

2010 Special 301 Report

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Prepared by the Office of the United States Trade Representative

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TABLE OF CONTENTS

EXECUTIVE SUMMARY	1
SECTION I. DEVELOPMENTS IN IPR PROTECTION AND ENFORCEMENT	5
Positive Developments	5
Initiatives to Strengthen IPR Internationally	7
Capacity Building Efforts	8
Trends in Counterfeiting and Piracy	9
Internet and Digital Piracy	11
Trademarks and Domain Name Disputes	12
Government Use of Software	12
Intellectual Property and Health Policy	12
Supporting Pharmaceutical and Medical Device Innovation through Improved Market Access	13
Implementation of the WTO TRIPS Agreement	15
WTO Dispute Settlement	16
SECTION II. COUNTRY REPORTS	19
PRIORITY WATCH LIST	19
China	19
Russia	23
Algeria	24
Argentina	24
Canada	25
Chile	25
India	26
Indonesia	26
Pakistan	27
Thailand	27
Venezuela	28
WATCH LIST	28
Belarus	28

Bolivia	29
Brazil	29
Brunei	29
Colombia	30
Costa Rica	30
Dominican Republic	31
Ecuador	31
Egypt	31
Finland	32
Greece	32
Guatemala	33
Italy	33
Jamaica	33
Kuwait	34
Lebanon	34
Malaysia	34
Mexico	35
Norway	35
Peru	36
Philippines	36
Romania	36
Spain	37
Tajikistan	37
Turkey	38
Turkmenistan	38
Ukraine	38
Uzbekistan	39
Vietnam	39
SECTION 306 MONITORING	40
Paraguay	40
STATUS PENDING	40
Israel	40
SECTION III. NOTORIOUS MARKETS	43
ANNEX 1. STATUTORY BACKGROUND ON SPECIAL 301	47
ANNEX 2. THE WIPO PERFORMANCES AND PHONOGRAMS TREATY (WPPT) AND THE WIPO COPYRIGHT TREATY (WCT)	49

EXECUTIVE SUMMARY

The “Special 301” Report is an annual review of the global state of intellectual property rights (IPR) protection and enforcement, conducted by the Office of the United States Trade Representative (USTR) pursuant to 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 serious concerns, ranging from troubling “indigenous innovation” policies that may unfairly disadvantage U.S. rights holders in China, to the continuing challenges of Internet piracy in countries such as Canada and Spain, to the ongoing systemic IPR enforcement challenges in many countries around the world. Positive accomplishments recognized in this year’s Report include improved efforts by trading partners the Czech Republic, Hungary, and Poland, all of whom have been removed from the Watch List. Additionally, after successful Out-of-Cycle Reviews in 2009, Saudi Arabia was removed from the Watch List, and Israel has entered into an understanding with the United States whereby it will address key outstanding IPR issues.

In the year ahead, USTR looks forward to working with our trading partners to address emerging and continuing concerns, and building on the positive results achieved thus far.

Public Engagement

Consistent with the goals articulated in the President’s 2010 Trade Policy Agenda, USTR has enhanced its 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 issues involving intellectual property and to help facilitate sound, well-balanced assessments of developments in particular countries.

USTR requested written submissions from the public through a notice published in the *Federal Register* on January 15, 2010. This year’s review yielded 571 comments from interested parties, a significant increase from 2009. The submissions received by USTR were made available to the public online at www.regulations.gov, docket number USTR-2010-0003. Further, on March 3, 2010, 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 included testimony from 23 witnesses, ranging from foreign governments to industry representatives to 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 close consultations with affected stakeholders, interested parties, foreign governments, the U.S. Congress, and of interagency discussions within the U.S. Government.

USTR, together with the interagency Special 301 subcommittee, works to make a well-balanced assessment of intellectual property protection and enforcement, as well as related market access issues, in accordance with the statutory criteria set out by Congress in the Special 301 statute (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 IPR Protection and Enforcement*. However, the assessment is especially based upon the particular facts and circumstances that shape IPR protection and enforcement regimes in a particular trading partner.

Going forward, USTR will continue to interact closely with the governments of the countries 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 to ensure that the U.S. position with the foreign country is well-informed by the full range of views on the pertinent issues;
- conduct extensive discussions with individual countries regarding their respective IPR regimes;
- encourage those countries to engage fully and with the greatest degree of transparency with the full 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 the countries with which it is engaging.

Additionally, USTR works closely with other agencies to ensure consistency of United States trade policy with other Administration policies. For example, USTR works closely with the Department of Health and Human Services to ensure consistency of the Administration's trade policy (including support for the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health) with the Administration's health policy.

2010 Special 301 List

The 2010 Special 301 review process examined IPR protection and enforcement in 77 countries. Following extensive research and analysis, USTR designates the 42 countries below as follows:

Priority Watch List: Algeria, Argentina, Canada, Chile, China, India, 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.

Status Pending: Israel.

2010 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 the trading partner on those issues. Successful resolution of specific IPR issues may in some circumstances lead to a change in a country's status on the Special 301 list outside of the typical time frame for the annual Special 301 Report. In 2010, USTR will conduct OCRs of the Philippines and Thailand to monitor progress on IPR protection and enforcement in those countries, and to consider again their Special 301 status.

Format of the Special 301 Report

The Special 301 Report is divided into the following three 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 in particular countries.
- **Section III: Notorious Markets** is a listing of Internet markets and physical markets of concern.
- **Annex 1** provides the statutory background for the Special 301 Report.

- **Annex 2** provides a list of contracting 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 IPR PROTECTION AND ENFORCEMENT

An important part of the mission of the United States Trade Representative is supporting and implementing the Administration's commitment to aggressively protect American intellectual property overseas. IPR infringement 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 can also endanger the public. Counterfeiting of some products, such as automobile parts and medicines, poses a real risk to health and safety. 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 and to the support of countless jobs in the United States, USTR works to protect American inventiveness and creativity with all the tools of trade policy, including this Report.

Positive Developments

Several countries made significant positive progress on IPR protection and enforcement in 2009 and early 2010. For example:

Countries being removed from the Special 301 Watch List:

- **Czech Republic** – The Czech Republic is being removed from the Special 301 Watch List because of significant progress made to effectively control its border markets over the past two years. Moreover, a new criminal code raising the maximum penalties for IPR related crimes from 2 to 8 years imprisonment and criminalizing the manufacture and storage of counterfeit items came into effect January 1, 2010. The United States will continue to monitor whether the new law results in the imposition of deterrent penalties.
- **Hungary** – Hungary is being removed from the Special 301 Watch List in recognition of the significant improvements on enforcement and other actions taken during the past year. Hungary has taken proactive steps to address the growing threat of Internet piracy, and its Customs and police officials have developed their ability to effectively identify infringing products. Through effective and consistent enforcement actions, Hungary has closed its notorious Verseny street market, which was home to an array of illegitimate products. Furthermore, Hungary has taken effective measures to protect IPR, including numerous public awareness raising campaigns and training and educational seminars for police, prosecutors, and judges. The United States will continue to monitor Hungary's progress to ensure that IPR protection and enforcement improvements are ongoing.

- **Poland** –Poland is being removed from the Special 301 Watch list in recognition of a significant reduction in the availability of pirated and counterfeit goods at border markets, increased and improved enforcement efforts, and to strong cooperation between rights holders and enforcement officials. The government has also taken some initial steps to address Internet piracy concerns. The United States will continue to monitor Poland’s progress to ensure that IPR protection and enforcement improvements are ongoing.

Results from the 2009 OCRs:

- **Fiji** – Fiji made progress on IPR enforcement during the 2009 OCR period and will not be placed on a list in the 2010 Special 301 Report. The United States encourages Fiji to continue its efforts to ensure that IPR are properly protected and enforced in the country, and will continue to monitor Fiji’s progress.
- **Israel** – The United States has recently concluded an understanding with Israel to address several longstanding issues with its IPR regime for pharmaceutical products. The understanding more closely aligns key aspects of Israel’s IPR system for pharmaceutical products with the levels of protection afforded by other countries at Israel’s advanced stage of development. The United States will continue to work with Israel through the implementation of this understanding and to address other outstanding concerns in IPR protection and enforcement.
- **Saudi Arabia** – Saudi Arabia significantly improved its IPR protection and enforcement regime and as a result was removed from the Watch List in February 2010, following the conclusion of an OCR. Enforcement, prosecutions, and transparency issues were successfully addressed in the past year, and the United States will continue to engage with Saudi Arabia to address remaining issues.

Other positive developments:

- **Sweden** – The government of Sweden has implemented several measures to improve its IPR regime within the past year. As a result of such efforts, many of the Bit Torrent tracker websites and DC-hubs (types of peer-to-peer protocols that allow users to either download files from websites containing links, or from a central hub with infringing material) that previously operated out of Sweden have now moved elsewhere. In their place, legal alternatives, such as Spotify, Film2Home, and Voddler have generated growing interest. Sweden’s implementation of the EU’s Enforcement Directive has increased public awareness of IPR protection.
- **EU** – In 2009 the European Union (EU) ratified the World Intellectual Property Organization (WIPO) Copyright Treaty (WCT) and the Performances and Phonograms Treaty (WPPT) (collectively, the “WIPO Internet Treaties”). This marked a significant

step forward for international norms of IPR protection, particularly with regard to Internet-based delivery of copyrighted works. With the EU's ratification of the WIPO Internet Treaties, there are now 88 members of the WCT and 86 members of the WPPT. These treaties have raised the standard of IPR protection around the world, particularly with regard to Internet-based delivery of copyrighted works.

