2013 Special 301 Report



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EXECUTIVE SUMMARY

The "Special 301" Report is the result of an annual review of the state of intellectual property rights (IPR) protection and enforcement in trading partners around world, which the Office of the United States Trade Representative (USTR) conducts 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.

This Report reflects the Administration's continued resolve to encourage and maintain adequate and effective IPR protection and enforcement worldwide. It identifies a wide range of concerns, including the continued deterioration in IPR protection, enforcement, and market access for persons relying on IPR in Ukraine; the growing problem of misappropriation of trade secrets in China and elsewhere; troubling "indigenous innovation" policies that may unfairly disadvantage U.S. rights holders in China; the continuing challenges of copyright piracy over the Internet in countries such as Brazil, Italy, and Russia; and other ongoing, systemic IPR enforcement issues presented in many trading partners around the world.

USTR looks forward to working closely with the governments of the trading partners that are identified in this year's Special 301 Report, to address both emerging and continuing concerns, and to continue to build on the positive results that many of these governments have achieved.

Public Engagement

USTR continued its enhanced approach to public engagement activities in this year's Special 301 process. These activities are designed to help facilitate sound, well-balanced assessments of IPR protection and enforcement efforts of particular trading partners, and to help ensure that Special 301 decisions are based on a robust understanding of the complicated IPR issues that various trading partners may encounter.

USTR requested written submissions from the public through a notice published in the *Federal Register* on December 31, 2012. This year's notice yielded 41 comments from interested parties, and 17 submissions from trading partners. The submissions that USTR received were made available to the public online at www.regulations.gov, docket number USTR-2012-0022. In addition, on February 20, 2013, USTR conducted a public hearing that allowed interested persons to testify before the interagency Special 301 subcommittee about issues relevant to the review. The hearing featured testimony from 13 witnesses, including representatives of foreign governments, industry, and non-governmental organizations. A transcript of the hearing is available at www.ustr.gov.

Country Placement

The Special 301 designations and actions announced in this Report are the result of deliberations among all relevant agencies within the U.S. Government, informed by extensive consultation with affected stakeholders, foreign governments, the U.S. Congress, and other interested parties.

USTR, together with the Special 301 subcommittee of the Trade Policy Staff Committee, works to make a balanced assessment of U.S. trading partners' IPR protection and enforcement, as well as related market access issues, in accordance with the statutory criteria set out by Congress (see Annex 1).

This assessment is necessarily conducted on a case-by-case basis, taking into account diverse factors such as a trading partner's level of development, its international obligations and commitments, the concerns of rights holders and other interested parties, and the trade and investment policies of the United States. It is informed by the various cross-cutting issues and trends identified below in *Section I – Developments in Intellectual Property Rights Protection and Enforcement*. Each assessment is based upon the specific facts and circumstances that shape IPR protection and enforcement regimes in a particular trading partner.

In the year ahead, USTR will continue its bilateral engagement with the governments of the trading partners that are discussed in this Report. In preparation for and in the course of those interactions, USTR will:

- Engage with U.S. stakeholders, the U.S. Congress, and other interested parties to ensure that the U.S. Government's position is well-informed by the full range of views on the pertinent issues;
- Conduct extensive discussions with individual trading partners regarding their respective IPR regimes;
- Encourage those trading partners to engage fully, and with the greatest degree of transparency, with the range of stakeholders on IPR matters; and
- Identify, where possible, appropriate ways in which the U.S. Government can be of assistance.

USTR will conduct these discussions in a manner that both advances the policy goals of the United States and respects the importance of meaningful policy dialogue with U.S. trading partners. Additionally, USTR will continue to work closely with other U.S. Government agencies to ensure consistency of U.S. trade policy objectives with other Administration policies.

2013 Special 301 List

The 2013 Special 301 review process examined IPR protection and enforcement in 95 trading partners. Following extensive research and analysis, USTR has listed 41 trading partners below as follows:

Priority Foreign Country: Ukraine.

<u>Priority Watch List</u>: Algeria, Argentina, Chile, China, India, Indonesia, Pakistan, Russia, Thailand, Venezuela.

Watch List: Barbados, Belarus, Bolivia, Brazil, Bulgaria, Canada, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, Finland, Greece, Guatemala, Israel, Italy, Jamaica, Kuwait, Lebanon, Mexico, Paraguay, Peru, Philippines, Romania, Tajikistan, Trinidad and Tobago, Turkey, Turkmenistan, Uzbekistan, Vietnam.

Priority Foreign Country Designation

In this year's Special 301 Report, USTR designates Ukraine a Priority Foreign Country (PFC), marking the first time in seven years that a country is listed in that category. The PFC designation is reserved by statute for countries with the most egregious IPR-related acts, policies and practices with the greatest adverse impact on relevant U.S. products, and that are not entering into good faith negotiations or making significant progress in negotiations to provide adequate and effective IPR protection. While the three specific grounds for Ukraine's designation as PFC are set out below, in general, the 2013 Special 301 review found Ukraine distinct from other trading partners both in its persistent failure to meet its commitments to improve IPR protection, including commitments in an Action Plan negotiated with the United States in 2010, and in the degree of deterioration in IPR protection, enforcement, and market access for persons relying on IPR in Ukraine. Ukraine's actions or inactions are causing significant damage to these industries reliant on those IPR in Ukraine's market, and in other markets as well.

Within 30 days from the date of this designation, the USTR will decide whether to initiate an investigation under section 301 of the Trade Act of 1974 based on the grounds identified in this report as the basis for Ukraine's designation as a PFC. If USTR initiates an investigation, USTR will request consultations with the Government of Ukraine and seek to resolve the issues that led to Ukraine's designation as a PFC.

When Ukraine was designated a PFC in the past, it failed to address the grounds for its designation during the following investigation. As a result, Ukraine lost its eligibility for benefits under the Generalized System of Preferences (GSP). Once Ukraine addressed the issues that led to its designation as a PFC, its eligibility for GSP benefits was reinstated.

Ukraine's designation as a PFC in this report is solely based on the IPR-related concerns identified below as the grounds for the designation, and not on any other aspect of Ukraine's international or domestic actions or policies. The Government of Ukraine has publicly noted that the Special 301 process is limited to IPR trade concerns.

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¹19 U.S.C. § 2242 (b). It is important to note that the PFC designation is not reserved for the largest markets; in fact, Ukraine was the most recent recipient of this designation, and the country which has earned this designation for the longest period of time. Ukraine was designated a PFC in 2001 and maintained that status though 2005.

While Ukraine's broader intellectual property environment has several flaws, as discussed in previous Special 301 Reports, the specific grounds for the U.S. Trade Representative's designation of Ukraine as a PFC are: (1) the unfair, nontransparent administration of the system for collecting societies, which are responsible for collecting and distributing royalties to U.S. and other rights holders; (2) widespread (and admitted) use of illegal software by Ukrainian government agencies; and (3) failure to implement an effective means to combat the widespread online infringement of copyright and related rights in Ukraine, including the lack of transparent and predictable provisions on intermediary liability and liability for third parties that facilitate piracy, limitations on such liability for Internet Service Providers (ISPs), and enforcement of takedown notices for infringing online content.

Out-of-Cycle Reviews

An Out-of-Cycle Review (OCR) is a tool that USTR uses to encourage progress on IPR issues of concern. It provides an opportunity for heightened engagement with trading partners to address and remedy such issues. Successful resolution of specific IPR issues of concern can lead to a change in a trading partner's status on a Special 301 list outside of the typical time frame for the annual Special 301 Report. Although Spain is not listed in the 2013 Special 301 Report, USTR will conduct an OCR of Spain focusing in particular on Spain's concrete steps to combat copyright piracy over the Internet. USTR will also conduct an OCR of El Salvador, which remains unlisted, to monitor progress on IPR protection and enforcement, in particular with respect to the implementation of new legislation on pharmaceuticals and with respect to enforcement efforts, among other concerns. Several trading partners have requested that USTR conduct OCRs based on their projections for improvements in IPR protection and enforcement; USTR may conduct additional OCRs in consultation with a trading partner as circumstances warrant.

Out-of-Cycle Review of Notorious Markets

In 2010, USTR began publishing the Notorious Markets List as an OCR separately from the annual Special 301 Report. The Notorious Markets List identifies selected markets, including online markets, that are reportedly engaged in piracy and counterfeiting, according to information submitted to USTR in response to a request for comments. USTR requested such comments on August 14, 2012, and published the 2012 OCR of Notorious Markets on December 13, 2012. USTR plans to conduct an OCR on notorious markets in the fall of 2013.

Format of the Special 301 Report

The Special 301 Report is divided into the following two main sections and two Annexes:

- Section I: Developments in Intellectual Property Rights Protection and Enforcement discusses broad global trends and issues in IPR protection and enforcement that USTR works to address on a daily basis.
- **Section II: Country Reports** includes descriptions of issues of concern with respect to particular trading partners.
- Annex 1 describes the statutory background of the Special 301 Report.
- Annex 2 provides information about parties to the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty (WPPT) and the WIPO Copyright Treaty (WCT) (collectively, the WIPO Internet Treaties).

SECTION I. DEVELOPMENTS IN INTELLECTUAL PROPERTY RIGHTS PROTECTION AND ENFORCEMENT

An important part of the mission of the Office of the United States Trade Representative (USTR) is to support and implement the Administration's commitment to aggressively protect American intellectual property (IP) overseas. Infringement of intellectual property rights (IPR) causes significant financial losses for rights holders and legitimate businesses around the world. It undermines key U.S. comparative advantages in innovation and creativity, to the detriment of American businesses and workers. In its most pernicious forms, IPR infringement endangers the public. Some counterfeit products, such as semiconductors, automobile parts, and medicines, pose significant risks to consumer health and safety. In addition, trade in counterfeit and pirated products often fuels cross-border organized criminal networks and hinders the sustainable economic development of many countries.

Because fostering innovation and creativity is essential to U.S. prosperity, competitiveness, and the support of an estimated 40 million U.S. jobs that directly or indirectly rely on IPR-intensive industries, USTR works to protect American inventiveness and creativity with all the tools of U.S. trade policy, including this Report.

Positive Developments

The United States welcomes the following important steps by our trading partners in 2012 and early 2013:

- Bahamas The United States welcomes recent action by the Copyright Royalty Tribunal to pay royalties due to U.S. rights holders. These royalties had been collected under a now repealed provision of the 1998 Bahamian Copyright Law which until 2009 allowed the government-owned Cable Bahamas to retransmit and sell pay television programming of U.S. rights holders without their authorization. The United States notes, however, that royalties have yet to be paid to representatives of songwriters for the public performance of their works under this regime. The United States looks forward to such action in the near term.
- **Brunei Darussalam** Brunei has been removed from the Watch List in 2013. Brunei has significantly increased its focus on IPR protection and enforcement in recent years, through substantial and meaningful enforcement efforts, including both civil and for the first time criminal actions. Brunei recently created its first patent office and enacted patent law amendments that significantly strengthen its patent regime. Brunei has also announced recently that it is taking steps to join the WIPO Internet Treaties. While concerns remain in some areas, including with respect to Brunei's implementation of data protection regulations and IPR border enforcement, particularly against transshipments, the United States is removing Brunei from the Watch List in recognition of the significant IPR legal reforms and commitments referenced above. The United States will continue

- to work closely with Brunei to ensure that progress is sustained and to address remaining areas of concern, including through the Trans-Pacific Partnership negotiations.
- Canada Canada enacted the long-awaited Copyright Modernization Act in 2012, which, among other things, is designed to implement Canada's obligations under the WIPO Internet Treaties and address the challenges of copyright piracy in the digital age. In 2013, Canada also introduced a bill designed to strengthen IPR enforcement, including by providing ex officio authority to customs officials. In light of these important developments, the United States is moving Canada from the Priority Watch List to the Watch List in this year's Special 301 Report.
- China The Supreme People's Court of China issued a judicial interpretation (JI), effective January 1, 2013, on the liability of Internet intermediaries ("Rules of Supreme Court on Several Issues Concerning the Application of Law in Adjudication of Civil Disputes Related to Infringement of Right of Communication over Information Networks"). This JI builds on a Joint Commission Commerce and Trade (JCCT) commitment to make clear that those who facilitate online infringement will be held jointly liable for that conduct. The United States looks forward to appropriate implementation of this JI.
- **Israel** Israel enacted a law improving its procedures for the publication of patent applications. Furthermore, in light of progress toward implementing the Memorandum of Understanding with the United States that was signed in 2010, the United States moved Israel from the Priority Watch List to the Watch List in September of 2012.
- Lao People's Democratic Republic The Lao PDR became the 158th member of the World Trade Organization on February 2, 2013, and in connection with its accession, enacted a sweeping reform of its laws governing the protection and enforcement of IPR.
- Panama On October 31, 2012, the United States-Panama Trade Promotion Agreement entered into force, providing for strong standards for the protection and enforcement of IPR.
- Philippines The Philippines passed long-awaited legislation to implement the WIPO Internet Treaties and to provide *ex officio* authority for customs officials. While the United States hopes that additional clarifying provisions will be included in implementing regulations, the United States applauds these developments. Additional challenges remain with respect to addressing piracy over the Internet, in particular notorious online markets, and the need to strengthen IPR enforcement efforts. The United States looks forward to working with the Philippines in the coming year to address these issues and will review its Special 301 status if the Philippines continues to achieve progress in key areas.
- Russia In December 2012, the United States and Russia developed an IPR Action Plan that addresses the areas of greatest mutual concern in IPR protection and enforcement. Russia also enacted a law to establish a specialized IPR court in 2013 and amended its Criminal Code to revise criminal thresholds for copyright piracy.

- Taiwan In January 2013, Taiwan's Government passed amendments to the Trade Secret Act to increase deterrent penalties for trade secret misappropriation, including enhanced penalties to deter cross-border theft. Taiwan also launched a two-year pilot program to help create a more stable market for medicines, including innovative medicines, in Taiwan's health care system. The United States will engage closely with Taiwan in the implementation of its legal reforms and pilot program, and with respect to other legislation on IPR protection.
- **Turkey** In 2012, the Turkish National Police State Security Department, with the approval of the Minister of the Interior, established specialized enforcement offices for IP crimes in 81 cities in Turkey.

The United States will continue to work with its trading partners to further enhance IPR protection and enforcement during the coming year.

