2005 SPECIAL 301 REPORT

EXECUTIVE SUMMARY

The 2005 "Special 301" annual review examines in detail the adequacy and effectiveness of intellectual property rights (IPR) protection in 90 countries. Based on a lengthy process of information-gathering and analysis, the United States Trade Representative (USTR) has identified 52 countries that are designated in the categories of Priority Foreign Country, Section 306 Monitoring, Priority Watch List, or Watch List. The Special 301 Report reflects the Administration's resolve to take consistently strong actions under the Special 301 provisions of the Trade Act.

This Administration is determined to ensure the adequate and effective protection of intellectual property and fair and equitable market access for U.S. products. The designations and corresponding requisite measures announced today result from close consultations with affected industry groups, other private sector representatives, and Congressional leaders, and demonstrate the Administration's commitment to use all available methods to resolve IPR issues.

Addressing weak IPR protection and enforcement in China continues to be one of the Administration's top priorities. These IPR issues, outlined in the China section of the Special 301 Report, are critical in light of the rampant counterfeit and piracy problems that plague China's domestic market and the fact that China has become a leading exporter of counterfeit and pirated goods to the world. In the China section of the Special 301 Report, we are announcing the results of the out-of-cycle review conducted in early 2005. This year's Special 301 Report also sets forth the United States' plan to work with U.S. industry and other stakeholders to further build a factual record and to develop arguments with an eye toward utilizing World Trade Organization (WTO) procedures to bring China into compliance with its WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) obligations, to invoke the transparency provisions of the TRIPS Agreement, to elevate China to the Priority Watch List, and to maintain Section 306 monitoring. We will be monitoring closely China's IPR activities throughout the coming year.

USTR notes the continued need for Ukraine to take effective action against significant levels of optical media piracy and to implement intellectual property laws that provide adequate and effective protection. As a result, Ukraine will continue to be designated a Priority Foreign Country, and the $75 million in sanctions, first imposed on Ukrainian products on January 23, 2002, will remain in place. Ukraine's failure to protect IPR jeopardizes its efforts to join the WTO and undermines its ability to attract trade and investment. The United States notes with optimism, however, that Ukraine has recently renewed efforts to enact needed optical media legislative amendments, and has expressed its commitment to resolving IPR issues. The United States encourages Ukraine to enact necessary IPR laws and regulations as well as increase its enforcement efforts to combat piracy, and today announces the commencement of a Special 301 out-of-cycle review to monitor Ukraine's progress in providing effective copyright protection and IPR enforcement.

The Special 301 report addresses significant concerns with respect to such trading partners as Argentina, Brazil, Egypt, India, Indonesia, Israel, Kuwait, Lebanon, Pakistan, Paraguay, the Philippines, Russia, Turkey, and Venezuela. In addition, the report notes that the United States will consider all options, including, but not limited to, initiation of dispute settlement consultations, in cases where countries do not appear to have implemented fully their obligations under the TRIPS Agreement.

In this year's review, USTR devotes special attention to the need for significantly improved enforcement against counterfeiting and piracy. We place particular emphasis on the ongoing campaign to reduce production of unauthorized copies of optical media products such as compact discs (CDs), video compact discs (VCDs), digital versatile discs (DVDs), and compact disc read-only memory (CD-ROMs), as well as on the counterfeiting of trademarked goods. Optical media piracy and trademark counterfeiting are increasing problems in many countries, including Brazil, Bulgaria, China, India, Indonesia, Lebanon, Mexico, Pakistan, Paraguay, the Philippines, Russia, Thailand, Venezuela, and Vietnam. At issue in these and other countries is the foreign governments' political will to effectively address piracy and counterfeiting. In addition, USTR continues to focus on other critically important issues, including Internet piracy, proper implementation of the TRIPS Agreement by developed and developing country WTO Members, and full implementation of TRIPS standards by new WTO Members at the time of their accession. USTR also continues to insist that other countries' government ministries use only authorized software.