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

Initiatives to Strengthen IPR 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:

- **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 worked 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 several countries, including many in the Middle East and Asia, have facilitated discussions on enhancing IPR protection and enforcement.
- **Anti-Counterfeiting Trade Agreement (ACTA):** The goal of the ACTA initiative is to work with trading partners in favor of strong IPR enforcement to achieve an agreement that raises the international standard for the enforcement of IPR. On April 21, 2010, the ACTA participants released the current draft of the ACTA text, following the 8th round of the ACTA negotiations in Wellington, New Zealand. USTR has made the draft text available to the public at www.ustr.gov/acta.
- **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), and regional programs such as the Caribbean Basin Economic Recovery Act (CBERA). USTR will continue to review IPR practices in Russia, Lebanon, and Uzbekistan under ongoing GSP reviews.
- **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 listed above, we anticipate engaging with our trading partners in initiatives such as the U.S.-EU Summit, our trilateral cooperation with Canada and Mexico, the Asia Pacific Economic Cooperation (APEC) forum, the Organization for Economic Cooperation and Development (OECD), and other multilateral and regional fora.

Capacity Building Efforts

In addition to identifying concerns, this Report also highlights opportunities for the U.S. Government to work collaboratively with trading partners to address those concerns. The U.S. Government collaborates on training and IPR-related capacity building with various partner countries around the world. Both in Washington D.C. and abroad, through bilateral collaborations and in regional groupings, the U.S. Government remains engaged in building stronger, more streamlined and more effective systems for the promotion, and protection and enforcement of IPR.

For example, in the United States, the U.S. Patent and Trademark Office (USPTO) invites training participants from around the world to its Global Intellectual Property Academy, which has over 75 training programs a year, focusing on a variety of topics from patent and trademark examination to IP management to technology transfer. 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 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 each year to cities across the U.S. to learn more about IPR and related trade and business issues. Other U.S. Government agencies hold well-attended conferences in Washington, such as the international program conducted by the U.S. Copyright Office, cosponsored by WIPO, which in March 2010 hosted developing countries and countries in transition for training on emerging issues in copyright and related rights and issues pertaining to blind and visually impaired persons.

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. These activities are conducted by a number of different agencies. For example:

- The USPTO's Office of External Affairs provides capacity building in countries around the world and has developed agreements with regional and international IP organizations, such as the African Regional Intellectual Property Organization (ARIPO) and Interpol, to partner on IPR training activities.

- The U.S. 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 which provide such training include the U.S. Department of Justice (DOJ), the USPTO, and the Department of Homeland Security's (DHS) bureau of Customs and Border Protection (CBP) and bureau of Immigrations and Customs Enforcement (ICE). In 2009, State Department funds supported 18 training events for over 1,500 Customs, police, and judicial officials from more than 21 developing countries, including Ukraine, Mexico, Russia, Vietnam, and Nigeria. 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 regional organizations, like the APEC Intellectual Property Experts Group (IPEG).
- The Department of Commerce's Commercial Law Development Program (CLDP) provides training to foreign lawmakers, regulators, judges, and educators seeking to improve the legal environment for doing business in their countries, including on IPR. CLDP currently works with more than 35 countries and has conducted cooperative programs in Central and Eastern Europe, the former Soviet Union, the Middle East, North Africa, Sub-Saharan Africa and Asia. For example, in April 2009, CLDP organized the Second National Workshop on Intellectual Property and Technology Commercialization in Manila, Philippines, jointly with the Philippines Intellectual Property Research and Training Institute (IPRTI).

These programs are often coordinated across many U.S. Government agencies.

Although many trading partners have implemented IPR legislation, the lack of criminal prosecutions and deterrent sentencing has left effective IPR enforcement to languish in many regions. Lack of knowledge regarding IPR law and policy on the part of judges and enforcement officials, and a lack of enforcement resources, are repeatedly cited as primary reasons for this growing concern. 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 Counterfeiting and 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 affects the profits of legitimate producers and impacts consumers whose lives and safety are at risk when they purchase fake goods. It also damages the economies of the countries in which it occurs by decreasing tax revenue and deterring investment. Counterfeiters and pirates 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 diversity in the types of goods that are being counterfeited, as well as the production of labels and components for these fake products. Exploiting free trade zones (FTZs), counterfeiters are establishing a global trade in counterfeit items, shipping them separately to FTZs to be assembled and distributed in another country. FTZs are also often used 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. Counterfeiters and pirates require little up-front capital investment and even if caught and charged with a crime, the penalties imposed in many countries are so low that they offer little or no deterrence against further infringements.
- A growth in the online sale of physical pirated and counterfeit products that is rapid and that is matching the volumes associated with street vendors and physical markets. Legal and investigative institutions face difficulties in responding to this trend. Online advertisements for sale of illegitimate physical goods that are delivered through the mail or by hand are found in many countries including China, Romania, and Ukraine. For example, in China, although the largest Internet-based sales portals have responded to rights holders' complaints of counterfeit and pirated product listings, 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.

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 that penalties 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, 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 not declaring that the bulk chemical is intended for use in pharmaceutical products. This contributes to China being a major source country for APIs used in counterfeit pharmaceutical products. Although China has taken some welcome steps, such as requiring manufacturers to register with the State Food and Drug Administration, more effective regulatory controls are needed to assist China and its trading partners in their efforts to address this problem.

Internet and Digital Piracy

While the increased availability of broadband Internet connections around the world is generating many benefits, from increased economic activity and new on-line business models to greater access to and exchange of information, this phenomenon has also made the Internet an extremely efficient vehicle for disseminating copyright-infringing products.

Internet piracy 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 concern in many countries, particularly China, and “linking sites,” many reportedly based in the Netherlands, 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 cellular telephones, palm devices, flash drives, and other mobile technologies. In some countries, these devices are being pre-loaded with illegal content before they are sold. In addition to piracy of music and films using these new technologies, piracy of ring tones, games, and scanned books also occurs. The United States will work with our trading partners to combat these growing problems. The United States urges governments to ratify and implement the WIPO Internet Treaties, which provide tools necessary for protecting copyrighted works in the digital environment.

Although Internet piracy 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 countries, such as Malaysia, the Philippines, and Romania, have made progress toward implementing controls on optical media production. Other countries still need to adopt and implement legislation or improve existing measures to combat illegal optical disc production and distribution, including China, India, Paraguay, and Thailand, which have not made sufficient progress in this area. The United States continues to urge its trading partners who face challenges of illegal optical media 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 ccTLDs lacking transparent and predictable uniform domain name dispute resolution policies (UDRPs). Effective UDRPs should assist in quickly and efficiently resolving these disputes.

The United States encourages our 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, United States Government agencies maintain procedures to ensure that they use 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 asset management 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 countries and territories mandating that only authorized, legitimate software may be used by government ministries. Further work on this issue remains with certain trading partners, such as China, Costa Rica, India, Pakistan, Paraguay, Peru, and Ukraine. The United States looks forward to these governments' adoption of effective and transparent procedures to ensure legitimate governmental use of software.

Intellectual Property and Health Policy

Numerous comments in the 2010 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 (Doha Declaration on TRIPS 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 country'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 our trading partners' rights to grant compulsory licenses, in a manner consistent with the provisions of the TRIPS Agreement, and encourages our 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 countries to address the serious public health problems that they may face. We strongly support 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 our bilateral and regional trade agreements are consistent with these views and do not impede the taking of measures necessary to protect public health. Accordingly, USTR will continue its close cooperation with the Department of Health and Human Services to ensure that public health challenges are addressed and the patent system 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 faced by U.S. pharmaceutical and medical device companies 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 country'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 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, France, Italy, 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. For example:

- With respect to Japan, pharmaceutical and medical device issues are an integral part of bilateral discussions. While Japan has made progress on these issues, the United States continues to press for improved transparency, which would facilitate the introduction of innovative pharmaceuticals and medical devices into Japan's market. Ways to improve transparency include ensuring meaningful opportunities for interested stakeholders to provide input into important regulatory, reimbursement, and pricing matters.
- With regard to Poland, the United States remains concerned about Poland's enactment in 2006 of a regulation that appears to reduce the official maximum wholesale and retail prices for imported drugs by 13 percent, while generally leaving the prices for drugs of Polish origin unchanged. The U.S. pharmaceutical industry reports that this regulation has had a significant impact by reducing prices for numerous products manufactured outside Poland. The United States is concerned that this regulation created an impediment to market access for this industry and will continue to monitor the situation in Poland throughout the coming year.

The United States is seeking to establish or continue dialogues with Organization for Economic Cooperation and Development (OECD) members and other developed economies 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. Separately, 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 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) requires all WTO members to provide certain minimum standards of IPR protection and enforcement, and was one of the most significant achievements of the Uruguay Round. 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 TRIPS 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 implementation. Additionally, the LDC members have until 2016 to implement their TRIPS obligations for patent and data protection for pharmaceutical products, as proposed by the United States at the Doha Ministerial conference of the WTO. The United States looks forward to the successful completion of this transition.

The United States will continue to work with WTO members and expects further progress in the near term towards completing their TRIPS 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 dispute settlement consultations.

The United States participates actively in the WTO TRIPS Council's scheduled reviews of WTO members' implementation of the TRIPS Agreement and also uses the WTO's Trade Policy Review mechanism to pose questions and seek constructive engagement on issues related to TRIPS implementation. Furthermore, the United States continues to work with other WTO members, including the European Union (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 therefore preferred manner of resolving our 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 ruling 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. The United States is working with China on its 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. These measures appear to be inconsistent with various WTO obligations of China. The U.S. claims challenged China's prohibition on foreign companies importing all of the products, China's prohibitions and discriminatory requirements imposed on foreign distributors of publications, music, and videos 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. As the United States and China were unable to resolve this dispute in these consultations, the United States filed a request for the establishment of a WTO panel. A WTO panel was established to examine this matter on November 27, 2007. On August

12, 2009, the panel rules in favor of the United States on the vast majority of its claims. Significantly, the panel also found that China's restriction on the right of foreign enterprises to import the products at issue was not justified by the exception in the GATT 1994 related to the protection of public morals, as China had argued. 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. On February 18, 2010, China notified the DSB that China intends to implement the recommendations and rulings of the DSB in this dispute, and stated it would need a reasonable period of time for implementation.

