

2015 Special 301 Report



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EXECUTIVE SUMMARY

The Special 301 Report (Report) is the result of an annual review of the state of intellectual property rights (IPR) protection and enforcement in U.S. trading partners around the world, which the Office of the United States Trade Representative (USTR) conducts pursuant to Section 182 of the Trade Act of 1974, as amended by the Omnibus Trade and Competitiveness Act of 1988 and the Uruguay Round Agreements Act (19 U.S.C. § 2242).

This Report reflects the Administration's continued resolve to encourage and maintain adequate and effective IPR protection and enforcement worldwide. The Report identifies a wide range of concerns, including: (a) the deterioration in IPR protection, enforcement, and market access for persons relying on IPR in a number of trading partners; (b) reported inadequacies in trade secret protection in China, India, and elsewhere, as well as an increasing incidence of trade secret misappropriation; (c) troubling "indigenous innovation" policies that may unfairly disadvantage U.S. rights holders in China; (d) the continuing challenges of online copyright piracy in countries such as Brazil, China, India, and Russia and trademark counterfeiting in China and elsewhere; (e) market access barriers, including nontransparent and discriminatory measures, that appear to impede access to products embodying IPR and measures that impede market access for U.S. entities that rely upon IPR protection; and (f) other ongoing, systemic IPR enforcement issues in many trading partners around the world.

The Report serves a critical function by identifying opportunities and challenges facing U.S. innovative and creative industries in foreign markets and by promoting job creation, economic development, and many other benefits that effective IPR protection and enforcement support. The Report informs the public and our trading partners and can serve as a positive catalyst for change.

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

The Special 301 Process

The Congressionally-mandated annual Special 301 Report is the result of an extensive multi-stakeholder process. Pursuant to the statute mandating the Report, USTR is charged with designating as Priority Foreign Countries those 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. (*See Annex 1*). To facilitate administration of the statute, USTR has created a Priority Watch List and Watch List within this Report.

Placement of a trading partner on the Priority Watch List or Watch List indicates that particular problems exist in that country with respect to IPR protection, enforcement, or market access for persons relying on IPR.

Public Engagement

USTR solicited broad public participation in the 2015 Special 301 review process to facilitate sound, well-balanced assessments of the IPR protection and enforcement efforts of trading partners, and to help ensure that the Special 301 review would be based on comprehensive information regarding IPR issues in trading partner markets.

USTR requested written submissions from the public through a notice published in the *Federal Register* on December 29, 2014 (*Federal Register* notice). In addition, on February 24, 2015, USTR conducted a public hearing that provided the opportunity for interested persons to testify before the inter-agency Special 301 Subcommittee of the Trade Policy Staff Committee (TPSC) about issues relevant to the review. The hearing featured testimony from witnesses, including representatives of foreign governments, industry, and non-governmental organizations. USTR recorded and posted on its public website the testimony at the Special 301 hearing, and offered a post-hearing comment period during which hearing participants and interested parties could submit additional information in support of, or in response to, hearing testimony. The *Federal Register* notice and post-hearing comment opportunity drew submissions from 55 interested parties, including 21 trading partner governments.

The submissions filed in response to the *Federal Register* notice, and during the post-hearing comment period, are available to the public online at www.regulations.gov, docket number USTR-2014-0025. The public can access both the video and transcript of the hearing at www.ustr.gov.

Country Placement

The Special 301 listings and actions announced in this Report follow intensive deliberations among all relevant agencies within the U.S. Government, informed by extensive consultation with participating stakeholders, foreign governments, the U.S. Congress, and other interested parties.

USTR, together with the Special 301 Subcommittee, conducts a broad and balanced assessment of U.S. trading partners' IPR protection and enforcement, as well as related market access issues affecting IPR-intensive industries, in accordance with the statutory criteria set out by the U.S. Congress. (See Annex 1). The Special 301 Subcommittee, through the TPSC, provides country placement recommendations to the USTR based on this assessment.

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

In the year ahead, USTR will continue to engage trading partners that are discussed in this Report. In preparation for, and in the course of, those interactions, USTR will:

- Engage with U.S. stakeholders, the U.S. Congress, and other interested parties to ensure that the U.S. Government's position is informed by the full range of views on the pertinent issues;
- Conduct extensive discussions with individual trading partners regarding their respective IPR regimes;
- Encourage trading partners to engage fully, and with the greatest degree of transparency, with the full range of stakeholders on IPR matters; and
- Identify, where possible, appropriate ways in which the U.S. Government can be of assistance. (*See Annex 2*).