Over the past year, many developing countries and newly acceding WTO Members have made progress toward implementing their TRIPS obligations. Nevertheless, full implementation of TRIPS Agreement obligations has yet to be achieved in certain countries, particularly with respect to the TRIPS Agreement's enforcement provisions. Levels of piracy and counterfeiting of intellectual property remain unacceptably high in these countries. The annual Special 301 review provides an opportunity to assess these issues, and the Special 301 Report sends a necessary message to the governments of countries where serious IPR-related problems exist.

The United States is committed to a policy of promoting increased intellectual property protection. In this regard, we are making progress in advancing the protection of these rights through a variety of mechanisms, including through the negotiation of Free Trade Agreements (FTAs). The intellectual property chapters of the FTAs provide for higher levels of intellectual property protection in a number of areas covered by the TRIPS Agreement. We are pleased that the recent FTAs with Morocco and Australia will strengthen the protection of IPR in those countries. When the pending Bahrain FTA and Central American Free Trade Agreement (CAFTA-DR) (with Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic) are adopted, we look forward to seeing strengthened IPR regimes in those countries as well. We are also seeking higher levels of protection and enforcement in the FTAs that are currently under negotiation with Panama, Thailand, the Southern Africa Customs Union, the Andean countries, the United Arab Emirates, and Oman, and in the ongoing negotiation of a Free Trade Area of the Americas. Another opportunity we are using to strengthen the protection and enforcement of intellectual property is the increasing number of Trade and Investment Framework Agreement (TIFA) negotiations with several countries in regions such as the Middle East and Asia.

USTR will continue to use all statutory tools, as appropriate, to improve intellectual property protection in countries where it is inadequate. For example, USTR examines IPR practices through the implementation of trade preference programs, such as the ongoing Generalized System of Preferences (GSP) reviews of countries, including Brazil, Kazakhstan, Lebanon, Pakistan, Russia, and Uzbekistan.

Global Scope of Counterfeiting and Piracy

Global IPR theft and trade in fakes have grown to unprecedented levels, threatening innovative and creative economies around the world. Counterfeiting and digital piracy remain areas of particular concern in this year's report. Counterfeiting has developed from a localized industry concentrated on the copying of high-end designer goods into a massive, sophisticated global business involving the manufacturing and sale of counterfeit versions of a vast array of products, including soaps, shampoos, razors, batteries, cigarettes, alcoholic beverages, golf clubs, automobile parts, motorcycles, medicines, and health care products, to name a few. Counterfeiting of such a broad range of products on a global scale affects more than just the companies that produce legitimate products. While it has a direct impact on the sales and profits of those companies, counterfeits also hurt the consumers who waste their money and sometimes put themselves at risk by purchasing fake goods. It also hurts the countries concerned by decreasing tax revenues and deterring investments. In addition, counterfeiters generally pay neither taxes nor duties, and do not comply with basic manufacturing standards for the health and safety of workers or product quality and performance. Piracy of copyrighted products in digital, print (e.g., books, journals, and other printed materials), and other analog formats, as well as counterfeiting of all types of trademarked products, have grown rapidly because these illegal activities offer enormous profits and little risk for the criminal element of society. Criminals can enter into the counterfeiting and pirating business with little capital investment, and even if caught and charged with a crime, the penalties actually imposed in many countries are so low that they offer no deterrent.

The global scope of piracy and counterfeiting requires stronger and more effective border enforcement to stop the import, export, and transit of pirated and counterfeit goods. For example, effective enforcement efforts are needed at the national and local levels in free trade zones in Belize, Panama, and the United Arab Emirates.

This is why USTR seeks through our FTAs and our bilateral consultations to maximize the deterrent effect of remedies, including requirements that pirated and counterfeit products, as well as the equipment used to make them, are seized and destroyed. The economic damage caused by counterfeiting to the legitimate companies whose products are counterfeited is enormous. Losses to U.S. industries alone are estimated at $200-$250 billion per year.

