

## **EXECUTIVE SUMMARY**

### **Introduction**

The “Special 301” Report is an annual review of the global state of intellectual property rights (IPR) protection and enforcement, conducted by the Office of the United States Trade Representative (USTR) pursuant to Special 301 provisions of the Trade Act of 1974 (Trade Act). The 2007 Special 301 review process examines IPR protection and enforcement in 79 countries. Following extensive research and analysis, USTR designates 43 countries in this year’s Special 301 Report in the categories of Priority Watch List, Watch List, and/or Section 306 Monitoring status. This report reflects the Administration’s resolve to encourage and maintain effective IPR protection and enforcement worldwide.

The Special 301 designations and actions announced in this report are the result of close consultations with affected industry groups and other private sector representatives, foreign governments, Congressional leaders, and interagency coordination within the United States Government. This Administration is committed to using all available methods to resolve IPR-related issues and ensure that market access is fair and equitable for U.S. products.

The Administration’s top priorities this year continue to be addressing weak IPR protection and enforcement, particularly in China and Russia. Although this year’s Special 301 Report shows positive progress in many countries, rampant counterfeiting and piracy problems have continued to plague China and Russia, indicating a need for stronger IPR regimes.

With respect to Russia, the Special 301 Report describes the Bilateral Market Access Agreement between the United States and Russia, concluded in November 2006, which includes a letter setting out important commitments that will strengthen IPR protection and enforcement in Russia. Under the terms of the agreement, Russia will take action to address piracy and counterfeiting and further improve its laws on IPR protection and enforcement. The agreement sets the stage for further progress on IPR issues in ongoing multilateral negotiations concerning Russia’s bid to enter the WTO. This year’s Special 301 Report also continues heightened scrutiny of Russia by maintaining Russia on the Priority Watch List and announcing plans for an Out-of-Cycle Review.

With respect to China, this year’s Special 301 Report describes the United States’ plan to maintain China on the Priority Watch List and to continue Section 306 monitoring, as well as to pursue World Trade Organization (WTO) dispute settlement with China on a number of IPR protection and enforcement issues. In addition, the United States is reporting on IPR protection and enforcement in China in the section entitled “Special Provincial Review of China,” following an unprecedented special provincial review conducted over the past year. 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, Chile, Egypt, India, Israel, Lebanon, Thailand, 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. 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.

### **USTR Focus on Intellectual Property and Innovation**

In June 2006, USTR created a new Office of Intellectual Property and Innovation. Intellectual property issues were previously covered at USTR in the Office of Services, Investment and Intellectual Property. USTR also appointed a Chief Negotiator for Intellectual Property Enforcement. The creation of this new office and additional staff dedicated to intellectual property at USTR enhances our focus on protecting and enforcing IPR.

### **Positive Developments**

Several countries made significant positive progress on IPR protection and enforcement in 2006. For example, Vietnam joined the WTO in January 2007. As part of its accession efforts, Vietnam enacted a comprehensive intellectual property law and implementing regulations to create a modern legal framework for IPR protection and enforcement. Taiwan also made significant strides in its IPR enforcement efforts and passed legislation to create a specialized IPR court. China recently joined the two key World Intellectual Property Organization (WIPO) treaties for copyright protection, and Russia has made strong commitments to improve intellectual property protection and enforcement as part of the path towards WTO accession.

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

- Bahamas has been removed from the Watch List due to improvements in IPR enforcement efforts. The United States continues to urge the Government of the Bahamas to implement the amendments to its copyright law.
- Belize has been moved from the Priority Watch List to the Watch List due to improvements in IPR enforcement efforts in response to heightened engagement with the United States.
- Brazil has been moved from the Priority Watch List to the Watch List due to improvements in IPR enforcement efforts and the United States will conduct an Out-of-Cycle Review.
- Bulgaria has been removed from the Watch List due to improvements in IPR enforcement efforts and passage of IPR legislation in response to heightened engagement with the United States.

