

2006 SPECIAL 301 REPORT

EXECUTIVE SUMMARY

The 2006 “Special 301” annual review examines in detail the adequacy and effectiveness of intellectual property rights (IPR) protection in 87 countries. Based on a lengthy process of information gathering and analysis, the United States Trade Representative (USTR) has identified 48 countries that are designated in the categories of Priority Watch List, Watch List, or Section 306 Monitoring. The Special 301 Report reflects the Administration’s resolve to take consistently strong actions under the Special 301 provisions of the Trade Act of 1974 (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 actions announced today result from close consultations with affected industry groups, other private sector representatives, Congressional leaders, foreign governments, and numerous agencies within the United States Government, and demonstrate the Administration's commitment to use all available methods to resolve IPR issues.

Addressing weak IPR protection and enforcement, particularly in China and Russia, continues to be one of the Administration’s top priorities. Although this year’s Special 301 Report shows positive progress in many countries, rampant counterfeiting and piracy problems continue to plague both China and Russia, indicating a critical need for stronger intellectual property protection in China and Russia.

With respect to China, this year’s Special 301 Report describes the United States’ plan to continue heightened scrutiny of China by maintaining China on the Priority Watch List and continuing Section 306 monitoring, as well as stepping up consideration of World Trade Organization (WTO) dispute settlement options. In addition, the United States will scrutinize IPR protection and enforcement at China’s provincial level through an unprecedented special provincial review to be conducted in the coming year.

With respect to Russia, the Special 301 Report describes the United States’ on-going IPR discussions with Russia, outlines the United States’ efforts to bring Russia’s IPR regime in line with international standards, notes some progress in Russia’s recent efforts to combat IPR piracy and counterfeiting, and announces continued heightened scrutiny of Russia by maintaining Russia on the Priority Watch List. The United States will be monitoring closely China’s and Russia’s IPR activities throughout the coming year.

In addition to China and Russia, the Special 301 Report sets out significant concerns with respect to such trading partners as Argentina, Belize, Brazil, Egypt, India, Indonesia, Israel, Lebanon, Paraguay, Turkey, Ukraine, 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 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

In this year's review, USTR devotes special attention to the need for significantly improved enforcement against counterfeiting and piracy. The United States places 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 reducing the counterfeiting of trademarked goods. There are high rates of piracy and counterfeiting in many countries, including in China, India, and Russia. In addition, USTR continues to focus on other critically important issues, including Internet piracy, counterfeit pharmaceuticals, transshipment of pirated and counterfeit goods, requiring authorized use of legal software by government ministries, proper implementation of the TRIPS Agreement by developed and developing country WTO members, and full implementation of TRIPS Agreement standards by new WTO members at the time of their accession.

Over the past year, many developing countries and newly acceding WTO members have made progress toward implementing their TRIPS Agreement 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 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.

Positive Progress

There has been significant positive progress on IPR protection and enforcement in several countries this past year. For example, Ukraine passed and implemented legislation to combat pirate production in optical media factories. Brazil made significant progress during the past year on copyright enforcement, specifically by adopting a National Action Plan to enforce copyrights and reduce piracy, drafting IPR legislation, increasing seizures and prosecutions, and developing strong public awareness campaigns to fight piracy. Pakistan also made significant progress by closing down numerous pirate optical disc production plants, establishing a Pakistan Intellectual Property Organization to centralize enforcement, and increasing border enforcement efforts, as well as increasing the number of raids, seizures, and arrests of IPR infringers.

Several other countries in Asia also have made significant progress on IPR issues in the past year. For example,

- Taiwan issued the first conviction to a defendant for copyright infringement over the Internet through a peer-to-peer file sharing service.
- Indonesia has made progress in combating optical disc piracy in retail shops, and has begun to increase the numbers of raids against pirate optical media production plants, seizures of pirated goods and manufacturing equipment, and arrests of IPR infringers.
- Malaysia took steps to combat pirate optical disc production by increasing the numbers of raids against illegal factories, seizing pirated goods and manufacturing equipment, and increasing arrests of copyright pirates.

