

2012 Special 301 Report



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Office of the United States Trade Representative

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EXECUTIVE SUMMARY

The “Special 301” Report is 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 (enacted in 1994).

This Report reflects the Administration’s resolve to encourage and maintain adequate and effective IPR protection and enforcement worldwide. It identifies a wide range of concerns, including 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 Canada, 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 28, 2011. This year’s notice yielded 42 comments from interested parties. USTR also received submissions from 18 trading partners. The submissions that USTR received were made available to the public online at www.regulations.gov, docket number USTR-2011-0021. In addition, on February 23, 2012, 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 12 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 well-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 to interact closely 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 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, ways in which the United States 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 works closely with other U.S. Government agencies to ensure consistency of U.S. trade policy objectives with other Administration policies. For example, as described in Section I of this Report, USTR has convened a new subcommittee of the interagency Trade Policy Staff Committee, called the "Trade Enhancing Access to Medicines" (TEAM), to investigate how to best deploy the tools of trade policy to further the Administration's objective of promoting trade in, reducing obstacles to, and enhancing access to both innovative and generic medicines.

2012 Special 301 List

The 2012 Special 301 review process examined IPR protection and enforcement in 77 trading partners. Following extensive research and analysis, USTR has listed the 40 trading partners below as follows:

Priority Watch List: Algeria, Argentina, Canada, Chile, China, India, Indonesia, Israel, Pakistan, Russia, Thailand, Ukraine, Venezuela.

Watch List: Belarus, Bolivia, Brazil, Brunei Darussalam, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, Finland, Greece, Guatemala, Italy, Jamaica, Kuwait, Lebanon, Mexico, Norway, Peru, Philippines, Romania, Tajikistan, Turkey, Turkmenistan, Uzbekistan, Vietnam.

Section 306 Monitoring: Paraguay.

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. USTR may conduct 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 ones on the Internet, that are reportedly engaged in piracy and counterfeiting, according to information submitted to the USTR in response to a request for comments. USTR requested such comments on September 22, 2011, and published the 2011 OCR of Notorious Markets on December 20, 2011.

USTR plans to conduct an OCR on notorious markets in the fall of 2012.

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 United States Trade Representative (USTR) is to support and implement the Administration's commitment to aggressively protect American intellectual property 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, it endangers the public. Some counterfeit products, such as 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 our 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 2011 and early 2012:

- **Malaysia** –Malaysia passed copyright amendments that significantly strengthen its protection of copyrights and its enforcement against piracy. These amendments include provisions on: preventing the circumvention of technological protection measures; establishing a mechanism for cooperation by Internet service providers (ISPs) against piracy over the Internet; and prohibiting the unauthorized camcording of motion pictures in theaters. Malaysia also established mechanisms to facilitate rights holder assistance in IPR enforcement efforts. Further, in 2011, Malaysia promulgated regulations designed to provide protection against the unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval of pharmaceutical products. Nevertheless, concerns remain, including concerns regarding the implementation of Malaysia's pharmaceutical data protection regulations, and regarding border enforcement, in particular with respect to transshipment. However, in recognition of Malaysia's recent improved efforts with respect to IPR protection and enforcement, the United States has removed Malaysia from the Watch List. The United States will continue to work closely with Malaysia to ensure that progress is sustained and to address our remaining areas of concern, including through the Trans-Pacific Partnership negotiations.

- **Spain** – In recognition of Spain’s recent efforts with respect to IPR protection and enforcement, the United States has removed Spain from the Watch List. The United States applauds Spain’s adoption of regulations implementing the “Ley Sinde,” a law to combat copyright piracy over the Internet. The United States will monitor the implementation of these measures and their overall effectiveness in addressing online piracy. The United States continues to have serious concerns with respect to criminal IPR enforcement, particularly the 2006 Prosecutor General Circular that appears to decriminalize peer-to-peer file sharing of infringing materials, and urges Spain to take steps to remedy this significant problem. The United States will work with Spain to address these and other issues.
- **Israel** – Israel enacted a law protecting against the unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval of pharmaceutical products.
- **Philippines** – The Philippines promulgated long-awaited specialized IPR procedural rules, which are designed to improve judicial efficiency in IPR cases.
- **Russia** – Russia enacted a law to establish a specialized IPR court by February 2013 and appropriately amended its Criminal Code to revise criminal thresholds for copyright piracy. In addition, the United States recognizes progress in connection with criminal proceedings against interfilm.ru, an infringing website in Russia, and the civil findings against vKontakte, Russia’s largest social networking site, for copyright infringement. Russian law enforcement authorities led several significant actions against pirated optical disc distributors, including a seizure of two million optical discs – the largest known such seizure in Russia. As part of the 2011 Out-of-Cycle Review (OCR) of Notorious Markets, USTR removed the Savelovskiy Market from the Notorious Markets List as a result of the Savelovskiy Market’s adoption and implementation of an action plan to stop the distribution of infringing goods.
- **China** – China has established a State Council-level leadership structure, headed by Vice Premier Wang Qishan, to lead and coordinate IPR enforcement across China. This leadership structure, which China established under the 2010-2011 Special IPR Campaign, and which China has now made into a permanent structure, is meant to enhance China’s ability to address IPR infringement. In addition, China’s leadership committed to increased political accountability, as the performance of provincial level officials will be measured based on enforcement of IPR in their regions.
- **Korea and Colombia** – On March 15, 2012, the United States-Korea Free Trade Agreement entered into force. On May 15, 2012, the United States-Colombia Trade Promotion Agreement will enter into force. Both Agreements include strong standards for the protection and enforcement of IPR.

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:** The Trans-Pacific Partnership is a key initiative through which the United States seeks to advance the multi-faceted 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. The Trans-Pacific Partnership negotiations have begun with this initial group of like-minded countries with the goal of creating a platform for integration across the region. The Trans-Pacific Partnership will include strong standards for the protection and enforcement of IPR in the 21st Century.
- **Anti-Counterfeiting Trade Agreement (ACTA):** Australia, Canada, the European Union (EU) and 22 of its Member States, Japan, Korea, Morocco, New Zealand, and Singapore, along with the United States, signed the ACTA, an important new tool to fight trademark counterfeiting and copyright piracy. The ACTA is the first IPR agreement to make clear that it will be implemented in a way that preserves freedom of expression, fair process, and privacy. The Agreement will also contribute to protecting the public against threats posed by unsafe counterfeit goods, such as toothpaste with diethylene glycol and auto parts of unknown quality. A number of signatories are now undertaking the necessary domestic processes in order to deposit instruments of acceptance. The United States looks forward to the remaining original negotiating parties signing the ACTA as well.
- **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 Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), and WTO's Dispute Settlement Body.
- **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.
- **Trade Preference Program Reviews:** USTR 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. USTR will continue to review IPR practices in Russia, Lebanon, and Uzbekistan under ongoing GSP reviews. In December 2011, USTR received new country practice petitions related to IPR in Ukraine and Indonesia.

- **Expanded International Cooperation:** USTR, in coordination with other 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, and in the Asia Pacific Economic Cooperation (APEC) forum, the Organization for Economic Cooperation and Development (OECD), and other multilateral and regional fora. As an example of an outcome of such engagement, in November 2011, APEC Ministers endorsed the *APEC Effective Practices for Addressing Unauthorized Camcording*, which will assist APEC economies to implement public awareness efforts, engage in cooperation with the private sector on capacity building, and adopt effective legal frameworks to address the challenges of unauthorized camcording in cinemas.

Best IPR Practices by Trading Partners

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

- In the 2011 Special 301 Report, USTR invited trading partners appearing on the Special 301 Priority Watch List or Watch List to work with the United States to develop mutually agreed-upon action plans, designed to lead to that trading partner's removal from the relevant list. Based on that initiative, USTR is working with several trading partners to develop action plans that would be designed to resolve 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 report that where foreign governments are open and transparent in bringing about legislative or regulatory change, and where such governments ensure that there is open dialogue between government officials and affected parties, it is easier for those stakeholders to comply with legislative or regulatory changes. For example, the United States commends the Czech Republic's continued efforts to inform stakeholders, as well as the United States Government, about recent developments in the protection and enforcement of IPR.
- Cooperation between different government agencies is another example of a best practice. For example, the United States notes positive reports regarding Russia's efforts to combat counterfeit medicines through a Memorandum of Understanding between the Ministry of Health and the Federal Service for Intellectual Property.
- Stakeholders have commended Hong Kong Customs officials for their effective enforcement against IPR infringement in marketplaces. Enforcement officials took a wide ranging set of actions that led to significant advances in limiting the availability of pirated and counterfeit products in Hong Kong marketplaces.
- 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 in the world to share patents with the Medicines Patent Pool, an independent foundation hosted by the World Health Organization, 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 HIV medicines, primarily used to treat drug-resistant HIV infection. 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, in order 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. Both 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) 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 Copyright Office, conduct conferences and training symposia in Washington, D.C..

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 2011, GIPA provided training to over 5,300 foreign IP officials from 138 countries, through 149 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 79 percent of all attendees reported that they had taken some steps to implement positive policy change in their respective organizations.
- 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 Caribbean Community (CARICOM), the Association of Southeast Asian Nations (ASEAN), the African Regional Intellectual Property Organization (ARIPO), the World Intellectual Property Organization (WIPO), the International Union for the Protection of New Varieties of Plants (UPOV), and Interpol, 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 2011, the Department of Homeland Security's (DHS) Bureau of Customs and Border Protection (CBP) conducted regional border training programs that focused on IPR enforcement in Morocco, El Salvador, Thailand and India. Also in 2011, the National IPR Coordination Center, in conjunction with Interpol, conducted training programs in 11 countries, and also conducted three advanced IPR training sessions at the U.S. International Law Enforcement Academies (ILEAs) in Thailand and El Salvador for participants from 22 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 Immigration and Customs Enforcement (ICE). In 2011, the Department of State provided funds for 12 training programs for customs, police, and

judicial officials from various trading partners including the Brazil, Colombia, India, Mexico, Philippines, Thailand, and Turkey, , as well as regional groups, such as ASEAN, and through regional trainings in East, West, and Central 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.