- Croatia has been removed from the Watch List due to improvements in IPR enforcement and passage of IPR legislation in response to heightened engagement with the United States.
- The European Union (EU) has been removed from the Watch List, principally as a result of the EU's adoption of new regulations concerning geographical indications (GIs) following an adverse ruling by the WTO Dispute Settlement Body in April 2005. While the United States maintains certain concerns with respect to the EU's implementation of the revised GI rules, these will continue to be addressed outside the Special 301 context. The United States looks forward to continued cooperation with the EU on this and other intellectual property matters, including EU border enforcement and other IP initiatives.
- Latvia has been removed from the Watch List at the conclusion of an Out-of-Cycle Review in recognition of Latvia's improvements in IPR enforcement.

The United States commends this positive progress by our trading partners. The United States will continue to work with these and other countries to achieve further improvements in IPR protection and enforcement during the coming year.

### **Free Trade Agreements and Implementation**

The United States is committed to promoting strong intellectual property rights through a variety of mechanisms, including the negotiation of free trade agreements (FTAs), which contain intellectual property chapters that establish strong protections for copyrights, patents, and trademarks, as well as rules for enforcement.

The United States is pleased to have worked together with many countries to strengthen IPR protection and enforcement through bilateral and multilateral FTAs. Agreements concluded in recent years include the Republic of Korea FTA (KORUS FTA), Panama Trade Promotion Agreement, Bahrain FTA, Oman FTA, Morocco FTA, the Peru Trade Promotion Agreement, the Colombia Trade Promotion Agreement, and the Central America-Dominican Republic Free Trade Agreement (CAFTA-DR) which covers Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic. In regions such as the Middle East and Asia, the United States has used an increasing number of trade and investment framework agreement (TIFA) negotiations to enhance intellectual property protection and enforcement.

Following the conclusion of these agreements, the United States continues to work closely with our trading partners to implement FTA obligations under domestic law. Over the past year, the United States has engaged in this process with Australia, Singapore, Morocco, Bahrain, Oman, Jordan, and parties to CAFTA-DR.

## **Generalized System of Preferences (GSP) Reviews**

As another mechanism for promoting strong intellectual property regimes around the world, USTR reviews IPR practices in connection with the implementation of trade preference programs such as the Generalized System of Preferences (GSP). USTR will continue to review IPR practices in Russia, Lebanon, and Uzbekistan under ongoing GSP reviews.

## **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 continues to advocate the adoption of best practices guidelines for IPR enforcement. This year, USTR will continue its efforts to explore ways of strengthening IPR laws and enforcement and further solidifying international alliances 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 U.S.-EU Summit, the Security and Prosperity Partnership (SPP) with Canada and Mexico, the Organization for Economic Cooperation and Development (OECD), and the Asia-Pacific Economic Cooperation (APEC) forum.

Implementation of the U.S.-EU Action Strategy for IPR Enforcement has focused on addressing concerns in key countries such as China and Russia through closer coordination and information exchange, in addition to increasing customs cooperation and providing technical assistance to third countries. Through a bilateral working group, the two sides have established regular information exchanges on efforts to improve China's intellectual property climate, and have deepened their IPR-related cooperation in the context of Russia's WTO accession. The Parties will endeavor to increase and expand these cooperative efforts.

Building on the 2005 APEC Anti-Counterfeiting and Piracy Initiative, APEC economies endorsed two new IPR guidelines in 2006: one, to better inform citizens about the importance of IPR protection and enforcement, and another to help secure business supply chains against counterfeit and pirated goods. These two new guidelines add to three guidelines endorsed in 2005 that are designed to reduce trade in counterfeit and pirated goods, reduce on-line piracy and protect against unauthorized copying in digital form, and prevent the sale of counterfeit and pirated products over the Internet. All five guidelines set high standards for IPR protection and enforcement in the APEC region.

## **Global Scope of Counterfeiting and Piracy**

The continuing growth of IPR theft and trade in fakes and pirated materials threatens innovative and creative economies worldwide. Counterfeiting has evolved in recent years from a localized industry concentrated on copying high-end designer goods to a sophisticated global business involving the mass production and sale of a vast array of fake goods, including items such as soaps, shampoos, razors, electronics, batteries, cigarettes, alcoholic beverages, sporting goods, automobile parts, motorcycles, medicines, and health care products, among others.

