

2011 Special 301 Report



Ambassador Ronald Kirk
Office of the United States Trade Representative

ACKNOWLEDGEMENTS

The Office of the United States Trade Representative (USTR) is responsible for the preparation of this report. U.S. Trade Representative Ron Kirk gratefully acknowledges in particular the contributions of Deputy U.S. Trade Representative Miriam Sapiro; USTR General Counsel Timothy Reif; Chief of Staff Lisa Garcia; Assistant USTR for Public/Media Affairs Carol Guthrie, Special Assistant Stephen Ostrowski and all USTR staff who contributed to the drafting and review of this report. Thanks are extended to partner agencies, including the Departments of Agriculture, Commerce, Health and Human Services, Justice, Labor, Transportation, Treasury, and State, the U.S. Patent and Trademark Office and the U.S. Copyright Office.

In preparing the report, substantial information was solicited from U.S. Embassies around the world and from interested stakeholders. The draft of this report was circulated through the Special 301 Subcommittee of the interagency Trade Policy Staff Committee.

April 2011

Table of Contents

EXECUTIVE SUMMARY	1
SECTION I. DEVELOPMENTS IN INTELLECTUAL PROPERTY RIGHTS.....	5
PROTECTION AND ENFORCEMENT	5
Initiative for Special 301 Action Plans.....	5
Positive Developments.....	5
Initiatives to Strengthen IPR Protection and Enforcement Internationally.....	6
Best Practices by Trading Partners – IPR Enforcement.....	7
Capacity Building Efforts	8
Trends in Trademark Counterfeiting and Copyright Piracy	9
Piracy Over the Internet and Digital Piracy.....	11
Trademarks and Domain Name Disputes	12
Government Use of Software	12
Intellectual Property and Health Policy	13
Supporting Pharmaceutical and Medical Device Innovation through Improved Market Access.....	13
Implementation of the WTO TRIPS Agreement.....	15
WTO Dispute Settlement	15
SECTION II. COUNTRY REPORTS	19
PRIORITY WATCH LIST	19
China	19
Russia	25
Algeria	27
Argentina	27
Canada	27
Chile	28
India	28
Indonesia.....	29
Israel.....	29
Pakistan.....	30
Thailand.....	30
Venezuela.....	31
WATCH LIST	31
Belarus	31
Bolivia.....	32
Brazil.....	32
Brunei.....	32
Colombia	33
Costa Rica	33
Dominican Republic	34
Ecuador	34

Egypt	34
Finland.....	35
Greece.....	35
Guatemala.....	35
Italy	36
Jamaica.....	36
Kuwait	36
Malaysia	37
Mexico.....	37
Norway.....	38
Peru.....	38
Philippines.....	39
Romania	39
Spain.....	39
Tajikistan	40
Turkey	40
Turkmenistan	40
Ukraine.....	41
Uzbekistan.....	41
Vietnam.....	41
SECTION 306 MONITORING	43
Paraguay.....	43
ANNEX 1. STATUTORY BACKGROUND ON SPECIAL 301.....	45
ANNEX 2. THE WIPO PERFORMANCES AND PHONOGRAMS TREATY (WPPT) AND THE WIPO COPYRIGHT TREATY (WCT).....	47

EXECUTIVE SUMMARY

The “Special 301” Report is an annual review of the global state of intellectual property rights (IPR) protection and enforcement, 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 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, Spain, Italy and Russia, and the ongoing, systemic IPR enforcement issues presented in many trading partners around the world.

USTR is pleased to announce a new initiative in the 2011 review, whereby it invites any trading partner appearing on the Special 301 Priority Watch List or Watch List to negotiate a mutually agreed action plan designed to lead to that trading partner’s removal from the relevant list. This initiative is further described in Section I below. Through action plans and other engagement in the coming year, USTR looks forward to working with U.S. trading partners to address both emerging and continuing concerns, and to building on the positive results achieved thus far.

Public Engagement

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

USTR requested written submissions from the public through a notice published in the *Federal Register* on December 30, 2010. This year’s review yielded 49 comments from interested parties. The submissions received by USTR were made available to the public online at www.regulations.gov, docket number USTR-2010-0037. Further, on March 2, 2011, USTR conducted a public hearing that permitted interested persons to testify before the interagency Special 301 subcommittee about issues relevant to the review. The hearing featured testimony from 17 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 deliberation 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. USTR expects that, in preparation for and in the course of those interactions, it 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 agencies to ensure consistency of U.S. trade policy objectives with other Administration policies. As one example, USTR works closely with the Department of Health and Human Services to ensure that the Administration's trade policy (including support for the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health) is consistent with the Administration's public health policies and priorities.

2011 Special 301 List

The 2011 Special 301 review process examined IPR protection and enforcement in 77 trading partners. Following extensive research and analysis, USTR has listed the 42 trading partners below as follows:

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

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

Section 306 Monitoring: Paraguay.

2011 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 the Special 301 list outside of the typical time frame for the annual Special 301 Report. In 2011, USTR will conduct an OCR of Italy to monitor progress on IPR protection and enforcement, in particular in the area of piracy over the Internet. USTR may conduct additional

OCRs in consultation with a trading partner as circumstances warrant. Once again, USTR plans to conduct an OCR on notorious markets, consistent with the Administration's 2010 Joint Strategic Plan on IP Enforcement.

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 particular trading partners.
- **Annex 1** provides the statutory background for 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) (*i.e.*, 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 supporting and implementing 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 countless jobs in the United States, USTR works to protect American inventiveness and creativity with all the tools of U.S. trade policy, including this Report.

Initiative for Special 301 Action Plans

The United States develops action plans and similar programs to address IPR issues in various contexts, including the Special 301 process. These plans and programs establish benchmarks, such as legislative, policy, or regulatory action by which to measure progress. Additionally, these plans can serve as tools to encourage U.S. trading partners to make improvements to their IPR regimes, thereby increasing the likelihood that they may be removed from the Special 301 list.

As called for in the Administration's 2010 Joint Strategic Plan on IPR Enforcement, USTR, in coordination with the Intellectual Property Enforcement Coordinator (IPEC), initiated an interagency process to increase the effectiveness of, and strengthen implementation of Special 301 action plans.

As a result of that process, **USTR is announcing that it invites any trading partner appearing on the Special 301 Priority Watch List or Watch List to work with the United States to develop a mutually agreed action plan designed to lead to that trading partner's removal from the relevant list.** Agreement on such a plan will not by itself change a trading partner's status in the Special 301 Report. However, in the past, successful completion of action plans has led to the removal of trading partners such as Saudi Arabia, Taiwan, and many others from Special 301 lists. An action plan may take more than one year to complete. Action plans differ from OCRs, which are conducted between Special 301 annual reports.

Positive Developments

The United States welcomes the following important steps by our trading partners in 2010 and early 2011:

- **Australia, Canada, the European Union (EU) and its Member States, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland** – These trading partners, along with the United States, worked cooperatively to finalize the text of the Anti-Counterfeiting Trade Agreement – an important new tool to fight trademark counterfeiting and copyright piracy.

- **Mexico** – Mexico enacted legislation granting *ex officio* authority to its law enforcement officials to initiate criminal investigations against trademark counterfeiting and copyright piracy without requiring the rights holder to first file a complaint.
- **Philippines** – The Philippines enacted legislation to address unauthorized camcording of motion pictures in theaters.
- **Russia** – Russia enacted four pieces of IPR legislation, which complete the legislative commitments it made in the 2006 Bilateral Agreement on Protection and Enforcement of Intellectual Property Rights. These measures are: (1) amendments to Part IV of the Civil Code (governing intellectual property generally); (2) enactment of the Federal Law on Customs Regulation granting *ex officio* authority to customs officials; (3) amendments to the Law on Activity Licensing, which ensures that infringers cannot renew optical media production licenses; and (4) amendments to the Law on Circulation of Medicines to protect undisclosed test or other undisclosed data generated to obtain marketing approval.
- **Spain** – Spain took action to address the problem of copyright piracy over the Internet by passing legislation that will provide a mechanism for rights holders to remove or block access to infringing content online.

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 initiatives:

- **Anti-Counterfeiting Trade Agreement (ACTA):** The ACTA negotiations, which concluded in November 2010, reflect a commitment by the negotiating parties not only to have strong laws on the books, but also to pursue the international cooperation and meaningful enforcement practices necessary to make intellectual property protection effective. ACTA will be the first agreement of its kind to both require strong enforcement provisions and promote the cooperation and key practices that make these provisions effective, raising international standards for the enforcement of IPR.
- **Trans-Pacific Partnership Agreement (TPP):** The TPP 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 TPP negotiations have begun with this initial group of like-minded countries with the goal of creating a platform for integration across the region, and the TPP will include strong standards for the protection and enforcement of IPR.
- **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 accession processes for prospective members; the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council); and WTO dispute settlement.
- **Bilateral and Regional Initiatives:** The United States works with many countries 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, including in the Middle East and Asia, 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 (CBERA). USTR will continue to review IPR practices in Russia, Lebanon, and Uzbekistan under ongoing GSP reviews, in anticipation of the reauthorization of the GSP program.
- **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 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.

