perceived that, in the absence of such an exemption, the Regional Health Authorities could be indulging in collusive conduct and price fixing in breach of the Act. The point was that by all four Regional Health Authorities agreeing to reimburse and, therefore, purchase medicines at the same price under the reimbursement regime, this would, prima facie, breach provisions in Part II of the Act.

When the four Regional Health Authorities were disbanded in 1998 and replaced by a single Health Funding Authority (HFA), there was no further justification for the exemption. However, the New Zealand Government chose to overlook the significant change in circumstances, where now there was only one monopsony buyer, the HFA, and PHARMAC was acting as its sole agent.

With the current reforms in the New Zealand health sector, there is now no justification for anything more than the limited exemption necessary to enable PHARMAC to continue its centralized purchasing role on behalf of the District Health Boards. Subject to this limited exception, PHARMAC should be required to comply with the Act.

There is also an inherent contradiction in the New Zealand Government's stance. On the one hand, it claims that PHARMAC's practices and objectives are supportive of competition. On the other hand, the Government insists that the exemption must be retained. PhRMA believes that, if the former were true, the latter would be unnecessary.

The reality is that if the broad exemption is retained, PHARMAC will continue to be insulated from quite proper challenges of misuse of market power. This is a crucial point of principle, as through the administration of the reimbursement regime, PHARMAC and the Health Funding Authority can dictate who enjoys market access. They have the ultimate market power in circumstances where they can restrict, deter or eliminate suppliers from the market place, something that would otherwise be in clear breach of s.36 of the New Zealand Commerce Act, if it were not for the exemption. The empirical evidence shows that if pharmaceutical suppliers do not have their medicines listed on the Pharmaceutical Schedule and thus reimbursed, their ability to access the market is extremely limited, if not impossible, in most cases.

The pharmaceutical industry and PhRMA member company affiliates in New Zealand have no countervailing power in the literal sense. In the current context of the reimbursement regime, the necessary balance does not exist, because pharmaceutical suppliers, unlike PHARMAC and the District Health Boards, operate in a competitive

market. The effect of competition is to eliminate precisely those unfortunate consequences, if the pharmaceutical suppliers are to challenge PHARMAC and the District Health Boards from positions of strength, by, for example, withdrawing supplies. In the absence of such extreme action by the pharmaceutical industry, PHARMAC and the District Health Boards have little incentive to agree to change, knowing that by refusing to do so, the pharmaceutical industry has no option but to accept the current position.

The exemption is a complete anomaly in the current "light-handed regulatory environment," where the Government and New Zealand-based economists are promoting the principles of competition and open market access. There is only a need for a limited exemption. PhRMA believes that PHARMAC, in its own capacity, and as agent for the District Health Boards, should be required to comply with New Zealand's competition laws. If the "owner" of PHARMAC, the Ministry of Health, is expressly subject to the Act in relation to PHARMAC's activities, as is the Crown or Government when it acts "in trade," there is really no reason why PHARMAC should be fully exempt as it is.

PhRMA strongly urges a reduction in the current broad exemption from the New Zealand Commerce Act. This will have no prejudice to PHARMAC, as PHARMAC officers reportedly have stated that they are quite prepared to comply with the Act without the protection of the exemption.

Sole Supply Tenders

PHARMAC has expanded its restrictive listing policies in efforts to further reduce Government expenditure on pharmaceuticals. Several options have been enforced including those for expanded national tendering and further restricting indications and/or patient eligibility criteria for which a medicine can be prescribed.

PHARMAC already has successfully implemented a number of tenders during 1998 and 1999 with the most recent invitation to tender for sole supply, which includes a number of products still on patent, to be released in December 2000. The selection of tender winners, for a tender period ending in July 2003 or July 2004, is scheduled for the first and second quarters of 2001. Sole supply arrangements, including the delisting of products currently on the Pharmaceutical Schedule, will be implemented in the third and fourth quarter 2001. The value of the products in the existing tender is approximately NZ$ 200 million.

As with past tenders, PHARMAC intends to reduce reimbursement of products that are not part of the tender process through reference pricing, to the level of the lowest priced sole supply product in the established therapeutic sub-group. At the same time PHARMAC may change existing therapeutic sub-groups or establish

additional therapeutic sub-groups before the tender is held. Reference pricing would also apply to products in any new or changed therapeutic sub-groups.

There are a number of potential distortions to the market and restriction upon competition from awarding sole supply arrangements. Likely distortions include:

- the risk of price increases, or withdrawal, of alternative dosage forms;
- the risk of the emergence of monopoly suppliers;
- the risk that there will be a significant increase in the number of medicines with premiums over and above the level of patient reimbursement available and also increases in the amounts of those premiums; and,
- the risk that companies' ability to make available modern medicines to the New Zealand market will be further restricted.

Manufacturers that are not successful in the tender process would have their currently reimbursed products delisted, in cases where a sole supply tender was granted to a competitor. In other cases, where a preferred supply tender was granted, the pharmacists' contracts with the Health Funding Authority compels them to dispense only the "preferred" product on generic prescriptions, or alternatively on brand-name prescriptions from doctors who have given blanket consent (or specific consent) to substitute.

New generic entrants are encouraged to provide low cost tender applications, not only by the attractive sole or preferred status arrangements, but also (in some cases) through offers by PHARMAC that it will pay up front registration fees, should they win the tender. Such successful tendered products are, therefore, promised sole or preferred status before they are even registered for sale in New Zealand.

As a result of tenders offered and concluded to-date, at least six PhRMA member company affiliates have significantly reduced their staff numbers, as well as withdrawn from clinical research programs and terminated funding for independently run post-graduate education programs. The next round of tenders may affect many more major companies in a similar way.

Industry and U.S. Government Action

Although the U.S. industry has pursued dialogue with New Zealand Government officials to modify the discriminatory aspects of their system, no progress has been made. Moreover, the New Zealand Government has regularly implemented new policies that further prohibit market access for imported products. In 1998, the U.S.

industry sought strong engagement by the U.S. Government with the New Zealand Ministry of Foreign Affairs. The New Zealand Government apparently agreed, as a "down-payment," to engage in consultations with the U.S. Government to address U.S. concerns regarding PHARMAC's policies and practices. The New Zealand Government agreed at least to discuss the following proposals in the bilateral consultations:

1. Expanded Pharmaceutical Schedule

   a) Based on presentation of health economic data that supports the cost efficacy of new drugs, the New Zealand Government would remove the requirement that new drugs must accept a reimbursement level equivalent to or lower than the current reference price in order to gain access to the Pharmaceutical Schedule.

   b) Elimination of Government-mandated cross-therapeutic reference pricing.

   c) Separation of reimbursement price from market price for patented products.

   d) Separation of patented products from generics in therapeutic/reimbursement groups.

   e) Elimination of national tendering for patented pharmaceuticals.

2. Governance of PHARMAC

   a) Implementation of a dispute resolution process, particularly a formal process that would allow for appeal to PHARMAC's decisions.

   b) Elimination of PHARMAC's exemption from Part II of the New Zealand Commerce Act of 1986 that governs antitrust behavior through legislative remedy or a change in the PHARMAC rules.

3. Transparency and Consultative Mechanism

   a) Inclusion of industry in the policy review process, including the establishment of an industry-Government working group.

   b) Transparency and publication of procedural changes.

In September 1998, the U.S. Trade Representative engaged in the first round of bilateral discussions with the New Zealand Ministry of Foreign Affairs (MoFA) to address the highly restrictive and anti-competitive policies and practices of PHARMAC. Although no formal resolution of the industry's issues was achieved at the meeting, both the U.S. and New Zealand Governments stated their positions and agreed to continue the consultations and focus future discussions on the development of new near term procedural mechanisms. The proposed procedural measures included:

   a) reform of the independent scientific experts committee, the Pharmacology and Therapeutic Advisory Committee, that reviews applications submitted to PHARMAC;

b) recommendation for Pharmaceutical Schedule listing decisions made within three months;
c) establishment of 30-day public comment period;
d) a public hearing of experts;
e) final decisions on listing within six months;
f) establishment of an independent appeal process for listing denials, and public disclosure of analysis of reasons for denial; and,
g) automatic initiation of appeal process for inaction on applications.

Progress on Procedural Measures

The pharmaceutical industry proposed to the Government of New Zealand a series of procedural mechanisms to improve the operating environment. The New Zealand Government rejected all but one of these proposals.

The industry presented to the New Zealand Government detailed views on the more immediately achievable and less difficult procedural mechanisms described at 3(a) - (g), plus:

- the case for quarterly meetings between the Researched Medicines Industry (RMI) Board (local trade industry association) and PHARMAC representatives under the chairmanship of the Minister with an open agenda;
- the appointment of membership of the PHARMAC Board and Pharmacology and Therapeutic Advisory Committee to be the responsibility of Ministers;
- the transfer of the administration of the Pharmacology and Therapeutic Advisory Committee to the Ministry of Health; and,
- the removal of the exemption from the anti-competitive provisions of the Commerce Act enjoyed by PHARMAC.

More difficult issues, such as the separation of patented and generic products in therapeutic grouping for reference pricing and elimination of the practice of conditioning access to the Pharmaceutical Schedule upon setting price equal to or less than the level of reimbursement or other concessions were deliberately held over.

This was to allow concentration on issues that could be implemented with minimal effort and cost to the taxpayer should there be a willingness on the part of the New Zealand Government and its advisors to improve the harsh environment within which the international pharmaceutical companies operate. These could be seen as potential confidence building steps.

The New Zealand Government rejected all but one of these proposals in 1999. The New Zealand Government's single positive response was for: "*Reform of the independent scientific experts committee (Pharmacology and Therapeutic Advisory Committee) that reviews applications submitted to PHARMAC*."

This has resulted in a largely inconsequential proposal that has done little, if anything, to engender the confidence of the pharmaceutical industry in the appropriate independence and transparency of the operations of the Pharmacology and Therapeutic Advisory Committee.

Subsequently, as the new Government considered the future structure of PHARMAC, the pharmaceutical industry again promoted procedural changes to the operations and processes of PHARMAC that would deliver greater transparency and improved consultations between PHARMAC and the industry.

The industry notes that one change that has arisen is the appointment of membership of the PHARMAC Board, for a fixed term, to be the responsibility of the Minister of Health. However, this development is inevitable considering that the Health Funding Authority, from which the members of the PHARMAC Board were largely drawn, is being disestablished. The remaining proposals for procedural changes have not been taken up.

Notwithstanding these efforts to make advances upon procedural matters, PhRMA believes that the many more fundamental issues raised by the industry in its submissions to the New Zealand Government remain outstanding.

Intellectual Property Protection

PHARMAC's policies and practices substantially erode the value of U.S. companies' intellectual property. The manner in which the pharmaceutical reimbursement system is implemented effectively discounts the value of patents for new, innovative, and more-effective medicines. PHARMAC places patented products in therapeutic groups that are referenced for purposes of reimbursement with generic products and allots the same reimbursement price for both.

Without price differentiation between patented products and generics, the increased value of patented products is not recognized. In addition, the lack of access for patented products to the New Zealand Pharmaceutical Schedule, and requirements to subsidize the product cost by lowering the price of another product in a different therapeutic subgroup, further devalues patented products to the level of generics.

Through its control of the levels of reimbursement and application of its reference pricing policies and other planned initiatives such as tendering, PHARMAC's actions burden and restrict U.S. trade in pharmaceuticals, and negatively affect the value of the intellectual property on which these innovative medicines depend. This is because:

- The period over which a level of reimbursement is negotiated or denied shortens the effective patent life. In discussing the problem of delayed listing in a 1997

report on the New Zealand pharmaceutical pricing situation, one authoritative article cites the view of the RMI Association that "companies can ill afford further delays to market (entry). (The RMI) estimates that the average effective patent term, already short at 7.72 years in 1995, will fall to 6.9 years by 2000." Indeed, without a known reimbursement level for a specific medicine, the supplier virtually is denied the opportunity to market the medicine.

- Government-mandated cross therapeutic reference pricing by PHARMAC forces price reductions on patent-protected medicines, or can expose the manufacturer to significant volume losses. These, together with practices that effectively deny market access reduce the opportunity to earn an expected return on medicines whose value is inherent within their intellectual property.

In order to achieve or maintain reasonable market share, research-based pharmaceutical companies are forced by PHARMAC to provide these medicines at the price of off-patent medicines or prices that prevail as a result of trade-offs for unrelated medicines. PhRMA believes that these practices by PHARMAC, which the New Zealand Government allows and encourages, seriously undermine the value of intellectual property and fail to give adequate recognition to the value of innovation.

Damage Estimate

PhRMA is currently studying methodology for estimating damages caused by the aforementioned trade barriers in New Zealand. The current size of the New Zealand pharmaceutical market is U.S.$ 408 million, of which U.S. companies enjoy a market share of around 29% or U.S.$ 118 million. It is not possible at the current time to provide a reliable estimate of the losses in sales that have accrued to the research-based companies in New Zealand due to current market access barriers and intellectual property problems.

PHILIPPINES

As with other markets, PhRMA seeks compliance by the Philippines with WTO rules and principles, transparency in the issuance and enforcement of regulations affecting its member companies, adequate protection for intellectual property rights and the removal of non-tariff barriers to trade. For reasons described herein, the Philippines fails to provide adequate and effective protection for intellectual property rights and to guarantee market access for products reliant upon intellectual property rights. Accordingly, PhRMA requests that the Philippines be included in the 2001 "Special 301" Priority Watch List.

Market Access Barriers

Over the past 18 months, a series of policy initiatives have been proposed by the Philippines Government, each of which threaten the Philippines' compliance with its international obligations. Among the proposed policy measures are:

- Import reduction measures and local manufacturing requirements.
- Conditioning renewal of product registrations on (1) the registration of a comparable generic, and (2) the annual sale of an amount of the generic at least equal to the amount sold of the branded product. As an alternative to the second requirement, manufacturers would be permitted to reduce the price of the branded product by 50%.
- Elimination of brand names (trademarks).
- Compulsory licensing.

PhRMA has questioned the validity of these actions and their capacity to provide significant improvements to healthcare in the Philippines. To date, none of the measures have been implemented and the government has confirmed its intention to abide by its international obligations.

Instead the government created a Pharmaceutical Affairs Consultative Committee (PACC) to consider issues relating to pharmaceutical pricing. At first the PACC held promise of providing a forum in which the government, pharmaceutical manufacturers, distributors, doctors, and insurance providers would work cooperatively to seek improvements in healthcare for the Philippines public. However, subsequent actions by the government strongly suggest that it intends to use the PACC to introduce the measures described above.

The October 5, 1999, Memorandum of Understanding (MoU) that established the PACC and was signed by all the stakeholders gave a broad mandate to "formulate

recommendations to serve as inputs in the review and revision of government policies and programs on the pharmaceutical industry." Suddenly, without prior consultation, the Philippine Government issued an Advisory Opinion (A.O.) requiring the PACC to respond to proposals to: (1) initially require that all drugs be made available in generic form; (2) require eventual elimination of branded drugs; (3) require compulsory licensing under conditions not consistent with TRIPS; and, (4) authorize parallel imports. Since the issuance of this A.O., the Philippine Government has proposed in PACC meetings that the industry reduce by 50% the prices of its 50 top-selling products and agree to a moratorium on any price increases.

Registration of Products in the Philippines

PhRMA understands that the Philippine Bureau of Food and Drugs (BFAD) has also required the declaration of a suggested retail price (SRP) by companies seeking product registration in that country. This is now required under Department of Health (DoH) Administrative Order No. 48-C, dated November 21, 1999. We believe that there is no legal basis for either the Department of Health (DoH) or BFAD to require the declaration of the SRP of a pharmaceutical as an additional requirement for product registration. There is nothing in the statutes cited in the Administrative Order that requires the disclosure of the SRP. Neither the Philippine Consumer Act nor the Food, Drugs, Devices and Cosmetics Act concerns itself with the suggested retail prices of drugs. In fact, the latter statute only pertains to *the safety and purity of drugs* and does not in any way regulate the commercial or economic aspects of the drug industry.

For its part, the Price Act of the Philippines deals with price manipulation and other predatory practices that affect the general public. Nothing in this law expressly authorizes the DoH or the BFAD to require the disclosure of the SRP of pharmaceutical products.

The Administrative Order also in no way implements any provision of the Price Act. Obviously, any price information necessary to implement the aims of the Price Act must pertain to current information. The SRP, in this regard, would be useless since it refers to the price **at the time of registration** and bears no relevance to any future price adjustments. In addition, the SRP does not take into consideration price differentials brought about by extrinsic factors such as additional distribution expenses for drugs sold in the provinces, availability of raw materials, and fluctuations in fixed costs. It is not unusual for drugs to be sold at varying prices in different retail outlets.

PhRMA believes that the Secretary of Health possesses no legal authority to issue the AO in question. The AO is, therefore, illegal and is assailable on this basis.

PhRMA also understands that the BFAD has announced a “temporary” suspension in acceptance of applications for initial registration of medicines in the

Philippines. PhRMA believes that this suspension violates provisions of the GATT WTO Agreements that represent international commitments of the Philippines.

The indefinite suspension of registration constitutes a "technical regulation" violation within the meaning of Annex I of the Technical Barriers to Trade Agreement (TBT). The announced suspension violates Article 2.2 of the TBT, which requires that technical regulations not be prepared with a view to or the effect of creating **unnecessary obstacle** to international trade. It also requires that technical regulations not be more trade restrictive than necessary to fulfill legitimate objectives.

Specifically, Article 2.2. of the TBT reads as follows:

> Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create. Such legitimate objectives are, *inter alia*; national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of such products

The announced restriction is more than an unnecessary trade restriction because it amounts to an effective "embargo" on imports of new (or existing but unregistered) pharmaceutical products since they are effectively barred from being registered and imported in the Philippines. Moreover, under the Philippines Republic Act No. 8203, such unregistered drugs would be considered counterfeit and therefore their importation into the Philippines would constitute a criminal offense. Even assuming that the objective behind the announced restriction is to ensure public health and safety, indefinitely suspending the initial registration of pharmaceutical products is by no definition an optimal means of ensuring compliance with that objective.

PhRMA considers these measures as presenting a market access barrier to U.S. products in the Philippines, and believes they are in violation of WTO principles. PhRMA believes that approval of medicines and renewal of registrations should be based on scientific principles. PhRMA is currently unsure as to whether these new measures are being selectively applied to certain categories of foreign medicines, but the new government measures may not be consistent with the Sanitary and Phyto-Sanitary (SPS) requirements of the WTO.

Intellectual Property Protection

Some of the activities described above, such as the encumbrance of the use of

trademarks, or even possible elimination of trademarks, may threaten the Philippines ability to meet minimum international standards under the WTO TRIPS Agreement and to generally provide adequate and effective protection of intellectual property. In addition, the Philippine Government may soon act in direct violation of TRIPS requirements in the areas of data protection (Article 39.3), as well as enforcement and provisional relief measures (Articles 42-61).

Threat of Parallel Imports

The Government also has begun parallel importation of medicines from sources outside the Philippines. Legitimate generic pharmaceutical products, i.e. products no longer protected by patent or subject to data exclusivity, and produced according to Good Manufacturing Practices (GMP) as regulated by the U.S. Food and Drug Administration (FDA), may be imported in 2001 through parallel trade consistent with the TRIPS Agreement. The vast majority of products on the WHO list of essential medicines are available generically, consistent with the above. Parallel importation violates intellectual property rights when the exclusive right to the use (including import and export) of a patented and/or trademarked good, provided to the owner of the intellectual property in the country of registration, is infringed. The Philippines actions deny effective and adequate protection for intellectual property as found under U.S. law and practice, in addition to failing to meet the lower standards of the WTO TRIPS Agreement.

TRIPS includes the exclusive right of a patent holder to control importation of a product into third markets. Specifically, TRIPS Article 28 states that "[a] patent shall confer on its owner the following exclusive rights: to prevent third parties not having his consent from the acts of: making, offering for sale, selling, or *importing* for these purposes that product." (Emphasis added). This right to control importation bars imports of a product from one market, where the patent holder offers it for sale, into another, or parallel market. Further, TRIPS Article 27.1 provides that "... patent rights (shall be) enjoyable without discrimination as to the place of invention, *the field of technology* and whether the product imported or locally produced" (emphasis added).

Although the agreement does not resolve the issue of exhaustion (see TRIPS Article 6), it is generally not possible for a government to permit parallel import of a product under patent protection in that country without recourse to unfair reliance on confidential test data or other information protected under TRIPS Article 39(3), or without violating TRIPS enforcement provisions designed to permit a right owner to fast and effective relief for IP infringements. In order for a pharmaceutical product to be proven to be bioequivalent to a registered product in a given country, for example, the data relating to the second product would have to be compared to confidential information for the patented product that should be protected under Article 39(3). Accordingly, although a WTO dispute cannot be initiated on the basis of parallel importation itself, there are other TRIPS-related protections that may be violated by the

operation of a parallel import regime that permits importation of pharmaceutical products currently under patent in that country. In addition, under enforcement provisions of the TRIPS Agreement (Articles 41 - 61), WTO members are obligated to provide effective and timely remedies to ensure that products that infringe on a patent holder's rights are kept out of the stream of commerce, including provisional remedies, injunctive relief and border measures. An effective patent system in the Philippines and elsewhere depends on the ability by the patent holder to control the distribution of his or her patented pharmaceuticals -- a system that would be greatly undermined in an environment described by unfettered parallel imports.

Administrative Order (A.O.) No. 85 was issued by the Secretary of Health with grave abuse of discretion, amounting to a lack or excess of jurisdiction, rendering same constitutionally infirm. PhRMA believes that A.O. No. 85 violates existing Philippine law. There is no existing law which A.O. No. 85 implements. Furthermore, A.O. No. 85 abandons the long-standing policy and practice of allowing only one registrant per brand per product that was necessary to protect public health.

A.O. No. 85 runs counter to the primary constitutional right of due process. As regards substantive due process, patent rights and contractual rights of exclusive distributors/licensees are violated. With regard to procedural due process, lack of public hearing renders A.O. No. 85 ineffective, if not invalid.

In violating the constitutional right of equal protection, A.O. No. 85 exempts a government agency, to the prejudice and damage of private local run drug companies, from complying with the standard requirements for product registration, and makes this government agency a much favored competitor of private business.

Apart from being null and void, A.O. No. 85 will pave the way for the importation of poor quality, if not counterfeit or adulterated medicines, and their distribution to the public both in the cities and the countryside. This is because said A.O. has authorized the government or any of its agencies to import low priced medicines and sell them to the public, without complying with rigid and strict registration and testing requirements required of pharmaceutical companies in the country before these medicines are distributed to the public. These strict registration requirements are precisely intended to prevent the sale of poor quality, if not outright counterfeit medicines, thus posing a clear and present danger to the health and even the lives of the people who will use them.

Damage Estimate

With the current market valued at approximately US$1 billion, PhRMA estimates that the proposed compulsory licensing provisions would have caused losses around US$75 million for PhRMA member company affiliates over a 12 month period.

THAILAND

For the reasons outlined below, PhRMA requests that Thailand be included in the 2001 "Special 301" Priority Watch List.

Intellectual Property Protection

While the Thai patent act changed in 1999 with the abolishment of the Price Review board, there are still many troubling features of the Thai Patent Act which remain:

- Patentable subject matter – Section 9(1) still excludes naturally existing biologicals, which is not in compliance with the requirements of TRIPS. Article 27(3) of TRIPS provides clearly that members may exclude from patentability, plants and animals, other than microorganisms. Therefore, all kinds of microorganisms must be patentable under the Thai Patent Act to comply with TRIPS.

- Compulsory licensing if the patented product is not produced in Thailand is still incorporated in Section 46. However, the Royal Thai Government will now recognize importation as working the patent.

- Under Section 36(7), if the patentee permits or gives consent to the manufacture or sale of a product then importation is automatically allowed. This is inconsistent with Thailand's WTO obligations in that TRIPS Article 28 explicitly states that a patent shall confer on its owner the exclusive right to prevent third parties not having his consent from the acts of: making, offering for sale, selling, or importing. Nothing in TRIPS diminishes this right.

- The current interpretation of the Thai Department of Intellectual Property of Section 36 *bis* of the 1992 law is directly opposite to the agreed intent of the law before the law was enacted. The focus is to prevent pending applications from having product claims inserted – as was intended. This calls into question the sincerity of the RTG in providing Intellectual Property Protection.

<u>Draft Trade Secrets Law</u>

Thailand is preparing a new trade secrets law to comply with TRIPS. Unfortunately, Section 7(2) attempts to exclude disclosure of trade secrets by a government agency to protect any "public interest" not having commercial objectives. This provision may be used to allow the use of registration data for generic regulatory filings. For this use, Section 11(4) is inconsistent with Thailand's WTO obligations in that TRIPS Article 39.3 specifically recognizes the "protection of undisclosed information" as being a category of intellectual property subject to protection.

Article 39.3 provides that:

> "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical entities, the submission of undisclosed test or other data, the origination of which involves considerable effort, shall protect such data against unfair commercial use."

Use of such data to support the regulatory filing of generic products certainly constitutes "unfair commercial use." Protection of registration data, through the data exclusivity that results from non-reliance on the data, is a governmental function. The authorities may not consider an application for a marketing authorization during the period of data protection. An application relying upon a third party's data may only be submitted after the period of data protection has expired.