Counterfeiting not only affects the profits of legitimate producers, but also impacts consumers who waste money and sometimes risk their safety by purchasing fake goods. It also damages the economies of the countries in which it occurs by decreasing tax revenue and deterring investment. Counterfeiters generally pay no taxes or duties, and they often disregard basic standards for worker health, safety, and product quality and performance. Piracy of copyrighted products in virtually all formats, as well as counterfeiting of trademarked goods, has grown rapidly because these criminal enterprises offer enormous profits and little risk. Counterfeiters require little up-front capital investment, and even if caught and charged with a crime, the penalties imposed on convictions in many countries are so low that they offer little or no deterrent.

Stronger and more effective criminal and border enforcement is required to stop the manufacture, import, export, transit, and distribution of pirated and counterfeit goods. Through bilateral consultations, FTAs, and international organizations, USTR is working to maximize the deterrent effects of remedies, including stronger penalties, requirements for the seizure and destruction of pirated and counterfeit goods, and the equipment used in their production.

### *Counterfeit Pharmaceuticals*

The manufacture and distribution of counterfeit pharmaceuticals is a growing problem that poses special concerns for consumer health and safety. The United States notes its concern with the proliferation of the manufacture of counterfeit pharmaceuticals in China, India, and Russia, and the sale and distribution of counterfeit pharmaceuticals in many countries. A significant contributing factor in this problem is the unauthorized use of bulk active pharmaceutical ingredients (APIs) to manufacture counterfeit pharmaceuticals. Countries must do more to provide its relevant agencies with the authority to regulate and enforce against the unauthorized use of APIs domestically and to ensure that they are not exported for unauthorized use abroad. Also, countries must do more to enforce vigilantly against the manufacture and distribution of counterfeit pharmaceuticals.

### **Notorious Markets**

Global piracy and counterfeiting continue to thrive, in part due to large marketplaces that deal in infringing goods. This year's Special 301 Report notes 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. To date, efforts to shut down the site have 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. The Beijing Intermediate Court sided with Baidu in a 2006 court decision; more recently, however, rights holders have prevailed in a similar case involving a different defendant.

### *Physical Markets*

**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 compliance with IPR laws. In 2006, right holders prevailed in several court actions related to the market, and executed a Memorandum of Understanding with the landlords in June 2006. Industry reports that similar memoranda have been successfully relied upon in the 3.3 and Hongqiao markets in Beijing, but implementation has not been successful in Silk Market. A January 2007 industry survey of the market reportedly showed that counterfeiting has worsened, with apparent violations in 65 percent of all outlets in the market, and the proportion of apparent counterfeit goods in certain categories (eyewear, leather goods, footwear, watches) ranging from 80 to 100 percent.

**China Small Commodities Market (Yiwu, China).** The China Small Commodities Market in Yiwu reportedly sells approximately 410,000 different items, mostly small consumer goods. Industry has cited the market as a center for wholesaling of infringing goods. Officials in Yiwu have met repeatedly with U.S. Government officials and stressed their work to improve IPR enforcement. Industry confirms that enforcement in Yiwu has improved. Continued improvement is needed, particularly in the area of criminal enforcement.

**Gorbushka, Rubin Trade Center, Tsaritsino, and Mitino (Moscow, Russia).** Industry representatives report that piracy problems persist in these markets, though the situation has improved at the Rubin Trade Center.

**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 many 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.

**Tepito, Plaza Meave, Eje Central, Lomas Verdes, and Pericoapa Bazaar (Mexico City); Simitrio-La Cuchilla, San Martin Texmelucan, Emiliano Zapata, and Independence (Puebla, Mexico); San Juan de Dios (Guadalajara, Mexico); and Pulgas Mitras and La Ranita (Monterrey).** 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. In early 2007, Mexico won praise from industry groups for carrying out multiple major raids in Tepito, as well as major raids in La Cuchilla and San Juan de Dios.