Best Practices by Trading Partners – IPR Enforcement

Pursuant to the Administration’s Joint Strategic Plan on IP Enforcement, USTR is highlighting best practices by trading partners in the area of IPR enforcement. In comments submitted for this year’s Special 301 review process, stakeholders highlighted several key examples of best practices by U.S. trading partners:

- 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. Trading partners commended for improved cooperation and stakeholder engagement include Argentina, Canada, Guatemala, Italy, Malaysia, Mexico, and Pakistan, among others.
- Another important best practice may be found in trading partners’ efforts to tackle new challenges in IPR protection and enforcement. For example, industry reports positive efforts by China in tackling the serious problem of counterfeit drugs available through online advertisements and “Internet pharmacies” by working across ministries to target websites that knowingly violate local IPR laws. There were also 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.
- Finally, a significant best practice is the active participation of government officials in capacity building efforts and 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.

For example, in the United States, the U.S. Patent and Trademark Office (USPTO) invites officials from around the world for training at its Global Intellectual Property Academy, which conducts over 75 programs per year, training more than 4,500 participants from over 120 trading partners. These programs focus on a variety of topics, including patent and trademark examination, copyright, industrial designs, IPR management, and technology transfer. Furthermore, over half of the USPTO programs are directed to IPR enforcement capacity building, on topics such as border enforcement, prosecution practices, and judicial development. 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 State Department'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 State Department and the U.S. Copyright Office, conduct well-attended conferences in Washington.

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. These activities are conducted by a number of U.S. Government agencies. For example:

- The USPTO's Office of Policy and External Affairs provides capacity building in countries around the world and has developed 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 the basics of IPR.

- In 2010, the Department of Homeland Security's (DHS) bureau of Customs and Border Protection (CBP) conducted regional border trainings programs that focused on IPR enforcement in Angola, Brunei, Egypt, Mali, Peru, Ukraine, and Thailand.
- 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), the USPTO, CBP and DHS's Immigrations and Customs Enforcement bureau. In 2010, the State Department provided funds for 11 training programs for customs, police, and judicial officials from various trading partners including Indonesia, Mexico, Russia, and Vietnam, as well as regional groups, including ASEAN, and through regional trainings in the South Asia region, including India, and in sub-Saharan Africa. The U.S. Government works collaboratively on many of these training programs with the private sector and with various international entities such as WIPO, and with regional organizations, such as the APEC Intellectual Property Experts Group.
- The Department of Commerce's Commercial Law Development Program (CLDP) provides training to foreign lawmakers, regulators, judges, and educators focused on IPR enforcement. 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, North Africa, Sub-Saharan Africa, and Asia. For example, since 2009, CLDP has organized annual judicial capacity building programs in Bosnia-Herzegovina focused on the fair, predictable, and efficient adjudication of intellectual property cases. In Egypt, CLDP conducted a two-day training workshop in December 2010 at the Internal Trade Development Authority for trademark officers and board of appeals judges to provide an overview of the trademark system in the United States, and to address various topics, including the likelihood of confusion standard, distinctiveness of marks, and registration of trade dress. In Pakistan, CLDP has trained justices from Pakistan's national and regional supreme courts on IPR enforcement. In Sub-Saharan Africa, CLDP organized interagency bilateral IPR enforcement programs in Ghana, Liberia, and Mali, and regional IPR programs in Botswana, Senegal, and Uganda.

Although many trading partners have implemented 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.

Trends in Trademark Counterfeiting and Copyright Piracy

Counterfeiting has evolved in recent years from a localized industry concentrated on copying high-end designer goods to a sophisticated global business involving the mass production and sale of a vast array of fake goods, including items such as counterfeit medicines, health care products, food

and beverages, automobile and airplane parts, toothpaste, shampoos, razors, electronics, batteries, chemicals, and sporting goods.

Counterfeiting and piracy diminish the profits of legitimate producers and risk harm to consumers who may purchase fraudulent, potentially dangerous products. Trading partners where rampant counterfeiting and piracy occur lose tax revenue and may find it more difficult to attract investment. Those engaged in trademark counterfeiting and piracy generally pay no taxes or duties, and they often disregard basic standards for worker health and safety and product quality and performance. Industry reports trends in counterfeiting and piracy that include:

- A greater variety in the types of goods that are being counterfeited, as well as the production of labels and components for these fake products. Counterfeiters are establishing a global trade in counterfeit items, shipping them separately to free trade zones (FTZs) to be assembled and distributed in another country. Counterfeiters have also abused FTZs to disguise the origin of counterfeit goods.
- A rapid growth in the piracy of copyrighted products in virtually all formats, as well as counterfeiting of trademarked goods, because these criminal enterprises offer enormous profits and little risk. Such enterprises require little up-front capital investment, and even if they are detected and prosecuted, the penalties imposed on them in many countries are so low that such penalties offer little or no deterrence against further infringements and are viewed merely as a cost of doing business.
- A growth in the online sale of pirated and counterfeit hard goods that is rapidly approaching the volume of goods that sold by street vendors and in other physical markets. Legal and investigative institutions face difficulties in responding to this trend. Online advertisements for sale of unlawful physical goods that are delivered through the mail or by hand are found in many places, including China, France, Germany, Japan, Spain, and Taiwan. 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.
- Another notable trend involves shipping counterfeit products separately from labels and packaging 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 these counterfeit and pirated product assemblers. There are reports of transit of illicit labels through other countries as well, including Mexico and the Philippines.

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 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 countries such as Brazil, China, India, Indonesia, Lebanon, Peru, and Russia.

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 APIs can avoid regulatory oversight by failing to declare that the bulk chemical is intended for use in pharmaceutical products. This factor 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 to assist China and its trading partners in their efforts to address this problem.

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.

Piracy over the Internet is a significant concern with respect to a number of trading partners, including Brazil, Canada, China, India, Italy, Russia, Spain, and Ukraine. Unauthorized retransmission of live sports telecasts over the Internet continues to be a growing problem for many trading partners, particularly in 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. The United States 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, Canada, Colombia, India, Italy, Malaysia, Mexico, Philippines, Romania, Russia, Spain, Thailand, Turkey, Ukraine, Venezuela, and Vietnam. In particular, the United States

will encourage trading partners implement the WIPO Internet Treaties, including by providing protection against the circumvention of technological protection measures. The United States also encourages trading partners to adopt appropriate measures where needed with respect to the unauthorized camcording of motion pictures in theaters. 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, Thailand, and Vietnam. The United States continues to urge its 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.

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 misuse of trademarks.

Government Use of Software

Under Executive Order 13103 issued in September 1998, U.S. Government agencies maintain procedures to ensure that they use only authorized business software. Pursuant to the same directive, USTR has undertaken an initiative to work with other governments, particularly in countries that are modernizing their software systems or where concerns have been raised, to stop governmental use of illegal software. Considerable progress has been made under this initiative, leading to numerous trading partners mandating that only authorized, legitimate software may be used by their government bodies. Further work on this issue remains with certain trading partners, such as China, Costa Rica, India, Pakistan, Paraguay, Peru, Tajikistan, and Ukraine. 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 2011 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 intellectual property 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 to see at least two-thirds of the WTO membership accept this amendment by the December 31, 2011 deadline, at which point the amendment will go into effect for those members that accept it. 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 intellectual property and health policy and do not impede its trading partners from taking measures necessary to protect public health. Accordingly, USTR will continue its close cooperation with relevant agencies, including the Department of Health and Human Services and the United States Agency for International Development, to ensure that public health challenges are addressed and IPR protection and enforcement is supported as a mechanism to promote research and innovation.

Supporting Pharmaceutical and Medical Device Innovation through Improved Market Access

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, 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 Japan, pharmaceutical and medical device issues are an integral part of regular bilateral discussions. While Japan has made progress on these issues, the United States continues to work with Japan to seek continued improvements in transparency in addition to further reform of reimbursement and regulatory systems that would facilitate the timely introduction of innovative pharmaceuticals and medical devices into Japan's market.
- 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 transparency, fairness, and predictability of the PHARMAC pricing and reimbursement regime, as well as the overall climate for innovative medicines in New Zealand.

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, once in force, would 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. The United States looks forward to the successful completion of this transition.

The United States will continue to work with WTO members and expects further progress in the near term towards completing their TRIPS Agreement implementation process. However, in those instances in which additional progress is not achieved, the United States will consider alternative means of encouraging implementation, including the possibility of recourse to WTO dispute settlement.

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, including the EU, Japan, and Switzerland, to encourage a discussion within the WTO TRIPS Council on implementation of the enforcement-related provisions of the TRIPS Agreement. The United States hopes that the TRIPS Council can generate a useful sharing of experiences related to IPR enforcement 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 products (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. However, 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. Despite its commitment to do so, China did not bring all of its measures into compliance with the DSB recommendations by the agreed-upon deadline of March 19, 2011. The United States is working closely with China to resolve the issues in this dispute on terms agreeable to both parties.

Following the 1999 Special 301 review, the United States initiated dispute settlement consultations concerning the EU regulation on food-related geographical indications (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.

SECTION II. COUNTRY REPORTS

PRIORITY WATCH LIST

China

China remains on the Priority Watch List and subject to Section 306 monitoring. China's enforcement of IPR, as well as its implementation of its WTO obligations, remains top priorities for the United States. China made constructive commitments related to intellectual property generally, and software legalization specifically, during the December 2010 Joint Commission on Commerce and Trade (JCCT) meeting, and during President Hu's visit to Washington in January 2011. The United States is focused on seeing significant and measureable progress on these commitments in the coming year.

