

2008 SPECIAL 301 REPORT

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

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 2008 Special 301 review process examined IPR protection and enforcement in 78 countries. Following extensive research and analysis, USTR designates 46 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 of IPR-intensive industries.

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 and enforcement in those countries.

In addition to China and Russia, the Special 301 Report sets out significant concerns with respect to such trading partners as Argentina, Chile, India, Israel, Pakistan, Thailand, 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 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

In this year’s review, USTR highlights the need for significantly improved enforcement against counterfeiting and piracy, Internet piracy, counterfeit pharmaceuticals, transshipment of pirated and counterfeit goods, requirements for 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.

Positive Developments

Several countries made significant positive progress on IPR protection and enforcement in 2007. For example, Russia has increased penalties for copyright crimes and stepped up action against unlicensed optical disc plants. China has made progress on implementation of measures to

reduce end-user software piracy and agreed to strengthen enforcement against company name misuse. In Taiwan, prosecutions for business software piracy have increased, and Taiwan passed legislation making illegal and subjecting to civil and criminal liability services that intentionally facilitate peer-to-peer file sharing. Seizures of counterfeit pharmaceuticals have increased in Indonesia and Nigeria. India has approved initiating action for accession to the Madrid Protocol. China and Australia joined the two key World Intellectual Property Organization (WIPO) treaties for copyright protection. Malaysia launched a new intellectual property (IP) Court, consisting of 15 sessions courts and 6 high courts. Vietnam has taken actions to address the problem of signal piracy. The country sections of this Report describe numerous other positive developments.

In 2007, the United States worked to strengthen IPR laws and enforcement around the globe. The three pending free trade agreements (FTAs) all contain world-class IPR provisions, and FTA partner countries such as the Dominican Republic and Oman overhauled their IPR laws as part of the FTA implementation process.

In addition, USTR is pleased to announce that the following countries are having their status improved in the Special 301 Report or are being removed entirely because of progress on IPR issues this past year:

- Belize is being removed from the Watch List due to improvements in IPR enforcement efforts following heightened engagement with the United States.
- Egypt is being moved from the Priority Watch List to the Watch List due to improvements in pharmaceutical IPR protection. The United States urges Egypt to make further improvements, however, in its IPR enforcement efforts and to further clarify its practices with respect to data protection.
- Lebanon is being moved from the Priority Watch List to the Watch List due to improvements in IPR enforcement efforts. Despite this progress, the United States urges Lebanon to pass long-awaited IPR amendments.
- Lithuania is being removed from the Watch List due to improvements in IPR enforcement and passage of IPR legislation following heightened engagement with the United States.
- Turkey is being moved from the Priority Watch List to the Watch List due to improvements in IPR protection. The United States encourages Turkey to make further improvements to its IPR protection and enforcement regimes.
- Ukraine is being moved from the Priority Watch List to the Watch List due to improvements in IPR protection following close engagement with the United States during WTO accession negotiations. The United States urges Ukraine to continue, however, to make improvements in IPR enforcement and to effectively implement its recently passed IPR laws.

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 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, 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. Each of these FTAs has resulted in commitments to strengthen IPR protection and enforcement in those countries. 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 ensure proper implementation of FTA obligations under domestic law and strengthen bilateral cooperation.

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.

Anti-Counterfeiting Trade Agreement (ACTA)

On October 23, 2007, U.S. Trade Representative Susan C. Schwab announced that the United States will seek to negotiate an Anti-Counterfeiting Trade Agreement (ACTA). ACTA will bring together countries that recognize the critical importance of strong IPR enforcement for a prosperous economy. The ACTA is envisioned as a leadership effort among countries that will raise the international standard for IPR enforcement to address today's challenges of counterfeiting and piracy. ACTA will build upon the Administration's prior bilateral and regional cooperation successes.

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 trading partners – to take concerted action to crack 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.

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. In addition to the ACTA effort described above, 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 have expanded this cooperative dynamic to other regions of the world including Southeast Asia and Latin America.

The Leaders of Canada, Mexico, and the United States launched the Security and Prosperity Partnership of North America (SPP) in 2005 to address issues related to economic competition resulting from shifting patterns of trade and investment worldwide. The governments subsequently established an Intellectual Property Working Group under the SPP. USTR, together with the Department of Commerce, jointly leads the U.S. delegation to the SPP IP Working Group. The SPP IP Working Group developed a trilateral Intellectual Property Rights Action Plan, which leaders announced at the SPP Summit in Montebello, Canada, in August 2007. The Action Plan constitutes a strategy for governments and the private sector to combat piracy and counterfeiting in North America. The governments of Canada, Mexico, and the United States have agreed to take action in three areas: (1) detecting and deterring trade in counterfeit and pirated goods; (2) increasing consumer awareness of the adverse effects of counterfeiting and piracy; and (3) measuring the depth and scope of counterfeiting and piracy.

Through efforts by the United States, APEC endorsed the "Anti-Counterfeiting and Piracy Initiative" in 2005, which paved the way for the adoption of a number of U.S. led proposals. Some of these initiatives include Model Guidelines on reducing trade in counterfeit and pirated goods by protecting against unauthorized copies, preventing the sale of counterfeit goods over the Internet, raising public awareness on IP protection and enforcement efforts, and securing supply chains. Other initiatives include a paper on innovative techniques for IPR border enforcement and commitments made by the APEC leadership on combating signal theft, and addressing markets that knowingly sell counterfeit and pirated goods. The United States will continue to introduce initiatives that build on past accomplishments.

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. Not only is there greater diversification in the types of goods that are being counterfeited, but industry reports a growing trend in the production of labels and components for these fake products. Exploiting free trade zones, counterfeiters are establishing a global trade in these items, shipping them separately to be assembled and distributed in another country.

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 and 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 and pirates 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 deterrence.

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 and 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 Brazil, China, India, Mexico, 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 their 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.

Consumer Safety

While counterfeit pharmaceuticals and medical devices pose the most obvious health and safety hazards to consumers, many industries are affected by counterfeit goods that can put consumers at risk. Substandard products in the automotive, chemical, wine and spirits, tobacco, food, and consumer goods/personal care product sectors could have considerable adverse effects on consumer health and safety. This issue is of particular concern in China and Russia, but also affects consumers in the United States. Weaknesses in the distribution and supply chains must be addressed in order to prevent injury to consumers who believe that they are purchasing or using a legitimate product.

Notorious Markets

Global piracy and counterfeiting continue to thrive, due in part 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. The United States encourages the responsible authorities to step up efforts to combat piracy and counterfeiting in these and similar markets.

Virtual Markets

Allofmp3 (Russia). Industry reports that allofmp3 was formerly the world's largest server-based pirate music website. Although the site's commercial operations appear to have been disabled in 2007 and a criminal prosecution is pending, other Russian-based websites are reportedly continuing operations with similar infringing content.

Baidu (China). Industry has identified Baidu as the largest China-based "MP3 search engine" offering deep links to copyright-protected music files for unauthorized downloads or streaming. Baidu is the target of ongoing infringement actions.

Business-to-business (B2B) and business-to-consumer (B2C) websites (China). A large number of these Chinese websites, such as Alibaba and Taobao, have been cited by industry as offering infringing products to consumers and businesses. The Internet traders who use these online markets to offer counterfeit goods are difficult to investigate, and contribute to the growth of global counterfeiting.

PirateBay (Sweden). Industry reports that PirateBay is one of the world's largest BitTorrent tracker sites and a major global conduit for the unauthorized exchange of copyright-protected film and music files. PirateBay was raided by Swedish police in 2006, and the government initiated the prosecution of four Swedes associated with the site in January 2008, but the site has continued to operate, reportedly relying on servers located outside of Sweden.

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. A January 2007 industry survey of the market reportedly showed that counterfeiting has worsened, with apparent violations in 65 percent of all outlets. More recent industry reports indicate that counterfeiting at Silk Street Market remains at critical levels.

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, and Tsaritsino Markets (Moscow, Russia). Industry representatives report that piracy problems persist in these markets, though the situation has improved at the Gorbushka and 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. Although Ciudad del Este remains the hub for pirate activities in Paraguay, industry reports that trade there has declined and that commercial concentrations are shifting to other cities. Through a revised Memorandum of Understanding between the United States and Paraguay on IPR enforcement, the United States will be encouraging Paraguay to increase enforcement action with respect to a number of specifically-identified markets in that country.

Tepito, Plaza Meave, Eje Central, Lomas Verdes, and Pericoapa Bazaar (Mexico City); Simitrio-La Cuchilla (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.

Czech Border Markets (Czech Republic). Hundreds of open air market stalls are notorious for selling pirated and counterfeit products near the Czech border, including at the notorious Asia Dragon Bazaar in Cheb City. Many of these markets are highly organized, and even advertise on the Internet.

La Salada (Buenos Aires, Argentina). This is the largest of more than 40 large, well-established markets in Buenos Aires that have been cited as being heavily involved in the sale of

counterfeit goods. An estimated 6,000 vendors sell 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. Other notorious markets in Manila include Binondo, Greenhills, Makati Cinema Square, and Metrowalk.

Harco Glodok (Jakarta, Indonesia). This is reported to be one of the largest markets for counterfeit and pirated goods in Indonesia, 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.

Panhip Plaza, Mah Boon Krong (MBK) Center, Klong Thom, Patpong, and Sukhumvit Road (Bangkok, Thailand). These locations are notorious for openly selling pirated and counterfeit goods. They are all designated as “red zones” by Thai authorities, which indicates that they are places where infringing products are most readily available.

Destruction of Seized Counterfeit Goods and Manufacturing Equipment

The destruction of seized counterfeit goods, materials, and related manufacturing equipment is a reliable way to ensure that these goods do not wind up in the hands of consumers. Many countries resort to less effective, alternative measures, such as auctioning off the goods and manufacturing equipment without the right holder’s consent, or removing the trademarks on the goods and then reselling them. These methods do not effectively keep these goods out of the hands of consumers, and frequently put them back into the hands of counterfeiters. Industry reports highlight China, Egypt, the Philippines, Russia, Ukraine, and Uruguay as countries that do not sufficiently enable the destruction of goods or equipment.

In-Transit Goods

In-transit goods pose continuing IPR problems. “In-transit goods” means goods under “Customs transit” and “transshipped” goods as defined in the International Convention on Simplification and Harmonization of Customs Procedures (Kyoto Convention). These are goods that enter one customs territory but are intended for another destination. They 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. 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, Egypt, Paraguay, the Philippines, United Arab Emirates, and Vietnam, among others. The United States urges these countries to improve their IPR border enforcement systems.

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. Internet piracy is a significant concern in a number of countries, including Canada, China, Sweden, Spain, and Russia, among others. In addition, unauthorized retransmission of live sports telecasts over the Internet is reportedly becoming an increasing problem internationally, particularly in China.

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 these global problems. 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 on-line 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 2008, there are 64 members of the WCT and 62 members of the WPPT. China and Australia acceded to these treaties in 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.

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, telecasts, and scanned books also occurs. Countries with significant problems of piracy using new

technologies include China, India, Indonesia, and Malaysia, among others. The United States will work with these governments to combat these increasing problems.

IPR and Interoperability

During recent years, 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, Germany, Norway, and Sweden. In addition, these issues are receiving attention within the European Commission. 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.

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, China, 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.

Government Use of Software

Under an Executive Order issued in October 1998, United States Government agencies maintain appropriate and effective procedures to ensure the 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 requires all WTO members to provide certain minimum standards of IPR protection and enforcement, and was one of the most significant achievements of the Uruguay Round General Agreement on Tariffs and Trade (GATT). 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. The United States participates actively in the WTO TRIPS Council's scheduled reviews of WTO Members' implementation of the TRIPS Agreement, and also uses the WTO's Trade Policy Review mechanism to pose questions and seek constructive engagement on issues related to TRIPS implementation.