- The Department of Commerce’s Commercial Law Development Program (CLDP) provides training to foreign lawmakers, regulators, judges, and educators. CLDP currently works with more than 35 governments and has conducted cooperative programs in Central and Eastern Europe, the Commonwealth of Independent States (CIS), the Middle East, Africa, and Asia. For example, CLDP worked with the judiciary in Mali, Bosnia-Herzegovina, and Rwanda to improve the skills necessary to fairly, efficiently, and effectively adjudicate IPR cases. CLDP likewise organized interagency bilateral IPR enforcement programs in Ukraine and Pakistan, as well as on a regional level with Armenia, Georgia, Turkey, Kenya, and the East African Community member states.
- 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 three regional conferences in Africa.

Trends in Trademark Counterfeiting and Copyright Piracy

The problem of counterfeiting and piracy continues to present local challenges even as it has evolved into a sophisticated global business involving the mass production and far-reaching sales of a vast array of fake goods, including items such as counterfeit medicines, health care products, food and beverages, automobile and airplane parts, toothpaste, shampoos, razors, electronics, batteries, chemicals, sporting goods, motion pictures, and music.

Legitimate producers constantly face illicit competition from trademark counterfeiting and copyright piracy operations that diminish their profits and risk harm to consumers who may purchase fraudulent, potentially dangerous products. Where there is rampant counterfeiting and piracy, governments may lose tax revenue, and may find it more difficult to attract investment. Those engaged in such illegal activity 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. A reason for the rise in these criminal enterprises is that they 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 the mail or by hand are found in many places. For example, in China, although the largest Internet-based sales portals have responded to rights holders' complaints of counterfeit and pirated product listings, and even though major online sellers and distributors seem to be making efforts to ensure that the content available on their websites is legal, more than 75 percent of illicit sellers have reportedly re-listed the infringing goods.
- A surge 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 Russia reportedly import unbranded products, package these products with unauthorized packaging materials bearing the rights holders' trademarks, and subsequently export the products to various countries. Infringers in countries such as Paraguay reportedly facilitate these illegal activities by exporting label and packaging components to counterfeit and pirated product assemblers. There are reports of the transit of such labels through other countries as well, including Mexico and China.
- Growing challenges facing rights holders seeking to collect royalties that are legally owed for the public performance of their musical works in certain regions. This is a significant issue in the Caribbean region, including in the Bahamas, Barbados, Jamaica and Trinidad and Tobago. For example, in Trinidad and Tobago, there is ongoing litigation concerning the collection of unpaid performance royalties from cable system operators, a problem which occurs in Jamaica and in the Bahamas as well. In addition, a government owned broadcasting service in Barbados has reportedly refused to pay for a license to broadcast U.S. musical works on its network. Despite a ruling against this broadcasting service by the Barbados Supreme Court in 2007, U.S. composers have been unable to receive royalties because the government has not established a Copyright Tribunal to determine the appropriate compensation. The problem also persists in India and Vietnam, and in China where the public performance of musical works has been subject to a compulsory license since 2001, but no tariff was set until 2009 when it was ultimately set at the lowest rate in world.

Stronger and more effective criminal and border enforcement is required to stop the manufacture, import, export, transit, and distribution of pirated and counterfeit goods. Through bilateral consultations, FTAs, and international organizations, USTR is working to 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 United States 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, 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 can avoid regulatory oversight by failing to declare that the 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 “linking sites” are exacerbating the problem. In addition, piracy using new technologies 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 using these new technologies, piracy of ring tones, apps, games, and scanned books also occurs. Recent developments include the creation of “hybrid” websites that offer counterfeit goods in addition to pirated copyrighted works, in an effort to create a “one-stop-shop” for users looking for cheap or free content or goods. 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 strong 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, Brunei Darussalam, Canada, Chile, China, Colombia, India, Italy, Mexico, Philippines, Romania, Russia, Spain, Switzerland, 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. Regarding Switzerland in particular, the United States has serious concerns regarding the inability of rights holders to secure legal redress involving copyright piracy over the Internet. The United States strongly encourages Switzerland to combat online piracy vigorously and to ensure that rights holders can protect their rights on the Internet. 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 will encourage trading partners to enhance enforcement efforts including, for example, 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 of illegal optical disc production to pass effective legislation to counter this problem, and to enforce existing laws and regulations aggressively.

Trade Secrets and Forced Technology Transfer

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 results in significant costs to U.S. companies, and threatens the economic security of the United States. If a company’s trade secrets are stolen, its past investments in research and development, and its future profits, may be lost.

U.S. companies are experiencing an increase in the theft of their trade secrets outside of the U.S. 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.

Another troubling trend involving trade secrets and other IPR is an increasing tendency of governments to adopt trade-distortive policies, which are sometimes designed to promote “indigenous innovation.” 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-espionage.
- 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 that information.

The United States urges its trading partners to reject such policies. Further, 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.

The United States notes in this context that 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. IPR protection is essential to facilitate access to and transfer of today’s environmental technologies, and to promote tomorrow’s innovation. Without IPR, many of the technologies on which we rely today and will rely upon in the future would not have been developed. 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 to be 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 green technology goods and services without fear of misappropriation, or outright theft, of their IPR.

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 risk losing valuable Internet traffic because of such uses. A related and growing concern is that 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, India, Pakistan, Paraguay, Peru, Tajikistan, and Ukraine and Vietnam. The United States looks forward to these trading partners' adoption of effective and transparent procedures to ensure legitimate governmental use of software.

Intellectual Property and Health Policy

Numerous comments in the 2012 Special 301 review highlighted important concerns arising at the intersection of IPR policy and health policy. 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.

Consistent with these views, 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 investment, research, and innovation.

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. The United States strongly supports 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 World Health Organization, 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 mechanisms to promote research and innovation.

To further this cooperation, USTR has convened a new subcommittee of the interagency Trade Policy Staff Committee, called “Trade Enhancing Access to Medicines” (TEAM), which is intended to further facilitate communication and collaboration toward this shared objective. With the understanding that trade policy tools can impact only some of the relevant issues, the subcommittee is designed to investigate how to best deploy the tools of trade policy to further the Administration’s objective of promoting trade in, reducing obstacles to, and enhancing access to both innovative and generic medicines. The subcommittee is currently composed of representatives of diverse offices within the United States Government, including, those from: the Office of the Global AIDS Coordinator, International Health and Biodefense, USAID, and the Bureau for Economic Affairs, within the Department of State; the Office of Global Affairs, and the Food and Drug Administration, within the Department of Health and Human Services; the Department of Commerce; the Department of the Treasury; and several government officials with relevant expertise.

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. For example, this year’s Special 301 Report highlights concerns regarding market access barriers affecting pharmaceutical products in Algeria and Indonesia.

Even where a trading partner's IPR regime demonstrates a commitment to strong IPR protection, other types of measures have the potential to affect market access in the pharmaceutical and medical device sector. For example, government practices including unreasonable regulatory approval delays and potentially unfair 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 industrialized trading partners, including Finland, Germany, Greece, Japan, Korea, New Zealand, Poland, 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 Poland, U.S. industry is concerned about healthcare reform legislation introduced in 2010 that would alter Poland's pricing, reimbursement, and clinical trials policies. Industry continues to express concern about the pharmaceutical industry's general lack of ability to meet with the Ministry of Health to provide their perspectives on policy initiatives.
- 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 expresses 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. For example, the United States-Korea Free Trade Agreement will improve access to innovative medical products and ensure the transparent, predictable, and non-discriminatory pricing and reimbursement of innovative and generic pharmaceutical products, and medical devices. 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 to address specific concerns related to reimbursements, regulatory policies, and transparency.

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 countries 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 countries (LDCs), 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 decided to invite the TRIPS Council to give full consideration to a duly motivated request from LDC members for an extension of the TRIPS Agreement transition period. The U.S. supports this decision and looks forward to continuing to work with LDCs and other WTO members in this regard.

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. Furthermore, the United States continues to work with other WTO members to encourage a discussion within the WTO TRIPS Council on implementation of the enforcement-related provisions of the TRIPS Agreement. The United States hopes that the TRIPS Council can generate a useful sharing of experiences related to IPR enforcement to ensure effective implementation of enforcement obligations.

WTO Dispute Settlement

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

In April 2007, the United States requested WTO dispute settlement consultations with China over deficiencies in China's legal regime for protecting and enforcing copyrights and trademarks on a wide range of products. After those consultations failed to resolve the matter, the United States requested the establishment of a WTO panel. A WTO panel was established to examine

this matter on September 25, 2007. On March 20, 2009, the WTO Dispute Settlement Body (DSB) adopted a panel report finding in favor of the United States that found (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 the 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 April 15, 2009, China notified the DSB that China intended to implement the recommendations and rulings of the DSB in this dispute, and stated it would need a reasonable period of time for implementation. On June 29, 2009, the United States and China notified the DSB that they had agreed on a one-year period of time for implementation, to end on March 20, 2010. 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 distribution and market access for publications, movies, and music, and audio-visual home entertainment (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. A WTO panel was established to examine this matter on November 27, 2007. On August 12, 2009, the panel found in favor of the United States on the vast majority of its claims. China subsequently appealed certain of the panel's findings. On December 21, 2009, the WTO Appellate Body rejected each of China's claims on appeal and sustained the panel's findings in those respects. On January 19, 2010, the DSB adopted the panel and Appellate Body reports. China committed to bring all relevant measures into compliance with the DSB recommendations by March 19, 2011. China subsequently revised or revoked several measures relating to reading materials, AVHE products, and sound recordings. 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 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). Thereafter, on February 28, 2012, the President issued an Executive Order that established the ITEC. The ITEC will serve as the primary forum within the federal government for USTR and other agencies to coordinate enforcement of obligations under international trade agreements, which can include the identification of unfair trade practices and barriers that involve IPR.