The U.S. Government has been following closely the efforts under China's Special Campaign. If China makes permanent the temporary leadership structure created to manage the Special Campaign, including the key role for the Vice Premier, it could drive lasting improvements in IPR enforcement. The U.S. Government has also been following the development of China's indigenous innovation and other intellectual property-related industrial policies and is paying particularly close attention to China's policies that require or encourage U.S. parties to transfer their IPR to Chinese parties or to Chinese subsidiaries of U.S. firms. Innovation will produce greater societal and global gains when market participants, irrespective of their nationality or the places where they may own or develop intellectual property, are able to enjoy the fruits of their investments without the danger that their efforts, including in developing and commercializing intellectual property, will be undermined, or shared with others who did not undertake the initial risk. The United States encourages China to adopt policies that eliminate improper government intervention in intellectual property licensing and other lawful contractual business arrangements, and that welcome exports to and investments in China, irrespective of where the intellectual property in the products and services is owned or developed.

Special Campaign

In October 2010, Premier Wen Jiabao announced the launch of the "Program for Special Campaign on Combating IPR Infringement and Manufacture and Sales of Counterfeiting and Shoddy Commodities" (Special Campaign).

The Special Campaign was originally slated to end in March 2011, but has been extended for another three months. Enforcement efforts in the Special Campaign are aimed at a broad range of intellectual property violations: IPR infringement over the Internet, such as through illegal downloads of music and movies; sale of pirated CDs and DVDs; infringing software; and trademark infringement, particularly related to counterfeit mobile phones, auto parts, bulk commodity exports, and pharmaceuticals. China's agencies are to summarize and report on lessons learned at the end of the Special Campaign. The Special Campaign is led by Vice Premier Wang Qishan, who chairs a national "leading group" that was established at the campaign's start. The leading group consists of 26 member agencies, and the leading coordinating office is based in China's Ministry of Commerce. Reports from industry stakeholders indicate that the high-level leadership structure of the Special

Campaign appears to have resulted in improved coordination among various IPR enforcement authorities in China at the central, provincial, and local levels.

The Special Campaign has produced regulatory and judicial changes, as well as strengthened enforcement activities. In late November 2010, the State Council issued the “Notice on Further Strengthening the Management of the Software Assets of Central Administrative Entities and Public Institutions,” obligating, for the first time in China, central government budget allocations for legitimate software purchases. It further required that government asset management include software, and that only legitimate software be used in central government networks. Furthermore, on January 11, 2011, the Supreme People’s Court, the Supreme People’s Procuratorate, and the Ministry of Public Security jointly issued a document entitled, “Opinions on Handling Several Issues in IP Criminal Cases,” which appears to modify the proof requirements in copyright infringement cases involving multiple copies of works.

Anecdotally, individual companies and industry trade associations report some increases in investigative and enforcement activity, particularly in the online environment, where China’s media have reported more than 200 website closures and suspensions of online business licenses. Trade associations state that their members are seeing increased enforcement activity in luxury- and branded-goods sectors. Over the past few months, local and provincial branches of China’s Administration for Industry and Commerce (AIC) claim to have conducted 1,372 raids involving more than 700,000 law enforcement personnel, logging 5,000 trademark violations in 16,000 cases valued at over \$15 million. Pharmaceutical manufacturers report positive results from the Special Campaign, which has focused in part on public health and safety. According to rights holders in this sector, law enforcement has been reaching out to individual companies, investigating leads early on, and bringing criminal prosecutions against infringers. Rights holders detect more diligence and promptness on the part of Chinese authorities in developing criminal counterfeit pharmaceutical cases. Anecdotal accounts also suggest that Chinese police may be pursuing production networks and distribution channels, and seizing counterfeit products as well as manufacturing equipment.

However, some companies and trade associations report mixed results and remain skeptical about whether current activity levels will be maintained once the Special Campaign ends. As an example, the software industry reports no discernable increase in legitimate software sales to date, and no significant changes in software-related enforcement activity. This is despite China’s assertion in its Special Campaign plans that software legalization is a high priority. For this sector, it appears that this latest campaign is not yet having a positive effect. One company noted that most of the Chinese government’s efforts to purchase legal software have been focused on low-end and pirated domestic software.

Online Piracy

Piracy over the Internet in China continues to be a source of concern and injury to the copyright industries and the United States. It is estimated that there are 457 million Internet users in China, as compared with 223 million in the United States; when coupled with reports that 99% of all music downloads in China are illegal, the concerns of industry are understandable. However, there appear to be early signs of progress in this area. As a result of the Special Campaign, several websites and portals, including VeryCD, qishi.com and 5474.com have been shut down, and three of the operators of these last two sites were arrested and sentenced to prison terms that ranged from three to five years,

along with fines levied between the equivalent of \$30,000 and \$228,000. The most progress seems to be occurring with respect to video distribution: Youku.com and Toudu.com have entered into licensing agreements with major U.S. studios to stream their movies and television programming, thereby starting to shift their business models from offering pirated content to providing legitimately licensed content. The United States is also encouraged by media reports that Baidu, recently listed for the fifth year in a row in the USTR Notorious Markets report, will be launching a licensed music search service soon. At this moment it appears that a licensing agreement has only been reached with Chinese rights holders. The United States urges Baidu to reach a similar agreement with U.S. rights holders, and eliminate all pirated music from their site. Recent reports also indicate that Baidu has removed 2.8 million items from an online library after Chinese authors complained it was distributing their works without permission. However, the publishing industry continues to report problems involving unauthorized distribution of electronic journals in libraries.

Counterfeiting Issues

China's global manufacturing capacity also extends to all phases of the production and global distribution of counterfeit goods. According to industry reports, the range of goods counterfeited in China includes apparel and footwear, mobile phones, pharmaceuticals and medical equipment, herbal remedies, wine and liquor, other beverages, agricultural chemicals, electronic components, computer and networking equipment, software and related products, batteries, cigarettes, cosmetics, home appliances, cement, and auto parts, as well as merchandise based on copyrighted works. Many of these activities can be traced back to Guangdong Province. Traditional counterfeit markets, such as the Silk Market in Beijing or wholesale markets like Yiwu City, are no longer the only places where these counterfeits are pervasive. Increasingly, the use of online sales platforms and global express delivery services are facilitating international distribution of these counterfeit goods.

With respect to Internet distribution, the past year has seen some positive developments, in part due to the Special Campaign. These developments include new measures issued by the State Administration of Industry and Commerce (SAIC) that require ISPs to verify the identity of online traders and to take "necessary measures to protect registered trademarks." Local AICs have also demonstrated greater willingness to intervene directly against online advertisements of fake products. Recently, one of the largest online platforms for sales of counterfeit goods, Taobao, launched a new initiative to examine advertising and sale activities using its platform, and to provide leads to Chinese law enforcement authorities regarding infringing activities. In this connection, the fashion industry reports that it has been approached by Chinese enforcement authorities seeking information to support criminal prosecutions against online traders caught with large quantities of counterfeit products in their warehouses. The United States urges other online platforms, especially those cited in the "Notorious Markets" report, to follow Taobao's lead to increase cooperation with Chinese police and U.S. rights holders. The United States also encourages Chinese enforcement agencies to reach out not only to the larger foreign enterprises, but also to small and medium enterprises that are also being injured by counterfeit goods.

Despite these positive developments, including the raids that have taken place under the Special Campaign, the United States is troubled by China's May 2010 prosecution guidelines that tripled the threshold for investigating and prosecuting trade in counterfeit products. High thresholds for initiating criminal actions have always been a significant barrier to effective enforcement against the sale of counterfeits. Raising these thresholds introduces new problems into an already difficult

enforcement environment in which administrative fines lack deterrent effect and are viewed merely as a cost of doing business. The United States urges the Chinese government to make the manufacturing of counterfeit goods a crime regardless of value. However, if China maintains these thresholds, it could mitigate the effects of doing so by valuing the counterfeit goods based on the retail price of those goods, and by including the costs of components sold together with the product, such as bottles and packaging, in the determination of whether the threshold is met.

While the counterfeit goods are seized in the course of raids, that is not typically the case with equipment used to produce those goods. To ensure that such enforcement actions are truly effective in stopping the manufacturing of counterfeit goods, the equipment used to manufacture those goods must also be seized and destroyed. If such equipment is not seized and destroyed, counterfeiters can resume their operations as soon as law enforcement officers have left their premises. It is also important to permit direct acceptance of serious IPR cases by the Public Security Bureau (PSB). While administrative agencies such as the local AICs can seize counterfeits, only the PSB has the power to search and arrest. A follow-on action to the Special Campaign would be to grant the PSB authority to accept all manufacturing cases directly. Lastly, since Guangdong Province is the source of most counterfeits, a coordinated, province-wide effort should be undertaken to address this problem. It should be noted that when the Asian Games were held in Guangzhou in November 2010, officials not only conducted robust enforcement of IPR with respect to that event, but also undertook additional crackdowns on counterfeit goods and optical disk outlets. This same political will should be continued and expanded throughout the whole province.

Patents Used in Chinese National Standards

In recent years, concerns have arisen regarding China's proposed treatment of patented technology in connection with domestic standards development processes. First, in late 2004, concerns arose after the Standardization Commission of China (SAC) issued draft *Provisional Regulations for National Standards Relating to Patents (Provisional Regulations)* and key Chinese government officials made public statements that appeared to contemplate compulsory licensing of patented technologies that are used in national standards in China.

In November 2009, SAC circulated a new draft of the *Provisional Regulations* for public comment. This draft measure would implement China's vision for a standards development process and establish the general principle that mandatory national standards should not incorporate patented technologies. However, the draft measures provide that when mandatory national standards incorporate patented technologies, there is the possibility of a compulsory license if a patent holder does not grant a royalty-free license. This differs from the typical practice of accredited standards developing organizations in other countries, which require disclosure of intellectual property in the standards development process and support "reasonable and nondiscriminatory" (RAND) licensing policies with respect to intellectual property that is incorporated into a standard. RAND policies require concerned patent rights holders to make any intellectual property incorporated into the standards that these bodies develop available to all interested parties on RAND terms. Within the standards development process, licensing terms are typically negotiated between the right holder and parties interested in implementing the standards.