- The Philippines made progress by taking steps to combat pirate production in plants, including increasing the number of raids and enforcement actions.
- The Republic of Korea established a Copyright Protection Center and increased enforcement against institutions using illegal software.

In addition, USTR is pleased to announce that the following countries are being removed from the Watch List because of progress on IPR issues this past year:

- Azerbaijan was removed from the Watch List due to IPR enforcement progress.
- Kazakhstan was removed from the Watch List due to progress on copyright enforcement.
- The Slovak Republic was removed from the Watch List due to progress on protection against unfair commercial use of undisclosed test and other data submitted by pharmaceutical companies seeking marketing approval for their products.
- Uruguay was removed from the Watch List due to progress on copyright enforcement.

The United States commends this positive progress by our trading partners, and urges each one to set a positive example by continuing to take strong IPR enforcement actions to combat piracy and counterfeiting. The United States will continue to work with these and other countries to achieve further improvements in IPR enforcement during the coming year.

Free Trade Agreements and Implementation

The United States is committed to a policy of promoting stronger protection of intellectual property rights. In this regard, the United States is advancing the protection of these rights through a variety of mechanisms, including the negotiation of free trade agreements (FTAs). The intellectual property chapters of U.S. FTAs establish high standards for intellectual property protection for copyright works, trademarks, and patents, and additionally provide strong rules for enforcement.

The United States is pleased that recently concluded FTAs, including the Bahrain FTA, Oman FTA, the Peru Trade Promotion Agreement, the Colombia Trade Promotion Agreement, and the Central America-Dominican Republic Free Trade Agreement (CAFTA-DR) (with Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic), will strengthen the protection of IPR in those countries. The United States also is seeking high levels of IPR protection and enforcement in the FTAs that are currently under negotiation with Panama, Thailand, the Southern Africa Customs Union, Ecuador, the United Arab Emirates, and in the ongoing negotiation of a Free Trade Area of the Americas. The United States will also seek strong IPR protection and enforcement in the recently announced FTA negotiations with the Republic of Korea and Malaysia. Another opportunity the United States uses 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.

In addition, once an FTA is concluded, the United States works closely with our trading partners to achieve appropriate implementation of FTA obligations in domestic law. The United States

engaged in this process over the past year with Australia, Singapore, Morocco, CAFTA-DR parties, Bahrain, and Oman. For example, in 2005 Morocco completed the implementation of its IPR obligations in the United States-Morocco FTA, and as a result, Morocco has comprehensive IPR legislation which provides a high standard of IPR protection.

Generalized System of Preferences (GSP) reviews

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 in connection with its implementation of trade preference programs, such as the ongoing Generalized System of Preferences (GSP) reviews of countries. This year, because of significant progress in improving enforcement, USTR was pleased to announce the conclusion of the GSP reviews of Brazil, Kazakhstan and Pakistan. In addition, in January 2006, USTR restored GSP benefits to Ukraine because of progress in combating illegal optical disc production, including the passage of new legislation. USTR will continue to review the IPR practices of Russia, Lebanon and Uzbekistan under the ongoing GSP reviews of those countries.

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 adoption of best practices guidelines for enforcement. In 2005, USTR led interagency teams to meet with a number of key trading partners, including Japan, Korea, Hong Kong, Singapore, UK, France, Germany, and the European Union, to establish greater cooperation on IPR enforcement. This year, USTR will continue these efforts to strengthen IPR laws and enforcement and create an international alliance against counterfeiting and piracy.

As part of this effort, USTR, in coordination with other agencies, is introducing new initiatives in multilateral fora to improve the global intellectual property environment that will aid in disrupting the operations of pirates and counterfeiters. Key initiatives have gained endorsement and are undergoing implementation in the G-8, the US-EU Summit, the Organization for Economic Cooperation and Development (OECD), and the Asia-Pacific Economic Cooperation (APEC) forum.