Following the 1999 Special 301 review, the United States initiated dispute settlement consultations concerning the European Union's (EU) regulation on food-related geographical indications (GIs), 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 ruling in favor of the United States that the EU GI regulation is inconsistent with the EU's obligations under the TRIPS Agreement and the General Agreement on Tariffs and Trade 1994. 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 will remain on the Priority Watch List in 2010 and will remain subject to Section 306 monitoring. China's enforcement of IPR and implementation of its TRIPS Agreement obligations remain top priorities for the United States. The United States is heartened by many positive steps the Chinese government took in 2009 with respect to these issues, including the largest software piracy prosecution in Chinese history, and an increase in the numbers of civil IP cases in the courts. The U.S. Government welcomes the continued and constructive discussions of these matters in the Joint Commission on Commerce and Trade (JCCT) and the JCCT Intellectual Property Rights Working Group. However, the overall level of IPR theft in China remains unacceptable.

The United States is also deeply troubled by the development of policies that may unfairly disadvantage U.S. rights holders by promoting "indigenous innovation" including through, among other things, preferential government procurement and other measures that could severely restrict market access for foreign technology and products.

China's IPR enforcement regime remains largely ineffective and non-deterrent. Widespread IPR infringement continues to affect products, brands and technologies from a wide range of industries, including movies, music, publishing, entertainment software, apparel, athletic footwear, textile fabrics and floor coverings, consumer goods, chemicals, electrical equipment, and information technology, among many others. The share of IPR-infringing product seizures at the U.S. border that were of Chinese origin was 79 percent in 2009, a small decrease from 81 percent in 2008.

The U.S. copyright industries report severe losses due to piracy in China. Trade in pirated optical discs continues to thrive, supplied by both licensed and unlicensed factories as well as by smugglers. These pirated optical discs are exported to markets across the region, impacting legitimate sales outside of China as well. Small retail shops continue to be the major commercial outlets for pirated movies and music. The theft of software, books and journals also remain key concerns. Business software theft by enterprises is particularly troubling as it not only results in lost revenues to software companies but also lowers the business costs of offending enterprises, and may give these firms an unfair advantage against their law-abiding competitors.

Strong action to curb trademark counterfeiting and copyright piracy on the Internet is critical to the future of IPR enforcement in China. China should significantly increase criminal

prosecutions and other enforcement actions against Internet-based piracy and counterfeiting operations through a sustained national effort backed by appropriate resources. A recent internet enforcement campaign in which 558 cases were investigated and 375 websites were shut down demonstrates that when the Chinese government chooses to utilize its enforcement resources and personnel to deal with an IPR problem, it can produce results. The United States notes that at times particular enforcement actions are directed not only at copyright or trademark infringement, but also include infringement activities that may be considered more serious under the Chinese legal system. There is a concern that such actions lead to the public perception that the enforcement authorities are not focused on enforcing intellectual property specifically. This perception can be reinforced when effective enforcement measures are not taken against well-known infringers. The United States urges the Chinese government to demonstrate consistent resolve when fighting piracy and counterfeiting on the Internet by taking firm action against such infringers, so that they will adjust their business models to respect intellectual property laws, and thereby send a strong signal throughout the country.

Additionally, in October 2009, in response to allegations that some state-run libraries were providing unauthorized electronic copies of scientific and medical journal articles to for-profit entities, the NCAC, the Ministry of Education, the Ministry of Culture, and the National Anti-Pornography Office issued the *Notice on Strengthening Library Protection of Copyright*, which directs libraries to strictly adhere to the disciplines of the *Copyright Law*. This was a welcome step, and the United States will monitor implementation of this directive in 2010. In particular, the United States will look to the Chinese authorities to implement this directive through unannounced audits and inspections. Emphasis should be placed on preventing the unauthorized commercial sale of journals, either directly to consumers or through online intermediaries. Counterfeiting remains pervasive in many retail and wholesale markets. This problem continues in spite of significant attention and resources from brand owners, administrative supervision, civil lawsuits, agreements with landlords, and attention from China's central government and from foreign governments. There have been some improvements, including judicial enforcement related to infringing activities in retail markets in Beijing and Shanghai. Other welcome steps include judicial authorities sentencing wholesalers to prison terms, and holding retail market landlords liable for failing to take appropriate measures to prevent infringement. Unfortunately, outside Beijing and Shanghai, there have been limited efforts to hold landlords liable for infringement that occurs on their premises. Even in Beijing and Shanghai, the relatively minor penalties levied by courts, and examples of landlords and infringers ignoring applicable court rulings, indicate that additional measures, including criminal sanctions, will be necessary to bring this problem under control.

There are a number of other obstacles to effective enforcement. These include high value and volume thresholds that must be met in order to initiate criminal prosecution of IPR infringement. U.S. trademark and copyright industries report that administrative fines are too low, and imposed

too infrequently, to provide deterrence. Consequently, infringers view administrative seizures and fines merely as a cost of doing business. Civil damages for infringement are likewise inadequate.

Exacerbating its enforcement difficulties, China maintains market access barriers, such as import restrictions and restrictions on wholesale and retail distribution, which can discourage and delay the introduction into China's market of a number of legitimate foreign products that rely on IPR. The United States challenged certain restrictions in connection with a WTO dispute filed in April 2007. (See Section I above for further information.)

China's market access barriers create additional incentives to infringe products such as movies, video games, and books, and lead consumers to the black market, thereby compounding the severe problems already faced by China's enforcement authorities. An example of such a barrier is a Ministry of Culture circular regarding digital music was issued in September 2009. That circular bars providers of imported – but not domestic – digital music from distributing their content online unless they obtain content approval, and meet unrealistic obligations, such as entering into mandatory exclusive licensing arrangement with a wholly Chinese-owned entity. The United States is also very concerned about a troubling trend whereby China adopts policies that unfairly advantage domestic or “indigenous” innovation over foreign innovation and technologies. In November 2009, Chinese government agencies issued the Circular on *Launching the 2009 National Indigenous Innovation Product Accreditation Work*, requiring companies to file applications by December 2009 for their products to be considered for accreditation as “indigenous innovation products.” This Circular, and revisions to it issued in April 2010, provides for subsequent catalogs to be issued that provide preferential treatment in government procurement to any products that are granted this accreditation. Provinces and municipal governments have also reportedly issued their own “indigenous innovation” catalogs related to government procurement. The Circular, and the April 2010 revisions, contain provisions that allow Chinese authorities to require that R&D on products receiving accreditation be conducted, at least partially, in China. The United States has raised concerns regarding this and other problematic criteria with Chinese authorities.

Draft *Regulations for the Administration of the Formulation and Revision of Patent-Involving National Standards*, released for public comment in November 2009 by the Standardization Administration of China (SAC), raise concerns regarding their expansive scope, the feasibility of certain patent disclosure requirements, and the possible use of compulsory licensing for essential patents included in national standards. If adopted in their current form, these provisions may have the unintended effect of undermining the incentives for innovation and, by discouraging foreign rights holders from participating in the development of standards in China, depriving the standard setting process of potentially superior technology.

With respect to patents, on October 1, 2009, the *Third Amendment to China's Patent Law*, passed in December 2008, went into effect. While many provisions of the Patent Law were clarified and improved, rights holders have raised a number of concerns about the new law and implementing regulations, including the effect of disclosure of origin requirements on patent validity, inventor remuneration, and the scope of and procedures related to compulsory licensing, among other matters. The United States will closely follow the implementation of these measures in 2010.

The United States encourages China to provide an effective system to expeditiously address patent issues in connection with applications to market pharmaceutical products. Additionally, the United States continues to have concerns about the extent to which China provides effective protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products.

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 work with China on IPR enforcement and protection strategies, innovation policies, and the range of other important IPR-related matters in our bilateral economic relationship, including through the Joint Commission on Commerce and Trade (JCCT) and other fora.

Provincial and local issues

Progress, or lack thereof, in protecting and enforcing IPR in China can vary greatly by region. For example, industry stakeholders continue to identify Shanghai municipality as a bright spot in China's IPR landscape. Stakeholders hope that additional improvements may result from Shanghai's hosting of the 2010 World Expo. Neighboring Zhejiang province has also shown progress. Zhejiang courts have set an example of transparency by publishing IPR decisions on the Internet. In 2009, Zhejiang undertook more trademark infringement investigations than any other Chinese province, thereby highlighting both the increasing responsiveness of officials to industry requests for enforcement, and the scale of the problem in the province.

Jiangsu province, with its focus on promoting high technology, has demonstrated its recognition of the importance of IPR protection, including through a Suzhou court's criminal sentences in a high-profile software piracy case. However, right holders continue to express frustration at the level and scale of counterfeit manufacturing in Guangzhou province, one of China's largest manufacturing hubs. Enforcement is undermined by inconsistencies with respect to matters such as the valuation methodologies for calculating damages, fines, and penalties. Moreover, fines and penalties are not deterrent and the numbers of criminal IPR cases that are initiated is too low to bring about measurable improvements in the region.

Generally, IPR enforcement at the local level is hampered by poor coordination among Chinese government ministries and agencies, local protectionism and corruption, high thresholds for initiating investigations and prosecuting criminal cases, lack of training, and inadequate and non-transparent processes. As in the past, the United States will continue to review the policies and enforcement situation in China at the sub-national levels of government.