Parallel Imports & Counterfeits

The Thai pharmaceutical market suffers a relatively high level of parallel imports and counterfeits from other parts of Asia, yet insufficient progress has been made to rectify the situation, despite the dangers that such imports pose to national health. There is recent evidence the Thai FDA is being more diligent in enforcing restrictions on parallel imports and counterfeits and has offered to work with industry on a guidebook on counterfeit drugs in an effort to prevent proliferation of the problem. The FDA alone, however, cannot end these practices without other government agencies and resources. Police enforcement of anti-counterfeiting laws has increased as well, though the police officials most responsible for this improvement are being targeted for transfer to other duties. PhRMA encourages the government of Thailand to continue and drastically increase its involvement in this important public safety issue.

Market Access Barriers

Restrictive Drug Lists

The original list National List of Essential Drugs (NLED) has been in place for several years and was an adaptation of the WHO 'essential drug list' (designed as a minimal list of drugs that should be available to satisfy basic health care needs in developing countries). The WHO list maintains some 250 compounds. Thailand expanded its list to about 1,400 compounds, but applied a restrictive pricing scheme to limit reimbursement. Because of the severe price restrictions, companies avoided applying for listing on the National List and sought listing on individual hospital formularies since there were no restrictions on having their products prescribed and reimbursed within the hospital system.

The MoPH recently indicated that the NLED will now become a maximum list for government hospitals and that products with "provisional registration" subject to a

Safety Monitoring Protocol (SMP)[6] would be excluded from the list. Non-NLED medicines may be acquired in government hospitals on a case-by-case basis, though this process is unnecessarily burdensome.

The intention of the 1994 Thai FDA Rules on Transitory Provision to Conduct Safety Monitoring and Bioequivalence Study of New Drug, to provide pipeline protection for pharmaceutical products patented elsewhere in the world between January 1,1986 and September 30, 1991 is clearly stated. The procedure required companies to report adverse reactions for a two-year period. If requested by the company this could be rolled over for a further "two plus one" year reporting period during which time the FDA would not accept a registration file for a generic copy. The rules provided up to five years market exclusivity; the only restriction being that sales were restricted to hospitals and clinics (i.e., no drugstore sales).

The treatment of the NLED as a maximum list and the exclusion of the opportunity to have SMP drugs included in the list effectively negates the original intent of the provisions to provide pipeline protection and market exclusivity for new products in Thailand. Innovative products qualifying for the SMP will not be listed or stocked in most hospitals.

PhRMA believes that the Royal Thai Government's removal of the opportunity to market new products through government hospitals represents a market access barrier to the introduction of new medicines in Thailand.

Import Policies

Drug and raw material imports are subject to duty, which currently ranges from 10% to 30%. (In the recent economic stimulation initiative, the duty for certain intermediate hormones was reduced to 1%.) The duty rate for drugs where a generic equivalent is not manufactured in Thailand is normally 10%. The duty rate for imported finished goods that compete with locally manufactured product is 20% to 30%. While there are no specific policies that mandate "BUY THAI," the government hospitals are strongly encouraged to buy locally produced products wherever possible.

Standards, Testing and Labeling Requirements

A new chemical entity can be registered in Thailand, but the filing will not be accepted unless a Free Sales Certificate (FSC) from the country of origin is supplied. Additionally, samples of biological products must be submitted to the Thai Department of Medical Science for analysis prior to acceptance of registration filings. This analysis usually takes 6 months. For all drugs once the file is received, the FDA can take up to

[6] The SMP, established in 1992, represents a form of pipeline protection, or the granting of marketing exclusivity, to certain qualifying products in the Kingdom of Thailand.

18 months ensuring that it is complete, to its satisfaction, before submitting the clinical work to the Review Committee for consideration. The Committee may ask additional questions or require that a local study be carried out to ensure that Thai national companies under local conditions can duplicate the clinical data in Thailand. Some progress, though, is being made in meeting a 12-month total review time.

Additionally, there is movement in the regulatory environment towards the acceptance of a FSC from a country other than country of manufacture. In such cases, companies are required to show a CPP (certificate of pharmaceutical product) from country of origin as well as the manufacturer's Good Manufacturing Practices (GMP) certificate. If this process is in fact adopted and followed and depending on specific cases, registration timing is expected to improve by up to two to four months. It is important to note though that the obtaining of a CPP certificate is often as time consuming and burdensome as that for a FSC. The two documents are essentially the same though the granting authority is different (i.e., the FSC comes from more central authorities and CCP from more local authorities).

The Thai FDA has implemented "user fees" to quicken the registration process and this policy has improved registration timing. However, these user fees are being politically challenged and may be eliminated in the near future. If this occurs, registration timing may fall back to the old two year filing term.

The Ministry of Public Health has eliminated the requirement for sample analysis before filing of registration dossiers. The Ministry still requires an FSC to allow filings for imported products. An FSC is not required for regulatory filings where the product is to be based upon local production. PhRMA believes this is in contravention of WTO principles of national treatment.

Median Pricing Policy

The Government of Thailand's procurement policies include a pricing requirement whereby a product is procured based on the median price of other products in the same therapeutic class, regardless of origin or quality. This policy discriminates against innovative, largely imported medicines due to the price differentials between brand-name and generic products. Such differentials are based on differentials in product quality, the risk inherent in the drug development process for innovative, western medicines, and the investment needed to market such products.

The effect of the policy is to assign a below average price for innovative, imported medicines while subsidizing lower cost local generic medicines. Discrimination against patented medicines reduces the ability of right holders to enjoy the intellectual property rights that come with patents. This policy disproportionately affects imported products, is contrary to the principle of national treatment, and discourages investment in high risk, high cost research and development.

Government Pharmaceutical Organization

This organization, established by the Royal Thai Government to manufacture medicines in the government's name, is exempted from registration and GMP requirements and has rights to an exclusive position in supplying government hospitals with products on the NLED. PhRMA believes this also is in contravention of WTO principles regarding national treatment. The GPO may with impunity manufacture any product, even those still under SMP protection. It is hoped that the new Drug Act will end this practice.

Damage Estimate

PhRMA is currently studying methodology for estimating damages caused by the aforementioned trade barriers in Thailand. As a provisional estimate, on the basis of Thai sales data and from estimates based on the size and buying power of the Thai population, PhRMA estimates that the losses its companies are facing are in the area of approximately US$30 million.

EUROPE

HUNGARY

Certain aspects of Hungary's patent protection regime are inconsistent with its TRIPS obligations, which came into force on January 1, 2000, if not earlier, to the extent that Hungary did not invoke the transition period for developing countries found in Article 65.3 of TRIPS. PhRMA welcomes recent indications that the Government of Hungary is willing to protect the confidential test data for products that will be registered after January 1, 2003. However, there remains a large portfolio of innovative products that are currently on the market or will be registered within the next two years and remain exposed to easy copying. Until it provides adequate and effective protection for patented pharmaceutical products in compliance with its TRIPS obligations, PhRMA requests that Hungary be included on the 2001 "Special 301" Priority Watch list.

Intellectual Property Protection

Data Exclusivity – Confidentiality

As it takes 10 to 12 years to bring a new medicine to the market, the benefits of the 1994 Patent Act will not be felt before 2004-2006. Until then, data exclusivity is the only type of protection that may prevent early copying.

TRIPS Article 39.3 requires WTO members to protect against "unfair commercial use" of undisclosed test data and other confidential protected data submitted to governments as a condition for obtaining marketing approval of pharmaceutical products utilizing new chemical entities. In most industrialized countries, a special legal regime provides that no person may, without the permission of the person who generated and originally submitted the costly and confidential data, rely on such undisclosed and proprietary test data in support of an application for product approval, not only while the originator's marketing application is pending before the regulatory authorities, but also for a specified period from the marketing approval date of the original product. However, current Hungarian law contains no restrictions on its regulatory agency with regard to reliance on the original filing data for any specific time period. In fact, the health regulatory authority has permitted registration of second filing applications, which rely on the original filing, without the originator's consent, even in cases where the time between the original filing and the second filing is less than five years and in some instances as little as a few months. The health regulatory authority has taken the position – stated, for example, in a recent reply to U.S.

Unfair Competition Law is not suited to fulfill these obligations, for several reasons. First, the UCL is not directed at the behavior of governments, which is the intent of this paragraph of TRIPS, but at the actions of private parties. Second, the UCL is designed to allow for a civil action *after* the breach of confidentiality has occurred; it has no power to *prevent* the breach, which is the intent of Article 39.3. Third, confidentiality obligations imposed on governments, including those of Article 39.3, would inhibit any data gathering process that would be necessary to pursue a case through the UCL. In other words, there is nothing in the UCL to prevent the government from creating an anti-competitive situation as a result of not protecting the data of the original filer. Since this is the intent of TRIPS Article 39.3, the UCL is an insufficient means of fulfilling Hungary's obligations under that article. As long as Hungary does not have a specific regime in place to guarantee the protection of original filing data, it is in violation of TRIPS.

A draft data exclusivity law is being discussed and apparently provides for a six-year period of protection. However, the data exclusivity term would begin at the date of the first marketing authorization in the EU. Since Hungarian marketing authorizations are typically issued later than authorizations in the EU with its central and mutual recognition approval procedures, the Hungarian reference to a third country can considerably shorten the data exclusivity period. Furthermore, reference to third country marketing approval dates is not provided for nor is it in the spirit of Article 39.3 TRIPS. Moreover, despite a formal marketing authorization, a pharmaceutical company may not market the product before the price of the product approved by the government is published in the Official Gazette. This requirement typically takes one year, but recently up to two years, thereby reducing a would-be six-year period correspondingly.

In addition, although the period of protection for confidential data is a maximum of six years, the data exclusivity period ends earlier than six years – possibly at zero years – if and when the patent expires earlier. This opens the possibility for unfair commercial use of the originator's data in violation of Article 39.3 TRIPS which does not provide for a linkage of data exclusivity to a patent.

Requirement of Local Working

Current Hungarian patent law does not explicitly recognize the importation of a patented product as meeting the "working the patent" requirements contained in the law. As such, Hungarian law should be amended to guard against the granting of a compulsory license when patented products have been imported. Local manufacture should not be necessary to satisfy the working requirement.

Failure to comply with U.S.-Hungary Bilateral Trade Agreement

Hungary has failed to implement the Agreement properly by improperly defining the filing date of certain "pipeline" patent applications.

Enforcement

TRIPS Article 41 requires that WTO members ensure that their enforcement procedures permit "effective action" against intellectual property infringement acts and include "expeditious remedies to prevent infringements and remedies, which constitute a deterrent to further infringements." As such, it is not enough for a WTO Member to merely make available in their statutes the remedies that are enumerated in the TRIPS Agreement, such as preliminary injunctions and damages, but it must also ensure that these remedies are effectively and expeditiously applied by their judiciary in relevant cases.

Among the obstacles that U.S. patent holders, especially those holding pharmaceutical patents, are facing with respect to the enforcement in the Hungarian courts of their intellectual property rights, is the difficulty of obtaining preliminary injunctions against infringements of their process patents. This problem is especially exacerbated by the seeming unwillingness of the Hungarian judiciary to reverse the burden of proof in process patent infringement cases involving new products, as required by TRIPS Article 34. The unwillingness to order the defendant to demonstrate the actual process used in producing an identical product in a process patent infringement case involving a new product makes it very difficult, if not impossible, to enforce a process patent in the Hungarian courts. This is particularly true given the difficulty that process patent holders have in determining, through reasonable efforts, the process that was actually used by the defendant.

In addition, lax civil procedural practices by Hungarian courts unfairly allow a defendant to introduce new defenses at advanced stages of infringement cases – sometimes even during appeals that are pending in the second instance – resulting in protracted litigation from which the alleged infringer unfairly benefits. Furthermore, Hungarian courts fail to revoke the rights of defendants who fail to comply with requests to submit sufficient evidence.

Finally, current damages for intellectual property rights violations are not adequate to compensate for the injury the right holder has suffered because of an infringement of his intellectual property right. It is also rare that the infringer is ordered to pay the right holder expenses associated with the defense of the right holder's intellectual property right, or ordered to recover profits. This is not in compliance with TRIPS Article 45.

Taken together, these current practices provide less-than-expeditious enforcement of intellectual property rights. As a result, the enforcement of patent rights that is envisaged by the TRIPS Agreement is rendered ineffective in Hungary.

Market Access Barriers

There is a general lack of objective and verifiable criteria by which medicinal products are admitted to reimbursement lists. This is especially blatant in the case of the positive list for indigent patients (*Közgyogy)* affecting approximately six percent of the population but nearly 20% of total pharmaceutical demand. Indigent patients receive all medical care, including pharmaceuticals, free of charge. The list contains all categories on the general positive list, as well as additional categories that are not reimbursed through the general list.

The vast majority of the products on the *Közgyogy* list are locally produced products. Even when an imported product is available at equal or lower price, preference is given to the local one. Additional products – not reimbursed through the general list – are exclusively locally produced. Companies are not informed about the reasons for non-inclusion of their products and no appeal procedure is available.

In June, the Hungarian Government ordered a pricing and reimbursement freeze on pharmaceutical products for 180 days. This freeze was carried out in a non-transparent manner, and adversely impacted U.S. firms which provide a large proportion of innovative pharmaceutical products and that have been denied access to the reimbursement list.

Damage Estimate

PhRMA conservatively estimates that the industry loses between US$ 50 million and US$ 100 million annually because of the aforementioned trade barriers.

POLAND

Given the many inadequacies in Poland's industrial property protection, PhRMA requests that Poland be included on the 2001 "Special 301" Priority Watch List.

Intellectual Property Protection

More than one year after Poland's deadline for implementation of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), Poland has failed to extend the term for all process patents (new and existing) to 20 years, despite Poland's obligation to do so under TRIPS. In fact, the majority of both in-line and new products suffer from inadequate patent protection in Poland because they were patented prior to the enactment of a new patent law in 1993 and also due to the lengthiness of the development and registration process (10-12 years or more in many cases). Poland's pipeline protection enacted in 1993 contains so many limitations as to be rendered worthless. In particular, products that had a first marketing authorization anywhere in the world in the six months prior to December 1992 only benefited from market exclusivity if the product was actually manufactured in Poland. As outlined below, Poland's new patent law, recently given final passage by the legislature, has further eroded the effective patent protection available to the pharmaceutical industry in Poland.

Poland's draft Industrial Property Law has just passed through the legislative process in Parliament. Unfortunately, the new law introduces additional inconsistencies with Poland's international intellectual property obligations, as it contains several provisions that are incompatible with TRIPS:

- lack of clarity of patent holders rights so that infringer can invoke the law as a defense;
- lack of statement that governments can invoke compulsory license only in terms of public safety or order for non commercial production;
- Roche-Bolar provision;
- lack of Supplementary Patent Certificates provision (patent restoration term);
- international exhaustion of patents;
- lack of scope and duration provision for compulsory licensing;
- non-transparent and undefined use of words "excessively high price" of pharmaceuticals as a reason to grant compulsory license; and,
- no reversal of burden of proof for process patents

The law awaits the President's signature, but additional uncertainty has been introduced due to constitutional questions regarding trademark provisions of the law. The President referred the law to the Constitutional Tribunal in July 2000 to resolve the issue (unrelated to patents or data exclusivity provisions). If the trademark provision in

question is judged to be unconstitutional the remaining provisions of law will come into effect, but it is not clear when this will occur.

Data Exclusivity

Article 39.3 TRIPS requires WTO members to protect against "unfair commercial use" of the costly and confidential test data submitted to governments as a condition for obtaining marketing approval of pharmaceutical products utilizing new chemical entities, although it does not specify a data exclusivity period. The term of data exclusivity understood to be in compliance with TRIPS is 6-10 years in the EU Member States; five years *net* in U.S., with an additional three years for new indications of existing products. The average period of effective market exclusivity in Poland for innovative products is three to four years, after which time copy products are launched onto the market while the innovative products still enjoy market exclusivity in the U.S. and EU via data protection.

Poland fails to provide effective data exclusivity. There is clearly a policy to encourage the production and rapid registration of copies while there is still a "window" before EU accession and higher intellectual property (IP) standards make this impossible. There was a steep increase in the number of both genuine generics and infringing copycat products registered in 1999. There appear to be two reasons for this. First, the view that weak IP protection is a valid and effective healthcare cost control mechanism prevails in Poland. The Polish Government promotes pre-expiry registration of copycat products to bring down prices and particularly reference prices set for innovative products. Second, the government behaves in this way in protection of local manufacturers (inconsistent with WTO and GATT obligations). Local industry, in turn, fails to comprehend the need to adapt to becoming a real generic industry in view of global generic competition and in view of EU accession. Data exclusivity, of course, is an independent form of intellectual property protection that may not be linked to the existence of a patent. In the absence of effective patent protection for in-line products, however, data protection is also the only means to protect innovative products still under patent in Europe from being exposed to premature copies. Poland has missed deadlines under international agreements (TRIPS, Europe Poland Agreement) to implement data exclusivity.

Data exclusivity is not part of the industrial property law and may be regulated through provisions governing drug registration. Currently, Polish law provides for an abridged registration dossier if the originator product has been on the market for more than 3 years (Ordinance on Register of Pharmaceuticals and Medical Materials 15 December 1993 §8.5). However, §10 provides that the Registration Committee may in appropriate circumstances at the request of the applicant defer from requesting some of the documents, which would normally have to be submitted. Because Poland provides a period of only three years of data exclusivity, falling short of regional and other precedents, PhRMA believes that the U.S. Government should conclude that

Poland does not meet acceptable minimum international standards for data exclusivity. It is likely that health authorities in Poland will continue to provide marketing approval to infringing products relying on proprietary test data of patented products without the approval of the right holder; in some cases, even before the right holder has obtained marketing approval for the innovative drug.

A new draft Pharmaceutical Law is currently under development. However, its data exclusivity provisions, at Article 14, remain inadequate:

- The length of the effective data exclusivity will be curtailed: Although the law provides for six years for original products registered in the EU, the term begins to run down from the initial registration date in the EU, significantly reducing the effective period of data exclusivity given Polish regulatory delay.

- The law introduces impermissible patent linkage for data exclusivity. TRIPS Article 39.3 does not permit limitation of the availability of data protection based on expiration of patents on the chemical compound. As stated, many in-line products are not adequately patent protected because the 15-year patent period (that Poland never extended to 20 years) has already expired. Under the new draft law, the data exclusivity period would end before the conclusion of the six-year data protection term, if there is no valid patent for the chemical compound in the product for which the data has been submitted. The patent linkage would leave these products unprotected against unfair commercial use.

The draft law is expected to reach Parliament at the end of January.

Poland maintains that according to the provisions of its 1993 Act on Unfair Competition (UCA), Polish ordinary courts would be competent to hear cases involving cases of test data protection and that these courts were bound to apply TRIPS as of January 1, 2000. In reality, the UCA is an insufficient means of fulfilling Poland's obligations consistent with the intent of TRIPS Article 39.3. Poland refers owners of data to seek protection of their proprietary information in a court proceeding. However, UCA is not suited to fulfill the TRIPS obligations under Article 39.3 for several reasons. First, the UCA is not directed at the behavior of governments, which is the intent of this paragraph of TRIPS, but at the actions of private parties. Second, the UCA is designed to allow for a civil action *after* the breach of confidentiality has occurred or data have been used otherwise unfairly; it has no power to *prevent* the breach, which is the intent of Article 39.3. The governmental agency to which the data are entrusted by the owner of the data is able to prevent the unfair use if appropriate legislation so directs the agency. Third, confidentiality obligations imposed on governments, including those of Article 39.3 would inhibit any data gathering process that would be necessary to pursue a case through the UCA. In other words, there is nothing in the UCA to prevent the government from creating an anti-competitive situation as a result of not protecting the

data of the original filer. As long as Poland does not have a specific regime in place to guarantee the protection of original filing data, it is in violation of TRIPS.

Compulsory Licensing

Article 31 TRIPS sets out a number of requirements that must be satisfied in order to ensure that the use of inventions without consent of the patent owner complies with the TRIPS Agreement. Although several of these conditions appear to be incorporated into the recently approved patent law, others are not. In particular:

- Article 82.4 of the draft law states that a compulsory license can only be granted if the applicant can prove that he has applied for a license from the right holder in all good faith. This does not comply with the requirement of Article 31(b) TRIPS that (other than in cases of emergency) the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and that such efforts have not been successful within a reasonable period of time;

- Article 84.2 of the draft law requires the Patent Office to define the scope and duration of the compulsory license. It does not, however, comply with the requirement in Article 31(c) TRIPS that the scope and duration must be limited to the purpose for which the use was authorized.

National Exhaustion

Article 70 of the draft patent law provides for exhaustion patent rights for products introduced in countries with which Poland has concluded a free trade agreement. Therefore, it exempts from infringement importation into Poland of products that are placed on the market outside Poland by third parties without the consent of the patent owner. In essence Poland is providing for international exhaustion of patent rights, which itself undermines the rights of the patent owner. It is in direct contravention of the exclusive right to import provided by Article 28, and the standard applied by the U.S. Government in determining whether a trade partner provides for effective and adequate protection of intellectual property rights.

Weak Enforcement of Existing Patent Rights

TRIPS Article 41 *et seq*. requires Poland to provide for fair and equitable enforcement of intellectual property rights. The current patent law does not provide for preliminary injunctions, without which a patent may lose much of its value to the patent holder due to the time it takes to litigate a patent action. This is a key remedy in patent infringement actions. In addition, intellectual property judicial proceedings are often delayed by as much as three years.

The draft Industrial Property Law provides for preliminary injunction, but this is in terms of a generalized statement. The law states that the patent holder can apply to the court (and not the patent office) in cases of infringement. It is noteworthy that a

patent section will be established in the Supreme Administrative Court, although the legislative framework for this has not yet been created. Article 71 of the new law would allow a party who was, in good faith, using an invention at the time of a decision on patent precedence was being taken, to continue to use the invention without charge even when patent precedence by another party is confirmed.

Current damages for intellectual property rights violations are not adequate to compensate for the injury the right holder has suffered because of an infringement of his intellectual property right. In addition, the infringer is only rarely ordered to pay the right holder expenses associated with the defense of the right holder's intellectual property right, or that the right holder is permitted to recover profits. These practices fail to comply with TRIPS Article 45.

- There is nothing in the draft Industrial Property Law indicating that the use permitted under the compulsory license must be predominantly for the supply of the domestic market as is required by Article 31(f) TRIPS.

- Although Article 86 of the draft law provides that in certain circumstances, there is a power to amend compulsory licenses, this does not comply with Article 31(g) TRIPS which provides that a compulsory license must be terminated if and when the circumstances which led to it being granted cease to exist and are unlikely to recur;

- The amount payable in respect of the compulsory license is to be based on "the market value of the license." This is at best ambiguous and possibly inconsistent with Article 31(h) TRIPS, which requires the amount payable to be adequate in the circumstances of the case: the economic value of the license being only one factor to be taken into account.

- In addition, the draft Industrial Property Law, at Article 68, prohibits the enforcement of patent rights in an abusive manner. The draft patent law also provides that the abusive enforcement of a patent right is grounds for a compulsory license. However, Article 68 does not appear in the chapter of the law that deals with Compulsory Licenses, suggesting that this article is intended to have further effects. If this is the case, two possibilities arise. The first is that a third party infringer of a patent can invoke Article 68 as a defense. This would contravene the exclusive rights conferred by a patent under Article 28 TRIPS, and cannot be justified under Article 30 TRIPS. Secondly, acts falling within Article 68 will mean that Poland's competition laws can be invoked against the patent owner.

Market Access Barriers

Lack of Transparency

Registration and reimbursement and pricing systems lack transparency and the framework in which they are conducted undermine competition and consistently penalize foreign products and manufacturers. Criteria for pricing and reimbursement have not been made public and there are no standard procedures. In January 1999 an ordinance came into effect that provided some criteria for grouping similar products for reference price purposes. However, this ordinance is not respected by the authorities and was weakened by substituting the original phrase "the same" with regard to criteria such as mechanism of action and indications for the word "similar". Furthermore the reference price instrument is applied inconsistently. The ATC/DDD system, which was developed as an instrument to measure drug consumption, is used inappropriately contrary to the WHO guidelines for its use.

Discriminatory Pricing and Reimbursement

In late March 2000, a new pricing proposal was sent out from the Ministry of Finance. However, representatives of foreign-based firms were not among the list of reviewers. While the current law imposes significant market barriers to the research-based pharmaceutical industry, the new law will make it even more difficult for the U.S. research-based pharmaceutical industry to operate in Poland.

A draft pricing law is beginning the legislative procedure in Parliament. The provisions concern reimbursed drugs but there is a facultative possibility to extend the system to hospital products. The intention is to treat both domestic and foreign products in the same way, instead of the current administrative price fixing for domestic producers operated by the Ministry of Finance (MoF). Prices will be negotiated by the Ministry of Health (MoH) based upon a recommendation from a drug management advisory team including two representatives from each of MoH, MoF, Ministry of Economy, and the Union of Health Insurance Funds.

Recommendations will be based upon five criteria;

- level of prices in countries with a similar per capita GDP;
- comparison of prices used by producers and importers;
- costs of production and importation;
- volume of achieved and declared sales; and,
- results of pharmacoeconomic analysis.