SECTION II. COUNTRY REPORTS

Priority Watch List

Algeria

Algeria remains on the Priority Watch List in 2012. The United States remains concerned about an Algerian law that bans an increasing number of imported pharmaceutical products and medical devices in favor of local products. The United States also 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. Algeria should strengthen patent protection and enforcement efforts to address widespread piracy and counterfeiting. The United States will continue to work with Algeria to address these and other issues.

Argentina

Argentina remains on the Priority Watch List in 2012. Argentina made some progress with respect to IPR enforcement. That progress included two significant actions that Argentina's judicial authorities, both civil and criminal, took against the unauthorized distribution of pirated content over the Internet. However, significant concerns remain, including regarding the widespread availability of pirated and counterfeit goods, and a longstanding patent backlog. Although some industries report good cooperation with law enforcement authorities, Argentina's judicial system remains inefficient, and it remains important that authorities issue more deterrent-level sentences. Piracy over the Internet is a growing concern, and overall levels of copyright piracy, in both the online and hard goods environments, remain high. The United States 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. The United States will continue to work with Argentina to address these and other matters.

Canada

Canada remains on the Priority Watch List in 2012, subject to review if Canada enacts long-awaited copyright legislation. The Government of Canada has given priority to that legislation. The United States welcomes that prioritization and looks forward to studying the legislation once it is finalized, and will consider, among other things, whether it fully implements the WIPO Internet Treaties, and whether it fully addresses the challenges of piracy over the Internet. The United States also continues to urge Canada to strengthen its border enforcement efforts,

including by providing customs officials with *ex officio* authority to take action against the importation, exportation, and transshipment of pirated or counterfeit goods. The United States remains concerned about the availability of rights of appeal in Canada's administrative process for reviewing the regulatory approval of pharmaceutical products, as well as limitations in Canada's trademark regime. The United States looks forward to continuing its close cooperation with Canada on IPR issues, and will continue to work with the Government of Canada to resolve these and other matters.

Chile

Chile remains on the Priority Watch List in 2012. In 2011, Chile took steps towards addressing some, but not all, outstanding IPR issues under the United States-Chile Free Trade Agreement. Recent action included accession to the *Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite* and the *Trademark Law Treaty*. Chile has also taken steps toward acceding to and ratifying the *International Convention for the Protection of New Varieties of Plants*. While this progress is welcome, major issues remain outstanding. The United States urges 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 protections against the circumvention of technological protection measures and protections for encrypted program-carrying satellite signals, and to ensure that effective administrative and judicial procedures, as well as deterrent remedies are made available to rights holders. The United States also 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 liability regime to permit effective action against piracy over the Internet. The United States will continue to work with Chile to resolve these and other issues, including through the Trans-Pacific Partnership negotiations.

China

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

A wide spectrum of U.S. rights holders reports serious obstacles to effective protection and enforcement of all forms of IPR in China, including patents, trademarks, copyrights, trade secrets, and protection of pharmaceutical test data. Compounding these obstacles is the troubling direction that China's policies in the IPR area have taken recently. These policies include China's efforts to link eligibility for government preferences to the national origin of the IPR in products. In addition, many companies are concerned that Chinese government agencies are inappropriately using market access and investment approvals as a means to compel foreign firms to license or sell their IPR to domestic Chinese entities. Further, for many industries, sales of IP-intensive goods and services in China remain disproportionately low when compared to sales in similar markets that provide stronger environments for IPR protection and more open market access. These concerns, coupled with the size of China both as a consumer marketplace

as well as a globally significant producer of a wide array of products, mean that China's protection and enforcement of IPR must remain key priorities for U.S. trade policy.

It is important to recognize that there were some improvements in China's IPR situation in 2011. Specifically, the Chinese Government continued to carry out the Special IPR Enforcement Campaign that was begun in 2010, which resulted in some improvements in targeted sectors. In November 2011, Premier Wen Jiabao announced that this campaign would be made permanent, through the creation of a National Leading Group on IPR Enforcement. In addition, in a significant shift, Chinese Internet giant Baidu reached a landmark agreement with international music rights holders to ensure that its online music platform transmits legal content. Following that agreement, USTR removed Baidu from the Notorious Markets list. The United States is encouraged that on April 22, 2012, China's Supreme People's Court issued a draft Judicial Interpretation entitled *Regulations for the Applicability of Laws in Hearing Cases Regarding Civil Disputes Concerning Infringement on Information Network Broadcasting Rights*. This draft measure is intended to clarify, among other issues, legal standards surrounding inducement of infringement. The United States looks forward to the adoption of a Judicial Interpretation consistent with China's past JCCT commitments.

Despite these signs of progress, IPR protection and enforcement in China remain a significant challenge. Significant concerns persist in light of continuing high levels of trademark counterfeiting and copyright piracy, including over the Internet, the persistence of notorious physical and online markets selling IPR infringing goods, the manufacture and availability of counterfeit pharmaceuticals, the lack of effective means to protect pharmaceutical test and other data against unfair commercial use, as well as disclosure, and the export of counterfeit goods of all sorts, including products posing significant risks to the environment and human health and safety. Many knowledge-based industries remain concerned that the Chinese government is using certain policies intended to promote "indigenous innovation" to disadvantage foreign enterprises through measures or actions that effectively coerce the transfer of IPR from foreign rights holders to domestic entities. A recent alarming increase in cases involving the theft of trade secrets in China, as well as cases of trade secret theft that occur outside China for the benefit of Chinese entities, also demonstrate that there is a systemic lack of effective protection and enforcement of IPR. The failure to impose deterrent penalties that are sufficient to change behavior is another continuing concern that affects all forms of IPR. These matters will continue to be a top bilateral priority for the foreseeable future.

Special Campaign/Leading Group

In March 2011, the State Council extended through June 2011 the Special IPR Campaign begun in October 2010. The Special IPR Campaign continued targeting a broad range of IPR violations including copyright piracy and trademark counterfeiting over the Internet, distribution of infringing optical discs and publications, counterfeit cell phones, counterfeit pharmaceuticals, counterfeit seeds, and counterfeit bulk commodities for export.

U.S. industry reported positive enforcement developments in several of the sectors that the Special IPR Campaign targeted. During the Campaign, the National Copyright Administration of China (NCAC) identified key copyright infringement cases for special investigation and supervision. NCAC also named 18 popular video websites for close supervision and follow-up

(including website shutdown when appropriate) for allegedly providing a wide variety of pirated material, including UUsee, Sina, Letv, Youku, Sohu, Baidu, Ku6.com, Joy.com, PPStream, verycd, Tudou, QQ.com, 56.com, Xunlei, Baofeng, Funshion, PPTV, and pipi.cn. U.S. industry reported significant progress in online licensing agreements involving audiovisual products, particularly movies and TV series. As noted above, Baidu signed contracts with three international record companies - Universal Music, Warner Music, and Sony Music - that, through Baidu's joint venture online music portal, One Stop China, authorized Baidu to upload an entire catalogue of music available for paid user legal downloads and streaming.

Chinese authorities also targeted online sales of counterfeit hard goods during the Special Campaign, focusing on audio-visual products, electronic appliances, apparel, cosmetics, foods, fake or adulterated medicines, and mother and baby products. Numerous enforcement raids and other activities were carried out in key areas of Zhejiang, Shanghai, Guangdong, and Beijing. The State Administration for Industry and Commerce (SAIC) also issued Order 49, which addresses some of the enforcement issues that pertain to online counterfeit offerings and sales/payment platforms, but its implementing regulations are still being developed. Numerous websites and online stores were closed down, and notable sales sites including Taobao, eBay, and Paipai worked with authorities in an apparent effort to improve their IPR enforcement practices.

In summary, U.S. rights holders in the trademark and copyright sectors have reported that enforcement agencies in China were markedly more active in conducting raids, seizures and arrests during the Special Campaign. It also appears that during the Special Campaign the Chinese Government focused its efforts with respect to infringement that occurs online in a manner that was meant to ensure that online entities were more responsive to requests from rights holders to remove infringing materials. At least one industry submission commented positively that the Chinese Government's efforts during the Special Campaign "generated goodwill" among rights holders and sparked some cautious optimism that a recognition of the need for IPR protection and enforcement in China may finally be starting to take root.

Given the results of the Special Campaign, the United States welcomes the creation of the National Intellectual Property Enforcement Office, which is led by Vice Premier Wang Qishan and staffed by the Ministry of Commerce (MOFCOM) and its division on Market Order and Supervision. The office was established in November 2011 under State Council Order 37 to provide a permanent mechanism under senior leadership for IPR enforcement and investigation. The United States looks forward to engaging with the office and working to ensure that the good progress made on these issues during the Special Campaign continues unabated.

Software legalization

Another key component of the Special Campaign was a software legalization initiative designed to ensure that government agencies use only legitimate, licensed copies of software. Central authorities announced they had completed software legalization in central-level government offices in May 2011 and would continue provincial-level legalization through October 2011. Because the legalization efforts were not completed at the provincial-level, the government extended the process into 2012. As a result of these efforts, U.S. software companies have seen a modest increase in sales to the government. However, much work remains to be done with

respect to the state-owned enterprise (SOEs) sector, which reportedly continues to suffer from high piracy rates and which, according to the World Bank, accounts for 27 percent of China's industrial output. Software piracy by SOEs is particularly pernicious, because it not only results in lost sales for software producers, but also provides an unfair commercial advantage to such SOEs. Many SOEs compete directly with U.S. businesses, and to the degree that these SOEs do not pay for the software that runs many of their operations, they obtain an advantage relative to their U.S. and other competitors, who pay to acquire software lawfully.