Russia

Russia will remain on the Priority Watch List in 2010. While Russia has made some progress over the past several years in improving IPR protection and enforcement, concerns remain, particularly with respect to Russia's continued failure to implement fully its commitments in the November 2006 Bilateral Agreement on Protection and Enforcement of Intellectual Property Rights ("IPR Bilateral Agreement").

In the IPR Bilateral Agreement, Russia committed to fight optical disc and Internet piracy, enact legislation to protect against unfair commercial use of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, deter piracy and counterfeiting through enhanced criminal penalties, strengthen border enforcement, and conform its laws to international IPR norms. Russia's continued delays in fully implementing this Agreement are particularly troubling, since, with respect to several of the obligations, the IPR Bilateral Agreement established an agreed-upon deadline of June 1, 2007. While the amendments to the Civil Code and Customs Code have been introduced into the Duma they have not yet become law. Amendments to the Law on Medicines were enacted in 2010; they did not implement the provisions of the IPR Bilateral Agreement on protection of pharmaceutical test data.

The United States urges Russia to strengthen its enforcement efforts against piracy and counterfeiting, which remain major concerns. The U.S. copyright industries report significant losses due to copyright infringement, especially through online piracy, which has continued to grow. Despite the closing of some illegal websites offering pirated music, many more have sprung up in their place. In 2009, Russian law enforcement agencies conducted raids on optical disc production facilities suspected of engaging in pirate activities; however, many surprise raids are minimally effective because the date and time of pending raids is often leaked to the optical disc plant in advance. While the level of cooperation among Russian agencies in optical disc raids is increasing, the quality of raids, and the level of police expertise, is uneven nationwide. A number of factors limit the effectiveness of raids, including the monetary damages threshold required to initiate criminal actions, and the general reluctance of prosecutors to initiate criminal cases in the field of IPR, even when there is evidence of a violation of criminal code provisions.

In addition, rights holders continue to report counterfeiting of trademarked goods as a problem, especially for consumer goods, distilled spirits, agricultural chemicals, biotechnology, and pharmaceuticals.

On a positive note, industry reports that legitimate DVD sales in Russia are on the rise, in part due to increased law enforcement action in this area, including a 2008 ban on camcording in movie theaters, and a growing preference for high quality products. While in the past U.S. firms complained about “trademark squatting” by Russian enterprises attempting to appropriate well-known trademarks, rights holders have recently been more successful in countering these schemes through the Russian court system or the Russian Federal Service for Intellectual Property, Patents, and Trademarks (Rospatent). In an effort to advance administrative IPR protection, a specialized higher patent chamber at Rospatent has brought greater expertise and efficiency to the adjudication of patent and trademark disputes. Industry has also reported a decline in the estimated business software piracy rate in Russia. Industry attributed the decrease to software legalization programs, government engagement, user education, and enforcement.

Algeria

Algeria will remain on the Priority Watch List in 2010. The United States continues to have serious concerns regarding an Algerian law that bans numerous imported pharmaceutical products and medical devices in favor of local production. Additional concerns remain over 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. Industry continues to raise concerns over the weak protection of patents in Algeria. Copyright piracy is also of concern, as is the overall weakness of Algerian enforcement efforts. The United States encourages Algeria to continue its WTO accession efforts and will continue to work with Algeria to address these IPR concerns.

Argentina

Argentina will remain on the Priority Watch List in 2010. The United States encourages Argentina to increase its efforts to combat rampant piracy and counterfeiting. Although industry reports continued cooperation with Argentine Customs and other law enforcement authorities in 2009, they also observe continuing enforcement challenges. Copyright piracy continues to present a problem, and industry reports concerns about growing Internet piracy. Positive developments in 2009 included an increase in the term of protection for sound recordings and performances, Argentina’s conclusion of an agreement with local universities to curb book piracy, and significant seizures of counterfeit goods by Customs. Problems persist in the civil and criminal enforcement areas, however, including ineffective civil damages, non-deterrent penalties in criminal cases, and delays in the adjudication of IPR infringement cases. Argentina also continues to face a backlog of patent applications. 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 will continue to monitor and assist with Argentina's efforts to address these IPR concerns.

Canada

Canada will remain on the Priority Watch List in 2010. The United States looks forward to the government of Canada's implementation of its previous commitments, recently reaffirmed in 2010, to improve IPR protection, and is encouraged by the high level of cooperation between the Canadian and United States governments on IPR matters. However, Canada has not completed the legislative reforms in the copyright area that are necessary to deliver on its commitments. The United States urges Canada to enact legislation in the near term to update its copyright laws and address the challenge of Internet piracy. Canada should fully implement the WIPO Internet Treaties, which Canada signed in 1997. Canada's weak enforcement of intellectual property rights is also of concern, and the United States continues to encourage Canada to improve its IPR enforcement system to provide for deterrent sentences and stronger enforcement powers. In particular, border enforcement continues to be weak. The United States encourages Canada to provide its border officials with the authority to seize suspected infringing materials without the need for a court order. The United States will continue to follow Canada's progress toward implementing an adequate and effective IPR protection and enforcement regime, including its progress on actions to address Internet piracy and improve border enforcement.

Chile

Chile will remain on the Priority Watch List in 2010. The United States continues to engage in discussions with Chile concerning the implementation of Chile's IPR commitments under the U.S.-Chile Free Trade Agreement (FTA). The United States notes that Chile took positive steps in 2009 and early 2010, including the creation of the National Institute for Industrial Property to oversee industrial property registration and protection, undertaking law enforcement actions targeting sale of counterfeit and pirated products, and engaging in constructive cooperation between rights holders and enforcement officials. In early 2010, Chile enacted amendments to its intellectual property law, including measures designed to implement a number of commitments under the FTA. However, it appears that the legislation fell short of fully addressing Chile's multilateral and bilateral commitments. For example, the legislation did not include protections against the circumvention of technological protection measures. The United States remains concerned that the relatively low rate of prosecutions and the tendency to apply minimum sentences for counterfeiting and piracy in Chile may not effectively deter future infringement. Chile can take quick action on laws that would ratify the International Convention for the Protection of New Varieties of Plants (UPOV Convention) (1991) and the Trademark Law Treaty. The United States positively notes that the U.S. pharmaceutical industry has indicated that authorities in Chile have signaled a willingness to discuss issues of importance to the industry. However, the United States remains concerned about inadequate 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 urges Chile to provide an effective system to address patent issues expeditiously in connection with applications to market pharmaceutical products. The United States looks forward to working with Chile's new administration on its implementation of Chile's IPR commitments in the FTA.

India

India will remain on the Priority Watch List in 2010. India continues to make gradual progress on efforts to improve its legislative, administrative, and enforcement infrastructure for IPR. India has made incremental improvements on enforcement, and its IP offices continued to pursue promising modernization efforts. Among other steps, the United States is encouraged by the Indian government's consideration of possible trademark law amendments that would facilitate India's accession to the Madrid Protocol. The United States encourages the continuation of efforts to reduce patent application backlogs and streamline patent opposition proceedings. Some industries report improved engagement and commitment from enforcement officials on key enforcement challenges such as optical disc and book piracy. However, concerns remain over India's inadequate legal framework and ineffective enforcement. Piracy and counterfeiting, including the counterfeiting of medicines, remains widespread and India's enforcement regime remains ineffective at addressing this problem. Amendments are needed to bring India's copyright law in line with international standards, including by implementing the provisions of the WIPO Internet Treaties. Additionally, a law designed to address the unauthorized manufacture and distribution of optical discs remains in draft form and should be enacted in the near term. The United States continues to urge India to improve its IPR regime by providing stronger protection for patents. One concern in this regard is a provision in India's Patent Law that prohibits patents on certain chemical forms absent a showing of increased efficacy. While the full import of this provision remains unclear, it appears to limit the patentability of potentially beneficial innovations, such as temperature-stable forms of a drug or new means of drug delivery. The United States also encourages India to provide protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. The United States encourages India to improve its criminal enforcement regime by providing for expeditious judicial disposition of IPR infringement cases as well as deterrent sentences, and to change the perception that IPR offenses are low priority crimes. The United States urges India to strengthen its IPR regime and will continue to work with India on these issues in the coming year.

Indonesia

Indonesia will remain on the Priority Watch List in 2010. Indonesia was placed on the Priority Watch List in 2009 because of the overall deterioration of the IP protection and enforcement climate, and a lack of follow-through on earlier promising steps. Although enforcement efforts against pirated optical discs continue, the overall level of enforcement remains insufficient to address the country's major piracy and counterfeiting problem, including with respect to the

counterfeiting of pharmaceutical products. Concerns remain over weaknesses in the IPR enforcement system, including an unreliable judicial system for IPR cases, a low number of criminal prosecutions, and non-deterrent penalties. Regulations intended to implement the Customs law amendments passed more than two years ago are still pending. Indonesia should provide effective protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. Serious market access barriers remain, including a law imposing requirements that restrict the importation of medicines by foreign pharmaceutical companies. The United States urges Indonesia to strengthen its IPR protection and enforcement regime.

Pakistan

Pakistan will remain on the Priority Watch List in 2010. There were various improvements with respect to IPR protection in 2009, including the government's recognition of IPR protection as a key area in its economic reforms, and enhanced coordination of IPR enforcement efforts. Pakistan established IPR investigation and intelligence units within the Federal Investigative Agency and Customs authorities and made progress in enforcement efforts against the manufacture of infringing optical discs. Another positive development was the establishment of an e-filing system for patent applications. However, serious concerns remain about inadequate IPR protection and enforcement. The United States continues to encourage Pakistan to provide effective protection against unfair commercial use, as well as unauthorized disclosure, of pharmaceutical test or other data generated to obtain marketing approvals for pharmaceutical products. Pakistan also lacks an effective system to address patent issues expeditiously in connection with applications to market pharmaceutical products. The United States encourages Pakistan to strengthen enforcement against book and optical disc piracy, to aggressively prosecute IPR crimes, and to seek deterrent sentences for IPR infringers. The United States will continue to monitor Pakistan's efforts to address these and other shortcomings in Pakistan's IPR protection and enforcement regime.