STOP! Initiative

USTR is actively engaged in implementing the Administration's Strategy Targeting Organized Piracy (STOP!) initiative. Announced in October 2004, STOP! brings together all the major players – the federal government, private sector and trade partners – to take concerted action in

cracking down on piracy and counterfeiting. The initiative is part of an effort to enhance coordination among all relevant U.S. Government agencies and U.S. trading partners to tackle this global problem. As part of STOP!, USTR is advocating international adoption of best practices guidelines incorporating enhanced enforcement disciplines drawn from the IP chapters of recent FTAs. USTR is also introducing in multilateral fora new initiatives to improve the global intellectual property environment that will aid in disrupting the operations of pirates and counterfeiters. Key initiatives are currently underway in the G-8, Organization for Economic Cooperation and Development (OECD), and the Asia-Pacific Economic Cooperation (APEC) forum. As part of the STOP! Initiative, USTR requests recommendations from interested parties on criteria to be used in the Special 301 Report with respect to individual businesses that have been found to have significantly infringed IPR.

Transshipment and Transiting of Goods

"Transshipment" and "in transit goods" are expanding problems that USTR highlights in this year's Special 301 Report. Transshipped goods enter the customs territory of a country, are transferred from one importing means to another, and then leave from the same port for another destination. In transit goods, on the other hand, move "under customs control" from one customs office to another customs office. In transit goods may move entirely within one customs territory or may cross borders from one customs territory to another customs territory. Frequently goods moving under one of these procedures will be "diverted" for consumption into the customs territory where they first arrive. Transshipped and in transit goods pose a high risk for counterfeiting and piracy because those customs procedures may be used to disguise the true country of origin of the goods or to enter goods into customs territories where border enforcement for transshipped or in transit goods is known to be weak with the intention of passing the goods through those customs territories to their destination. The Special 301 Report notes that transshipment or in transit goods are growing problems in Ukraine, Belize, Canada, Latvia, Lithuania, Taiwan, and Thailand. We urge these countries to provide stronger intellectual property border enforcement protections, and the United States will work together with these countries to improve their IPR border enforcement systems.

Free Trade Zones

We are concerned with the growing problem of pirated and counterfeit goods moving through "free trade zones," which are geographic areas considered to be outside of a nation's customs territory for the purposes of collecting import duties and taxes. Free trade zones range in size from small commercial warehouses to complexes housing hundreds of businesses. Free trade zones are generally established by governments to promote legitimate trade and offer the advantage of providing a free trading environment whereby a minimum level of regulation is demanded of companies approved to operate within them. Permissible operations within free trade zones include preserving goods, preparing goods for shipping, and handling goods in order to improve their packaging or marketing to manufacturing processes. Free trade zones present a considerable risk, however, of serving as a conduit for counterfeit and pirated goods, and as a situs of manufacturing of IPR infringing goods. The United States has received complaints from U.S. industry regarding the Colon Free Zone in Panama, the Jebel Ali Free Zone in the United Arab Emirates, the Corozal Commercial Free Trade Zone in Belize, and the Manaus Free Trade

Zone in Brazil, among others. The United States urges all countries having free trade zones located within their territories to bring the operation of the free trade zones under the rule of law and its consistent application. The United States is working with Panama through the FTA negotiations to strengthen IPR enforcement in Panama's Free Zones.

Controlling Optical Media Production

Over the past year some of our trading partners, such as the Philippines, Poland, and Indonesia, have taken important steps toward implementing much-needed controls on optical media production in order to address and prevent future pirate activity. We have seen particular progress this year in the Philippines' enforcement of its optical media law. However, other countries urgently need to implement controls or improve existing inadequate measures, including India, Pakistan, Russia, Ukraine, Thailand, and Bulgaria, none of which have made sufficient progress in this regard. Some governments, such as those of Hong Kong and Macau, which implemented optical media controls in previous years, have clearly demonstrated their commitment to continue to enforce these measures. Malaysia is steadily improving its enforcement efforts, and Taiwan continues to make significant progress in providing improved IPR enforcement. The effectiveness of such measures is underscored by the direct experience of these governments in successfully reducing pirate production of optical media. We continue to urge our trading partners facing the threat of pirate optical media production within their borders to adopt similar controls or aggressively enforce existing regulations in the coming year.