Online piracy

In 2011, China reportedly sanctioned 14 websites for providing illegal music downloads, requiring those web sites to remove links to offending files, which had been identified by the government (in addition to the 18 mentioned above). Nevertheless, illegal downloads account for an estimated 99 percent of all music downloads in China, and piracy of copyrighted material over the Internet thus continues to be a major problem. China's Internet users are increasingly turning to streaming media to watch foreign television shows and movies. While it appears that a number of user generated content sites have eliminated most of their pirated content, these streaming sites have become the preferred method to watch illegal content. The United States urges the Chinese Government to focus on these streaming sites, and to prevent illegal transmission and rebroadcast of motion pictures and television and sports programming.

Industry submissions detail the improvements as a result of the Special Campaign and the increased emphasis on ensuring that IPR is protected in the digital environment. However, despite many "Special Campaigns" in China over the years to combat IPR infringement, and despite repeated bilateral commitments to increase IPR enforcement in China, the United States Government is concerned that sales of IP-intensive goods and services to China from U.S. companies remain substantially below levels in other markets, measured in a variety of ways, ranging from spending on legitimate music as a percentage of GDP to software sales per personal computer. For example, total music revenue (which includes both legitimate physical and digital sales) in China for 2010 was only US\$64.3 million. This compares to almost \$4.2 billion in the U.S., US\$178.4 million in South Korea and US\$68.9 million in Thailand — a country with less than 5 percent of China's population and with roughly the same per capita GDP. If Chinese sales were equivalent to Thailand's on a per capita basis, music sales would be almost US\$1.4 billion. The United States urges China to continue its efforts to improve IPR protection and enforcement and to ensure that this results in an increase of sales of legitimate goods and services from all sources, including imports.

Counterfeiting

As we noted in last year's report, China's manufacturing capacity also extends to all phases of the production and global distribution of counterfeit goods. The list of goods that are counterfeited includes apparel and footwear, mobile phones, pharmaceuticals and medical equipment, herbal remedies, agricultural chemicals, computer and networking equipment, software and related products, batteries, cigarettes, cosmetics, home appliances, cement, auto parts, and merchandise based on copyrighted works. This year we also received lengthy submissions concerning the impact that counterfeiting was having on U.S. agricultural industries including the fruit and vegetable industry and the wine industry. Of particular concern was the

submission of the Semiconductor Industry Association that warned of counterfeit semiconductors entering the supply chain, noting the risks of installing fake and shoddy semiconductor components in electronic equipment, including in equipment used for critical functions related to safety and security.

Where counterfeiting manufacturing and sales are concerned, attitudes regarding IPR infringement vary greatly by province and locality. For instance, administrative authorities in Shenzhen have lowered the criminal case thresholds for bringing cases against optical disk pirates, and those authorities regularly transfer cases for investigation to the Public Security Bureau. In one case, those authorities followed up regularly with online sales platform TenCent to discuss the company's enforcement efforts. By contrast, rights holders have expressed concerns that local Administrations for Industry and Commerce (AIC) in Guangdong and Fujian have refused to refer cases for criminal prosecution even when thresholds are met. Even more worrisome are reports that in Fujian and Guangdong, local protectionism has impeded rights holders who have investigated and provided clear evidence of counterfeiting operations (including, in one case, evidence of an entire supply chain to support massive counterfeiting of children's toys and accessories, from design to manufacturing to packaging) only to be stymied by provincial officials who have turned a blind eye to the evidence and have failed to act. The United States is encouraged that State Council Order 37 notes that provincial and local officials will be rated on their ability to enforce against IPR infringement in their provinces and localities, and hope that this will help motivate provincial and local leaders to shut down infringing operations.

On a positive note, trademark rights holders are beginning to report that there has been a noticeable reduction in the visibility of counterfeit goods for sale in some of the notorious physical markets. This appears to be the result of intensified criminal enforcement, and more proactive intervention by landlords. This may be attributable to steps taken by national and local AICs to target landlords of physical markets as part of a wider effort to promote enforcement of IPR rights, as well as Court decisions that have found landlords liable for infringement they knew or should have known was taking place on their premises. However, guidelines regarding landlord liability are not legally binding, and Court decisions in China's civil law system are not precedential. The United States therefore continues to urge the Chinese Government to include explicit provisions on landlord liability in the new amendments to the Trademark Law that are currently under consideration by the State Council's Legislative Affairs Office.

Furthermore, there remain many markets that continue to trade in counterfeit and pirated merchandise. In particular, there are still many markets that serve as wholesalers for counterfeits distributed around the world. These include the notorious Yiwu market where all types of products can be copied and exported throughout the world; or the night market in Putian which specializes in counterfeit athletic shoes, sports equipment, handbags, and watches, and where most products are being sold for export to U.S., European and African markets. The United States will examine markets such as these during the Out-of-Cycle Notorious Markets review in autumn 2012.

Counterfeit goods are also prevalent in online markets and auction sites, including those listed in the 2011 USTR Notorious Markets Report, as well as others such as DHGate, TradeMe, HC360, and Global Sources. Rights holders, however, are encouraged that the Chinese Government

appears committed to intensifying efforts to address online counterfeiting, including through the issuance of SAIC Order 49, and through civil court decisions which have imposed liability on the operators of online sales websites similar to those that have been imposed on the landlords of physical markets. The United States urges the Chinese Government to continue their efforts, begun during the Special Campaign, to improve IPR enforcement in online marketplaces to ensure that infringing products are removed and counterfeiters are punished.

The consumer shift to online sales has also changed the pattern of export trade; previously counterfeits were shipped in large containers, which resulted in large value and capacity seizures at the U.S. border. However, increasingly goods are sold by online traders in China (and elsewhere) and delivered to consumers by mail and express delivery service. This phenomenon is confirmed by the continued reduction in the level of seizures of wholesale quantities by customs officials in China and abroad. The United States urges Chinese customs authorities to inspect not only large containers, but also to increase their scrutiny of small consignment exports, especially Express Mail Service.

Trade Secrets

The United States is concerned about a growing number of cases in which important trade secrets of U.S. firms have been stolen by, or for the benefit of, Chinese companies. It has been difficult for some U.S. companies to obtain relief against those who have benefitted from this misappropriation, despite compelling evidence demonstrating misappropriation or theft. The United States is concerned that many more trade secrets cases involving U.S. companies and Chinese competitors go unreported because U.S. firms fear the cost and likelihood of failure of pursuing these cases through legal channels, as well as the possible commercial repercussions for bringing such cases to light. Although U.S. firms have recently seen some improvement in enforcement of other types of IPR-related cases, as described above, protecting trade secrets in China remains a significant challenge and is of growing concern. The United States and China have increased their bilateral exchanges on this important issue, including in the JCCT IPR Working Group and through senior level government engagements. Ensuring that companies are able to effectively protect and enforce their IPR in China, including trade secrets, is essential to promoting successful commercial relationships between U.S. and Chinese firms.

Market Access and Technology Use

In addition to the risks of IPR infringement, including trade secret theft, and the difficulties discussed above regarding effective enforcement, many companies remain very concerned that the Chinese government has adopted policies or practices that systematically disadvantage foreign rights holders, by inappropriately conditioning market access and investment approvals, and other government benefits on the sale or licensing of IPR and other proprietary information to domestic Chinese entities.

While the United States welcomes China's commitment, reiterated in the joint fact sheet issued during Vice President Xi Jinping's visit to Washington on February 14, 2012 "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", the United States will

continue to work with China to develop a mechanism designed to resolve, in an expeditious manner, any concerns regarding the implementation of this commitment.

IPR and Innovation

Chinese government agencies, including at national, provincial, and local levels, frequently release documents, including regulations, rules, and regulatory documents (e.g., opinions, notices, circulars) that seek to promote China's development into an innovative, IP-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 has expressed concerns to China regarding China's innovation-related policies and other industrial policies that may discriminate against or otherwise disadvantage U.S. exports or U.S. investors and their investments. Chinese regulations, rules, and regulatory documents frequently call for technology transfer and, in certain cases, require, or propose to require, that eligibility for government benefits or preferences is 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 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 obligations.

In November 2009, MOST, NDRC, and MOF issued the *Circular on Launching the 2009 National Indigenous Innovation Product Accreditation Work*, requiring companies to file applications by December 2009 for their products to be considered for accreditation as "indigenous innovation products." This measure provides for preferential treatment in government procurement to any products that are granted this accreditation, which is based on criteria such as the ownership or development of a product's IPR in China. Subsequently, the United States and U.S. industry, along with the governments and industries of many of China's other trading partners, expressed serious concerns to China about this measure, as it appears to establish a system designed to provide preferential treatment in government procurement to products developed by Chinese enterprises.

In April 2010, MOST, NDRC, and MOF issued a draft measure for public comment, the *Circular on Launching 2010 National Innovation Product Accreditation Work*. The draft measure would amend certain of the product accreditation criteria set forth in the November 2009 measure, but would leave other problematic criteria intact, along with the accreditation principles, application form, and link to government procurement. In addition, the draft measure originally was to become effective the day after comments were due. The United States submitted comments in May 2010, in which it asked China to suspend the implementation of the indigenous innovation accreditation system and to engage in consultations with the United States to address U.S. concerns about the system. This draft measure was not finalized. At the May 2010 S&ED, China agreed that its innovation policies would be consistent with the following principles: nondiscrimination; support for market competition and open international trade and investment; strong enforcement of intellectual property rights; and, consistent with WTO rules, leaving the terms and conditions of technology transfer, production processes, and other proprietary information to agreement between individual enterprises. In addition, the United

States and China began intensive multi-agency discussions of their respective innovation policies.