Thailand

Thailand will remain on the Priority Watch List in 2010 with an Out-of-Cycle Review (OCR) to be conducted this year. The United States is encouraged by the Royal Thai government's senior level commitment to stronger IPR protection and enforcement through the creation of the National Task Force, and its action plan to improve its IPR regime. Under this action plan, Thailand acceded to the Patent Cooperation Treaty, implementation of which should help to expedite patent application processing. Thailand also proposed legislation to address landlord liability for infringement, to address illegal camcording, and to enhance the authority of Thai Customs to take enforcement actions *ex officio*. Thailand is also considering possible amendments to its patent law, as well as amendments to its copyright law to implement the WIPO Internet Treaties. The United States looks forward to the passage and implementation of appropriate laws to strengthen IPR protection and enforcement in Thailand. In 2009, Thailand

increased IP awareness campaigns and enforcement efforts. However, piracy and counterfeiting remain widespread, and industry reports a growing challenge in the areas of Internet, cable, and signal piracy. In the pharmaceutical sector, the United States encourages Thailand to engage in a meaningful and transparent manner with all relevant stakeholders, including owners of intellectual property rights, 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. Overall, the United States encourages Thailand to continue its efforts to strengthen its IPR protection and enforcement regime, and looks forward to working with Thailand in the coming year through the OCR.

Venezuela

Venezuela will remain on the Priority Watch List in 2010. The protection and enforcement of intellectual property rights in Venezuela continued to deteriorate in 2009 following the trend witnessed in previous years. In 2006, when Venezuela withdrew from the Andean Community, it reinstated the 1955 Industrial Property Law. That version of the law prohibits patents for pharmaceuticals, foodstuffs, and other products. The reinstatement of the 1955 law also creates uncertainty as to whether trademarks previously registered under the Andean Community law will be recognized. In 2009, Venezuela revoked two pharmaceutical patents for antibiotics after a foreign company sued domestic producers of generic copies. The United States urges Venezuela to provide protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products. Additionally, the United States remains concerned about widespread copyright piracy. The United States urges Venezuela to improve its IPR protection and enforcement efforts.

WATCH LIST

Belarus

Belarus will remain on the Watch List in 2010. The United States remains concerned about Belarus' delayed implementation of IPR commitments under the United States-Belarus Trade Relations Agreement. Positive steps in 2009 included Belarus' adoption of amendments to its trademark law, including amendments to provide greater protection for well-known trademarks. Amendments to the copyright law are still needed to implement obligations of the WIPO Internet Treaties. In addition, the government should take action to ensure the use of licensed software by government entities. Counterfeit and pirated goods, including pre-release films, continue to be widely available. Enforcement officials continue to lack *ex officio* authority to investigate, seize infringing goods, and prosecute IPR cases, and Belorussian law does not allow adequate scope for *ex parte* searches. Reports indicate that IPR enforcement remains largely non-existent.

The United States plans to monitor the impact of the recently formed Russia-Belarus-Kazakhstan Customs Union on the border enforcement of IPR and on Belarus' WTO accession. The United States continues to urge Belarus to strengthen its IPR laws and to take enforcement actions against piracy and counterfeiting.

Bolivia

Bolivia will remain on the Watch List in 2010. Piracy and counterfeiting, including counterfeiting of medicines, continue to be widespread in Bolivia. There continues to be a need for significant improvements to the Bolivian IPR regime. The Bolivian copyright law should be amended to conform to international standards. Despite a notable enforcement action resulting in the seizure of more than 30 tons of counterfeit pharmaceutical products and corresponding prosecutions, substantial additional resources and a commitment by enforcement and judicial authorities are needed to improve enforcement actions against piracy and counterfeiting. The United States continues to urge Bolivia to improve its IPR protection and enforcement regimes, and to further its IPR enforcement efforts.

Brazil

Brazil will remain on the Watch List in 2010. Brazil continued to show a commitment to fighting counterfeiting and piracy and to strengthening its enforcement efforts; however, significant levels of piracy and counterfeiting continue. Affected industries report positive cooperation with law enforcement, and the National Council to Combat Piracy has issued a new action plan to combat piracy. Nevertheless, concerns remain over border enforcement and the lack of expeditious and deterrent sentences. The United States encourages Brazil to continue to improve its enforcement actions, as well as strengthen its IPR legislation by acceding to and fully implementing the WIPO Internet Treaties. The planned revision of its copyright law, expected in 2010, is a promising opportunity. Industry reports heightened concerns about Internet piracy, and book piracy also remains a concern. Patent concerns remain, including about the scope of patentability and the uncertain role of ANVISA, Brazil's sanitary regulatory agency, in examination of certain patent applications. Brazil also does not provide for the adequate protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. The United States will continue to engage with Brazil to resolve IPR concerns the U.S.-Brazil Bilateral Consultative Mechanism and other relevant bilateral fora.

Brunei

Brunei will remain on the Watch List in 2010. Brunei made notable progress in 2009. Local retailers and recording industry representatives coordinated efforts to remove pirated music from stores. Additionally, retailers and recording industry representatives cooperated in an anti-piracy campaign. There have been some improvements in prosecuting IPR infringers, demonstrated by a recent conviction in a business software case. However, retailers continue to sell pirated

goods, and many appear to go unpunished by the authorities. Amendments to Brunei's copyright law that would strengthen enforcement authority have been pending for years. Brunei should sustain its recent efforts to enforce against the retail sale of pirated goods through consistent raids, prosecutions, and deterrent penalties, and by passing needed amendments to the copyright law. The United States will continue to engage with Brunei to encourage the continuation of efforts to improve IPR protection and enforcement.

Colombia

Colombia will remain on the Watch List in 2010. Colombia continues to improve its efforts to combat IPR infringement through enforcement actions. Coordination of the many agencies responsible for enforcing IPR improved in 2009; however, these agencies need additional training and resources. There are also concerns over the lack of deterrent sentences. Another area of improvement has been the reduction in patent approval times from more than six to less than five years, in keeping with commitments Colombia made during the U.S.-Colombia Trade Promotion Agreement negotiations. 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 infringement on the Internet, and notes that optical disc piracy remains a concern. The United States looks forward to working with Colombia to address these issues in the coming year.

Costa Rica

Costa Rica will remain on the Watch List in 2010. To implement IPR commitments in the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR), Costa Rica passed legislation providing for stronger IPR protection and enforcement. Technical corrections to this legislation are pending. In addition, Costa Rica recently published regulations to provide for the protection of undisclosed information submitted in support of the registration of new agricultural chemical products in Costa Rica. The United States remains concerned, however, about weak IPR enforcement in Costa Rica, particularly with respect to copyright piracy and trademark counterfeiting. Of particular concern is the lack of willingness by the relevant authority to initiate prosecutions for copyright and other IPR violations. The United States strongly encourages the government of Costa Rica to address the shortcomings in its IPR enforcement system by assigning higher priority and greater resources to combating piracy and counterfeiting, by bringing cases against individuals and organizations engaged in criminal IPR infringements, and by providing deterrent penalties for these crimes. The United States will continue to monitor Costa Rica's implementation of its international obligations and IPR commitments under CAFTA-DR.

Dominican Republic

The Dominican Republic will remain on the Watch List in 2010. The Dominican Republic continued its efforts to implement its commitments under CAFTA-DR, but enforcement remains weak and requires improved coordination, additional resources, and training of enforcement personnel. The United States recognizes and appreciates that there were some improvements in 2009 with respect to the government's use of licensed software and television broadcast piracy, but we remain concerned that pirated goods continue to be widely available. The United States is also concerned about excessive delays in the issuance of patents. The United States will continue to monitor the Dominican Republic's implementation of its bilateral and multilateral obligations to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approvals for pharmaceutical and agrochemical 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 future cooperation on IPR matters with the Dominican Republic, and will continue to monitor the Dominican Republic's implementation of its IPR commitments under CAFTA-DR.

Ecuador

Ecuador will remain on the Watch List in 2010. Ecuador's Intellectual Property Institute continued to make progress in 2009 by continuing to reduce the processing time of patent applications, and by working to implement an electronic system for patent and trademark applications. The government is also undertaking public awareness and training efforts. However, serious concerns remain about overall IPR enforcement efforts, which decreased in 2009. Industry reported increases in piracy of music, movies, books, and business and entertainment software. Dedicated IPR units created in 2008 appear to lack the level of specialization required to be effective, and Ecuador has not yet established the specialized IPR courts required under its 1998 IPR law. The United States encourages Ecuador to provide effective protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, as well as to provide an effective system to address patent issues expeditiously in connection with applications to market pharmaceutical products. The United States will continue to monitor recent 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 urges Ecuador to continue public awareness campaigns, and to strengthen its IPR protection and enforcement efforts.

Egypt

Egypt will remain on the Watch List in 2010. Egypt undertook positive efforts in 2009, including acceding to various international IPR treaties, such as the Patent Cooperation Treaty,

the Madrid Protocol, and the Nice Classification Agreement. The Egyptian Information Technology Industry Development Agency (ITIDA), which is responsible for the enforcement of IPR in relation to software and databases, reports improved enforcement efforts, including an increase in prosecutions and raids. Authorities also improved enforcement against counterfeit pharmaceuticals. However, piracy rates for books, music, and motion pictures remain high, and the United States encourages the Ministry of Culture and other Egyptian ministries to increase their enforcement efforts. The economic courts established in 2008 have been effective in prosecuting IPR infringement, but judges and prosecutors need additional training. Enforcement agencies, including Customs, are also in need of capacity building. The United States continues to urge the Ministry of Health to clarify its commitment to protect 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 provide an effective system to address patent issues expeditiously in connection with applications to market pharmaceutical products. The United States will continue to engage on these issues through the U.S.-Egypt Strategic Economic Partnership.