Implementation of the WTO TRIPS Agreement

One of the most significant achievements of the Uruguay Round was the negotiation of the TRIPS Agreement, which requires all WTO Members to provide certain minimum standards of protection for patents, copyrights, trademarks, trade secrets, geographical indications, and other forms of intellectual property. The Agreement also requires countries to provide effective IPR enforcement. The TRIPS Agreement is the first broadly-subscribed multilateral intellectual property agreement that is subject to mandatory dispute settlement provisions.

Developed countries were required to fully implement the TRIPS Agreement as of January 1, 1996, while developing countries were given a transition period for many obligations until January 1, 2000. Ensuring that developing countries are in full compliance with the TRIPS Agreement obligations now that this transition period has come to an end is one of this Administration's highest IPR priorities. The least-developed countries have until January 1, 2006 to implement the TRIPS Agreement, and the United States looks forward to the successful completion of this transition. However, in order to address the concerns raised by the least-developed countries, the United States suggested, and all other WTO members agreed, to extend the transition period for ten years, until 2016, for the least-developed countries to implement their TRIPS obligations for patent and data protection for pharmaceutical products.

Developing countries continue to make progress toward full implementation of their TRIPS obligations. Nevertheless, certain countries are still in the process of finalizing implementing legislation and establishing adequate IPR enforcement mechanisms. Every year the U.S. Government provides extensive technical assistance and training on the implementation of the

TRIPS Agreement to a large number of U.S. trading partners. Such assistance is provided by a number of U.S. Government agencies, including the U.S. Patent and Trademark Office, the U.S. Copyright Office, the Department of State, the U.S. Agency for International Development, U.S. Customs and Border Protection, the Department of Justice, and the Department of Commerce. This assistance is provided on a country-by-country basis, as well as in group seminars, including those co-sponsored with the World Intellectual Property Organization (WIPO) and the WTO. In addition, U.S. industry is actively involved in providing specific enforcement-oriented training in key markets around the world. Technical assistance involves the review of, and drafting assistance on, laws concerning intellectual property and enforcement. Training programs usually cover the substantive provisions of the TRIPS Agreement, including IPR enforcement. The United States will continue to work with WTO Members and expects further progress in the near term to complete the TRIPS implementation process. However, in those instances in which additional progress is not achieved, the United States will consider other means of encouraging implementation, including the possibility of dispute settlement consultations.

One of the key implementation priorities that we have focused on in this year's review is the implementation of Article 39.3 of the TRIPS Agreement, which requires WTO Members to protect test data submitted by companies to health authorities against "unfair commercial use" for pharmaceutical and agricultural chemical products.[1]

Most countries, including the United States, impose stringent regulatory testing requirements on companies seeking to market a new drug or agricultural chemical product. Many countries have recognized, however, the value of allowing abbreviated approval procedures for "second-comers" seeking to market a product identical to one that has already been approved. Generally, these second applicants may be required to demonstrate the bioequivalence of their products with the product of the first company, and will be allowed to rely on the test data, rather than repeat all of the expensive and laborious clinical tests conducted by the first company to prove the safety of the product.

However, because of the considerable effort involved in producing the safety and efficacy data needed to obtain marketing approval, the TRIPS Agreement requires that the original applicant must receive protection for that data against unfair commercial use. Accordingly, the United States and other countries provide a period of protection during which second-comers may not rely on the data submitted by the innovative company to obtain approval for their copies of the product. This means that, during the period of exclusivity, the data provided by the originator cannot be relied upon by regulatory officials to approve similar products. This period of protection is five years in the United States and six to ten years in the EU Member States. Other countries that provide a period of protection against reliance on data include Australia, China, Japan, Jordan, Korea, Mexico, New Zealand, and Switzerland. We commend Bulgaria on its recent implementation of data protection for pharmaceutical and agricultural chemical products. We urge all WTO members to swiftly complete their implementation of TRIPS Article 39.3, including certain Andean countries, Israel and Turkey.