The provisions of the law are likely to come into effect in 2001. This proposal will distort free trade and hamper open competition by continuing to impose a non-market-based approach to the purchase and consumption of pharmaceuticals. Since the U.S. research-based industry is the world leader in the development of new medicines, our members and their innovative products will invariably and disproportionately bear the

brunt of these measures and will also be denied the opportunity to compete fairly in the market.

The draft law also introduces an amendment of the Health Insurance Law concerning reimbursement. It appears that some of the provisions of the EU Pricing Transparency Directive have been incorporated as a direction for the Minister of Health to set criteria and procedures. The law states that pricing and reimbursement procedure cannot extend beyond 180 days.

Restrictive Formularies

In mid 1999 the Office of the Government Plenipotentiary for implementation of Health Insurance produced a formulary for primary care physicians supposedly based upon the "competencies of the primary care physician", indicating which products could be prescribed directly by them and which only after a specialist initiated therapy. Compared with the reimbursement lists the formulary was restrictive and left out many innovative products. The individual Health Insurance Funds were to decide on whether to implement the formulary or not.

Recently, very restrictive local formularies have been appearing which discriminate against innovative products and favor copies of products that still enjoy patent protection in the U.S. and EU.

The formularies violate the Polish Constitution (unequal treatment of citizens, restriction by a statutory instrument of a higher legal provision) in the following ways: they are non-transparent; they are discriminatory (unfair competition); and they limit the autonomy of the physician. The Office for Health Insurance Supervision (OHIS), a regulatory body, has recently stated that these formularies are illegal. However, there is evidence that some regional health Insurance Funds have not yet withdrawn their local formularies. The OHIS has no power to execute the provisions of the Statement directly, but they may undertake a review of the activities of the Health Insurance Fund in question and challenge them in court on this issue.

Protectionism in Registration:

The Polish system discriminates in favor of local companies:

- Registration of original products may take twice as long as the registration of subsequent copy products by local producers for products still under patent in the EU. Since 1998, the ratio between product registrations of generic products versus innovative products in Poland has developed to the disadvantage of the latter. There was a more recent decline of this trend.

- Prices of locally manufactured products are set by the Ministry of Finance and then serve as reference price limits for reimbursement. Since locally produced products are not innovative products and are often less expensive than those which are imported, this results in high patient co-payment and, therefore, constitutes a trade barrier for U.S. pharmaceutical exports to Poland.

- Even though current legislation requires the Ministry of Health to update the reimbursement list at least once a year, the last substantive update occurred in 1998. In the last three years, only generic and copy (often produced locally) have been added to the Basic and Supplementary Drug List, while original products are constantly omitted. The same applies to the Chronic Disease list, which was last updated with innovative products two years ago. In fact, generic products represent approximately 70% of the reimbursement list. Because U.S. manufacturers source a large proportion of innovative pharmaceuticals, these practices impact U.S. research-based companies more significantly than others.

Corruption

Health services and markets are characterized by interdependence of supply and demand, asymmetric information, gatekeeper power, divergence between public and private interests and incentives, and other characteristics, which provide fertile ground for corruption. With respect to pharmaceuticals, a large part of this stems from the fact that there is an evident lack of transparency in both registration and reimbursement procedures. Patients are in a uniquely weak position to counter these difficulties, especially if they are poor. In Poland, the situation is further complicated by:

- The overhang of socialist mentality and practices – including frequent bribery, lack of financial discipline and an arrears habit – inherited from the previous regime.
- Inexperience and weakness of new institutions created by the 1998 health reform.
- The vast sums of money that will be transferred to and disbursed by the new Regional Health Funds
- Inadequate pay of doctors and other medical personnel.

A recent World Bank study (Corruption in Poland: Review of Priority Areas and Proposals for Action. The World Bank Warsaw Office, October 11, 1999) states that corruption in the health sector is so great that health reforms would not work. Even if the impact falls short of this, it seems clear that access to health services and their efficiency and effectiveness are compromised by corruption.

Damage Estimate

PhRMA is currently studying methodology for estimating damages caused by the aforementioned trade barriers in Poland. Poland's intellectual property regime, and in particular its inadequate protection of original filing data, and the considerable market access barriers for foreign pharmaceutical products have significant adverse impact on the research-based pharmaceutical industry. Preliminary estimates suggest that potential increase in exports per annum if the trade barriers described were removed is between US$ 100 – US$ 500 million.

SLOVENIA

Intellectual Property Protection

Data Exclusivity

After initially enacting a data exclusivity law that was to come into effect on December 31,1999, Slovenia reversed itself and has suspended the implementation of its data exclusivity law until December 31, 2002. Article 39.3 TRIPS requires WTO members to protect against "unfair commercial use" of the costly and confidential test data submitted to governments as a condition for obtaining marketing approval of pharmaceutical products utilizing new chemical entities. PhRMA believes that this delay in implementing data exclusivity represents a significant step backwards for Slovenia. Recently, Slovenia has indicated willingness to implement the suspended data exclusivity law. PhRMA believes that Slovenia has been required to protect confidential test data since TRIPS became effective on January 1, 2000. Until Slovenia provides the U.S. Government firm assurances that such protection will be protected, and that the registration of copycat pharmaceutical products will immediately cease, PhRMA requests that Slovenia be included in the 2001 "Special 301" Priority Watch List.

In addition, the Slovenian data exclusivity provision as written suffers from several other shortcomings. Although the period of protection for confidential data is a maximum of six years, the data exclusivity period ends earlier than six years – possibly at zero years – if and when the patent expires earlier. This opens the possibility for unfair commercial use of the originator's data in violation of Article 39.3 TRIPS, which does not provide for a linkage of data exclusivity to a patent. The six-year data exclusivity period under the Slovenian law starts with the marketing authorization either in Slovenia or in any of the EU Member States. Because Slovenian marketing authorizations are typically issued later than authorizations in the EU with its central and mutual recognition approval procedures, the Slovenian reference to a third country can considerably shorten the data exclusivity period. Furthermore, reference to third-country marketing approval dates is not provided for, nor is it in the spirit of, Article 39.3 TRIPS.

Other TRIPS Inconsistencies

Article 32 of the Slovenian Intellectual Property Act (IPA) permits the interpretation of a patent right only as a positive right of use, whereas U.S. and European patent concepts unanimously provide for a right to restrict others from using the patented invention. Without patent rights predicated on exclusive use of the invention as outlined in TRIPS Article 28, there is little benefit to patent protection for pharmaceutical products. Furthermore, Article 121 of the Slovenian Law on Industrial

Property discriminates against the patentability of medicines versus products from other industry sectors in violation of Article 28 TRIPS. The effect of Article 121 is to prevent those pharmaceutical substances that were protected by a product patent under Yugoslav law with a priority date before January 1, 1993 and subsequently transferred to Slovenia from enjoying continued product patent protection in Slovenia. Such denial results in lower patent protection of pharmaceutical products compared to products from other industrial sectors for which patents were transferred from Yugoslavia to Slovenia. PhRMA believes that Article 121 should no longer be applied in Slovenia.

Lack of Pipeline Protection

Product patent protection became available in 1993. However, because there is no pipeline protection, the full effect of this law will not be felt until 2013. Patent applications must be filed very early in the research and development process, and it may take up to 8 - 12 years to develop a patented product to meet safety, efficacy and quality standards before regulatory marketing authorization is granted. Therefore, the majority of currently marketed pharmaceutical products, as well as those that will be launched in the next few years, are protected in Slovenia only by a process patent, and are exposed to easy copying by local firms. Unless appropriate pipeline protection is provided, 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 R&D companies will enjoy the same level of protection available today in the U.S. and most of the EU. This lack of protection has allowed and continues to allow local and other companies to copy pharmaceuticals patented in the U.S. and EU. Although pipeline protection is not a TRIPS obligation, the absence of it in Slovenia has contributed to a situation where there is little effective protection for patented pharmaceutical products.

Contributory infringement

The IPA does not provide for relief against contributory infringements (see Article 26 of the Community Patent Convention), such as supplying third parties, domestic or foreign, with intermediary products used in the synthesis of a protected substance.

Absence of Provisional Relief

Article 93 of the IPA grants relief only against infringements of a patent, but does not specify that this applies also to threatened infringements as required by TRIPS Arts. 41 and 50.

Protection against equivalents

Article 94(1) of the IPA prohibits the imitation of a protected model, design, trade or service mark, but does not extend this to patents, although the imitation of a protected invention in the way of equivalents is the most common form of infringement.

Weak Enforcement of Existing Patent Rights

Attempts to enforce the existing process patents in the Slovenian courts have been largely unsuccessful. The Slovenian courts have repeatedly denied enforcement measures under TRIPS such as preliminary injunctions and the reversal of the burden of proof. Slovenian courts have held that the burden of proof rests on the plaintiff where the alleged infringing defendant has been granted its own process patent subsequent to the plaintiff's. This interpretation is incompatible with TRIPS and with EU law. Several cases on intellectual property against domestic copy producers have been pending in Slovenian courts for more than four and up to six years, due the inaction or inappropriate delays of the courts. This results in a *de facto* denial of a fair and equitable enforcement of intellectual property rights as provided for in Article 41 TRIPS.

Effective action, expeditious remedies to prevent infringement, and remedies that constitute a deterrent to further infringements are not available. This is evidenced by the delay of intellectual property proceedings for as much as five years. This is not in compliance with TRIPS Article 41.

In addition, current damages for intellectual property rights violations are not adequate to compensate for the injury the right holder has suffered because of an infringement of his intellectual property right. It is also rare that the infringer is ordered to pay the right holder expenses associated with the defense of the right holder's intellectual property right, or ordered to recover profits. This is not in compliance with TRIPS Article 45.

Market Access Barriers

Sample Products

The Slovenian regulatory authorities continue to require pharmaceutical companies applying for marketing authorization to submit product samples even though Slovenia no longer conducts analytical testing as part of the marketing approval process. This has resulted in a trade barrier for patented pharmaceutical products.

Import Tariffs for U.S. Products

The regimes under which Slovenia is gradually lowering import tariffs for pharmaceuticals produced in the EU in the context of EU accession negotiations is

becoming a trade barrier. In certain cases, the difference of tariff between products of EU origin as opposed to U.S. origin can be as high as 15%. Such significant differences in tariffs influence government decisions on whether or not to reimburse the cost of a medicine, and thus put products of U.S. origin at a great disadvantage.

Additional Violation of National Treatment

In January 1999 the Slovenian government commenced implementation of pricing regulations (sub-law of the Medicines Act) first introduced in April 1998, which on average represented a price reduction for imported products of 30-40%. The regulations discriminate against imported pharmaceutical products, to the benefit of local producers. There is much evidence to suggest that this was in fact the original intent of the regulations, and not a coincidental result.

The regulations fix Slovenian wholesale prices based on the average of the wholesale prices in three reference countries in the EU – over which the manufacturers have no control – multiplied by an arbitrary factor of 0.85 (innovative products are, however, exempted from the factor requirement). Four percent for import costs can be added. As a result, foreign companies were forced to lower their prices between 20-30%, with more extreme consequences for individual products where pirated copies exist.

However, in reality the foreign companies have to pay a 7% wholesale margin, 1% import costs and custom duty (EU origin: 0% as of January 1, 2000; non-EU origin: 10-15%). As long as Slovenia is not a full member of the EU, the MFN clause should remain applicable, and tariffs for products such be reduced to EU levels. Furthermore, Slovenia should be encouraged to follow the Czech example and sign a zero-for-zero agreement.

The exchange rate in these regulations is the middle exchange rate of the Bank of Slovenia. However, wholesalers have to buy foreign currency at commercial exchange rates that are much higher. Thus, wholesalers are further discouraged from purchasing imported rather than local products.

Conflict of Interest

In Slovenia there are a number of conflict of interest situations that hamper fair decision-making and result in trade barriers. For example, the CEO of a local pharmaceutical company is a president of the Assembly of the State Sick Fund, which has responsibility for approving decisions made by the Reimbursement Committee, which determines what drugs will be reimbursed. The Assembly meets four times a year, and decisions of the Reimbursement Committee are reviewed. This has an influence on the choice of products for, and the level of, reimbursement. If a product is excluded from reimbursement, it has virtually no acceptance in the market, because

Slovenian patients will not pay out-of-pocket for medicines. The main criteria considered by the Reimbursement Committee is price, and in general pricing and reimbursement decisions are not transparent and are taken without the involvement of the pharmaceutical companies. No mechanism of appeal exists.

Product Registration

Product registration in Slovenia lacks transparency and discriminates against foreign products. For new product applications under review, the Slovenian MoH requirements for product prescribing information are frequently inconsistent and often require more extensive information from foreign companies than from local firms.

- The MoH does not accept foreign clinical data for product registration, but insists upon a local expert report. In addition, the Ministry accepts only original documentation and certificates. These requirements are not based on scientific principles, but are clearly discriminatory and intended to delay the time to market foreign products.
- Local testing of foreign products takes up to one year despite the fact that the products are manufactured according to the international standards and are accompanied by the manufacturer's Certification of Quality Assurance. The local trials offer no additional verification of safety, quality and efficacy beyond those already established by the manufacturer's initial clinical trials conducted abroad.
- Every batch of imported products must be tested, causing further delays in receiving import documentation and additional costs.

Damage Estimate

PhRMA estimates that the industry's losses in Slovenia are in the range of US$ 50 million to US$ 100 million due to the aforementioned trade barriers.

MIDDLE EAST, AFRICA, SOUTH ASIA

EGYPT

PhRMA recognizes that Egypt has taken some positive steps to meet international GATT and WTO obligations. However, because of the substantial number of areas in which Egypt remains out of compliance with its current WTO obligations, as well as the threat posed by new language in the draft patent law, PhRMA members ask that Egypt remain on the "Special 301" Priority Watch List for 2001.

Intellectual Property Protection

PhRMA members continue efforts to work with Egypt cooperatively to achieve compliance with current WTO TRIPS obligations. Although there are some positive signs, Egypt has thus far failed to implement needed measures to meet its current (January 1, 2000) obligations, including data exclusivity (Article 39.3), enactment of a patent mailbox (Article 70.8), and exclusive marketing rights (Article 70.9). In addition, Egypt's current draft industrial property legislation falls far short of meeting minimum TRIPS standards, and the latest draft may incorporate new counterproductive and TRIPS-inconsistent provisions that are highly discriminatory. Under these circumstances, the U.S. Government should resist continuing pressure from Egypt to initiate a Free Trade Agreement (FTA), unless and until Egypt demonstrates its ability to meet current WTO obligations, including full TRIPS compliance.[*]

Current TRIPS Obligations

In the past year, Egypt made limited progress towards compliance with WTO TRIPS obligations by administratively extending the period of protection for process patents to 20 years. PhRMA appreciates the constructive steps that the Government of Egypt has taken to date on Data Protection and Exclusive Marketing Rights (EMR), whereby the Government has issued Prime Ministerial Decrees indicating the intent of Egypt to meet its TRIPS obligations. These include Prime Ministerial Decree 2211 of the year 2000 on Data protection, Prime Ministerial Decree 547 of the year 2000 on EMR, as well as subsidiary EMR decrees including a Prime Ministerial Decree XXXX setting up the EMR committee, Ministerial Decree from the Ministry of Higher Education and Scientific Research, and publication of implementing regulations by the Academy of Scientific Research and Technology. PhRMA members await formal implementation of both the data protection and the EMR decrees.

[*] For further discussion of PhRMA views on recent and ongoing FTA negotiations with U.S. trade partners, please see Appendix B.

With respect to the Data Protection Ministerial Decree 2211, PhRMA members remain concerned that the absence of formal implementation may provide an opportunity for opponents of data protection to gain marketing approval for infringing products in Egypt. It is particularly important that generic marketing approvals not be granted on products that had not entered the market as of January 1, 2000, the date that the WTO TRIPS Agreement came into force in Egypt. Implementing instructions or regulations are also needed to clarify ambiguous provisions in Prime Ministerial Decree 2211 both to ensure the decree covers products currently being marketed in the U.S. or elsewhere that have not yet entered the Egyptian market and that a period of protection of at least five years from the time the product was first registered in Egypt is provided. Implementing instructions should also provide explicit protection against unfair commercial use including both direct and indirect reliance by the Ministry of Health on the data package used to support initial marketing approval. This means that the protection should extend to the data itself as well as to conclusions based on that data, so that an application not filed by the innovator would not gain approval for the full term of protection. No connection should be made between the status of patent protection and the provision of data exclusivity, consistent with TRIPS requirements. On a positive note, PhRMA recognizes that the Government of Egypt has thus far not approved product applications for registration and marketing approval of pharmaceutical products that make reference to, rely directly or indirectly on, or otherwise make use of, protected data since January 1, 2000.[#]

Similarly, to date Egypt has failed to formally implement any of the numerous EMR decrees or regulations issued by the Government. Egypt has yet to approve the first EMR application for Eli Lilly's product Zyprexa® (olanzapine). Egypt was required to provide EMRs to products meeting requirements specified in TRIPS Article 70.9, as of January 1, 1995. Lilly's mailbox patent application in 1996 initiated the EMR approval process. Egypt is now more than four years behind in meeting its obligation to implement EMRs, and more than one year delayed in providing formal data protection. Zyprexa® does enjoy de facto exclusivity in the market, as to date the Government of Egypt has not approved any of the pending applications for infringing copies of the product.

Draft Industrial Property Law

The draft Egyptian patent law is currently under review by the Shura Council, and will soon be transferred to the People's Assembly for debate and approval as part of the overall TRIPS package of intellectual property legislation. PhMRA has received reports that the current draft patent law may now include some of the comments provided by knowledgeable experts, but has not yet seen the final results of the Shura

[#] PhRMA has provided a list to the Government of Egypt of products that are eligible for data protection in order to ensure that there will be no inadvertent approval provided for infringing products. PhRMA members also agreed to note that data protection should be provided for all new product applications.

Council process, and so reserves comments on the current status of much of the draft patent law.

There is, however, reason to believe that very damaging language may have been added to the patent law that would threaten the ability of the Government of Egypt to ever provide effective patent protection for pharmaceutical products or processes. PhRMA has become aware that the Ministry of Health is attempting to add language to the patent law that would require all patent applications for health-related subject matter, including pharmaceutical chemical entities, to be reviewed by the Ministry of Health rather than by the normal patent office procedures. This proposal would, if adopted, constitute a major violation of the TRIPS Agreement, as it clearly provides discriminatory treatment for certain classes of patented products. In addition, this would almost certainly undermine the ability of the Government of Egypt to implement patent protection for pharmaceutical products or processes, and so would result in a number of additional violations, both now and in the future. It is important that the U.S. Government deliver a strong message that the Government of Egypt should adopt a patent law that at the very least does not fall below minimum international standards for protection of industrial property contained in the WTO TRIPS Agreement.

Market Access Barriers

Egypt maintains an onerous price control system that does not allow for price increases to compensate for inflation. Also, many regulations regarding manufacture and registration are opaque and vague. In fact, the lack of clear accountability, timelines and procedures lead to long delays in new product registration, in some cases as long as two to three years. Delays in new product registration unnecessarily deprive patients from access to new medicines, and constitute a serious trade barrier for foreign manufacturers.

Furthermore, Egypt bans the import of many pharmaceuticals in finished dosage forms, and requires foreign companies to license the manufacture and sale of imported drugs to local companies. All of these requirements appear to violate Egypt's WTO commitments regarding national treatment of foreign investors. Moreover, as the government has shown considerable progress in divesting and liberalizing large segments of the Egyptian economy, the pharmaceutical sector appears increasingly to be unfairly targeted for control. The sector remains under very tight price controls that distort competition and delay or discourage the introduction of new products.

Damage Estimate

PhRMA is currently preparing methodology to estimate damage to U.S. companies from the problems described above. Egypt has a great deal to gain by coming into compliance with WTO TRIPS obligations, including the possibility of a

Free Trade Agreement with the United States, and substantial direct foreign investment opportunities. PhRMA member companies would like to move forward with an estimated U.S.$ 300 million in planned investments in Egypt's pharmaceutical sector. Given its location and large population, if Egypt were to adopt a modern patent law, market-based pricing, and streamlined registration procedures, it would become a likely regional center for multinational pharmaceutical production. Even so, Egypt remains one of the largest markets in the Middle East/Africa region. Under current adverse circumstances, U.S. firms hold an estimated 18% share of the Egyptian pharmaceutical market, in a market estimated at approximately one billion dollars in 2000. If Egypt were to meet its WTO obligations, the U.S. share of the market would likely increase to at least 25%, and the market itself would likely show substantial expansion. In addition, given its location and large population, if Egypt were to adopt a modern patent law and market-based pricing, it would enhance its potential as a regional center for multi-national pharmaceutical production. PhRMA estimates current losses in Egypt as in excess of US$ 100 million.

PAKISTAN

Although attracting substantially less attention than India, the commercial environment in Pakistan suffers from a similarly broad range of market access barriers and deficiencies in intellectual property protection. Although the new Pakistani Government has expressed willingness to open a dialogue with PhRMA member companies to redress these concerns, PhRMA believes that Pakistan should be placed on the 2000 "Special 301" Priority Watch List.

Market Access Barriers

Price Controls and Forced Price Reductions:

Although the Governments of Nawaz Sharif and Benazir Bhutto had committed to allowing annual price increases for a group of so-called "Controlled" products, utilizing a formula put in place in October 1994 (SRO 1038), which considered currency devaluation and local inflation, the Government has not met its commitments in this regard. On June 19, 2000, the Ministry of Health announced an 8% price increase for Controlled Drugs and a 10% increase for Decontrolled Drugs effective from June 19, 2000. But this price increase, like those allowed in 1995 and 1996, was substantially below the indexed figure, which represented the true cost increases which the industry had to bear. Unfortunately, there is no indication that the Administration of General Pervez Musharraf has any intention of honoring this commitment – even though he has publicly stressed the importance he places on attracting foreign investment. All other products in the so-called "De-

⇒ For "De-controlled" drugs, the price increase was only cumulatively *39%* in the last seven and a half years.

In October 1997 and again in February 1999 the Sharif Government imposed compulsory price reductions on targeted products, many of which were based on an unjustified price comparison with India. The drive behind this move was political and the reason given was, either the lower prices, which prevail for the same Multinational products in India, or simply the belief in the MoH that the price was too high. Comparisons of prices in the Indian market are inappropriate when applied to the prices of pharmaceuticals in Pakistan, as India has significantly lower cost base for all materials, utilities and employee costs, and the purchasing power of the average Indian is significantly below a Pakistani. Furthermore, they ignore all those products where there is a much lower price in Pakistan than in India, and a recent study has shown that around 75% of products produced by multinational companies available in both countries are, in fact, lower priced in Pakistan. The U.S. ITC has indicated recently that it may be impossible to achieve meaningful international price comparisons for these and other reasons.

Again in 1999, the Sharif Government compared the import prices of raw materials of the Multinational companies with those imported by the local companies, without giving any consideration to comparable quality. Consequently, the multinationals were forced to reduce the import prices under threat from the MoH of unilateral action, just so that the then Minister of Health could make political mileage from having "stood up to the Macs."

A recent development, which would further damage the Industry's confidence in its future in Pakistan, is a recommendation, emanating from the Ministry of Health, to rescind SRO 1038. This would remove the only legal mechanism for awarding annual price increases and risk loss of Transparency in the process and so increase the danger of discretionary powers being used to fuel corruption.

This information clearly demonstrates the serious difficulty facing the pharmaceutical industry. No other industry has been put under such stringent price control; and no other industry has been forced to reduce prices in an economic environment of high inflation and regular currency devaluation. Given the significant level of foreign investment and international quality of locally produced products, it is only fair that the government seriously consider the negative impacts of the current economic environment upon the industry when making decisions regarding the price increases which are now due.

In order to return to the profitability level of seven years ago (i.e. June 1993), and utilizing the formula embodied in SRO1038 of October 1994, increases well in excess of 50% would be needed. However, the industry understands that the

government for political reasons cannot approve such a large increase. Furthermore, the industry would not wish to burden the people for humanitarian reasons.

Therefore, in order to return to an acceptable minimum profitability level, PhRMA requests that the U.S. Trade Representative seek the following redress in Pakistan:

Continued implementation of regular price increases for "controlled" products to build on the progress made last year. A figure in excess of 20% will in no way compensate for the historical shortfall, but will allow the industry to maintain supply of high quality products.

The government must commit to honoring annual price increases for controlled products in future, according to an acceptable formula, which will enable the industry to plan for the future with some confidence.

The MoH should enter into discussions with the Industry as to how the anomalous price differences for certain, specific products between India and Pakistan, both the higher and lower prices, can be resolved.

The government should reintroduce free market driven pricing for the prices of "decontrolled" products, as originally intended and practiced between June 1993 and February 1994 (i.e. abolish any controls over these prices.)

The MoH should revise the Controlled Drug list to a rational number of truly 'essential' drugs, as is the case in India, where only 78 molecules are price controlled.