Finland

Finland will remain on the Watch List in 2010. 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 and encourage Finland to resolve this matter.

Greece

Greece will remain on the 2010 Watch List. Greece improved its IPR legal framework in 2009 by ratifying the WIPO Internet Treaties together with other EU Member States. There were also some improvements in enforcement efforts. These included steps to facilitate communication between the police, the Hellenic Copyright Organization, and other IPR-related agencies, and the creation of a department at the Ministry of Citizen's Protections focusing on economic and cyber crimes, including IPR. Greece also took action against Internet piracy by shutting down infringing sites, with one such action resulting in felony charges, and by preparing a Draft Code of Conduct establishing cooperation between Internet service providers and rights holders. Despite these efforts, overall enforcement remained weak and inconsistent. Additionally, Greece did not follow through on initiatives begun in 2008 and 2009. For example, the Inter-Ministerial Coordinating Committee on IPR, which was formed in 2008, was not very active in 2009, and the National Action Plan for IPR was not significantly implemented in the last year. The United States encourages Greece to implement its National Action Plan on IPR, and to improve IPR protection and enforcement.

Guatemala

Guatemala will remain on the Watch List in 2010. Guatemala has been improving its IPR protection and enforcement frameworks in connection with CAFTA-DR. Specific improvements in 2009 included the appointment of a new IPR prosecutor and the establishment of an interagency IPR working group under the leadership of the IPR prosecutor to strengthen enforcement and inter-governmental cooperation. These improvements, fortified by a program of U.S. training for relevant officials, have contributed to an increase in enforcement actions, including raids, seizures, and prosecutions. The United States recognizes and appreciates Guatemala's efforts to date in these areas. The United States encourages Guatemala to ensure that proper resources are available for its enforcement activities, to achieve improved coordination among enforcement agencies, and to focus its enforcement efforts on manufacturers of pirated and counterfeit goods. The United States will continue to monitor Guatemala's implementation of its commitments under CAFTA-DR.

Italy

Italy will remain on the Watch List in 2010. In 2009, Italy expressed a renewed commitment to tackling IPR issues, especially with respect to Internet piracy, including by ratifying the WIPO Internet Treaties along with the other EU Member States. Copyright enforcement problems and the growth of Internet piracy remain serious challenges. One notable success was a 2009 Italian Supreme Court ruling that it is lawful to block illegal file-sharing sites. Italy also passed a law increasing criminal penalties against counterfeiters. Overall, much remains to be done to address Italy's IPR protection and enforcement deficiencies. Piracy and counterfeiting remain widespread, and industry reports growing online piracy of books and journals. The lack of an expeditious legal mechanism for right holders to address Internet piracy and a recent Data Protection Agency decision affecting a rights holders' ability to monitor peer-to-peer networks are obstacles to effectively combating this trend. The United States is hopeful that the Inter-Ministerial Committee on Internet Piracy will take prompt and concrete action to address this growing challenge. While the Finance Police and Customs Police carry out investigations and seizures, few cases reach final sentencing and courts still fail to impose deterrent sentences. The United States will continue to work with Italy to encourage a resolution to these issues.

Jamaica

Jamaica will remain on the Watch List in 2010. Jamaica's continued delay in enacting the Patents and Designs Act, which is intended to implement certain obligations under the TRIPS Agreement and the United States-Jamaica Bilateral Intellectual Property Agreement, remains an issue of concern. Positive developments in 2009 included increased enforcement activity and public awareness efforts. The United States urges the government of Jamaica to reform its patent law in accordance with international standards for patent protection.

Kuwait

Kuwait will remain on the Watch List in 2010. Kuwaiti officials, particularly Customs authorities, continue to make progress on enforcement against piracy and counterfeiting, and to pursue cases through the judicial process. However, the lack of deterrent criminal penalties limits the effectiveness of these efforts. The United States is concerned that several key pieces of IPR legislation have remained pending for many years. The United States has provided extensive technical assistance on legislative updates. The United States encourages Kuwait to pass the necessary IPR-related legislation and to improve its enforcement efforts.

Lebanon

Lebanon will remain on the Watch List in 2010. Lebanon has been moving forward incrementally on fighting piracy and strengthening enforcement of existing IPR laws, and actions by the Cyber Crime and Intellectual Property Rights Bureau of the police department have been responsive to rights holders' concerns. The government has demonstrated a commitment to protecting IPR by expressing its intention to ratify the WIPO Internet Treaties, by reengaging with U.S. technical experts on the update of the 1999 Copyright Law, and through training and public campaigns aimed at raising awareness about the importance of IPR protection. However, concerns remain over weak enforcement against piracy and counterfeiting, including counterfeiting of medicines. The Cyber Crime and Intellectual Property Rights Bureau lacks *ex officio* authority and requires continued training to deal effectively with infringements on the Internet. There is also a need for deterrent sentencing for IPR crimes. Lebanon also does not provide effective protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test data or other data generated to obtain marketing approval for pharmaceutical products. The United States encourages Lebanon to pass the pending legislative amendments to strengthen IPR protection, and will continue to engage with Lebanon through its WTO accession process and through an ongoing review under the U.S. Generalized System of Preferences program.

Malaysia

Malaysia will remain on the Watch List in 2010. Malaysia continues to express a commitment to protecting and enforcing IPR, and to pursuing needed legislative and regulatory improvements. Enforcement efforts, especially in the business software area, improved last year, and industry reports increased responsiveness from the Ministry of Domestic Trade, Cooperatives, and Consumerism to their requests for enforcement actions. However, piracy and counterfeiting remain widespread, and enforcement efforts continue to decline. The United States encourages Customs officials to initiate IPR investigations *ex officio*, as authorized under Malaysian law. Enforcement campaigns were successful in targeting pirated business software, but book piracy remains problematic, and industry reports a rise in Internet piracy. The specialized IPR courts continue to face a backlog, and additional resources and training are required to address this problem. The United States encourages Malaysia to accede to the WIPO Internet Treaties and

the Budapest Treaty, and to consider legislation to address unauthorized camcording. The United States also encourages Malaysia to provide effective protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, 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 Malaysia to make progress on these IPR issues.

Mexico

Mexico will remain on the Watch List in 2010. Mexico's enforcement efforts continue to improve, demonstrated by an increase in the number of raids, arrests, and indictments in 2009, and the imposition of the longest prison sentence on record in Mexico for an IPR violation (six and half years). Bilateral cooperation among agencies charged with intellectual property protection and enforcement is encouraging, especially among those participating in a series of training and exchange programs over the past year. However, the United States urges Mexico to increase resources devoted to protecting intellectual property and improve coordination among enforcement officials at the federal, state, and municipal levels. Concerns also remain over enforcement procedures and the inconsistent issuance of deterrent penalties. The United States welcomes Mexico's recent passage of legislation that would provide the Attorney General's office and certain Mexican enforcement officials with *ex officio* authority to prosecute IPR infringement. Legislation is still needed to provide *ex officio* authority to Customs officers. The United States has also been encouraged to learn about the steps that Mexico is taking to establish a voluntary recordation system at the border, coupled with new procedures with respect to detention of seized goods at the border. The United States welcomes signs that Mexico may be prepared to move forward with additional legislation to strengthen its IPR regime, including an anti-camcording law and the implementation of the WIPO Internet Treaties. The United States encourages Mexico to provide effective protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. The United States also welcomes recent efforts by Mexican authorities to improve Mexico's system to address patent issues in connection with applications to market pharmaceutical products; the existing system has generated considerable litigation and uncertainty. The United States will continue to work with Mexico to resolve IPR concerns through bilateral, regional, and other means of engagement.

Norway

Norway will remain on the Watch List in 2010. 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 and encourage Norway to find a solution to this issue.

Peru

Peru will remain on the Watch List in 2010. Peru has enhanced its IPR legal framework by enacting legislation designed to implement its obligations under the United States-Peru Trade Promotion Agreement (PTPA). Additionally, Peru has strengthened its Intellectual Property Office (INDECOPI) and created a National Strategic Plan to combat counterfeiting and piracy. However, several concerns remain, including continued overall weak enforcement resulting in the widespread availability of pirated and counterfeit goods. A further concern is that courts fail to impose deterrent penalties in criminal IPR cases and against businesses found to have engaged in infringing activity. There is a continuing need for measures to prevent government use of unlicensed software. In connection with its obligations under the PTPA, Peru should clarify its system for protecting undisclosed test or other data submitted to obtain approval of agricultural chemical products, particularly in light of recent measures that appear to provide for automatic approval of generic products. The United States will work closely with Peru on these and other issues through the framework provided by the PTPA.

Philippines

The Philippines will remain on the Watch List in 2010 with an Out-of-Cycle Review to be conducted this year. Ineffective enforcement of IPR continues to be a concern. Although some agencies continue making progress to increase raid and seizure activity, these efforts have proven insufficient to address widespread piracy and counterfeiting in the country. The United States encourages ongoing efforts to address inefficiencies in the judicial system, and to establish specialized IPR courts so that rights holders have a reliable avenue for recourse and prosecutions move forward effectively and without delay. The United States also encourages the Philippines to complete its work on legislative reforms needed to strengthen IPR protection, including the implementation of the WIPO Internet Treaties, which has been pending in Congress for years, and the final signing of the anti-camcording bill. The United States remains concerned about amendments to the patent law that prohibit patents on certain chemical forms unless the applicant demonstrates increased efficacy. The United States urges the Philippines to address its IPR protection and enforcement challenges, and looks forward to working with the Philippines in the coming year to address these and other issues.