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.

The United States continues to work with other WTO Members, including the European Communities, Japan, and Switzerland, to encourage a discussion within the WTO TRIPS Council on 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, 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. Under the TRIPS/health solution concluded in August 2003, Members are permitted, in accordance with specified procedures, to issue compulsory licenses to export pharmaceutical products to countries that cannot produce drugs for themselves. The General Council adopted a Decision in December 2005 that incorporated this solution into an amendment to the TRIPS Agreement, and later that month the United States became the first WTO Member to formally accept this amendment. Other WTO Members now have until December 31, 2009 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 takes effect.

In recent free trade agreements with the parties to the U.S. – Central America – Dominican Republic FTA (CAFTA-DR), and with Korea, Morocco, Bahrain, Oman, Peru, Colombia, and Panama, the United States has clarified that the intellectual property provisions in the FTAs 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 the first half of 2008 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 held constructive discussions 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 while 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.

The United States remains 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.

The United States shares policy goals and concerns related to health care with other industrialized countries, including challenges surrounding 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.

During the coming year, the U.S. Government will continue to engage in dialogue with industrialized country trading partners, including Italy, Germany, Canada, and France, on issues related to innovation in the pharmaceutical sector and other aspects of health care goods and services. In addition to continuing to advocate for pricing and reimbursement policies that appropriately value innovation and which are administered in a transparent and open manner, the United States will devote additional attention to trends in the area of health technology assessment (HTA) and the relationship of such assessments to pricing policies. The United States believes it important that HTA policies be implemented in a transparent manner and in keeping with international standards of science-based evaluation. In addition, issues surrounding the ability of health care consumers to obtain information about pharmaceutical and other medical products merits additional attention and dialogue.

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.

In April 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. After those consultations failed to resolve the matter, on August 13, 2007, the United States requested the establishment of a WTO panel. The panel request expresses United States concerns that certain Chinese measures are inconsistent with China's obligations under the TRIPS Agreement. The panel request focuses 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. A WTO panel was established to examine this matter on September 25, 2007, and panelists were appointed on December 13, 2007.

In addition, 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, that severely impedes the efficient and effective distribution of publications, music and videos within China, and that disadvantages imported publications, movies and music *vis-à-vis* their domestic counterparts in their distribution. As the United States and China were unable to resolve this dispute in these consultations, the United States filed on October 10, 2007, a request for the establishment of a WTO panel. A WTO panel was established to examine this matter on November 27, 2007, and was composed on March 27, 2008.

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.

BACKGROUND ON SPECIAL 301

Pursuant to Section 182 of the Trade Act of 1974, as amended by the Omnibus Trade and Competitiveness Act of 1988 and the Uruguay Round Agreements Act (enacted in 1994) (“Special 301”), under Special 301 provisions, USTR must identify those countries that deny adequate and effective protection for IPR or deny fair and equitable market access for persons that rely on intellectual property protection. Countries that have the most onerous or egregious acts, policies, or practices and whose acts, policies, or practices have the greatest adverse impact (actual or potential) on the relevant U.S. products must be designated as “Priority Foreign Countries.”

Priority Foreign Countries are potentially subject to an investigation under the Section 301 provisions of the Trade Act of 1974. USTR may not designate a country as a Priority Foreign Country if it is entering into good faith negotiations or making significant progress in bilateral or multilateral negotiations to provide adequate and effective protection of IPR.

USTR must decide whether to identify countries within 30 days after issuance of the annual National Trade Estimate Report. In addition, USTR may identify a trading partner as a Priority Foreign Country or remove such identification whenever warranted.

USTR has created a “Priority Watch List” and “Watch List” under Special 301 provisions. Placement of a trading partner on the Priority Watch List or Watch List indicates that particular problems exist in that country with respect to IPR protection, enforcement, or market access for persons relying on intellectual property. Countries placed on the Priority Watch List are the focus of increased bilateral attention concerning the problem areas.

Additionally, under Section 306, USTR monitors a country’s compliance with bilateral intellectual property agreements that are the basis for resolving an investigation under Section 301. USTR may apply sanctions if a country fails to satisfactorily implement an agreement.

The interagency Trade Policy Staff Committee, in advising USTR on the implementation of Special 301, obtains information from and holds consultations with the private sector, U.S. embassies, foreign governments, and the U.S. Congress, among other sources.

PRIORITY WATCH LIST

CHINA

China remains a top intellectual property enforcement and TRIPS compliance priority for the United States. China will remain on the Priority Watch List, and remain subject to Section 306 monitoring. The United States is seeking to resolve its concerns with respect to three IPR protection and enforcement issues through WTO dispute settlement with China. (See the “Dispute Settlement” section above).

The United States recognizes and appreciates the efforts of the many officials in China who continue to give voice to China’s commitment to protecting intellectual property rights and are working hard to make it a reality. In spite of these efforts, the shared goal of significantly reducing IPR infringement throughout China has not yet been achieved.

China has made welcome progress in some areas. Notable IPR improvements included completion of China’s accession to the WIPO Internet Treaties and its ongoing implementation of rules that require computers to be pre-installed with licensed operating system software. The United States believes that continued bilateral dialogue and cooperation can lead to further progress in these and other areas. The United States will continue to put serious efforts into its joint work with China on intellectual property enforcement and protection strategies, innovation policies, and the range of other important IPR-related matters in our bilateral economic relationship, including through the U.S. – China Strategic Economic Dialogue (SED), the Joint Commission on Commerce and Trade (JCCT), and other fora.

At the December 2007 JCCT meeting, China reported on steps it has taken since the previous JCCT meeting in April 2006 to improve protection of IPR in China, including accession to the World Intellectual Property Organization (WIPO) Internet Treaties, a crackdown on the sale of computers not pre-loaded with legitimate software, enforcement efforts against counterfeit textbooks and teaching materials, and joint enforcement raids conducted by the U.S. Federal Bureau of Investigation (FBI) and Chinese security agencies. China and the United States agreed to exchange information on customs seizures of counterfeit goods in order to further focus China’s enforcement resources on companies exporting such goods. China agreed to strengthen enforcement of laws against company name misuse, a practice in which some Chinese companies have registered legitimate U.S. trademarks and trade names without legal authority to do so. The two sides also agreed to cooperate on case-by-case enforcement against such company name misuse. In addition, China agreed to eliminate the requirement to submit viable biotech seeds for testing, a policy change which reduces the possibility of illegal copying of patented agricultural materials.

At the SED meeting in May 2007, the United States and China agreed to Principles and Outcomes for Strengthening Innovation Cooperation (SED Principles and Outcomes), including a decision to “jointly host a seminar on the innovation ecosystem in 2007 that would gather experts to discuss and share experiences on both sides regarding the critical elements of developing an environment conducive to technological innovation.” To realize this commitment, the two governments co-hosted an Innovation Conference on December 10, 2007 in Beijing. At this meeting, both sides reaffirmed that innovation is best fostered where there is effective rule of

law, and where governments pursue market-oriented policies that encourage merit-based competition, entrepreneurship, commercialization of new technologies, and flexibility for users and producers in choosing among competing technologies. Both sides also confirmed the essential role of a robust intellectual property protection and enforcement regime in supporting an innovation ecosystem.

Despite anti-piracy campaigns in China and an increasing number of IPR cases in Chinese courts, overall piracy and counterfeiting levels in China remained unacceptably high in 2007. The U.S. copyright industries estimate that 85 percent to 95 percent of all of their members' copyrighted works sold in China was pirated, indicating no improvement over 2006. Internet piracy is increasing, as is piracy over closed networks such as those of universities, in addition to concerns over webcasting of various kinds. The rapid increase in the Internet to over 210 million users suggests that this challenge is likely to continue to grow, with many industry groups focused predominantly on Internet piracy. Notwithstanding these new challenges, trade in pirated optical discs continues to thrive, supplied by both licensed and unlicensed factories and by smugglers. A crackdown in Beijing and certain other cities by municipal management authorities appears to have reduced the incidence of "backpack" vendors. However, small retail shops continue to be the major commercial outlets for pirated movies and music and a wide variety of counterfeit goods. Piracy of books and journals and end-user piracy of business software also remain key concerns. In addition, the share of IPR infringing product seizures of Chinese origin at the U.S. border was 80 percent in 2007, virtually unchanged from 81 percent in 2006. Chinese counterfeits include many products, such as pharmaceuticals, electronics, batteries, auto parts, industrial equipment, toys, and many other products, that pose a direct threat to the health and safety of consumers in the United States, China and elsewhere.

Inadequate IPR enforcement is a key factor contributing to these shortcomings, with high criminal thresholds as well as difficulties in initiating or transferring cases for criminal prosecution resulting in limited deterrence. Civil damages are also low.

There have been some successful enforcement actions, most notably the joint "Summer Solstice" investigation between the FBI and China's Ministry of Public Security (MPS). In 2007, MPS engaged with U.S. law enforcement on IP law enforcement initiatives as part of the Intellectual Property Criminal Enforcement Working Group (IPCEWG) of the U.S.-China Joint Liaison Group for Law Enforcement Cooperation (JLG). The IPCEWG includes participation by Chinese law enforcement officials from the MPS as well as officials from the Justice Department, the FBI, and U.S. Immigration and Customs Enforcement. The IPCEWG focuses on the development of more U.S.-China joint operations to combat transnational IP crime, in particular crimes committed by organized criminal groups and crimes that threaten public health and safety. In July 2007, this collaboration resulted in the largest ever joint FBI-MPS piracy investigation and prosecution, code-named "Operation Summer Solstice," which involved seizures of more than 290,000 counterfeit software discs worth more than a half billion dollars and arrests of over 25 Chinese nationals, and eliminated numerous manufacturing plants in China. This joint operation is believed to have dismantled the largest piracy syndicate of its kind in the world, estimated to have distributed more than 2 billion copies of counterfeit Microsoft software. U.S. law enforcement authorities look forward to continuing this cooperative relationship as this and other investigations continue.

However, right holders report that enforcement efforts, particularly at the local level, are hampered by poor coordination among Chinese Government ministries and agencies, local protectionism and corruption, high thresholds for initiating investigations and prosecuting criminal cases, lack of training, and inadequate and non-transparent processes.

Several factors contribute to China's poor IPR enforcement record. One major factor is China's chronic underutilization of deterrent criminal remedies. China channels the vast majority of enforcement to administrative authorities. The trademark and copyright industries continue to point out that administrative fines are too low to provide a deterrent, and as a result, infringers continue to consider administrative seizures and fines as a cost of doing business. Rules designed to promote transfer of cases to criminal authorities do not appear to have solved the problem.

At the 2005 JCCT, China agreed to increase the number of criminal prosecutions for IPR violations relative to the total number of IPR administrative cases. Unfortunately, there has been no sign yet of a significant shift in emphasis toward criminal enforcement. The safe harbors from criminal liability created by China's high thresholds for criminal liability (*i.e.*, minimum values or volumes required to initiate criminal prosecution, normally calculated on the basis of the infringer's actual or marked price) continue to be a major reason for the lack of an effective criminal deterrent. These safe harbors are among the matters for which the United States has requested WTO dispute settlement with China.

In April 2007, China issued a new Judicial Interpretation that appears to clarify certain aspects of China's criminal thresholds. Although the 2007 Judicial Interpretation appears to have resolved the problem in China's *Criminal Law* that required unauthorized distribution in order to prosecute unauthorized reproduction, other legal obstacles in the area of criminal enforcement remain. They include, for example, the lack of criminal liability for certain acts of copyright infringement; the profit motive requirement in copyright cases, which hampers efforts to fight Internet piracy where there is no clear motive of financial gain; the requirement of identical trademarks in counterfeiting cases; and the absence of minimum, proportionate sentences and clear standards for initiation of police investigations in cases where there is a reasonable suspicion of criminal activity. The United States remains willing to work with China to achieve further progress in the area of criminal remedies.