At the December 2010 JCCT meeting, China took important steps to address U.S. concerns about its indigenous innovation policies. China agreed not to maintain any measures that provide government procurement preferences for goods or services based on the location where the intellectual property is owned or was developed. China also agreed to take into account U.S. views on its *Draft Regulations Implementing the Government Procurement Law*, which provide for government procurement preferences for indigenous innovation products. During President Hu Jintao's January 2011 state visit, China further committed to delink its innovation policies from the provision of government procurement preferences. To implement President Hu's commitment, at the May 2011 S&ED, China agreed to eliminate all of its government procurement product accreditation catalogues and revise the *Draft Regulations Implementing the Government Procurement Law* to eliminate the provision requiring government procurement preferences for indigenous innovation products. During the 2011 JCCT meeting, China announced that the State Council had issued a measure requiring provincial, municipal, and autonomous regional governments to eliminate by December 1, 2011 any catalogues or other measures linking innovation policies to government procurement preferences. The United States is carefully monitoring China's commitments in this area.

Indigenous Innovation and Place of Intellectual Property Ownership or Development

During the 2010 JCCT process, including at a meeting of the JCCT IPR Working Group and at the JCCT plenary meeting, the United States requested that China not condition government preferences on the location of intellectual property ownership and development. The United States recognized that the requirement for "Chinese intellectual property and proprietary brands" in the Indigenous Innovation Product Accreditation System was also a factor referenced in important Chinese government statements and other Chinese measures. For example, the October 2010 State Council *Decision on Accelerating the Cultivation and Development of Strategic Emerging Industries* states that, "China shall boost the cultivation and development of strategic emerging industry and hold the core technologies and intellectual property as well as enhance independent growth capability." In addition, the *Measures for Administration of Recognition of Innovative and High-Tech Enterprises*, *Guo Ke Fa Huo [2008] No. 172*, adopted in final form, without opportunity for public comment, by MOST, MOF, and the State Administration of Taxation, provide for certain tax benefits for qualifying enterprises. One of the eligibility criteria is that "Enterprises registered in China . . . have independent intellectual property rights over the core technology of major products through independent research and development, transfer, recipient, mergers and acquisitions within three years or through exclusive licensing over five years."

At the 2010 JCCT, China agreed not to "adopt or maintain measures that make the location of the development or ownership of intellectual property a direct or indirect condition for eligibility for government procurement preferences for products and services. China and the United States will continue to discuss whether this principle applies to other government measures."

During the 2011 JCCT, China and the United States agreed, building on the previous years' commitment, and the innovation principles agreed to in the APEC 2011 Leaders' Declaration, to

study other measures, including investment and tax related measures in 2012, to determine whether the receipt of government benefits is linked to where intellectual property is owned or developed, or to the licensing of technology by foreign investors to host country entities. Furthermore, the two sides agreed to actively discuss removal of these barriers that distort trade and investment. The United States will continue to discuss the implementation of these innovation-related commitments by China in bilateral meetings and dialogues with the Chinese Government in 2012

Patent-Related and Other Policies

Compulsory Licensing

In 2011, China's State Intellectual Property Office (SIPO) issued "Draft Measures for Compulsory Licensing of Patents" for public comments. These measures are intended to provide greater guidance to SIPO, patent holders, and individuals and entities that seek the grant of a compulsory license under China's Patent Law. The United States appreciates that SIPO provided an opportunity for interested stakeholders to comment upon the draft. A number of companies and governments, including the United States, provided comments on these measures, raising concerns ranging from the length of time provided for certain procedural steps, to substantive concerns regarding the scope and grounds for the application of a compulsory license. On March 19, SIPO issued a slightly revised document, dated March 15, 2012, with indications that the document will go into effect on May 1, 2012. The United States is concerned that many stakeholder concerns were not reflected in the final document. The United States looks forward to working with stakeholders and the Government of China to ensure that the implementation of these measures is consistent with China's international obligations and does not unfairly disadvantage foreign patent holders, including through further amendments to the measure if necessary.

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. More recently, China has announced that when it develops standards, it will rely on either non-patented technology or patented technology with prices lower than those that patent owners would otherwise seek to charge. As a result, China's treatment of patents in the standard setting process has garnered increasing attention and concern around the world, including in the United States. These concerns have been reported in depth in previous editions of this Report, as well as in USTR's 2012 Report on Technical Barriers to Trade (TBT Report).

IPR Protection for Pharmaceutical Products

The United States continues to encourage China to provide an effective system to expeditiously address 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 commitment during WTO accession, requires 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 manufactures 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 looks forward to working with the SFDA and other relevant agencies to address this concern, including through on-going work in the JCCT.

In conclusion, the United States believes that continued bilateral dialogue and cooperation can lead to further progress in these and other areas. The United States will continue to put serious efforts into its joint work with China on IPR enforcement and protection strategies, innovation policies, and the range of other important IPR-related matters in this bilateral economic relationship, including through the JCCT and other fora.

India

India remains on the Priority Watch List in 2012. India made limited progress on IPR protection and enforcement in 2011, and its legal framework and enforcement system remain weak. The challenge of piracy over the Internet continues to grow, but the Copyright (Amendment) Bill 2010, which proposed partial implementation of the WIPO Internet Treaties and other reforms appears to have stalled. The United States continues to encourage India to promote a stable and predictable patent system that can nurture domestic innovation, including by resolving concerns with respect to the prohibition on patents for certain chemical forms absent a showing of increased efficacy. The United States recognizes India's recent efforts to address its patent application backlog, and urges India to take additional steps in this regard. The United States also urges India to continue to work to streamline its patent opposition proceedings. The United States will closely monitor developments concerning compulsory licensing of patents in India following the broad interpretation of Indian law in a recent decision by the Controller General of Patents, while also bearing in mind the Doha Declaration on TRIPS and Public Health found in the Intellectual Property and Health Policy section of this Report. The United States urges India to provide an effective system for protecting against 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 notes some improvements with respect to IPR enforcement, including reports of good cooperation of enforcement officials with some in the copyright industry, 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 commends India's recognition of the importance of innovation as part of its efforts to promote

domestic manufacturing, and urges India to resist imposing discriminatory policies or other counterproductive measures in pursuit of that objective, and at the expense of adequate and effective protection of intellectual property rights. The United States will continue to work with India to address these and other issues.

Indonesia

Indonesia remains on the Priority Watch List in 2012. Indonesian authorities made positive efforts in 2011 to strengthen IPR protections, and some rights holders reported good cooperation with enforcement authorities. However, the United States remains 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 and to impose deterrent-level sentences. While authorities conducted some enforcement against cable piracy, and although rights holders welcomed efforts to ensure that operators are properly licensed, cable piracy rates rose significantly in 2011. The United States is also concerned about the long-term effects of a recent decree that imposed strict limitations on the delivery of ringtones, undermining a once-thriving legitimate market for music distribution. The United States encourages Indonesia 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 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 will continue to engage with Indonesia on these and other matters.

Israel

Israel remains on the Priority Watch List in 2012. Israel has taken steps towards implementing an Understanding on IPR that it concluded with the United States in 2010; however, further action is needed to fully implement that Understanding. The United States stands ready to work closely with the Government of Israel to achieve full implementation of the Understanding.

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 Israel would submit legislation regarding these matters within 180 days of the conclusion of the Understanding. The United States agreed to move Israel to the Watch List once Israel submitted appropriate legislation to the Knesset, and to remove Israel from the Special 301 Watch List once the Government enacted legislation implemented Israel's obligations fully.

Israel has already enacted legislation regarding pharmaceutical test data, and has submitted legislation to the Knesset regarding patent publication. The United States commends Israel for taking those important steps, and looks forward to the enactment of the latter bill. To date, however, Israel has not submitted legislation to the Knesset regarding patent term extension, although a bill is under development. The United States encourages Israel to submit legislation to the Knesset that fully implements the Understanding as soon as possible. Pursuant to the Understanding, once Israel submits appropriate legislation to the Knesset regarding this matter, the United States will move Israel to 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 additional effective 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. In addition, the United States urges Israel to clarify whether, under its existing copyright law, enterprises that engage in this activity are subject to prosecution. The United States also encourages Israel to enforce judicial decisions requiring cable operators to compensate copyright holders for the unauthorized retransmission of television broadcast signals containing their works, and to establish a fair remuneration structure for future retransmissions. The United States will continue to work with Israel to resolve these and other matters.

Pakistan

Pakistan remains on the Priority Watch List in 2012. Pakistan continued its efforts on IPR enforcement, including through raids, seizures, and arrests by various enforcement authorities. However, widespread counterfeiting and piracy, particularly book and optical disc piracy, continue to present serious concerns for U.S. industry. Pakistan should provide *ex officio* authority to its enforcement officials, and should provide for deterrent-level penalties for criminal IPR infringement. Pakistan should also take the necessary steps to reform its copyright law. 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, and 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 Pakistan to address these and other issues.

Russia

Russia remains on the Priority Watch List in 2012. While Russia made important progress in the past year to improve IPR protection and enforcement, significant concerns remain, particularly with respect to piracy over the Internet and enforcement generally.

The United States welcomes several positive steps that Russia took, including enactment of a law to establish a specialized IPR court by February 2013, and amendments to Russia's Criminal

Code that revise criminal thresholds for copyright piracy. The United States also commends progress on criminal proceedings against interfilm.ru, an infringing website in Russia, and on civil findings against vKontakte, Russia's largest social networking site, for copyright infringement. Russian law enforcement authorities also led several significant actions against pirated optical disc distributors, including the largest known seizure in Russia involving two million optical discs. As part of the 2011 out-of-cycle review of notorious markets, the Savelovskiy Market was removed from the notorious markets list as a result of the Savelovskiy Market's adoption and implementation of an action plan to stop the distribution of infringing goods.