Romania

Romania will remain on the Watch List in 2010. Romania took some positive steps in 2009, including increased cooperation between enforcement authorities, such as the National Police and General Prosecutor's Office, the use of a national database to improve interagency coordination on enforcement, and coordination with rights holders on enforcement matters. Although large scale optical disc piracy has been greatly reduced and Romania has made further positive efforts aimed at ensuring the government's use of licensed software, rights holders report an increase in Internet piracy, compounded by coordination problems with Internet service providers. Despite gradual improvements in enforcement, concerns remain over weaknesses in

the prosecution of IPR infringers, judicial inefficiency, and a failure to impose deterrent sentences. Additionally, some Romanian judges continue to dismiss IPR cases for a “lack of social harm.” However, the United States is encouraged by recent convictions against companies for business software piracy, and by the indictment of a company and website administrator for enabling infringement on a peer-to-peer network. The United States will continue to work with Romania to improve its IPR protection and enforcement efforts and encourages Romania to consult with all relevant stakeholders, including rights holders, as it explores reforming its copyright law.

Spain

Spain will remain on the Watch List in 2010. The United States remains concerned about particularly significant Internet piracy in Spain, and strongly urges prompt and effective action to address the issue. The Spanish government has not amended portions of a 2006 Prosecutor General Circular that appears to decriminalize illegal peer-to-peer file sharing of infringing materials, contributing to a public misperception in Spain that such activity is lawful. Spain’s existing legal and regulatory framework has not led to cooperation between Internet service providers (ISPs) and rights holders to reduce online piracy. On the contrary, rights holders in Spain report an inability to obtain information necessary to prosecute online IPR infringers, further reducing their ability to seek appropriate remedies. Spain’s legal system also generally does not result in criminal penalties for intellectual property infringement. The United States is encouraged by some recent positive developments in Spain, including the establishment of an Inter-Ministerial Commission with a mandate to propose changes in Spanish law and policy that will strengthen efforts to reduce Internet piracy. In January 2010, the Commission proposed legislation that would allow a committee based in the Ministry of Culture to request that an ISP block access to infringing materials hosted online. The United States urges Spain to continue taking positive steps to address Internet piracy, and will closely monitor progress in the next year.

Tajikistan

Tajikistan will remain on the Watch List in 2010. Tajikistan has yet to fully implement its IPR commitments under the 1993 U.S.-Tajikistan Trade Agreement. Tajikistan made progress in 2009 by acceding to the WIPO Copyright Treaty and by amending its Administrative Code in an effort to implement Article 18 of the Berne Convention to provide protection for certain preexisting works. The United States encourages the Ministry of Culture to continue working towards accession to the WIPO Performances and Phonograms Treaty in 2010. Tajikistan does not provide protection for U.S. and other foreign sound recordings, and concerns remain over the lack of proper *ex officio* authority for criminal and border enforcement, and over insufficient criminal penalties for IPR infringement. The United States will continue to work with Tajikistan on these matters.

Turkey

Turkey will remain on the Watch List in 2010. Turkey increased enforcement actions and conducted successful public awareness and training campaigns in 2009. However, piracy and counterfeiting remain serious problems, and Turkey has not yet completed many of the legislative reforms needed to ensure effective IPR protection and enforcement throughout the country. Industry reports an increase in business software and online music piracy, and book and entertainment software piracy remain a concern. Turkey is also becoming a major exporter, as well as a transshipment point, for counterfeit and pirated products. Undue delays in the judicial process contribute to deficiencies in the overall IPR protection and enforcement regime, and the 2008 dismissal of several trademark-related cases continues to cause uncertainty about the status of protection for trademarks at issue in those cases. The United States encourages Turkey to maintain deterrent penalties for all categories of IPR infringements. The United States also encourages Turkey to clarify its protection against unfair commercial use, as well as unauthorized disclosure, of pharmaceutical test data or other data generated to obtain marketing approvals for pharmaceutical products. The United States urges Turkey to increase its efforts to enhance IPR protection and enforcement.

Turkmenistan

Turkmenistan will remain on the Watch List in 2010. Turkmenistan has yet to implement the IPR provisions of the 1993 U.S.-Turkmenistan Trade Agreement (Bilateral Trade Agreement). Turkmenistan has not joined the treaties identified in the Bilateral Trade Agreement, including the Berne Convention, Geneva Phonograms Convention, and the WIPO Internet Treaties. The Civil and Criminal Codes provide some degree of protection against IPR infringement; however, Turkmenistan still must adopt explicit and comprehensive administrative and civil procedures and criminal penalties for IPR infringement. Turkmenistan has not adopted a separate copyright law and does not provide protection for foreign sound recordings and preexisting works. IPR enforcement is inadequate in part because Customs officials do not have *ex officio* authority to interdict suspected infringing material at the border. The United States urges Turkmenistan to adopt the necessary legal reforms to implement its obligations under the Bilateral Trade Agreement, and to improve its IPR regime.

Ukraine

Ukraine will remain on the Watch List in 2010. Ukraine continued to make progress in 2009, including by updating its IPR laws, but enforcement efforts remain weak and piracy and counterfeiting are widespread. Ukraine has taken some positive steps to address its Internet piracy problem by creating a Cyber-Crime Unit under the Interior Ministry's Economic Crimes Division, and by enforcing against websites offering illegal content. These efforts have resulted in investigations and criminal charges. However, more needs to be done to ensure that government entities use only licensed software. Additional action is also needed to address Internet piracy, including providing law enforcement with the authority to shut down infringing

websites. In general, Ukraine increased enforcement actions in 2009, and the Enforcement Cooperation Group, which coordinates all IPR enforcement efforts in Ukraine, continued to meet throughout 2009. However, serious concerns remain regarding the transshipment of counterfeit and pirated goods through Ukraine and that Customs officials lack *ex officio* authority to effectively address such transshipment. Concerns also remain about the judicial system, which suffers from a lack of deterrent sentencing, a lack of IPR expertise, and overall inefficiencies. The United States encourages Ukraine to address its IPR protection and enforcement deficiencies.

Uzbekistan

Uzbekistan will remain on the Watch List in 2010. Uzbekistan has yet to fully implement its commitments under the 1994 U.S.-Uzbekistan Trade Agreement. Uzbekistan's copyright law does not provide protection for preexisting works for U.S. and other foreign sound recordings. Uzbekistan has not joined the Geneva Phonograms Convention. Enforcement remains weak and criminal penalties for IPR violations are not sufficient to provide a deterrent effect. Additionally, amendments are needed to provide enforcement officials, including Customs officials, with *ex officio* authority to initiate enforcement actions and investigations. The United States will continue to work with Uzbekistan through its WTO accession process and the ongoing review under the U.S. Generalized System of Preferences program.

Vietnam

Vietnam will remain on the Watch List in 2010. However, the United States is encouraged by recent steps that the government has taken to improve IPR protection and enforcement, including recent amendments to the IP Law, an increase in administrative fines for copyright infringement, and a continuation of efforts to address Internet piracy. An amendment to the Criminal Code was also a positive step, although some questions remain about the scope of criminal penalties, particularly for copyright infringement. Enforcement efforts appear to have been better targeted and coordinated over the past year. Of particular note were efforts that led to a large seizure of optical discs and related equipment, as well as raids of a bookstore and a printing facility suspected of producing infringing goods. However, overall enforcement efforts remain insufficient to address rampant piracy and counterfeiting. Additionally, industry reports growth in Internet piracy. There is also a need for deterrent penalties to be imposed more regularly, and enforcement agencies should consider initiating more criminal prosecutions. Positive progress made in the area of cable and satellite broadcasting over the past several years is threatened by recent sporadic pirating of content by cable providers. The United States encourages Vietnam to continue considering regulations 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. The United States will continue to engage with Vietnam under the U.S.-Vietnam Trade and Investment Framework Agreement working group and

through cooperative IPR capacity-building programs to support the improvement of IP enforcement efforts in the country.

SECTION 306 MONITORING

Paraguay

Paraguay will remain under Section 306 monitoring in 2010, specifically with respect to its implementation of the bilateral agreement regarding IPR protection and enforcement. In 2009, the United States and Paraguay signed an extension and revision of the previous Memorandum of Understanding on Intellectual Property Rights, which will remain in effect through 2011. While Paraguay has offered assurances of continued commitment to IPR enforcement in keeping with its obligations under the revised Memorandum of Understanding, the country experienced a marked decline in IPR enforcement actions during 2009 and early 2010. Turnover in personnel and limited resources contributed to unfavorable enforcement trends, as did longstanding problems with porous borders, ineffective prosecutions of IPR infringers, and a lack of deterrent sentences. Disappointing enforcement results contrasted with progress made in the area of public awareness and the adoption of a new penal code that increased penalties for IPR offenses. To date, however, industry reports that there have been no deterrent sentences and no criminal convictions for copyright piracy. The United States has concerns about inadequate protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, as well as shortcomings in Paraguay's patent regime. The United States will continue to work with Paraguay to address these IPR concerns during the coming year, including through the Joint Commission on Trade and Investment.

STATUS PENDING

Israel

On February 18, 2010, in connection with the Special 301 Out-of-Cycle Review that was extended in 2009, the United States and Israel reached an understanding on several longstanding issues concerning Israel's IPR regime for pharmaceutical products. Israel's commitments pursuant to the understanding more closely align key aspects of Israel's IPR system for pharmaceutical products with the levels of protection afforded by other countries at Israel's advanced level of development.