At the same time, the United States has also been encouraging China to consider a variety of changes to its administrative and civil enforcement regimes, such as the restoration of minimum (and deterrent) fines in administrative trademark enforcement cases, increased referral of administrative enforcement actions for criminal prosecution, elimination of the need for legalization and consularization of foreign evidence, implementation of a discovery process with compulsory measures for evidence protection, provision of meaningful injunctive relief, and enforcement of judicial orders.

In addition, the United States calls upon China to take more aggressive action to prosecute manufacturers of counterfeit goods, producers of pirated optical discs, and entities engaged in commercial reproduction of pirated books, journals, and periodicals. Authorities should

investigate when right holders present evidence supporting a reasonable suspicion of illegal production, and should permanently close down, revoke the business licenses, and confiscate and destroy the machinery and materials of commercial pirates and counterfeiters, as well as criminally prosecute the persons responsible.

Trade in pirated optical discs continues to thrive, supplied by smugglers and by both licensed and unlicensed factories. China needs to do more to criminally prosecute the manufacturers of pirated optical discs. The United States also encourages China to facilitate cooperation in fighting optical disc piracy by sharing exemplar discs from Chinese factories with the international library and forensic facility maintained by right holder organizations.

Right holders report only moderate success in reducing piracy of pre-release titles. Lack of copyright protection for titles undergoing content review is another issue of concern. The United States has included this issue in its WTO dispute challenging apparent deficiencies in China's IPR enforcement regime. The United States also urges China to adopt and apply deterrent penalties for piracy of any title not yet authorized for distribution.

Strong action to curb counterfeiting and piracy on the Internet is critical to the future of IPR protection in China. China should significantly increase criminal prosecutions and other enforcement actions against Internet-based piracy and counterfeiting operations through a coordinated, national effort backed by appropriate resources.

The United States welcomes China's recent accession to the WIPO Internet Treaties. A number of gaps remain to be filled for China to meet the challenges of Internet piracy and fully implement the WIPO Internet Treaties. In May 2006, the State Council adopted an important Internet-related measure, the Regulations on the Protection of Copyright Over Information Networks, which went into effect in July 2006. Although it does not appear to fully implement the WIPO Internet Treaties, this measure represents a welcome step, demonstrating China's determination to improve protection of the Internet-based right of communication to the public. Several aspects still require further clarification. For example, China could benefit from further clarification that certain Internet "deep linking" and other services that effectively encourage or induce infringement are unlawful.

China should also provide strong administrative supervision, backed by penalties, to ensure that Internet service providers take down infringing content and/or links immediately upon receipt of a notice from internationally recognized right holders' representatives; take steps to suspend or terminate the accounts of serious or repeat infringers when they become aware of such infringers; and provide information about the identity of direct infringers to right holders (or to groups representing right holders) when requested.

China also maintains market access barriers, such as import restrictions and restrictions on wholesale and retail distribution, which discourage and delay the introduction of a number of legitimate foreign products into China's market. These barriers create additional incentives for infringement of products like movies, video games, and books, and inevitably lead consumers to the black market, again compounding the severe problems already faced by China's enforcement

authorities. The United States has requested WTO dispute settlement on several market access barriers affecting U.S. copyright industries.

Right holders report that in the seven years since China's current Copyright Law was adopted, China has yet to set a rate under Article 42 of that law for the remuneration of right holders for the use of their works by radio or television broadcasters. This has resulted in the unauthorized and, thus far, uncompensated broadcasting of musical works, prejudicing right holders in China and the United States. The United States urges China to set a fair rate for compensation under Article 42 of its Copyright Law without further delay, and to apply that rate to all of the broadcasts of works that have occurred since 2001.

Retail and wholesale counterfeiting in China is a major source of frustration for international brand owners. In spite of significant attention and resources from brand owners, administrative supervision, civil lawsuits, agreements with landlords, and attention from China's central government and foreign governments, counterfeiting remains pervasive in many retail and wholesale markets. It appears that further measures, including criminal sanctions, will be necessary to bring this problem under control.

In addition to stepping up administrative and criminal action against trademark counterfeiting at the manufacturing, wholesale, and retail levels, the United States calls on China to launch and publicize significant administrative and criminal enforcement actions against optical media piracy, Internet piracy, software end-user piracy, and other forms of piracy affecting U.S. copyright owners.

The United States recognizes that China recently announced a 2008 Action Plan laying out detailed strategies for improving IPR protection. China has the opportunity to achieve real and transparent results for U.S. right holders through implementation of the Action Plan. The United States has worked with China in the past few years on many legislative and policy efforts, including the National IPR Strategy, Internet Regulations, antimonopoly law and patent and trademark law reform. We welcome continued engagement on these issues including transparency and fair opportunities for the public and foreign governments to comment on proposed laws and policies.

The United States also looks forward to working with China to examine a variety of other reforms that would contribute to improving IPR enforcement. In addition to reforming China's criminal laws as discussed above, other areas that China should explore include the positive results that could be achieved through specialized national IPR courts and prosecutors (expanding a practice that already exists in some areas); reducing pendency and backlog in trademark opposition and cancellation proceedings; introducing regulatory mechanisms to ensure that active pharmaceutical ingredients produced in China are not used in counterfeit medicines; implementing effective, detailed plans and strategies for reducing the use of infringing materials by students, staff, and lecturers on school and university campuses; and ensuring that the resources available to local administrative, police, and judicial authorities charged with protecting and enforcing IPR are adequate to the task.

Customs Enforcement: The export of infringing products from China is of grave concern worldwide. Right holders have praised the achievements of China Customs over the past year in increasing seizures, starting to refer criminal cases to police and prosecutors, and cooperating with U.S. right holders. The United States is encouraged by the 2007 Memorandum of Agreement between China's Customs Administration and U.S. customs authorities to cooperate on preventing the exportation of counterfeit and pirated goods. Nonetheless, the statistics on seizures of Chinese-origin goods at the U.S. border, cited above, indicate that additional efforts are needed to stop outbound infringing products at China's borders. The United States calls on China to begin an aggressive campaign to prosecute exporters of infringing products and to expand enforcement cooperation as agreed at successive JCCT meetings. Also, the United States remains concerned about China's rules for disposal of IPR-infringing goods, seized by Chinese customs authorities, which among other things, appear in some circumstances to mandate auction of seized goods following removal of infringing features, rather than destruction or disposal outside of the channels of commerce. The United States has included these customs border enforcement measures as part of its WTO dispute challenging apparent deficiencies in China's IPR enforcement regime.

Civil Enforcement: U.S. right holders won several victories in civil IPR litigation in China in 2007. However, the United States continues to hear complaints of a lack of consistent, uniform, and fair enforcement of China's IPR laws and regulations in the civil courts. Litigants have found that most judges lack necessary technical training; that court rules regarding evidence, expert witnesses, and protection of confidential information are vague or ineffective; and that costs of investigation and bringing cases are prohibitively high. In the patent area, where civil enforcement is of particular importance, the process is inefficient and unpredictable. Concerns have also been raised that some Chinese companies may be inviting local protectionism, for example by bringing civil cases in their home areas against foreign companies in order to obtain disproportionately high damages, compelling detention of foreign nationals, and obtaining litigation or patent filing subsidies, among other things.

Patents and Data Protection: While China's patent laws are largely compliant with the TRIPS Agreement, right holders have noted that the narrow scope of patentable subject matter under Chinese law makes patents for transgenic plants and animals and methods of treatment or diagnosis virtually unobtainable. Concerns have been raised regarding draft amendments to the Patent Law that were recently made available for public comment on issues such as: the role of compulsory licensing; introduction of a two-year period of "laches" after the expiration of the two year statute of limitation; continuing challenges with low quality utility model and design patents; the introduction of disclosure of origins of genetic resources used in the completion of an invention and the concern that that claims in a patent application may be rejected on the basis that this disclosure requirement is not met. A lack of clarity in laws involving generic drug patent infringement is contributing to the continued growth of drug counterfeiting, with corresponding health and safety problems. In that regard, the United States welcomes proposals in the 2008 Action Plan to more closely link patent grants to pharmaceutical marketing approval. In addition, the United States has concerns about the extent to which China provides adequate protection against unfair commercial use for data generated to obtain marketing approval.

Emerging Developments: Apart from longstanding concerns over IPR enforcement, the United States is alert to U.S. industry concerns about the possibility that laws or policies in a variety of fields might be used or misused to favor domestic over foreign IPR. Such concerns are especially acute in light of Chinese government policies establishing a procurement preference for domestically innovated products, statements and consideration of legal and/or policy changes regarding such areas as the scope of compulsory licensing, the use of IPR in setting standards, and other emerging developments that have the potential to affect IPR protection and market access for IPR-bearing goods and services. The United States will monitor these developments closely to ensure fair treatment for U.S. right holders.

The treatment of intellectual property in standards-setting processes has garnered recent attention in China and elsewhere. In China, standards for third generation (3G) wireless technology are an example. China has committed to accord technology-neutral treatment to different 3G standards. To date, China has not licensed any 3G wireless technology. However, Chinese operators have taken steps to procure equipment and services for the installation of a network that appears will be dedicated to support wireless communications based on the TD-SCDMA standard. China Mobile, the world's largest mobile operator, began rolling out a massive "test" TD-SCDMA network in nine coastal cities in late 2007. As China Mobile's webpage attested in mid-April 2008, this service is now commercially available. No other operator has been permitted to deploy alternative 3G technology, even on the kind of "test" basis authorized to China Mobile. Such steps to advance the standard containing Chinese technology raise questions about China's commitment to accord technology neutrality to the different 3G standards.

More generally, the Chinese Electronics Standardization Institute (CESI) is in the process of drafting IPR rules for standards-setting organizations (SSOs). These draft rules provide for SSOs to report to government authorities on the possible relevance of patent claims in draft standards submitted for examination and approval by the authorities. It is unclear what purpose is envisaged for this governmental review, including whether such a review of the possible relevance of patent claims could involve governmental authorities in the determination of the terms and conditions for licensing essential patents.

Provincial and Local Issues

Regional Coordination of IPR protection and enforcement. To promote greater coordination, most municipal authorities in China have established a working group on IPR, appointed a vice mayor, adopted action plans, and opened IPR complaint centers. The widespread use of databases by provincial and local authorities, as well as information provided through www.ipr.gov.cn, has provided greater access to information regarding regional IPR protection and enforcement activities. The United States encourages coordinating authorities to regularly publish white papers, summaries of regional enforcement cooperation, and English language complaint forms, and establish English language complaint call centers. We also encourage publication of information on relevant local laws and regulations

Beijing City is both the nation's capital and one of its most visible centers for retail counterfeiting and piracy. IPR enforcement in Beijing varies between different districts and

authorities. Beijing courts enjoy a generally good reputation, which contributes to Beijing having the nation's highest number of civil IPR cases.

Hot spots. According to industry reports:

- Retail and wholesale markets such as the Silk Market, Tianyi Market, and Yaxiu Market are associated with trade in counterfeit fashion, jewelry, sports, and apparel products.
- Chaoyang District authorities have agreed to enhance their cooperation with copyright owners.
- Local protectionism remains strong in Chaoyang District.
- Much of this counterfeiting and piracy is occurring notwithstanding an apparent lower incidence in the infringement of Olympic-related merchandise. We look forward to China addressing these additional areas at the time of the Olympics, as mentioned in the Action Plan, and on an ongoing basis thereafter.

Retail and wholesale markets. Retail piracy and counterfeiting remain widespread in Beijing; progress in getting the problem under control has been very limited.