Intellectual Property Protection

General Musharraf has publicly stated the intention of his administration to comply with all elements of the WTO agreements. Pakistan had committed, therefore, to implement TRIPS legislation by January 1, 2000. Although the Ministry of Industries is in the process of drafting and agreeing to the wording of the laws, the deadline will be missed. In addition, for pharmaceuticals, there is still no clear mechanism for obtaining Exclusive Marketing Rights (EMR) for a new chemical entity under the "Mailbox" provision, and the concerned Government Departments are unaware of their obligations under the law. Therefore, the potential for failing to provide adequate protection to new molecules does still exist. The U.S. Government should be encouraging Pakistan to implement its WTO commitments in word and spirit as soon as is possible.

<u>Product Registration Process:</u>

It is the general experience of most multinational pharmaceutical companies in Pakistan that the time required for the registration process often is in excess of two

years, especially for New Chemical Entities. At the same time, favor is given to local companies who wish to register "me-too" copies, when registration can be obtained in just a few months. Often the delay is caused by unwillingness from the MoH to accept that the price of a NCE with worldwide patent protection cannot be very much lower in Pakistan than in other countries – further evidence of the reluctance to allow market forces to govern the demand for new products. For the benefit of patients in Pakistan, it is vital to keep the procedure for registration as brief as possible, and, since there is never any question of reimbursement from the Government's budget, the world pricing of a NCE should be accepted. A target of a maximum period of 12 months for the registration of a NCE should be set.

Damage Estimate

PhRMA is currently studying methodology for estimating damages caused by the aforementioned trade barriers in Pakistan. However, it is safe to say that at this time research-based pharmaceutical companies are being forced, by virtue of the Government of Pakistan's policies, to reconsider investment and production in Pakistan. Although the situation has been difficult for several years, 2001 is a critical year for the future of PhRMA member companies in Pakistan.

UNITED ARAB EMIRATES (U.A.E.)

PhRMA member companies operating in the United Arab Emirates had hoped that the UAE would reverse recent decisions taken to register infringing copies of products for sale throughout the region. However, despite continuing assurances of the intent of the Government to meet its express international and bilateral commitments, the UAE has failed to carry these words into deeds. Accordingly, PhRMA members request that the UAE be included in the "Special 301" Priority Watch List for 2001.

Intellectual Property Protection

In late summer 2000, the UAE health regulatory authority approved for registration in the UAE, and subsequently for sale throughout the region, dozens of new unauthorized (pirate) copies of cutting-edge innovative products. Despite several years of UAE Government statements to the press and reassurances to European and U.S. diplomats, the UAE has failed to implement adequate and effective patent protection for pharmaceuticals more than a full year after the January 1, 2000 TRIPS deadline. Th

meetings were scheduled at the express request of the U.S. Ambassador, and senior officials of both the Embassy and the consulate in Dubai attended the meetings, serving as witnesses to the UAE's commitments. The Ambassador has taken every possible step to obtain UAE compliance with the MoU and its own undertakings in this regard, but to date these efforts have not been rewarded

The UAE's actions have enabled the sale of these unauthorized copies throughout the Gulf Cooperation Council region and beyond. The UAE has further signaled its intent to authorize for sale dozens of additional infringing copies of patented pharmaceutical products manufactured by a local company, products which rely either directly or indirectly on original data submitted by PhRMA member companies, and therefore infringe their rights. Finally, the UAE has not yet begun serious consideration of a TRIPS-consistent patent law, which was another condition of the April 2000 MoU, a pledge critical to PhRMA's amended Special 301 report recommending the UAE be removed from the Watch List.

In addition to the "Special 301" OCR petition, the pharmaceutical industry may ultimately ask the U.S. Trade Representative to initiate a formal WTO case against the UAE for failure to implement its TRIPS obligations. The UAE is an excellent candidate for a data protection case; USTR is known to be in search of a so-called "slam dunk" case, and in this case the UAE has reneged on its own commitments on data protection. As a high-income oil-producing state, the UAE is unlikely to draw sympathy either internationally or on the Hill. PhRMA members are currently considering whether to request that the U.S. Government initiate formal consultations with the UAE in Geneva as the first step in a WTO dispute resolution process.

Market Access Barriers

Transparency: Research based companies are concerned about a perceived lack of transparency and possible conflict of interest at the Ministry of Health. It would appear that some health officials might hold financial interests in certain local health and/or pharmaceutical companies. Indeed, on more than one occasion, research industry has observed local health officials, many of whom have responsibility for policies and procedures affecting multinational companies, openly working to promote local companies to other Gulf and Middle East officials. In fact, it has been alleged that conflict of interest or other financial incentive may have played a direct role in the registration of the products in question.

Regulatory Delay: There is also concern about a proposed new scheme to centralize the registration of new pharmaceutical products in GCC countries. Research industry is concerned that the scheme, which has few successful international examples to emulate, could result in longer delays in the introduction of new medicines, thus creating a new trade barrier. Industry has advocated a gradual, go slow approach. The scheme will reportedly begin in 2000-2001.

Government Procurement Discrimination: As is the case with other GCC countries, the U.A.E. allows "local" GCC producers up to 20% higher prices in public sector bidding and procurement vs. multinational companies. This rule is in place despite ongoing government cost containment programs, and allows local generics companies to "shadow price" foreign competitors.

Damage Estimate

The UAE market is estimated at CIF$220 million, and represents the second largest GCC market after Saudi Arabia. PhRMA does not have damage estimate methodology specific to the Gulf market and these circumstances. Given the large number of infringing products now authorized to enter the UAE market (estimated by the UAE Government at 90), and the recent GCC approval for marketing of infringing UAE copies throughout the Gulf, the actual commercial damages are substantial and run into millions of dollars in losses on an annual basis. In addition, the UAE situation threatens to undermine progress elsewhere in the region. In past years, PhRMA has expressed concern that the Ministry of Health would acquiesce to pressure from the local company, Julphar, to register large numbers of new pirate copies in advance of anticipated changes to the patent law. This now appears well underway. Damages fall into three categories: direct losses in the UAE; losses due to GCC sales to Ministries of Health, and potential losses from future private sector sales in the Gulf, and the greater Middle East region, including North Africa. The latter is due to the fact that Julphar will be able to bid on tenders throughout the Middle East and North Africa as long as the UAE Government in Abu Dhabi fails to rescind the infringing registrations.

As a single example, one affected U.S. company stands to lose export sales of US$ 1.5 – 2.0 million per year in the UAE alone due to the infringing registration of a pirated antihistamine product. Beyond the UAE, as both public sector and private sector purchasers move to buy the Julphar products, companies face increasing losses. One PhRMA member estimates that it will lose sales of up to $10 million per year through the introduction of a single Julphar copycat product for its widely prescribed cardiovascular product in the Gulf-wide tender, nearly 20% of the company's annual sales in the region. A second PhRMA member estimates losses of $15 million in total from regional losses due to the registration of an infringing copy of a blood product. Other pirated products include the leading anti-depressant and the leading pediatric antibiotic worldwide. Because Julphar has chosen to pirate cutting-edge, block-buster products, almost every infringing product registered in August and September will lead to direct losses in the millions for PhRMA members active in GCC markets.

PhRMA urges U.S. officials to prioritize the IPR issue on the bilateral agenda. Pending the outcome of the current negotiations, PhRMA members are evaluating whether to formally request that the U.S. Trade Representative seek bilateral

consultations as the first step in a WTO dispute resolution process against UAE. The failure to provide data exclusivity and to meet other WTO obligations contained in the TRIPS Agreement provide a firm basis for a successful case.

WESTERN HEMISPHERE

BRAZIL

PhRMA believes that Brazil's industrial property law (No. 9279/96) is quite strong in many respects. It provides: a 20-year product patent term; pipeline protection for products in the approval process; basic biotechnology protections in accordance with TRIPS; a ban on parallel imports; and a one-year implementation period (TRIPS allows Brazil until 2005). In recognition of the significance of Brazil's expedited adoption of product patent protection, the research-based pharmaceutical industry invested US$ 2.1 billion in Brazil by 2000. Unfortunately, a narrow aspect of the Brazilian law directly conflicts with Brazil's WTO TRIPS Obligations, as will be described below. For this reason, the U.S. has initiated a WTO Dispute Settlement

government announced in September 2000 that it would invoke this decree if it were unable to produce 80% of the market for AIDS drugs by the year 2002.

In addition, "Medidas Provisorias" (Temporary Measures) issued in December 1999 require that, under a revised Article 229-C of the law, the National Sanitary Supervision Agency (ANVS) approve all patent applications related to pharmaceutical products or processes. While our industry has long advocated a formal linkage mechanism between the patent office and ANVS to safeguard confidential data (consistent with Brazil's TRIPS obligations), this measure poses numerous problems and will potentially delay patent approvals even further. Its consistency with the anti-discrimination clause of TRIPS Article 27.1 is questionable, as products from other industries are not subjected to the same review by relevant regulatory authorities. Also, any review of the applications other than for the patentability criteria set forth in TRIPS Article 27.1 would not be consistent with TRIPS, and any review of patentability criteria is beyond the expertise of ANVS.

Several pieces of draft legislation pending in the Brazilian Congress would severely limit intellectual property protection, including measures that would exclude the patentability of AIDS drugs and increase the issuance of compulsory licenses in violation of patent rights. Health Minister Jose Serra has publicly stated his desire to use loopholes in the patent law to achieve his objective of reducing drug prices. While the research-based pharmaceutical industry shares the goal of improving access to medicine, violating international obligations is the wrong route to attain this goal.

Brazilian legislation also appears inconsistent with TRIPS, particularly Article 27.1, in several areas: various exclusions from patentability, forfeiture of patent rights, term of protection, and the absence of protection of test data and other confidential, valuable information against unfair commercial use.

We remain concerned about continuing delays in processing patents. The National Institute of Industrial Property (INPI) lacks sufficient resources to process applications in a timely fashion, resulting in a substantial backlog (estimated at 10,000 pending patent applications). These delays will seriously hinder our industry's ability to plan effective product launches. We endorse additional training of INPI staff and a greater allocation of resources for automation and other administrative needs.

Market Access Barriers

Price Controls

On December 18, 2000, the Brazilian government issued a "Medida Provisoria" freezing pharmaceutical prices at 4.4% above their August 1999 level until the end of 2001. This anti-free market measure was imposed in a non-transparent manner, does

not take into account the economic impact of devaluation and other factors on pharmaceutical manufacturing costs, and sends a negative message to investors.

Damage Estimate

Brazil is the largest market for pharmaceuticals in Latin America. It is not possible at this time to determine the impact on sales of PhRMA member company affiliates in Brazil, if the aforementioned provisions were strengthened and renewed pricing concerns resolved. As a result of Brazil's devaluation, compounded by some of the measures described, the Brazilian market declined steeply from an estimated value of $7.2 billion in 1998 to $5.3 billion in 1999 -- a drop of 25%. The 2000 estimate is for $5.5 billion, a slight improvement over 1999, but still significantly less than 1998, reflecting the lingering effects of Brazil's economic crisis and the prize freeze imposed by the Brazilian government.

CANADA

Canada has made noteworthy progress since 1992 to provide improved patent protection. As a result, several PhRMA member companies have made significant investments in Canada. However, Canada's industrial property regime was found lacking in two WTO cases in 2000, and Canada has yet to comply fully with the WTO rulings. For these reasons, PhRMA requests that the U.S. Trade Representative include Canada in the 2001 "Special 301" Priority Watch List.

Intellectual Property Protection

Canada's patent law, amended to comply with TRIPS, only provided 20-year patent protection from the date of filing for all patent applications filed on or after October 1, 1989. The United States successfully argued before the WTO Dispute Resolution Body that this did not provide the required 20-year protection to those patents which had been filed before October 1, 1989, and which took less than three years to obtain. Important innovative pharmaceutical products were denied the full length of protection required by TRIPS and would have been prematurely forced off patent.

In addition, Canada lost, in part, a WTO case filed by the European Union challenging the operation of Canada's "Bolar" provisions. The WTO panel found in favor of the EU on the issue of "stockpiling," wherein Canada allowed generic companies to produce and warehouse patented pharmaceuticals for ultimate commercial export immediately upon expiration. Canada has agreed to amend its practices and related regulations in this area.

Data Protection

Despite two WTO losses, in whole or in part, Canada continues to fall short of its TRIPS requirements. PhRMA remains seriously concerned by the failure of Canadian regulatory authorities to provide effective data exclusivity, as required by TRIPS Article 39.3. In many cases, cutting-edge innovative products are not approved for marketing in the U.S. and Canada until just before or even after the expiration of patent protection, so innovators must rely on data protection instead. Although Canada has statutory data protection, recent judicial decisions have rendered those protections meaningless. Canadian authorities allow parties other than the right holder to gain marketing approval in direct reliance of protected confidential data. This violates TRIPS Article 39.3 as it eliminates the TRIPS requirement to prevent "unfair commercial use" of protected data. We urge the United States Government to move data protection to the top of the bilateral commercial agenda with Canada.

Absence of Linkage and other Enforcement Issues

Canada is required under both TRIPS and NAFTA to ensure effective enforcement of the standards of patent protection provided for in those Agreements. 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.

WTO TRIPS Article 41 et seq. and NAFTA Article 1714 et seq. 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 covered by (these) Agreements, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements." Canada falls short of meeting these obligations.

Systemic inadequacies in Canada's administrative and judicial procedures call into question whether Canada is meeting its TRIPS and NAFTA obligations with respect to pharmaceutical patents. These inadequacies allow generic versions of patented medicines to be approved by Health Canada, to be listed for use by doctors and use or even mandatory substitution by pharmacists, and to reach or be ready to reach the market in commercial quantities while valid patents are still in force. This can occur under the *Patented Medicines (Notice of Compliance) Regulations*, the so-called "linkage regulations" administered by Health Canada, and as a result of how patent infringement claims are treated in the Canadian Courts.

Further, Canada's linkage regulations fail to provide for transparent and equitable consideration of the rights of patent owners and prevention of patent infringement. Under the linkage regulations, generic producers can apply at any time for approval by Health Canada of generic medicines. Such generic medicines are assessed for safety and efficacy against data and clinical trials relating to previously approved patented medicines. These regulations extend significant advantages to generic companies.

The linkage regulations indicate that Health Canada must determine whether there are patents registered that could be infringed if approval, i.e., a Notice of Compliance (NOC), was granted for the generic medicine. If a patent is identified, the generic producer is required, in principle, to issue a Notice of Allegation (that there would be no infringement) to the brand name company who, if it believes the allegation is not justified, may challenge that allegation in the Court. Thus, the brand name company has access to a judicial procedure to present its claim and seek an order of prohibition to prevent the issuance of an NOC.

This arrangement, in principle, could provide the basis for effective protection of pharmaceutical patent owners' rights as required under TRIPS and NAFTA. Experience shows, however, that the manner in which the procedures are applied fails to extend such protection in a majority of cases where infringement is at issue. Indeed, there is a pattern that reveals clear bias in favor of generic companies.

This is seen in a number of ways:

- The legal burden is on the brand name company to prove that the generic company's allegation of non-infringement is not justified. Access to information on the generic company's product may be restricted, however, because there is not necessarily discovery in such proceedings. The brand name company may therefore be reliant on whatever information the generic company is prepared to supply. This approach is open to abuse to the detriment of the brand name company.

- Health Canada has been inconsistent in its policies and practices relating to the listing of brand name companies' patents and in requiring generic companies to send a Notice of Allegation. In some cases no Notice is provided. This means that the brand name company has no opportunity to present a claim and, in fact, may remain unaware that a generic version of its drug has been submitted for approval until an NOC is issued. This has occurred and could easily occur again in future.

- The linkage regulations do not apply to process patents, notwithstanding the fact that claims to a medicine itself were previously forbidden under Canadian patent law. This means that many brand name companies have only process patents to protect their inventions. This situation will continue for a period of years.

As a result of these inadequacies, there have been dozens of cases since 1993 (when the linkage regulations came into effect) in which patentees had an infringement claim but were unable to prevent the issuance of an NOC and the marketing of a generic version of a patented medicine.

The Canadian courts fail to provide effective recourse in cases where an NOC is issued for an infringing generic medicine.

If a patentee is unsuccessful in preventing the issuance of an NOC by Health Canada, the next step would be to seek relief through an infringement action. In the first instance, a patentee could apply for an interlocutory injunction to maintain its rights and, in particular, to prevent the marketing of an infringing generic version pending trial.

It is virtually impossible, however, to obtain an interlocutory injunction. It is estimated that less than 10% of requests for such injunctions are granted.

- The Canadian Courts apply a very high standard of "irreparable harm," the test applied for the granting of an interlocutory injunction. This standard is impossible to meet in practical terms.

- A patentee is required to establish that there will be irreparable harm that cannot be compensated by the eventual award of damages. The Courts do not accept that a monetary damage award may not provide full compensation for loss of market share for the product and related products, lost business, lost investment and research opportunities due to the absence of income from sales, or for loss of reputation and goodwill.

- It generally takes two to five years before an action for patent infringement is tried. After this amount of time, a brand name company's market share has been severely eroded. Moreover, Canadian Courts may be reluctant to grant the large damage awards that a brand name company would be owed in such cases.

The standards applied by the Canadian Courts are not consistent with the standards provided for in TRIPS and NAFTA.

- The fundamental private right under these Agreements is, of course, the exclusive right to prevent the making, use or sale of a patented product or process that is not authorized by the patentee.

- Article 50 of TRIPS and Article 1716 of NAFTA call for "prompt and effective" provisional measures, i.e., including interlocutory injunctions, "to prevent an infringement of any intellectual property right, and in particular to prevent the entry into the channels of commerce in their jurisdiction of allegedly infringing goods." The test under TRIPS and NAFTA for provisional measures is that "any delay in the issuance of such measures is likely to cause irreparable harm to the right holder," a clearly lower standard than that applied by the Canadian Courts.

The concerns of pharmaceutical patent owners are serious and have important implications beyond economic losses in Canada. If a major developed country such as Canada is failing and continues to fail to comply with the spirit and letter of TRIPS, this will set a negative example for developing countries. Canadian practices that create a dangerous precedent should be addressed before they are adopted in other jurisdictions.

In conclusion, although Canada has eliminated its former compulsory licensing system for pharmaceuticals as a result of NAFTA and TRIPS, there continues to be a strong bias favoring the early and often infringing entry of generic versions of patented medicines into the marketplace. There are systemic inadequacies in administrative and judicial procedures that allow this to occur, resulting in substantial and on-going economic losses to patent owners and calling into question Canada's compliance with its obligations under both NAFTA and TRIPS.

Moreover, Canada's policies and practices constitute a problematic example that could be followed by others, particularly developing countries. PhRMA requests that the U.S. Trade Representative place high priority to remedying this situation.

Market Access Barriers

Price Controls

The Patented Medicine Prices Review Board (PMPRB) continues to work toward revising its overall approach to setting price ceilings. Reports emerging from the Federal/ Provincial/Territorial Pharmaceutical Issues Committee suggest the likelihood of increased collaboration among different levels of government toward more stringent, non-market based interventions.

The use of international price comparisons and the establishment of price ceilings on patented medicines are counterproductive to initiatives to provide high quality health care, and thus improve the health of patients, or to help contain health care spending. The following are among the principal concerns regarding such practices.

- *Using international comparisons ignores valid reasons for price differentials across countries.* The prices of pharmaceutical products, as well as all other types of goods and services, differ widely across countries, for many legitimate reasons. These include living standards, income levels, consumer preferences, disease and drug consumption patterns, product volume, exchange rates, product liability, regulatory requirements, as well as the degree of competition in the health services and pharmaceutical markets. Superimposed on these factors are government-mandated reimbursement and price controls, which affect prices throughout the distribution chain. As a result, establishing price ceilings by using prices from other countries ignores prevailing market conditions and impedes biomedical innovation by prohibiting each innovator from establishing prices for its medicines based on market factors.

- *There is little evidence that international price benchmarking leading to price controls actually curbs overall pharmaceutical spending.* Government-set prices

preclude the benefits of price competition. In these circumstances, such government interventions in the market have little, if any, positive impact on the rate of growth in pharmaceutical expenditures over the long term. Under market conditions, however, price competition has proven to be an effective way to hold overall spending down and to provide high quality health care.

- *International price benchmarking threatens patients' health by dampening incentives to improve on today's treatments, thus lowering health-care quality.* In order to fund critical long-term activities to discover and develop potentially life-saving drugs, pharmaceutical companies must be able to fairly and adequately recoup investment in research and development. Price control practices that prevent innovators from covering their costs will thus impede biomedical innovation and can jeopardize high quality healthcare for future patients.

The recent U.S. International Trade Commission (ITC) study, for these and other reasons, concludes that meaningful international price comparison is not possible, and in fact may be counterproductive. The PMPRB's proposal to further restrict pricing flexibility as a means of allocating health care resources will likely fail to resolve the tension between controlling health-care spending and improved health for the Canadian medical consumer, and will likely undermine incentives to the research-based pharmaceutical industry to continue to deliver cost-effective innovations for patients.

Damage Estimate

It is not possible at this time to determine the impact on sales for affiliates of PhRMA members in Canada if the aforementioned issues were to be resolved. However, the level of pharmaceutical research in Canada is only 5% of the level of total research in the United States, which demonstrates how little incentive the Canadian intellectual property regime provides for pharmaceutical innovation.

Dominican Republic

PhRMA member companies appreciate the continuing efforts of the U.S. Government to try to ameliorate the worst aspects of the Dominican Republic's new industrial property law. The new law continues to fails to meet the basic minimum standards contained in the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Given the threat this presents adequate and effective protection for intellectual property from, PhRMA requests that the U.S. Trade Representative include the Dominican Republic in the 2001 "Special 301" Priority Watch List.

Intellectual Property Protection

On May 11, 2000, then-President Fernandez signed into law an industrial property bill whose numerous deficiencies make it the worst in the Western Hemisphere. Many of its provisions make it non-compliant with TRIPS, including:

Overly Broad Exclusions from Patentability

The law excludes patenting of second uses, does not include protection for vegetable inventions, business or economic plans or non-biological methods and processes connected with living materials.

Overly Broad Authority for Compulsory Licensing

The law allows the granting of compulsory licenses on the sole basis of the denial of a contractual license within 210 days after the contractual license is requested. There is no need to prove any fault by the patent holder. The only grounds a patent owner can allege is the impossibility to exploit a patented invention. Additionally, the law allows for issuance of compulsory licenses on patents on raw materials, i.e. the potential licensee would be authorized to finish the product locally, thereby discriminating between imported finished products and those locally produced. (The law provides for other, permissible bases for compulsory licenses granted in cases of lack of exploitation, abuse due to non-competitive practices, public interest and cases of dependent patents.)

Protectionist Local Working Requirement

Article 39 of the law discriminates between imported finished products and locally manufactured products, by requiring both importation and local manufacture, in a clear violation of Article 27.1 of TRIPS. The law discriminates between foreigners and nationals, requiring foreigners to place a bond in an amount sufficient to cover court costs and legal fees in cases where they appear as plaintiffs in a lawsuit (where the

patent or trademark was issued prior to the publication of the new law, that is May 11, 2000). This goes against the national treatment stipulated by Article 3 of TRIPS. (Paradoxically, the new Dominican copyright law adopted in 2000 expressly states that such a bond will not be required in any case.)

Data Protection

WTO TRIPS Article 39.3 requires the protection of undisclosed tests or other data filed before sanitary authorities as a precondition of approving the marketing of pharmaceutical, agricultural, or chemical products. The new Dominican law completely undermines the protections required by Article 39.3 by authorizing all uses of a patent which are necessary to obtain health registration or approval for commercialization of a product. Additionally, the Department of Health continues its practice of issuing health registrations (equivalent to a permission to commercialize) to products that violate locally registered patents in spite of legal requests to the contrary.

Inadequate Patent Term

Article 186 (2) only grants issued patents the term granted pursuant to the old law (fifteen years), thereby denying extension to 20 years in view of Article 70.2 of TRIPS.

Damage Estimate

PhRMA is still in the process of developing data estimate methodology to apply in this and other similar cases to measure the cost to PhRMA members of the elimination of key intellectual property protections. It is clear that the Dominican Republic has moved farther, not closer to compliance with TRIPS obligations. PhRMA member companies in the Dominican Republic estimate that, if trade barriers were removed, exports to that country could increase from U.S.$ 50 to U.S.$ 100 million. Further, the Dominican Republic approach is being heralded by those who would weaken the TRIPS Agreement as a way for developing countries to evade their multilateral IP obligations. Accordingly, the damage caused extends beyond the borders of the Dominican Republic.

WATCH LIST COUNTRIES

ASIA-PACIFIC

AUSTRALIA

For the reasons described below, PhRMA requests that Australia be included among the 2001 "Special 301" Watch Countries.

Market Access Barriers

The Australian Government operates effectively as a monopsony purchaser of prescription pharmaceuticals through its operation of the Pharmaceutical Benefits Scheme (PBS). The PBS system accounts for approximately 80% of total prescription drug sales. The PBS aims to provide reliable and affordable access to medicines for the Australian community. Under the PBS, capped co-payments and safety net provisions limit the cost of pharmaceuticals to consumers, with the government paying the remainder.

The Industry Commission Inquiry into the Pharmaceutical Industry (May 1996) found that "the Government's use of market power saves taxpayers up to $A860 million a year." In effect, the industry thus subsidizes taxpayers to this extent.

In recognition of this price suppression, in April 1997, the Australian Government announced the Pharmaceutical Industry Investment Program (PIIP), under which the Government will allocate A$300 million over the next five years to eligible companies in return for activity.