Another important step Russia took was to close down operations of optical disc plants located on Russian state-owned restricted access regime enterprises (RARE) sites that were engaged in the production of pirated media. Russia agreed to take this action in the 2006 Bilateral Agreement on Protection and Enforcement of Intellectual Property Rights (2006 Bilateral Agreement on IPR). According to industry reports, however, warehouses storing pirated CDs and DVDs remain on several government-controlled military-industrial sites. This situation leaves Russian enforcement agencies and rights holders with limited opportunities to conduct successful raids against such warehouses.

The United States also recalls Russia's enactment, as part of the WTO accession process, of four important IPR laws in 2010. These achievements complete the legislative commitments Russia made in the 2006 Bilateral Agreement on IPR. Upon its accession to the WTO, Russia must comply with all of the obligations of the WTO TRIPS Agreement, which sets out minimum requirements for protecting and enforcing IPR, including with respect to key rights relied on by the U.S. copyright-based industries, such as the software, motion picture and sound recording industries, as well as industries that rely on patents, trademarks, trade secrets, and test data protection. Regarding test data protection, Russia is obligated to implement the 2010 amendments to the Law on Circulation of Medicines upon its WTO accession. Once Russia becomes a WTO Member, it will be required to comply with the rules governing the enforcement of IPR, covering, *inter alia*, civil and administrative procedures and remedies, provisional measures (*i.e.*, preliminary injunctions), customs measures to enforce IPRs at the border, and criminal procedures. Furthermore, Russia should implement specific commitments regarding areas of concern, including piracy over the Internet and enforcement generally. Russia's implementation of its WTO obligations, once it is a Member, will be subject to WTO dispute settlement procedures.

The United States urges Russia to take additional steps to improve the protection and enforcement of IPR in Russia, especially with respect to piracy over the Internet and enforcement generally. Regarding piracy over the Internet, the United States advocates both further legal reform and enhanced enforcement efforts. The United States encourages Russia to address the problems of websites hosting infringing material and of services that are intended to promote the infringement of copyright by enacting legislation that includes, among other things, appropriate liability standards and requirements for notice and takedown that provide for the swift removal of infringing content. The United States urges Russia to engage in takedown and enforcement actions against infringing sites, including services affiliated with social networking sites such as vKontakte and odnoklassniki.ru.

The United States also urges Russia to strengthen its overall enforcement efforts, including its criminal enforcement efforts, against counterfeiting, piracy (including unauthorized camcording) and the circumvention of technological protection measures. While the software industry reports a decline in piracy rates in 2011 resulting from civil and criminal enforcement efforts and advances in the government's use of legitimate software, the book/journal publishing, entertainment software, motion picture and movie industries continue to face serious challenges with respect to IPR enforcement in Russia. As MVD acknowledged, the number of raids decreased significantly in 2011. The Russian police force was also reduced by 20 percent, which has significant implications for IPR enforcement efforts. Even where raids are conducted in a sustained and vigorous manner, investigation of cases, prosecutions, and criminal verdicts do not necessarily follow. The United States urges Russia's enforcement officials to increase the number of IPR-related investigations, and to seek deterrent penalties in judicial proceedings.

The United States also urges Russia to provide adequate resources and clear authority to specialized law enforcement officials within Department K of the Ministry of Internal Affairs (MVD) in order to prioritize and improve its enforcement efforts with respect to piracy over the Internet. This unit should work closely with rights holders' representatives to target and to take action against priority infringing websites.

Thailand

Thailand remains on the Priority Watch List in 2012. The United States is encouraged that Thailand's new government has affirmed its commitment to improving IPR protection and enforcement. Some U.S. rights holders report good cooperation with Thai enforcement authorities, including the Royal Thai Police and Royal Thai Customs. Thailand has also taken some steps to address its longstanding problem of piracy of cable and satellite signals, although significant concerns remain about the prevalence of this problem in Thailand. The United States remains seriously concerned about Thailand's failure to complete many of the initiatives begun in past years. Several key pieces of legislation remain pending, including legislation to address landlord liability, to address unauthorized camcording of motion pictures in theaters, to provide Thai Customs with *ex officio* authority, to implement 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 urges Thailand to improve its enforcement efforts and to provide for, and impose, deterrent-level sentences. Thailand should also make greater efforts to address widespread copyright piracy and trademark counterfeiting. 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 investment, research, and innovation. In this context, the United States reiterates its support for the 2001 Doha Declaration on the TRIPS Agreement and Public Health, as described in Section I of this Report. The United States will continue to work with Thailand to address these and other matters.

Ukraine

Ukraine is on the Priority Watch List. Ukraine made minimal progress in implementing its 2010 IPR action plan commitments, including addressing the government's use of unlicensed software, amending the copyright law, and increasing IPR enforcement. Ukraine has also done little to address counterfeiting and piracy, and in some cases took steps backwards. For example, several days after Ukrainian police took down the country's largest infringing website (ex.ua), authorities allowed the site to re-open. Likewise, the number of IP inspectors at the State Intellectual Property Service of Ukraine has been significantly reduced. While Ukrainian authorities took steps to curb the unauthorized video camcording of motion pictures in theaters, the unauthorized recording of the audio portion of motion pictures continues to be a serious concern. Enforcement efforts remain ineffective against the widespread availability of counterfeit and pirated products, many of which are transshipped through Ukraine to third countries, and customs officials continue to lack *ex officio* authority to interdict shipments. The United States continues to urge Ukraine to take steps to address serious concerns regarding piracy over the Internet, including by adopting proposed legislation to provide an appropriate regime for notice and takedown. The United States also continues to encourage Ukraine to improve its judicial system, which suffers from significant delays, a lack of deterrent-level sentences, and judges who lack relevant IPR expertise. The United States will continue to work with Ukraine to address these and other issues.

Venezuela

Venezuela remains on the Priority Watch List in 2012. Venezuela made some progress in 2011, notably through the seizure of a larger number of counterfeit and pirated products than in previous years and through steps to enforce the 2010 Law on Crimes and Contraband, including the penalty provisions of that law. However, serious concerns remain with respect to IPR protection and enforcement. In 2006, Venezuela withdrew from the Andean Community and subsequently reinstated the 1955 Industrial Property Law. Under the 1955 Law, protection for certain inventions patentable under the Andean Community Law was eliminated. In addition, reinstatement of the 1955 Law creates uncertainty about the status of protection for trademarks that were registered under the Andean Community law. Piracy and counterfeiting remain widespread, including piracy over the Internet, and should be addressed. Venezuela also should 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 products. The United States will continue to monitor Venezuela's progress on these and other issues.

Watch List

Belarus

Belarus remains on the Watch List in 2012. The United States remains concerned about Belarus' implementation of the IPR commitments made under the United States-Belarus Trade Relations Agreement of 1993. Belarus took some steps in 2011 to strengthen IPR protection and enforcement, including notably the adoption of measures to liberalize foreign trade requirements, including with respect to IPR, and the enactment of the law on copyrights and related rights. In addition, the creation of the Customs Union with Kazakhstan and Russia has led to some improvements through the harmonization of regulatory principles for IPR, although more work in this area is necessary. Piracy and counterfeiting, however, remain widespread in Belarus, and IPR enforcement efforts continue to be weak and ineffective. The United States encourages Belarus to enact regulations to implement the 2011 law on copyright and neighboring rights and continues to urge Belarus to provide its enforcement officials with *ex officio* authority to investigate cases, seize infringing goods, and prosecute IPR violations. Belarus should also provide adequate scope for *ex parte* searches. The United States continues to encourage Belarus to improve its copyright legal framework and to fully implement the WIPO Internet Treaties. The United States will continue to monitor Belarus' progress on these and other matters, including efforts to implement provisions of the Custom Union Customs Code that authorize Belarus to grant *ex officio* authority to its customs officials, and to create a unified trademark registry.

Bolivia

Bolivia remains on the Watch List in 2012. Bolivia's Intellectual Property Office recently undertook efforts to improve public awareness about IPR protection and enforcement, and the United States finds these efforts encouraging. However, high levels of piracy and counterfeiting persist, and there is a continued need to improve criminal and civil IPR enforcement. Bolivia should provide for more efficient prosecution of IPR violations, for better coordination among Bolivian enforcement authorities, and for additional resources to be allocated to enforcement officials. The United States looks forward to continuing to work with Bolivia to address these and other matters.

Brazil

Brazil remains on the Watch List in 2012. Brazil continued to made progress in 2011, in particular by undertaking significant enforcement efforts across the country. Enforcement officials, under the coordination of the National Council to Combat Piracy (CNCP), conducted raids that resulted in the seizure of millions of items with a value estimated at over \$1 billion dollars, and in the permanent closure of hundreds of shops selling pirated and counterfeit goods. The United States encourages Brazil to follow through with arrests and prosecutions of IPR

violators. The United States also encourages Brazil to take the necessary steps to formalize the Federal Attorney General opinion clarifying that Brazil's sanitary regulatory agency, ANVISA, does not have the authority to review patentability requirements when analyzing pharmaceutical patent applications. The United States continues to be concerned about the widespread availability of pirated and counterfeit products in Brazil, especially pirated books, and about the growing challenge of piracy over the Internet. The United States urges Brazil to strengthen pending amendments to its copyright law to better protect IPR in the digital environment. Brazil should also continue to strengthen its border enforcement efforts. The United States encourages Brazil to clarify and strengthen its 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 encourages Brazil to continue to take concrete steps to address its backlog of pending patent applications, including by developing a new electronic patent application system. The United States looks forward to continuing to work with Brazil to address these and other matters.