Initiatives to Strengthen IPR Protection and Enforcement Internationally

The United States has worked to promote adequate and effective protection and enforcement of IPR through a variety of mechanisms, including the following:

- Trans-Pacific Partnership (TPP) Agreement: The Trans-Pacific Partnership is a key initiative through which the United States seeks to advance the multifaceted U.S. trade and investment interests in the Asia-Pacific region by negotiating an ambitious, 21st-century regional trade agreement along with Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam, in addition to Canada and Mexico, which joined negotiations in 2012. The United States also welcomes Japan's participation in the TPP negotiations once each of the current TPP countries successfully completes its respective domestic process for approving that participation. The TPP negotiations are being undertaken with this group of like-minded countries with the goal of creating a platform for integration across the region, including strong standards for the protection and enforcement of IPR in the 21st century.
- Transatlantic Trade and Investment Partnership (TTIP) Agreement: On February 13, 2013, the United States and the European Union announced that they will each initiate the internal procedures necessary to launch negotiations on the TTIP. On March 20, 2013, the USTR notified Congress of the President's intent to enter into negotiations for a trade agreement with the EU. The United States and the EU provide among the highest levels of IPR protection and among the most robust IPR enforcement in the world. Together, the United States and the EU have developed mechanisms, including the Transatlantic IPR Working Group, to successfully cooperate on IPR matters, including in third countries and international organizations. Through the TTIP Agreement, the United States is committed to promoting a high level of IPR protection and enforcement, and to sustaining and enhancing its work with the EU on IPR issues.

- World Trade Organization (WTO): The multilateral structure of WTO agreements provides opportunities for USTR to lead engagement with trading partners on IPR issues in several contexts, including through accession negotiations for prospective Members, the WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), and WTO's Dispute Settlement Body. In the past year, the United States sponsored discussions in the TRIPS Council on the positive role of IPR protection and enforcement in contributing to national innovation environments, including with respect to small and medium sized enterprises. These discussions, which involved contributions from a broad array of WTO Members, including developed, developing, and least-developed countries, addressed national IPR strategies to promote innovation, focusing in particular on the role IPR plays in driving critical financing, commercialization, and partnerships to bring ideas to market.
- **Bilateral and Regional Initiatives**: The United States works with many trading partners to strengthen IPR protection and enforcement through the provisions of bilateral and regional agreements, including free trade agreements (FTAs). In addition, Trade and Investment Framework Agreements (TIFAs) between the United States and numerous trading partners around the world have facilitated discussions on enhancing IPR protection and enforcement.
- Anti-Counterfeiting Trade Agreement (ACTA): On October 5, 2012, Japan became the first signatory to ACTA to deposit its instrument of acceptance. The United States is working with Japan and other negotiating parties to bring the ACTA into force. The ACTA effort, launched in October 2007, brought together a number of countries prepared to embrace strong IPR enforcement through a new agreement calling for cooperation, strong enforcement practices, and a strong legal framework. ACTA signatories are Australia, Canada, Japan, South Korea, Mexico, Morocco, New Zealand, Singapore, and the United States. The European Union and 22 EU Member States signed the Agreement in January 2012, but it was not approved by the European Parliament. For signatories, the next step towards bringing the ACTA into force is to deposit instruments of ratification, acceptance, or approval. The ACTA will enter into force for those signatories thirty days following the deposit of the sixth such instrument. Consistent with the Administration's emphasis on IPR enforcement, the ACTA intensifies efforts against the global proliferation of commercial-scale counterfeiting and piracy in the 21st century. The ACTA includes innovative provisions to deepen international cooperation and to promote strong enforcement practices, and will ultimately help sustain American jobs in innovative and creative industries.
- Trade Preference Program Reviews: USTR, in coordination with other agencies, reviews IPR practices in connection with the implementation of trade preference programs, such as the Generalized System of Preferences (GSP) program, and regional programs including the Caribbean Basin Economic Recovery Act and the Caribbean Basin Trade Partnership Act.
- Expanded International Cooperation: USTR, in coordination with other U.S. Government agencies, looks forward to continuing engagement with trading partners in bilateral, regional, and multilateral fora to improve the global IPR environment. In

addition to the work described above, the United States anticipates engaging with its trading partners in trade-related initiatives such as the U.S.-EU Summit, in the G-8, and in the Asia Pacific Economic Cooperation (APEC), Organization for Economic Cooperation and Development (OECD) and other multilateral and regional fora.

Trade Secrets and Forced Technology Transfer

This year's Special 301 Report reflects increased emphasis on the need to protect trade secrets. Companies in a wide variety of industry sectors – including information and communication technologies, services, biopharmaceuticals, manufacturing, and environmental technologies – rely on the ability to protect their trade secrets and other proprietary information. Indeed, trade secrets are often among a company's core business assets, and a company's competitiveness may depend on its capacity to protect such assets.

The theft of trade secrets and other forms of economic espionage, which results in significant costs to U.S. companies and threatens the economic security of the United States, appears to be escalating. If a company's trade secrets are stolen, its past investments in research and development, and its future profits, may be lost. Moreover, trade secret theft threatens national security and the U.S. economy, diminishes U.S. prospects around the globe, and puts American jobs at risk.

For these reasons, the United States is concerned by the apparent growth of trade secret theft, particularly in China. Thefts may arise in a variety of circumstances, including those involving departing employees, failed joint ventures, cyber intrusion and hacking, and misuse of information submitted to government entities for purposes of complying with regulatory obligations. In practice, remedies under Chinese law are difficult to obtain. The U.S. National Counterintelligence Executive has stated that "Chinese actors are the world's most active and persistent perpetrators of economic espionage." Public reports, such as a recent report published by the independent information security firm Mandiant have further indicated that actors affiliated with the Chinese military and Chinese Government have systematically infiltrated the computer systems of over one hundred U.S. companies and stolen hundreds of terabytes of data, including all forms of trade secrets, such as proprietary technology, manufacturing processes, and confidential business information.

The United States urges its trading partners to ensure that they have robust systems for protecting trade secrets, including deterrent penalties for criminal trade secret theft. USTR will monitor developments in this area. For example, a notable positive development was Taiwan's amendment of its *Trade Secrets Act*, effective in February 2013, to increase criminal and civil penalties for corporate IP theft, including enhanced sanctions of up to 10 years imprisonment for trade secrets stolen and transferred to other countries. The United States welcomes Taiwan's positive action on this important issue.

On February 20, 2013, the U.S. Intellectual Property Enforcement Coordinator issued the *Administration Strategy on Mitigating the Theft of U.S. Trade Secrets*. The Strategy highlights U.S. efforts to combat the theft of trade secrets that could be used by foreign governments or

companies to gain an unfair economic advantage by harming U.S. innovation and creativity, including:

- Focusing diplomatic efforts to protect trade secrets overseas, which include sustained and coordinated engagement with trading partners, the use of trade policy tools (including through the use of the Special 301 Report), cooperation, and training, among others;
- Promoting voluntary best practices by private industry to protect trade secrets, including information security, physical security, and human resources policies;
- Enhancing domestic law enforcement operations, especially through the activities of the Department of Justice, Federal Bureau of Investigations, Department of Defense, and the National IPR Coordination Center;
- Improving domestic legislation to protect against trade secret theft, as exemplified by the *Theft of Trade Secrets Clarification Act of 2012*, which clarified provisions in the *Economic Espionage Act* with respect to the theft of trade secret source code, and the *Foreign and Economic Espionage Penalty Enhancement Act of 2012*, which increased criminal penalties for economic espionage; and
- Conducting public awareness campaigns and stakeholder outreach to encourage all stakeholders to be aware of the dangers of trade secret theft.

The threat of trade secret theft is not the only way that foreign actors may seek to undermine U.S. commercial advantages. In addition to protecting against theft of trade secrets, the United States continues to urge trading partners to reject trade-distortive policies, which are sometimes designed to promote "indigenous innovation" by forcing U.S. companies to hand over valuable commercial information. These policies include:

- Requiring the transfer of technology as a condition for allowing access to a market, or for allowing a company to continue to do business in the market.
- Directing state-owned enterprises in innovative sectors to seek non-commercial terms from their foreign business partners, including with respect to the acquisition and licensing of IPR.
- Failing to effectively enforce IPR, including patents, trademarks, trade secrets, and copyrights, thereby allowing firms to gain competitive advantages from their misappropriation or infringement of another's IPR.
- Failing to take meaningful measures to prevent or deter cyber intrusions.
- Requiring use of, or providing preferences to, products or services in which IPR is either developed or owned locally, including with respect to government procurement.
- Manipulating the standards development process to create unfair advantages for domestic firms, including with respect to the terms on which IPR is licensed.

• Requiring unnecessary disclosure of confidential business information for regulatory approval, or failing to protect such information.

The United States urges that, in adopting innovation and other policies, trading partners take account of the increasingly cross-border nature of commercial research and development, and of the importance of voluntary and mutually agreed-upon commercial partnerships.

IPR protection is essential to facilitate access to and transfer of today's technologies, and to promote tomorrow's innovation. Without IPR incentives, many of the technologies on which we rely today and will rely upon in the future would not have been developed. For example, in the field of environmental technologies, strong IPR protection can provide incentives for the voluntary transfer of critical green goods and services, and can promote economic growth and create jobs, particularly in developing and least-developed countries that need these benefits most. Without such technologies, inventors and consumers alike would be deprived of critical advances with respect to key environmental challenges, including the mitigation of, and adaptation to, climate change. In addition, firms are likely reluctant to enter into technology transfer arrangements in countries with weak IPR enforcement regimes. Intellectual property rights are thus a key driver of private sector investment. The United States continues to work internationally to ensure robust IPR protection and enforcement, which gives inventors and creators the confidence to invest in the production, adoption, and delivery of goods and services without fear of misappropriation, or outright theft, of their IPR.

Best IPR Practices by Trading Partners

USTR is highlighting certain best practices by trading partners in the area of IPR protection and enforcement:

- USTR continues to encourage trading partners to work with the United States to develop
 mutually agreed-upon action plans to advance the protection and enforcement of IPR.
 USTR welcomes the action plan with Russia announced in December 2012, and is
 working with several trading partners to develop action plans to address the issues
 discussed in the Special 301 Report. USTR looks forward to continuing to work with
 these trading partners to finalize and implement these action plans.
- Stakeholders continue to report that a foreign government's transparency in developing legislative or regulatory changes and procedures, as well as its meaningful engagement with them, make it is easier for those stakeholders to comply with legislative or regulatory changes.
- Cooperation among different government agencies is another example of a best practice. Several countries including the United States, have introduced IPR enforcement coordination mechanisms to enhance interagency cooperation. The United States encourages further such efforts internationally.

- Several trading partners have participated or supported participation in innovative mechanisms that enable government and private sector rights holders to voluntarily donate or license IPR on mutually-agreed terms and conditions. In these arrangements, parties use existing IPR to advance innovation and public policy goals. The United States was the first government in the world to share its patents with the Medicines Patent Pool, an independent foundation hosted by the World Health Organization (WHO), and hopes that additional public and private patent holders will explore voluntary licenses with the Medicines Patent Pool as one of many innovative ways to help improve the availability of medicines in developing countries. The patents that the United States shared were related to protease inhibitor medicines, primarily used to treat drug-resistant HIV infections. In addition, the United States, Brazil, and South Africa are providers in the WIPO Re:Search Consortium, a voluntary mechanism for making IPR and know-how available on mutually agreed-upon terms and conditions to the global health research community to find cures or treatments for neglected tropical diseases, and for malaria and tuberculosis. Other countries have joined as supporters.
- Finally, a significant best practice is the active participation of government officials in capacity building efforts and in training. As further explained below, the United States strongly encourages foreign governments to make training opportunities available to their officials, and it actively engages with its trading partners in capacity building efforts both in the United States and abroad.

Capacity Building Efforts

In addition to identifying concerns, this Report also highlights opportunities for the U.S. Government to work closely with trading partners to address those concerns. The U.S. Government collaborates with various trading partners on IPR-related training and capacity building around the world. Domestically and abroad, bilaterally, and in regional groupings, the U.S. Government remains engaged in building stronger, more streamlined, and more effective systems for the protection and enforcement of IPR.

Although many trading partners have enacted IPR legislation, a lack of criminal prosecutions and deterrent sentencing has reduced the effectiveness of IPR enforcement in many regions. These problems result from several factors, including a lack of knowledge of IPR law on the part of judges and enforcement officials, and insufficient enforcement resources. The United States welcomes steps by a number of trading partners to educate their judiciary and enforcement officials on IPR matters. The United States will continue to work collaboratively with trading partners to address these issues.

The U.S. Patent and Trademark Office's (USPTO) Office of Policy and External Affairs' Global Intellectual Property Academy (GIPA) offers programs in the United States and around the world to provide education, training, and capacity building on IPR protection and enforcement. These programs are offered to patent, trademark, and copyright officials, judges and prosecutors, police and customs officials, foreign policy makers, and U.S. rights holders.

Other U.S. Government agencies bring foreign government and private sector representatives to the United States on study tours to meet with IPR professionals and to visit the institutions and businesses responsible for developing, protecting, and promoting IPR in the United States. One such program is the Department of State's International Visitors Leadership Program, which brings groups from around the world to cities across the United States to learn more about IPR and related trade and business issues. In addition, U.S. Government agencies, such as the Department of State and the U.S. Copyright Office, conduct conferences and training symposia in Washington, D.C. In March 2012, for example, the Copyright Office, with co-sponsorship from WIPO, hosted an international training symposium for representatives from 17 developing countries and countries in transition on emerging issues in copyright and related rights.

Overseas, the U.S. Government is also active in partnering to provide training, technical assistance, capacity building, exchange of best practices, and other collaborative activities to improve IPR protection and enforcement. For example:

- In 2012, GIPA provided training to 9,217 foreign IPR officials from 130 countries, through 140 separate programs. Attendees included IPR policy makers, judges, prosecutors, customs officers, and examiners, and training topics covered the entire spectrum of IPR. Post-training surveys demonstrated that 69 percent of all attendees reported that they had taken some steps to implement positive policy change in their respective organizations.
- GIPA also has produced seven free distance-learning modules, available on its website in multiple languages (English, Spanish, French, Arabic, and Russian). There have been over 32,000 hits on those modules since being placed on our site in early 2010.
- In addition, the USPTO's Office of Policy and External Affairs provides capacity building in countries around the world, and has concluded agreements with more than 40 national, regional, and international IPR organizations, such as the Association of Southeast Asian Nations (ASEAN), the African Regional Intellectual Property Organization (ARIPO), WIPO, and the International Union for the Protection of New Varieties of Plants (UPOV), to partner on IPR training activities. These partnerships help ensure that capacity building and training efforts are demand-driven and meet the particular needs of each organization and trading partner.
- The Department of Commerce's International Trade Administration (ITA) collaborates
 with the private sector to develop programs to heighten the awareness of the dangers of
 counterfeit products and of the economic value of IPR to national economies.
 Additionally, ITA develops and shares small business tools to help domestic and foreign
 businesses understand IPR.
- In 2012, the Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI), through the National IPR Coordination Center (IPR Center) and in conjunction with INTERPOL, conducted training programs in Ecuador, Panama, India, South Korea, and Taiwan. ICE-HSI trained officials from Chile, Ecuador, El Salvador, Guatemala, Mexico, Nicaragua, Panama, Paraguay, Peru, and Uruguay, as well as police

from India, South Korea, and Taiwan. The IPR Center also conducted Advanced ILEA trainings in El Salvador, Hungary, and Peru for participants from 19 countries.