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

The 2015 Special 301 List

The Special 301 Subcommittee reviewed 72 trading partners during the 2015 Special 301 process. The Subcommittee received stakeholder input on nearly 100 trading partners, but focused its review on those submissions that responded to the request set forth in the notice published in the *Federal Register* to identify whether a particular trading partner should be named as a Priority Foreign Country (PFC), placed on the Priority Watch List (PWL) or Watch List (WL), or not listed in the Report. Following extensive research and analysis, USTR has listed 37 trading partners as follows:

Priority Watch List: Algeria; Argentina; Chile; China; Ecuador; India; Indonesia; Kuwait; Pakistan; Russia; Thailand; Ukraine; and Venezuela; and

Watch List: Barbados; Belarus; Bolivia; Brazil; Bulgaria; Canada; Colombia; Costa Rica; Dominican Republic; Egypt; Greece; Guatemala; Jamaica; Lebanon; Mexico; Paraguay; Peru; Romania; Tajikistan; Trinidad and Tobago; Turkey; Turkmenistan; Uzbekistan; and Vietnam.¹

Out-of-Cycle Reviews

An Out-of-Cycle Review (OCR) is a tool that USTR uses to encourage progress on IPR issues of concern. OCRs provide an opportunity for heightened engagement and cooperation with trading partners and other stakeholders to address and remedy such issues.

Country-Specific Out-of-Cycle Reviews

OCRs focus on identified IPR challenges in specific trading partner markets. Successful resolution of specific IPR issues of concern can lead to a positive change in a trading partner's Special 301 status outside of the typical time frame for the annual review. Conversely, failure to address identified IPR concerns, or further deterioration as to an IPR-related concern within the specified timeframe, can lead to an adverse change in status.

In the coming months, USTR will conduct several OCRs, including of the following trading partners.

- USTR has noted the willingness of two Watch List countries, **Turkmenistan** and **Tajikistan**, to work with the United States on improving their IPR protection and enforcement regimes and will conduct an OCR for each country to evaluate whether specific steps taken merit their removal from the Watch List.
- USTR will conduct an OCR of **Honduras**, which is not listed in the 2015 Report, to determine whether to place that country on the Watch List. This OCR will assess whether Honduras has acted to address widespread cable and satellite signal piracy, including through increased regulatory oversight, strengthened criminal IPR enforcement capacity, increased clarity in procedures relating to geographical indications, and improved the protection of test or other data generated to obtain marketing approval for certain regulated products.
- USTR extends the current OCR of **Paraguay**, which is currently on the Watch List, to provide additional time for conclusion of a bilateral IPR Memorandum of Understanding (MOU). USTR encourages Paraguay to conclude the MOU by June 30, 2015, and notes that,

¹ 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. Given that the term for such patents is set to expire shortly, Finland is removed from the WL in 2015.

if Paraguay does not do so, USTR will evaluate possible implications accordingly, including with respect to Paraguay's status under Special 301.

- Although **Spain** is not listed in the 2015 Report, USTR continues the OCR of Spain, announced in 2013, which is focused, in particular, on concrete steps taken by Spain to combat copyright piracy over the Internet. While Spain has taken several positive steps, concerns remain, and additional steps are necessary.

USTR may conduct additional OCRs of other trading partners as circumstances warrant, or as requested by the trading partner.

Out-of-Cycle Review of Notorious Markets

In 2010, USTR began publishing the Notorious Markets List as an OCR separately from the annual Special 301 Report. The Notorious Markets List identifies selected online and physical markets that are reportedly engaged in copyright piracy and trademark counterfeiting, according to information submitted to USTR in response to a notice published in the *Federal Register* requesting public comments. USTR requested such comments on September 26, 2014, and published the *2014 Notorious Markets List* on March 5, 2015. USTR plans to conduct its next Notorious Markets OCR in the fall of 2015. The Notorious Markets List is available at www.ustr.gov.

Structure of the Special 301 Report

The 2015 Report contains the following Sections and Annexes:

Section I. Developments in Intellectual Property Rights Protection and Enforcement discusses global trends and issues in IPR protection and enforcement that the U.S. Government works to address on a daily basis;

Section II. Country Reports includes descriptions of issues of concern with respect to particular trading partners;

Annex 1 describes the statutory basis of the Special 301 Report; and

Annex 2 highlights U.S. Government-sponsored technical assistance and capacity building efforts.