- In spite of increasing attention from foreign governments, the media, and China's central and local governments, the Silk Market in Beijing remains possibly the world's most notorious market for counterfeit goods. Landlords at the market have signed agreements to oust counterfeiters, and Chaoyang District officials believe the situation at the market has improved.
- In September 2007, the Silk Street Market was found to bear civil liability for infringement based on the failure to provide evidence that it had implemented the required "trademark authorization systems" established by the Beijing City and Chaoyang District Administrations in March 2006. However, right holders' surveys show no real change in the level of sales of counterfeit goods.

Internet. Beijing authorities have been among the most proactive in China in recognizing and moving to address the serious challenges of Internet piracy that are emerging throughout China.

- Internet cases have successfully been transferred from the copyright bureau to the Public Security Bureau (PSB), and suspects have been tried and convicted. However, suspects who violate copyrights are often convicted for illegal business operations rather than copyright infringement.
- Beijing authorities have been proactive in looking for ways to make Internet enforcement procedures more effective and to address new technological challenges, such as retransmission via the Internet of sporting events.
- Beijing's courts are considering significant copyright cases regarding provision by Internet service providers of "deep links" directly to unlicensed music downloads.

Universities. Beijing's university campuses have also been cited by right holders as magnets for textbook piracy, and they offer a broadband environment that can support copyright infringement. Beijing authorities state that universities receive no safe harbor from IPR laws. Industry praised authorities for enforcement actions involving a Tsinghua University textbook center, and called for investigations to be repeated at the beginning of the school term and at other peak copying times.

Fujian Province is home to large-scale manufacturing, including athletic footwear companies that have repeatedly been the target of infringement allegations by U.S. right holders.

Hot spots. According to industry reports the cities of Jinjiang, Putian, and Quanzhou are particularly associated with counterfeiting in the footwear sector. Local protectionism appears to be a problem.

Criminal enforcement. Right holders in the footwear sector praised the willingness of provincial public security authorities to take the lead in a number of cases where other approaches proved ineffective. However, there is a continuing need for more criminal enforcement in other sectors, including copyright cases.

Administrative enforcement. Right holders in both trademark and copyright industries have noted that in Fujian, like other parts of China, low administrative penalties often have little or no deterrent effect.

Export. Xiamen is one of China's major ports of lading for infringing goods seized at U.S. borders. Xiamen Customs has jurisdiction over approximately half of Fujian province, including the port cities of Quanzhou and Zhangzhou, and has a special division that handles IPR enforcement. Xiamen Customs has worked closely with foreign right holders, and has won praise for its work. Reports in early 2008 indicate that due to better enforcement of IPR by Customs authorities in Xiamen, shippers of pirated and counterfeit goods now seek to avoid using the port of Xiamen.

Guangdong Province is the center of large-scale counterfeit and pirate manufacturing in China for a variety of goods, ranging from low-cost consumer goods, such as household items, clothing and optical media, to high-technology products, such as computer equipment, video game consoles (and game discs/cartridges), and other electronics. A leading industry group calls Guangdong "the biggest problem spot for counterfeiting in China." Right holders have also complained of patent infringement by Guangdong-based companies.

Last year, Provincial officials in Guangdong acknowledged the need to improve deterrence against IPR violations, and expressed a welcome openness to closer engagement with U.S. and other foreign right holders. However, law enforcement cooperation with U.S. right holders appears to have deteriorated since last year's Special 301 Report.

Hot spots. Provincial officials stated that specific cities targeted for enforcement during the past five years included Guangzhou, Shenzhen, Shantou, Jieyang, and Chaozhou. According to industry reports:

- The cities of Guangzhou and Dongguan are particularly associated with counterfeiting in the fashion and sports equipment sectors.
- Internet based vendors trafficking in counterfeit apparel are increasing at alarming rates.
- Guangzhou and Shantou are associated with counterfeiting of health, beauty, and household care products.
- Shenzhen is associated with counterfeiting in the information technology, fashion, and cosmetics sectors, as well as e-commerce in all products.

- Chaozhou and Jieyang are associated with counterfeiting of pharmaceuticals and cigarettes.
- Local protectionism remains strong in the Baiyun and Huadu Districts of Guangzhou.

Criminal enforcement. Availability of criminal remedies is a continuing problem in Guangdong. Statistics for 2006 showed that Guangdong referred only 36 copyright infringement cases for criminal prosecution. Viewed in light of the size of Guangdong's economy and its role as a center of manufacturing, this number was surprisingly low.

In the sector of health, beauty, and household care products, Guangdong has been identified as a relatively difficult place to criminally prosecute counterfeiters. Industry has called for particular attention to intensifying criminal enforcement in hot spots, such as Shenzhen, Guangzhou, and Dongguan. Guangdong Province reported that police handled 396 cases of criminal IPR infringement in 2006, solving 288 cases. Criminal fines and prison sentences were criticized by right holders as being relatively light in Guangdong province.

Administrative enforcement. According to official statistics, trademark infringement cases in Guangdong Province increased by about 30% in 2007, and 31 cases were transferred for criminal investigation, down from 38 in 2006. Guangdong IP officials report that since 2004 they have participated in a Pan-Pearl River Delta group to improve regional cooperation on IPR protection and enforcement.

In spite of being a manufacturing hub and center for counterfeiting, Guangdong in 2006 had fewer copyright infringement cases, relative to its economic size, than other jurisdictions. Provincial authorities recognize that administrative enforcement at trade fairs is especially important given Guangdong's role as host of the Canton Trade Fair and other major fairs; the U.S. Government looks forward to continuing to work closely with local officials and trade fair organizers to improve enforcement at these fairs.

Export. Guangdong's role as an export engine creates a need for more deterrent customs remedies. Despite Guangdong Customs reportedly solving 636 IPR cases in 2006, its ports remain significant sources for infringing goods seized at U.S. borders. Reports in early 2008 indicate that shippers of pirated and counterfeit are seeking to avoid using the port of Shenzhen due to better enforcement of IPR by its Customs authorities.

Optical disc production. The 2007 Special 301 Report highlighted the need for criminal prosecutions to address optical media piracy in Guangdong. The use of online distribution and on-site OD burning facilities is increasing the challenges of addressing OD piracy.

Retail and wholesale markets. Local authorities in Guangdong have achieved mixed results in their efforts to address piracy and counterfeiting in retail and wholesale markets.

- Among other problem areas, right holders cited Ziyuangang Market in Guangzhou and Lowu market in Shenzhen.

Internet. Guangdong is increasingly a center for Internet piracy. It has taken some positive actions in this area, but, like the rest of China, faces serious challenges.

- In 2006, Guangdong ranked in the top five in China in the number of notices for alleged Internet infringement sent by a recording industry group.
- Industry commended Guangdong authorities for taking action in some cases, but awaited action on other sites that had been the subject of complaints.
- Trademark owners are increasingly concerned about use of the Internet, in connection with express delivery services, for direct marketing of counterfeit products to foreign consumers.

Universities. Right holders have expressed concern regarding a lack of transparency in the process of inspection and punishment decisions against university textbook centers.

Jiangsu Province is another large-scale manufacturing center in China. Jiangsu has been recognized for innovative and proactive IPR protection and enforcement efforts, including promulgation of local regulations and policies, and engagement with domestic and foreign institutions on IPR training and cooperation. In early 2007, Jiangsu officially entered into a cooperative IPR program with the U.S. Chamber of Commerce.

Despite high-level attention to IPR issues, industry reports local level discrepancies in IPR enforcement efforts with respect to case transfer practices, trade secret protection, and seized good valuations. As in many other Chinese provinces, Jiangsu IPR enforcement efforts continue to focus on administrative remedies, resulting in fewer criminal referrals.

Hot spots. According to industry reports:

- IP infringers are moving their operations to the less-developed northern part of Jiangsu province to escape raids and other IPR enforcement activities.
- The southern Jiangsu city of Wuxi is particularly associated with the manufacture of counterfeit auto parts.
- In 2006, Jiangsu was home to the largest share of China's Internet Service Providers (ISPs) receiving cease and desist notices for alleged Internet infringement by a recording industry group. The northern city of Yancheng has been referred to as the "home of pirate servers."

Administrative enforcement. In 2006, Jiangsu Administration of Industry and Commerce (AIC) reportedly handled 1,543 trademark cases.

- The Nanjing IPR Complaint Center reported that it handles mostly administrative cases but reported transferring one case to the PSB in 2007, which resulted in a 10 year prison term and a RMB 100,000 fine.
- Nanjing Customs reportedly investigated 92 cases of suspected IP infringement in 2006.
- Nanjing issued a rule that reverts the burden of proof in administrative copyright cases to the suspect to prove that the source of seized goods is legitimate.
- The Nanjing Copyright Bureau has also enlisted local computer repair shops to refuse to service computers that contain pirated software.
- Jiangsu IP administrative authorities report actively participating in the Yangtze River Delta Protection Network to coordinate with other administrative and enforcement officials on cases where right holders and infringers are located in different provinces.

Criminal enforcement. Increasing criminal prosecutions and case transfers should remain a priority for Jiangsu authorities.

- Distinctions in methodologies for valuation of infringing goods continue to impede criminal prosecutions for trademark and copyright infringement in Jiangsu. The courts should accept criminal cases based on thresholds met by combined sales volume and seized inventory.
- Despite positive steps, criminal fines and prison sentences in Jiangsu remain relatively light, as in many other Chinese localities.

Retail and wholesale markets. Local authorities in Jiangsu continue to expand efforts to prevent the sale of infringing goods in retail and wholesale markets.

- Local Nanjing officials reported that, after recognizing Nanjing was becoming a transit center for retailers and wholesalers of counterfeit optical discs, they formed an interagency anti-piracy task force to better monitor areas known for selling pirated audio-visual (AV) products.
- Jiangsu promulgated Provincial Rules on AV Market Management, which require that AV business operators carry proof of relevant licenses of the publishers and distributors of the AV product and proof of the legality of the AV product.
- Jiangsu has established landlord liability rules, but IP authorities report difficulty pursuing cases because of the need to establish proof that the landlord is aware of IP-infringing business.

Internet. Piracy on the Internet remains a problem for Jiangsu province, along with many other localities around China. Officials in Jiangsu and elsewhere noted the difficulty for enforcement officials to collect evidence and establish a profit motive, in accordance with Chinese law. A recording industry survey found Jiangsu as the top Chinese location of ISPs allegedly hosting infringing products in March 2007.

Shanghai City has been praised by industry observers as a relatively bright spot in China's IPR protection environment. Shanghai IPR officials are generally well-trained and responsive to industry requests for IPR actions, welcome cooperation with foreign industry and governments, and have instituted creative programs to improve coordination among relevant IPR agencies. Shanghai is also increasingly becoming the venue of choice for foreign companies filing IP-related cases because of the expertise and competency of Shanghai judicial officials. However, the continued widespread availability of counterfeit and pirated products through retail venues in Shanghai demonstrates the limited effectiveness of administrative remedies and need for Shanghai to pursue more deterrent criminal enforcement.

Hot spots. According to industry reports:

- Despite the welcome July 1, 2006 closing of the notorious Xiangyang Market, infringing products in retail markets and through mobile vendors remain widely available in Shanghai.
- Industry reported that most vendors from Xiangyang relocated to other markets, including nearby Yatai, Fengxiang, Longhua, and Qipu Road markets.

Retail and wholesale markets. Government officials have responded to concerns over widespread retail piracy and counterfeiting rates through increased actions.

- Shanghai administrative authorities have devised a strategy to proactively visit retail outlets (conducting 20,000 visits in the first half of 2006).
- Throughout anti-piracy and anti-counterfeiting campaigns, industry surveys show that infringing goods remain widely available in Shanghai.

Administrative Enforcement.