Second, in 2006, China's Electronic Standardization Institute (CESI), released draft intellectual property policy rules for standards-setting organizations (SSOs). These draft rules envisage Chinese

government involvement in standards-setting processes, and include a requirement that SSOs obtain government approval for patent claims. Such government involvement could be exercised in a way that affects private party transactions and could raise concerns under certain circumstances.

In January 2010, the China National Institute of Standardization (CNIS) solicited public comments on its notice entitled, “Disposal Rules for the Inclusion of Patents in National Standards.” The “Disposal Rules” are the supporting documents for SAC’s Provisional Regulations. In October 2010, CNIS finished the second draft of the Provisional Regulations, “Special Procedure on Standards Making—Inclusion of Patents in National Standards,” and submitted them to SAC for review.

U.S. companies have expressed serious concerns regarding these proposals. The United States will continue to monitor how China treats intellectual property through its SSOs, including in connection with the development and finalization of CESI’s rules, as well as the development of SAC’s revised Provisional Regulations. In addition, the United States will discuss these issues with China in the JCCT IPR Working Group, where both sides have agreed to discuss related issues with participants from all relevant Chinese and U.S. agencies.

Indigenous 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 as 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 also expressed concerns to China regarding its innovation-related policies and other industrial policies that discriminate against or otherwise disadvantage U.S. exports or U.S. investors and their investments. Chinese regulations, rules and other regulatory documents frequently call for technology transfer, and in certain cases, condition, or propose to condition, eligibility for government benefits or preferences on intellectual property being owned or developed in China, or being licensed, in some cases exclusively, to a Chinese party. Such arrangements may not ordinarily be commercially optimal but for the conditions or incentives established by the government. Government intervention in the commercial decisions of enterprises regarding intellectual property ownership, development, registration or licensing is not consistent with international practice, and may raise concerns relative to China’s WTO obligations. The United States encourages China to abandon policies and practices that involve the government in enterprises’ licensing and other contractual arrangements.

Indigenous Innovation and Product Accreditation for Government Procurement Preferences

In late 2009, three Chinese agencies -- the Ministry of Science and Technology (MOST), the Ministry of Finance (MOF) and the National Development and Reform Commission (NDRC) -- announced a National Indigenous Innovation Product Accreditation System, that would, among other things, condition government procurement preferences on certain criteria, including several specifically relating to intellectual property. For example: (1) An applicant’s products would need to have “Chinese intellectual property and proprietary brands;” (2) An applicant would need to be a Chinese enterprise, institution or citizen owning such intellectual property lawfully; (3) An applicant’s use, handling and secondary development of such intellectual property would need to be totally independent of overseas organizations or individuals; and (4) An applicant would be required to own the trademark of eligible products, and the trademark’s original place of registration would need to be in China, and also be independent of overseas brands.

After the United States and other countries raised significant concerns, the issuing agencies proposed amendments for public comment to some, but not all, of the intellectual property-related requirements, in April 2010. For example, China proposed to eliminate a requirement relating to trademarks. However, the requirement relating to Chinese enterprise ownership of the intellectual property was only proposed to be changed to require a grant or transfer of intellectual property, e.g., through a license, irrespective of whether the owner preferred not to license its intellectual property to a Chinese entity. In addition, China did not propose to amend a provision relating to the requirement for eligible products to contain “Chinese intellectual property and proprietary brands.”

The United States and other governments, as well as international business associations, made their comments and concerns known regarding these and other aspects of the National Indigenous Innovation Product Accreditation System. The U.S. Government also requested that the Chinese government invalidate the many Chinese provincial and municipal indigenous innovation product accreditation measures that conditioned accreditation for government procurement preferences on – for example – the location of the development or ownership of intellectual property. In addition, the U.S. Government requested that China’s draft *Regulations Implementing the Government Procurement Law*, which had been published by China’s Ministry of Finance in proposed form for public comment, be amended to remove the requirement in proposed Article 9 to formulate indigenous innovation product lists for government procurement preferences, mandates and other purposes.

The United States raised these concerns at the May 2010 Strategic and Economic Dialogue. China agreed to ensure that its innovation policies will be consistent with the following principles: non-discrimination; support for market competition and open international trade and investment; strong enforcement of intellectual property rights; and, consistent with WTO rules, leaving to agreement between individual enterprises the terms and conditions of technology transfer, production processes and other proprietary information. China and the United States also agreed to create an Innovation Dialogue involving all relevant U.S. and Chinese agencies, which meets at the Minister-led and experts’ level to discuss, *inter alia*, Chinese innovation and technology transfer policies.

Additionally, at the 2010 JCCT, in 2010 meetings of the JCCT IPR Working Group, and at the summit meeting in January 2011 between President Obama and President Hu Jintao, the United States raised its concerns regarding China’s indigenous innovation product accreditation system. Notably, President Hu stated that “China will not link its innovation policies to the provision of government procurement preferences.” This is a very important commitment, and the United States looks forward to full implementation of this commitment in all Chinese central, provincial and municipal laws, regulations, rules and regulatory documents that link innovation policies to the provision of government procurement preferences.

Indigenous Innovation and Place of Intellectual Property Ownership or Development

During the 2010 JCCT process, including in 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.”

The United States also looks forward to expanding this commitment to clarify that the location of development or ownership shall not be a condition for eligibility for other forms of government preferences as well.

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.

Russia

Russia has taken significant steps in the past year to improve IPR protection and enforcement, and the United States commends this important progress. Because of ongoing concerns, particularly with respect to piracy over the Internet and enforcement generally, Russia remains on the Priority Watch List. Russia is therefore encouraged to work with the United States to set metrics, including through the establishment of an action plan, to resolve these issues.

The United States welcomes Russia’s enactment, as part of the WTO accession process, of four important IPR laws. These achievements complete the legislative commitments it made in the 2006 Bilateral Agreement on Protection and Enforcement of Intellectual Property Rights (2006 Bilateral Agreement on IPR). In 2010, Russia passed: (1) amendments to Part IV of the Civil Code (governing intellectual property generally); (2) enactment of the Federal Law on Customs Regulation granting *ex officio* authority to customs officials; (3) amendments to the Law on Activity Licensing, which ensures that infringers cannot renew optical media production licenses; and (4) amendments to the Law on Circulation of Medicines to protect undisclosed test or other undisclosed data generated to obtain marketing approval.

In addition to these legislative reform efforts, Russia has had additional success with respect to reducing hard goods counterfeiting and piracy. The pharmaceutical and software industries, for example, report a reduction in the number of counterfeit medicines and optical discs available in

markets, including in large markets such as the Gorbushka market and the Rubin Trade Center in Moscow. Despite these improvements, the United States is concerned that hard goods counterfeiting and piracy continue to be widespread, particularly for the motion picture, television and entertainment software industries.

Another important step Russia took was to close down operations of all optical disc plants engaging in production of pirated media located on Russian state-owned restricted access regime enterprises (RARE) sites, pursuant to the 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 leaves Russian enforcement agencies and rights holders with limited opportunities to conduct successful raids against such warehouses.

The United States recommends that Russia take steps to address these and other IPR concerns. The United States is concerned that, with respect to piracy over the Internet, significant gaps exist in Russian law and enforcement efforts. This creates obstacles to Russia's ability to keep pace with changing technology. To deal with websites hosting illegal material, the United States encourages Russia to pass notice and take down legislation that addresses all forms of piracy over the Internet and provides for the swift removal of infringing content. In addition, numerous pay-per-download websites as well as cyberlockers, BitTorrent sites, and unauthorized music services, including services affiliated with social networking sites such as vKontakte, reside in Russia. The United States urges Russia to engage in vigorous, sustained, and measureable takedown and enforcement actions, including criminal enforcement actions with deterrent penalties, against existing as well as future infringing sites. Furthermore, intensified criminal investigations and criminal convictions against operators of illegal Internet sites are needed. The United States also urges Russia to assign specially trained personnel and other appropriate resources to a specialized law enforcement unit 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.

The United States therefore urges Russia to strengthen its overall enforcement efforts, including criminal enforcement efforts, against piracy and counterfeiting. Enforcement continues to vary greatly among regions. According to MVD, the number of raids, and the extent of cooperation with rights holders, decreased in 2010. While Russian police continue to carry out end-user raids against businesses using pirated products, there are indications that such raids are sometimes done on a selective basis. Even where raids are conducted in a sustained and vigorous manner, prosecutions and convictions do not necessarily follow. The United States urges Russia's enforcement officials to increase the number of IPR-related investigations, and prosecutors to seek deterrent penalties in judicial proceedings. The United States encourages Russia to pass legislation establishing a specialized IPR court. The United States looks forward to working together with Russia on continuing education opportunities for judges with respect to IPR.

Concerns have also been raised about Russia's accreditation process for collecting societies. Additionally, recent litigation with respect to the single collecting society accredited to collect royalties on behalf of all performers and record companies (*i.e.*, the All-Russia Organization for Intellectual Property (VOIS)) has introduced uncertainty regarding VOIS's status and the status of the accreditation process generally. The United States looks forward to working with Russia on these and other issues.