[1] Such data is typically required by health authorities in order to establish the safety and efficacy of a drug, and to obtain government approval to market the drug.

Internet Piracy and the WIPO Internet Treaties

The Internet has undergone explosive growth and, coupled with the increased availability of broadband connections, serves as an extremely efficient global distribution network for pirated products. The explosive growth of copyright piracy on the Internet is a serious problem. We are continuing to work with other governments, and consult with U.S. industry, to develop the best strategy to address Internet piracy. An important first step in the fight against Internet piracy was achieved at WIPO when it concluded two copyright treaties in 1996: the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT) (collectively, the "WIPO Internet Treaties"). The WIPO Internet Treaties help to raise the minimum standards of intellectual property protection around the world, particularly with respect to Internet-based delivery of copyrighted works. They clarify exclusive rights in the on-line environment and specifically prohibit the devices and services intended to circumvent technological protection measures for copyrighted works. Both treaties entered into force in 2002. As of April 29, 2005, there are 51 members of the WCT and 49 members of the WPPT; this number will rise significantly when the EU joins, which, by internal arrangement, is expected to occur when the last five EU Member States complete their implementation processes. Even more countries have implemented in their national laws key provisions of these treaties even though they have not yet formally ratified them. At this point, therefore, the WIPO Internet Treaties are now part of the international IPR legal regime and represent the consensus view of the world community that the vital framework of protection under existing agreements, including the TRIPS Agreement, should be supplemented to eliminate any remaining gaps in copyright protection on the Internet that could impede the development of electronic commerce.

In order to realize the enormous potential of the Internet, a growing number of countries are implementing the WIPO Internet Treaties and creating a legal environment conducive to investment and growth in Internet-related businesses and technologies. In the competition for foreign direct investment, these countries now hold a decided advantage. We urge other governments to ratify and implement the two WIPO Internet Treaties.

Other Initiatives Regarding Internet Piracy

We are seeking to heighten the standards of protection for intellectual property, by incorporating standards of the WIPO Internet Treaties as substantive obligations in the bilateral and regional trade agreements that we negotiate. Moreover, our proposals in our FTA negotiations will continue to include up-to-date copyright and enforcement obligations to reflect the technological challenges we face today as well as those that may exist at the time negotiations are concluded.

Government Use of Software

In October 1998, the United States announced an Executive Order directing U.S. Government agencies to maintain appropriate and effective procedures to ensure legitimate use of software. In addition, USTR was directed to undertake an initiative to work with other governments, particularly those in need of modernizing their software management systems or about which concerns have been expressed, regarding government use of illegal software.

The United States has achieved considerable progress under this initiative. Countries and territories that have issued decrees mandating the use of only authorized software by government ministries include Bolivia, Chile, China, Colombia, Costa Rica, the Czech Republic, France, Greece, Hong Kong, Hungary, Ireland, Israel, Jordan, Korea, Lebanon, Macau, Paraguay, Peru, the Philippines, Spain, Taiwan, Thailand, Turkey, and the United Kingdom. The United States is pleased that these governments have recognized the importance of setting an example in this area and expects that these decrees will be fully implemented. The United States looks forward to the adoption of similar decrees, with effective and transparent procedures that ensure legitimate use of software, by additional governments in the coming year.

Intellectual Property and Health Policy

The Administration is dedicated to addressing the serious health problems, such as HIV/AIDS, afflicting African and other least-developed countries. The United States is firmly of the conviction that intellectual property protection, including for pharmaceutical patents, is critical to the long term viability of a health care system capable of developing new and innovative lifesaving medicines. Intellectual property rights are necessary to encourage rapid innovation, development, and commercialization of effective and safe drug therapies. Financial incentives are needed to develop new medications; no one benefits if research on such products is discouraged.