- In 2006, Shanghai reportedly handled 2,217 trademark cases, among which, foreign related cases accounted for 75.6 percent. In 2007, Shanghai handled 2,946 trademark cases, among which, foreign related cases accounted for 72.5 percent.
- In 2006, Shanghai Culture Task Force launched a special action on audio-video markets and in total handled 2,232 cases.
- In 2007, the Shanghai IP Administration set up IPR information desks in 16 exhibitions and handled over 80 IPR infringement cases involving exhibitions.
- In early 2008, Shanghai established an IPR Aid Center to give legal advice and counseling to both foreign and Chinese businesses with IPR-related issues.
- From January to November 2007, Shanghai Customs reportedly investigated 241 IPR cases, increasing by 91.1% over the same period in 2006.
- Shanghai has drafted special regulations and plans regarding IPR protection during the World Expo in 2010. According to Shanghai IP officials an “experts group” will be established to handle complex IPR issues.
- The Shanghai IP Coordinating Office created the Yangtze River Delta Protection Network in 2003, which includes 26 cities in the area, to facilitate communication among administrative and enforcement officials on cases where right holders and infringers are located in different provinces. The IP Coordinating Office reports that cooperation is increasing under this network and plans to expand its coverage to other areas. The IPR Complaint Centers throughout the region also cooperate by transferring cases.

Internet.

- In 2007, Shanghai courts reportedly handled 207 cases involving infringement on the Internet, an increase of 91.7% compared with 2006.
- In 2007, Shanghai reportedly referred one Internet piracy case for criminal prosecution.
- Local authorities have worked closely with the telecommunications industry to close down over 1,000 Internet sites to date that facilitated illegal downloads.
- In 2007, Shanghai established the Leading Group of Anti-Infringement on Internet, a working group of Internet and IP officials and experts working on ways to combat Internet piracy.

Criminal Enforcement. The number of IPR criminal case transfers in Shanghai remains much too low relative to the size of the local economy. The Shanghai government should be commended for initiating a number of pilot programs to assist in better administrative-criminal coordination on IPR.

- Shanghai PSB launched a pilot program whereby it initiates criminal investigations based on “suspicious leads” rather than evidence of illegal activity. Industry continues to

commend Shanghai for this initiative and would like to see it copied in other jurisdictions.

- Shanghai has also instituted a cross-agency, horizontal Case Monitoring System digital database that tracks IPR cases from initial raids to the transfer of information to the police and prosecutors, to judicial adjudication of a case.

Courts.

- Industry commends the efficiency of many Shanghai courts. Cases there typically move quickly, usually within 6 months for the first trial, with the courts awarding statutory damages if they find infringement.

Universities. Shanghai authorities recognize that illegal copying of textbooks is an issue at Shanghai universities, particularly in small-scale student-run facilities.

- Well-known Shanghai universities have reportedly allowed wholesale book copying in on-campus textbook centers. Shanghai authorities should proactively continue to monitor campuses to prevent continuation of this illegal activity.
- The Shanghai Copyright Bureau reports coordinating with universities to train students on IPR awareness.

Zhejiang Province, a manufacturing hub in eastern China with a large proportion of privately owned production facilities and the major Ningbo port, has been identified over the years as a major distribution center for infringing goods to overseas markets. Right holders have repeatedly drawn attention to the city of Yiwu as an important distribution center for small commercial goods.

Hot Spots. According to industry reports:

- The cities of Ningbo, Cixi, Yiwu and Wenzhou have been particularly associated with counterfeiting manufacturing and distribution (including export).
- Industry representatives have noted that counterfeiters have been moving to the smaller cities of Yuhuan and Taizhou in response to increased enforcement efforts in Yiwu, Cixi and Ningbo.

Retail and Wholesale Markets. Zhejiang is home of the China Small Commodities Market in Yiwu, reportedly the world's largest wholesale market.

- Yiwu officials have set up a coordination body to improve enforcement. They are pursuing closer coordination between industries and the Yiwu government, training for officials on IPR issues, a policy of revoking business licenses for repeat IPR offenders, and employment of undercover Consumer Protection Office investigators to root out underground sales of pirated and counterfeit goods.
- Industry reports that local enforcement authorities are increasingly responsive to right holders' complaints.

Administrative Enforcement.

- Industry reports that Zhejiang AIC is one of the most active in helping right holders investigate trademark infringement.
- The Zhejiang AIC handled 8,403 trademark cases in 2006.

- In comparison to trademark issues, the Copyright Bureau handled 61 copyright cases in 2006.
- To improve coordination and oversight of cultural product markets, Zhejiang State Administration of Radio Film and Television, Culture and Copyright Bureau offices are now co-located.

Criminal Enforcement.

- In 2006, Zhejiang transferred 119 cases of trademark infringement for criminal investigation. There were no reported transfers of copyright cases.
- Criminal remedies continue to be largely non-deterrent, as in other parts of China.
- Zhejiang authorities have confirmed that facilitating more criminal transfers of copyright, patent and trademark cases remains a top priority.
- Local court officials in Yiwu and Ningbo described efforts to increase IPR training for judges and expedite the handling of IPR cases, and industry sources have reported that, in recent years, it has become easier to file criminal IPR complaints in Yiwu.
- Valuation of seized goods remains a key problem..
- Industry reports continued resistance by local administrative officials to transfer cases for criminal investigation and prosecution, a problem in many localities around China.

Exports. The Ningbo port is a significant port of lading for infringing goods seized at U.S. borders. In 2006, Ningbo Customs handled 235 IPR infringement cases valued at RMB 27.51 million, and Hangzhou Customs investigated 123 cases valued at RMB 12 million.

RUSSIA

Russia will remain on the Priority Watch List in 2008. The United States will continue to monitor closely Russia's progress on IPR protection and enforcement and to assess implementation of the November 19, 2006 bilateral agreement on intellectual property rights ("IPR Bilateral Agreement").

Piracy and counterfeiting remain major concerns in Russia. The U.S. copyright industries estimate that they lost in excess of \$1.4 billion in 2007 due to copyright piracy in Russia. The U.S. copyright industries continued to report that in 2007, Russia's optical disc production capacity was far in excess of domestic demand, with pirated products being produced both for domestic consumption and export. Due to growing broadband penetration and the continued proliferation of pirate websites, the United States remains concerned about Internet piracy in Russia.

In spite of some improvements, weak enforcement against piracy and counterfeiting in Russia remains a serious problem. In 2007, Russian law enforcement authorities initiated raids on optical disc production facilities and retail sites, and investigations of Internet sites. However, prosecutions and adjudications of IP cases remain sporadic and inadequate; there is also a lack of transparency and a failure by courts to impose deterrent penalties for IPR violators.

The United States conducted an Out-of-Cycle Review in 2007 to encourage Russia to implement its commitments in the IPR Bilateral Agreement and evaluate further actions that Russia needs to take to improve protection and enforcement of intellectual property rights. As part of the IPR Bilateral Agreement, Russia has committed to fight optical disc and Internet piracy, protect against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, deter piracy and counterfeiting through criminal penalties, strengthen border enforcement, and bring Russian laws into compliance with WTO and international IPR norms. Russia's implementation of those IPR commitments will be essential to completing the final WTO accession process. While Russia has made some progress in implementation, additional work remains for Russia to fully implement its commitments under the IPR Bilateral Agreement.

Part IV of Russia's Civil Code, which covers IPR, went into effect on January 1, 2008. Russia has pledged in the IPR Bilateral Agreement to ensure that Part IV and its other IPR measures will be fully consistent with the TRIPS Agreement upon Russia's accession to the WTO. Russia has also committed to introduce legislation in the Duma to implement its TRIPS Agreement obligations that will take effect upon Russia's accession. The United States is awaiting additional efforts by Russia in this area.

In addition to the multilateral work to ensure Russia's compliance with the TRIPS Agreement and Russia's other international IPR obligations, the United States continues to work with Russia on the enforcement of IPR and Russia's compliance with its bilateral obligations through the United States – Russia Bilateral Working Group on Intellectual Property Rights. In addition, the United States is reviewing Russia's status as a beneficiary country under the U.S. Generalized System of Preferences (GSP) Program.

ARGENTINA

Argentina will remain on the Priority Watch List in 2008. Although cooperation has improved between Argentina's enforcement authorities and U.S. copyright industries, and the Argentine Customs authority has taken steps to improve enforcement, the United States encourages stronger IPR enforcement actions to combat the widespread availability of pirated and counterfeit products. Copyright piracy remains a significant problem in numerous industry sectors. Civil damages are ineffective and in criminal cases the judiciary is apparently reluctant to impose deterrent-level penalties. The United States notes that Argentina continues to make progress in decreasing its backlog of patent applications. However, Argentina still does not provide adequate protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products. The United States also urges Argentina to implement an effective coordination system between its health and patent authorities to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products. The United States will continue to monitor Argentina's efforts to address these IPR concerns.

CHILE

Chile will remain on the Priority Watch List in 2008. Chile's IPR performance continues to fall well below expectations for a U.S. free trade agreement partner. The United States remains concerned about inadequate protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products and insufficient coordination between Chile's health and patent authorities to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products. While some U.S. pharmaceutical companies have reported positive outcomes in patent infringement cases, the underlying weaknesses in Chile's legal regime require resolution in order for Chile to fully implement its obligations under the U.S.-Chile FTA Free Trade Agreement (FTA). The United States also remains concerned about continuing copyright piracy and trademark counterfeiting. Chile's Congress is continuing to consider legislation to implement various provisions of the FTA regarding Internet service provider liability, limitations and exceptions to copyright protection, and enforcement and penalties against copyright infringement. Further amendments to Chile's IPR legislation are needed to bring Chile's IPR regime into line with its multilateral and bilateral commitments. The United States will continue to work together with Chile on the implementation of its IPR commitments in the FTA.

INDIA

India will remain on the Priority Watch List in 2008. The United States remains concerned about inadequate IPR protection and enforcement in India. The United States continues to urge India to improve its IPR regime by providing stronger protection for copyrights, trademarks, and patents, as well as protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products. The United States encourages India to implement the WIPO Internet Treaties by strengthening its copyright laws, and to improve its IPR enforcement system by enacting and implementing an effective optical disc licensing scheme to combat optical disc piracy. Piracy remains a serious problem in India, as does trademark counterfeiting, including of pharmaceuticals and distilled spirits. India's criminal IPR enforcement regime remains weak, with improvements needed in the areas of police action against pirates and counterfeiters, expeditious judicial dispositions for copyright

and trademark infringement with imposition of deterrent-level sentences for IPR infringers, and stronger border enforcement against counterfeit and pirated goods. The United States urges India to strengthen its IPR regime and stands ready to work with India on these issues during the coming year through the Trade Policy Forum and other bilateral mechanisms.

ISRAEL

Israel will remain on the Priority Watch List in 2008 and the United States will conduct an Out-of-Cycle Review as a positive step to encourage progress in Israel on IPR issues. The United States is encouraged by recent progress on certain IPR issues in Israel, including: the passage of copyright legislation and issuance of a decree in 2007 that ensures national treatment for U.S. rights holders in accordance with the 1950 exchange of letters between the United States and Israel; the issuance of regulations in 2007 and policy clarifications in 2008 on the manufacturing of pharmaceutical products for export; and increased positive engagement between the United States and Israel on IPR issues. The United States remains seriously concerned, however, with Israel's inadequate level of protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products, and Israel's laws that adversely affect the term of pharmaceutical patent protection by effectively reducing the time granted to compensate for delays in obtaining regulatory approval of a drug. The United States hopes to see Israel accede to and implement the WIPO Internet Treaties in order to address the growing problem of Internet piracy in Israel. As noted in last year's report, the United States expects Israel to provide an appropriately high level of IP protection that reflects its status as a partner in the U.S. – Israel FTA and its objective of becoming a member of the Organization for Economic Co-operation and Development (OECD). The United States will continue to work together with Israel during the Out-of-Cycle Review to ensure the strengthening of Israel's IPR regime.