One month later, in May 1997, the Australian Government announced its intention to introduce Therapeutic Group Premiums (TGP) (reference pricing) from February 1, 1998, for certain classes of drugs which have "similar clinical activity." For each of these classes, a base or benchmark price was established. The government reimburses drugs in the class to the level of the base/benchmark price product. For other drugs in the class, patients have to pay any additional premium.

Originally, six classes of drugs were proposed for the TGP; however, strong opposition by industry and medical groups to the inclusion of beta-blockers and SSRIs resulted in their exemption from the TGP. The four remaining classes affected by the TGP include: ACE inhibitors and calcium channel blockers used to treat high blood pressure and heart disease; the HMG class of drugs for treating high cholesterol; and, H2 receptor antagonists for the treatment of ulcers.

The government hopes to achieve PBS savings of A$460 million over four years, through the introduction of TGPs. The TGP proposal is expected to return to government revenue almost double the average A$60 million per year foreshadowed in the PIIP.

The TGP proposal should be considered in the context of Australia's mandatory cost effectiveness criteria, under which manufacturers must already justify the price of their drug through economic and therapeutic evidence, in order to gain reimbursement.

The research-based pharmaceutical industry maintains the position that there are several reasons why TGPs are not appropriate in the Australian reimbursement system. More specifically, TGPs:

- contradict the principle of evidence-based medicine;
- do not recognize that some products are not interchangeable, and that individuals do not necessarily respond in an average or predictable way;
- shift costs to other arms of the health-care system;
- tend to create a two-tier system of drug access;
- send a negative message to industry because prices in the Australian market are already low;
- discourage R&D and marketing of the latest products;
- result in loss of investment and employment; and,
- undermine the principles of patent protection.

Access

In the Australian context, market access effectively equates to reimbursement. This is because the PBS system accounts for approximately 80% of total prescription drug sales.

The 1996 Australian Industry Commission inquiry found evidence that community access to some drugs was adversely affected by the PBS; and that while Australia has not suffered too much in this area, the position is unlikely to be sustainable because when low prices are taken into account, the overall impact of the PBS has been to reduce sales revenues of some companies, increasing the risk of non-supply.

The introduction to TGPs inevitably will lead to increased risk of non-supply. As Paul Gross, a consultant to the research-based industry, concludes in his report, "There is serious concern amongst pharmaceutical manufacturers that a second stage of TGP pricing in Australia might attempt to use the price relativities established in prior economic appraisals of different drugs (cost effectiveness analysis) to readjust the first year relative prices between reference priced and non reference priced drugs. Such an adjustment would debase both future and past economic appraisals of drugs on the PBS and places manufacturers in double jeopardy when an arbitrary price control scheme (i.e., TGP) is superimposed on the more objective world recognized economic appraisal guidelines."

A concise example of Gross's conclusion is where a new proton pump inhibitor would have to prove cost effectiveness against generic Cimetidine. Given the low price of Cimetidine, it will be hard to justify cost effectiveness to a level sufficient to make it economically worthwhile for a manufacturer to gain reimbursement of the PPI. The likely outcome is that the PPI will not be reimbursed because the subsidy offered by the government is too low, and the product will not be made widely available to the Australian community. Market access is effectively denied.

Intellectual Property Protection

The TGP system effectively negates the economic value of the entire remaining patent life of a patented medicine in the affected classes. This occurs through a combination of the way in which the proposal operates and the culture of the Australian health-care system. The system involves the grouping of newer patent-protected products with generic versions of older molecules within a therapeutic class (e.g. generic captopril is grouped with patented enalapril; generic Cimetidine is grouped with patented famotidine).

The benchmark product/price for each class is likely to be set by a generic product – in effect, this generic product becomes the *'de facto'* generic for all other patented products in the class, regardless of patent life. The government will reduce the level of reimbursement it currently provides to all products in the class to that of the benchmark product. The government claims that the TGP system allows manufacturers to charge whatever price they wish – a claim that is theoretically correct.

However, the PBS, which has operated for over 50 years, has created a climate *in which free medicine (apart from the co-payment to Government) is seen as the norm***.** Market experience has shown that consumers are unwilling to pay more than a A$2 premium for any medicine (in addition to any co-payment).

Given this environment, manufacturers have the choice of maintaining their current prices and losing substantial volume, or reducing their price and revenue. In either case, the economic return is substantially less than would otherwise have occurred in the absence of TGPs. The reduced return is sustained throughout the remaining life of any patent, devaluing the value of the intellectual property.

<u>Patent Term Length</u>

PhRMA considers it essential for an adequate patent life to be afforded to pharmaceuticals in Australia, as in the rest of the world. Many members of PhRMA's International Section maintain affiliates in Australia, and consider Australia an important country in their overall global business and investment planning. PhRMA welcomes recognition by the Australian Government of the importance of patent

protection to the pharmaceutical industry, particularly to encourage research, development and investment in Australia.

In 1998, the Australian Government enacted patent term extension for pharmaceuticals by up to five years, in order to bring Australia into line with international practice. The new policy applies to patents that were still viable as of July 1, 1999. The five-year extension makes possible an effective patent life of 15 years. Where patent extensions are granted, "spring boarding" or Bolar-type provisions will apply, so that generic manufacturers are able to do all necessary testing of their products before the expiration of the innovator's patent rights.

The Australian Government long has viewed any extension for *existing* patents as a "windfall" for the industry, as several companies could benefit from the immediate extension of the patent life for their products. It therefore made the commitment to offer generic firms a "spring boarding" benefit in exchange for the "benefit" to the research-based industry of patent term extension. However, the Australian Government overlooked at least two issues in this regard:

(1) that the market launch of pharmaceuticals in Australia is delayed by the complex and lengthy requirements in a strict cost containment environment, which includes the submission of "cost effectiveness" data; and

(2) that economic returns from currently marketed products in Australia provide the funding for future research and development (R&D), so patent term restoration applied to current products on the market in Australia will provide the foundation for investment to support future R&D in that country.

PhRMA does not agree with the necessity of maintaining a "spring boarding" provision that basically undercuts the current value of intellectual property protection in Australia, and certainly does not agree that a "spring boarding" provision is needed to "compensate" for the value of patent term restoration.

<u>Protection of Proprietary Data</u>

PhRMA applauds the recent enactment by the Australian Government of a law governing data protection that commits Australia to abide by the WTO TRIPS Agreement. PhRMA hopes that the Australian Government would provide protection for confidential data to all chemical entities, to the extent a particular use for which approval is sought has not been granted approval for that particular entity. This should include new indications for entities already approved, in addition to the first approved usage.

Furthermore, while the Australian Government has moved to provide five years of data protection for new chemical entities in the first instance, PhRMA believes that

this period of protection should be ***ten years from the date of marketing approval***, to allow for the additional time that it takes for a product to be listed on Australia's Pharmaceutical Benefits Scheme (PBS). If the period of data protection begins before this date, the effectiveness of such protection would be eroded through the lengthy time needed for listing approval.

Damage Estimate

PhRMA is currently studying methodology for estimating damages caused by the aforementioned trade barriers in Australia. Australia's cost containment policies, particularly the recent TGP initiative, are undermining the intellectual property rights of pharmaceutical manufacturers, by devaluing the value of patents and effectively denying market access to new medicines.

INDONESIA

The economic and political turbulence in Indonesia has continued into 2000 despite changes in the political arena under President Wahid. There seems to be little will to make the necessary adjustments to encourage investment, repatriation of funds or elimination of corruption in government and business circles. The currency began the year stronger at Rp7000 to U.S. dollar but weakened as the year progressed to Rp8500/U.S. dollar by August. The key issues affecting the U.S. research-based pharmaceutical industry more or less remain the same with some progress being made in certain areas, and so PhRMA requests that Indonesia be included in the 2001 "Special 301" Watch List.

Market Access Barriers

NCE and Pharmaceutical Product Registration

It has taken 21 months to persuade the Director General of POM Drs Sampoerno that a new, more efficient system of New Drug Registration was necessary. Following consistent pressure from the International Pharmaceutical Manufacturers Group (IPMG) and foreign embassies, a new system was announced in July 2000. It looks very similar to the one proposed by IPMG with cosmetic adjustments. However, three major issues are yet to be clarified and resolved:

1. The timetable of the approval process (Number of working days for completion).
2. The cost of the applications (NDA Tariff system).
3. The documentation required to determine the pathway. (Summary basis of approval/EPAR or Independent Assessment Reports.)

With approvals now taking over two years under the old system, it is hoped that this new process will be implemented before too long.

PhRMA also objects to the discrimination against imported products in the process of registration. In principle, the Indonesian FDA grants registration only to locally manufactured products. Import licenses can be obtained for the following 'categories': (i) life saving, (ii) cannot technically be produced locally, (iii) extremely low volumes, and (iv) export of locally manufactured product larger than imported volume. Licenses are issued for two-year periods after which extensions can be obtained but only after a full re-review of the case.

Many years ago, only companies that specifically invested in Indonesia in Manufacturing Units could hold product/marketing licenses and therefore be a "Market Company." No investment in manufacturing meant that the company concerned had to appoint a local or foreign licensee (who had a factory). Many companies still do this

today through a local distributor.

PhRMA believes that the Indonesian local manufacturing requirement may be a violation of the WTO. In general, the WTO (GATT Article III) flatly prohibits local manufacturing/local content requirements. This prohibition includes measures that condition import licenses or investment approvals on local manufacturing or local content plans/commitments.

Marketing Practices

During 2000, the official GP Farmasi Congress, held in Bali, approved the 1999 Code of Pharmaceutical Marketing Practices. It was, however, not made compulsory and therefore only IPMG members implemented it. The Ministry of Health (MoH) has been critical recently of the pharmaceutical industry, in general, for high prices and unethical business practices and they have requested the Director General POM to draft new regulations on these issues. IPMG is monitoring the situation carefully and will continue its dialogue with POM. We do not expect any dramatic improvement in business and marketing practices in the short-term.

Intellectual Property Protection

The new Patent Law amendment of 1999/2000 is presently before Parliament but is not expected to be approved in the immediate future. The modifications to the existing law are positive although there are sections that remain non-compliant with TRIPS. IPMG, however, now recommends that all research-based companies file for Product and Process patents for NCEs in Indonesia within one year of the country of origin/discovery application. IPMG is also working on proposals to modify the present amendment to make it more TRIPS compliant. Implementation of all IPR laws will remain the major hurdle for foreign companies operating in Indonesia.

The lack of protection of trade secrets remains an issue for the pharmaceutical industry and a glaring inconsistency with Indonesia's TRIPS obligations under Article 39.

Counterfeiting and Smuggling

These practices continue unabated and in fact have probably become more commonplace with the deterioration in the economic and political arenas in Indonesia. No quick fix seen in the near future.

Damage Estimate

PhRMA is currently studying methodology that may be used for estimating damages caused by the aforementioned trade barriers in Indonesia. Current estimates of losses suffered by U.S. companies are in the area of US$ 87 million.

SINGAPORE

In December 2000, the Pharmaceutical Research and Manufacturers of America (PhRMA) added its strong support to USTR's proposal to negotiate US-Singapore Free Trade Agreement. Singapore is a worthy candidate for a Free Trade Agreement (FTA) that will serve as a strong model for future U.S. FTAs in the Asia-Pacific region. PhRMA appreciates Singapore's strong commitment to drug discovery and development, open trade and investment policies, and market-based approaches to pharmaceutical pricing. As a result, PhRMA companies manufacture over $4 billion of innovative medicines in Singapore annually for sale in other Asian markets. Singapore has also emerged as one of the leading Asia-Pacific centers for advanced biotechnology research. U.S. pharmaceutical research firms have invested in world-class manufacturing and clinical research facilities in Singapore to supply Asian demand for innovative U.S. medicines.

Despite the need for certain additional improvements, PhRMA believes that Singapore's laws and regulations generally: (1) adhere to global scientific standards, (2) implement the WTO Agreement on Trade-Related Aspects of Intellectual Property

Protection of Test Data

Despite the obligations found in the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), Article 39.3, the Singapore Medicines Act (Section 19A) permits disclosure of confidential information submitted in support of an application for marketing approval. In addition, Singapore does not provide an adequate and effective term of protection and fails to extend protection to all approvals requiring such data. For example, the term of protection in Singapore commences the period of non-reliance on the date that the originator submits its marketing application rather than from the date that marketing approval is granted. PhRMA accordingly urges the U.S. Government to gain a commitment from Singapore on data protection at the TRIPS level prior to conclusion of the FTA.

Furthermore, the FTA itself should contain well-defined, specific obligations regarding protection of test data that will provide a level of protection in Singapore that is consistent with that found in the United States (as can be found in the U.S./Jordan FTA). Such obligations should (a) mandate protection for all situations where test data must be generated and submitted to obtain marketing approval, rather than only in situations involving approval of new chemical entities, and (b) impose a model of non-reliance on data for a minimum of five years from the approval date of the pioneer applicant in Singapore. If Singapore adopts an expedited approval structure that relies on approvals in other countries, the language of the FTA should extend this protection obligation to such expedited approvals.

National Exhaustion

Patents are national instruments, valid only within the sovereign territory of the nation that granted them, and exhausted only by acts that take place in that country. Article 66(2)(g) of the Singaporean law, however, provides that patents may be "exhausted" by acts performed outside Singapore. This practice is inconsistent with that found in the United States and most other countries, conflicts with standards in the TRIPS Agreement and the Paris Convention, and undermines the exclusive rights of patent holders in Singapore. Any trend towards so-called "international exhaustion" also renders impossible the current efforts of PhRMA members to increase access to essential medicines, including HIV/AIDS treatments, in developing countries. The United States should require Singapore to provide only for the possibility of national exhaustion under their patent system.

Compulsory Licensing

The compulsory licensing provisions in the Singaporean law generally conform to the model defined in the TRIPS Agreement, except in the following respects: The law continues to permit the grant of a compulsory license to sanction insufficient or "unreasonable" working of the patented invention. Compulsory licenses to sanction

inadequate working are unnecessary in the modern commercial environment. Accordingly, the FTA should restrict the possibility of imposing compulsory licenses to situations where such licenses are necessary to deal with a national emergency or are required to address antitrust violations of committed by the patent owner, as was the case in recently concluded US/Jordan FTA. We urge the United States to incorporate limitations in the FTA that would prohibit the granting of compulsory licenses other than in these two circumstances, and would ensure strict compliance with the provisions of the TRIPS Agreement.

Excessive Non-Commercial Public use Authority

PhRMA has highlighted the overly broad scope of the Singaporean government use authority in recent NTE and Special 301 submissions. This authority, which was amended in 1995, continues to permit the Government to use patented technology without the consent of the patent owner in an unacceptably broad manner. Specifically, Singaporean law permits the Government to use the patented invention for export to governments of other countries, and to sell products produced under this authority in the open market if the quantity produced exceeds the needs of the Singaporean Government. Neither of these grounds can be termed legitimate "government" use. We accordingly urge the United States to include provisions in the FTA that curtail the authority provided in the Singaporean law to situations required to enable the Singaporean Government to carry out a legitimate governmental functions.

Patent Term Restoration

Singapore provides no relief to patent owners who have the effective term of their patents reduced by regulatory or administrative delays. Thus, in Singapore, a delay before the marketing approval authorities or within the patent office that are unreasonable cannot give rise to a patent term restoration. The United States should require the Government of Singapore to grant an effective term of protection under patents in situations where such extensions are granted in the United States. In particular, we urge the United States to include provisions in the FTA that will obligate Singapore to grant extensions where there has been a delay before a regulatory authorities that require approval before marketing of products is permitted and in administrative delays that delay the granting of the patent. The obligation should apply to situations where the delay was encountered within the Singaporean authority, or, in cases where the relevant Singaporean authority relies on the approval or grant by an authority in another country, on the delays that occur before that other authority. This would, for example, justify the extension of a patent where there has been a substantial delay before the USPTO that causes a corresponding delay in the grant of a patent in Singapore.

Enforcement: Restrictive Requirements for Recovery of Damages

The Singaporean patent law restricts the ability of a patent owner to recover damages in circumstances where the infringer did not have specific notice of the infringement. The standard employed in the Singaporean law is unduly restrictive in comparison to practices followed in U.S. system and most other countries, and operates to unfairly reduce the liability of an infringer of the patent rights, in contradiction to Singapore's obligations under TRIPS Articles 42 et. seq. We urge the

generic name than the trademark or which remove rights for use of a trademark instead of a generic name for a pharmaceutical product.

Damage Estimate

PhRMA is not currently able to provide a reasonable damage estimate in Singapore at this time.

VIETNAM

PhRMA is pleased that Vietnam has accepted the basic principles of the World Trade Organization (WTO) in the recently concluded U.S.-Vietnam trade agreement. PhRMA hopes for additional transparency in the issuance and enforcement of regulations affecting its companies in Vietnam, national treatment for foreign pharmaceutical companies in Vietnam, the dismantling of tariff and non-tariff barriers to trade, and the elimination of protectionism in all its forms. PhRMA also hopes that an acceptable level of compliance with these principles can be achieved as soon as possible so that Vietnam can be granted U.S. Most-Favored-Nation (MFN) status and admission to the WTO at the earliest possible date. Given the remaining deficiencies in Vietnam's intellectual property regime and barriers to market access for patented pharmaceutical products, PhRMA asks that Vietnam be included in the 2001 "Special 301" Watch List.

Intellectual Property Protection

PhRMA applauds provisions in the new Vietnamese Civil Code and related implementing legislation that extend the term of protection for patents from 15 years to 20 years and provide temporary protection to patent owners during the examination process. PhRMA is also pleased that Vietnam has accepted obligations regarding its patent regime that are reflected in the TRIPS Agreement, and in some cases, exceed the obligations of the TRIPS Agreement.

PhRMA member companies in Vietnam, however, remain concerned about the lack of adequate patent protection in that country today, and are unclear as to the status of implementation of reforms in the patent system consistent with its new obligations under the U.S.-Vietnam trade agreement.

Compulsory Licensing

Under existing law, the National Office of Industrial Property (NOIP) may order a "compulsory license" i) if a patent is not used, or is inadequately used, during the period of protection, ii) if a prospective licensee has attempted to obtain a license for a patent, but the owner has refused "notwithstanding that a reasonable price has been offered", or iii) if the patent is needed for prevention and treatment of disease. Specifically, the legislation provides no guidance as to what constitutes adequate "use" of the patent or how "reasonable" compensation is to be determined, though PhRMA looks positively on the fact that patent owners will be permitted to rebut another party's request for a "compulsory license".

PhRMA believes that patent compulsory licensing systems are counter-productive except in cases of national emergency or other urgent circumstances.

Consequently, we believe that the current law should be amended to eliminate the existing grounds for granting non-voluntary licenses, and to include conditions provided in the U.S.-Vietnam Agreement and the WTO TRIPS Agreement. In particular, we believe that the second and third grounds are not likely to be consistent with these obligations, and should be deleted. The working requirement specified in the first paragraph should be scaled back significantly, if it is not eliminated.

In addition, the Vietnamese Government should include in their implementation package measures that specify that importation of a patented product (as opposed to manufacturing the patented product or Using the patented process in Vietnam) will be legally equivalent to manufacturing of 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. Such a change is necessary to render the Vietnamese law consistent with obligations of Articles 27 and 31 of the TRIPS Agreement (Articles 27 and 31). The reforms should also specify that licenses based on refusal to license voluntarily should only be issued in extraordinary circumstances. In addition, the patent law should be amended to require "compulsory licensees" to pay a level of compensation commensurate with the patent's market or "economic" value as provided in the TRIPS Agreement and the U.S.-Vietnam trade agreement, and should meet other conditions required for compulsory licensing outlined in Article 31. This will encourage the transfer of patented technology to Vietnam.

Trademark Infringement

Although the new Civil Code and associated implementing legislation provide a clear legal basis for protecting registered industrial property rights in Vietnam, infringement of registered trademarks is systematic and widespread in Vietnam, causing substantial financial losses to members of PhRMA. State-owned pharmaceutical companies under the jurisdiction of the Ministry of Health (MoH), and manufacturers and distributors from foreign countries figure prominently in infringement of the registered trademarks of PhRMA member companies. The substandard quality of some of these imported infringing products adds a public health dimension to the consumer confusion generated by the acts of infringement. Trademark infringement is also one of the deterrents to investment and technology transfer in the production of pharmaceuticals in Vietnam.

Inadequate Enforcement

In the absence of a legal basis supporting a formal administrative mechanism for enforcing registered intellectual property rights, a mechanism has evolved in practice to

enforcing NOIP decisions through the *de facto* administrative mechanism for the following reasons:

- State-owned manufacturers and importers of pharmaceutical products sometimes refuse to comply with the NOIP decisions on the ground that they are subject to the regulatory authority of the MoH only, not the NOIP;

- The administrative enforcement bodies, specifically the Market Management Bureau and the Economic Police, sometimes say they are confused over whether the NOIP has authority to issue instructions to pharmaceutical companies that are primarily regulated by the MoH;

- The administrative enforcement bodies are influenced by the local authorities who claim they have the authority to make an independent decision as to whether an infringement has actually occurred; and

- The MoH does not cooperate closely with the NOIP to resolve cases of trademark infringement by pharmaceutical companies. (In a few cases, the MoH has acted in unison with the NOIP by following up NOIP decisions of infringement with letters of its own instructing the infringing company to change the name of its product. However, this is not being done in all cases and even when there is such follow-up, little is done to compel recalcitrant infringers to comply with the MoH directive).

PhRMA believes that Vietnam is obliged by its acceptance of intellectual property enforcement obligations under the U.S.-Vietnam trade agreement to change its enforcement environment to remove these deficiencies. In particular, PhRMA believes Vietnam must make changes to its legislation governing enforcement of intellectual property rights to comply with its new obligations. In addition PhRMA requests that the U.S. Trade Representative seek a confirmation from Vietnam that it will issue new guidance, pursuant to Article 65 of Decree No. 63/CP *of the Government providing Detailed Regulations and Guidelines for Implementing the Civil Code Provisions on Industrial Property* dated 24 October 1996 which stipulates that i) all companies operating in Vietnam, including local and foreign manufacturers and distributors of pharmaceutical products, are required to comply with NOIP's decisions concerning infringement of industrial property and ii) the administrative enforcement bodies are required to comply with NOIP decisions irrespective of the opinion of local authorities.

PhRMA also believes that the MoH and NOIP should coordinate more closely to resolve infringement problems in respect of pharmaceutical trademarks, at least until it is made clear that infringers and local enforcement bodies must comply with NOIP instructions. PhRMA welcomes *Decision No. 1203/BYT/QD of the Ministry of Health Promulgating Regulations on Medicine Registration* to the extent it requires local and

foreign pharmaceutical companies, before registering their products, to present a verification from the NOIP that the name of the product does not infringe the registered trademark of another company. It is hoped that this portends closer cooperation between the MoH and NOIP on this important issue.

Insufficient Protection for Product Trade Dress

Vietnam is obligated under the U.S.-Vietnam trade agreement to eliminate 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 such product "trade dress". Vietnam must amend its legislation to provide protection for both foreign and local companies from this type of unfair competition. It is hoped Article 9 of the new Commercial Law will provide a basis for legal action against companies that attempt to deceive consumers by imitating the unregistered trade dress of another company's products.

Market Access Barriers

Vietnam's National Drug Policy

On 20 June 1996, the Vietnamese Government announced a National Drug Policy in conjunction with *Decree No. 37/CP on the Strategic Orientation for the Care and Protection of the People's Health.* PhRMA believes that several fundamental aspects of Vietnam's National Drug Policy should be reconsidered in light of WTO standards. These include:

- moves toward reinforcing centralized management of the production and distribution of pharmaceutical products which fetter competition and reduce efficiencies, resulting in higher costs for Vietnamese consumers;

- a pronounced trend toward protectionism in favor of locally-manufactured pharmaceutical products with the apparent goal of replacing imports of a large number of foreign pharmaceutical products; and

- restrictions on the forms in which foreign pharmaceutical companies may invest and do business in Vietnam, which impede the transfer of technology.

These general features of Vietnam's National Drug Policy have given rise to a number of specific problems for foreign pharmaceutical companies that are addressed as follows:

Restrictions on the Import and Distribution of Products

PhRMA member company affiliates are not permitted to freely import and distribute their products in Vietnam. According to *Decision No. 1523/BYT/QD of the Ministry of Health on Permitting Foreign Companies to Engage in the Trading of Medicines and Medicinal Raw Materials for Humans in Vietnam* dated September 9, 1996, foreign pharmaceutical companies are permitted to import and trade in their products only on the basis of contractual relationships with designated Vietnamese companies authorized to engage in the import and export of pharmaceuticals and pharmaceutical raw materials. This inefficient and anti-competitive practice of preserving state control over pharmaceutical distribution in Vietnam ultimately leads to higher costs to Vietnamese consumers. It also forces foreign pharmaceutical

PhRMA requests that the U.S. Trade Representative seek the gradual elimination of all import quotas so that the market may determine the amount of pharmaceutical products that are imported into Vietnam. During the transitional period, the criteria for establishing quotas should be transparent.