Brunei Darussalam

Brunei remains on the Watch List in 2012. Brunei made progress in 2011 by establishing its first patent office, and authorities also recently issued notices warning some retailers to remove pirated and counterfeit goods. The United States hopes that such actions will lead to a significant and permanent reduction in Brunei's high piracy and counterfeiting rates. Further, rights holders have established an organization to assist law enforcement officials in their efforts, and to assist the Bruneian Authors and Composers Association, which is actively negotiating with television and radio broadcasters for payment of music royalties due. The United States remains concerned, however, that Brunei has not enacted pending copyright amendments, and IPR enforcement authorities still lack *ex officio* authority. Brunei should also take steps to further educate its business community on IPR and to improve its enforcement efforts, including by pursuing criminal prosecutions, imposing deterrent-level sentences, and ensuring that enforcement officials have adequate resources. The United States looks forward to continuing to work with Brunei to address these and other matters, including through the Trans-Pacific Partnership negotiations.

Colombia

Colombia remains on the Watch List in 2012. Colombia continued to make progress in 2011 by improving its enforcement operations, including by increasing the number of investigations and raids that were conducted. In addition, Colombia enhanced coordination of enforcement efforts among its agencies. Colombia is also continuing its efforts to improve its legislative framework for IPR protection and enforcement through the implementation of the United States-Colombia Trade Promotion Agreement. However, concerns remain with respect to IPR enforcement. A lack of resources and training continue to hamper enforcement efforts. The United States looks forward to working with Colombia on the implementation of obligations regarding protections against piracy over the Internet, which is a growing problem in Colombia, and to Colombia

taking steps to address continuing problems with optical disc piracy. The United States looks forward to continuing to work with Colombia to address these and other matters.

Costa Rica

Costa Rica remains on the Watch List in 2012. Costa Rica made progress in 2011 by enacting legislation to provide for criminal remedies for violations of performers' rights and of other related rights, and by promulgating regulations to implement its CAFTA-DR commitment with respect to limitations on liability for Internet service providers. Costa Rica also took steps to address concerns over the lack of enforcement actions against IPR violations, and the prosecutor has established a new policy regarding the prosecution of IPR-related crimes. The United States encourages Costa Rica to continue its efforts to resolve these longstanding issues. In addition, Costa Rica should take concrete steps to improve its overall IPR enforcement efforts, and should make actively combating IPR violations a higher priority. Costa Rica should devote more resources to enforcement efforts, and should impose deterrent penalties. The United States looks forward to continuing to work with Costa Rica to address these and other matters.

Dominican Republic

The Dominican Republic remains on the Watch List in 2012. The Dominican Republic took positive steps in 2011 to continue its implementation of obligations under CAFTA-DR, including by making progress toward ensuring that the government uses only licensed software, by acceding to the Trademark Law Treaty, and by continuing its IPR enforcement efforts. However, concerns remain, especially with respect to the widespread availability of pirated and counterfeit products. IPR enforcement agencies in the Dominican Republic continue to suffer from a lack of coordination, cooperation among enforcement agencies, 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 test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products, and to provide an effective system to address patent issues expeditiously in connection with applications to market pharmaceutical products. The United States also urges the Dominican Republic to fully implement its CAFTA-DR obligations with respect to patent term adjustment. 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 2012. The United States appreciates recent statements from Ecuador's IPR officials regarding the need to create a culture of respect for IPR and hopes that Ecuador will work to translate these statements into effective IPR protection and enforcement. Concerns remain about rampant piracy and counterfeiting. Ecuador has not established the specialized IPR courts required under Ecuador's 1998 IPR law. The United

States encourages Ecuador to further clarify its system for protecting against unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical products, and to provide such protection for agricultural chemical products. Ecuador should also 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 matters.

Egypt

Egypt remains on the Watch List in 2012. The United States welcomes the Government's recognition that IPR is important both to Egypt's economic development and to enhanced trade relations. Egypt continued to work to improve IPR protection and enforcement in 2011. The Information Technology Industry Development Agency conducted more raids, including raids against manufacturers and distributors of infringing goods, and increased training for prosecutors regarding counterfeiting of medical products. However, concerns remain regarding the need for additional enforcement efforts for the full range of IPR, including issuance of deterrent-level sentences by courts, and the need for additional training for enforcement officials. The United States is encouraged that Egypt has drafted regulations to clarify border procedures for the destruction of counterfeit products and to provide customs officials with the authority to take *ex officio* action. The United States urges Egypt to enact those regulations expeditiously. Although Egypt is working to upgrade its trademark system, rights holders have expressed concerns about the registration of invalid trademarks. Rights holders also report that businesses offering pirated television content are impairing the ability of legitimate distribution outlets to operate in the market. The United States also urges Egypt to ratify the WIPO Internet Treaties. The United States continues to encourage Egypt to clarify its plans for implementing its commitments with respect to the protection against the unfair commercial use, as well as unauthorized disclosure, of test or 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. The United States welcomes Egypt's establishment of a consultative committee to monitor the implementation of pharmaceutical regulations and policies. The United States looks forward to continuing to work together to advance shared IPR-related economic and trade goals, and to addressing these and other matters.

Finland

Finland remains on the Watch List in 2012. The United States continues to be concerned about the lack of product patent protection for certain pharmaceutical products. U.S. industry continues to express 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 this and other matters.

Greece

Greece remains on the Watch List in 2012. Greece took some significant steps to improve its IPR protection and enforcement framework in 2011. Greece shut down some of the country's more notorious websites that were involved in distribution of pirated content and repealed long-standing laws that limited copyright enforcement on university grounds. In 2011, Greece established a cybercrime section at the Hellenic National Police to assist with IPR enforcement, and created a new IPR department within the Authority for the Prosecution of Financial Crimes (SDOE). The number of cases brought to trial, as well as the number and percentage of convictions that resulted in incarceration for a year or more, have increased since 2009. A law that was enacted in 2011 that provides for *ex officio* authority for the seizure and destruction of pirated and counterfeit goods at open-air markets appears to have led to more efficient enforcement efforts. Despite these improvements, significant concerns remain. The United States encourages Greece to continue to implement its 2009 IPR action plan. Greece should fully implement legislation and regulations regarding copyright protection and enforcement, including legislation and regulations that pertain to administrative fines for software infringement and to civil actions by rights holders concerning piracy over the Internet. In addition, Greece should expand on recent enforcement efforts to address the continuing widespread availability of pirated and counterfeit goods. Greece should also take steps to ensure that it has an effective mechanism to address piracy over the Internet. The United States continues to encourage Greece to improve its judicial system, which suffers from significant delays. 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 2012. Guatemala continued to make progress in 2011 by enacting legislation to strengthen penalties for the production and distribution of counterfeit medications. In addition, Guatemala's IPR prosecutor remained active in the past year, despite a lack of resources, and enforcement efforts resulted in a sustained level of seizures and an increase in convictions. The interagency IPR working group also remained active in working to improve coordination among IPR-related agencies, and Guatemala participated actively in training efforts. However, 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 its judicial system. The United States looks forward to continuing to work with Guatemala to address these and other matters.

Italy

Italy remains on the Watch List in 2012. Piracy over the Internet continues to be a serious concern in Italy. While Italy took some positive steps on IPR enforcement in 2011, these efforts

were insufficient to address rampant copyright piracy. The OCR of Italy that USTR announced in the 2011 Special 301 Report was inconclusive due to lingering concerns about piracy over the Internet. In particular, the Italian Communications Authority (AGCOM) has not yet made sufficient progress with respect to adoption of draft regulations to combat piracy over the Internet. The United States urges Italy to intensify its recent efforts to address piracy over the Internet, including by adopting and implementing the AGCOM regulations expeditiously, and by ensuring that those regulations create an effective mechanism against all types of copyright piracy over the Internet. The United States also remains concerned about a Data Protection Agency opinion concerning the monitoring of peer-to-peer networks. The United States encourages Italy to enhance enforcement of its law against the unauthorized camcording of motion pictures in theaters, and 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 looks forward to continuing to work with Italy to address these and other matters.

Jamaica

Jamaica remains on the Watch List in 2012. Jamaica improved its IPR enforcement and training efforts in 2011, and continued public awareness efforts, including an anti-piracy campaign. The United States hopes that a prosecutorial handbook developed with assistance from the U.S. Department of Justice will help to bring about an increase in the imposition of deterrent-level sentences against IPR infringers. The United States continues to urge Jamaica 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 yet to compensate performing rights organizations for the public performances of music. We also understand that some cable operators are offering unauthorized programming, and urge the Jamaican Government to take action against these cable systems. 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 2012. Although Kuwaiti officials continued enforcement efforts in the past year, the United States remains concerned about the ongoing lack of deterrent-level sentences for IPR crimes. The United States is also concerned that several key pieces of IPR legislation remain pending in Kuwait, including amendments to the 1999 copyright law that have been pending for several years. The United States looks forward to continuing to work with Kuwait to address these and other IPR concerns.

Lebanon

Lebanon remains on the Watch List in 2012. In 2011, Lebanon participated actively in training programs and conducted IPR awareness-raising programs. Rights holders report good

cooperation from the Cybercrime and IP Unit of the police branch of the Internal Security Forces (ISF) on enforcement efforts, including a notable action against a manufacturer of counterfeit medicines. However, problems persist. Lebanon should take further action to address concerns regarding counterfeit medicines by extending operations to shut down offending factories. The United States encourages Lebanon to clarify its protection against the unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval of pharmaceutical products. The United States also encourages Lebanon to complete its accession to the WIPO Internet Treaties. Several key legislative reforms remain pending, and progress on the copyright law amendments has stalled. Lebanon should provide its enforcement authorities, including the Cybercrime and IP Unit of the ISF and customs officials, with *ex officio* authority. 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 2012. There were positive developments on IPR in 2011, including enactment of legislation to penalize enterprises that refuse entry to government IPR inspectors. There were also other improvements in IPR enforcement, especially actions led by Mexican customs authorities, as well as positive collaboration with Mexican officials working at the U.S. National IPR Coordination Center. However, serious concerns remain, including with respect to the widespread availability of pirated and counterfeit goods in Mexico. Criminal enforcement efforts overall suffer from improved but still weak coordination among federal, state and municipal officials. In addition, the need for increased resources for and more IPR prosecutions, and the need for deterrent level penalties against infringers remains crucial to addressing high levels of IP infringement in Mexico. The United States continues to encourage 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 by providing stronger protection against the unauthorized camcording of motion pictures in theaters. In addition, the United States also urges Mexico to implement its longstanding NAFTA obligations 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. Mexico should also clarify its system for addressing patent issues expeditiously in connection with applications to market pharmaceutical products. The United States looks forward to Mexico's signature, ratification, and implementation of the ACTA, which Mexico negotiated. The United States looks forward to continuing to work with Mexico to address these and other matters.