PAKISTAN

Pakistan will be elevated to the Priority Watch List in 2008. In 2007, the United States conducted an Out-of-Cycle Review to monitor Pakistan's progress on enacting legislation to provide effective protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products, as well as a system of coordination between its health and patent authorities to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products. Due to a lack of progress this year in either of these areas, Pakistan is being elevated to the Priority Watch List. The United States and Pakistan will remain closely engaged on these issues during the coming year. The United States commends Pakistan for continuing to take enforcement actions against large-scale illegal optical disc production and retail sales of pirated and counterfeit products, but encourages Pakistan to take enforcement actions against book piracy, aggressively prosecute IPR crimes, and ensure that its courts issue deterrent-level sentences for IPR infringers, especially against those connected with the optical disc pirate plants that were shut down in 2005. The United States will continue to monitor closely the IPR situation, and will work together with Pakistan to achieve further improvements in its IPR protection and enforcement regimes.

THAILAND

Thailand will remain on the Priority Watch List in 2008 due to a broad range of concerns surrounding IPR protection and enforcement. Elections in December 2007 re-established

democratic governance in Thailand, and the United States looks forward to working with the new Thai government to seek resolution of these concerns. The United States recognizes that in 2007, Thai law enforcement officials continued to conduct actions against infringing activity at the retail and distribution levels. Despite these efforts, however, piracy and counterfeiting rates remained high. The United States strongly urges Thailand's authorities to take additional concrete actions to strengthen its IPR regime that include continuous and sustained enforcement actions that get to the source of the infringing activity and issuance of deterrent penalties to IPR infringers, specific steps to improve interagency coordination, and to combat optical disc piracy, large-scale organized book piracy, cable and signal theft, and entertainment and business software piracy. Thai authorities should also take steps to address production and distribution of counterfeit products, as well as delays in the granting of patents. While the United States recognizes the importance of Thailand's public health challenges, Thailand's recent policies and actions regarding the compulsory licensing of patented medicines have contributed to continuing concerns regarding the adequate and effective protection of IPR in Thailand. The United States is awaiting further information on the new Thai government's approach in this area and hopes to work constructively on this and other IPR issues in order to strengthen Thailand's IPR regime.

VENEZUELA

Venezuela will remain on the Priority Watch List in 2008. Venezuela made no effort to improve its weak IPR regime in 2007. Copyright piracy continues to worsen, while proposed copyright legislation, if re-introduced, would severely undercut the existing Venezuelan copyright law, as well as bilateral and international standards of IP protection. The U.S. pharmaceutical industry reports that Venezuela has not issued a patent to a foreign pharmaceutical product since 2003, and has not issued any patents at all since 2005. Venezuela also does not provide protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products. In April 2006, Venezuela withdrew from the Andean Community, raising questions about Venezuela's ability to fulfill its international IPR obligations and whether it will provide for the effective administration of its IPR system. The United States urges the Venezuelan government to take immediate action to improve IPR protection, particularly by addressing piracy and counterfeiting, amending inadequate legislative proposals or laws, protecting against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products, and improving IPR enforcement.

WATCH LIST

ALGERIA

Algeria will be added to the Watch List in 2008. The United States is concerned about the lack of protection in Algeria against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products, as well as insufficient coordination between Algeria's health and patent authorities to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products. For example, industry has noted concern over Algeria's lack of data protection legislation, Algeria's granting of marketing approval in 2007 to generic copies of drugs protected by Algerian patents, and the lack of effective judicial remedies to enable a right holder to challenge in court the granting of marketing approval for generic pharmaceutical products that infringe Algerian patents. The United States also has concerns about weak enforcement against piracy and counterfeiting in Algeria. The United States will work together with Algeria to address these IPR concerns, including through Algeria's bid for accession to the WTO and the bilateral Trade and Investment Framework Agreement.

BELARUS

Belarus will remain on the Watch List in 2008. The United States remains concerned about Belarus' delayed implementation of its intellectual property commitments under the U.S.-Belarus Trade Agreement. The United States encourages Belarus to strengthen its IPR laws, reduce piracy and counterfeiting levels, and increase its IPR enforcement efforts. Belarus reportedly plans to amend its copyright law in 2008, and the United States will continue to monitor Belarus' progress to ensure that it provides adequate protection for sound recordings and pre-existing works and properly implements the WIPO Internet Treaties, which Belarus ratified in 1998. Belarus' IP laws neither provide *ex officio* authority to allow police officials to initiate criminal copyright cases or for customs officials to seize illegal products at the border, nor provide for civil *ex parte* search procedures necessary to protect against end-user software piracy. The United States will work together with Belarus to strengthen its IPR laws.

BOLIVIA

Bolivia will remain on the Watch List in 2008. Piracy and counterfeiting persist in Bolivia, and there were no notable improvements to Bolivia's IPR regime during 2007. As a WTO member, Bolivia committed to increase its levels of IPR protection substantially. The United States encourages Bolivia to accede to and implement the WIPO Internet Treaties. In addition to rampant piracy and counterfeiting in Bolivia, concerns remain about the erosion of IP protection for pharmaceutical products in Bolivia. The United States encourages Bolivia to improve its IPR protection regime in 2008, as well as increase its IPR enforcement efforts to combat piracy and counterfeiting.

BRAZIL

Brazil will remain on the Watch List in 2008. The United States conducted an Out-of-Cycle Review in 2007, which resulted in Brazil being maintained on the Watch List in February 2008. This decision recognizes Brazil's continued positive momentum on IPR enforcement that led to the decision to improve Brazil's ranking from the Priority Watch List to the Watch List in the

2007 Special 301 review. The United States will continue to pursue bilateral dialogue on IPR enforcement and other IPR issues. In particular, the United States encourages Brazil to strengthen its IPR enforcement legislation, take more vigorous action to address book and Internet piracy, and consider acceding to and implementing the WIPO Internet Treaties. With regard to patent, trademark, and data protection matters, Brazil's posture of hindering IP protection in these areas remains a matter of concern, although capacity improvements at the Brazilian Industrial Property Institute do hold the prospect of streamlined processing and a reduction in the patent and trademark application backlogs. The United States will continue to engage with Brazil bilaterally on these IPR protection and enforcement issues, including through the U.S.-Brazil Bilateral Consultative Mechanism and other means.

CANADA

Canada will remain on the Watch List, subject to essential progress on key issues in the coming months. Canada embraced improving IPR protection and enforcement as a priority in the Speech from the Throne in October 2007. The United States looks to the Government of Canada to deliver on these priorities through prompt and effective action on key issues, such as copyright reform and enhanced border enforcement of intellectual property rights. The United States welcomes Canada's continued cooperation on bilateral and multilateral IPR initiatives, and notes progress in the form of Canada's issuance of measures in 2007 to criminalize camcording of copyrighted films in movie theaters. The United States notes its continuing serious concerns, however, with Canada's failure to accede to and implement the WIPO Internet Treaties. The United States also continues to urge Canada to improve its IPR enforcement system to enable authorities to take effective action against the trade in counterfeit and pirated products within Canada, as well as curb the volume of infringing products transshipped and transiting through Canada. Canada's weak border measures continue to be a serious concern for IP owners. The United States hopes that Canada will implement legislative changes to provide a stronger border enforcement system by giving its customs officers *ex officio* authority to seize products suspected of being pirated or counterfeit without the need for a court order. The provision of additional resources and training to customs officers and domestic law enforcement personnel would enhance IPR enforcement. The United States will continue to monitor Canada's progress in providing an adequate and effective IPR protection and enforcement regime, including improved border enforcement and near term accession to and implementation of the WIPO Internet Treaties.

CZECH REPUBLIC

The Czech Republic will remain on the Watch List, where it was placed as the result of an Out-of-Cycle Review in January 2008. The United States remains concerned about the significant amount of pirated and counterfeit goods sold in retail markets on the border between the Czech Republic and Germany and Austria, reported by the U.S. recording industry to be "the highest concentration and largest number of pirate outdoor markets in the world." Some of these markets are reportedly located on government-owned property. The United States urges the Czech Republic to implement its IPR Action Plan and to take concrete enforcement actions, including prosecutions and deterrent-level sentencing of IPR infringers to reduce substantially the sale of pirated and counterfeit goods at these border markets. The United States will continue to monitor this situation and work with the Czech Republic to make significant IPR improvements before it assumes the Presidency of the European Union in 2009.

ECUADOR

Ecuador will remain on the Watch List in 2008. Ecuador made some progress in 2007 towards eliminating its backlog of pending patent applications. Overall IPR enforcement in Ecuador remains problematic, however, and Ecuador has not yet established the specialized IPR courts required by its 1998 IPR law. Concerns also remain over Ecuador's lack of effective protection against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, as well as Ecuador's lack of an effective coordination system between its health and patent authorities to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products. The United States urges Ecuador to strengthen its IPR regime and to enhance its IPR enforcement efforts, and will monitor Ecuador's efforts to address these IPR concerns.

EGYPT

Egypt will be moved in 2008 to the Watch List from the Priority Watch List, in recognition of improvements in pharmaceutical IPR protection, notably the Ministry of Health's progress in streamlining applications for marketing approval of pharmaceutical products, Egypt's attention to its backlog of pending patent applications, and the renewed dialogue between the U.S. and Egypt on IPR issues. Serious concerns remain, however, about continuing deficiencies in Egypt's IPR enforcement regime, particularly related to copyright enforcement against book piracy and entertainment software piracy. Egypt needs to improve its court system by increasing its efficiency and transparency, as well as encouraging judges to impose deterrent-level sentences in copyright and trademark infringement cases. The United States is concerned with the transshipment of counterfeit and pirated goods through Egypt, including in the Damietta Port and Port Said Free Trade Zones. The United States urges the Ministry of Health to further clarify its commitment to protection against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, and to continue its efforts to provide coordination between its health and patent authorities to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products. The United States will continue to work closely with Egypt on improving its IPR regime.

GREECE

Greece will be added to the Watch List in 2008. IPR enforcement in Greece is weak and uneven, and efforts to improve enforcement generally lack effective coordination. The U.S. copyright industries estimate that Greece has one of the highest levels of piracy in the European Union. The United States recognizes that in 2007, Greece increased cooperation with industry, executed an extensive education and outreach plan, provided IPR training to police and customs officers, and conducted a Christmas season raid/seizure campaign, and recently established a formal interagency coordinating IPR committee. However, the United States urges improvements in IPR enforcement, including sustained implementation of enforcement measures against street vendors, more effective raids and seizures, increased prosecutions, encouragement of judges to impose deterrent-level penalties, strengthened border enforcement, and establishment of a national action plan to combat IPR infringement. The United States will continue to work with Greece, with the goal of improving IPR protection and enforcement.

HUNGARY

Hungary will remain on the Watch List in 2008. Hungary has made some IPR improvements, including the establishment in January 2008 of a National Board Against Counterfeiting. The United States will monitor the progress of Hungary's efforts to combat piracy and counterfeiting. Further improvements are needed to ensure that prosecutors follow through with cases against IP infringers, and that judges are encouraged to impose deterrent-level sentences for civil and criminal IP infringement. U.S. copyright industries also report that Internet piracy in Hungary is a growing problem. The United States will continue to work with the Hungarian Government to address these IPR concerns.