SECTION I. DEVELOPMENTS IN INTELLECTUAL PROPERTY RIGHTS PROTECTION AND ENFORCEMENT

An important mission of USTR is to support and implement the Administration's commitment to vigorously protect the interests of American holders of IPR in other countries while preserving the incentives that ensure access to, and widespread dissemination of, the fruits of innovation and creativity. IPR infringement, including trademark counterfeiting and copyright piracy,² causes significant financial losses for rights holders and legitimate businesses around the world. It undermines U.S. comparative advantages in innovation and creativity, to the detriment of American businesses and workers. In its most pernicious forms, IPR infringement endangers the public. Some counterfeit products, including semiconductors, automobile parts, and medicines, pose significant risks to consumer health and safety. In addition, trade in counterfeit and pirated products often fuels cross-border organized criminal networks and hinders sustainable economic development in many countries.

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

Initiatives to Strengthen IPR Protection and Enforcement Internationally

Positive Developments

The United States welcomes the following important developments in 2014 and early 2015:

- High-level planning documents issued by the Government of **China** in 2014 and 2015 articulated a commitment to protect and enforce IPR, to allow industry and entrepreneurs a greater voice in policy development, and to allow market mechanisms to play a greater role in guiding research and development (R&D) efforts. China has also continued an ongoing overhaul of its intellectual property laws. The United States welcomes pro-innovation statements by China, and urges China to continue to engage with foreign governments and stakeholders and to ensure that legal and regulatory reforms adhere to these articulated principles.
- Administrative enforcement reforms in the **Philippines** have resulted in streamlined procedures, enhanced inter-agency cooperation, and more enforcement action, including increased seizures of pirated and counterfeit goods.

² The terms "copyright piracy" and "trademark counterfeiting" may appear below also as "piracy" and "counterfeiting," respectively.

- On December 12, 2013, the Communications Regulatory Authority (AGCOM) in **Italy** adopted regulations to combat copyright piracy over the Internet. The regulations, which entered into force on March 31, 2014, provide notice-and-takedown procedures that incorporate due process safeguards and establish a mechanism for addressing large-scale piracy. Italy's subsequent implementation of the regulations has been positive, resulting in successful enforcement actions against several websites that offered infringing content. These websites have ceased operations in Italy, removed infringing content, or initiated cooperation with copyright holders. The adoption and effective ongoing enforcement of these regulations is a significant achievement, which the United States continues to welcome.
- The Ministry of Justice in **Latvia**, in close cooperation with other domestic agencies, has drafted new five-year guidelines regarding IPR protection. The guidelines promote advanced research and innovation, training of customs officials and police, exchanges among judges and prosecutors, intellectual property education in universities, and public awareness about the importance and benefits of IPR. The guidelines, which were approved by the Cabinet of Ministers in March 2015, signal Latvia's commitment to pursuing innovation, encouraging economic growth, and creating jobs.
- **Denmark** has established a unit to be housed under the Danish Patent and Trademark Office that will assist in enforcement efforts by serving those consumers and businesses that have allegedly been the victims of patent, design, and trademark infringement. The unit has no direct enforcement authority, but will collect and assess evidence of alleged infringement and provide such evidence to appropriate law enforcement agencies for further consideration. This type of creative inter-agency coordination on intellectual property issues bolsters the pool of resources available to consumers and small- and medium-sized businesses and supplements law enforcement resources.
- As of April 2015, there are 94 Parties to the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty (WPPT) and 93 Parties to the WIPO Copyright Treaty (WCT), collectively known as the **WIPO Internet Treaties**. Canada became a party to the WCT and WPPT on August 13, 2014 as did Madagascar, on February 24, 2015. During the past year, other trading partners have implemented key provisions of the WIPO Internet Treaties in their national laws.
- As of April 2015, there are 64 contracting parties to the **Hague Agreement Concerning the International Registration of Industrial Designs**. Korea, Japan, and the United States are the most recent to join the Agreement.