Algeria

Algeria remains on the Priority Watch List. The United States remains deeply concerned about an Algerian law that bans numerous imported pharmaceutical products and medical devices in favor of local production. Additional matters that also give rise to concerns include the lack of protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products. The pharmaceutical industry continues to express concern about the weak level of patent protection that Algeria accords. In addition, copyright piracy and trademark counterfeiting remain widespread and enforcement efforts remain insufficient. The United States will continue to work with Algeria to address these and other issues.

Argentina

Argentina remains on the Priority Watch List. The Government of Argentina has taken a number of positive and encouraging steps that the United States welcomes. Argentina stepped up its enforcement efforts in 2010, and industry continues to report encouraging cooperation with police officers regarding raids. Other positive developments include the Attorney General's issuance of new guidance on IPR crimes, which should improve coordination among enforcement agencies and lead to more aggressive treatment of criminal IPR cases. Argentina also took steps to address its patent backlog, although additional work is required. However, serious problems persist, including widespread availability of pirated and counterfeit goods, an inefficient judicial system, and a failure to adjudicate civil and criminal cases and impose deterrent level sentences. While efforts by the Argentine Center for the Administration of Photocopying Rights (CADRA) and major libraries have led to a decrease in book piracy, overall levels of copyright piracy continue to present a problem, as reflected, for example, in a reported growth in piracy over the Internet. The United States encourages Argentina to provide for protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approvals 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 Argentina to address these and other concerns.

Canada

Canada remains on the Priority Watch List. The United States continues to urge Canada to implement its previous commitments to improve its legal framework for IPR protection and enforcement. Unfortunately, Canadian efforts in 2010 to enact long-awaited copyright legislation were unsuccessful. The United States encourages Canada to make the enactment of copyright legislation that addresses the challenges of piracy over the Internet, including by fully implementing the WIPO Internet Treaties, a priority for its new government. The United States encourages Canada to provide for deterrent-level sentences to be imposed for IPR violations, as well as to strengthen enforcement efforts, including at the border. Canada should provide its Customs officials with *ex officio* authority to effectively stop the transit of counterfeit and pirated products through its territory. U.S. stakeholders have also expressed strong concerns about Canada's administrative process for reviewing the regulatory approval of pharmaceutical products, as well as limitations in Canada's trademark regime. The United States appreciates the high level of cooperation between the

Canadian and U.S. Governments, and looks forward to continuing engagement on these important issues.

Chile

Chile remains on the Priority Watch List. The United States welcomes the Piñera Administration's significant commitment to address outstanding IPR issues under the United States-Chile Free Trade Agreement (FTA) in 2011. Positive steps taken in 2010 include the launch of a Ministerial-level interagency committee on IPR with a mandate to examine these issues, and the implementation of the new copyright legislation. In addition, Chile ratified the Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellites (Brussels Convention) and the Trademark Law Treaty. The United States encourages Chile to take further action by acceding to, and ratifying, the International Convention for the Protection of New Varieties of Plants. The United States also encourages Chile to implement its commitment to provide an effective system to address patent issues expeditiously in connection with applications to market pharmaceutical products, to implement protections against the circumvention of technological protection measures, to implement protection for encrypted program-carrying satellite signals, and to ensure that administrative and judicial procedures and 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 approvals for pharmaceutical products, and to amend its Internet service provider liability regime to permit effective action against any act of infringement of copyright and related rights. The United States commends Chile's efforts and looks forward to continued engagement with Chile to resolve these and other matters.

India

India remains on the Priority Watch List. India continued to make incremental progress in 2010 to address its IPR legislative, administrative, and enforcement issues. Improvements in 2010 included the introduction of a Copyright Amendment Bill, which may assist in addressing some aspects of the widespread piracy of copyrighted materials on the Internet. However, the bill may not fully implement the WIPO Internet Treaties. The United States encourages India to revise and enact these amendments, and to thereby bring India's copyright law into line with international standards. India has also developed a national IPR policy which should help focus the government's efforts to address widespread piracy and counterfeiting, including counterfeit medicines, effectively. Some industries also report improved cooperation with enforcement officials of certain state governments. Nevertheless, India continues to have a weak legal framework, and ineffective overall IPR enforcement persists. The United States encourages India to take action on its draft optical disc law and generally to combat widespread optical disc piracy. The United States also recommends that India improve its IPR regime by providing for stronger patent protection. Particular concerns have been raised regarding provisions of India's Patent Law that prohibit patents on certain chemical forms absent a showing of increased efficacy, thereby possibly limiting the patentability of potentially beneficial innovations, such as temperature-stable forms of a drug or new means of drug delivery. India should also take additional steps to address its patent application backlog and to streamline its patent opposition proceedings. The United States encourages India to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approval for pharmaceutical and agricultural chemical

products. Finally, the United States recommends that India take steps to improve the efficiency of judicial proceedings, and strengthen its criminal enforcement regime, by encouraging the imposition of deterrent-level sentences for IPR violations and by giving prosecution of IPR offenses greater priority. The United States looks forward to increased engagement with India to address these and other matters in the coming year.

Indonesia

Indonesia remains on the Priority Watch List. Indonesia continued its enforcement efforts and enhanced its cooperation with rights holders in 2010. For example, rights holders report that Indonesia has adopted helpful practices and policies with respect to cable piracy. However, enforcement efforts were insufficient to keep pace with Indonesia's piracy and counterfeiting problem, including with respect to the widespread availability of counterfeit pharmaceutical products and other counterfeit hard goods. The United States urges Indonesia to improve its enforcement efforts, to address problems that its prosecutorial and judicial systems confront, to provide deterrent penalties for IPR violations, and to encourage courts to impose those penalties. While the number of criminal IPR cases handled by the Attorney General appears to have increased during the past year, investigatory and prosecution efforts remain limited. The United States encourages Indonesia to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. The United States also urges Indonesia to address its serious market access barriers for IPR-intensive products. These barriers include measures imposing requirements that restrict the importation of medicines by foreign pharmaceutical companies, a troubling change to its customs valuation methodology for imported motion pictures, and continuing market access restrictions in the entertainment industry. The United States will continue to engage with Indonesia on these and other issues.

Israel

Israel remains on the Priority Watch List. While Israel has taken steps towards implementing an Understanding on IPR it concluded with the United States in 2010, further action is needed. The United States stands ready to work closely with the government of Israel in 2011 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 all Special 301 lists once the government enacted legislation that implemented Israel's obligations fully.

Israel has submitted legislation to the Knesset regarding the protection of pharmaceutical test data. The United States commends Israel for taking that important step, and looks forward to enactment of that legislation. To date, however, Israel has not submitted legislation to the Knesset regarding patent term extension or patent publication. The United States encourages Israel to submit bills to

the Knesset that fully implement the Understanding as soon as possible. Pursuant to the Understanding, once Israel submits appropriate legislation to the Knesset regarding those matters, the United States will move Israel to the Watch List.

Separately, the United States encourages Israel to accede to and implement the WIPO Internet Treaties. Doing so would strengthen Israel's IPR regime, and would afford rights holders with additional effective enforcement remedies against 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 State urges Israel to confirm that enterprises are criminally liable for end-user software piracy; it is currently unclear whether enterprises that engage in this activity are subject to prosecution. The United States encourages Israel to enforce judicial decisions requiring cable operators to compensate copyright holders for the unauthorized retransmissions 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. Progress in the enforcement of IPR in 2010 included improved cooperation between the copyright industry and enforcement authorities, as well as more vigorous enforcement against optical disc and book piracy. However, widespread copyright piracy (including book piracy and piracy of software programs in enterprises), as well as trademark counterfeiting, persist. The United States encourages Pakistan to provide *ex officio* authority to its enforcement officials, and to provide for deterrent-level penalties for IPR violations. Further work is needed to reform Pakistan's copyright law. The United States is encouraged that Pakistan's Intellectual Property Office has endorsed reform of the Copyright Ordinance, to conform that Ordinance to international standards. In addition, the United States continues to encourage Pakistan to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed 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 Pakistan on these and other issues.

Thailand

Thailand remains on the Priority Watch List. The United States is encouraged that senior level officials of the Royal Thai Government have shown a continuing commitment to improving IPR protection and enforcement. The United States is likewise encouraged that the government has implemented the Creative Economy initiative. In connection with that initiative, the government announced several public awareness and educational projects regarding IPR, and established a National Committee on Creative Economy. The United States also welcomes the formation of the Thai-U.S. Creative Partnership; intellectual property is an important component of many of the issues that this partnership will address. However, Thailand failed to make substantial progress on several key pieces of legislation that remain pending, including legislation to address landlord liability, legislation regarding unauthorized camcording of motion pictures in theaters, and legislation to provide Thai Customs officials with the authority to seize suspect goods absent a formal complaint by a rights holder. In addition, Thailand has also not enacted amendments to the Copyright Act that,

among other things, would implement the WIPO Internet Treaties. While IPR public awareness and education has improved, enforcement efforts remain weak and non-deterrent. Piracy and counterfeiting, including illegal downloading of pirated works from the Internet, and the theft of cable and satellite signals, remain rampant in Thailand, and the motion picture industry has reported a significant increase in unauthorized camcording of motion pictures in theaters. The United States continues to encourage Thailand to engage in a meaningful and transparent manner with all relevant stakeholders, including owners of IPR, as it considers ways to address Thailand's public health challenges while maintaining a patent system that promotes investment, research, and innovation. In addition, 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 encourages Thailand to make progress on its IPR initiatives and looks forward to working with Thailand on these and other matters.