INDONESIA

Indonesia will remain on the Watch List in 2008. Indonesia took some positive steps toward combating piracy and counterfeiting in 2007, including several major raids of optical disc manufacturing plants as well as actions against distributors of counterfeit pharmaceuticals. However, on the whole, there has been little improvement in Indonesia's IPR climate, nor any signs that the government is taking significant steps to address the weaknesses in its system. The United States urges Indonesia to take a comprehensive approach to enforcing IPRs that includes proper application of IPR laws by the courts; effective interagency coordination to ensure that enforcement actions are continuous and sustained; enforcement actions resulting in prosecutions where appropriate; and where there are convictions, the issuance of deterrent penalties. The United States urges Indonesia to improve examination of trademark applications, and to provide an expeditious and effective avenue to challenge questionable registrations. In addition, Indonesia should provide effective protection against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products and improve coordination between Indonesia's health and patent authorities to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products. Also, despite some enforcement actions taken by Indonesia against distributors of counterfeit pharmaceuticals, the U.S. pharmaceutical industry estimates that approximately 25 percent of drugs in Indonesia are counterfeit; this dangerous situation requires greater attention by Indonesia. The United States will continue to use the bilateral Trade and Investment Framework Agreement process to work with Indonesia to improve its IPR protection and enforcement regimes.

ITALY

Italy will remain on the Watch List in 2008. Italy made progress in 2007, including through increased senior-level support for IPR enforcement, and some enforcement actions by the Guardia di Finanza. U.S. copyright industries continue to report, however, that Italy maintains one of the highest overall piracy rates in Western Europe. The United States is particularly concerned about the lack of judicial imposition of deterrent-level penalties for criminal copyright and trademark infringers. The United States urges Italy to make IPR enforcement a top priority, including encouraging judges to impose deterrent-level sentences and establishing a national action plan to address commercial-scale piracy, with a particular focus on Internet piracy. The United States will continue to work with Italy, with the goal of improving IPR protection and enforcement.

JAMAICA

Jamaica will remain on the Watch List in 2008. The United States remains concerned over Jamaica's continued delay in enacting the Patents and Designs Act, which is intended to implement Jamaica's obligations under the TRIPS Agreement and to comply with the United States-Jamaica Bilateral Intellectual Property Agreement. The United States urges the Government of Jamaica to reform its patent law as soon as possible to comply fully with international standards for patent protection.

KUWAIT

Kuwait will remain on the Watch List in 2008. Although Kuwait customs, police, and Ministry of Interior officials continued to make progress on IPR enforcement in 2007, Kuwait failed to make similar progress on amending its outdated IPR laws. The United States remains concerned that several key pieces of IPR legislation have been pending for many years, including legislation regarding copyrights, data protection, geographical indications, trademarks, patents, and customs, and urges Kuwait to enact and implement this legislation in the near term. The United States will continue to work with Kuwait on the passage of this IPR legislation and improved IPR enforcement through the United States-Kuwait Trade and Investment Framework Agreement in order to ensure that Kuwait meets its international IPR commitments.

LEBANON

Lebanon will be moved to the Watch List in 2008 from the Priority Watch List. Lebanon took some IPR enforcement actions in 2007, especially in the form of the Cyber Crime and Intellectual Property Rights Bureau within Lebanon's police department. The United States remains concerned, however, about copyright piracy in Lebanon, particularly in the sectors of cable and book piracy. The United States is also concerned about inadequate protection against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, as well as a growing problem with counterfeit pharmaceutical products in Lebanon. The United States urges Lebanon to improve IPR protection and enforcement in the coming year, particularly in light of Lebanon's bid for accession to the WTO.

MALAYSIA

Malaysia will remain on the Watch List in 2008. Malaysia continued to show a strong commitment to strengthening IPR protection and enforcement this past year, but still needs to make further IPR improvements. In 2007, Malaysia continued to take positive actions against piracy and counterfeiting. Notably, the Malaysian Government established a specialized IP court, which began to adjudicate IPR cases in 2007. The United States urges Malaysia to continue its IPR enforcement efforts and to accede to and fully implement the WIPO Internet Treaties. The United States also encourages Malaysia to provide effective protection against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, and create a coordination mechanism between its health and patent authorities to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products. The United States will continue to work with Malaysia to make progress on these pressing IPR issues through the ongoing U.S.-Malaysia Free Trade Agreement negotiations.

MEXICO

Mexico will remain on the Watch List in 2008. Overall IPR enforcement efforts remained weak in Mexico in 2007, although there were notable improvements during the year in the State of Mexico and the Municipality of Toluca. The United States encourages Mexico to take the following actions to strengthen its IPR regime: continue to build a consistent record of aggressive prosecutions and deterrent-level penalties imposed by courts; improve domestic cooperation efforts between federal, state, and local enforcement authorities; increase IPR enforcement efforts by customs authorities; pass legislation to provide *ex officio* authority to law enforcement and customs authorities; criminalize camcording in theaters; and implement fully the WIPO Internet Treaties. The United States also encourages Mexico to provide adequate protection against unfair commercial use for test or other data generated to obtain marketing approval for pharmaceutical products, and improve coordination between its health and patent authorities to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products. Counterfeit pharmaceuticals also appear to be a growing problem in Mexico. The United States will continue to work with Mexico to address and resolve these IPR concerns in an effective manner.

NORWAY

Norway will be added to the Watch List in 2008. The United States is concerned about the lack of product patent protection for certain pharmaceutical products. The regulatory framework in Norway regarding process patents filed prior to 1992 denies adequate protection to nearly 75 percent of the pharmaceutical products currently on the Norwegian market, according to U.S. industry reports. The United States will continue to encourage Norway to resolve this issue.

PHILIPPINES

The Philippines will remain on the Watch List in 2008. The United States is concerned about U.S. industry reports of an apparent increase in piracy in the Philippines, particularly in the areas of book piracy, illegal downloads using mobile devices, piracy on the Internet, and the illegal camcording of films in theaters. The United States urges the Philippines to take steps to reverse these trends and strengthen its enforcement regime against piracy and counterfeiting. Specifically, the Philippines should pursue final determinations in outstanding IPR cases, including those related to cable piracy, with imposition and implementation of deterrent-level penalties. The Philippines also should strengthen the Optical Media Board and provide it with adequate resources to expand and improve the effectiveness of its activities; strengthen the Customs IP unit; ensure that its patent regime complies with the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights; enforce copyright protection of printed material; and seek to obtain amendments to the Copyright Act to implement the WIPO Internet treaties. The United States will continue to work with the Philippine Government under the bilateral Trade and Investment Framework Agreement to strengthen the Philippines IPR regime.

POLAND

Poland will remain on the Watch List in 2008. Poland made some IPR improvements in 2007, including the closure of the Warsaw Stadium that was notorious for selling counterfeit and pirated goods, amendments to its IP laws to strengthen criminal penalties, and closer cooperation between law enforcement authorities and the private sector. Numerous IPR concerns remain,

however, such as increasing Internet piracy, trade in pirated goods at markets on Poland's border with Germany, weak border enforcement, inefficient prosecutions, and lack of deterrent-level sentences imposed by courts. The United States is also concerned by Poland's lack of coordination between its health and patent authorities to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products, as well as a reported lack of adequate enforcement remedies when generic pharmaceutical products are launched during the term of an innovator's patent. The United States encourages Poland to commit its resources and attention to addressing these IPR protection and enforcement issues over the next year.

ROMANIA

Romania will remain on the Watch List in 2008. Though there was a decrease in pirated optical discs sold by street vendors, Internet piracy grew significantly in 2007. Prosecutors in Romania often fail to pursue IPR cases and judges often dismiss IPR cases due to a perceived "lack of social harm." The United States urges Romania to encourage its prosecutors to vigorously prosecute IPR cases and its judges to impose deterrent-level sentences against IPR infringers, and to remove delays and obstacles in criminal investigations. The United States will work with Romania to improve its IPR enforcement efforts.

SAUDI ARABIA

Saudi Arabia will remain on the Watch List in 2008. The United States has been working closely with Saudi Arabia on IPR issues during 2007. Saudi Arabia has made some progress in IPR enforcement, including an increased number of IPR raids and the reported disposition of numerous cases by the copyright enforcement Violations Review Committee. The United States recognizes that Saudi Arabia is pursuing IPR improvements, especially with regard to increasing transparency of its copyright enforcement administrative processes within the Ministry of Culture and Information and the Violations Review Committee. The United States welcomes preliminary reports in late April that the long-awaited Ministry of Culture and Information website became operational, and we expect that transparency will increase as more information is added to this website. Saudi Arabia also has reportedly increased its cooperation with private right holders. Saudi Arabia needs to make further IPR improvements by continuing sustained raids and inspections to combat piracy and counterfeiting; encouraging courts to impose deterrent-level sentences, including jail sentences for serious offenses against IPR infringers; and improving border enforcement. The United States welcomes Saudi Arabia's agreement to establish a United States – Saudi Arabia IPR Working Group, and will work closely with Saudi Arabia to address the outstanding IPR issues during the coming year through this IPR Working Group and the Trade and Investment Framework Agreement.

SPAIN

Spain will be added to the Watch List in 2008. The United States is concerned by the Spanish government's inadequate efforts to address the growing problem of Internet piracy, described by U.S. copyright industries as one of the worst in Europe. There is also a widespread misperception in Spain that peer-to-peer file sharing is legal. While Spanish law enforcement authorities have taken some positive measures against pirate Internet websites, prosecutors have failed to pursue IPR cases, judges have failed to impose deterrent-level sentences against IPR infringers, and right holders do not have access to important legal tools needed to bring

meaningful civil infringement suits. The United States will continue to work closely with Spain to address these IPR enforcement issues during the next year.

TAIWAN

An Out-of-Cycle Review will be initiated in the immediate future and completed this summer to monitor progress on selected outstanding issues to consider whether Taiwan should be removed from the Watch List. Progress by Taiwan on improving its IPR regime this past year includes the June passage by the Legislative Yuan (LY) of a new law aimed at ending illegal file-sharing over peer-to-peer (P2P) platforms, which enabled officials to shut down some of the worst violators; continued efforts to establish an IP section at the Special Prosecutor's Office; and creation and issuance in October 2007 of the Action Plan for Protecting IP Rights on School Campuses. The United States urges Taiwan to make the specialized IPR Court operational as soon as possible. The United States urges Taiwan to continue to implement the 2007 Campus Action Plan, continue its efforts to combat counterfeiting and Internet piracy, and to work closely with the LY to pass pending IPR legislation regarding liability of Internet service providers for copyright infringements. The United States asks that Taiwan continue to take effective action against piracy on the Internet, especially on TANet, the Internet service provider administered by Taiwan's Ministry of Education, and against the unauthorized use of copyrighted material on or near universities.

TAJIKISTAN

Tajikistan will remain on the Watch List in 2008. Tajikistan made progress passing IPR legislation this past year. The United States remains concerned, however, that Tajikistan has not yet fulfilled its IPR obligations under the U.S.-Tajikistan Bilateral Agreement, and encourages Tajikistan to take the necessary steps to fully implement the TRIPS Agreement as part of its ongoing efforts to join the WTO. In addition, Tajikistan continues to have a weak enforcement regime that lacks criminal penalties for IPR violations, *ex officio* authority to commence criminal cases, and civil *ex parte* search procedures necessary for effective enforcement against end-user pirates, among other important enforcement measures. The Tajik Customs Code also fails to provide customs officials with *ex officio* authority to suspend the release of suspected infringing materials at the border. Legal reforms are also needed, for example, in Tajikistan's copyright law, which does not provide protection for sound recordings or pre-existing works. The United States also encourages Tajikistan to accede to and implement the WIPO Internet Treaties. The United States will continue to work with Tajikistan through the Trade and Investment Framework Agreement and the ongoing WTO accession negotiations to address deficiencies in its IPR laws and strengthen IPR protection and enforcement.