**Czech Border Markets (Czech Republic).** Hundreds of open air market stalls sell pirated and counterfeit products on the Czech border, including at the notorious Asia Dragon Bazaar in Cheb City. Czech Republic authorities are focused on IPR enforcement actions, and the United States encourages the Czech Republic to step up its efforts to combat piracy and counterfeiting in the markets. The United States will conduct an Out-of-Cycle Review to monitor progress in the Czech Republic.

**La Salada (Buenos Aires, Argentina).** This is the largest of more than 40 large, well-established markets in Buenos Aires that are almost completely dedicated to the sale of counterfeit goods. An estimated 6,000 vendors sell fake goods to 20,000 customers daily. The market is reputed to be a haven for organized criminal gangs that operate from within it, resulting in little to no IPR enforcement.

**Neighborhood of Quiapo (Manila, Philippines).** Street stalls in this neighborhood are notorious for selling counterfeit and pirated merchandise. These stalls were targeted for multiple raids in 2006.

**Harco Glodok (Jakarta, Indonesia).** This is one of the largest markets for counterfeit and pirated goods, particularly well-known for pirated optical discs. Enforcement officials are reportedly reluctant to conduct regular enforcement actions because of the presence of organized criminal gangs.

**Panthip Plaza (Bangkok, Thailand).** This location is notorious for pirated optical discs, primarily pirated movies. There were signs of improvement when closed circuit cameras with videotaping capabilities were installed, but recently, the trade in pirated goods has reasserted itself.

### **Transshipped and In Transit Goods**

“Transshipped” and “in transit goods” pose continuing IPR problems. Transshipped and in transit goods, which are goods that enter one customs territory but are intended for another destination, 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 is known to be weak. Transshipped or in transit goods are significant problems in Hong Kong, Paraguay, the Philippines, Ukraine, and Thailand, among others. In addition, U.S. industries report significant problems in free trade zones in Belize, Chile,

Paraguay, the Philippines, and United Arab Emirates, among others. The United States urges these countries to improve their IPR border enforcement systems.

### **Controlling Optical Media Production**

In recent years, some countries, such as Brazil, Indonesia, Malaysia, Nigeria, Pakistan, the Philippines, and Ukraine, have made progress toward implementing controls on optical media production. Other countries still need to adopt and implement legislation or improve existing measures to combat pirate optical disc production, including Bangladesh, India, Russia, and Thailand, which have not made sufficient progress in this area. The United States continues to urge its trading partners who face pirate optical media production within their borders to pass effective legislation and aggressively enforce existing laws and regulations.

### **Internet Piracy and the WIPO Internet Treaties**

The increased availability of broadband Internet connections around the world has made the Internet an extremely efficient vehicle for disseminating pirated products. The United States is continuing to work with other governments, in consultation with U.S. copyright industries and other affected sectors, to develop strategies to address this global problem. An important first step was achieved in 1996 when WIPO concluded two copyright treaties, the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT) (collectively, the “WIPO Internet Treaties”). Following their entry into force in 2002, these treaties have raised minimum standards of intellectual property protection around the world, particularly with regard to Internet-based delivery of copyrighted works. The WIPO Internet Treaties have clarified exclusive rights and prohibit the circumvention of certain technological measures that protect copyrighted works in online environments.

A growing number of countries are implementing the WIPO Internet Treaties to create a legal environment conducive to investment and growth in Internet-related businesses and technologies. As of April 2007, there are 63 members of the WCT and 61 members of the WPPT. China deposited its instruments of accession to the treaties on March 9, 2007. Membership will rise significantly when the various EU member States join. Other countries have implemented key provisions of the treaties in their national laws without formally ratifying them. As a new part of the international IPR legal regime, the WIPO Internet Treaties 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 WIPO Internet Treaties.

#### *Other Initiatives Regarding Internet Piracy*

The United States is committed to a policy of promoting higher standards of intellectual property protection by incorporating standards from the WIPO Internet Treaties as substantive obligations in our bilateral and regional trade agreements, and by seeking accession to those treaties as a substantive obligation under these agreements. Proposals by the United States within ongoing



FTA negotiations will continue to include up-to-date copyright and enforcement obligations that reflect contemporary technological challenges.