- The Department of State provides training funds each year to U.S. Government agencies that provide IPR enforcement training and technical assistance to foreign governments. The agencies that provide such training include the U.S. Department of Justice (DOJ), USPTO, CBP, and ICE. In 2012, the Department of State provided funds for 15 training programs for customs, police, and judicial officials from various trading partners including Bangladesh, Brazil, Cambodia, Mexico, Paraguay, and Ukraine, as well as regional trainings in the Balkans and Eastern Europe, and in sub-Saharan Africa. The U.S. Government works collaboratively on many of these training programs with the private sector and with various international entities such as WIPO, and with regional organizations such as the APEC Intellectual Property Experts Group.
- IPR protection is a main focus of the government-to-government technical assistance provided by the Commerce Department's Commercial Law Development Program (CLDP). CLDP programs address enforcement and adjudication of disputes, as well as IPR protection and its impact on the economy, IPR law compliance with the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), IPR curricula in law schools, and public awareness campaigns. In 2012, CLDP supported capacity building in innovation and technology transfer in Armenia, Georgia, Egypt, Iraq, and Pakistan, as well as in patent examination in Iraq and copyright management in Georgia. CLDP worked with the judiciary in Bosnia-Herzegovina, Georgia, Mali, and Ukraine to improve the skills to effectively adjudicate IPR cases and conducted interagency coordination programs in Ukraine and in Kenya with the East African Community (EAC).
- The DOJ's Criminal Division, funded by the Department of State, and in cooperation
 with other U.S. agencies, provided IPR enforcement training to foreign officials. Topics
 covered in these programs included cooperation between law enforcement agencies,
 prosecution under economic and organized crime statutes, and the importance of reducing
 counterfeiting and piracy. Major ongoing initiatives included multiple programs in
 Mexico and regional events in Africa.

The United States reports annually to the WTO on its IPR capacity building efforts, including most recently in October 2012 (*see* "Technical Cooperation Activities: Information from Members – United States", IP/C/W/582/Add.6).

Trends in Trademark Counterfeiting and Copyright Piracy

The problems of trademark counterfeiting and copyright piracy continue on a global scale, involving the mass production and far-reaching sales of a vast array of fake goods, including counterfeit semiconductors, medicines, health care products, food and beverages, automobile parts, such as air bags, aircraft parts, apparel and footwear, toothpaste, shampoos, razors, electronics, batteries, chemicals, sporting goods, motion pictures, and music.

Consumers, legitimate producers, and governments are all harmed by rampant trademark counterfeiting and copyright piracy. Consumers may be harmed by fraudulent and potentially dangerous products including fake medicines, auto and airplane parts, as well as through fake semiconductors that may cause critical equipment to fail. Producers face the risk of diminished profits and loss of reputation when consumers who may purchase fake products and governments may lose tax revenue and may find it more difficult to attract investment. Infringers generally pay no taxes or duties, and often disregard basic standards for worker health and safety and product quality and performance. Industry reports trends in counterfeiting and piracy that include:

- Sustained growth in the piracy of copyrighted products in virtually all formats, as well as counterfeiting of trademarked goods. The involvement of criminal enterprises continues to rise, often because piracy and counterfeiting offer enormous profits and little risk. Such enterprises require little up-front capital investment, and even when they are detected and prosecuted, the penalties imposed on them in many countries are very low and therefore offer little or no deterrence against further infringements. Instead, the penalties are viewed merely as a cost of doing business.
- Continued growth in the online sale of pirated and counterfeit hard goods that will soon surpass the volume of such goods sold by street vendors and in other physical markets.
 Enforcement authorities, unfortunately, face difficulties in responding to this trend.
 Online advertisements for the sale of illicit physical goods that are delivered through express mail shipments or by small consignments are found in many places.
- A continued increase in the use of legitimate courier services to deliver infringing goods, making it more difficult for enforcement officials to detect these goods.
- An increase in the practice of shipping of counterfeit products separately from labels and packaging in order to evade enforcement efforts. For example, infringers in Canada reportedly sell fake certificates of authenticity for illicit software programs. There are also reports of the importation of packaging, labels, and other components separate from the infringing good into Vietnam for assembly and further distribution.
- The emergence of Media Box piracy, whereby "boxes," often with capability to play high definition content, are loaded with large quantities of pirated works. These boxes may be sold with preloaded content, but can later have new content uploaded for a relatively low fee. Boxes may be purchased online, with the user's chosen content, and delivered via postal service, or may have online capabilities allowing consumers to download infringing content from the Internet or through downloadable apps. This problem has been reported in China, Indonesia, Malaysia, Taiwan, Thailand, and Vietnam.

The United States continues to urge stronger and more effective criminal and border enforcement to stop the manufacture, import, export, transit, and distribution of pirated and counterfeit goods. USTR engages extensively with its trading partners through bilateral consultations, FTAs, and international organizations, to ensure that penalties have deterrent effects, and include significant monetary fines and meaningful sentences of imprisonment. Additionally, important elements of

a deterrent enforcement system include requirements that pirated and counterfeit goods, as well as the materials and implements used for their production, are seized and destroyed.

The manufacture and distribution of pharmaceutical products bearing counterfeit trademarks is a growing problem that has important consequences for consumer health and safety. Such trademark counterfeiting is one dimension of the larger problem of substandard medicines. The United States notes its particular concern with the proliferation of the manufacture, sale, and distribution of counterfeit pharmaceuticals in trading partners such as Brazil, China, India, Indonesia, Lebanon, Peru, and Russia. The U.S. Government, through the United States Agency for International Development (USAID), and other agencies, supports programs in Sub-Saharan Africa and elsewhere that assist trading partners in protecting the public against counterfeit medicines introduced into their markets.

In many cases, the bulk active pharmaceutical ingredients (API) that are used to manufacture pharmaceuticals that bear counterfeit trademarks are not made according to good manufacturing practices. Hence, these products may contain sub-standard and potentially hazardous materials. For instance, in China, domestic chemical manufacturers that produce API have avoided regulatory oversight by failing to declare that a bulk chemical is intended for use in pharmaceutical products. This contributes to China being a major source country for APIs used in counterfeit pharmaceutical products. Although China has taken some welcome steps, such as requiring manufacturers to register with the State Food and Drug Administration, more effective regulatory controls are needed.

Piracy over the Internet and Digital Piracy

The increased availability of broadband Internet connections around the world is generating many benefits, from increased economic activity and new online business models to greater access to and exchange of information. However, this phenomenon has also made the Internet an extremely efficient vehicle for disseminating copyright-infringing products, replacing legitimate markets for rights holders.

Piracy over the Internet is a significant concern in many U.S. trading partners. Unauthorized retransmission of live sports telecasts over the Internet continues to be a growing problem for many trading partners, particularly China, and websites that link to infringing content are exacerbating the problem. In addition, piracy using new technologies, such as media boxes, is an emerging problem internationally. U.S. copyright industries also report growing problems with piracy using mobile telephones, tablets, 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, U.S. industry reports the emergence of pirate servers, or "grey shards," whereby players of cloud-based entertainment software access these unauthorized servers to play copyrighted video games that are made available through hacked software and/or circumvention of the rights holders' technological protection measures.

Also of concern is the distribution over the Internet of software that allows for the circumvention of technological protection measures used by rights holders to protect their content. A

particularly troubling example is that of SlySoft, a company headquartered and operating in Antigua, which developed and sells a program called "Any DVD HD" enabling the user to defeat the encryption technology embedded in Blu-ray Discs that prevents unauthorized reproduction and distribution. Antigua's Copyright Act makes it illegal to manufacture or import for sale or rental any such circumvention device. The consortium of electronic manufacturers, software companies, and motion picture studios that developed these technological protection measures has worked with the criminal enforcement authorities in Antigua for over 5 years to enforce this statute and have this case prosecuted. However this case has proceeded very slowly.

The United States will work with its trading partners to combat these growing problems, and urges trading partners to adequately implement the WIPO Internet Treaties, which provide tools necessary for protecting copyrighted works in the digital environment.

To encourage effective action against piracy over the Internet, the United States will seek to work with the following trading partners to strengthen legal regimes and enhance enforcement: Argentina, Belarus, Brazil, Chile, China, Colombia, India, Indonesia, Italy, Mexico, Philippines, Romania, Russia, Spain, Switzerland, Taiwan, Thailand, Turkey, Ukraine, Venezuela, and Vietnam. In particular, the United States will encourage trading partners to implement the WIPO Internet Treaties, which will provide, among other things, protection against the circumvention of technological protection measures.

The United States continues to have serious concerns regarding the inability of rights holders to secure legal redress in Switzerland in cases involving copyright piracy over the Internet. The United States strongly encourages Switzerland to demonstrate its commitment to copyright protection and to combating online piracy vigorously, including by taking steps to ensure that rights holders can protect their rights. The United States will be closely monitoring the results of the current AGUR12 ("Arbeitsgruppe Urheberrecht 2012," or "Working Group on Copyright 2012") process as well as the Swiss Ministry of Economy (SECO)-led roundtable process.

The United States also encourages trading partners to adopt appropriate measures where needed with respect to the unauthorized camcording of motion pictures in theaters. Material that is recorded in this manner is often distributed without authorization over the Internet. In addition, the United States encourages trading partners to enhance enforcement efforts including through the following: strengthening enforcement against major channels of piracy over the Internet, including notorious markets; creating specialized enforcement units or undertaking special initiatives against piracy over the Internet; and undertaking training to strengthen capacity to fight piracy over the Internet.

Although piracy over the Internet is rapidly supplanting physical piracy in many markets around the world, the production of, and trade in, pirated optical discs remain major problems in many regions. In recent years, some trading partners, such as the Czech Republic, Poland, Romania, and Russia, have made progress toward implementing controls on optical media production. Other trading partners still need to adopt and implement legislation or improve existing measures to combat illegal optical disc production and distribution, including China, India, Paraguay, and Vietnam. The United States continues to urge those trading partners who face challenges regarding illegal optical disc production to pass effective legislation to counter this problem, and to enforce existing laws and regulations aggressively.

Trademarks and Domain Name Disputes

A growing area of concern for trademark holders is the protection of their trademarks against unauthorized uses under country code top level domain name (ccTLD) extensions. U.S. rights holders face significant trademark infringement, as well as losing valuable Internet traffic because of such uses. A related and growing concern is that certain ccTLDs lack transparent and predictable uniform domain name dispute resolution policies (UDRPs). Effective UDRPs should assist in the quick and efficient resolution of these disputes.

The United States encourages its trading partners to provide procedures that allow for the protection of trademarks used in domain names, and to ensure that dispute resolution procedures are available to effectively enforce against the misuse of trademarks.

Government Use of Software

Under Executive Order 13103 issued in September 1998, U.S. Government agencies maintain procedures to ensure that they use only authorized 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 systems or where concerns have been raised, to stop governmental use of illegal software. Considerable progress has been made under this initiative, leading to numerous trading partners mandating that only authorized, legitimate software may be used by their government bodies. Further work on this issue remains with certain trading partners, such as China, Costa Rica, India, Pakistan, Paraguay, Peru, Tajikistan, Turkey, Ukraine, and Vietnam. The United States urges trading partners to adopt and implement effective and transparent procedures to ensure legitimate governmental use of software.

Intellectual Property and Health Policy

Numerous comments in the 2013 Special 301 review highlighted important concerns arising at the intersection of IPR policy and health policy.

IP plays an important role in providing the incentives necessary for the development and marketing of new medicines. An effective, transparent, and predictable IP system is necessary for both manufacturers of innovative medicines and manufacturers of generic medicines.

The 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health recognized the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics. As affirmed in the Doha Declaration on TRIPS and Public Health, the United States respects a trading partner's right to protect public health and, in particular, to promote access to medicines for all and supports the vital role of the patent system in promoting the development and creation of new and innovative lifesaving medicines. The assessments set forth in this Report are based

on various critical factors, including, where relevant, the Doha Declaration on TRIPS and Public Health.

The United States is firmly of the view that international obligations such as those in the TRIPS Agreement have sufficient flexibility to allow trading partners to address the serious public health problems that they may face. Consistent with this view, the United States respects its trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement, and encourages its trading partners to consider ways to address their public health challenges while maintaining IPR systems that promote innovation.

The United States also strongly supports WTO General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the WTO TRIPS/health solution) concluded in August 2003, in which 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. The United States hopes that at least two-thirds of the WTO membership accept this amendment by the December 31, 2013 deadline, at which point the amendment will go into effect for those accepting members. The August 2003 waiver will remain in place and available until the amendment takes effect.

The United States will work to ensure that the provisions of its bilateral and regional trade agreements, as well as U.S. engagement in international organizations, including the United Nations and related institutions such as WIPO and the WHO, are consistent with U.S. Government policies concerning IPR and health policy and do not impede its trading partners from taking necessary measures necessary to protect public health. Accordingly, USTR will continue its close cooperation with relevant agencies to ensure that public health challenges are addressed and IPR protection and enforcement are supported as one of various mechanisms to promote research and innovation.

Supporting Pharmaceutical and Medical Device Innovation through Improved Market Access

Among other mechanisms to support pharmaceutical and medical device innovation, USTR has sought to reduce market access barriers that U.S. pharmaceutical and medical device companies face in many countries, and to facilitate both affordable health care today and the innovation that assures improved health care tomorrow.

Various measures have the potential to affect market access in the pharmaceutical and medical device sector. For example, taxes or tariffs may be levied on medicines and the increased expense associated with those levies is then passed directly to healthcare institutions and patients. Discriminatory and non-transparent regulatory regimes, unnecessarily burdensome customs requirements, and other trade barriers also hinder market access. For example, this

year's Special 301 Report highlights concerns regarding market access barriers affecting pharmaceutical products in Algeria and Indonesia.

In this respect, the United States notes that, according to a October 2012 WTO report entitled "More Trade for Better Health?, International Trade and Tariffs on Health Products", India maintains the highest tariffs on medicines, inputs to medicines and medical devices among the WTO members identified in the report. These tariffs, combined with burdensome internal charges and regulatory challenges facing pharmaceuticals and medical devices, can hinder the Indian government's efforts to promote increased access to healthcare products.

Moreover, government practices including unreasonable regulatory approval delays and unfairness that may arise from non-transparent reimbursement policies can discourage the development of new drugs and other medical products. The criteria, rationale, and operation of such measures are often nontransparent or not fully disclosed to patients or to pharmaceutical and medical device companies seeking to market their products. USTR encourages trading partners to provide appropriate mechanisms for transparency, procedural and due process protections, and opportunities for public engagement in the context of their relevant health care systems.