TURKEY

Turkey will be lowered to the Watch List in 2008, due to notable progress on copyright enforcement, including an increased number of raids against copyright pirates and seizures of pirated goods, impositions of deterrent-level penalties by the courts, improved pharmaceutical protection, and increased cooperation between law enforcement authorities and the private sector. U.S. copyright industries note that Turkey's enforcement actions are "beginning to reap benefits in the market in terms of decreased piracy." The United States encourages Turkey to build upon this positive momentum, including addressing end-user software piracy more vigorously. The United States also encourages Turkey to consider strengthening its protection

against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, particularly with respect to the start date of the period of protection and the inappropriate linkage of the term of data protection to the remaining term of the patent, as well as ensuring coordination between Turkey's health and patent authorities to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products. The United States hopes to see Turkey's continued progress on these issues during the coming year, and will continue to monitor Turkey's progress in strengthening its IPR regime.

TURKMENISTAN

Turkmenistan will remain on the Watch List in 2008. The United States remains concerned about Turkmenistan's lack of progress on IPR issues and its lack of fulfillment of its IPR obligations under the United States-Turkmenistan Trade Agreement. For example, Turkmenistan has neither acceded to nor implemented the Berne Convention for the Protection of Artistic and Literary Works (Berne Convention), the Geneva Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of Their Phonograms (Geneva Phonograms Convention), or the WIPO Internet Treaties. Turkmenistan does not have a copyright law and does not provide clear criminal procedures or penalties for IPR infringement as required by the U.S.-Turkmenistan Trade Agreement. Its Customs Code does not provide *ex officio* authority to seize suspected infringing material at the border, and there are no known civil *ex parte* search procedures. The United States urges Turkmenistan to adopt the legal reforms that will bring Turkmenistan into compliance with its obligations under the bilateral United States-Turkmenistan Trade Agreement and to undertake enforcement activities that will help to strengthen its IPR regime.

UKRAINE

Ukraine will be lowered to the Watch List in 2008. Ukraine made significant progress in 2006 and 2007 by passing IP legislation and regulations as part of its bid for accession to the WTO (the WTO approved Ukraine's terms of accession in February 2008, and the deadline for parliamentary approval of the accession is July 4, 2008). Since adopting amendments to its optical disc law in 2005, Ukraine has continued to enforce against pirate optical disc manufacturing, and no evidence of pirate manufacturing has been detected in several years. The Government of Ukraine has continued to participate regularly in an Enforcement Cooperation Group with the U.S. Embassy in Ukraine and U.S. industry representatives. Despite these improvements, however, Ukraine needs to address numerous important IP issues, including full implementation of its new IP legislation; continuation of enforcement actions against optical disc factories; stronger border enforcement to address transshipment of illegal optical media produced in Russia and elsewhere; continued raids and arrests of IPR infringers, as well as follow through with vigorous prosecutions and imposition of deterrent-level sentences by courts; concrete actions to combat the growing problem of Internet piracy in Ukraine; ensuring that government ministries use only legal software; and curbing the production and distribution of pirated and counterfeit products throughout Ukraine, including in notorious markets in Ukraine. The United States will monitor Ukraine's implementation of its 2006 Law on Medicines that provides protection against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products to ensure that it fulfills its WTO obligations. The United States recognizes Ukraine's improvements in 2006 and 2007 in IPR protection, while also recognizing that significant efforts need to be made to achieve further progress on IPR

protection and enforcement. The United States will continue to work with Ukraine to ensure sustained progress on these IPR issues in a number of fora, including a new Trade and Investment Cooperation Agreement, the IPR Enforcement Cooperation Group, and the WTO.

UZBEKISTAN

Uzbekistan will remain on the Watch List in 2008. The United States remains concerned about Uzbekistan's lack of progress on IPR issues. Although Uzbekistan passed a revised copyright law in 2006 and recently has started to close down shops that sell pirated products, numerous IPR deficiencies remain. Uzbekistan has acceded to the Berne Convention, but the United States notes its concern with Uzbekistan's continuing reservation to Article 18 of the Convention, which requires that signatory countries provide copyright protection to pre-existing works. Uzbekistan does not provide protection for sound recordings or pre-existing works, and has not acceded to the Geneva Phonograms Convention or the WIPO Internet Treaties. In addition, IPR enforcement in Uzbekistan remains weak due to a lack of *ex officio* authority that would allow customs officials to seize infringing goods at the border, a lack of civil *ex parte* search procedures, and inadequate criminal penalties for IPR violations. The United States urges Uzbekistan to address these deficiencies in its IPR legal regime and to take immediate and effective measures to improve IPR enforcement. The United States will continue to work together with Uzbekistan on these outstanding IPR issues through discussions related to Uzbekistan's bid for WTO accession and in the on-going review of Uzbekistan's status as a beneficiary country under the U.S. Generalized System of Preferences (GSP) Program.

VIETNAM

Vietnam will remain on the Watch List in 2008. Vietnam made progress in 2007 by continuing to build its legal framework for IP protection, strengthening enforcement capacity, and improving interagency coordination. Vietnamese agencies have taken steps to increase enforcement efforts including initiatives to improve IP coordination between enforcement ministries, signing an agreement for government procurement of legal software, taking actions against cable piracy, and raising public awareness of IPR. Nevertheless, significant weaknesses remain, particularly with respect to its criminal regime, administrative regime, and its border enforcement regime. In addition, there is a lack of enforcement against Internet piracy and optical media containing unauthorized content. Vietnam has indicated it is taking steps to put in place more deterrent fines and penalties for copyright infringement and is in the early stages of drafting legislation to control optical media. However, concern is rising among right holders that Vietnam's IP enforcement system has not yet developed sufficiently to control the rapid growth of piracy and counterfeiting despite the substantial legislative work completed over the past several years. The United States has strongly urged Vietnam to address weaknesses in its criminal law relating to trademark infringement and copyright piracy. The United States will continue to work closely with Vietnamese authorities to strengthen capacity on IPR and to support Vietnam's efforts to implement fully its WTO TRIPS commitments.

WATCH LIST – RECENTLY COMPLETED FREE TRADE AGREEMENTS

COLOMBIA

Colombia will remain on the Watch List in 2008. The United States commends Colombia for its continued actions to combat IPR violations through launching public awareness campaigns, conducting raids, prosecuting IP infringers, and designating special IP judges. The United States remains concerned, however, that further IPR improvements are needed, including efficient prosecutions of IP infringers, issuance of deterrent-level criminal sentences by courts, and stronger IPR border enforcement. The United States will continue to monitor Colombia's compliance with its bilateral and multilateral obligations to protect against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, and encourages Colombia to develop procedures and remedies to prevent the issuance of marketing approvals for patent-infringing pharmaceutical products. The United States will work with Colombia to achieve progress on these pressing IPR issues through the implementation of its IPR commitments under the United States – Colombia Trade Promotion Agreement (CTPA), in which Colombia has committed to implement high standards of IPR protection through its legal structures and enforcement practices.

COSTA RICA

Costa Rica will remain on the Watch List in 2008. The United States remains concerned about weak IPR enforcement in Costa Rica, particularly with respect to copyright piracy and trademark counterfeiting. The United States encourages the Government of Costa Rica to address the shortcomings in its IPR enforcement system by assigning high priority and resources to combating piracy and counterfeiting and providing deterrent penalties. Additional IPR areas of concern include inadequate protection against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, and inadequate protection for patents, copyrights, and trademarks. Costa Rica ratified the United States – Central America – Dominican Republic Free Trade Agreement (CAFTA–DR) in October 2007. The United States will continue to work closely with Costa Rica to ensure implementation of its IPR commitments under CAFTA–DR in the near term.

DOMINICAN REPUBLIC

The Dominican Republic will remain on the Watch List in 2008. The Dominican Republic passed IPR laws in 2006 and 2007 to implement its commitments under CAFTA–DR. These legislative reforms have enhanced the Dominican Republic's protections for patents, copyrights, and trademarks, as well as strengthened its IPR enforcement regime. The United States will continue to monitor the Dominican Republic's compliance with its bilateral and multilateral obligations to protect against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, and encourages the Dominican Republic to provide coordination between its health and patent authorities to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products. The United States encourages the Dominican Republic to enforce its new IPR laws and hopes to see a resulting decline in the high levels of piracy and counterfeiting in the Dominican Republic.

GUATEMALA

Guatemala will remain on the Watch List in 2008. Through the implementation of Guatemala's IPR obligations under the CAFTA-DR, Guatemala's laws provide for stronger IPR protection and enforcement. Nevertheless, IPR enforcement remains a problem. The United States notes that Guatemala's new administration has expressed support for improving IPR protection and enforcement. The United States will continue to monitor Guatemala's compliance with its IPR obligations under CAFTA-DR.

PERU

Peru will remain on the Watch List in 2008. The United States remains concerned with the IPR situation in Peru. The U.S. copyright industries report that piracy levels remain high. The United States encourages the Government of Peru to continue its efforts to combat IPR piracy by: conducting more raids and seizures; ensuring that arrests of IPR infringers result in convictions and the imposition of deterrent-level sentences that include imprisonment; applying effective civil remedies; and giving increasing attention to IPR enforcement measures at its borders. Additional IPR areas of concern include inadequate protection against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, and inadequate protection for patents, copyrights, and trademarks. The United States will work closely with Peru to ensure implementation of Peru's IPR commitments under the United States – Peru Trade Promotion Agreement (PTPA), in which Peru has committed to implement high standards of IPR protection through its legal structures and enforcement practices. The United States urges Peru to strengthen IPR protection and enforcement to ensure that it will meet its international and PTPA commitments.

REPUBLIC OF KOREA

The Republic of Korea (Korea) will remain on the Watch List in 2008. The United States welcomes the strong and far-reaching IPR commitments that Korea agreed to undertake under the U.S. – Korea Free Trade Agreement (KORUS FTA) concluded in 2007. In the areas of patents, trademarks, copyrights, protection against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, and enforcement, Korea has agreed to strengthen considerably its IPR protection and enforcement regimes. The United States believes that adherence to these commitments will lead to a significant improvement in IPR protection as well as a reduction in piracy and counterfeiting in the Korean market. The United States will continue to work closely with Korea as it implements its IPR commitments in the KORUS FTA.

SECTION 306

PARAGUAY

In 2008, the United States will continue to monitor Paraguay under Section 306, specifically related to Paraguay's implementation of bilateral understandings regarding IPR protection and enforcement. During the meeting of the Joint Commission on Trade and Investment in December 2007, the United States and Paraguay negotiated an extension and revision of a previous Memorandum of Understanding (MOU). Formal signature of the revised MOU is expected soon, and the agreement will remain in effect through 2009. While there have been continued strong efforts by Paraguay to improve IPR enforcement, particularly by increasing the number of raids and seizures of pirated and counterfeit goods (by the IPR investigative unit in particular), Paraguay continues to have problems providing effective IPR protection due to porous borders, ineffective prosecutions of IPR infringers, and the lack of deterrent-level sentences in court cases. The United States has concerns about the inadequate protection against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products as well as shortcomings in Paraguay's patent regime. The United States will continue to work with Paraguay to address these IPR concerns during the coming year, including through the Joint Commission on Trade and Investment.

**WIPO Internet Treaties:
WIPO Performance and Phonograms Treaty (WPPT)
and the WIPO Copyright Treaty (WCT)**

The following two countries became parties to the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaties (WPPT) during May 2007-April 2008. The WPPT entered into force on May 20, 2002, and now has 62 contracting parties.

<u>Country</u>	<u>Date of Entry Into Force</u>
Australia	July 26, 2007
China	June 9, 2007

The following two countries became parties to the World Intellectual Property Organization (WIPO) Copyright Treaty (WCT) during May 2007-April 2008. The WCT entered into effect on March 6, 2002, and now has 64 contracting parties.

<u>Country</u>	<u>Date of Entry Into Force</u>
Australia	July 26, 2007
China	June 9, 2007