At the same time, the United States is committed to the principle that international obligations such as the TRIPS Agreement have sufficient flexibility to allow countries, particularly developing and least-developed countries, to address the serious public health problems that they face.

At the WTO Doha Ministerial in November 2001, WTO Ministers issued a separate Declaration on the TRIPS Agreement and Public Health, acknowledging the serious public health problems afflicting Africa and other developing and least-developed countries, especially those resulting from HIV/AIDS, malaria, tuberculosis, and other epidemics. Ministers agreed that intellectual property rules contain flexibilities to meet the dual objectives of, on the one hand, meeting the needs of poor countries without the resources to pay for cutting edge pharmaceuticals and, on the other hand, ensuring that the patent rights system continues to promote the development and creation of new lifesaving drugs.

The United States proposed, and all WTO members agreed, that the Doha Declaration should provide an additional ten year transition period (until 2016) for least-developed countries to implement the pharmaceutical-related provisions of the TRIPS Agreement. This extended transition period balances the interests of intellectual property rights holders and the needs of the least-developed countries.

In addition, in paragraph 6 of the Declaration, Ministers recognized that WTO Members with "insufficient or no manufacturing capacities in the pharmaceutical sector" could have difficulty using the compulsory licensing provisions of the TRIPS Agreement and directed the TRIPS Council to find an expeditious solution to this problem. In December 2002, the United States

announced a framework to ease WTO rules to allow countries in need to import life-saving drugs.

On August 30, 2003, the WTO General Council adopted the TRIPS/health "solution," which is comprised of a Decision and an accompanying Chairman's Statement that sets out the shared understandings of WTO Members on how the Decision should be interpreted and applied. Under the solution, Members are permitted, in accordance with specified procedures, to issue compulsory licenses to export pharmaceutical products to countries that cannot produce drugs for themselves.

The United States strongly supports effective and appropriate use of the TRIPS/health solution to facilitate access to life-saving medicines by countries in need. The United States would be willing to discuss the need to provide technical assistance if some Members encounter difficulties in implementing or utilizing the solution.

In fact, the United States has already taken steps to ensure that the solution can be implemented. For example, in July 2004, the United States reached an agreement with Canada to ensure that NAFTA's provisions will not impede implementation of the TRIPS/health solution.

The TRIPS Council is under instructions to incorporate the solution into an amendment of the TRIPS Agreement. The United States supports an amendment that reflects the agreement reached in August 2003, and will remain committed to working with the other Members to reach a consensus for an amendment as expeditiously as possible. In order to move towards an amendment, the United States submitted a paper at the March 2005 meeting of the WTO TRIPS Council expressing support for the amendment and setting out a simple and effective approach to do so. The solution will continue to be available as a WTO waiver until an amendment is finalized.

In the recent Free Trade Agreements with CAFTA-DR, Morocco, and Bahrain, the United States has clarified that the intellectual property provisions in the agreements do not stand in the way of measures necessary to protect public health. Specifically, the United States has confirmed that the intellectual property chapters of the FTAs do not affect the ability of the United States or our FTA partners to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. The United States has also made clear that the intellectual property chapter of the FTAs will not prevent effective utilization of the TRIPS/health solution.

Sustainable Innovation

The ability of innovative industries to continue to develop new products depends largely upon two factors: (1) a strong and effective intellectual property system; and (2) the capacity to market new products effectively during the period of time when the exclusive intellectual property rights exist. Although intellectual property protection is a necessary condition for encouraging innovation in all sectors, it is the ability to market products effectively that provides the incentive for continued innovation and generates the returns on investment necessary to fund new research

and development and production of new products. This cycle of innovation produces significant economic and social benefits by accelerating economic growth and raising standards of living.