Venezuela

Venezuela remains on the Priority Watch List. The protection and enforcement of IPR in Venezuela continued to deteriorate in 2010. The reinstatement of the 1955 Industrial Property Law, which followed Venezuela's 2006 withdrawal from the Andean Community, eliminated protections for certain formerly patentable inventions and created uncertainty about the status of protection for trademarks registered under the Andean Community law. Additionally, copyright piracy, including piracy over the Internet, as well as trademark counterfeiting, remain widespread. On a positive note, Venezuela passed a Law on Crime and Contraband in 2010, which imposes penalties for smuggling violations and provides for the seizure of goods that infringe IPR. This includes providing an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products. Overall, the United States urges Venezuela to make significant improvements to its regime for IPR protection and enforcement.

WATCH LIST

Belarus

Belarus remains on the Watch List. The United States continues to be concerned about the delayed implementation of the IPR commitments Belarus made under the United States-Belarus Trade Relations Agreement of 1993. Belarus took some positive steps in 2010 by amending its Law on Trademarks to protect trademarks on the Internet, and by developing a National Strategy for Intellectual Property. However, enforcement efforts continue to be weak and ineffective and counterfeit and pirated goods continue to be widely available. Belarus should provide enforcement officials with authority to effectively investigate cases, seize infringing goods, and prosecute IPR cases without waiting for a right holder to file a complaint. Furthermore, Belarusian law does not provide adequate scope for *ex parte* searches. The United States encourages Belarus to amend its copyright law to implement the obligations of the WIPO Internet Treaties. The Russia-Belarus-Kazakhstan Customs Union entered into force in July 2010, and the United States will be monitoring the implementation of provisions granting *ex officio* authority to Customs officials and the creation of a unified trademark database to determine if this results in improved protection

and enforcement. The United States urges Belarus to take further steps to improve its protection and enforcement of IPR.

Bolivia

Bolivia remains on the Watch List. The United States remains concerned about high levels of piracy and counterfeiting in Bolivia, including the availability of counterfeit medical products, and the overarching need to improve its IPR enforcement. The United States recommends that Bolivia address the problem of unclear lines of responsibility among Bolivian authorities, as well as the need for additional human and financial resources. The United States also recommends that Bolivia work to ensure that judicial authorities prosecute IPR violations efficiently. The United States encourages the new leadership at the Bolivian Intellectual Property Office to increase its efforts with respect to IPR enforcement, and to increase efforts to improve public awareness about IPR protection and enforcement. The United States will continue to monitor Bolivia's progress on these and other issues.

Brazil

Brazil remains on the Watch List. The United States is encouraged by recent improvements that Brazil made with respect to IPR protection and enforcement. Of note was a recent opinion by the Federal Attorney General that the Brazilian sanitary regulatory agency, ANVISA, does not have authority to review patentability requirements when analyzing pharmaceutical patent applications. Instead, the National Industrial Property Institute (INPI) is the only administrative agency with authority to decide questions of patentability with respect to patent applications. Enforcement actions have increased, under the coordination of the National Council to Combat Piracy (CNCP), and these increased actions included several major operations in the beginning of 2011. The United States encourages Brazil to continue this work in 2011. In addition, Brazil took steps to address a backlog of pending patent applications. However, piracy and counterfeiting persist at significant levels in Brazil, including book piracy and a reported growth in piracy over the Internet. While enforcement efforts improved, including a larger number of raids and seizures, stronger enforcement at the border and deterrent level sentences are still needed. The United States urges Brazil to ensure that any amendments to its copyright law provide strong protections and establish means to enable effective enforcement against IPR violations that are committed on the Internet. The United States also encourages Brazil to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products. The United States looks forward to working with Brazil on these and other matters, including under the new United States-Brazil Agreement on Trade and Economic Cooperation.

Brunei

Brunei remains on the Watch List. Brunei made efforts to address the widespread availability of pirated music through a collaborative effort that it undertook with retailers and the recording industry in 2009. However, despite those efforts, the recording industry reports a recent increase in the availability of pirated music in retail outlets in Brunei. In addition, there is a significant growth of illegal downloading of pirated works of all kinds from the Internet, ranging from entertainment

software and business software to audiovisual works, including movies and television programs. The United States encourages Brunei to redouble its enforcement efforts against pirated and counterfeit products, including by granting *ex officio* authority to law enforcement officials, conducting targeted raids, seizing pirated and counterfeit goods, educating the business community, pursuing criminal prosecutions, and imposing deterrent penalties. To strengthen its legal infrastructure for IPR protection and enforcement, Brunei should also take the necessary steps to update its IPR laws and regulations so that these address fully the challenges of e-commerce and transnational intellectual property crime. Such steps should include enactment of long-pending amendments to the copyright decree, the adoption of measures to strengthen enforcement authority, and the allocation of necessary resources to IPR protection and enforcement. The United States looks forward to engaging with Brunei on these and other issues.

Colombia

Colombia remains on the Watch List. The United States commends Colombia for acknowledging the importance of IPR by including IPR protection in its National Development Plan. Colombia has taken steps to address its patent backlog by hiring additional examiners and by digitizing its patent database. Colombia has also continued its efforts to combat IPR infringement through enforcement actions, and has improved not only coordination among agencies responsible for IPR enforcement, but also cooperation of such agencies with rights holder organizations. The United States remains concerned, however, that the lack of additional resources and training continue to hamper enforcement efforts. The United States encourages Colombia to develop an effective system to address patent issues expeditiously in connection with applications to market pharmaceutical products. The United States also encourages Colombia to develop a mechanism to improve enforcement against IPR piracy over the Internet, including through the identification of effective enforcement procedures for dealing with such infringement. Optical disc piracy also remains a concern and should be addressed. The United States looks forward to working with Colombia to address these and other issues in the coming year.

Costa Rica

Costa Rica remains on the Watch List. Costa Rica enacted legislation to implement its commitments under the CAFTA-DR last year, and made progress by reviving an interagency IPR task force, collecting enforcement statistics, and taking steps to address its patent backlog. However, questions remain about Costa Rica's commitment to effective protection and enforcement of IPR, and overall IPR enforcement remains inadequate. The United States urges Costa Rica to address the relevant authorities' unwillingness to initiate prosecutions for copyright and other violations. The United States also urges Costa Rica to make combating IPR violations a higher priority, and in particular, to devote more resources to enforcement efforts, to prosecute cases against criminal IPR infringers, and to impose deterrent penalties. The United States will continue to monitor these and other issues relevant to Costa Rica's implementation of its international obligations and of its commitments under CAFTA-DR.

Dominican Republic

The Dominican Republic remains on the Watch List. The Dominican Republic continued its efforts to implement its commitments under CAFTA-DR and the United States commends the Dominican Republic on its progress in combating television broadcast piracy. Additionally, the Dominican Republic has taken important steps to increase the efficiency and capacity of its patent office. However, the United States continues to be concerned about the persistence of various problems, including a need for increased cooperation among enforcement agencies, a failure to devote sufficient resources to IPR enforcement, and the failure to train enforcement officials. In addition, pirated and counterfeit goods remain widely available. The United States will continue to monitor the Dominican Republic's implementation of its bilateral and multilateral commitments to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and 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 looks forward to continuing its engagement on these and other matters with the Dominican Republic and will monitor the Dominican Republic's implementation of its commitments under CAFTA-DR.

Ecuador

Ecuador remains on the Watch List. The United States welcomes the progress Ecuador achieved with respect to IPR protection and enforcement in 2010. Ecuador's IPR undertakings included an enforcement campaign that Ecuador's Intellectual Property Institute (IEPI) initiated. That campaign includes efforts to work directly with shop owners at large markets to ensure that those shop owners do not offer pirated or counterfeit products. IEPI has also begun efforts to extend its services to other areas of the country and to facilitate access to patent information. Ecuador has expanded its IPR educational efforts by conducting a multimedia public awareness campaign and by training the public on IPR matters. However, there are still concerns about the widespread availability of pirated and counterfeit products in retail markets in Ecuador, and about the lack of specialized IPR courts. Such courts were required under Ecuador's 1998 IPR law. The United States encourages Ecuador to implement a recently promulgated regulation regarding protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. Ecuador should provide an effective system to address patent issues expeditiously in connection with applications to market pharmaceutical products. The United States will continue to monitor developments concerning compulsory licensing of pharmaceutical and agricultural chemical products in Ecuador, bearing in mind the discussion of the Doha Declaration on TRIPS and Public Health in Section I of this Report. The United States looks forward to continuing to work with Ecuador address these and other matters.

Egypt

Egypt remains on the Watch List. Egypt continued to make progress towards improving its IPR regime in 2010. One highlight was the establishment of the National Observatory for Industry Products, an organization that inspects goods for patent and trademark infringement. Egypt also conducted campaigns to raise public awareness about counterfeit pharmaceutical products. However, several obstacles to effective IPR protection and enforcement remain. These include

inadequate enforcement efforts, and a failure to provide additional training for judges who preside over IPR matters. In addition, Egypt should clarify its commitment to protect against unfair commercial use, as well as unauthorized disclosure, of undisclosed 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 engaging with Egyptian officials at the appropriate time on these and other matters.

Finland

Finland remains on the Watch List. 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 will continue to work with Finland to address this and other matters.

Greece

Greece remains on the Watch List. Greece made some progress in 2010, including by creating a Special IP Protection Department within its tax police, establishing special IPR courts, and by creating two new IPR divisions within the Ministry of Finance's Financial Crime Prosecution Agency. In addition, Greece amended its copyright law to provide for administrative fines against shops that sell illegal sound recordings. While the United States appreciates the impact of the financial crisis on various initiatives, the United States is concerned that steps that Greece took to improve the coordination of enforcement efforts did not continue in 2010 and that enforcement efforts remain weak. Greece has also made only incremental progress in implementing its 2009 IPR action plan. The United States urges Greece to take more sustained action against IPR infringement and ensure that the appropriate tools are available to address counterfeiting and piracy. The United States will continue to work with Greece to address these and other issues.