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

Best IPR Practices by Trading Partners

USTR highlights the following best practices by trading partners in the area of IPR protection and enforcement:

- USTR supports **predictability, transparency, and meaningful engagement between governments and stakeholders** in the development of laws, regulations, procedures, and other measures. Stakeholders report that such transparency and participation allow governments to avoid unintended consequences and facilitate stakeholder compliance with legislative and regulatory changes. In late 2014, **India** initiated a process of soliciting widespread stakeholder input regarding its development of a draft National IPR Policy. USTR encourages continued engagement with interested stakeholders as India continues to develop this policy framework. In contrast, **Thailand's** failure to address concerns identified by the United States, other foreign governments, and stakeholders has resulted in missed opportunities to address IPR challenges in recent amendments to Thailand's copyright law.
- **Cooperation among government agencies** is another example of a best practice. Several countries, including the United States, have introduced IPR enforcement coordination mechanisms or agreements to enhance inter-agency cooperation. The United States encourages other trading partners to consider adopting similar cooperative IPR arrangements. In **Paraguay** and the **Philippines**, commitment to a whole-of-government approach to IPR enforcement has been critical to enhancing the effectiveness of IPR enforcement and has resulted in positive reports from a number of affected stakeholder groups. In contrast, despite the commitment of individual government agencies and offices, lack of intra-governmental coordination has impeded actions to enforce IPR in **Guatemala**.
- Several trading partners have participated, or supported participation, in **innovative mechanisms that enable government and private sector rights holders to donate or license pharmaceutical patents** voluntarily and **on mutually-agreed terms and conditions**. In these arrangements, parties use existing patent rights to facilitate the diffusion of technology in support of public policy goals. The United States was the first government to share patents with the Medicines Patent Pool, an independent foundation hosted by the World Health Organization (WHO). The United States encourages additional public and private patent holders to explore voluntary licenses with the Medicines Patent Pool as one of many innovative ways to help improve the availability of medicines in developing countries. The patents that the United States shared were related to protease inhibitor medicines, primarily used to treat drug-resistant HIV infections. In addition, the United States, **Brazil**, and **South**

Africa participate as providers in the WIPO Re:Search Consortium, a voluntary mechanism for making IPR and know-how available on mutually-agreed terms and conditions to the global health research community to find cures or treatments for neglected tropical diseases, malaria, and tuberculosis. Other countries participate as supporters. These arrangements have been used successfully to enhance access to medicines.

- Another best practice is the active participation of government officials in **technical assistance and capacity building**. As further explained in Annex 2, the United States encourages foreign governments to make training opportunities available to their officials and actively engages with trading partners in capacity building efforts both in the United States and abroad.

Multilateral and Plurilateral Initiatives

The United States works to promote adequate and effective IPR protection and enforcement through the following mechanisms:

- **Trans-Pacific Partnership (TPP)**: Through the TPP, the United States is seeking to advance multifaceted U.S. trade and investment interests in the Asia-Pacific region. The TPP is an ambitious, 21st-century regional trade negotiation involving Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, Vietnam, and the United States. The TPP negotiations are being undertaken by this group of countries with the goal of creating a platform for integration of trade and investment frameworks across the Asia-Pacific region, and for addressing emerging IPR issues in the 21st century, including with respect to strong and balanced standards for the protection and enforcement of IPR.
- **Transatlantic Trade and Investment Partnership (T-TIP)**: In 2013, the USTR notified the U.S. Congress of the President's intent to enter into negotiations for a comprehensive trade and investment agreement with the European Union (EU). Since that notification, the United States and the EU have held several rounds of negotiations, most recently in April 2015. The United States and the EU provide among the highest levels of IPR protection and enforcement in the world. In the T-TIP, the United States is pursuing a targeted approach on IPR that will reflect the shared U.S.-EU objective of high-level IPR protection and enforcement, and sustained and enhanced joint leadership on IPR issues. The United States will seek new opportunities to advance and defend the interests of U.S. creators, innovators, businesses, farmers, ranchers, and workers with respect to strong protection and effective enforcement of IPR, including the ability to compete in foreign markets.

- **World Trade Organization (WTO):** The multilateral structure of the WTO provides opportunities for USTR to lead engagement with trading partners on IPR issues, including through accession negotiations for prospective Members, the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), and the Dispute Settlement Body. In the past year, the United States sponsored discussions in the TRIPS Council on the positive and mutually-reinforcing relationship between the protection and enforcement of IPR and innovation. For example, in February 2015, the United States co-sponsored an agenda item on the role of women in innovation. The United States joined the EU, Japan, Montenegro, Norway, and Turkey as proponents of this first-of-its-kind initiative in the TRIPS Council to recognize the accomplishments of women creators and innovators and to address the challenges they continue to confront. These countries, along with numerous others, exchanged best practices and policy experience in promoting women innovators. In its presentation, the United States highlighted the exemplary advances of American women in a variety of technology sectors, from medicine to computer science, advanced manufacturing, and education.