U.S. industry has expressed concerns regarding the policies of several developed trading partners, including Finland, Germany, Greece, Hungary, Italy, Korea, New Zealand, Poland, Portugal, Romania, Spain, Turkey, and Taiwan, on issues related to innovation in the pharmaceutical sector and other aspects of health care goods and services. Examples include:

- With respect to New Zealand, U.S. industry has expressed serious concerns about the
 policies and operation of New Zealand's Pharmaceutical Management Agency
 (PhARMAC). Industry continues to express concerns regarding, among other things, the
 lack of transparency, fairness, and predictability of the PhARMAC pricing and
 reimbursement regime, as well as the negative aspects of the overall climate for
 innovative medicines in New Zealand.
- With respect to Turkey, U.S. industry continues to express significant concern regarding the lack of fairness and the slow pace of pharmaceutical manufacturing inspections.

The United States is seeking to establish or continue dialogues with relevant trading partners to address these and other sectoral concerns, and encourage a common understanding on questions related to innovation in the pharmaceutical and medical device sectors. The United States is also continuing its engagement with China to promote fair and transparent policies in this sector.

The United States shares policy goals and concerns related to health care with other 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 the objective of delivering care in the most efficient and responsive way possible. The United States looks forward to engaging with these trading partners on the concerns noted above.

Implementation of the WTO TRIPS Agreement

The TRIPS Agreement, one of the most significant achievements of the Uruguay Round, requires all WTO members to provide certain minimum standards of IPR protection and enforcement. The TRIPS Agreement is the first broadly-subscribed multilateral IPR 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 country Members were given a transition period for many obligations until January 1, 2000, and in some cases, until January 1, 2005. Nevertheless, certain Members are still in the process of finalizing implementing legislation, and many are still engaged in establishing adequate and effective IPR enforcement mechanisms.

Recognizing the particular challenges faced by least-developed country (LDC) Members, 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 LDC Members in turn pledged to preserve the progress that some have already made toward TRIPS Agreement implementation. Additionally, the LDC Members have until 2016 to implement their TRIPS Agreement obligations for patent and data protection for pharmaceutical products, as proposed by the United States at the Doha Ministerial Conference of the WTO.

In December 2011, WTO Ministers invited the TRIPS Council to give full consideration to a request from LDC Members for an extension of the TRIPS Agreement transition period. The United States looks forward to continuing to work on a mutually agreeable solution with LDC and other WTO Members on these issues, including at the June 2013 meeting of the WTO TRIPS Council.

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 Agreement implementation.

WTO Dispute Settlement

The United States continues to monitor the resolution of disputes announced in previous Special 301 reviews. The most efficient and preferred manner of resolving concerns is through bilateral dialogue. Where these efforts are unsuccessful, the United States will not hesitate to use the WTO dispute settlement procedures, as appropriate.

In April 2007, the United States initiated dispute settlement procedures relating to deficiencies in China's legal regime for protecting and enforcing copyrights and trademarks on a wide range of products. In March 2009, the WTO Dispute Settlement Body (DSB) adopted a panel report that had found, in favor of the United States, that (1) China's denial of copyright protection to works that do not meet China's content review standards is impermissible under the TRIPS Agreement; and (2) China's Customs rules cannot allow seized counterfeit goods to be publicly auctioned after only removing the infringing mark. With respect to a third claim concerning China's

thresholds for criminal prosecution and conviction of counterfeiting and piracy, while the United States prevailed on the interpretation of the important legal standards in Article 61 of the TRIPS Agreement, including the finding that criminal enforcement measures must reflect and respond to the realities of the commercial marketplace, the panel found that it needed additional evidence before it could uphold the overall U.S. claim that China's criminal thresholds are too high. On March 19, 2010, China announced that it had completed all the necessary domestic legislative procedures to implement the DSB recommendations and rulings. The United States continues to monitor China's implementation of the DSB recommendations and rulings in this dispute.

In addition, the United States requested WTO dispute settlement consultations with China concerning certain other Chinese measures affecting market access and distribution for imported publications, movies, and music, and audio-visual home entertainment products (e.g. DVDs, Blu-ray discs, etc.) ("AVHE products"). The U.S. claims challenged China's prohibition on foreign companies' importation of all products at issue; China's prohibitions and discriminatory requirements imposed on foreign distributors of publications, music, and AVHE products within China; and China's imposition of more burdensome requirements on the distribution of imported publications, movies, and music vis-à-vis their domestic counterparts. On January 19, 2010, the DSB adopted panel and Appellate Body reports that found in favor of the United States on the vast majority of its claims. China committed to bring all relevant measures into compliance with the DSB recommendations by March 19, 2011, and subsequently revised or revoked several measures relating to publications, AVHE products, and music. China did not issue any measures relating to theatrical films, but instead proposed bilateral discussions. The United States and China reached agreement in February 2012 on the terms of a Memorandum of Understanding that provides significantly increased market access for imported films and significantly improved compensation for foreign film producers. The United States continues to review and monitor the steps that China has taken toward compliance in this matter.

Following the 1999 Special 301 review, the United States initiated dispute settlement consultations concerning the EU regulation on food-related GIs, which appeared to discriminate against foreign products and persons, notably by requiring that EU trading partners adopt an "EU-style" system of GI protection, and appeared to provide insufficient protections to trademark owners. On April 20, 2005, the DSB adopted a panel report finding 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. On March 31, 2006, the EU 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 EU to address, and the United States intends to continue monitoring this situation. The United States is also working intensively through bilateral and multilateral fora to advance U.S. market access interests, and to ensure that the trade initiatives of other countries, including with respect to GIs, do not undercut our market access.

Interagency Trade Enforcement Center

In his State of the Union address on January 24, 2012, President Obama announced the creation of the Interagency Trade Enforcement Center (ITEC) to take a "whole-of-government" approach to monitoring and enforcing Americans' trade rights around the world. Thereafter, on February 28, 2012, the President issued an Executive Order that established the ITEC. The ITEC uses expertise from across the federal government to assist in asserting U.S. trade rights obtained through various international trade agreements and serves as the primary forum within the federal government for agencies to coordinate enforcement of obligations under international trade agreements, including the identification of unfair trade practices and barriers that involve IPR.

SECTION II. COUNTRY REPORTS

PRIORITY FOREIGN COUNTRY

Ukraine

As a result of the 2013 Special 301 Review, the U.S. Trade Representative (USTR) designates Ukraine as a priority foreign country (PFC). This designation is the culmination of several years of growing concern over widespread IP theft, including the growing entrenchment of IPR infringement that is facilitated by government actors.

During intensive bilateral engagement, Ukraine has made a series of commitments to make specific improvements in the areas of government use of pirated software, nontransparent administration of royalty collecting societies, and online piracy. Notably, Ukraine and the United States agreed to an IPR Action Plan in 2010, which Ukraine publicized in 2011. Implementation of this plan was the subject of intensive bilateral engagement in 2012, including through the Trade and Investment Council meeting. Unfortunately, the situation has continued to deteriorate on each of the issues identified below. Recent efforts on the side of the Government of Ukraine have not gone far enough to demonstrate a commitment to resolving long-standing problems.

Background

Unfair, nontransparent administration of the system governing collecting societies.

The United States is deeply concerned by the deterioration of the entire system for collecting and disbursing music royalties in Ukraine. Ukraine has recognized that it has a significant problem with the operation of illegal or "rogue" collecting societies, *i.e.*, organizations that collect royalties by falsely claiming they are authorized to do so. Such organizations tend to operate without adequate transparency and rarely disburse sufficient funds that they collect to the rights holders entitled to the royalties. The government has not prosecuted several rogue collecting societies -- even societies that the Government of Ukraine determined were collecting money without the necessary authorization.

Furthermore, in 2012, the State Intellectual Property Service of Ukraine revoked the authorization of the Ukrainian Music Rights League, a collecting society that producers report had fairly disbursed royalties. This action has been credibly characterized as an attempt to empower rogue collecting societies, including a rogue collecting society that reportedly has strong ties to government officials. Moreover, in August 2012, Ukrainian courts issued a ruling that eliminated the current procedure for accrediting all collecting societies. Currently there are no authorized collecting societies for producers' or performers' rights in Ukraine.

Moreover, despite committing to promoting legislation to improve the collecting society system, the only legislative amendment proposed to change the collecting society system was an amendment proposed by the government in January 2013 which appeared to empower the

aforementioned rogue collecting society that has ties to government officials. That amendment has been withdrawn, but no alternative has been proposed.

The current system of collecting societies in Ukraine institutionalizes misappropriation of royalties. Ukraine must implement a fair and transparent system for authorizing collecting societies as soon as possible and must provide rights holders with a fair and transparent mechanism for enforcing their rights.

Widespread and admitted use of infringing software by the Ukrainian Government.

The United States has repeatedly conveyed its concern about software piracy in Ukraine. The Government of Ukraine acknowledges that a significant percentage of the software used by the government itself is unlicensed. The most recent industry data identify Ukraine as having a higher software piracy rate than almost all other countries on the Priority Watch List. Ukraine has acknowledged the need for the government to use legal software, and has issued repeated official documents calling for such legalization as far back as 2002, and most recently, in April 2013.

However, these statements have not produced results. In the past, the Government of Ukraine has stated that it will allocate funds that are "necessary to transition government ministries to licensed software, to include training for inspectors, as well as ongoing technical assistance to each Ministry in setting up an internal monitoring and compliance system," but has failed to do so. While the Government of Ukraine budgeted 100 million UAH (\$12.3 million) for 2013 software legalization in state institutions (which the Government of Ukraine admits does not reflect the value of the illegal software being used), the government has not spent this money or taken other steps toward legalization, and disbursement of the funds is uncertain. Ukraine must adopt a transparent and effective system to transition to the use of legal software by the government and ensure that legal software is used on an ongoing basis.

Persistent failure to implement any effective and transparent system to combat online piracy.

The United States has repeatedly raised its strong concerns about the significant and growing piracy of copyrighted content. Optical disc piracy was one of the principal reasons underlying the U.S. decision to add Ukraine to the Watch List in 1998, the Priority Watch List in 1999 and 2000 and to designate Ukraine a PFC from 2001 through 2005. Online piracy now has significant and growing consequences for both the Ukrainian market and for international trade. For example, ExtraTorrent.com, which is based in Ukraine, professes to be "The World's Largest BitTorrent System." This site is the 76th most visited site in India, and among the top 200 sites in six other countries (including the United Kingdom and Australia), illustrating how Ukraine has become perceived as a safe haven for online piracy enterprises serving other markets.

There was not a single online piracy-related conviction in Ukraine in 2012. In late January 2012, the Government of Ukraine seized servers as part of a criminal investigation into EX.UA, which is both the country's twelfth most visited website and a prolific source of infringing international music, software, and video. (It also appears on USTR's Notorious Markets list.) Following intense negative public reaction, and public statements in support of the website by influential figures, the site reopened shortly thereafter and continues to monetize infringing content today.

The United States views the few *ad hoc* and nontransparent government actions against online piracy as underscoring the need for Ukraine to establish a predictable and transparent system to combat online piracy. Enhanced interagency coordination, consultation with all affected stakeholders and targeted legal reforms to provide clarity and predictability are necessary to creating an adequate and effective strategy to combat online piracy.

Other IPR Concerns

In addition to the acts, policies, and practices that are the grounds for this PFC designation, the United States remains concerned about other IPR matters discussed in previous Special 301 Reports. Industry has reported that criminal prosecution for counterfeiting crimes are stalled and ineffective, and that seized goods are not disposed of or released in a timely manner. Additionally, large amounts of counterfeit products, as well as pirated goods, are openly sold in physical market in Ukraine. The United States will continue to engage Ukraine bilaterally on these and other matters, outside of the Section 301 investigation.

The acts, policies, and practices described as the grounds for PFC have cumulatively resulted in significant financial damage to U.S. copyright-related industries, including the foregone market opportunities and the impact on the markets in other countries. Intensive bilateral engagement by the United States has not resulted in meaningful change, and the situation in Ukraine appears to have worsened rather than improved in 2012.

As a consequence of this PFC designation, the USTR will determine pursuant to section 302 of the Trade Act of 1974 whether to initiate an investigation of Ukraine's acts, policies, and practices that are the basis for its designation as a PFC.

PRIORITY WATCH LIST

Algeria

Algeria remains on the Priority Watch List in 2013. The United States continues to urge Algeria to address the ban on an increasing number of imported pharmaceutical products and medical devices in favor of local products. Among other problems, this ban has caused shortages of critical medications as local manufacturers have been unable to meet demand. The United States is particularly concerned that Algeria has suspended processing of applications for drug registrations by foreign manufacturers. The United States remains concerned about the lack of protection against the unfair commercial use, as well as unauthorized disclosure, of test and other data generated to obtain marketing approval for pharmaceutical products. A notable positive step in in late 2012 and early 2013 was Algeria's counterfeit awareness campaign, which resulted in the seizure and destruction of counterfeited goods. If sustained, such a campaign could help to curb the increase over the past two years in the number of physical markets for pirated goods operating in Algeria. The United States looks forward to continuing to work with Algeria to address these and other issues.

Argentina

Argentina remains on the Priority Watch List in 2013. Argentina continued to improve IPR enforcement by increasing the number of enforcement raids in 2012 and improving cooperation between enforcement officials and industry. Argentina's judicial authorities also initiated civil and criminal actions against the unauthorized distribution of pirated content over the Internet. Despite these actions, significant concerns remain with respect to rampant piracy and counterfeiting, including in the digital environment. The United States urges Argentina to take additional steps to curb growing piracy over the Internet. Argentina's judicial system remains inefficient and there is a need for more deterrent-level sentences. The United States also encourages Argentina to provide for protection against unfair commercial use, as well as unauthorized disclosure, of test and other data generated to obtain marketing approval for pharmaceutical products, and to provide an effective system to address patent issues expeditiously in connection with applications to market pharmaceutical products, and eliminate the longstanding backlog of patent applications. The United States looks forward to continuing to work with Argentina to address these and other issues.

Chile

Chile remains on the Priority Watch List in 2013. The United States continues to have serious concerns regarding outstanding IPR issues under the United States-Chile Free Trade Agreement. Although Chile took some steps in 2012 to propose legislation, the United States continues to urge Chile to implement an effective system for addressing patent issues expeditiously in connection with applications to market pharmaceutical products. The United States also continues to urge Chile to implement both protections against the unlawful circumvention of technological protection measures, and protections for encrypted program-carrying satellite signals. It is also important for Chile to ensure that effective administrative and judicial procedures, as well as deterrent remedies are made available to rights holders and satellite and cable service providers. In addition, the United States urges Chile to provide adequate protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, and to amend its Internet service provider (ISP) liability regime to permit effective action against piracy over the Internet. The United States looks forward to continuing to work with Chile to resolve these and other issues, including through the TPP negotiations.

China

China remains on the Priority Watch List and subject to section 306 monitoring.

In the past year, the climate for IPR protection and enforcement continued to reflect efforts toward and opportunities for improvement, as well as challenges for U.S. rights holders. Obtaining effective enforcement of IPR in China remains a central challenge, as it has been for many years. This situation has been made worse by cybertheft, as information suggests that

actors located in China have been engaged in sophisticated, targeted efforts to steal IP from U.S. corporate systems.