Guatemala

Guatemala remains on the Watch List. Guatemala continues to improve its IPR enforcement framework. The new IPR prosecutor has worked to improve enforcement efforts by increasing the number of investigations, issuing more fines, securing more convictions for IPR violations, and seizing a significant amount of pirated and counterfeit products. In addition, the interagency IPR working group has focused its efforts on the training of judges and officials, including training aimed at identifying and preserving evidence of counterfeit medications. Training efforts have also led to improved cooperation between the IPR prosecutor, enforcement agencies, and rights holders. However, piracy and counterfeiting remain widespread, and concerns remain that the resources available for enforcement activities may be inadequate. The United States encourages Guatemala to continue its efforts, despite recent budget cuts, and to focus its enforcement efforts against manufacturers of pirated and counterfeit goods. The United States looks forward to continuing engagement with Guatemala on these and other matters and will monitor Guatemala's implementation of its commitments under CAFTA-DR.

Italy

Italy remains on the Watch List with an Out-of-Cycle review to be conducted this year. Italy continued to make progress in improving its IPR protection and enforcement in 2010, including by increased cooperation among law enforcement officials and improved enforcement actions against certain types of IPR violations. The United States remains concerned that, overall enforcement against copyright piracy continues to be inadequate and that piracy over the Internet continues to grow, severely damaging the legitimate market for distribution of copyrighted works. The United States welcomes recent efforts to address piracy over the Internet, and looks forward to measures to help ameliorate this problem. Specifically, proposed regulations by the Italian Communications Authority (AGCOM) could provide rights holders with an avenue to curb IPR violations online in an effective manner. The United States encourages Italy to ensure that the AGCOM regulations are swiftly promulgated and implemented, that these regulations create an effective mechanism against copyright piracy over the Internet, and that they address all types of piracy that takes place online. The United States also encourages Italy to address other IPR issues, including a troubling Data Protection Agency ruling prohibiting the monitoring of peer-to-peer networks. While rights holders report good efforts by the Finance Police and the Customs Police, few cases reach final sentencing and courts still fail to impose deterrent level sentences. The United States will continue to work with Italy to address these and other matters.

Jamaica

Jamaica remains on the Watch List. Jamaica has continued to make progress by increasing its IPR enforcement and training efforts. Rights holders are also filing an increasing number of cases in the Jamaican court system. However, the United States urges Jamaica to improve its IPR protection and enforcement. To date, Jamaica has not enacted the Patents and Designs Act, which is intended to implement certain provisions of the TRIPS Agreement and the United States-Jamaica Bilateral Intellectual Property Agreement. The United States recommends that Jamaica provide for deterrent level sentences to be imposed against IPR infringers. The United States will continue to work with Jamaica to address these and other issues.

Kuwait

Kuwait remains on the Watch List. Customs authorities continue to make progress on enforcement against piracy and counterfeiting. However, enforcement efforts are hampered by the lack of coordination among different agencies, and by the judiciary's failure to impose deterrent penalties against IPR violators. The United States remains concerned that several key pieces of draft IPR legislation, particularly proposed amendments to the 1999 copyright law, have remained pending for many years. The United States continues to provide technical assistance in connection with Kuwait's legislative efforts and encourages Kuwait to enact and implement legislation to strengthen its IPR protections, and to improve its enforcement efforts. The United States will continue to work with Kuwait to address these and other matters.

Lebanon

Lebanon remains on the Watch List. Lebanon continued working to improve its IPR legislative framework in 2010. Lebanon's parliament ratified the WIPO Internet Treaties, and began work on amendments to the Patent Law to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products. In the fall of 2011, the Judicial Training Institute will, for the first time, include IPR courses in its training program for new judges. The United States hopes this will help increase judicial awareness of the importance of effective protection and enforcement of IPR. However, several other necessary legislative measures concerning IPR remain pending. Although the Cyber Crime and Intellectual Property Rights Bureau of the police department tried to improve its enforcement efforts, the Bureau still lacks *ex officio* authority. A rights holder must file a complaint before the Bureau may initiate a criminal investigation, and this presents a hurdle to effective IPR enforcement. Rights holders continue to assert that more effort is necessary to combat piracy and counterfeiting effectively, including counterfeiting of medicines. The United States will continue to work with Lebanon to address these and other matters.

Malaysia

Malaysia remains on the Watch List. Malaysia continues to make positive progress with respect to the protection and enforcement of IPR. In 2010, Malaysia introduced amendments to its copyright law that intended to, among other things, implement the WIPO Internet Treaties and prohibit unauthorized camcording of motion pictures in theaters. In addition, the Ministry of Domestic Trade, Cooperatives, and Consumerism (MDTCC) offered more cooperation with, and was more responsive to, rights holders on matters pertaining to IPR enforcement. MDTCC revived its Special Anti-Piracy Taskforce, which led to more effective enforcement efforts. The MDTCC also instructed its enforcement division to begin to take *ex officio* action in 2010, resulting in significant seizures of pirated products. The United States is encouraged by Malaysia's establishment of specialized IPR courts, and by the training on IPR that Malaysia has provided to prosecutors. Nonetheless, enforcement efforts are hampered by a lack of follow-up investigations and effective prosecutions. Pirated and counterfeit products continue to be widely available in Malaysia, and book piracy remains a significant problem. Industry also reports an increase in piracy over the Internet. The United States encourages Malaysia to provide an effective system to address patent issues expeditiously in connection with applications for marketing of pharmaceutical products, and to address continuing concerns regarding Malaysia's protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. The United States looks forward to working with Malaysia to make progress on these and other issues.

Mexico

Mexico remains on the Watch List. Overall, Mexico continued to make progress in its IPR enforcement efforts in 2010, although piracy and counterfeiting rates remain high. Following recent leadership changes in several key agencies, the United States encourages Mexico to sustain positive momentum. Progress in 2010 was reflected in a record number of convictions for IPR violations, including Mexico's first conviction for unauthorized camcording of motion pictures in theaters. The

2010 enactment of legislation granting *ex officio* authority to Mexico's law enforcement officials was also positive, although the United States continues to encourage Mexico to provide its Customs officials with *ex officio* authority. There was also an increase in the number of prosecutions and deterrent-level sentences, although not all IPR violations are prosecuted in a uniform, consistent manner. Cooperation among enforcement officials has continued to improve, but coordination at the federal, state and municipal levels remains weak. The United States continues to encourage Mexico to increase resources devoted to prosecuting IPR violations and to improve enforcement efforts at the border. The United States recommends that Mexico enact legislation to strengthen its copyright regime, including by implementing the WIPO Internet Treaties and by providing stronger protection measures against unauthorized camcording of motion pictures in theaters. The United States also recommends that Mexico provide protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. Furthermore, in light of a January 2010 Supreme Court decision interpreting Mexico's Linkage Decree, the United States also recommends that Mexico clarify its system for addressing patent infringement allegations during the pendency of a related application for marketing approval of a pharmaceutical product. The United States looks forward to continuing to work with Mexico to address these and other issues.

Norway

Norway remains on the Watch List. The United States is encouraged by a proposed amendment to the Norwegian copyright law providing for the blocking of downloading and streaming sites, as well as the use of formal guidelines for warning letters. The United States continues to be concerned about the lack of product patent protection for certain pharmaceutical products. U.S. industry has expressed concerns that 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 will continue to work with Norway to address this IPR concern. The United States will continue to work with Norway to address these and other matters.

Peru

Peru remains on the Watch List. Peru continued implementing its National Strategic Plan to combat counterfeiting and piracy. Peru also improved its enforcement efforts in 2010, including through action by its tax authority and its intellectual property office that led to significant raids and seizures at ports and at some of the largest and most well-known markets in Peru. However, additional resources are needed to expand on these enforcement efforts, and Peru should improve its border controls and judicial system. Peru should increase its efforts to prevent the government's use of unlicensed software as provided for under the United States-Peru Trade Promotion Agreement. Industry reports some possible improvements in Peru's system for protecting undisclosed test or other data submitted to obtain marketing approval for agricultural chemical products. However, the United States is concerned by recent developments in the protection of patents in Peru, and encourages Peru to clarify its protections for biotechnologically-derived pharmaceutical products. The United States looks forward to continuing to engage with Peru on these and other issues.

Philippines

The Philippines remains on the Watch List. The United States recognizes that in 2010 the Philippines took the important step of enacting legislation to address unauthorized camcording of motion pictures in theaters, and encourages the Philippines to enforce this new law effectively in order to deter the theft of motion pictures. However, despite an increase in enforcement efforts, pirated and counterfeit goods remain widely available in the Philippines. The Philippines should also enact legislation to amend its copyright law, which has been pending for many years. That legislation would, among other things, implement the WIPO Internet Treaties. The United States also encourages the Philippines to take steps to implement its 2011 IPR action plan. While additional efforts have been made to improve coordination among enforcement officials and to strengthen enforcement powers, the judicial system remains inefficient, with very few criminal IPR cases resulting in convictions over the last decade. In addition, the judiciary's decisions with respect to provisional measures, in particular on whether to maintain or revoke search and seizure orders, have not been predictable. The United States encourages the Philippines to continue efforts to reform its judicial system, including by designating particular courts to adjudicate civil and criminal IPR cases, and by promulgating specialized IPR procedural rules that would streamline the judicial process for IPR cases. 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 urges the Philippines to make progress in the short term to address these and other matters.