At the November APEC Ministerial, APEC Leaders adopted best practices guidelines to improve border enforcement, protect digital copies and combat internet piracy. USTR is spearheading an effort to have APEC leaders endorse additional IPR guidelines that would keep supply chains free of pirated and counterfeit goods and improve IPR public awareness campaigns throughout the Asia-Pacific region.

Global Scope of Counterfeiting and Piracy

Global IPR theft and trade in fakes and pirated materials have continued to grow, threatening innovative and creative economies around the world. 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. Counterfeiters generally pay neither taxes nor duties, and counterfeiters often do not comply with basic manufacturing standards for the health and safety of workers or product quality and performance. Piracy of copyright products in digital, print (e.g., books, journals, and other printed materials), and other analog formats (including movies, music, business software, entertainment software, and books), 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.

Counterfeit Pharmaceuticals

The manufacture and distribution of counterfeit pharmaceuticals is an increasing problem that poses special concerns because of its health and safety risks. The United States notes its concern with the proliferation of counterfeit pharmaceutical manufacturing in China and Russia, and the sale and distribution of counterfeit pharmaceuticals in many countries.

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. Through bilateral consultations and our FTAs, USTR works 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.

Notorious Markets

Global piracy and counterfeiting thrive in part due to large marketplaces that deal in infringing goods. Information reviewed in this year's Special 301 process points to the following virtual and physical markets as examples of marketplaces that have been the subject of enforcement action, or may merit further investigation for possible IPR infringements, or both. The list represents a selective summary of information reviewed during the Special 301 process; it is not a finding of violations of law.

Virtual Markets

www.allofmp3.com (Russia). Industry reports that allofmp3.com is the world's largest server-based pirate music website. Allofmp3.com is currently under criminal investigation by Russian authorities. Efforts to shut down the site have so far been unsuccessful.

Baidu (China). Industry has identified Baidu as the largest of an estimated seven or more China-based "MP3 search engines" offering deep links to song files for downloads or streaming. Baidu has been the target of infringement actions. Notably, in September 2005 the People's Court of Haidian District in Beijing reportedly ordered Baidu to pay RMB 68,000 (\$8,400) to a music company for unauthorized downloads. Baidu has reportedly appealed.

Kuro (Taiwan). In September 2005, managers of Kuro, a peer-to-peer service, were found guilty along with a subscriber of criminal copyright infringement and sentenced to prison terms. In the 2005 Special 301 Report, the United States encouraged Taiwan to improve efforts toward effectively combating increasing levels of Internet piracy.

Physical Markets

Xiangyang Market (Shanghai, China). In early 2006, the Shanghai Municipal Government said it would close this market on grounds of rampant sale of counterfeit fashion and apparel products. More recently, authorities pushed the closure date back to June 30, 2006. The United States welcomes commitments to close Xiangyang Market, and will monitor their implementation. Authorities must remain alert to the possibility that vendors of infringing products may seek to migrate their operations to other Shanghai markets, or to the Internet.

Silk Street Market (Beijing, China). Industry has cited Beijing's Silk Street Market as "perhaps the single biggest symbol of China's IP enforcement problems." In 2005, authorities began to pressure the landlords of Silk Street Market and other major retail and wholesale markets in Beijing to improve IPR compliance. In contrast to Shanghai's Xiangyang Market, however, authorities have not said they would close down the Silk Street Market. Trademark owners filed civil claims in mid-2005 against the landlord, Beijing Xiushui Haosen Clothing Co. Ltd. In December 2005, the Beijing No. 2 Intermediate Court's IP Tribunal decided five cases in favor of the right holders, imposing liability on the landlords for failing to halt infringements; Beijing's High Court recently upheld that decision.

Yiwu Wholesale Market (Yiwu, China). Yiwu Wholesale Market reportedly sells approximately 410,000 different items, mostly consisting of bulk sales of small consumer goods. Market officials recently estimated receiving approximately 400 complaints of IPR violations from buyers in 2005. Local officials have acknowledged certain problems and stressed their commitment to IPR enforcement.