On a potentially more positive note, China is currently engaged in sustained legal reform efforts, which have resulted in the revision of laws, rules, guidelines, and judicial interpretations across the range of IPR disciplines. This large scale revision of the IPR legal regime presents an opportunity to improve IPR protection and enforcement, and the United States is hopeful that a legal reform effort on this scale signals China's commitment to achieving major improvements. The United States urges China to continue to give due consideration to concerns expressed by the U.S. Government as well as by private sector stakeholders as these revisions proceed through the system.

At the same time, real world conditions for rights holders have overall seen little significant improvement. As in past years, a wide range of U.S. stakeholders in China report serious obstacles to effective protection of IPR in all forms, including patents, copyrights, trademarks, and protection of pharmaceutical test data. As a result, sales of IPR-intensive goods and services in China remain disproportionately low when compared to sales in similar markets that provide a stronger environment for IPR protection and market access. Given the size of China's consumer marketplace and its global importance as a producer of a broad range of products, China's protection and enforcement of IPR will continue to be a focus of U.S. trade policy.

The theft of trade secrets is an escalating concern. Not only are repeated thefts occurring inside China, but also outside of China for the benefit of Chinese entities. Conditions are likely to deteriorate as long as those committing the thefts and those benefitting continue to operate with relative impunity, frequently entering into unfair competitive relationships with their victims. Too often, Chinese authorities view trade secrets cases as routine commercial disputes, rather than as serious violations of law. Particularly troubling are public reports by independent security firms that actors affiliated with the Chinese military and Chinese Government have systematically infiltrated the computer systems of a significant number of U.S. companies and stolen hundreds of terabytes of data, including IP, from these companies. The United States strongly urges the Chinese Government take serious steps to put an end to these activities and to deter further activity by rigorously investigating and prosecuting thefts of trade secrets by both cyber and conventional means.

A further significant concern surrounds the fact that in some cases, central, provincial and local level Chinese agencies inappropriately require or pressure rights holders to transfer IPR from foreign to domestic entities. Sometimes guided by government measures or policy statements intended to promote indigenous innovation and the development of strategic industries, government authorities deny or delay market access or otherwise condition government procurement, permissions, subsidies, tax treatment and other actions on IPR being owned or developed in China, or licensed to a Chinese entity. China has made commitments to the United States on these matters in various contexts; the United States will continue pressing China to comply with those commitments.

The United States takes note of several positive developments. Rights holders report a significant increase in administrative and criminal enforcement against trademark counterfeiting in China. They indicate that the number of administrative enforcement actions more than

doubled in 2012 compared to the prior year, and that the number of criminal convictions appears to have doubled as well. However, while rights holders report some impact on counterfeiting activity in China, the problem remains widespread.

Trade Secrets

As noted above, trade secret theft is a serious and growing problem in China. Thefts may arise in a variety of circumstances, including those involving departing employees, failed joint ventures, cyber intrusion and hacking, and misuse of information submitted to government entities for purposes of complying with regulatory obligations. In February 2013, the independent information security firm Mandiant released a report that detailed efforts by an arm of the People's Liberation Army starting in 2006 to systematically infiltrate 141 companies in over 20 major industries, including 115 U.S. companies. Information reportedly stolen by this entity included "technology blueprints, proprietary manufacturing processes, test results, business plans, pricing documents, partnership agreements and emails and contact lists from victim organizations' leadership." The industries targeted have been listed as "strategic," emerging industries that need to be fostered and encouraged as part of China's 12th Five Year Plan.

Available remedies under Chinese law are difficult to obtain, given that civil, administrative, and criminal enforcement of trade secrets theft remains severely constrained. Enforcement obstacles include various deficiencies in China's Anti Unfair Competition Law, constraints on gathering evidence for use in litigation, difficulties in meeting the criteria for establishing that information constitutes a trade secret, and criminal threshold requirements that are unclear. As noted above, rights holders identify deficiencies in China's Anti-Unfair Competition Law (AUCL). Unlike other Chinese IP laws, the AUCL does not expressly authorize judges to issue certain provisional orders that are critical to the successful pursuit of a civil enforcement action. While China's new Civil Procedure Law may address, or partially address, that problem, there has been insufficient time to ascertain whether this new law is facilitating access to civil remedies in practice. Additionally, the AUCL only applies to commercial undertakings and requires that a trade secret have "practical applicability," which can limit the scope of protection for early stage research. There are other important weaknesses in China's civil enforcement system, including insufficient evidence-gathering, difficulties in obtaining preliminary injunctions, problems in obtaining procedures and the weight afforded certain kinds of evidence, such as the overreliance of original documentary evidence over oral testimony. Without changes to address these weaknesses, effective enforcement against misappropriation of trade secrets in China will remain illusory. The United States will continue engaging with China on these matters.

Legal Reform

Despite serious reservations regarding certain measures, the United States welcomes China's sweeping legal reform effort overall. In 2012 and early 2013, China invited comment on draft revisions to the existing laws on patents, copyrights, and trademarks. On January 1, 2013, a new Civil Procedure Law came into effect, which it is hoped will address some obstacles encountered by U.S. rights holders attempting to enforce their rights in civil court actions. Also effective January 1, 2013 was a judicial interpretation (JI) issued by the Supreme People's Court on the liability of Internet intermediaries ("Rules of Supreme Court on Several Issues Concerning the

Application of Law in Adjudication of Civil Disputes Related to Infringement of Right of Communication over Information Networks.") This JI builds on a JCCT commitment to make clear that those who facilitate online infringement will be held jointly liable for that conduct. The US urges that this JI continue to bind judges after the amended copyright law takes effect or be reflected to the same degree of specificity in the amended law.

China also invited comment on draft rules and guidelines on proposed regulations for the remuneration of "service inventions" (i.e., inventions created by an employee as part of his or her employment), national standards involving patents, rules for antimonopoly enforcement in the field of intellectual property rights, and patent examination guidelines for utility model and design patents. Some proposed measures raise serious concerns, while others represent a marked improvement over prior drafts. The United States applauds China's openness to receiving comments and looks forward to continuing engagement as future drafts are developed and evaluated and as the drafts move through the State Council Legislative Affairs Office and National Peoples' Congress.

National Leading Group

Following the completion of China's 2010-11 Special IPR Campaign, the State Council established a permanent national leading group office (Leading Group) to better coordinate and improve China's efforts to combat IPR infringement and the manufacture and sale of counterfeit and shoddy goods. Under the Leading Group, eleven special campaigns concentrating on key IPR concerns were completed in 2012. The United States encourages China to work with foreign governments and rights holders to share information and demonstrate the concrete role the Leading Group can play to improve the protection and enforcement of IPR.

Software Legalization

The United States will continue to urge all levels of the Chinese Government, as well as state-owned enterprises (SOEs), to use only legitimate, licensed copies of software. In May 2011, China's Government reported that software legalization in central government offices was complete. At the provincial level, a similar effort was originally targeted for completion by October 2011, but the government extended the effort into 2012, and it was completed in June 2012 and December 2012, respectively. However, U.S. software companies have seen only a modest increase in sales to the government.

Software legalization efforts have more recently extended to China's SOE sector. Losses by software companies due to piracy at SOEs and other enterprises are very high. To the degree that Chinese firms do not pay for the software that runs many of their operations, they reap a cost advantage relative to competitors who pay for legally acquired software. Although these problems remain, the United States applauds China's confirmation at the 2012 JCCT that it requires SOEs "to purchase and use legitimate software, including but not limited to operating system and office suite software."

Online Piracy

Despite bilateral commitments to increase IPR enforcement in China, online piracy in that country continues on a large scale. The Supreme People's Court, in December 2012, issued a JI

entitled, "Rules of Supreme Court on Several Issues Concerning the Application of Law in Adjudication of Civil Disputes Related to Infringement of Right of Communication Over Information Networks," which, according to industry, has led to an unexplained drop in online infringement lawsuits. As of mid-2012, there were more than 500 million Internet users in China. Despite national campaigns and the leadership of the Leading Group, widespread piracy affects industries involved in the distribution of legitimate music, motion pictures, books and journals, video games, and software. For example, industry reports that in 2010 the value of digital music sales in China was \$48.8 million, compared to \$178.4 million in South Korea, and \$68.9 million in Thailand, which is a country with less than five percent of China's population and a roughly equivalent per capita GDP. Similarly, over 90 percent of the revenue generated by U.S. films in China comes in the form of box office revenues, compared to 25-30 percent in the United States. This difference is partly due to widespread piracy of motion pictures over the Internet and on optical discs. Online piracy extends to scientific, technical, and medical publications as well.

Parties in China are also facilitating online infringement, in China and third countries, through media box piracy. Manufactured in China and exported abroad, media boxes can be plugged directly into televisions. They enable the user to stream and download infringing online audio and visual content. The vast majority of the infringing websites to which media box users connect are reportedly located in China. The United States urges China to continue efforts to improve IPR protection and enforcement in this area.

Counterfeit Goods

Despite increased enforcement efforts, problems with counterfeiting in China remain widespread. A partial list of commonly counterfeited goods includes food and beverages; apparel, footwear, and accessories; consumer electronics, computers and networking equipment; entertainment and business software; batteries; chemicals; appliances; and auto parts. Impacts are not limited to lost sales volumes and damage to the reputation of the trademark owner. For example, higher defect and failure rates among counterfeit semiconductors may cause malfunctions in the equipment in which they are incorporated, which may include medical devices, vehicle safety and braking systems, and other critical applications. As one measure of the scale of the problem, products from China accounted for 72 percent of the value of the IPR infringing products seized by U.S. Customs in fiscal year 2012.

Rights holders report increased enforcement activities, mostly but not exclusively on behalf of local brands. Rights holders also report a limited, although noticeable, reduction in counterfeiting, demonstrated in part by the reduced visibility of counterfeit products in some major retail and wholesale markets. Enforcement efforts have not, however, slowed the sale of counterfeits online. Rights holders report that local Administrations for Industry and Commerce (AICs) typically confine their efforts to physical markets. While both the State Administration for Industry and Commerce and local AICs have called on online trading websites to improve notice-and-takedown procedures, these measures have not significantly deterred repeat and large-scale offenders who, after postings are removed because of a takedown notice, quickly place new postings offering the same infringing goods. It is reported that, shortly after the Trademark Law is revised, the Supreme People's Court may issue a judicial interpretation to address these concerns.

Innovation, IPR Localization, and Technology Transfer

Rights holders in China face challenges not only as a result of difficulties in protecting and enforcing their rights against unscrupulous actors, but also as a result of government measures, policies and practices that systematically disadvantage foreign rights holders. Chinese government agencies, including at national, provincial, and local levels, frequently release documents, including regulations, rules, and other measures (e.g., opinions, notices and circulars) that seek to promote China's development into an innovative, IPR-intensive economy. The United States recognizes the critical role of innovation in development and in improving living standards in the United States and China. However, the United States reiterates its concerns regarding China's innovation-related policies and other industrial policies, such as strategic emerging industry policies, that may discriminate against or otherwise disadvantage U.S. exports or U.S. investors and their investments, or may otherwise hamper the ability of IPR rights holders to obtain full and effective protection for their rights, including the ability to monetize products using their rights. Chinese regulations, rules, and other measures frequently call for technology transfer and, in certain cases, require, or propose to require, that eligibility for government benefits or preferences be contingent upon IPR being developed in China, or being owned by or licensed, in some cases exclusively, to a Chinese party. Such government imposed conditions or incentives may distort licensing and other private business arrangements, resulting in commercial outcomes that are not optimal for the firms involved or for promoting innovation. Government intervention in the commercial decisions that enterprises make regarding the ownership, development, registration, or licensing of IPR is not consistent with international practice, and may raise concerns relative to China's implementation of its WTO commitments.

Sustained U.S.-China engagement through the JCCT, the U.S.-China Strategic and Economic Dialogue (S&ED), and high-level visits has resulted in important Chinese commitments, including "that technology transfer and technological cooperation shall be decided by businesses independently and will not be used by the Chinese Government as a pre-condition for market access," and "to treat and protect intellectual property rights (IPR) owned or developed in other countries the same as domestically owned or developed IPR." In addition, at the 2012 JCCT, China "reaffirmed that technology transfer and technology cooperation are the autonomous decisions of enterprises" and pledged further that "[i]f departmental or local documents contain language inconsistent with the above commitment, China will correct them in a timely manner." The United States looks forward to China's full implementation of these commitments.

Patent-Related and Other Policies

Patents Used in Chinese National Standards

China has prioritized the development of Chinese national standards, as evidenced by its Outline for the National Medium to Long-Term Science and Technology Development Plan (2006-2020), issued by the State Council in February 2006, and amplified shortly thereafter in the 11th Five Year Plan (2006-2010) for Standardization Development, issued by the Standardization Administration of China (SAC) under the Administration for Quality Supervision, Inspection and Quarantine. In 2009, SAC welcomed comments on draft interim regulations on national standards involving patents. Of serious concern were provisions indicating that China would rely, during the standards development process, either on non-patented technology or on patented

technology licensed at a price significantly lower than normal royalties. The draft would also have empowered government authorities to grant a compulsory license if the authorities and patent holders were unable to reach agreement on licensing terms. These provisions and others raised significant concerns from several countries, including in the United States, as reported in depth in previous editions of this Report and in USTR's 2012 Report on Technical Barriers to Trade (TBT Report). In late 2012, China issued new draft interim rule for public comment. The United States welcomes the deletion from the new draft rule of provisions on below-normal royalties and compulsory licenses. The United States hopes that SAC will also revise other provisions in the draft about which the United States raised concerns.

IPR Protection for Pharmaceutical Products

The United States is very concerned about barriers in China to IPR protection for pharmaceutical products. In the patent area, China's revised implementation of Article 26.3 of its patent law has led the State Intellectual Property Office (SIPO) to refuse to consider post-filing supplementary test data supporting previously filed patent applications, contrary to the practice of the major patent offices around the world. This has led Chinese authorities not only to reject pending patent applications but also retroactively to revoke previously granted patents. These revisions make obtaining protection of patents of a reasonable scope very difficult in China when compared to other major markets. In addition, the United States continues to encourage China to provide an effective system for expeditiously addressing patent issues in connection with applications to market pharmaceutical products.

In addition, the United States continues to have concerns about the extent to which China provides effective protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. China's law and its WTO accession commitments require China to ensure that no subsequent applicant may rely on the undisclosed test or other data submitted in support of an application for marketing approval of new pharmaceutical products for a period of at least six years from the date of marketing approval in China. However, there is evidence that generic manufacturers have, in fact, been granted marketing approvals by the State Food and Drug Administration (SFDA) prior to the expiration of this period, and in some cases, even before the originator's product has been approved. The United States was encouraged by China's 2012 JCCT commitment to define "new chemical entity," a term that is central to the marketing approval process, in a manner consistent with international research and development practice. The United States looks forward to China's implementation of this commitment without undue delay.