Product Registration

PhRMA considers *Decision No. 1203/BYT/QD of the Ministry of Health Promulgating Regulations on Medicine Registration,* which took effect on August 1996, a positive step insofar as it i) stipulates specific and clear procedures for registering pharmaceuticals and ii) contains a welcome requirement that the MoH and Ministry of Science, Technology and the Environment ("MoSTE") cooperate in protecting the registered trademarks of Vietnamese and foreign pharmaceutical companies. However, the product registration regime should be reviewed in respect of the following issues:

Inconsistencies in Duration of Product Visas

In most countries, registrations for pharmaceutical products are valid for 5 years. This was the case in Vietnam until 1996, when the MoH began issuing product visas with validity periods of as short as one year. PhRMA is concerned that this reflects an intent on the part of MoH to require certain products to be re-registered annually after considering whether to deny re-registration altogether. This is cumbersome to companies that must prepare applications annually and to the MoH that must review them.

Discriminatory Enforcement of Product Registration Requirements

At the same time the MoH is issuing more stringent product registration requirements, state-owned importers of pharmaceutical products under the jurisdiction of the MoH continue to import and/or distribute products from companies that have not registered their products. This discriminates against foreign pharmaceutical companies that go to the trouble and expense of registering their products in accordance with applicable regulations. Many of the unregistered pharmaceutical products also infringe the registered trademark rights of others or violate applicable quotas.

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. Accordingly, PhRMA requests that the U.S. Trade Representative seek the following remedial measures with regard to the foregoing aspects of the registration process:

- limit paperwork to only what is necessary to achieve the legitimate objectives of registration;

- repeal the list of pharmaceutical products that are currently banned from registration and re-registration, and issue product visas with five-year validity

periods for all pharmaceutical products; and

- issue and enforce regulations strictly prohibiting the import of unregistered pharmaceutical products.

Requirements Concerning Shelf Life of Imported Raw Materials:

Under *Official Dispatch No. 5410/VD* dated 6 June 1996, Vietnamese importers of pharmaceutical raw materials with a shelf life of less than three years must obtain special approval from the MoH to import such raw materials. This restriction is unnecessary, as the shelf life of pharmaceutical raw materials has nothing to do with quality. The uncertainty associated with having to request approval each time they want to import quality raw materials affects production efficiencies of Vietnamese manufacturers and imposes further unnecessary strains on the efficient use of their limited capital resources.

It also pressures Vietnamese manufacturers to turn to disreputable suppliers who are circumventing this restriction by affixing labels to packaging which either lack a date of manufacture and "expiry date", or which contain fictitious expiry dates or dates of manufacture on the container. Such false labeling practices threaten the health of the Vietnamese population.

PhRMA requests that the U.S. Trade Representative seek the repeal of Official Dispatch No. 5410/VD. It should be replaced, if necessary, with a rule that requires pharmaceutical raw materials to be imported within six (6) months before the date of expiration of their shelf lives. Confiscation, fines and other penalties should be imposed on companies that place labels or product packaging that fail to list or falsely list the shelf-life of the product based on scientific criteria.

Requirement that Raw Materials Be Imported Within Six Months of Manufacture:

In addition to the aforementioned shelf-life requirement, *Official Dispatch No 5410* requires that all pharmaceutical raw materials be imported into Vietnam within six (6) months of the date of manufacture. This requirement, which lacks scientific justification, discriminates 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 in order to keep unit costs down. This also results in inefficiencies in the production and delivery of pharmaceuticals that in turn raise the cost of such products for Vietnamese consumers.

PhRMA requests that the U.S. Trade Representative seek extension of 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 lives.

Requirement that Clinical Trials of Vaccines Be Conducted in Vietnam:

Under *Decision No. 2010/BYT/QD of the Ministry of Health Promulgating the Regulations on Registration of Vaccines and Immunization Products* dated October 28, 1996, foreign manufacturers of vaccines are now required to conduct clinical trials in Vietnam before being permitted to register their vaccines for sale in Vietnam. This is unnecessary, as most international pharmaceutical companies that develop and manufacture vaccines will have already carried out safety and efficacy trials in accordance with the very stringent rules and rigorous protocols required by the U.S. Food and Drug Administration and/or other regulatory agencies before introducing their vaccines to Vietnam. Further, resources currently available in Vietnam would need to be upgraded significantly before clinical vaccine trials can be carried out in a manner that would achieve reliable results.

PhRMA requests that the U.S. Trade Representative seek agreement from Vietnam that foreign research-based vaccine manufacturers that conduct clinical trials outside of Vietnam in accordance with FDA or other high standards be exempt from the requirement that vaccine trials be conducted in Vietnam. Increased availability of high quality non-plasma based vaccines will help Vietnam reduce the high social cost of serious preventable diseases, including chronic Hepatitis B.

Ban on Toll Manufacturing

Toll manufacturing or "third party manufacturing" arrangements between foreign pharmaceutical companies and local Vietnamese companies were previously permitted under *Decision No. 106/BYT of the Ministry of Health Promulgating Regulations on the Processing of Medicine for Disease Prevention and Treatment of Humans* dated 30 January 1991 ("Decision No. 106"). However, MoH *Decision No. 1824* dated 11 November 1996 ("Decision No. 1824") repealed Decision No. 106, thus prohibiting this option for foreign pharmaceutical companies.

PhRMA requests that USTR ask Vietnam to repeal Decision No. 1824 or issue new legislation authorizing foreign pharmaceutical companies to enter into toll manufacturing arrangements with local manufacturers (including foreign-invested enterprises). Toll Manufacturing arrangements are the beginning of the process by which know-how and GMP standards are transferred and therefore should be encouraged by the Vietnamese Government.

Discriminatory Tariffs

Currently, some pharmaceutical products are subject to tariffs, while others are not. Different tariffs are applied in different provinces for the same product on arbitrary grounds. The tariff rate is often not known until the products are imported. Such

subjective and protectionist criteria conflict with the principles of the WTO and regional trade organizations and protocols, including some to which Vietnam belongs.

PhRMA requests that USTR ask Vietnam to reduce tariffs on foreign pharmaceutical products with a view to ultimately eliminating such tariffs in accordance with the Zero-For-Zero Tariff Agreement. As long as there are tariffs, the process by which they are determined should be transparent and tariffs should be applied consistently nationwide.

National Treatment for PhRMA Companies:

PhRMA member company affiliates, like other foreign companies in Vietnam, are required to pay higher rates for water, electricity, domestic airline tickets, hotel room, commercial office space, advertising space and other services than are Vietnamese companies. Such discriminatory treatment, which is at odds with the "national treatment" principles of the WTO, raises the already very high cost of doing business in Vietnam and thus is an additional deterrent to foreign investment and technology transfer.

PhRMA requests that USTR work to ensure that Vietnam require foreign companies to pay the same rates as Vietnamese companies for services and products in Vietnam.

Damage Estimate

PhRMA is currently studying methodology for estimating damages caused by the aforementioned trade barriers in Vietnam.

EUROPE

BULGARIA

Since 1992, Bulgarian Patent Law has made product protection available. In addition, a Bulgarian/U.S. bilateral treaty provides for a reasonable pipeline protection for those products with a qualifying patent protection in the U.S. However, in several respects, the level of Bulgarian IP protection falls short of TRIPS requirements:

In particular, Bulgaria has not introduced data exclusivity as required by to TRIPS Article 39(3). Further, medicines which do not qualify for pipeline protection under the Bulgarian/U.S. bilateral treaty, but for which product patents were granted in the U.S. and the EU before 1992, and which are enjoying protection there up to 2012, are and will remain unprotected in Bulgaria for their entire lifetime. In addition, market access barriers for pharmaceutical products in Bulgaria continue. For these reasons, PhRMA requests that Bulgaria be placed on the 2001 "Special 301" Watch List.

Intellectual Property Protection

Data Exclusivity

TRIPS Article 39.3 requires WTO Members to protect against "unfair commercial use" of undisclosed test data and other confidential protected data submitted to governments as a condition for obtaining marketing approval of pharmaceutical products utilizing new chemical entities. In most industrialized countries, a special legal regime provides that no person may, without the permission of the person who generated and originally submitted the costly and confidential data, rely on such undisclosed and proprietary test data in support of an application for product approval, not only while the originator's marketing application is pending before the regulatory authorities, but also for a specified period from the marketing approval date of the original product. However, current Bulgarian law contains no restrictions on its regulatory agency with regard to reliance on the original filing data for any specific time period.

Compulsory Licenses

Current Bulgarian patent law does not explicitly recognize the importation of a patented product as meeting the "working the patent" requirements contained in the law. As such, Bulgarian law should be amended to guard against the granting of a compulsory license when patented products have been imported. Local manufacture should not be necessary to satisfy the working requirement.

Experimental use Exemptions – "Bolar" provisions

Bulgarian law should explicitly prohibit the experimental use by second

applicants of patented products during their patent term for the purpose of preparing a registration file.

Other shortcomings of the Bulgarian Patent Law

- Contributory infringement: The Bulgarian patent law does not explicitly provide for relief against contributory infringements such as supplying third parties, domestic or foreign, with intermediary products used in the synthesis of a protected substance.

- Protection against threatened infringement: Bulgarian law does not specify that preliminary injunctions are available against threatened infringements as required by TRIPS (Article 41 (1)).

- Protection against equivalents: Bulgarian law does not explicitly prohibit the imitation of patents although the imitation of a protected invention in the way of equivalents is the most common form of infringement.

Enforcement

The practice of patent rights enforcement in Bulgaria is lacking, in particular with regard to rapidly obtainable interlocutory injunctions. Effective action, expeditious remedies to prevent infringement, and remedies that constitute a deterrent to further infringements are not available. Corrective action should include, for the short term, effective application of procedures already available under Bulgarian law, and, for the medium term, upgrading of these procedures to EU and U.S. levels.

Market Access Barriers

Pricing and Reimbursement

Bulgarian pricing and reimbursement decisions are not made based on objective and verifiable criteria as required by WTO principles. Such criteria are neither contained in the legislation nor are they practiced by the authorities. In addition, no appeal procedures for Government pricing and reimbursement decisions are provided for in Bulgarian law.

Product Registration

According to public statements of the Drug Institute, the Institute engages in the preparation of product registration files for local companies implying the use of the originators' dossiers. This lack of confidentiality is incompatible with TRIPS and discriminates against foreign companies.

Bulgaria still requires a batch control for each individually imported batch and does not allow for an inspection of the foreign production site instead.

Damage Estimate

Preliminary indications are that consolidated losses for U.S. pharmaceutical companies operating in Bulgaria are in the US$ 20 -25 million range.

CZECH REPUBLIC

Due to inadequacies in the Czech Republic's intellectual property legislative and enforcement regime, as well as WTO-inconsistent market access barriers for patented pharmaceutical products, PhRMA requests that the Czech Republic be included in the 2001 "Special 301" Watch list.

Intellectual Property Protection

The Czech Republic has made significant steps forward towards ensuring that its intellectual property regime is TRIPS compliant. In April 2000 the Czech Parliament endorsed an amendment to the Patent Law allowing Supplementary Protection Certificates and has rejected a proposed amendment allowing experimental use (Bolar principle).

Pipeline Protection

The Czech Patent Act of 1991 introducing product patent protection was the first of its kind in the Central and Eastern Europe countries. Paragraph 82 of the Patent Act also enabled pipeline protection. However, this was for a very limited time period only. As a consequence, the first patent-protected pharmaceutical products will start to appear on the Czech market between 1999 and 2001. Furthermore, pharmaceutical products which were granted product patents in the U.S. and the EU before 1991, and which are enjoying protection there up to 2011 are and will remain unprotected in the Czech Republic for their entire lifetime. Since 1991, 165 submissions have been made for pipeline protection, of which only 16 have been approved by the Patent Office.

While pipeline protection is not required under the WTO TRIPS Agreement, under the EU Association Agreement, the Czech Republic has promised to achieve a level of protection similar to that in the EU, including appropriate means of enforcement. In addition, the absence of pipeline protection in the Czech Republic has contributed to a situation where there is little effective protection for patented pharmaceutical products. PhRMA believes, therefore, that the Czech Republic should be held to this commitment.

Compulsory Licensing Amendments

The Czech Parliament recently amended its legislation with respect to compulsory licensing in order to bring it into conformity with the TRIPS agreement. The Patent Law has been adapted so as to explicitly consider the importation of a patented product as "working the product" and to consequently exclude the granting of a compulsory license for it.

Enforcement of Patents

The practice of patent rights enforcement in the Czech Republic is sadly lacking. The only mechanism for challenging patent violators is via lengthy and costly court proceedings. Intellectual property proceedings are often delayed for as much as three years. There is an urgent need for granting timely temporary injunctions in cases of suspected patent right infringements and for improving civil procedural rules, as required under the TRIPS Agreement (TRIPS Article 50 requires effective provisional measures). The Czech patent enforcement system does not permit effective actions against patent infringements as required under TRIPS Article 41. In the past, Czech courts have refused to consider an infringement action because the defendant did not have sufficient assets in the Czech Republic, even though the defendant sold the allegedly infringing product into the territory of the Czech Republic. In addition, under Czech law, either the court or the patent office can order the reversal of the burden of proof. However, the Czech courts have left requests for reversal of burden of proof unanswered and the patent office has denied its competence to reverse the burden of proof, resulting in a *de facto* denial of the reversal, in violation of TRIPS Article 43.

Current damages for intellectual property rights violations are not adequate to compensate for the injury the right holder has suffered because of an infringement of his intellectual property right. In addition, it is rare that the infringer is ordered to pay the right holder expenses associated with the defense of the right holder's intellectual property right, or ordered to recover profits. This is not in compliance with TRIPS Article 45.

Market Access Barriers

Marketing Authorization

The Medicines Act guarantees a final decision within 18 months for the registration for product submissions. The Amendment to the Medicines Act (April 2000) will reduce the registration time to 210 days. Since January, 1998 the State Institute for Drug Control (SUKL) began recognizing EU centralized procedures insuring a maximum of 4 months for the approval of marketing authorization. While PhRMA looks forward to the improved processing of marketing authorization applications, member companies operating in the Czech Republic still face registration delays for filings made before 1998, with older registrations often taking 3-5 years. In addition under legislation passed last year, generic products often receive a fast track registration, especially if the product is the first generic version of an innovative product.

Market Pricing

All pharmaceutical products registered for commercial purposes in the Czech Republic are subject to price regulation, but this price regulation is not applied in a transparent, non-discriminatory manner as required by WTO principles. Different criteria are applied for maximum pricing for domestic products versus imported R&D products. Moreover, the non-transparent criteria leave much room for misinterpretation by the Ministry of Finance. Additionally there are no firm rules in place for appeal of the process.

Reimbursement

The Czech Healthcare insurance reimbursement system also lacks objective and verifiable criteria for the inclusion and setting of reimbursement limits. The Categorization Committee, which reviews pharmaceutical products for reimbursement, generally sets price limits at the price of the least expensive drug in a specific ATC category with no consideration of the innovative/differential nature of a given product. There is no transparent and reliable process for appeal of reimbursement decisions despite ongoing appeals to the Ministry of Health.

Conflicts of Interest

Although members of the Drug Categorization Committee of the Ministry of Health (which determines which categories of medicines are eligible for reimbursement) are required to inform the Chair of the Committee of potential conflicts of interest, no such statements have been found in the minutes of the Committee. However, at least two members of the categorization committee are involved as members of the board, or supervisory board, either in a pharmaceutical company or in a wholesaler that is owned by a pharmaceutical company.

Damage Estimate

PhRMA is currently studying methodology for estimating damages caused by the aforementioned trade barriers in the Czech Republic. Preliminary indications are that consolidated losses for U.S. pharmaceutical companies operating in the Czech Republic are in the US$ 15-20 million range. However, on a *prima facie* basis, the Czech Republic has an inadequate patent enforcement regime. In addition, transparency with respect to the pricing and reimbursement of pharmaceutical products must be improved.

ESTONIA

Estonian Patent Law is not consistent with its TRIPS obligations in the area of data exclusivity, among others, and threatens the adequacy and effectiveness of Estonian industrial property protection for patented pharmaceutical products. Accordingly, PhRMA requests that Estonia be placed on the 2001 "Special 301" Watch List.

Intellectual Property Protection

The Estonian patent law took effect in 1994, at which time product patent protection for pharmaceutical products became available. Since the law does not provide for pipeline protection, pharmaceutical products will benefit from the law approximately in the year 2002-2006. Products launched prior to that are subject to insufficient protection, and exposed to being copied for their entire corresponding patent life in the EU. The proposal of the EU to build a specific mechanism for derogation of free movement of goods after Estonia's accession to the EU for all products with lower IP protection in Estonia than in the other EU members is necessary and welcome. "Pipeline" protection for marketed pharmaceutical products in Estonia is needed.

Industry welcomes Estonia's implementation of Supplementary Protection Certificate (SPC) that includes all products with a valid patent at the time of implementation of the Estonian SPC (i.e. also for those products for which the regular six-month period after the marketing authorization has expired by the time when Estonia enacted SPC).

<u>Data Exclusivity – Confidentiality</u>

As it takes 10 to 12 years to bring a new medicine to the market, the benefits of the 1994 patent act will not be felt before 2006. Until then, data exclusivity is the only type of protection that may prevent early copying.

Although the protection of undisclosed information is regulated by the Competition Act, which prohibits the misuse of confidential information, there is no provision in Estonian law corresponding directly to Estonia's WTO TRIPS obligations in the area of data exclusivity. Current Estonian Patent law does not include any provisions meeting the requirements of Article 39.3 of WTO-TRIPS on the use of a previous applicant's documents, and, in particular, does not provide that, in order to refer to documents submitted by a previous applicant, the second applicant has to obtain the consent of the previous applicant. There is therefore a high probability that health authorities in Estonia may provide marketing approval to a product relying on confidential test data of another patented product without approval of the right holder.

According to recent reports, data exclusivity should become available in Estonia as of February 2001, but no confirmation has yet been seen.

Damage Estimate

PhRMA is not able at this time to provide any reliable estimates of the damage caused in Estonia due to the aforementioned trade barriers.

LITHUANIA

PhRMA requests that Lithuania be included in the 2001 "Special 301" Watch List for failure to meet its bilateral obligation to provide transitional product patent protection for U.S. pharmaceutical products, and the absence of data protection.

Intellectual Property Protection

Lithuania's patent law took effect on February 1, 1994, and product patent protection for pharmaceutical products became available. The Agreement between the United States and Lithuania on Trade Relations and Intellectual Property Rights Protection was signed on April 26, 1994. According to Article VII, paragraph 5, a contracting party shall provide a transitional protection for pharmaceutical products for which product patents were not available prior to February 1, 1994, if the following conditions are satisfied:

- the U.S. patent has been issued for the product based on application filed 12 months or more before February 1, 1994, but not before February 1, 1984,
- the product has not been marketed in the territory of the Contracting Party providing such transitional protection.

However the Lithuanian government did not ratify this Agreement because of strong opposition of local pharmaceutical companies. Consequently, the products that could qualify for "pipeline" protection have now lost this benefit and now must compete against pirate copies. "Pipeline" protection for marketed pharmaceutical products in Lithuania is needed.

Data Exclusivity – Confidentiality

As it takes 10 to 12 years to bring a new medicine to the market, the benefits of the 1994 patent act will not be felt before 2006 because its "pipeline" provisions are ineffective. Until then, data exclusivity is the only type of protection that may prevent early copying.

However, current Lithuanian law does not include any provisions meeting the requirements of Article 39.3 of WTO-TRIPS on the use of a previous applicant's documents, and, in particular, does not provide that, in order to refer to documents submitted by a previous applicant, the second applicant has to obtain the consent of the previous applicant. The existence of many copy products on the Lithuanian market permits the conclusion that the Lithuanian health authorities provide marketing approval to a product relying on the confidential test data of the original products without approval of the right holder.

Damage Estimate

PhRMA is not able at this time to provide any reliable estimates of the increase in our industry's sales that would accompany the removal of the aforementioned trade barriers.

RUSSIA

The Russian Patent Law passed in 1995 considerably improved the situation regarding the defense of intellectual property, including the protection of patents for pharmaceutical products. Companies with new product patents are able to register their patents in Russia and receive full protection. The Government of Russia has also made substantial efforts to improve legislative and enforcement provisions for intellectual property protection towards its prospective WTO TRIPS obligations, despite difficult political and economic conditions. PhRMA requests that Russia be placed on the 2001 "Special 301" Watch list.

Intellectual Property Protection

PhRMA appreciates the previous efforts undertaken under the auspices of the US/Russian bilateral technical cooperation program, which has facilitated discussion of needed legislative and enforcement reforms, and law enforcement training for judges, prosecutors and investigators. Although problems remain in Russian administration and adjudication of patent disputes or violations of registered patents, we recognize that significant progress has been made. PhRMA has learned of two cases in which PhRMA member firms won patent infringement cases in the federal Commercial Court for Moscow and the Moscow Region, in one case for a patented product and in the second for a process patent. Given previous uncertainty in the process patent area, we hope that the most recent case in which the Commercial Court establishes legal protection for process patents will serve as useful precedent. Certainly the courts are gaining in experience in this area, but the degree of protection is dependent on the detail of each specific process patent.

In addition, the Russian Federation Law "On Competition and Restriction of Monopolistic Activities on Commodities Markets", which was enacted in 1991, as amended, enables the Russian Federation Ministry for Anti –Monopoly Policy and Support of Enterprise (MAP) to exercise control over unfair competition activities involving sale of goods and services with illegal use of intellectual property. Within the past two or three years, an increasing number of companies which have suffered from unfair competition practices in the form of unauthorized use of their intellectual property (patent and trademark infringement, the latter becoming an increasing problem in Russia for the pharmaceutical sector) have initiate proceedings before MAP. In many cases, these proceedings resulted in MAP decisions on prevention of illegal use of intellectual property. These decision have a mandatory nature, and are often no less legally effective than those of the Russian courts.

Given the progress noted, we do remain very concerned by the possibility that the Government of Russia may adopt detailed provisions on intellectual property as part of the ongoing work on the Civil Code Part III, which would preempt current patent

and enforcement provisions in Russian law and cause confusion for right holders and Russian law enforcement and judicial officers.

Data Exclusivity -- Confidentiality

The new Russian Civil Code, which was passed in 1997, contains language that appears to meet the requirements of Article 39.3 of the GATT-TRIPS. Article 139 of the Civil Code provides for serious penalties if commercial secrecy and confidentiality is violated. Further, the Patent Law provides protection for patents of new molecules and so far PhRMA members have experienced no problems in this regard.

Weak Enforcement of Existing Patent Rights

Effective action, expeditious remedies to prevent infringement, and remedies that constitute a deterrent to further infringements are not available. This is evidenced by the delay of intellectual property proceedings for as much as five years. This is not in compliance with TRIPS Article 41.

In addition, current damages for intellectual property rights violations are not adequate to compensate for the injury the right holder has suffered because of an infringement of his intellectual property right. It is also rare that the infringer is ordered to pay the right holder expenses associated with the defense of the right holder's intellectual property right, or ordered to recover profits. This is not in compliance with TRIPS Article 45.

Market Access Barriers

There is a lack of objective and verifiable criteria by which products are included on reimbursement lists. Lists and state purchases are conducted with virtually no transparency and little open or verifiable concern for the interests of quality and safety.

Efforts to improve this situation have been taken with the enactment in May 1999, of the Russian Federation Law "On Tenders for Allocation of Orders for Supply of Goods, Works, Services for State Needs". While this law substantially has clarified the procedures for conducting state purchases, it contains a discriminatory provision according to which foreign suppliers of goods may participate in tenders "only if the production of the corresponding goods is absent or economically unreasonable in the Russian Federation". One way around this restriction has been for foreign pharmaceutical companies to use Russian companies to participate in tenders. These companies then, if successful, purchase the relevant pharmaceuticals from the foreign supplier. However, it is still arguable whether this will remain a viable solution, especially in light of the recently declared increase of sales of domestic medicines by 46.9% during the period January through September 2000.

Corruption

In the 2000 Corruption Perceptions Index by Transparency International, out of the 90 countries surveyed, Russia ranked 82nd for its high levels of corruption. PhRMA supports efforts to rationalize regulatory codes, reduce multiplicity of licensing, and reduce the discretionary authority of officials. However, the political will to enforce new legislative changes is weak, and the current government's will to quicken the pace of reforms to join the WTO may be undermined by corruption and bureaucracy, which may affect how these reforms are implemented. In addition, widespread corruption of state inspection agencies has been identified as one of the primary barriers to Russia's economic development.

Damage Estimate

PhRMA is unable at this time to provide any reliable estimates of the increase in our industry's sales that would accompany the removal of the aforementioned trade barriers.

SLOVAK REPUBLIC

The Slovak Republic's industrial protection regime fails to meet its WTO TRIPS obligations, and PhRMA member companies continue to face substantial market access barriers for patented products. For these reasons, PhRMA requests that the Slovak Republic be placed on the 2001 "Special 301" Watch List.

Intellectual Property Protection

Lack of Pipeline Protection

Product patent protection law became available in 1991. However, the law provided for very limited pipeline protection. Because patent applications must be filed very early in the research and development process, and given the possibly 8 - 12 years necessary to develop a new pharmaceutical product, the majority of currently marketed pharmaceutical products in Slovakia and those that will be launched in the next few years will not be protected at all, or will be protected only by a process patent exposed to easy copying. In the absence of appropriate pipeline protection, all innovative products on the Slovak market will not be protected at the same level as the same patented products are today in the U.S. and most of the EU until 20 years from the 1991 patent law, i.e. not until 2011. Although pipeline protection is not a TRIPS obligation, the absence of it in Slovakia has contributed to a situation where there is little effective protection for patented pharmaceutical products.