The Special 301 process focuses on analyzing the intellectual property protection and enforcement of our trading partners, and this has been the primary subject of industry comments. In addition, however, industries – and in particular the pharmaceutical industry – have focused attention on regulatory barriers that impede their ability to sustain the cycle of innovation and may inhibit the availability of new, ground-breaking products. These types of regulatory barriers include, for example, non-transparent administrative regimes; decision-making that lacks a scientific basis; and cumbersome and lengthy drug listing and other administrative processes.

In the conference report accompanying the U.S. Medicare Prescription Drug, Improvement and Modernization Act of 2003 (House Report 108-391), the Congress directed the Secretary of Commerce, in consultation with the International Trade Commission, the Secretary of Health and Human Services and the United States Trade Representative, to prepare a report regarding trade in pharmaceuticals designed in part to provide an "[e]stimate of the impact . . . price controls, intellectual property laws, and other such measures have on fair pricing, innovation, generic competition, and research and development in the United States and each [OECD] country identified." Regarding pharmaceutical price controls, the conference report directed the Administration to examine drug pricing practices of OECD countries and assess, among other things, "whether those practices utilize nontariff barriers with respect to trade in pharmaceuticals."

The conference report directive reflects a concern in the United States that the regulatory practices of many other countries may be slowing the development of the next generation of life-saving drugs for use worldwide. Implicit in this proposition is a concern that, by adopting such mechanisms, foreign countries are not contributing adequately to research and development for new life-saving medicines.

The U.S. Department of Commerce released its report in December 2004, and found that regulatory practices in the OECD countries studied are reducing the funds available globally for pharmaceutical research and development and the creation of new, innovative life-saving drugs, and are driving up prices for generic pharmaceuticals. These practices include price controls, approval delays and procedural barriers, non-transparent processes, restrictions on dispensing and prescribing, and low reimbursement levels. The study also determined that addressing such practices in OECD countries would result in increased research and development in the pharmaceutical sector, development of three to four new innovative drugs each year, and lower prices of generic drugs.

The United States has worked with countries such as Australia, Japan, Korea, and China to address these types of issues and will continue to do so. Regarding Australia, our FTA has allowed us to address key issues relating to transparency and accountability that will improve market access for U.S. pharmaceutical companies. The Australian Government is following through on its commitments in this agreement, by setting up a transparent review system for appealing pharmaceutical listing decisions and working with U.S. officials to prepare for the first meeting of the Medicines Working Group.

With respect to Japan, pharmaceutical and medical device issues are an integral part of the Administration's regulatory reform work. The United States has made steady progress in improving transparency in this sector, ensuring that foreign pharmaceutical and medical device manufacturers have meaningful opportunities to provide input into important regulatory matters, and facilitating the introduction of innovative new pharmaceuticals and medical devices into the Japanese market.

Separately, the Administration has had a longstanding dialogue with Korea on pharmaceutical issues and, as a result, has seen considerable improvement over the past decade in U.S. pharmaceutical companies' access to the Korean market. The Administration is continuing these consultations and has made recent progress, focusing on further improvements in market access and transparency, and ensuring competition in this sector of the Korean market. In January, Korea's Health Insurance Reimbursement Agency began providing written justifications for its decisions on pricing and listing of new drugs.

With respect to China, the Administration has pressed the Government of China to price innovative drugs fairly and to add new drugs to its national formulary, which controls access to medicines for China's nearly 1.3 billion people. The Administration also is pressing the Government of China to address the production and export of counterfeit pharmaceuticals that both endanger lives and disrupt markets.

The Administration is examining other countries' practices including, for example, those of Canada and Germany. Canada's Patented Medicine Prices Review Board (PMPRB) regulates patented pharmaceutical products, but not generic products. The PMPRB sets the launch price for drugs when they enter the market and then limits further increases. Under the PMPRB's pricing system, the price for a new innovative drug cannot exceed the median of prices in seven developed countries that Canada uses as a basis for comparison (the United States, the United Kingdom, France, Germany, Sweden, Switzerland, and Italy). In addition, Canada's pharmaceutical approval process is protracted and the procedures for provincial listing decisions can be lengthy and inconsistent.