Utility Model/Design Patents

U.S. rights holders have become increasingly concerned about China's utility model and design patent system. Through a combination of subsidies and other benchmarks to incentivize the filing of utility model and design patents, Chinese applicants have been filing large numbers of utility model and design patent applications (507,538 design patent applications and 581,303 utility model applications in 2011, according to SIPO). SIPO does not provide substantive examination for utility model and design patents. This, combined with the large numbers of utility model/design patents granted by SIPO, has led to a flood of low quality patents that fuels

abusive litigation, and burdens legitimate applicants seeking to make patentability or freedom to operate determinations.

The United States looks forward to continuing to work with China to resolve these and other issues.

India

India remains on the Priority Watch List in 2013. In 2012, India made limited progress in improving its weak IPR legal framework and enforcement system. India enacted copyright amendments and published for comment draft rules to implement the Madrid Protocol and a draft National Intellectual Property Strategy, which proposes to create an enhanced IPR management system. In many areas, however, IPR protection and enforcement challenges are growing, and there are serious questions regarding the future condition of the innovation climate in India across multiple sectors and disciplines. The United States continues to urge India to reconsider how it can meet legitimate domestic policy objectives by fostering rather than undermining that innovation climate.

Patents & Regulatory Data Protection

The United States continues to encourage India to promote a stable and predictable patent system that can nurture innovation. As leading economies with a strong tradition of innovation, India and the United States can and should ensure supportive environments for innovators to achieve success and make significant contributions to economic growth in both countries. In that connection, the United States urges India to continue its recent efforts to address its patent application backlog and to streamline its patent opposition proceedings.

Recent actions by the Indian Government, however, have raised serious questions about the innovation climate in India and risk hindering the country's progress towards an innovation-focused economy. In the pharmaceutical sector, some innovators are facing serious challenges in securing and enforcing patents in India. The United States urges India instead to adopt policies that support both cutting-edge innovation to address important health challenges and a robust generic market.

For example, a patent system must encourage the development of inventions that meet the well-established international criteria of being new, involving an inventive step, and being capable of industrial application. The United States is concerned that the recent decision by India's Supreme Court with respect to India's prohibition on patents for certain chemical forms absent a showing of "enhanced efficacy" may have the effect of limiting the patentability of potentially beneficial innovations. Such innovations would include drugs with fewer side effects, decreased toxicity, or improved delivery systems. Moreover, the decision appears to confirm that India's law creates a special, additional criterion for select technologies, like pharmaceuticals, which could preclude issuance of a patent even if the applicant demonstrates that the invention is new, involves an inventive step, and is capable of industrial application.

The United States will also continue to monitor closely developments concerning compulsory licensing of patents in India, particularly following the broad interpretation of Indian law in a recent decision by the Indian Intellectual Property Appellate Board (IPAB), while also bearing in mind the Doha Declaration on TRIPS and Public Health, discussed in the Intellectual Property and Health Policy section of this Report. In particular, India's decision in this case to restrict patent rights of an innovator based, in part, on the innovator's decision to import its products, rather than manufacture them in India, establishes a troubling precedent. Unless overturned, the decision could potentially compel innovators outside India – including those in sectors well beyond pharmaceuticals, such as green technology and information and communications technology – to manufacture in India in order to avoid being forced to license an invention to third parties.

The United States also urges India to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products, and to ensure that a system applies to all pharmaceutical products and not just traditional Indian medicines.

Copyright

India boasts a vibrant domestic creative industry, but the challenge of piracy – particularly over the Internet – continues to grow. While the Copyright (Amendment) Bill 2012 provided limited improvements to India's copyright regime, the amendments raise a number of questions regarding the scope of exclusive rights under Indian law and the ability of rights holders to properly exercise those rights. Additional legislative changes are needed in order to ensure that content-based industries can effectively combat physical and online piracy and develop new models for the delivery of content. As part of this reform, India should enact anti-camcording legislation and provide further protections against online copyright piracy, signal theft, and circumvention of technological protection measures.

Enforcement

The United States notes limited improvements with respect to IPR enforcement, including reports that enforcement officials cooperate with music industry rights holders in conducting complaint-based raids, and increased use of judicial orders that have strengthened enforcement against pirated movies and music online. The United States encourages India to take additional steps to improve coordination with enforcement officials of certain state governments within India. The United States also continues to encourage India to address its judicial inefficiencies and to strengthen criminal enforcement efforts, including by imposing deterrent level sentences and giving IPR prosecutions greater priority. Finally, the United States recommends that India more fully address the challenges posed by online copyight piracy by clarifying the procedures for notice and takedown of infringing materials.

Localization Trends

The United States commends India's recognition of the importance of innovation as part of its efforts to promote manufacturing, but urges India to resist imposing discriminatory policies or other counterproductive measures in pursuit of that objective at the expense of adequate and

effective protection of IPR. Recent measures that raise such concerns include India's Preferential Market Access (PMA) policy for electronic products and a proposed drug pricing policy, both of which appear to condition certain preferential treatment on the indigenous development of IPR.

The United States looks forward to continuing to work with India to address these and other issues.

Indonesia

Indonesia remains on the Priority Watch List in 2013. Indonesian authorities continued educational efforts to encourage IPR awareness among the public, and some rights holders reported good cooperation with enforcement authorities. The United States welcomes Indonesia's efforts in the IPR Working Group under the Trade and Investment Framework Agreement and collaboration on an action plan to improve IPR protection and enforcement against high levels of IPR infringement in Indonesia. While the United States welcomes these steps, it remains concerned about gaps in Indonesia's laws relating to the protection and enforcement of IPR, including laws relating to copyright. The United States urges Indonesia to address these issues through appropriate revisions to its law. The United States is also concerned that Indonesia's IPR enforcement efforts have not been effective in addressing challenges such as rampant piracy and counterfeiting, including growing piracy over the Internet, and the widespread availability of counterfeit pharmaceutical products. The United States urges Indonesia to take steps to address inefficiencies in its judicial and prosecutorial systems which include a lack of transparency and deterrent-level sentences. In regard to cable piracy, rights holders report some enforcement activity, and report that authorities have stated an intention to require cable operators, during the cable operator licensing process, to specify the source of the programming they transmit. While the cable licensing process should discourage cable piracy, rights holders report that the licensing process is not transparent and is proceeding at a slow pace. The United States encourages Indonesia to provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. The United States also remains concerned about market access barriers in Indonesia, which include measures imposing requirements that restrict the importation of medicines and measures that could restrict market access for motion pictures. The United States notes with concern statements in Indonesia's Special 301 submission indicating that Indonesia failed to abide by its procedures in issuing a compulsory license decree in 2012, and that its patent law does not require individual merit review in connection with the grant of compulsory licenses. The United States further encourages Indonesia to provide for judicial or other independent review of any compulsory license authorizations. The United States looks forward to working with Indonesia on these and other matters.

Pakistan

Pakistan remains on the Priority Watch List in 2013. Pakistan continued its efforts on IPR enforcement, including through raids, seizures, and arrests by various enforcement authorities. Notably, the government enacted the Intellectual Property Organization of Pakistan Act, 2012 (IPO Act), which establishes a permanent coordinating structure for IPR protection and enforcement. The IPO Act provides national authorities with greater IPR enforcement powers, and provides for the establishment of specialized IP tribunals. However, Pakistan has yet to improve IPR protection, despite the new IPO Act. Widespread counterfeiting and piracy, particularly book and optical disc piracy, continue to present serious concerns for U.S. industry. Pakistan should ensure that its enforcement officials can exercise ex officio authority without the need for a formal complaint by a rights holder, and should provide for deterrent-level penalties for criminal IPR infringement. Pakistan should also take the necessary steps to reform its copyright law to address the piracy challenges of the digital age. The United States continues to encourage Pakistan to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of test and other data generated to obtain marketing approval for pharmaceutical products. The United States looks forward to continuing to work with Pakistan as Pakistan begins to implement the IPO Act, and to address these and other issues.

Russia

Russia remains on the Priority Watch List in 2013 as a result of continued significant challenges to IPR protection, notably inadequate enforcement against the growing problem of online piracy. However, the United States is encouraged by Russia's agreement to the United States-Russian Federation Intellectual Property Rights Action Plan (Action Plan) in December 2012, which identifies objectives for IPR protection and expresses a shared belief that "strong IPR protection and enforcement are vital to promoting innovation and creativity by securing the rights of innovators and the creative community, attracting high-technology investment, and fostering the jobs necessary for long-term sustainable growth."

After an 18-year negotiation process, Russia became a member of the WTO on August 22, 2012. The United States welcomes the improvements Russia has made to its protection of IPR during the accession process, including the adoption of legislation consistent with Russia's commitments in the 2006 United States-Russia Bilateral Agreement on IPR. Russia has established a new unified fee system for issuing patents and registering trademarks, licenses, and assignments. Russia enacted amendments to the Law on Circulation of Medicines, which addresses protection of undisclosed test data. Russia has also revoked its reservation to Article 18 of the Berne Convention for the Protection of Literary and Artistic Works, which commits Russia to providing protection for works that existed prior to 1995 that were still under copyright protection in the United States and all other Berne member countries.

The United States also welcomes the trends described in the most recent data available on the usage of pirated software in Russia, which is reported to have dropped during the last six years, although software piracy remains a significant problem despite this progress. The United States awaits with interest the operation of the IPR civil court that Russia is establishing this year, and

hopes that this court will be an effective tool for adjudicating civil IPR cases. The United States encourages Russia to harmonize its IPR regime with the regulatory principles adopted under the Customs Union established with Kazakhstan and Belarus, and to work with those countries to both ensure that those principles are executed in a manner that most effectively protects IPR and to create the required unified trademark registry.

The United States is concerned, however, by the data Russia provided on its overall enforcement of IPR. The information available indicates that enforcement has decreased in the last year, specifically that the number of criminal raids declined significantly in 2012, the number of resources devoted to IPR economic crime enforcement sharply declined over the past two years, and the initiation of criminal IPR cases also declined. While Russia notes that it has changed its methodology for reporting enforcement statistics, and that this change may exaggerate the difference over time, there remain significant obstacles to enforcement of IPR. The United States is particularly troubled by the fact that online piracy is growing in Russia and that no effective enforcement strategy has yet been launched to combat this problem.

For these reasons, the United States welcomes the fact that the Action Plan endorses action on these important issues, including increased enforcement actions against counterfeit goods, effective prosecution of persons responsible for IPR crimes including online crimes, establishment of a mechanism for appropriate ISP liability for copyright infringement, and dedication of resources and personnel to law enforcement agencies to investigate and prosecute online IPR crimes. The Action Plan also reflects a commitment to support legislation addressing online piracy. The United States is encouraged that several legislative proposals are currently being considered, and urges Russia to enact an adequate and effective ISP liability system for copyright infringement to facilitate cooperation between rights holders and ISPs and combat the growth of illegal online markets for infringing goods.

The Action Plan and joint efforts through the IPR Working Group reflect significant commitments by Russia to IPR. Effective implementation of these commitments will advance Russia's IPR protection and enforcement. The United States looks forward to its continued work with Russia on these and other matters.

Thailand

Thailand remains on the Priority Watch List in 2013. The United States is prepared to review that status if Thailand makes significant progress in passing key legislative initiatives mentioned below, and improves its overall enforcement efforts. The United States remains encouraged by Thailand's commitment to improving IPR protection and enforcement. The United States is also encouraged by the passage of the Anti-Money Laundering Act, which includes IPR offenses as a predicate crime, and the launch of the National IPR Center of Enforcement, and it is hopeful that this center will lead to improved coordination and more effective enforcement actions among enforcement agencies. U.S. rights holders continue to report good cooperation with Thai enforcement authorities, including the Royal Thai Police and Royal Thai Customs. The United States urges Thailand to complete many of the legislative initiatives begun in past years, including legislation to address landlord liability, to address unauthorized camcording of motion

pictures in theaters, to provide Thai Customs with *ex officio* authority, to fully implement the provisions of the WIPO Internet Treaties, and to establish improved legal mechanisms to address the rapidly growing problem of copyright piracy and trademark counterfeiting on the Internet. The United States also urges Thailand to take enforcement action against widespread piracy and counterfeiting in the country, and to impose deterrent-level sentences. The United States urges Thailand to effectively address its longstanding problem of piracy of cable and satellite signals. The United States encourages Thailand to provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. The United States continues to encourage Thailand to engage in a meaningful and transparent manner with all relevant stakeholders, including IPR owners, as it considers ways to address Thailand's public health challenges, while maintaining a patent system that promotes innovation. The United States looks forward to continuing to work with Thailand to address these and other issues.

Venezuela

Venezuela remains on the Priority Watch List in 2013. The United States encourages Venezuela to update its 1955 Industrial Property Law, which was reinstated in 2008, to create a strong IPR law that covers a wide range of patentable inventions and that brings its system into conformity with international norms. Venezuela should also clarify the status of trademarks that were registered under the Andean Community law, prior to Venezuela's withdrawal from the Andean Community. Venezuela took limited enforcement actions in 2012. Venezuela should more effectively enforce the 2010 Law on Crimes and Contraband to issue stronger penalties for IPR violations. The United States remains concerned about rampant piracy and counterfeiting, including piracy over the Internet. The United States encourages Venezuela to provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. The United States will continue to monitor Venezuela's progress on these and other issues.

WATCH LIST

Barbados

USTR is placing Barbados on the Watch List in 2013. The United States is concerned about local TV and radio broadcasters' refusal to pay for public performances of music. United States rights holders complain that both private and government-owned broadcasters in Barbados either fail to obtain licenses from the Copyright Society of Composers, Authors & Publishers Inc. (COSCAP) or fail to pay for all of the applicable rights even if they are licensed by COSCAP. In addition, even though the Barbados Copyright Tribunal was finally convened in 2012, it has not yet acted to determine the amount due to COSCAP pursuant to a 2007 judgment of the Barbados Supreme Court that found copyright infringement violations. The United States urges the

Government of Barbados to take all administrative action necessary to ensure that United States composers and songwriters receive compensation owed, without undue delay, for the public performance of their musical works. In addition, the United States is concerned that section 82 of the Copyright Act of 1988 creates a compulsory licensing scheme allowing for the interception and retransmission of United States cable programming by local cable operators without the consent of, and without adequately compensating, United States rights holders. The United States urges the Government of Barbados to repeal this provision. The United States looks forward to working with Barbados to resolve these and other issues.