Gorbushka, Rubin Trade Center, Tsaritsino, and Mitino (Moscow, Russia). In November 2005, a large Ministry of Interior operation reportedly resulted in police raids at numerous markets, including Gorbushka and Mitino. Industry previously reported that a closure of the

Gorbushka market resulted in migration of vendors to the nearby Rubin Trade Center. Industry reports infringement problems at newer markets on the outskirts of Moscow, including Tsaritsinio and Mitino. A raid against the Tsaritsinio market in January 2005 reportedly resulted in the commencement of five criminal investigations.

Tri-Border Region (Paraguay, Argentina, and Brazil). The Tri-Border Region of Paraguay, Argentina, and Brazil has a longstanding reputation as a hotbed of piracy and counterfeiting of all kinds of products. The U.S. Government is funding a training project through which U.S. Department of Justice and U.S. Department of Homeland Security officials will train prosecutors, police, and customs officials from the Tri-Border Region to combat intellectual property crime.

Stand Center, “25 de Marco” Shopping Center, and Promocenters (Sao Paulo, Brazil). In late 2005, over 1,500 Brazilian police and other law enforcement personnel reportedly raided these huge, well-known markets. Acknowledging that the effect on sales of pirated and counterfeit products from such raids is temporary, local enforcement and fiscal officials have pledged continued actions.

Tepito, Plaza Meave, Eje Central, Lomas Verdes, and Pericoapa Bazaar (Mexico City), CAPFU (Puebla, Mexico), and San Juan de Dios (Guadalajara, Mexico). An estimated 50,000 vendors sell IPR products in Mexico’s ubiquitous, unregulated street markets. Past police raids on such markets have sometimes been met with violent resistance, requiring large contingents of security personnel. Video game right holders reported raids on Pericoapa Bazaar in May and December 2005, as well as a raid at Plaza Meave near Mexico City in December.

Transshipment and Transiting of Goods

“Transshipment” and “in transit goods” pose growing IPR problems. Transshipped goods and in transit goods enter the customs territory of a country intended to be sent to another destination; such goods are sometimes “diverted” for consumption in the customs territory through which they are shipped. Transshipped and in transit goods pose a high risk for counterfeiting and piracy because 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. Transshipment or in transit goods are significant problems in Belize, Canada, Latvia, Lithuania, Paraguay, Ukraine and United Arab Emirates, among others. The United States urges these countries to provide stronger border enforcement of intellectual property rights. The United States pledges to work together with these countries to improve their IPR border enforcement systems.

Controlling Optical Media Production

Over the past year, some trading partners, such as Ukraine, Brazil, Pakistan, and the Philippines have taken important steps toward implementing much-needed controls on optical media production in order to address and prevent future pirate activity. However, other countries urgently need to implement controls or improve existing inadequate measures. Such countries include India, Thailand, and Russia, which have not made sufficient progress in this regard. In

contrast, Indonesia has begun to improve enforcement efforts, and Malaysia steadily continues to improve its enforcement efforts. Vietnam has agreed that optical disc regulation and its enforcement is an important method of attacking the problem there. The United States continues to urge its trading partners facing pirate optical media production within their borders to adopt similar controls or aggressively enforce existing regulations in the coming year.

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. The Administration is continuing to work with other governments, and to 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 the World Intellectual Property Organization (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.

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. As of April 28, 2006, there are 58 members of the WCT and 57 members of the WPPT; this number will rise significantly when the EU Member States join. Other countries have implemented key provisions of the treaties in their national laws, without having yet formally ratified them. The WIPO Internet Treaties are now part of the international IPR legal regime and represent a majority world community view 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. The United States urges other governments to ratify and implement the two WIPO Internet Treaties.

Other Initiatives Regarding Internet Piracy

The United States is strengthening 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 the United States negotiates, as well as by seeking accession to those treaties as a substantive obligation. Moreover, the United States’ proposals in its FTA negotiations will continue to include up-to-date copyright and enforcement obligations to reflect contemporary technological challenges.