Germany is in the process of implementing significant changes to its reference pricing system, which could impact the development and availability of innovative pharmaceuticals in that country. In 2004, the German Government required innovative drug makers to pay a 16 percent rebate on patent-protected pharmaceuticals (i.e., a mandatory price cut on patented-drug producers, but not generics). On January 1, 2005, Germany reduced the rebate to 6 percent, but put in place a reference pricing regime for patent-protected medicines. This new regime combines for the first time patent-protected and off-patent pharmaceuticals in "jumbo" reference pricing groups. This approach arbitrarily diminishes the value of innovative medicines by equating them with generic medicines for purposes of government reimbursement. Of the 12 new reference pricing groups established, four are jumbo groups, covering a wide range of innovative patented medicines. It has been estimated that reference price cuts for some of the most innovative drugs in the new jumbo groups are as much as 40 percent, which has the potential to affect the availability of such novel medicines and may lead to an increased burden on American patients in paying for the newest ground-breaking drugs. Although manufacturers

of patented pharmaceuticals can seek to have certain patented drugs excluded from the jumbo groups if they demonstrate that such products provide "significant therapeutic improvement," only two patented drugs, produced by German and Swiss manufacturers, have been excluded and the process for determining whether a drug provides significant therapeutic improvement lacks transparency. The only two requests by U.S. manufacturers to exclude patented products from the new jumbo groups were rejected. The German Government may put additional classes of drugs under its jumbo reference pricing system later this year.

It is important to understand how these types of regulatory regimes affect patient welfare, research and development funding, and innovation. The Department of Health and Human Services, along with USTR and other U.S. health and economic policy agencies, are jointly approaching individual OECD countries through bilateral consultations, such as with Germany and Canada. USTR, in close coordination with U.S. health and other economic policy agencies, also will lead efforts with such countries in FTA negotiations, such as with Australia. These discussions are tailored to the specific circumstances of each country, but utilize a common set of principles aimed at advancing U.S. interests, including promoting innovation in the pharmaceutical sector and enhanced patient access to innovative and generic drugs. These efforts, coupled with the ongoing analysis of global intellectual property protection through the Special 301 process, should provide a more complete picture of the impact of regulatory and intellectual property protection regimes on innovation and offer potential opportunities to encourage continued strong development worldwide by innovative industries, such as the pharmaceutical sector.

WTO Dispute Settlement

Dispute settlement efforts this year continue to focus on resolving disputes that were announced through previous Special 301 determinations, using the full range of tools available. These tools include informal consultations and settlement, which can be more efficient and are therefore the preferred manner of resolving disputes, or where those are unsuccessful, full utilization of the dispute settlement process.

At the conclusion of the 1999 Special 301 review, the United States initiated dispute settlement consultations concerning the European Union's (EU) regulation on food-related geographical indications (GIs), based on concerns that the regulation was inconsistent with the EU's TRIPS Agreement obligations. These consultations were based on the United States' long-standing complaint that the EU GI system discriminates against foreign products and persons – notably by requiring that EU trading partners adopt an "EU-style" system of GI protection – and provides insufficient protections to trademark owners. Because those consultations failed to resolve the matter, on August 18, 2003, the United States requested the establishment of a panel, and panelists were appointed on February 23, 2004.

On April 20, 2005, the WTO Dispute Settlement Body ("DSB") adopted a panel report ruling in favor of the United States that the EU GI regulation is inconsistent with the EU's obligations under the TRIPS Agreement and the General Agreement on Tariffs and Trade 1994. In the panel report adopted by the DSB, the panel agreed that the EU's GI regulation impermissibly discriminates against non-EU products and persons. The panel also agreed with the United

States that Europe could not, consistent with WTO rules, deny U.S. trademark owners their rights; it found that, under the regulation, any exceptions to trademark rights for the use of registered GIs were narrow, and limited to the actual GI name as registered. The DSB recommended that the EU amend its GI regulation to come into compliance with its WTO obligations.