Belarus

Belarus remains on the Watch List in 2013. In 2012, Belarus acceded to the Singapore Treaty on the Law of Trademarks, and improved the patent application process. However, Belarus should take further steps to implement an effective IPR enforcement regime. The United States remains concerned about Belarus' implementation of the IPR commitments made under the United States-Belarus Trade Relations Agreement of 1993. Piracy and counterfeiting remain widespread in Belarus, and IPR enforcement efforts continue to be weak and ineffective. The United States continues to urge Belarus to enact all regulations necessary to implement the amendments to the Belarusian Criminal and Administrative Codes related to IPR that have been pending since 2011, and to implement fully the WIPO Internet Treaties. The United States also encourages Belarus to harmonize its IPR regime with the regulatory principles adopted under the Customs Union established with Kazakhstan and Russia. Belarus should work with these countries to ensure that the Customs Union principles are executed in a manner that most effectively protects IPR and create the required unified trademark registry. For example, Belarus should implement and exercise the Customs Union Customs Code provisions on ex officio authority for customs officials in order to improve the investigation of suspected infringement cases, seizure of infringing goods, and prosecution of IPR violations. The United States will continue to monitor Belarus' progress on these and other matters.

Bolivia

Bolivia remains on the Watch List in 2013. In 2012, Bolivia's Intellectual Property Office continued its IPR public awareness efforts and Bolivia's police conducted two successful raids against manufacturers of counterfeit products. However, rampant piracy and counterfeiting persist. The United States is concerned about the alleged increase in the production of infringing goods in Bolivia. Bolivia should take steps to improve its enforcement of IPR, including by providing for more efficient prosecutions, by improving coordination among Bolivian enforcement authorities, and by allocating additional resources to enforcement officials. The United States will continue to monitor Bolivia's progress on these and other matters.

Brazil

Brazil remains on the Watch List in 2013. Brazil continued to make progress in 2012 by conducting notable enforcement efforts across the country under the coordination of the National Council to Combat Piracy. However, the United States is concerned about recent regulations that provide Brazil's sanitary regulatory agency, ANVISA, with the authority to review pharmaceutical patent applications for meeting patentability requirements. These regulations appear to contravene an earlier opinion by the Federal Attorney General that clarified that ANVISA did not have this authority. The United States urges Brazil to continue to work with stakeholders to ensure that its patent examination process is transparent and predictable. Brazil continues to experience widespread piracy and counterfeiting, and the availability of pirated books is a particular concern to the United States. The United States urges Brazil to take steps to address the growing challenge of piracy over the Internet, and to strengthen pending amendments to its copyright law to better protect against IPR violations in the digital environment. The United States also encourages Brazil to strengthen its border enforcement efforts, and strengthen enforcement generally by more consistently arresting and prosecuting IPR violators, and by imposing deterrent-level penalties for those who are convicted. The United States encourages Brazil to clarify and strengthen its system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. The United States also encourages Brazil to address its backlog of pending patent applications. The United States looks forward to continuing to work with Brazil to address these and other matters.

Bulgaria

Bulgaria is on the Watch List in 2013. Bulgaria has taken only limited steps to address persistant U.S. concerns regarding IPR infringement. Piracy over the Internet in Bulgaria remains a serious and growing concern. Numerous online infringing services operate in the market and enforcement actions have seldom resulted in convictions. Collecting societies continue to report serious challenges in collecting royalties and in enforcing their rights through administrative or judicial action. Bad faith trademark registrations have also become increasingly common and are often registered due to constraints of the Bulgarian Patent Office, which is responsible for trademark registrations. These and other concerns are compounded by inadequacies in the Bulgarian judicial system. Generally, rights holders face significant delays in the adjudication of IPR disputes, many of which do not reach final sentencing, and when they do, remedies are nondeterrent. Bulgaria's Government should coordinate with rights holders, and other interested parties, such as ISP, to develop recommendations for reducing Internet piracy. Notwithstanding these continuing issues, the United States recognizes the positive steps Bulgaria has taken to address IPR infringement in its market. For example, Bulgaria has engaged in enforcement actions, including by the Ministry of Culture as well as the Ministry of the Interior's Cybercrime Unit, and has cooperated with rights holders on campaigns to address software piracy. Bulgaria also undertook a software legalization initiative in 2012. The United States encourages Bulgaria to continue to enhance its IPR protection and enforcement efforts, and to work with the United States to devise strategies to resolve these issues. The United States looks forward to continuing to work with Bulgaria to address these and other issues.

Canada

USTR is moving Canada to the Watch List in 2013. In June 2012, the United States welcomed the passage of the Copyright Modernization Act, which, among other things, is designed to implement Canada's obligations under the WIPO Internet Treaties and to address the challenges of copyright piracy in the digital age. In March 2013, Canada also introduced the Combating Counterfeit Products Act to strengthen IPR enforcement, which included provisions that would provide *ex officio* authority to Canadian customs officials to seize pirated and counterfeit goods at the border. The United States supports Canada's commitment to address the serious problem of pirated and counterfeit goods entering our highly integrated supply chains and urges Canada to expand the legislation to also provide authority for its customs officials to take action against goods in-transit. With respect to pharmaceuticals, the United States continues to have serious concerns about the availability of rights of appeal in Canada's administrative process for reviewing regulatory approval of pharmaceutical products and also has serious concerns about the impact of the heightened utility requirements for patents that Canadian courts have been adopting recently. The United States looks forward to continuing its close cooperation with Canada on IPR issues, including through the TPP negotiations.

Colombia

Colombia remains on the Watch List in 2013. The United States continues to engage extensively with Colombia as it implements the United States-Colombia Trade Promotion Agreement (TPA). The United States applauds Colombia on its accession to the Madrid Protocol and the Trademark Law Treaty in 2012. Colombia also strengthened its enforcement operations through improved internal coordination of enforcement agencies. Colombia has taken significant steps to reduce its backlog of pending patent applications. The United States urges Colombia to swiftly pass key pieces of currently pending IPR legislation in connection with the implementation of that agreement. Concerns remain with an overall lack of adequate resources and training for enforcement officials. The United States will continue to work with Colombia on the implementation of TPA obligations regarding protections against piracy over the Internet, which is a growing problem in Colombia. Colombia should also take steps to address its continuing problem with optical disc piracy. The United States looks forward to continuing its engagement with Colombia to address these and other matters.

Costa Rica

Costa Rica remains on the Watch List in 2013. Costa Rica made initial progress in processing patent applications by adding examiners and achieving a reduction in the average time required to review patent applications. Nevertheless, significant concerns remain on IPR matters. Despite the need to implement a CAFTA-DR obligation to ensure that the software used by the government is legitimate, substantial progress on that front has not yet been realized. While the United States is aware of a recent measure intended to address this issue, it looks forward to confirming effective and timely implementation of the new measure later this year. Costa Rica

should also take steps to grant *ex officio* powers to law enforcement and customs officials. An additional concern is the failure to create a specialized IPR crime unit, despite the government's announced intention to do so in 2011. Costa Rica should take concrete steps to improve its overall IPR enforcement efforts by making IPR violations a higher priority, concluding prosecutions, and imposing deterrent penalties. The United States encourages Costa Rica to take concerted efforts to resolve these longstanding issues. The United States looks forward to continuing to work with Costa Rica to address these and other issues.

Dominican Republic

The Dominican Republic remains on the Watch List in 2013. Although the United States notes some progress in enforcement against pirated goods, and participation in technical assistance activities relating to IPR protection and enforcement, substantial concerns remain, especially with respect to the widespread availability of pirated and counterfeit products. IPR enforcement agencies in the Dominican Republic continue to experience a lack of coordination, resources, and training. The United States encourages the Dominican Republic to implement its obligations with respect to providing an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. It also urges the Dominican Republic to address a growing backlog of pending patent applications. The growing delays in the patent application and examination process highlight the need to fully implement CAFTA-DR obligations with respect to patent term adjustment. The United States also urges the Dominican Republic to provide an effective system to address patent issues expeditiously in connection with applications to market pharmaceutical products. The United States looks forward to continuing to work with the Dominican Republic to address these and other issues.

Ecuador

Ecuador remains on the Watch List in 2013. The United States is very concerned about a recent increase in the fees charged for applying for and maintaining patent rights and plant variety protection in Ecuador; these exorbitantly high fees create a disincentive for rights holders and negatively impact the operation of the Ecuadorian patent system. The United States is somewhat encouraged by recent enforcement efforts that led to temporary closures of stores selling pirated music and movies and to a decline in the piracy of satellite television signals. Ecuador continues to face widespread piracy and counterfeiting. The United States urges Ecuador to continue to improve its IPR enforcement efforts and to establish the specialized IPR courts required under Ecuador's 1998 IPR law. Ecuador should also further clarify its system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, and to provide such protection for agricultural chemical products, and provide an effective system to address patent issues expeditiously in connection with applications to market pharmaceutical products. The United States looks forward to continuing to work with Ecuador to address these and other issues.

Egypt

Egypt remains on the Watch List in 2013. IPR challenges for Egypt include the failure to issue deterrent-level sentences for IPR violations when offenders are convicted and the need for additional training for enforcement officials. However, the United States is encouraged by positive reports about recent improvements in efficiency and effectiveness of the Economic Courts in IPR cases and the Information Technology Industry Development Agency's increase in raids and investigations against distributors and producers of pirated or counterfeit merchandise. The United States encourages Egypt to finalize long-awaited regulations to clarify border procedures for the destruction of counterfeit products and to provide customs officials with the authority to take ex officio action. Although Egypt is working to upgrade its trademark registration system, rights holders have expressed concerns that Egypt has issued certain registrations improperly. Rights holders continue to express significant concerns that businesses offering pirated television content are impairing the ability of legitimate distribution outlets to operate in the market, and that print piracy continues to harm domestic and foreign publishers. The United States urges Egypt to amend its copyright law to clarify translation requirements for copyright protection, appropriate presumption of ownership in copyright works, and other concerns. The United States looks forward to continuing to work with Egypt on these and other issues.

Finland

Finland remains on the Watch List in 2013. The United States continues to be concerned about the lack of product patent protection for certain pharmaceutical products. U.S. industry also has expressed concern that the regulatory framework in Finland regarding process patents filed before 1995, and pending in 1996, denies adequate protection to many of the top-selling U.S. pharmaceutical products currently on the Finnish market. The United States looks forward to continuing to work with Finland to address these and other issues.

Greece

Greece remains on the Watch List in 2013. While Greece made some improvements to its IPR protection and enforcement regime in 2012, including adopting amendments to its Trademark Law and taking enforcement actions to combat infringement, numerous and notable problems persist. The 2009 IPR Action Plan addresses many of these issues, and the United States continues to urge Greece to implement the plan. Greece should fully implement legislation and regulations that provide administrative fines for software infringement. Greece should also take steps to ensure that it has effective legal mechanisms to address piracy over the Internet, including by implementing existing measures that allow civil actions by rights holders concerning piracy over the Internet, as well as by providing ISPs with clear incentives to cooperate with rights holders in removing unauthorized content. The current lack of adequate authority to combat piracy over the Internet has exacerbated this growing problem. In addition,

Greece should expand on recent enforcement efforts to address the continuing widespread availability of pirated and counterfeit goods. The United States also continues to encourage Greece to improve its judicial system, which suffers from significant delays and few infringement convictions. The United States looks forward to continuing to work with Greece to address these and other issues.

Guatemala

Guatemala remains on the Watch List in 2013. The United States remains optimistic about the coordination of IPR enforcement efforts in Guatemala. However, enforcement efforts weakened in 2012, and overall prosecutions were significantly down compared to the previous year. While the United States was encouraged by the 2011 enactment of legislation to strengthen penalties against the production and distribution of counterfeit medicines, the United States is not aware of any successful prosecutions under the law in 2012. Additional problems include a severe lack of resources. Trademark squatting is a significant and growing concern, and government use of unlicensed software remains problematic. In addition, pirated and counterfeit goods continue to be widely available in Guatemala, and enforcement efforts are hampered by limited resources and the need for better coordination among all enforcement agencies. The United States encourages Guatemala to continue its enforcement efforts against the manufacture of pirated and counterfeit goods, and to take steps to improve the operation of its judicial system. The United States looks forward to continuing to work with Guatemala to address these and other matters.

Israel

USTR moved Israel to the Watch List in September 2012 because Israel implemented the first portion of the Understanding on IPR that it concluded with the United States in 2010.

The United States and Israel reached the Understanding, which concerns several longstanding issues regarding Israel's regime for pharmaceutical products, on February 18, 2010. As part of the Understanding, Israel committed to strengthen its laws on protection of pharmaceutical test data and patent term extension, and to publish patent applications promptly after the expiration of a period of eighteen months from the time an application is filed. The Understanding provided, among other things, that the Government of Israel would submit legislation regarding these three matters to the Knesset. Israel has submitted legislation to the Knesset regarding all three issues, and the bills concerning pharmaceutical test data and patent publication have been enacted. The United States urges Israel to pass the final bill so that, pursuant to the Understanding, Israel will be removed from the Watch List.

Separately, the United States encourages Israel to ratify and implement the WIPO Internet Treaties. Doing so would strengthen Israel's IPR regime, and would afford rights holders with additional effective enforcement remedies against copyright infringement that occurs over the Internet. The United States also encourages Israel to amend its copyright law to provide for statutory damages.

Additionally, there remain challenges to enforcement of IPR in Israel. Stakeholders report that the Special Police Units designed to enforce IPR are under-funded and do not undertake *ex officio* action. The United States is concerned by a recent increase in websites selling counterfeit pharmaceuticals, but commends Israel for its efforts to cooperate with other countries, including the United States, to prosecute those who operate these enterprises. The United States looks forward to continuing to work with Israel to resolve these and other matters.

Italy

Italy remains on the Watch List in 2013. Piracy over the Internet remains high in Italy, with several content industries reporting that Italy has among the highest rates of online piracy in the world. While the Italian Communications Authority (AGCOM) made progress in 2011 and early 2012 on draft regulations to combat piracy over the Internet, that process has since stalled. As a result, rights holders continue to face serious challenges in combating piracy over the Internet in Italy. The United States underscores the importance of taking action to finalize and implement the AGCOM regulations to create an effective mechanism against all types of copyright piracy over the Internet. The United States also continues to have concerns about a Data Protection Agency opinion concerning the monitoring of peer-to-peer networks. The United States encourages to take further measures to significantly reduce delays in the adjudication of IPR disputes in Italian courts and ensure that cases reach final sentencing. The United States also looks forward to the report of the Parliamentary Committee of Inquiry on Counterfeiting and Piracy in the Commercial Field, which is an important opportunity to state the importance of strong IPR protection and enforcement in Italy and to identify solutions to address persistent concerns. The United States looks forward to continuing to work with Italy to address these and other matters.

Jamaica

Jamaica remains on the Watch List in 2013. In 2012, Jamaica continued to participate in the IPR training programs offered by the USPTO, and also conducted its own IPR training initiatives, including a workshop for Jamaican customs officials. Jamaica also continued its efforts to educate the public about IPR protection and enforcement, and launched a voluntary copyright registration system. However, the United States remains seriously concerned about the need to enact the draft Patents and Designs Act, which is intended to implement certain provisions of the TRIPS Agreement and the United States-Jamaica Bilateral Intellectual Property Agreement. In addition, Jamaica's largest cable operator has not yet compensated performing rights organizations for the public performances of music, and the United States urges Jamaica to resolve that problem. The United States looks forward to continuing to work with Jamaica to address these and other issues.