Norway

Norway remains on the Watch List in 2012. The United States is encouraged by the process under which Norway is considering draft legislation to combat piracy over the Internet. However, the United States remains concerned about the lack of product patent protection for certain pharmaceutical products; Norway's regulatory framework for process patents filed prior

to 1992, and pending in 1996, denies adequate patent protection for a number of pharmaceutical products currently on the Norwegian market. The United States looks forward to continuing to work with Norway to address these and other issues.

Peru

Peru remains on the Watch List in 2012. Peru recently enacted a law to criminalize the sales of counterfeit medicines. However, additional work is needed to coordinate enforcement efforts under that law and to pursue prosecutions. The United States remains concerned about the widespread availability of counterfeit and pirated products in Peru in general, and notes that Peru needs to devote additional resources for IPR enforcement, to improve coordination among enforcement agencies, improve its border controls, and strengthen its judicial system. The United States encourages Peru to take steps to implement its obligations under the United States-Peru Trade Promotion Agreement regarding the government's use of unlicensed software, and likewise to take steps to implement obligations with respect to protections against piracy over the Internet. It is important for Peru 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 2012. The United States is encouraged by the significant decline in the incidence of unauthorized camcording of motion pictures in theaters that followed the enactment of the Anti-Camcording Act of 2010. Philippine officials also improved enforcement efforts, leading to the closure of at least two significant notorious markets. In addition, the Philippine Supreme Court promulgated long-awaited IPR procedural rules in 2011. The United States is hopeful that effective implementation of these rules will help streamline the judicial process for IPR cases. The United States encourages the Philippines to strengthen the criminal enforcement of IPR by improving the quality of criminal investigations and prosecutions. The Philippines should also clarify its procedures for obtaining provisional measures, including by improving predictability with respect to search and seizure orders. The United States urges the Philippines to enact long-pending legislation to amend its copyright law and ensure that it fully implements the WIPO Internet Treaties. The United States 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 test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. The United States also remains concerned about policies that inhibit U.S. exports of IPR-intensive products to the Philippines, including measures that limit the market for imported pharmaceutical products. The United States looks forward to continuing to work with the Philippines to address these and other matters.

Romania

Romania remains on the Watch List in 2012. U.S. industry reports positive cooperation with Romanian enforcement officials and among enforcement agencies, evidenced by the taking down of 164 infringing websites. Romania should, however, ensure that authorities have the proper resources and training to address the country's high rates of piracy and counterfeiting effectively. The United States urges Romania to prioritize IPR protection and enforcement. Piracy over the Internet remains a serious concern, and more enforcement efforts are needed to address the problem. Judicial delays and a lack of deterrent-level sentencing also remain a 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 2012. The United States congratulates Tajikistan on completing accession to the *WIPO Performances and Phonograms Treaty*, which provides for protection of U.S. and other foreign sound recordings in Tajikistan. This step resolves a longstanding concern for U.S. rights holders. Tajikistan also took steps to implement the *Berne Convention for the Protection of Literary and Artistic Works*, and has introduced legislation 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. However, Tajikistan should implement its commitments under the 1993 United States-Tajikistan Trade Agreement. Additional concerns remain, including with respect to the lack of *ex officio* authority for border and criminal enforcement officials, and regarding the need for more prosecutions of criminal IPR infringement. The United States looks forward to continuing to work with Tajikistan on these and other matters.

Turkey

Turkey remains on the Watch List in 2012. There have been some improvements, including enhanced coordination among some enforcement agencies, discussions between the government and the private sector on IPR matters, and more training opportunities for IPR officials. However, Turkey's overall IPR protection and enforcement climate presents concerns for rights holders. Piracy and counterfeiting remain widespread in Turkey, including increasing levels of piracy over the Internet. Turkey should take action on the legislative reforms that are currently pending, and should take steps to provide an effective mechanism to address piracy in the digital environment, including full implementation of the WIPO Internet Treaties. Additional resources and training are needed to allow for more effective IPR enforcement efforts, including additional training for judges, especially with respect to piracy over the Internet. U.S. rights holders continue to raise serious concerns regarding the export from, and transshipment through, Turkey of counterfeit and pirated products. Additionally, they raise concerns that a lack of regulatory transparency and predictability for pharmaceutical products minimizes market access. U.S. industry also continues to report that the 2008 Constitutional Court dismissal of several

trademark-related cases has caused uncertainty with respect to the protection of the trademarks at issue in those cases, and that the Government has failed to take effective action to address that concern. 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 looks forward to continuing to work with Turkey to address these and other issues.

Turkmenistan

Turkmenistan remains on the Watch List in 2012. Turkmenistan made progress by adopting a Law on Copyright and Allied Rights and by amending its Civil Code to enhance IPR protection. However, Turkmenistan should implement its commitments under the 1993 United States-Turkmenistan Trade Agreement, and there continues to be a need for more comprehensive administrative, civil, and criminal procedures for adjudicating IPR cases. Turkmenistan should also provide *ex officio* authority to its customs officials. 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 to address these and other matters.

Uzbekistan

Uzbekistan remains on the Watch List in 2012. In 2011, Uzbekistan established a new Agency for Intellectual Property to improve the enforcement of IPR laws. Uzbekistan should ensure that this new agency has the necessary tools and resources to follow its mandate effectively. Concerns remain regarding the lack of copyright protection for preexisting works and for U.S. and foreign sound recordings. Uzbekistan should join the *Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of their Phonographs* (Geneva Phonograms Convention) and the WIPO Internet Treaties. Uzbekistan should also increase penalties for IPR violations and ensure that its law enforcement authorities have *ex officio* authority to initiate investigations and enforcement actions. The United States looks forward to continuing to work with Uzbekistan to address these and other matters.

Vietnam

Vietnam remains on the Watch List in 2012. Vietnam improved its regulatory framework in 2011 by passing decrees to strengthen copyright protection and border enforcement. Vietnam also took steps to resolve longstanding concerns with respect to signal theft by state-owned TV enterprises; it should build on this momentum to address other concerns with respect to cable and satellite signal theft. Although Vietnam continued to undertake enforcement efforts in 2011, including conducting significant raids to combat book piracy, but widespread piracy and counterfeiting remain a serious concern. Piracy over the Internet is a growing concern, and

counterfeit goods continue to be widely available in physical markets as well. The United States continues to encourage enforcement agencies to initiate more criminal prosecutions, and to impose deterrent level sentences in appropriate cases. Vietnam should also 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. The United States looks forward to continuing to work with Vietnam to address these and other issues, including through the Trans-Pacific Partnership negotiations.

Section 306 Monitoring

Paraguay

The United States continues to monitor Paraguay under Section 306, focusing on Paraguay's implementation of the Memorandum of Understanding on Intellectual Property Rights (MOU) with the United States and on the renegotiation of the MOU, which will expire shortly. Paraguay made progress in 2011 by producing obtaining the first conviction under its new criminal laws, which were strengthened by Penal Code amendments in 2009. Enforcement efforts continued, including efforts by the Specialized Technical Unit, and Paraguay has taken steps to improve coordination among its enforcement agencies. The United States also welcomes the efforts Paraguay has undertaken to improve IPR public awareness. However, serious concerns remain. Piracy and counterfeiting remain rampant in the country, and enforcement efforts internally and at the border have been insufficient to address this problem. Paraguay should intensify its customs actions and improve its cooperation with neighboring countries Brazil and Argentina on cross-border enforcement of IPR. The United States encourages Paraguay to take steps to improve the efficiency of its judicial system so that additional IPR violations can be addressed through the 2009 Penal Code amendments. 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 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.

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 (enacted in 1994) (“Special 301”), under Special 301 provisions, USTR must identify those countries that deny adequate and effective protection for IPR or deny fair and equitable market access for persons that rely on IPR protection. (“Countries” in this context include separate customs territories and the European Union). Countries that have the most onerous or egregious acts, policies, or practices and whose acts, policies, or practices have the greatest adverse impact (actual or potential) on the relevant U.S. products must be designated as “Priority Foreign Countries.” Priority Foreign Countries are potentially subject to an investigation under the Section 301 provisions of the Trade Act of 1974. USTR may not designate a country as a Priority Foreign Country if it is entering into good faith negotiations or making significant progress in bilateral or multilateral negotiations to provide adequate and effective protection of IPR.

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

USTR has created a “Priority Watch List” and “Watch List” under Special 301 provisions. Placement of a trading partner on the Priority Watch List or Watch List indicates that particular problems exist in that country with respect to IPR protection, enforcement, or market access for persons relying on 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.

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 2011, there are 89 contracting parties of the WPPT and 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 December 2010 and March 2012:

| | |
|---------|---------------------------------|
| Morocco | Entry into Force: July 20, 2011 |
|---------|---------------------------------|

The following three trading partners became parties to the WPPT between December 2010 and March 2012:

| | |
|----------------------------------|-------------------------------------|
| Morocco | Entry into Force: July 20, 2011 |
| Saint Vincent and the Grenadines | Entry into Force: February 12, 2011 |
| Tajikistan | Entry into Force: August 24, 2011 |