Government Use of Software

In October 1998, the United States announced an Executive Order directing United States Government agencies to maintain appropriate and effective procedures to ensure authorized use of legitimate 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 unauthorized use of software and use of illegal software.

The United States has achieved considerable progress under this initiative. Most recently, the United States welcomed the April 22, 2006 announcement by China that it will require computers to be pre-installed with licensed operating system software and government agencies to purchase only such computers. A number of countries and territories have issued decrees and other measures mandating the authorized use of only legitimate software by government ministries, some of which have yet to be fully implemented. Such countries 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 measures 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.

Implementation of the WTO TRIPS Agreement

The TRIPS Agreement, which requires all WTO members to provide certain minimum standards of intellectual property protection, as well as effective IPR enforcement, was one of the most significant achievements of the Uruguay Round. The TRIPS Agreement is the first broadly-subscribed multilateral intellectual property agreement that is subject to mandatory dispute settlement provisions.

Developed country members were required to implement the TRIPS Agreement fully as of January 1, 1996. Developing countries were given a transition period for many obligations until January 1, 2000. On November 29, 2005, the United States joined other WTO members in deciding to extend the deadline for least developed country members to comply with most remaining TRIPS provisions from January 2006 until July 2013. Recognizing the challenges faced by these countries, the United States worked closely with them and other WTO members to extend this date. The least developed country members in turn pledged to preserve the progress that some have already made toward TRIPS compliance. In addition, the least developed country members have until 2016 to implement their TRIPS obligations for patent and data protection for pharmaceutical products, as proposed by the United States at the Doha Ministerial. The United States looks forward to the successful completion of this transition.

Developing country members continue to make progress toward full implementation of their TRIPS obligations. Nevertheless, certain members are still in the process of finalizing

implementing legislation and many are still engaged in 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 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 as well as the enforcement provisions. 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.

The United States urges all WTO members to swiftly complete their TRIPS implementation process, as it believes that compliance with the minimum standards set forth in the TRIPS Agreement is important for ensuring social and economic development.

Intellectual Property and Health Policy

The Administration is dedicated to addressing the serious health problems, such as HIV/AIDS, afflicting least-developed countries in Africa and elsewhere. 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 also firmly of the view that international obligations such as those in 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 African and other developing and least-developed country members, 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.

At Doha, 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 country members 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 country members.

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 these WTO rules for 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 TRIPS/health 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.

On December 6, 2005, the WTO General Council agreed on an amendment to make the TRIPS/health solution reached in August 2003 a permanent part of the TRIPS Agreement. U.S. efforts in working with African nations and other developing country Members were instrumental to reaching this agreement. On December 16, 2005, the United States became the first WTO Member to formally notify the WTO that it had accepted the amendment. Other WTO Members now have until December 1, 2007 to accept the amendment. It will go into effect, for those Members that accept it, once two-thirds of the membership has accepted it. The August 2003 waiver will remain in place and available until the amendment is in force.

The TRIPS/health solution is a demonstration of how the WTO can work to address the needs of poor countries. 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 the provisions of the North American Free Trade Agreement (NAFTA) will not impede implementation of the TRIPS/health solution.

In recent free trade agreements with the parties to CAFTA-DR, Morocco, Bahrain, Oman, Peru and Colombia, 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.

Supporting Pharmaceutical Innovation

USTR has sought to eliminate market access barriers faced by U.S. pharmaceutical companies in many countries and to both provide for affordable health care today and support the innovation that assures improved health care tomorrow. In addition to direct and indirect government funding, a strong and effective intellectual property system is crucial to achieving these goals as are other policies that encourage innovation in the health technology sector.

In the United States, government action has focused on creating an environment that best encourages further innovation and yields a constant flow of new and innovative medicines to the market. The goal has been to ensure that consumers benefit from both technological breakthroughs as well as the competition that further innovation generates. The United States also relies on a strong generic pharmaceutical industry to increase competitive pressure to lower drug prices.