### *Piracy Using New Technologies*

Piracy using new technologies is an emerging problem internationally. For example, the U.S. copyright industries report growing problems with piracy not only on the Internet, but also using cellular telephones, palm devices, flash drives, and other mobile technologies. In some countries these devices are being pre-loaded with illegal content before they are sold. In addition to piracy of music and films using these new technologies, piracy of ring tones, games, and scanned books also occurs. Countries with significant problems of piracy using new technologies include India, Indonesia, Japan, and Malaysia, among others. The United States will work with these governments to combat this increasing problem.

### *IPR and Interoperability*

During the past year, a number of countries, mostly in Western Europe, have devoted increasing attention to the relationship between intellectual property rights, digital rights management technologies, and interoperability of consumer products and other devices. This emerging set of issues represents potential new challenges in the area of effective protection of IPR. In France, for example, copyright legislation enacted in August 2006 contains provisions enabling a government entity to mandate the disclosure of IP-protected digital rights management information in the interest of promoting interoperability. The United States has expressed concern that this legislation may, depending on its implementation, impinge upon IPR of both the creators of the digital rights management technologies and of creative works protected by those technologies. Similar approaches reportedly are being considered in other European countries, including Belgium, Sweden, Norway, and Germany. In some cases, consumer protection laws and regulatory authorities have been engaged to pursue interoperability at the potential expense of IP right holders. This complex intersection of issues will continue to receive U.S. policy attention in the coming year.

### **Government Use of Software**

Under an Executive Order issued in October 1998, United States Government agencies maintain appropriate and effective procedures to ensure the use of authorized and legitimate use of business software. Pursuant to the same directive, USTR has undertaken an initiative to work with other governments, particularly in countries that are modernizing their software management systems or where concerns have been raised, to stop governmental use of unauthorized or illegal software.

Considerable progress has been made under this initiative. In 2006, APEC economies agreed that central government agencies should use only legal software and other copyrighted materials and should implement effective policies intended to prevent copyright infringement on their computer systems and via the Internet. Numerous countries and territories have mandated that only authorized, legitimate software may be used by government ministries. Some countries that have enacted such decrees or are in the process of implementing them 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, the United Kingdom, and Vietnam, among others. The United States commends these governments for setting a positive example and expects these measures to be fully implemented. The United States looks forward to the adoption by other governments of effective and transparent procedures to ensure legitimate use of software.

### **Implementation of the WTO TRIPS Agreement**

The TRIPS Agreement, which requires all WTO members to provide certain minimum standards of IPR protection and 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. Recognizing the particular challenges faced by least-developed countries, in 2005 the United States worked closely with them and other WTO members to extend the implementation date for these countries from January 2006 to July 2013. 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 conference of the WTO. 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. In addition, U.S. industry is actively involved in providing specific enforcement-oriented training in key markets around the world. 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 recourse to dispute settlement consultations.

During 2006, the United States joined with the European Communities, Japan, and Switzerland to encourage a discussion within the WTO TRIPS Council of implementation of the enforcement-related provisions of the TRIPS Agreement. The United States hopes that the TRIPS Council can generate a useful sharing of experiences related to IPR enforcement, in the interest of ensuring effective implementation of enforcement obligations.

## **Intellectual Property and Health Policy**

The Administration is dedicated to addressing the serious health problems, such as HIV/AIDS, afflicting developing and least-developed countries in Africa and elsewhere. The United States believes firmly 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. In this context, the United States strongly supports the 2001 Doha Declaration on the TRIPS Agreement and Public Health. The Declaration acknowledged the serious public health problems afflicting African and other developing and least-developed country members, especially those relating to HIV/AIDS, malaria, tuberculosis, and other epidemics. Ministers agreed that WTO 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 system continues to promote the development and creation of new lifesaving drugs.

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. 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. This solution was subsequently converted into an amendment to the TRIPS Agreement in December 2005, and later that month the United States became the first WTO Member to formally accept this 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 United States strongly supports effective and appropriate use of the TRIPS/health solution to facilitate access to life-saving medicines by countries in need.