As part of the understanding with the United States, Israel has committed to strengthen its laws on protection of pharmaceutical test data and patent term extension, and to publish patent applications before they are granted. These developments are significant to U.S. companies,

which will benefit from stronger IPR protection in Israel. Additionally, Israel confirmed that it has taken steps to expedite approvals of new pharmaceutical drugs by the Ministry of Health, which means that Israeli citizens will get access to both innovative and generic medicines sooner. A copy of the understanding is available at www.ustr.gov.

In recognition of Israel's commitment to move forward on legislation to amend its IPR laws, and once the appropriate legislation is submitted to the Knesset, Israel will be moved from the Special 301 Priority Watch List to the Watch List. When that legislation is fully implemented (through passage by the Knesset of the agreed-upon amendments to Israeli law), Israel will be moved off the Special 301 list altogether.

Separately from the understanding discussed above, and in connection with its bid to join the OECD, Israel has signaled a new willingness to make progress on other IPR issues of concern. In particular, Israel announced plans to issue a draft copyright-related "exposure bill" (an early step in the legislative process) in one year. Israel has stated that the purpose of this step will be to solicit public comments on specific proposals pertaining to enacting core requirements of the WIPO Internet Treaties. The United States welcomes this step, and encourages Israel to proceed with full accession to, and implementation of, the WIPO Internet Treaties.

SECTION III. NOTORIOUS MARKETS

Global piracy and counterfeiting continue to thrive due in part to marketplaces that deal in infringing goods. The 2010 Special 301 Report notes the following markets, including those on the Internet, as examples of marketplaces that have been the subject of enforcement action or that may merit further investigation for possible IPR infringements, or both. The list represents a selective summary of information reviewed during the Special 301 process; it is not a finding of violations of law. The United States encourages the responsible authorities to step up efforts to combat piracy and counterfeiting in these and similar markets.

Internet Markets

- **Baidu (China).** The U.S. music industry reports that the vast majority of all illegal downloads of music in China are associated with Baidu. Baidu is the target of ongoing infringement actions by both domestic and foreign rights holders. Baidu executives continue to deny responsibility for content hosted by other websites. Several rights holders are pursuing legal action in Chinese courts.
- **Business-to-business (B2B) and business-to-consumer (B2C) websites (China).** A large number of Chinese websites, such as TaoBao and Alibaba, the top two online marketplaces selling game copiers, have been cited by industry as offering infringing products to consumers and businesses.
- **TV Ants (China).** Industry reports that this website is a notorious hub of online piracy with respect to sporting event telecasts.
- **Allofmp3.com clones (Russia).** Although allofmp3 (formerly the world's largest server-based pirate music website) was shut down in 2007, a nearly identical site has taken its place and continues illegally distribute copyrighted materials. Several other sites provide similar services. In addition, Russia is host to several major BitTorrent indexing sites that are popular channels for illegal peer-to-peer downloading.
- **Webhards (Korea).** Webhards are web-based storage services that offer high-volume storage space, some up to a terabyte, for sharing of pirated material. While two well-known webhards now provide legal content and the Korean government has prosecuted some webhard operators, there remain numerous webhards operating in Korean webspace that provide illegal content.

Physical Markets

- **Bahia Market (Guayaquil, Ecuador).** This expansive market of at least 1,000 vendors sells high quantities of illicit goods, many of which are either counterfeit products or goods stolen from the Guayaquil port.
- **China Small Commodities Market (Yiwu, China).** The China Small Commodities Market in Yiwu reportedly sells over 410,000 different items, mostly small consumer goods. Industry has cited the market as a center for wholesaling of infringing goods. Officials in Yiwu have met repeatedly with U.S. Government officials and stressed their work to improve IPR enforcement. Industry confirms that the enforcement in Yiwu has improved. Continued improvement is needed, particularly in the area of criminal enforcement.
- **Greenhills, Quiapo, Binondo, Makati Cinema Square, and 168 Mall (Manila, Philippines).** Street stalls in these areas are a haven for counterfeit clothing, shoes, watches, and handbags. Due to the unwillingness of local investigation agencies and government authorities to confront stall owners, trademark owners have had a difficult time obtaining meaningful enforcement action. Also, although a 2006 Executive Order establishes landlord liability, reportedly no landlords have yet been prosecuted for IPR violations.
- **Gorbushka and Rubin Trade Center and Savelovskiy Market (Moscow, Russia).** Industry representatives report that piracy problems persist in these markets, though the situation has improved at the Gorbushka and Rubin Trade Center. In Moscow, illegal optical discs are still available at the upscale Gorbushka consumer electronics market, but less overtly displayed than in previous years. Pirated goods are more widely and openly available at the Savelovskiy electronics market in Moscow.
- **Harco Glodok (Jakarta, Indonesia).** This is reported to be one of the largest markets in Indonesia for counterfeit and pirated goods, particularly well-known for pirated optical discs. Enforcement officials are reportedly reluctant to conduct regular enforcement actions because of the presence of organized criminal gangs. Indonesian law enforcement authorities have successfully utilized some U.S. assistance.
- **La Salada (Buenos Aires, Argentina).** La Salada is the largest of more than 40 well-established markets in Buenos Aires that have been cited as being heavily involved in the sale of counterfeit goods. Fewer raids were conducted at La Salada in 2009 due to high-profile efforts by the Buenos Aires provincial authorities in May 2009 to bring order to La Salada by verifying business licenses of vendors and by efforts to stop trucks headed towards the market to verify their contents. However, the results of such efforts have not yet been announced.

- **Lowu Market (Shenzhen, China).** The display of signs prohibiting the sale of counterfeit or pirated goods has not deterred their sale in Lowu market and other markets in Shenzhen and Guangzhou. Despite relative success in Beijing and other jurisdictions, efforts to use landlord liability have largely failed as well.
- **Nehru Place and Palika Bazaar in New Delhi, Richie Street and Burma Bazaar in Chennai, Manish Market, Heera Panna, Lamington Road, and the Fort District in Mumbai, and Chandni Chowk in Kolkata (India).** These markets are known for the high volume of pirated software, optical media, and counterfeit goods.
- **Panthip Plaza, the Klong Thom, Saphan Lek and Baan Mor shopping areas, the Patpong and Silom shopping areas, the Mah Boon Krong (MBK) Center, and the Sukhumvit Road area (Bangkok, Thailand).** These locations are notorious for openly selling pirated and counterfeit goods. These are all designated as “red zones” by Thai authorities, which are markets targeted for increased raids due to their high piracy and counterfeiting rates.
- **Petrivka Market (Kyiv, Ukraine).** This open air market houses as many as 300 stands that sell pirated goods, including music, films, games, and software.
- **San Andresitos (Colombia).** These large marketplaces scattered throughout Columbia are notorious for unauthorized reproduction of music, video games, and movies. Raids and seizures are difficult due to the presence of organized crime and narco-traffickers.
- **Silk Market (Beijing, China).** Industry has cited Beijing’s Silk Street Market as an egregious example of the counterfeiting of consumer and industrial products that is endemic in many retail and wholesale markets throughout China. Only limited progress has been made in addressing the severe IPR violations at this market since 2005. The United States encourages the appropriate authorities to ensure adequate enforcement of the trademark authorization measures mandated by the Beijing municipal courts.
- **Tepito, Plaza Meave, Eje Central, Lomas Verdes, and Pericoapa Bazaar (Mexico City, Mexico); San Juan de Dios (Guadalajara, Mexico); Simitrio-La Cuchilla (Puebla, Mexico); and Pulgas (Monterrey, Mexico).** With Tepito as the main warehousing and distribution center for infringing products, these informal markets sell pirated and counterfeit goods connected to or purchased from organized crime syndicates.
- **Tri-Border Region (Paraguay, Argentina, and Brazil).** The Tri-Border Region of Paraguay, Argentina, and Brazil has a longstanding reputation as a hotbed of piracy and counterfeiting of many products.

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 that have the most onerous or egregious acts, policies, or practices and whose acts, policies, or practices have the greatest adverse impact (actual or potential) on the relevant U.S. products must be designated as “Priority Foreign Countries.”

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

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

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

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

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

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 IPR protection around the world, particularly with regard to Internet based delivery of copyrighted works. 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 works in on-line environments. A growing number of countries are implementing the WIPO Internet Treaties to create a legal environment conducive to investment and growth in Internet-related businesses and technologies.

As of March 2010, there are 86 contracting parties of the WPPT and 88 contracting parties of the WCT. Membership has risen significantly as numerous EU Member States have joined. Other countries have implemented key provisions of these treaties in their national laws without formally ratifying them. The United States urges other governments to ratify and implement the provisions of the WIPO Internet Treaties.

The following eighteen trading partners became parties to the WPPT during November 2009-March 2010. Currently the WPPT has 86 contracting parties.

Country	Date of Entry Into Force
Austria	March 2010
Bosnia and Herzegovina	November 2009
Denmark	March 2010
Estonia	March 2010
European Union	March 2010
Finland	March 2010
France	March 2010
Germany	March 2010
Greece	March 2010
Ireland	March 2010
Italy	March 2010
Luxembourg	March 2010
Malta	March 2010
Netherlands	March 2010

Portugal	March 2010
Spain	March 2010
Sweden	March 2010
United Kingdom	March 2010

The following nineteen trading partners became parties to the WCT during June 2009-March 2010. Currently the WCT has 88 contracting parties.

Country	Date of Entry Into Force
Austria	March 2010
Bosnia and Herzegovina	November 2009
Denmark	March 2010
Estonia	March 2010
European Union	March 2010
Finland	March 2010
France	March 2010
Germany	March 2010
Greece	March 2010
Ireland	March 2010
Italy	March 2010
Luxembourg	March 2010
Malta	March 2010
Netherlands	March 2010
Portugal	March 2010
Spain	March 2010
Sweden	March 2010
United Kingdom	March 2010
Uruguay	June 2009