Term of Protection

A further discrepancy of patent protection between Slovakia on the one hand and the U.S. / EU on the other hand, results from the fact that Slovakia has not extended the 15 year patent life of the process patents under its old law to the international standard of 20 years. Consequently, the process patents for a number of in-line products have already expired in Slovakia while they are still under product patent in U.S. and the EU.

Data Exclusivity

The Slovak Medicine Act passed by the Parliament on February 10, 2000 provides for 6 years of data exclusivity. However, the Slovak provisions allow the 6 years data exclusivity period to be counted from the first marketing authorization in any EU country, despite the fact that the first EU marketing authorizations are regularly granted sooner than the Slovak authorization. There are many examples of products being registered in Slovakia only after a delay of three or more years after the first registration in an EU country. Consequently, by this provision, the data exclusivity right is in fact granted for a much shorter period, and in cases where the product is

registered in any EU country 6 years earlier than in Slovakia, there is no data exclusivity protection at all. The Ministry of Health refuse to amend or modify the respective provisions on data exclusivity in the Medicine Act.

As a result, the Slovak system still exposes highly sensitive and costly registration data to unfair commercial use by copy producers, although Slovakia should have implemented a system that safeguards against the unfair commercial use of such data as required by TRIPS Article 39.3 by the compliance deadline of January 1, 2000. Given the absence of product protection for many products on the market today and some years to come, the lack of effective data exclusivity is particularly damaging to the manufacturers of innovative products.

Comments on TRIPS incompatibility submitted to the Ministry of Health and to the Parliamentary Healthcare Committee have been refused with the explanation that the provision provides a justified and legitimate *protection for domestic industry*. However, any governmental measure that may discriminate against foreign products from other WTO members creates an additional conflict with the GATT Article III.

Furthermore, toxicological and clinical data filed for product registration with the Slovak regulatory authorities are archived in the facilities of the largest Slovakian pharmaceutical company, Slovakopharma, which controls 60% of domestic pharmaceutical production. Substandard intellectual property protection, coupled with the conflict of interest situation described above and the storage of files in the local producer's archives seriously damages the manufacturers of innovative products.

Other remaining issues include:

Protection against threatened infringement: Slovak law does not specify that preliminary injunctions are available against threatened infringements as required by TRIPS (Article 41.1).

Protection against equivalents: Slovak law does not explicitly prohibit the imitation of patents although the imitation of a protected invention in the way of equivalents is the most common form of infringement.

Contributory infringement: The Slovak patent law does not explicitly provide for relief against contributory infringements such as supplying third parties, domestic or foreign, with intermediary products used in the synthesis of a protected substance.

Despite the required TRIPS compliance deadline of January 1, 2000 there are indications that the Patent Law amendment with implemented TRIPS provisions will not be prepared and passed by the Slovak Parliament before the next general elections (autumn 2002). This would mean another TRIPS compliance delay of several years.

Weak Enforcement of Existing Patent Rights

Effective action, expeditious remedies to prevent infringement, and remedies that constitute a deterrent to further infringements are not available. This is evidenced by the delay of intellectual property proceedings for as much as three years. This is not in compliance with TRIPS Article 41.

In addition, current damages for intellectual property rights violations are not adequate to compensate for the injury the right holder has suffered because of an infringement of his intellectual property right by an infringer. It is also rare that the infringer is ordered to pay the right holder expenses associated with the defense of the right holder's intellectual property right, or ordered to recover profits. This is not in compliance with TRIPS Article 45.

Barriers to Market Access

Debt Execution Law Discriminates Against Foreign Companies

By Debt Execution Law Nr.280/1999 from October 1999, all debt created in the healthcare sector has been excluded from the legal procedure of execution. As a result, the creditors, foreign and local pharmaceutical companies included, have effectively been singled out for discriminatory treatment. Access to a legal procedure allowing collection of outstanding receivables is being denied to a narrow group of companies active on the Slovak market. The Slovak Constitutional Court has decided that provisions excluding debts created in healthcare from the legal procedure of execution are in conflict with the Slovak Constitution. However, no signs of repeal or modification of the discriminatory provisions have been given by the Government yet.

Product Registration Procedures

The requirements and practices for product registration in Slovakia lack transparency and discriminate against imported products.

Discriminatory Delays Against Foreign Products

Several foreign companies have been waiting for product registration for more than two years, while there are strong indications that local companies obtained marketing authorization in a number of cases the day of submission of a bio-equivalency study. The Ministry of Health has been conducting an inspection of the practices at SUKL (Slovak regulatory authority). Despite the fact that many legal violations have been found, the results of the investigation and corrective measures have not been communicated yet.

Procedures on Price Approvals and Price Regulation by Ministry of Finance (MoF)

MoF regulations on the pricing and price controls of pharmaceuticals do not specify the procedure and the decision making process on price setting and price adjustments in the MoF Pricing Committee. There are no deadlines set for the process. As a result, many price applications submitted to MoF are refused, or they are not handled for more than six months without any justification or notice sent to the applicant.

Inclusion into Reimbursement Lists, Setting of Reimbursement Levels

Provisions of Law No. 3/2000 Coll. clearly specify the process, particular procedures and criteria to include pharmaceuticals on the reimbursement lists. These provisions have not been enforced by the Ministry of Health (MoH). More than 160 pharmaceutical products have not been included on the reimbursement list. At the same time, MoH has preferentially included two pharmaceutical products on the list, despite the fact that they have obtained marketing approvals and price approvals significantly later than many other products on the waiting list.

Non-transparency in both described procedures means a significant delay in market access as well as shortening of patented product life cycle.

Delays and reluctance to implement TRIPS requirements, shortcomings in data exclusivity implementation, barriers to market access based on non-transparent procedures in drug registration, pricing and reimbursement, as well as lack of enforcement of existing laws have created an unpredictable environment for patented products. This development is in contradiction to expectations and to promises made by the state authorities in the past.

Damage Estimate

PhRMA is not able at this time to provide reliable estimates of the increase in our industry's sales that would accompany the removal of the aforementioned trade barriers.

MIDDLE EAST, AFRICA, SOUTH ASIA

LEBANON

Although Lebanon has taken steps towards meeting minimum international standards for IP protection and affording market access for products relying on intellectual property, there are a number of key outstanding implementation issues that need urgent resolution before PhRMA members will benefit from an improving investment climate. For that reason, PhRMA requests that Lebanon be included in the "Special 301" Watch List for 2001.

Intellectual Property Protection

In July, 2000, the Lebanese passed a new industrial property law, which represents a major improvement over the 1924 law. It provides a basic level of product patent protection with a 20-year term of protection and will provide incentives for new foreign direct investment generally, as well as technology transfer specifically to the pharmaceutical sector. Most of the language is compliant with the WTO TRIPS Agreement (including some level of data protection, limited compulsory licensing, increased penalties for infringement, and no phase in period for product protection for pharmaceutical products).

The new law provides a good basis for Lebanon's eventual WTO accession. PhRMA supports Lebanese efforts in advance of WTO membership to address longstanding trademark and patent issues. A number of amendments will be necessary in order to bring it into full compliance with TRIPS, but industry views this bill as a major step forward and is encouraged by the speed with which Lebanon appears to be moving forward to implement the legislation.

Although much work needs to be done, we note that credit is due to the first Government since independence to make significant efforts to modernize the copyright, trademark and patent laws.

<u>Recent Registrations of Copy-Cat Products:</u>

PhRMA members continue, however, to be concerned by potential infringing activities occurring during the period prior to full implementation of the law. As an example, a foreign company recently applied to the Lebanese Ministry of Health for marketing approval of a pirate version of a leading innovative American pharmaceutical product, which was itself introduced only recently to the market. Although still under consideration, the submission of a pirate for approval following the passage of a new patent law highlights the need for continued vigilance. As was reported in previous PhRMA "Special 301" submissions, several pirate products are known to be under active regulatory consideration, and several infringing copies have been approved by the Ministry of Health in the past eighteen months. In this regard, PhRMA appreciates

the continuing and effective advocacy efforts led by the American Embassy in Beirut to improve protection for intellectual property, including patented pharmaceutical products.

Parallel Importation:

During the past several years, there has been a substantial rise in the parallel (gray market) importation of pharmaceuticals. The importation of these products as a "cost containment" measure represents a violation of patent holder's right to control the offer to sell and importation. Moreover, due to the porous supply chain outside the manufacturer's control, parallel importation poses serious health and safety risks to Lebanese patients.

Senior ministry of health officials privately acknowledge that parallel importation has failed to produce any savings on medicines for patients. Parallel importers, distributors, wholesalers and retail pharmacists do not customarily pass on any "savings" associated with exchange rate arbitrage. Senior health officials recognize that parallel importing puts the drug supply at risk, but have failed to stop the practice. Industry has argued that it is very hard to police the supply of medicines once the chain of supply from manufacturer to authorized importer is broken. Counterfeiting and/or poor quality goods can easily enter the drug supply.

Market Access Barriers

Public Procurement:

A serious trade barrier concerns public sector procurement. The Government procurement policy discriminates against foreign suppliers by allowing local manufacturers a 15% price advantage in public sector business. This discriminatory practice contributes to higher costs for public sector procurement-ironic, considering Government efforts at cost containment-- and represents an added burden on taxpayers. It is also widely acknowledged that locally produced products have "priority standing" over imported products in Ministry of Health registration procedures, which translates into preferential waiting periods for obtaining marketing authorization.

Regulatory Barriers:

Research-based companies are urging the Ministry of Health to develop a "fast track" approval process for New Chemical Entities (NCE) and their associated line extensions. This would speed the introduction of new, innovative and often life and/or cost- saving medicines to patients. Unfortunately, a lack of resources, outmoded regulatory requirements, and the lack of criteria for distinguishing between innovation and imitation, contribute to unnecessary delays to registering new products. Delays of up to two years are common, while in neighboring Cyprus, new products are often

approved in as little as 90 days (based on prior "reference country" approvals, e.g., FDA or European agency approvals). To date, the Government has failed to take any action regarding industry proposals, meaning Lebanese patients often must travel abroad or rely on risky, uncontrolled "suitcase" importation to obtain the latest medicines on the black market.

Damage Estimate

PhRMA is currently studying methodology that could be used to estimate losses in Lebanon due to the problems outlined above. Lebanon represents one of the faster growing pharmaceutical markets in the Middle East, and there is significant market support for innovative, branded pharmaceuticals. However, as the country is still rebuilding following the civil war, it is not possible to estimate the potential growth in U.S. exports or sales.

MOROCCO

Despite its adoption of a new industrial property law designed to come into compliance with TRIPS, PhRMA members remain concerned that Morocco fails to live up to the minimum international standards embodied in the WTO Uruguay Round Agreements for intellectual property protection and fair market access. Accordingly, PhRMA requests that Morocco be included on the "Special 301" Watch List for 2001.

Intellectual Property Protection

In March 16, 2000, Morocco published Law No.17-97 relating to protection of industrial property. This law contains new patent and trademark legislation, which is intended to bring Morocco in compliance with its TRIPS obligations. It should be noted that this legislation has not been made available to industry in English, and that we are not assured that it is fully compliant with the WTO TRIPS Agreement. In particular, we understand that this law has been based on the French patent legislation, which is known not to be fully TRIPS compliant. Additionally, this law does not address the question of data exclusivity protection and does not create any system allowing for the protection of data exclusivity rights. PhRMA would appreciate any information available concerning the new law.

Market Access Barriers

Local Ownership Requirement

Under Law 1-59-367 of February 19, 1960 (the "Law"), only companies that are controlled by individual pharmacists can be regarded as "pharmaceutical companies" and be allowed to manufacture, stock, and market pharmaceutical products. The Law specifically requires for that purpose that 51% of the share capital of a pharmaceutical company be held by individual pharmacists and that 26% of the share capital be held by pharmacists licensed in Morocco (i.e. Moroccans).

As a result of this local ownership requirement, foreign companies creating a local subsidiary are compelled to make a choice between two evils: either (a) allow a pharmacist licensed in Morocco to own 26% of their local subsidiary in order that their local subsidiary be a "pharmaceutical company" (and may benefit from the rights granted to a pharmaceutical company), or (b) register all their products through a local licensee (or distributor for imports), and allow the local licensee (or distributor) to enjoy quasi-ownership rights over their products in Morocco. Indeed, in the latter case, the local licensee is treated by the Ministry of Health as the sole and true owner of the products registered by this licensee in Morocco. Throughout the life of the product in Morocco, and regardless of what the License Agreement provides, the local licensee is

fully empowered to act as if it was the owner of the licensed products. As a result, the foreign investor cannot:

- import and sell pharmaceutical products in the country;
- be the official contact to the Ministry of Health;
- officially negotiate the price of its products with the Ministry of Health;
- transfer the marketing license to another licensee;
- monitor the pharmaco-vigilance;
- control the continuous supply of the market, as the licensee is to decide when to buy and in what quantities; and
- enforce its rights under the License Agreement with the licensee in case of termination.

Actual ownership of the marketing licenses puts the licensee in a position of extreme strength vis-à-vis the foreign licensor. For example, in case of termination, regardless of the provisions of the License Agreement, the Ministry of Health will refuse to transfer the marketing license of the products without the licensee's prior written approval. The licensee can take unfair advantage of this extremely strong position and is thus able to impose an onerous indemnification payment on the licensor, regardless of the original terms and conditions of the License Agreement.

The health authorities also require that, to become a "pharmaceutical company," a company must own a manufacturing presence. The Law is unclear as to the extent and form of such a presence, but the health authorities generally take the view that only full ownership of a manufacturing facility will meet this requirement. As a result, import licenses are in practice only given to companies who have their own local factory. Those who do not cannot own the registrations for their products and cannot be seen as true pharmaceutical companies. These companies can only be seen as a promotional agency acting for its local pharmaceutical partner. The Law is truly antiquated (1960); in particular as it assumes that the pharmaceutical industry only comprises pharmacists working out of their own shop. It was originally intended to protect pharmacists as a guild. The Law should be amended in order to allow foreign companies to retain full ownership of their local investment and be entitled to register their products under their name in Morocco. The conditions required for pharmaceutical companies to manufacture and market their products should be modernized. Other countries have shown that there are other and better ways to ensure that pharmaceutical products are safely manufactured and marketed in the best interests of the public.

<u>High Customs Tariffs</u>

There are high customs barriers on drugs: approximately 17% on imported raw materials and imported finished products that cannot be manufactured locally; approximately 40% on imported finished products which are deemed to be "locally

manufacturable." This type of use of custom tariffs is solely protectionist and intended to safeguard local manufacturing. This also creates over-capacity at the local level. WTO membership should normally lead to a reduction in these tariffs, which adversely impact the competitiveness of foreign products.

Damage Estimate

PhRMA cannot provide a reasonable estimate at this time of lost sales or potential exports and growth in the market in Morocco, but would be interested in investigating new commercial opportunities in Morocco should the intellectual property and market access conditions improve materially.

SAUDI ARABIA

The Government of Saudi Arabia continues to view World Trade Organization (WTO) membership through a political lens, and has failed to make comprehensive economic and regulatory reform efforts needed to enter the WTO. Because of the foregoing, Saudi Arabia continues to lag minimum international standards both in protection of intellectual property, and in equitable and transparent conditions for market access for products relying on intellectual property. PhRMA requests that the U.S. Trade Representative include Saudi Arabia in the 2001 "Special 301" Watch List.

Intellectual Property Protection

Although Saudi Arabia has had a patent law in place providing product patent protection for pharmaceuticals since 1993, to date this has yielded only theoretical protection. In over four years, no patents have actually been granted or issued. The resulting ambiguity in the actual effectiveness of intellectual property protection exacerbates the difficult commercial operating environment in Saudi Arabia. The lack of issuance of any pharmaceutical product patents in the Kingdom represents a serious barrier to American inventors doing business in Saudi Arabia.

More serious concerns are raised by the increasing threat that the Saudi Ministry of Health has initiated purchases of copycat UAE-origin pharmaceutical products. Current events in the region appear to have emboldened at least one local Saudi copycat pharmaceutical producer. The company is now reportedly investigating the possibility of obtaining marketing approval for a blockbuster antibiotic produced by a PhRMA member company. Loss of this market for that product would alone cause losses of millions of dollars annually for that PhRMA member company.

In addition to Saudi Arabia's national policies, PhRMA members are concerned by continuing policies of the Gulf Cooperation Council that further weaken the ability of Saudi Arabia to provide adequate and effective protection for intellectual property. The Gulf Cooperation Council (GCC) secretariat has recently approved Gulf-wide sale of copycat products through the central procurement process (known as the Secretaries General of Health (SGH) pharmaceutical tender process in Riyadh, or the SGH process). PhRMA members face potential losses of multi-million dollar markets for their leading products throughout the Gulf. PhRMA understands from U.S. Government (USG) reports from Riyadh that pirated pharmaceuticals are also now beginning to be produced in Saudi Arabia.

GCC Practices Undermine the1999 GCC Patent Law

Despite the substantial efforts of individual members, the GCC's overall level of patent protection is less than meets the eye. PhRMA remains concerned that recent

activities of the GCC secretariat through the SGH Tender Committee undermine existing patent and data protection in GCC member states. For example, the GCC Secretariat has recently approved for sale a number of copycat products produced in the UAE (described above). The GCC is now marketing these pirated products to Ministries of Health throughout the Gulf. GCC Health Ministries appear unaware or unconcerned that these procurement practices violate the TRIPS Agreement. Although the GCC secretariat has declined to release the list of affected products, PhRMA understands that the list includes cutting-edge products from GlaxoWellcome, Johnson & Johnson (doing business as Janssen-Cilag), Merck, Pfizer, and other leading international innovative pharmaceutical companies.

Despite repeated USG and industry communications to the GCC on this subject, the Secretariat is moving forward with its plans to sell these products throughout the Gulf. The Director General of the GCC Patent Office, Mohammed Al-Rasheed responded to PhRMA's September correspondence via a letter dated November 19, 2000. In this letter he stated that unless a PhRMA member has sought patent protection through the GCC Patent Office, the GCC secretariat bears no responsibility to protect the intellectual property rights in question. This provides PhRMA members with a condition impossible to meet: Because the GCC began issuing patents only within the last year or so, PhRMA members could not have applied for patents with the GCC office at the time that these products were patented in individual GCC member states, or at the time that those members undertook to respect the validity of patents filed in the U.S. or the E.U. In effect, the GCC law acts to nullify patent protection in Saudi Arabia and in other GCC markets.

The GCC's new patent law and regulations were approved by GCC Ministers on November 27, 1999. In theory, they have been implemented by all GCC members. Neither industry nor the USG had the benefit of discussion or review of the proposed patent regime prior to final passage and implementation of the new regime. There are a number of basic problems in the regime, including a lack of data protection, and other WTO-inconsistent provisions.

In late November 1999, and again in the fall of 2000, USG representatives raised the issue of the new patent law and regulations with GCC members, but were unable to obtain definitive responses regarding the important issue of legislative preemption. For example, interlocutors were unable to answer whether the GCC laws take precedence over individual state laws that may be more consistent with TRIPS, and the relationship between GCC institutions and national regulatory or judicial bodies.

GCC Patent Provisions that Conflict with WTO Member TRIPS Obligations

The GCC legislation fails to meet the following WTO TRIPS requirements:

- The GCC patent law requires local working.

  - ♦ TRIPS requires that patents be available and patent rights enjoyable without discrimination as to the field of technology, place of invention, and whether products are imported or locally produced (Article 27.1). Importation must be considered to be equivalent to working the invention locally for purposes of any conditions placed on enforcement or use of patent rights. To the extent that individual GCC states fail to treat importation on the same terms as local manufacture of the patented invention, their patent regime will not rise to the minimum level required by TRIPS.

  - ♦ TRIPS Members cannot condition use of patent rights based on where a product subject to the patent has been manufactured. (Article 27.1) Thus, if a Member requires a patent owner to "work" the patented invention or face the sanction of a compulsory license, the patent owner must be allowed to satisfy this requirement by importation of the product. Given the experience we have had with so-called "working requirements," it is essential that the law explicitly provide that the "working requirement" can be met not only through local manufacture of the product but also the importation and sale of the product. This is one of the most important provisions of the TRIPS Agreement.

- The GCC Patent Law does not include Data Exclusivity.

  - ♦ In addition to enumerating patent standards, the TRIPS Agreement requires that Members protect undisclosed information. Specifically, it requires Members to permit owners of certain undisclosed information – often called trade secrets – to prevent others from disclosing, acquiring, or Using this information without their consent in a manner that is contrary to honest commercial practices. In addition, TRIPS requires Members to protect certain test data from disclosure and “unfair commercial use” if that data is submitted to the Member to obtain permission to market a pharmaceutical or agricultural chemical product. In other words, those who generate this valuable data must be able to prevent competitors from relying on this data to prove that their products are safe and effective for a reasonable period of time, which in most instances will be ten years (Article 39).

- The GCC Law does not provide full patent protection in all areas of technology.

- ♦ TRIPS requires that patents be available for inventions in all technological areas except for those specifically enumerated in the second and third paragraphs of Article 27. Given developments in communications and information technology, the term "invention" now includes processes executed on computers and processes for conducting business, especially those conducted electronically. As a result, some exceptions related to computer programs and methods of doing business that were often contained in patent laws are often now too broad to be consistent with the TRIPS Agreement.

- ♦ TRIPS Members can exclude certain inventions on grounds related to public order. This exclusion can only be used if it is necessary to prevent commercialization of the invention within the Member to protect the public order. The mere fact that it is illegal to market a particular type of invention is not sufficient to exclude it from patentable subject matter. (Article 27.2)

- ♦ TRIPS Members are permitted to exclude plants and animals from patentable subject matter. Such exclusions, however, will deter the development and marketing in the region of new biotechnology products that can provide great benefits in the forms of improved agricultural and medical products to residents of the region. Furthermore, TRIPS Members who fail to provide patent protection for new plants must protect plants under a separate form of protection, such a system consistent with the 1991 Act of the UPOV Agreement (Article 27.3).

- The GCC Patent Law contains Compulsory Licensing provisions that are not consistent with the TRIPS Agreement.

  - ♦ The TRIPS Agreement enumerates safeguards that Members must apply to protect patent owners if they chose to permit third parties to use patented inventions without the authorization of the patent owner (often called compulsory licenses). (Article 31) For example, there must be some merit or benefit to permitting unauthorized use of the patented invention. Further, the request for the compulsory license must be evaluated and granted on an individual basis. (Article 31(a)).

  - ♦ In instances other than antitrust violations or national emergency situations, those seeking to use the patented invention must request a voluntary license from the patent owner before requesting a compulsory license. (Clause (b))

  - ♦ Any compulsory license granted must allow use of the patented invention that is explicitly limited to the supply of the domestic market. The holder of a compulsory license may not manufacture the patented invention and export it

to foreign markets without authorization of the patent owner. (Clause (f))

- ♦ Third parties must compensate the patent owner for the unauthorized use of the patented invention and the compensation must take into account the "full economic value" of the use. This means that the compensation must be set at market value, not a pre-established royalty rate for a class of inventions. (Clause (h))

- ♦ Decisions permitting unauthorized use of a patented invention and on establishing compensation levels under the license must be subject to judicial or independent review. (Clauses (i) and (j))

- The GCC Patent Law does not provide for required enforcement mechanisms.

  - ♦ In addition to requiring that the Members' patent laws meet certain substantive standards, the TRIPS Agreement requires that Members have fair and equitable systems for granting and for enforcing patent rights. These systems must not be unnecessarily complicated or costly and must be expeditious. (Articles 41 and 62)

  - ♦ TRIPS requires all Members to make available provisional remedies (e.g., preliminary injunctions, temporary restraining orders, *ex parte* seizures). Provisional relief is critically important to most enterprises, and a failure to provide this relief will be viewed as a serious deficiency (Articles 44 and 50).

  - ♦ Members are also required to award damages to patent owners to provide full compensation for the economic damage caused by the infringement of the patent. In addition, judicial authorities must be authorized to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity. (Article 45)

PhRMA asks that the U.S. Trade Representative continue dialogue with the GCC in order to seek clarification and improved protection for intellectual property, as required by TRIPS. Further, prior to Saudi WTO accession, PhRMA asks that the U.S. Government receive assurances from Saudi Arabia that it will follow GCC practices only insofar as they do not weaken the minimum protections contained in the WTO TRIPS Agreement.

Market Access Barriers

The following practices in Saudi Arabia are inconsistent with WTO disciplines, and have a substantial and negative impact on the market share in Saudi Arabia for US-patented pharmaceutical products. We continue to bring these issues to the

attention of the U.S. Government in the context of Saudi Arabia's WTO accession negotiations:

Price Controls

The Saudi Government imposes a rigid registration and price control system that lacks transparency and delays product introduction. Saudi Arabia uses a very simplistic and burdensome reference price system. The Government requires companies applying for marketing authorization to provide the price of the candidate product in as many as 30 other countries, many of which, e.g., Lebanon or Jordan, are not comparable economically. The authorities will typically choose the lowest of the 30 prices as the Saudi price. Additionally, the Saudi Government is currently proposing a new pricing policy that, again, lacks transparency, is not based on the principle of market-based pricing, and stipulates compulsory price reductions.