Romania

Romania remains on the Watch List. Romania took some positive steps in 2010 by disseminating manuals on addressing software piracy and by issuing instructions for interagency cooperation. Romanian officials have also actively participated in IPR training programs. However, the United States is concerned by an apparent decrease in commitment to IPR enforcement in Romania, reflected for example in reduced cooperation among enforcement authorities, decreased cooperation of police and prosecutors with rights holders, and a decrease in the number of enforcement actions. These developments may have resulted both from budgetary factors and from amendments to the criminal procedure code. Moreover, while the availability of infringing optical discs has decreased, piracy over the Internet, especially peer-to-peer downloading, continues to increase, and enforcement efforts have not addressed the problem effectively. The United States will monitor the effects of recent changes to the Penal Code which, among other things, provide for IPR cases to be adjudicated in lower-level courts, whose judges and prosecutors have much less IPR expertise. There is concern that this could have a negative impact on prosecutions and sentencing in IPR cases. The United States urges Romania to take steps to address judicial delays and the lack of deterrent-level sentences. The United States will continue to work with Romania to address these and other concerns.

Spain

Spain remains on the Watch List. The United States welcomes the recent passage of legislation that will provide a mechanism for rights holders to remove or block access to infringing content online. Spain has demonstrated a serious commitment to addressing piracy over the Internet with this initiative. The United States will monitor implementation of the legislation and urges Spain to

ensure that it addresses all forms of piracy over the Internet and that it provides for the swift removal of infringing content. The United States also urges Spain to continue to work to address additional concerns about piracy over the Internet, including the inability of rights holders to obtain identifying information necessary to prosecute online IPR infringers. Additionally, a 2006 Prosecutor General Circular that appears to decriminalize illegal peer-to-peer file sharing of infringing materials remains of concern. Delays in the adjudication of cases are common within Spain's judicial system, and judges do not appear to impose criminal penalties for IPR infringement crimes. The United States looks forward to continuing to work with Spain to address these and other concerns.

Tajikistan

Tajikistan remains on the Watch List. Tajikistan made progress in 2010 by ratifying the WIPO Performances and Phonograms Treaty. Once Tajikistan accedes to that treaty, U.S. and other foreign sound recordings may enjoy protection in Tajikistan. The United States encourages the Ministry of Foreign Affairs to complete its accession to the treaty in 2011. However, Tajikistan has yet to fully implement its IPR commitments under the 1993 United States-Tajikistan Trade Agreement. Additionally, concerns persist because, among other things, Tajikistan has not provided its authorities with *ex officio* authority in the area of border and criminal enforcement. The United States will continue to work with Tajikistan on these and other matters.

Turkey

Turkey remains on the Watch List. Turkey made progress in 2010 by establishing specialized IPR courts in three major cities, by increasing public awareness of IPR issues, and by undertaking IPR training initiatives. However, the United States urges Turkey to do more. Counterfeiting and piracy remain widespread, including piracy of books and of entertainment and business software, and there has been a reported increase in piracy over the Internet. While Turkey has ratified several international IPR treaties, such as the WIPO Internet Treaties in 2009, it should enact many legislative reforms in order to ensure strong protection and enforcement of IPR. Turkey's IPR enforcement efforts are increasing, and the United States encourages Turkey to improve interagency coordination and to provide additional training for judges on IPR laws and principles. U.S. industry continues to raise serious concerns regarding the export from, and transshipment through, Turkey of counterfeit and pirated products. There are reports that the Constitutional Court's dismissal of several trademark-related cases in 2008 has caused uncertainty with respect to the protection of the trademarks at issue in those cases. The United States encourages Turkey to clarify its protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approvals for pharmaceutical products. The United States will continue to work cooperatively with Turkey on these and other matters.

Turkmenistan

Turkmenistan remains on the Watch List. The United States is encouraged by the Parliament's recent announcements that Turkmenistan plans to join the Berne Convention for 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) in 2011. Reports that Turkmenistan plans to enact a new copyright law in 2011 are likewise positive. However, Turkmenistan has yet to implement fully the IPR provisions of the 1993 United

States-Turkmenistan Trade Agreement. Turkmenistan should also adopt more comprehensive administrative, civil, and criminal procedures for adjudicating IPR cases, and impose penalties for IPR infringement. Such steps would help to combat copyright piracy and trademark counterfeiting. Other steps that Turkmenistan should take include granting *ex officio* authority to its Customs officials to interdict suspected infringing materials at the border. The United States urges Turkmenistan to improve its IPR regime, including by adopting the necessary legal reforms to implement its commitments under the 1993 bilateral trade agreement. The United States looks forward to working with Turkmenistan on these and other matters.

Ukraine

Ukraine remains on the Watch List. Ukraine made some improvements in 2010, including by developing and adopting a highly publicized IPR action plan. The United States encourages Ukraine to meet the goals set forth in that action plan, which include addressing the government's use of unlicensed software, amending the Ukrainian copyright law, and increasing IPR enforcement. Overall enforcement efforts in Ukraine have not yet effectively addressed the widespread availability of counterfeit and pirated products, many of which are transshipped through Ukraine to third countries. Customs officials continue to lack *ex officio* authority to interdict shipments. Piracy over the Internet has reportedly increased, and the United States encourages Ukraine to adopt proposed legislation to provide an appropriate regime for notice and takedown. While Ukraine remains one of the world's leading distributors of unauthorized camcorderd movies, reports indicate that this illegal activity decreased significantly in 2010. The United States encourages Ukraine to improve the operation of its judicial system, which suffers from significant delays, a lack of deterrent-level sentences, and judges who lack relevant IPR expertise. The United States looks forward to engaging with Ukraine to address these and other issues and to assess the results of Ukraine's implementation of its action plan.

Uzbekistan

Uzbekistan remains on the Watch List. Uzbekistan has yet to fully implement its IPR-related commitments under the 1994 United States-Uzbekistan Trade Agreement. Uzbekistan's copyright law contains a number of gaps, and does not provide protection for preexisting works or for U.S. and other foreign sound recordings. Uzbekistan has also not joined the Geneva Phonograms Convention. While enforcement has improved slightly, criminal penalties for IPR infringement are not sufficient to deter further infringement. Additionally, amendments are needed to provide enforcement officials, including Customs officials, with *ex officio* authority to initiate investigations and enforcement actions. The United States will continue to work with Uzbekistan on these and other issues.

Vietnam

Vietnam remains on the Watch List. While Vietnam took steps to implement important amendments to its IP Law in 2010, the United States urges Vietnam to do more to ensure full implementation. Vietnam made positive progress in 2010 by clarifying certain administrative procedures. However, additional work is needed to streamline enforcement efforts and to improve coordination among enforcement authorities, including by making clear the respective areas of responsibility of the

various enforcement agencies. Although the General Department of Customs established an investigative IPR protection task force to focus efforts on protecting IPRs at the border, a range of IPR enforcement problems remain. These problems include high levels of copyright piracy, increasing levels of piracy over the Internet, satellite and cable signal piracy, and the general availability of counterfeit goods in the marketplace. The United States continues to encourage Vietnam's enforcement agencies to initiate more criminal prosecutions, and to impose deterrent-level sentences in appropriate cases. The United States encourages Vietnam to clarify its system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products. The United States will continue to engage with Vietnam under the U.S.-Vietnam Trade and Investment Framework Agreement to address these and other issues.

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 with the United States. That Memorandum will expire on December 31, 2011, and the United States will work with Paraguay on its renewal. Paraguay made notable progress in 2010, including by making its Specialized Technical Unit (UTE), which addresses IPR matters, a permanent unit, and by funding that unit. Paraguay enacted a law in July 2010 that clarifies and streamlines procedures for administrative IPR litigation. The National Customs Administration issued a series of resolutions on combating IPR violations, including one that creates a task force to monitor the prevention, detection, and reporting of IPR crimes. These efforts, as well as training that Paraguay has provided, have led to improvements in IPR enforcement. In addition, Paraguay appointed its first IPR judge. There have also been more prosecutions of IPR violators and more criminal investigations. However, concerns remain, in part because of the persistence of various forms of piracy and counterfeiting, both in-country and at the border. The United States encourages Paraguay to improve enforcement actions in the Tri-Border region, including by increasing its cooperation with Argentina and Brazil, and by intensifying its Customs actions to address cross-border trade in counterfeit and pirated products effectively. The United States continues to encourage Paraguay to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products. The United States also continues to encourage Paraguay to improve patent protection, and to continue its efforts to increase public awareness regarding IPR protection and enforcement. The United States looks forward to working with Paraguay on these and other issues bilaterally and through the Joint Committee on Trade and Investment.

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 intellectual property 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 intellectual property. Countries placed on the Priority Watch List are the focus of increased bilateral attention concerning the problem areas.

Additionally, under Section 306, USTR monitors a 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 exclusive rights and require signatories to provide effective legal remedies against the circumvention of certain technological measures that protect copyrighted content in online environments. A growing number of trading partners are implementing the WIPO Internet Treaties to create a legal environment conducive to investment and growth in Internet-related businesses, services, and technologies.

As of April 2011, there are 87 contracting parties of the WPPT and 88 contracting parties to the WCT. Other trading partners have implemented key provisions of these treaties in their national laws without formally ratifying them. The United States urges other governments to ratify and implement the provisions of the WIPO Internet Treaties.