In recent free trade agreements with the parties to CAFTA-DR, Morocco, Bahrain, Oman, Peru, Colombia, and Panama, the United States has clarified that the intellectual property provisions in the agreements do not impede the taking 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 particularly 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 encourages 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 discourage the development of new drugs. These barriers may include unreasonable regulatory approval delays, linkages between dispensing and prescribing, and reference pricing and other potentially unfair reimbursement policies. The criteria, rationale, and operation of such measures are often nontransparent, not fully disclosed to patients or 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 that 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 United States-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 and Australia will

hold the second meeting of this Working Group in May to review implementation of the pharmaceutical provisions of the FTA and to discuss ongoing issues of mutual concern

On April 1, 2007, the United States concluded negotiations on the United States-Korea Free Trade Agreement (KORUS FTA). The KORUS FTA includes provisions on market access for pharmaceutical and medical devices that go beyond those in any other U.S. FTA. Specifically, the FTA includes commitments to improve access to innovative products and to ensure the transparent, predictable, and non-discriminatory pricing and reimbursement of innovative and generic pharmaceutical products, medical devices, and biologics. In addition, the Agreement contains provisions to promote ethical business practices, establish a Medicines and Medical Devices Committee to monitor implementation of commitments in this area, and create an independent mechanism to review pricing and reimbursement decisions.

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 helping to improve transparency in this sector, ensuring that foreign pharmaceutical and medical device manufacturers have meaningful opportunities to provide input into important regulatory, reimbursement, and pricing matters, 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 implements recent healthcare reform legislation.

The United States is concerned about Poland's enactment in 2006 of a regulation establishing wholesale and retail processes for drugs, which appears to reduce the official maximum wholesale and retail prices for imported drugs by 13 percent while generally leaving unchanged the prices for drugs of Polish origin. The U.S. pharmaceutical industry reports that this regulation has had a significant impact by causing reduced prices for numerous products manufactured outside Poland. The European Commission is currently conducting an investigation which may lead to an infringement action against Poland based on this 13 percent price cut. The United States shares the European Commission's concerns over this regulation, and will continue to monitor closely the situation in Poland throughout the coming year.

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 United States also urges China to adopt regulatory and reimbursement policies for medical devices that support innovation and increase the transparency and predictability in that market.

During the coming year, the U.S. Government will continue to promote expanded 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 to address specific concerns related to price controls and regulatory and transparency issues, as well as to develop a constructive dialogue with these countries on health policy issues of mutual concern.

### **WTO Dispute Settlement**

The United States will continue pursuing the resolution of WTO-related disputes announced in previous Special 301 reviews and determinations. The most efficient and therefore preferred manner of dispute resolution is through informal consultation and settlement, but where this is unsuccessful, the United States will consider fully utilizing the dispute settlement process.

On April 10, 2007, the United States requested WTO dispute settlement consultations with China over deficiencies in China's legal regime for protecting and enforcing copyrights and trademarks on a wide range of products. The consultation request expressed the U.S. concern that certain Chinese measures are inconsistent with China's obligations under the TRIPS Agreement. The consultation request focused on three main issues: quantitative thresholds in Chinese law that must be met in order to start criminal prosecutions of copyright piracy and trademark counterfeiting and that appear to create a substantial safe harbor for those who manufacture, distribute, or sell pirated and counterfeit products in China; rules for disposal of IPR infringing goods seized by Chinese customs authorities; and the apparent denial of copyright protection to works poised to enter the Chinese market but awaiting Chinese censorship approval. The consultation request also identifies provisions of Chinese law that appear to provide that someone is not subject to criminal liability unless he both reproduces a copyrighted work without the owner's permission and distributes the pirated work; the United States wishes to confirm through consultations that China has just reformed this measure. In addition, on the same day, the United States requested WTO dispute settlement consultations with China concerning certain other Chinese measures that appear to be inconsistent with various WTO obligations of China. This consultation request focuses on a Chinese legal structure that denies foreign companies the right to import publications, movies, music, and videos, as well as on Chinese rules that severely impede the efficient and effective distribution of publications and videos within China.

Following 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. After 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, however, with respect to this revised GI Regulation, which the United States has asked the EC to address, and the United States intends to continue monitoring this situation.