Kuwait

Kuwait remains on the Watch List in 2013. The United States is seriously concerned that key IPR legislation remains pending in Kuwait, including amendments to the 1999 copyright law that have been drafted for several years but have not yet been submitted to Parliament. Although Kuwaiti officials continued enforcement efforts in the past year, there remains an ongoing lack of deterrent-level sentences for IPR crimes as well as insufficient resources allocated to enforcement at the border. The United States urges Kuwait to amend its copyright law to provide adequate and effective protection, and looks forward to continuing to work with Kuwait to address these and other IPR concerns.

Lebanon

Lebanon remains on the Watch List in 2013. The United States is concerned that there has not been any progress on any of the pending IPR legislative reforms, including amendments to Lebanon's patent and copyright laws. Lebanon also has not completed its accession to the WIPO Internet Treaties, despite ratification of these treaties by Parliament in 2010, and several IPR treaties that have been approved by the Cabinet still await parliamentary approval, including the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, the Singapore Treaty on the Law of Trademarks, and the Patent Cooperation Treaty. Additionally, Lebanon should provide its enforcement authorities with ex officio authority. The United States encourages Lebanon to clarify its protection against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval of pharmaceutical products. Further, the manufacture and sale of counterfeit drugs remain a concern in Lebanon. A lack of transparency in the pharmaceutical registration process reportedly has enabled the registration of counterfeit products. However, the United States commends Lebanese enforcement officials for successfully conducting raids targeting sellers of counterfeit goods, including counterfeit pharmaceuticals. The United States is also encouraged that Lebanon has launched an online registration service for copyrights and trademarks. The United States looks forward to continuing to work with Lebanon to address these and other issues.

Mexico

Mexico remains on the Watch List in 2013. Positive developments in 2012 included Mexico's accession to the Madrid Protocol, the adoption of guidelines for protection of pharmaceutical test data, and clarification of the scope of its system for addressing patent issues expeditiously in connection with applications to market pharmaceutical products. However, serious concerns remain, particularly with respect to the widespread availability of pirated and counterfeit goods in Mexico and inadequate IPR enforcement. Criminal enforcement suffers from increased but inefficient coordination among federal and subfederal officials. In addition, to combat high levels of IPR infringement, Mexico needs to devote additional resources, bring more IPR prosecutions, and impose deterrent penalties against infringers. The United States continues to

urge Mexico to provide its customs officials with *ex officio* authority and to enact legislation to strengthen its copyright regime, including by implementing the WIPO Internet Treaties and providing stronger protection against the unauthorized camcording of motion pictures in theaters. Prior to 2011, Mexican customs authorities and the Attorney General's Office worked jointly to intercept and prosecute transshipments of counterfeit and pirated goods. Following a shift in policy, however, Mexican authorities now only take action against transshipments of suspected infringing goods if there is evidence of "intent for commercial gain" in Mexican territory, which is very difficult to prove. The United States strongly urges Mexico to revert to the previous policy that allowed for the interception of potentially dangerous counterfeit goods in transit to the United States and other countries. The United States also looks forward to the Mexican Senate's ratification of the Anti-Counterfeiting Trade Agreement. The United States looks forward to continuing to work with Mexico to address these and other issues, including through the TPP negotiations.

Paraguay

USTR is moving Paraguay to the Watch List in 2013. In addition, the United States continues to monitor Paraguay under Section 306. Although Paraguay failed to complete negotiations to renew the expired Memorandum of Understanding on Intellectual Property Rights (MOU) with the United States, the United States is encouraged by Paraguayan officials' recent interest to finalize the MOU, and by Paraguay's creation of the National Directorate of Intellectual Property. The new, autonomous Directorate has the potential to better ensure that law enforcement has sufficient resources and the necessary powers to effectively carry out its mission. Paraguay should also take steps to address its inefficient judicial system. Paraguay still faces rampant piracy and counterfeiting, and should take additional steps to improve enforcement efforts internally and at the border, including by strengthening its customs actions and improving its cooperation with neighboring countries Brazil and Argentina on cross-border enforcement of IPR. The United States continues to urge Paraguay to improve its patent protections and to provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval of pharmaceutical and agricultural chemical products. The United States looks forward to continuing to work with Paraguay to address these and other matters.

Peru

Peru remains on the Watch List in 2013. The United States remains concerned about the widespread availability of counterfeit and pirated products in Peru. The United States urges Peru to devote additional resources for IPR enforcement, improve coordination among enforcement agencies, enhance its border controls, and strengthen its judicial system. The United States encourages Peru to coordinate enforcement and pursue prosecutions under the law that criminalizes the sale of counterfeit medicines. In addition, the United States urges Peru to take steps to implement its obligations under the United States-Peru Trade Promotion Agreement regarding the prevention of government use of unlicensed software, and likewise urges steps to

implement obligations with respect to protections against piracy over the Internet, which continues to be a growing problem. Peru also needs to clarify its protections for biotechnologically-derived pharmaceutical products. The United States looks forward to continuing to work with Peru to address these and other issues, including through the TPP negotiations.

Philippines

The Philippines remains on the Watch List in 2013, subject to further review if the Philippines continues to make progress in key areas. The United States recognizes the efforts and achievements of high level IPR officials and legislators in strengthening the protection and enforcement of IPR in the Philippines. The United States looks forward to continued engagement in the coming year. In early 2013, the Philippines brought to a close a longstanding legislative effort to modernize its copyright and IPR enforcement regimes consistent with the WIPO Internet Treaties. That legislation also took the important step of providing ex officio authority to customs officers. The United States looks forward to the adoption of implementing regulations that will further strengthen and clarify the law, especially as to the circumvention of technological protection measures. The United States looks to the Philippines to take important steps to address piracy over the Internet, in particular with respect to notorious online markets. The United States applauds the Philippines on its accession to the Madrid Protocol. The United States is encouraged by IPR enforcement efforts generally in the Philippines and by the continuing drop in the incidence of unauthorized camcording of motion pictures in theaters. While the United States is hopeful that implementation of the 2011 Supreme Court IPR procedural rules will lead to a more efficient judicial process for IPR cases, the United States remains concerned about the need to strengthen criminal enforcement of IPR and to improve predictability with respect to search and seizure orders. The United States also remains concerned about amendments to the Patent Law that limit the patentability of certain chemical forms unless the applicant demonstrates increased efficacy. The United States encourages the Philippines to provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. The United States looks forward to continuing to work with the Philippines to address these and other issues.

Romania

Romania remains on the Watch List in 2013. The United States is encouraged by the continuing positive cooperation between Romanian enforcement officials and industry representatives and the increase in cases brought against IPR violators. However, Romania should devote the necessary resources and training for authorities to effectively address the continuing problems of piracy and counterfeiting. The United States continues to urge Romania to prioritize IPR protection and enforcement, and to take steps to address concerns over judicial delays and a lack of deterrent-level sentencing. Piracy over the Internet remains a serious concern, and more

enforcement efforts are needed to address the problem. The United States looks forward to continuing to work with Romania to address these and other issues.

Tajikistan

Tajikistan remains on the Watch List in 2013. The United States commends Tajikistan on its recent accession to the WTO in March 2013. Additionally, Tajikistan has taken the further positive step of adopting amendments to its laws relating to pharmaceutical products and agricultural chemical products to provide a system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for these products. Further, as part of its WTO accession process, Tajikistan committed to an amendment of its Customs Code to provide *ex officio* authority for border and criminal enforcement officials. However, Tajikistan has yet to fully implement its commitments under the 1993 United States-Tajikistan Trade Agreement. In particular, Tajikistan needs to increase prosecutions of criminal IPR infringement. The United States looks forward to continuing to work with Tajikistan to increase its enforcement capacity in general, and to implement the commitments that Tajikistan made as part of its WTO accession process.

Trinidad and Tobago

USTR is placing Trinidad and Tobago on the Watch List in 2013. The United States is concerned that the local cable operator refuses to negotiate with the Copyright Music Organization of Trinidad and Tobago ("COTT"), the local performing rights organization, for compensation for public performance of music, including for music written by American composers. Particularly troubling in this case is the fact that a court in 2011 found that the local cable operator was required to obtain a public performance license and nearly two years later judicial authorities have not completed the appeal hearing nor assessed royalties owed to COTT. Furthermore, notwithstanding this decision, the local cable operator failed to obtain this license. The United States is also concerned by ongoing delays in the resolution of the long-standing litigation over the collection of unpaid performance royalties from the same cable operator. The United States urges the Government of Trinidad and Tobago to take all necessary actions to ensure that cable operators in Trinidad and Tobago operate in compliance with the provisions of their cable license agreements related to IPR and that, more generally, IPR is protected in its territory. The United States looks forward to continuing to work with Trinidad and Tobago to address these and other issues

Turkey

Turkey remains on the Watch List in 2013. U.S. rights holders continue to raise serious concerns regarding the export from, and transshipment through, Turkey of counterfeit and pirated products. In particular, industry has expressed concern about the manufacture of counterfeited luxury goods. Currently, the Government of Turkey does not have an effective mechanism for

ensuring legal use of software, and government software piracy is a concern. Stakeholders report that judicial delay is a significant obstacle to enforcement of IPR in Turkey. Additional resources and training, including for customs officials and judges, are needed to allow for more effective IPR enforcement efforts. The United States understands that Turkey is considering legislative reforms in the areas of industrial property and copyright law, and hopes that this process will result in the amelioration of some of the persistent IPR problems. In particular, the copyright law should be amended to provide an effective mechanism to address piracy in the digital environment, including full implementation of the WIPO Internet Treaties, and the industrial property law should be amended to resolve the uncertainty about trademark-related cases stemming from a 2008 Constitutional Court decision that annulled certain trademark infringement penalties. Legislative reforms should provide for penalties for IPR infringement in order to deter such conduct, including deterrence against those who aid and abet those who manufacture and sell counterfeit goods. Royalty collecting societies should have fair and transparent procedures. Police should be given the ex officio authority they currently lack, which impedes police from acting on obvious infringement cases. The United States continues to encourage Turkey to clarify its protection against the unfair commercial use, as well as unauthorized disclosure, of test and other data generated to obtain marketing approval for pharmaceutical products. The United States was encouraged by constructive bilateral engagement with Turkey over the past year and looks forward to continuing to work with Turkey to address these and other issues.

Turkmenistan

Turkmenistan remains on the Watch List in 2013. In 2012, Turkmenistan adopted a Law on Copyright and Allied Rights and amended its Civil Code to enhance IPR protection. However, Turkmenistan should also provide for administrative and civil procedures for IPR enforcement, as well as criminal penalties against IPR infringement, and should provide *ex officio* authority to its customs officials. The United States urges Turkmenistan to implement its commitments under the 1993 United States-Turkmenistan Trade Agreement. In addition, the United States continues to encourage Turkmenistan to join the Berne Convention on the Protection of Literary and Artistic Works and the Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of their Phonographs (Geneva Phonograms Convention). The United States looks forward to continuing to work with Turkmenistan on these and other issues.

Uzbekistan

Uzbekistan remains on the Watch List in 2013. Uzbekistan's Agency for Intellectual Property has expressed a commitment to improve the protection of IPR. To that end, Uzbekistan should increase penalties for IPR violations and ensure that its law enforcement authorities have *ex officio* authority to initiate investigations and enforcement actions. Uzbekistan also needs to allocate more resources to IPR enforcement at its borders to stem the flow of pirated films and recordings as well as counterfeit goods into Uzbekistan. The Uzbek Parliament should immediately take several legislative steps to move forward to address longstanding deficiencies

in IPR protection. Specifically, it should: (1) approve Uzbekistan joining the *Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of their Phonographs* (Geneva Phonograms Convention); (2) approve Uzbekistan joining the WIPO Internet Treaties; (3) remove Uzbekistan's Article 18 reservation to the Berne Convention to ensure copyright protection for preexisting works; and (4) take legislative action to provide adequate copyright protection for foreign sound recordings The United States looks forward to continuing to work with Uzbekistan to address these and other issues.

Vietnam

Vietnam remains on the Watch List in 2013. Although Vietnam took certain steps to improve its regulatory framework in the last two years by passing decrees and issuing circulars to strengthen copyright protection and enforcement, significant areas of concern remain. Piracy and sales of counterfeit goods over the Internet is a growing concern, and counterfeit goods remain widely available in physical markets as well. In addition, book piracy, software piracy (including on government computer systems), and cable and satellite signal theft continue to be widespread. Although Vietnam took further steps on public awareness efforts, enforcement actions have showed little progress in 2012, with only a few criminal cases involving safety concerns prosecuted or pursued on non-IPR legal grounds, and enforcement agencies continue to have capacity constraints, due in part to a lack of resources and IPR expertise. Vietnam should clarify its system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. While Vietnam has broad laws criminalizing IPR crimes, the government has yet to draft the implementing guidelines that are necessary for law enforcement agencies and the courts to levy deterrent criminal penalties against IPR violators. The United States looks forward to continuing to work with Vietnam to address these and other issues, including in the TPP negotiations.

ANNEX 1. STATUTORY 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

("Special 301"), USTR is required to identify those countries that deny adequate and effective protection for IPR or deny fair and equitable market access for persons that rely on IPR protection.² The USTR is required to designate 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 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 is required to 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 IPR. 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 trading partner's compliance with measures that are the basis for resolving an investigation under Section 301. USTR may apply sanctions if a country fails to satisfactorily implement such measures.

The Trade Policy Staff Committee, in particular the Special 301 Subcommittee, 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.

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² "Countries" in this context include separate customs territories and the European Union.

ANNEX 2. THE WIPO PERFORMANCES AND PHONOGRAMS TREATY (WPPT) AND THE WIPO COPYRIGHT TREATY (WCT)

The United States continues to work with other governments, in consultation with U.S. copyright industries and other affected sectors, to develop strategies to address global IPR issues. In 1996, the WIPO concluded two copyright treaties, the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty. Following their entry into force in 2002, these treaties have raised the standard of copyright protection around the world, particularly with regard to Internet based delivery of copyrighted content. The WIPO Internet Treaties have clarified certain exclusive rights and require signatories to provide adequate legal protection and effective legal remedies against the circumvention of certain technological measures as well as certain acts affecting rights management information. A growing number of trading partners are implementing the WIPO Internet Treaties to create a legal environment conducive to investment and growth in legitimate Internet-related businesses, services, and technologies.

As of April 2013, there are 91 contracting parties to the WPPT and 90 contracting parties to the WCT. Other trading partners have implemented key provisions of these treaties in their national laws without formally ratifying them. The United States urges other governments to ratify and implement the provisions of the WIPO Internet Treaties.

The following trading partner became party to the WCT between January 2012 and March 2013:

Malaysia Entry into Force: December 27, 2012

The following two trading partners became parties to the WPPT between January 2012 and March 2013:

Ghana Entry into Force: February 16, 2013
Malaysia Entry into Force: December 27, 2012