Historically, the Special 301 process has focused on the strength of intellectual property protection and enforcement by our trading partners. However, even where a country's IPR regime is adequate, price controls and regulatory and other market access barriers can serve to discourage the development of new drugs. These barriers can arise in a variety of contexts, including reference pricing, approval delays and procedural barriers to approvals, restrictions on dispensing and prescribing, and unfair reimbursement policies. Such measures have the potential to be nontransparent, as the criteria and rationale for certain pharmaceutical prices or reimbursement amounts are often not fully disclosed even to the pharmaceutical companies seeking to market their drugs. A 2004 U.S. Government study, led by the Department of Commerce, found that price controls and regulatory and other barriers diminish returns on pharmaceutical products, and reduce the amount of global pharmaceutical research and development below what it would otherwise be under market conditions, inhibiting the development of the next generation of life-saving drugs.

To address these issues, USTR and the Departments of Health and Human Services, Commerce, and State, formed a task force. This task force is working to engage our OECD trading partners on the most effective way to promote continued innovation in the pharmaceutical sector and enhanced access to innovative pharmaceuticals now and in the future. This task force is working to achieve these goals through FTA negotiations and the establishment of bilateral dialogues with key countries.

The United States addressed transparency and accountability of the Australian pharmaceutical reimbursement system in the Australia FTA, which went into effect in 2005. The FTA also created a United States-Australia Medicines Working Group for continued discussion of emerging bilateral concerns and health policy issues. The United States held the first meeting of this Working Group in January to review implementation of the pharmaceutical provisions of the FTA and to discuss ongoing issues of mutual concern

In February 2006, the United States and the Republic of Korea (Korea) announced their intent to launch FTA negotiations. 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. In 2005, for example, Korea's Health Insurance Reimbursement Agency began providing written justifications for new drug pricing and listing decisions. The United States Government will seek additional progress on priority issues, including ensuring competition, supporting innovation, and addressing market access and transparency issues, in the FTA negotiations, which the Administration is seeking to conclude by the end of the year.

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

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 Japan's market.

The United States also has established a constructive dialogue with Germany on policy goals and concerns related to health care. During these discussions, the two sides have exchanged views on how best to deal with challenges of balancing health care spending with other priorities and of providing affordable health care today with supporting the innovation that assures improved health care is available in the future. The United States also raised specific concerns related to Germany's reference pricing system for determining product reimbursement and the transparency of the German Government's decision-making process regarding pharmaceutical pricing. The two governments plan to continue this dialogue as the German Government considers future healthcare reform.

The United States continues to urge China to price drugs in a manner that appropriately values innovations and to add new drugs to its national formulary, which controls access to medicines for China. The Administration also is pressing China to address the production and export of counterfeit pharmaceuticals, which endanger lives.

During the coming year, the U.S. Government is seeking to establish similar dialogues with Poland, Italy, France, Canada, and other countries. The United States shares policy goals and concerns related to health care with these countries, including aging populations and rising health care costs. The United States also shares the objective of continued improvement in the health and quality of life of its citizens and delivering care in the most efficient and responsive way possible. The United States hopes these dialogues will help address specific concerns related to price controls, and regulatory and transparency issues as well as develop a constructive dialogue with these countries on health policy issues of mutual concern.

WTO Dispute Settlement

Dispute settlement efforts this year continue to focus on resolving disputes that were announced through previous Special 301 reviews and 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 resulted from 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, and the EC was given until April 3, 2006 to do so. On March 31, 2006, the EC published a revised GI Regulation that is intended to comply with the DSB recommendations and rulings. There remain some concerns with respect to this revised GI Regulation, however, which the United States has asked the EC to address, and the United States intends to continue monitoring this situation.

The United States, in cooperation with other WTO members, has also made innovative use of WTO tools other than dispute settlement. For instance, in October 2005, the United States, Japan, and Switzerland made simultaneous transparency requests to China under Article 63.3 of the TRIPS Agreement.