Unnecessary laboratory analysis by the Saudi Ministry of Health also delays Introduction of new medicines in Saudi Arabia. The requirement applies to products approved by leading health regulatory authorities such as the Food and Drug Administration, the Medicines Control Agency or the European Medicines Enforcement Agency. These products are typically available in large, well-regulated markets in North America, Europe or Japan, where they are taken by millions of consumers. Laboratory testing which is inconsistent with International Conference on Harmonization (ICH) requirements or does not take into account the valid certification of these products in these major markets is simply redundant and time consuming, raise costs, and constitutes an unnecessary burden on companies and a barrier to trade.

Protectionism

Saudi Arabia does not allow foreign direct investment; rather, foreign investors are required to partner with local distributors who are the actual legal representatives of the company in the Kingdom. The new Foreign Investment Law did not change the situation for the international pharmaceutical industry, since trade regulations remained the same under this new law. Saudi Arabia still does not allow foreign direct investment in this sector; rather, foreign investors are required. In other words, foreign companies continue to lack legal status in the Kingdom. According to Saudi law, Saudi nationals must control or own 51% of enterprises. The ban on foreign majority ownership is a major impediment to foreign direct investment or technology transfer, and raises the cost of doing business in the Kingdom. It also raises the fundamental issue of reciprocity. Saudi nationals are allowed to freely and wholly own property and enterprises in the United States, but U.S. citizens and corporations are not extended the same rights in the Saudi domestic market.

There is also a lack of national treatment in public procurement with local and GCC-based companies such as Spimaco, Tabuk and Julphar being treated more favorably than international companies.

Government Procurement

Saudi Arabia's public tendering system fails to meet WTO disciplines in terms of national treatment and transparency, among other areas. The system discriminates in favor of local or regional (GCC) companies, providing both faster registration and preferential pricing (a 10% advantage in tenders as compared to multinational companies) for "locally" made products.

Damage Estimate

PhRMA is currently studying methodologies for estimating damage to U.S. industry from current IP practices in Saudi Arabia. The Saudi pharmaceutical market is the largest in the region, estimated at more than one billion dollars in 2000 by IMS Health. If the Government of Saudi Arabia were to adopt a patent regime consistent with WTO TRIPS standards, the U.S. share of this market would likely expand substantially, even if the market itself did not grow significantly.

SOUTH AFRICA

PhRMA member companies appreciate the good will and continuing statements of the current Government of South Africa that it intends to meet fully its multilateral obligations as spelled out in the WTO TRIPS Agreement. However, despite the South African Government's previous commitment to do so, Government has declined to revise SAMMDRA (housing Amendment Act 90 of 1997 and Section 15C) in ways that all sides recognize are needed to bring it into compliance with South Africa's TRIPS obligations. Instead, South Africa has forced PhRMA members active in South Africa back into Court to litigate a law that it knows requires revision and parliamentary review. Until South Africa completes it own parliamentary internal review and amendment of the Medicines Act in a manner consistent with its international commitments, PhRMA requests that the U.S. Trade Representative include South Africa on the 2001 "Special 301" Watch List.

Intellectual Property Protection

New Developments

At the launch of litigation in February 1998, the South African Government (SAG) voluntarily agreed not to promulgate or bring into effect Section 15C, (or any part of Act 90) pending a ruling by the Constitutional Court. Several attempts to reach a negotiated settlement followed. In June 1999, after national elections resulted in appointment of a new Cabinet, the pharmaceutical industry immediately made overtures to the new Government, for the purpose of reaching a mutually acceptable solution to the dispute over the Medicines Act, to no avail. In August of 1999, PhRMA members active in South Africa voluntarily suspended litigation after Health Minister Manto Tshabalala-Msimang announced that the Medicine Act would be returned to Parliament for extensive amendments. Despite several further public announcements that these amendments would be made during 2000, the law has not been returned to Parliament.

Notwithstanding the promised amendments, the Minister's legal advisors have insisted that petitioners continue litigation on the existing law – refusing to allow the continued and logical suspension of the case. PhRMA members ultimately were compelled by the Government of South Africa to file replying papers in July 2000, despite the lack of action on needed (and promised) amendments. A Court date of March 5, 2001 has been set.

PhRMA members active in the South African market continue to pursue every possible avenue to reach a negotiated settlement. PhRMA members would ultimately prefer a negotiated settlement and the forging of a partnership that immediately seeks to address the AIDS pandemic in Southern Africa. In particular, PhRMA members

U.S. investors in South Africa are further encumbered by the recent amendment of the SA Competition Act. In brief, this law no longer exempts from its scope intellectual property rights acquired through the country's IP laws. The Act now requires the holders of these rights to apply for exemptions to exercise these rights. Apart from the obvious logistical problems associated with such a requirement, the effect of this amendment is to create barriers to market entry for IP intensive industries and services.

TURKEY

More than one year after its effective date of obligations, Turkey has failed to meet the minimum international standards for intellectual property protection found in the TRIPS Agreement. For that reason. PhRMA asks that the U.S. Trade Representative include Turkey in the 2001 “Special 301” Watch List.

Intellectual Property Protection

The United States, the European Union and Turkey have been in negotiations over the improvement of Turkey's intellectual property regime for several years. With the conclusion of the Customs Union agreement between Turkey and the EU, Turkey has now implemented a patent law effective January 1, 1999. The patent law issued by Executive decree in June 1995, however, falls well short of TRIPS standards in numerous areas, including:

- Conditions of Patentability: Under Article 6 of the patent law, many important biotechnology inventions could be excluded. We note in particular Article 6(2) that exempts from patentability "plant and animal varieties or biological processes for the production thereof." In addition, there is no provision for the TRIPS-required transitional patent mailbox.

- Obligation to Work: Article 96 of the law requires actual “working” of the patented invention within three years of patent grant, it would appear to exclude pharmaceuticals and agricultural chemicals from patentability since the marketing registration period typically takes far longer than three years after patent grant.

- Local Working Requirement: Article 97 implies that importation does not satisfy working requirements since inspection of "manufacturing" facilities is a condition of patentability.

- Compulsory Licenses: The patent law provides a compulsory licensing section of unparalleled length in Articles 99-120. These provisions facilitate the granting of compulsory licenses in violation of the patent owner's rights. In general, the provisions are far too broad, allowing for compulsory licenses for technical progress if the invention is not of "significant merit" (opening the door to arbitrary government decisions), and for vague and undefined "public interest". There appear to be no provisions for the termination of a compulsory license when the conditions leading to its grant cease to exist. Lest there is any doubt of the government's intentions to facilitate the issuance of compulsory licenses, Article 120 requires the government to provide publicity and financial incentives for applicants to seek compulsory licenses. This entire section should be deleted

and re-written to conform with Article 31 of TRIPS.

- Lack of Protection of Proprietary Data: A principal means by which pharmaceutical intellectual property is pirated in Turkey is the unauthorized use of the originator's proprietary data submitted as part of the registration/marketing authorization process. The material, which includes safety and efficacy information gathered from lengthy and expensive clinical and human testing is often simply photocopied and submitted to the authorities, which then approve the copied product without requiring any bioequivalence or bioavailability testing. Turkish provisions on data protection fail to include prohibitions against unfair commercial use. This unsafe practice is also in direct conflict with TRIPS Article 39.3, "Protection of Undisclosed Information". PhRMA urges that the protection of proprietary information also be improved in Turkey. Turkey should be required to implement a system of data exclusivity consistent with TRIPS Article 39, as of the effective date of the new patent law, i.e., January 1999.

In addition to not meeting minimum international standards contained in the TRIPS Agreement, the patent law also lacks other common protections that have been adopted by most industrialized countries in recent years, including patent term extension. Pharmaceuticals and many other products such as agricultural chemicals require a lengthy registration/approval process before they are brought to market but after they are patented. Article 72 of the patent law should be changed to allow for the extension of patent terms for products that require a lengthy pre-marketing approval process.

Market Access Barriers

The Government of Turkey has undertaken a system of price controls that is arbitrary and non-transparent. The system violates the principle of national treatment, does not reward innovation, may endanger public health, and limits current and future pharmaceutical company investment in the country. In addition, new Ministry of Health policies aimed at limiting pharmaceutical import licenses benefit local industry while discriminating against foreign companies by requiring burdensome proof of the “necessity” of importing products in lieu of manufacturing locally.

Pricing

The Government of Turkey has arbitrarily altered its long-standing drug pricing policy, which requires companies to negotiate a product price in U.S. dollars at the time of product approval in Turkey. In order to adjust for currency fluctuations in Turkey’s hyperinflationary environment, the government formulates a price for each lot of product imported into the country based on the current exchange rate. In the past, domestically produced medicines were sold at established prices with increases

provided at predictable intervals by the Government of Turkey. The Turkish government and pharmaceutical companies have relied on this legal and transparent system for the last several years.

In June 1999, the Turkish Ministry of Health introduced a reference-pricing scheme that would force companies to immediately lower their negotiated prices to those of the lowest-priced country of the European Union. Additionally, the latest information from the Turkish Ministry of Health indicates that Turkey is considering the same reference-pricing scheme for products produced by local fill-finishing. Fully produced local products, however, will actually receive a price premium from the government, thus providing a competitive benefit to local companies that produce both bulk and final product, at the expense of importers.

This serious change in pricing presents several concerns to U.S. pharmaceutical companies. The pharmaceutical industry has chosen to invest in Turkey by establishing manufacturing operations, investing in research and development, bringing in technical expertise, and administering medical education and awareness programs. The negative economic atmosphere created by this abrupt pricing change may limit or discourage future pharmaceutical company investment in Turkey. Orders for drastic price reductions may inhibit the ability of companies to bring new, innovative, and often life-saving, products to market in Turkey. Given the lengthy time required (approximately 15 years) and high cost of research and development (nearly $500 million) to bring a drug to market, companies must be ensured they can recoup the costs of their investment in developing innovative medicines.

In addition, Turkey's new pricing policy is not fairly balanced. Currently, the government is referencing European prices for decreases only. Technically, to reference the European price, the government should allow a price increase to those products valued lower in Turkey's market than in any European country. There is also no future plan for the possibility of adjusting prices on the Turkish market should the European reference price increase. Clearly, the government hopes to enact a system of reference to Europe's prices only where it is convenient to contain costs. This system does not recognize the true value of high-technology medical treatments.

Perhaps most discouraging about these newly announced policies is the fact that Turkey has previously professed its desire to liberalize its economy and allow for a transparent marketplace. New policies in Turkey that disadvantage foreign investors may convince the international community and its financial institutions, such as the International Monetary Fund, that the country is not prepared for long-term reforms that will bring economic growth.

Local Production Requirements

In an effort to bolster the domestic drug industry in Turkey, the Government has issued both verbally and in writing, requests to foreign companies to manufacture products in-country. The Turkish government has asked these companies to explain the technical justification for importing products instead of producing them locally. In order to renew import licenses, Turkey will schedule a technical site visit to "ensure" that local production is not possible.

This discriminatory process interferes with foreign companies' ability to conduct business in Turkey. The inspection itself may be intrusive and may violate intellectual property standards by exposing companies' operating procedures to outside sources. Additionally, any delays in the inspection process that slow the process of obtaining an import license could seriously inhibit the flow of innovative imported products into Turkey. Therefore, this policy is not only a non-tariff trade barrier, it also may present a public health concern if citizens do not have full access to new, efficient medicines.

Damage Estimate

PhRMA is in the process of developing methodology to determine damages from the IP deficiencies and barriers to market access in Turkey. Although this methodology is not yet available, member companies active in Turkey provide the conservative estimate of losses in the range of $60 million annually.

WESTERN HEMISPHERE

ANDEAN COMMUNITY
(Bolivia, Colombia, Ecuador, Peru, Venezuela)

Members of the Andean Community have adopted common policies affecting intellectual property protection within the region. Unfortunately, these policies fail to meet the minimum international standard for intellectual property protection in the WTO TRIPS Agreement and fail to provide adequate market access to U.S. products that rely on IP protection. PhRMA requests that the U.S. Trade Representative include members of the Andean Community (Bolivia, Colombia, Ecuador, Peru, and Venezuela) in the 2001 "Special 301" Watch List.

Intellectual Property Protection

On September 14, 2000, the Governments of the Andean Community adopted Decision 486, which replaced Decision 344 (in effect since January 1994). The new Decision took effect on December 1, 2000. It improves upon Decision 344 in several ways, including expanding the definition of patentability and strengthening data exclusivity. Defining "unfair commercial use" and determining the term for data exclusivity was left up to each member country to determine individually by December 1, 2000. To date, none of the Andean Community member countries have issued those implementing regulations, however. In our view, the Andean Community should adopt a ten-year period standard against the use of proprietary data submitted for registration purposes, as is the case in several EU countries.

Unfortunately, Decision 486 falls short of adequate pharmaceutical patent protection by placing unjustified restrictions on biotech inventions and by creating ambiguity that has resulted in loss of rights to so-called "second use" patents. Also, the General Secretariat of the Andean Nations Community (ANC) ruled against Peru in 2000, disallowing "second use" patents. This represents a serious blow to intellectual property protection, and we hope that the Government of Peru will obtain a reversal of this ruling on appeal to the Andean Justice Court.

Several important medical advances would not be available to patients around the world without the availability of "second use" patents. These products are subject to the same review process as any other patent application, meaning they must be new, involve an inventive step, and be capable of industrial application. "Second use" patents are thus no different from any other patent and should be held to the standards found in TRIPS Article 27. Patent laws of the U.S. and our major trading partners do not differentiate between patent applications in this regard. Pharmaceutical research companies apply for patents on new molecules at the earliest possible opportunity. Additional, unforeseen medical indications may be discovered during the lengthy research phase that follows. The results benefit patients and, if they meet the patentability criteria outlined above, deserve patent protection. The Andean

Community, by outlawing these patents, is misinterpreting TRIPS and is out of step with accepted practices.

Pharmaceutical companies have filed product patent applications since Decision 344 took effect in 1994, and products that are the subject of these applications are on the market. However, the risk of patent piracy remains high due to administrative and other delays in the approval process and inadequate enforcement against unfair commercial use of patented products.

Moreover, health authorities often fail to coordinate with patent officials and inappropriately issue sanitary registrations for products already under patent, whose patent application is pending, or whose period of data exclusivity has not expired. PhRMA believes that the TRIPS Agreement obligates members to adopt "linkage" regulations, establishing a formal link between patent authorities, health regulatory authorities and enforcement agencies. This linkage would mitigate this situation, as it would require "second applicants" (i.e., local companies, or in some cases, "pirate" applicants) demonstrate that the product for which they are requesting market approval is not the subject of a valid patent or pending application. "Linkage" exists in the United States, Europe and Japan, and is crucial to maintaining the integrity of the intellectual property and patent system.

Another way in which the intellectual property environment could be improved in the Andean Community is for these countries to implement and enforce provisions guarding against the unauthorized commercial use of company proprietary data, as per the principles outlined in TRIPS Article 39. Pharmaceutical research and clinical trials represent an enormous investment, making the resulting safety and efficacy data extremely valuable. As is described in several other country sections in this submission, allowing the registration of "generic" products that use, or incorporate by reference, the company proprietary data of the innovator is an unfair trade practice that severely, and at times completely, undercuts intellectual property protection for pharmaceuticals.

Discussion of additional issues that apply to individual members of the Andean Pact follows:

Colombia

Intellectual Property Protection

Pharmaceutical companies continue to suffer greater commercial damage due to weak intellectual property protection in Colombia than in any other Andean country. Since the current patent regime went into effect in 1991, only a few patents have been examined and granted, and the process remains extremely slow. At the same time,

numerous copy products have inappropriately garnered significant market share. Data exclusivity norms expressly contemplated in both Decision 344 and Decision 486 are ignored by INVIMA (the National Institute of Supervision of Foods and Medicines), which allows copies to be placed on the market the day after the innovative product is approved for commercialization. Although some elements of the Colombian government, specifically the Ministry of Foreign Trade, have provided assurances of Colombia's commitment to intellectual property rights protection, copying remains rampant. The Government of Colombia needs to take steps to speed the patent process and get copy products off the market. Such steps include:

- improve the operational structure of the patent office;
- improve enforcement mechanisms to handle patent infringement issues;
- create linkage regulations between the regulatory and patent offices;
- implement pertinent judicial training programs.

Market Access Barriers

Price Controls

Even though prices were liberated in February 1999, this was done with one significant caveat, that at least three identical molecules be available in the marketplace. Products that do not have copies in the marketplace (less than three) remain under the price controls, with once a-year-adjustments determined through an

Community. Therefore, special attention and effort must be focused on the process initiated by the Andean Community General Secretariat against Peru, Venezuela and Ecuador (Resolutions 406, 223 and 424) on "second use" patents. Ecuador is a key player for both its particular case and as the Andean Tribunal of Justice is based in Quito.

Efforts must be made to prevent Ecuador from having to step back on this key issue. Therefore, the U.S. Government should request Ecuador to take a firm stand on defending its right under both local and international law to issue "second use" patents, and give full support to this initiative.

Market Access Barriers

Price Controls

Prices for branded pharmaceutical products are governed by the recently issued generic medicines law. A 12-memer pricing committee created by this law includes members representing organizations unrelated to pharmaceutical pricing matters, creating the potential for politicized decisions. The committee slows down the pricing approval process and works in a conflictive atmosphere. It recently issued a resolution shrinking the gross profit margin that pharmacies had enjoyed for the past 30 years, contrary to specific provisions in Ecuador's Protocol for WTO Accession. This may in turn jeopardize the pharmaceutical industry's profit margins, which originate from the same legal basis.

Peru

Intellectual Property Protection

Peruvian legislation on data exclusivity led the Peruvian Patent Office (INDECOPI) to request that the regulatory agency (DIGEMID) withdraw illegal copy products from the market. Enforcement remains inadequate, however. In a troubling development, sanitary registrations have been issued for copies of products that are patented, have pending patent applications, or whose period of data exclusivity has not yet expired. The Peruvian Government should rescind these registrations.

When patent infringement occurs, the innovator must take steps to file a claim for penalties to be applied to the copier. When a product or process is under patent in the country where it was originated, but is not yet registered in Peru, then Peruvian law allows it to be copied. Pipeline protection is not allowed in Peru, nor in the Andean Community (Decisions 344 and 486).

Communication between INDECOPI and DIGEMID is limited, and no formal linkage mechanism exists to protect products with issued or pending patents or still-current data exclusivity. Members of the Association of Peruvian Pharmaceutical Laboratories (ALAFARPE) have been told to inform DIGEMID directly when they have a patent pending or issued – something INDECOPI should do itself.

Peru does not require supporting scientific information to register a pharmaceutical product. The product simply must be included in a pharmacopoeia or have a certificate issued in the country of origin saying it could be sold without any restrictions. It is unclear whether Peruvian authorities recognize that confidential data were required for sales authorization in the country of origin.

Since 1998, Peru had recognized second use patents. However, as noted above, the Andean Tribunal has ordered Peru to stop issuing second use patents.

Venezuela

Intellectual Property Protection

Intellectual property rights are protected by law and generally respected in practice in Venezuela despite recent government rhetoric. Pharmaceutical products have received patents since 1992, but with no pipeline protection. Thus, the first medicines protected by patents are just beginning to appear on the Venezuelan market; many more will appear in the next two to four years. A complete evaluation of de facto patent protection is therefore premature. Confidential data is protected in practice; the government has not issued sanitary registrations for copies of innovative products under patent or with pending patent applications. However, there is no clearly defined government policy on this subject.

A draft industrial property law introduced in 1999 unfortunately failed to come to fruition in 2000. This proposal would have created a financially autonomous Institute of Intellectual Property.

Market Access Barriers

Price Controls

Despite drastic market reforms that lifted price controls for most industries, the pharmaceutical industry remains the target of political maneuvering. To date, only the prices of over-the-counter (OTC) medicines and products with more than four alternatives in the market have been liberated, while the prices for products that are most significant for the research-based industry continue to be heavily controlled.

A new medicine law (Ley de Medicamentos) was passed in 2000 containing provisions of concern to the research-based pharmaceutical industry, including:

- language allowing the government to regulate prices;
- a mandatory National Therapeutic Formulary at public institutions;
- a provision on prescription substitutions at the pharmacy level;
- a requirement that pharmaceutical companies produce individualized doses to meet the exact level required per patient;
- a requirement that all medicine imported into the country must be evaluated by clinical trials in Venezuela.

The new law also may be unconstitutional because it calls for accumulated sanctions.

CHILE

More than one year after its implementation deadline for WTO TRIPS commitments, Chile has failed to come into compliance with its minimum international intellectual property obligations. This issue takes on greater urgency given the possibility of a US/Chile Free Trade Agreement. PhRMA requests that until Chile brings its intellectual property regime into conformity with its TRIPS obligations that the U.S. Trade Representative include Chile on the 2001 "Special 301" Watch List.

Intellectual Property Protection

Chile implemented a flawed patent law (Number 10939) in 1991, which provides limited product patent protection for pharmaceuticals. This law offers an inadequate patent term (15 years from approval) and no transition (i.e., pipeline) protection for pharmaceuticals. Draft legislation designed to bring Chile into compliance with TRIPS obligations has not yet been adopted, over a year since the WTO-imposed January 1, 2000 deadline. Chile should take prompt steps to bring its legislation into conformity with its international legal obligations. The United States government should not conclude a Free Trade Agreement with Chile that lacks strong intellectual property provisions.

The draft legislation represents an improvement over the existing law in several ways, including:

- extending the patent term to 20 years;
- providing patent protection for processes and the products obtained by those processes;
- increasing fines for infringement;
- elimination of the burdensome and subjective requirement to prove that an infringer "acted in bad faith" (complainants must simply demonstrate that the infringing activities had a commercial purpose);
- expanded protection for confidential data.

The draft legislation could be improved in a number of ways, however. The research-based pharmaceutical industry advocates greater linkage between health authorities and patent officials. To that end, the new law should require so-called "second applicants" (i.e., applicants seeking to copy existing products) to demonstrate that the product for which they seek approval from health authorities is not the subject of valid patent or pending application. The 1991 law contained no mention of parallel

imports; the new law does, which we regard as a step backward. The language of Article 51, which discusses compulsory licenses, should be modified to avoid ambiguity about when such licenses might be issued.

Another way in which the intellectual property environment could be improved in Chile, until improved, adequate and effective *de jure* patent protection is in place, is for the government to implement and enforce provisions guarding against the unauthorized commercial use of company proprietary data, as per the principles outlined in TRIPS Article 39. As is described in several other country sections in this submission, allowing the registration of "generic" products that use, or incorporate by reference, the company proprietary data of the innovator is an unfair trade practice that severely if not completely undercuts intellectual property protection for pharmaceuticals. Chile should adopt a ten-year period standard against the use of proprietary data submitted for registration purposes, as is the case in several EU countries.

Damage Estimate

At this time it is estimated that if current barriers were removed, sales of PhRMA company affiliates could increase in the range of US$ 50 million to US$100 million.

COSTA RICA

Costa Rica's legislation fails to comply fully with its international intellectual property obligations. PhRMA requests that until Costa Rica brings its intellectual property regime into conformity with its TRIPS obligations that the U.S. Trade Representative include Costa Rica on the 2001 "Special 301" Watch List.

Intellectual Property Protection

Costa Rica updated its existing patent regime via Law 7979, adopted in December 1999. A separate law, Law 7978, was adopted to focus specifically on confidential information. Unfortunately, the changes were inadequate. The law is being reviewed by a local court because it contains potentially unconstitutional provisions. Compulsory licenses and patent exhaustion can occur if a patent is not worked within four years. The patent can also be canceled for non-working. Law 7978 permits government authorities to use confidential data.

Damage Estimate

PhRMA member company affiliates have suffered damages in Colombia of between US$ 10 to US$ 50 million dollars.

URUGUAY

Uruguay's intellectual property legislative regime fails to meet express requirements of the WTO TRIPS Agreement. For this reason, PhRMA requests that the U.S. Trade Representative include Uruguay in the 2001 "Special 301" Watch List.

Intellectual Property Protection

Uruguay updated its 1941 patent law on August 19, 1999 by passing Law 17.164, the Law of Patents of Invention, Utility Models and Industrial Designs. It does not comply with the minimum international requirements provided in the WTO TRIPS Agreement in several respects. Deficiencies include:

- Overly broad conditions for compulsory licensing;
- Omission of provisions for Data exclusivity, contrary to Article 39.3;
- Failure to provide for exclusive marketing rights, despite the clear obligation for Uruguay to provide them.

In addition, the Uruguay law fails to include many aspects of intellectual property protection valued by the U.S. and other industrialized trade partners:

- Pipeline patent protection is not considered;
- Parallel importation is allowed.

Damage Estimate

PhRMA is currently reviewing methodology for establishing reliable estimates for damage caused by inadequate intellectual property protection. Although this methodology is not yet available, PhRMA members operating in Uruguay estimate that current deficiencies cause the loss of sales and exports in the range of US$ 50 million to US$ 100 million for PhRMA members.