In 2014, the United States also co-sponsored several related agenda items in the TRIPS Council. In October 2014, the United States, the EU, and Switzerland co-organized the first-ever WTO Innovation Fair, which featured innovators, universities, start-ups, incubators, and accelerators from both developing and developed countries around the globe. This event provided a precedent-setting opportunity for trade and IPR delegates to observe first-hand the critical incentives for innovation provided by the TRIPS Agreement and IPR protection generally. In tandem with the Innovation Fair, the United States co-sponsored a TRIPS Council agenda item on IPR awareness. Under this agenda item, the United States and other WTO countries shared information on how to raise awareness regarding the factors that promote innovation and those that hinder innovation. This information-sharing exercise was built on the premise that one country's experiences may provide useful guidance for another country's innovation objectives.

In June 2014, the United States and Taiwan co-sponsored a TRIPS Council agenda item on IPR and innovation focused on innovation incubators. This discussion in the TRIPS Council stressed the importance of incubators, including their work with respect to IPR, as part of the enabling environment for innovation. WTO countries exchanged best practices and success stories regarding their national experiences with facilities and groups such as incubators and accelerators, which provide critical support to start-ups and other new innovative entities to assist in the early stages of development.

In February 2014, the United States sponsored a TRIPS Council agenda item on university technology partnerships. Discussions focused on the extent to which universities around the world are engines for innovation and technology transfer. Numerous WTO Members

underscored the critical role that IPR plays in helping to support the types of university technology partnerships that translate basic research into goods and services that benefit consumers and society at large.

- **Anti-Counterfeiting Trade Agreement (ACTA):** In October 2012, Japan became the first signatory to ACTA to deposit its instrument of acceptance. The ACTA effort, launched in October 2007, brought together a number of countries prepared to embrace strengthened IPR enforcement and cooperative enforcement practices. ACTA signatories are Australia, Canada, Japan, Mexico, Morocco, New Zealand, Singapore, South Korea, and the United States. The EU and 22 EU Member States also signed the Agreement in January 2012, although it was not approved by the European Parliament. For signatories, the next step towards bringing the ACTA into force is to deposit instruments of ratification, acceptance, or approval. The ACTA would enter into force for those signatories 30 days following the deposit of the sixth such instrument. The ACTA includes provisions that seek to deepen international cooperation and to promote strong enforcement practices and ultimately would help sustain American jobs in innovative and creative industries.

Regional and Bilateral Initiatives

The United States works with many trading partners to strengthen IPR protection and enforcement through the provisions of bilateral agreements, including trade agreements and bilateral memoranda of cooperation, and through regional initiatives.

The following are examples of bilateral coordination and cooperation:

- The **U.S.-China Joint Commission on Commerce and Trade (JCCT)** and the **U.S.-China Strategic and Economic Dialogue (S&ED)** are two very significant bilateral annual trade engagements through which the United States negotiates important intellectual property and innovation commitments with China.
- **Trade and Investment Framework Agreements (TIFAs)** between the United States and numerous trading partners around the world have facilitated discussions on enhancing IPR protection and enforcement. In 2014, TIFA meetings with Taiwan resulted in important commitments on IPR, although implementation of those commitments and improvements in other areas will be crucial.

The following are examples of regional coordination and cooperation:

- In February 2014, the **Asia-Pacific Economic Cooperation (APEC) Intellectual Property Experts Group (IPEG)** unanimously endorsed a U.S. proposal to enhance improved

protection and enforcement of trade secrets. Pursuant to the proposal, participating APEC economies returned survey responses, information from which was presented in a report endorsed by the IPEG in early 2015. The United States will continue to lead this initiative toward the identification of best practices and trade secret protection in APEC economies, as well as other efforts, in the coming year.

- Under its practice of conducting **trade preference program reviews**, USTR, in coordination with other U.S. Government agencies, reviews IPR practices in connection with the implementation of Congressionally-authorized trade preference programs, such as the Generalized System of Preferences (GSP) program, and regional programs, including the African Growth and Opportunity Act (AGOA), Caribbean Basin Economic Recovery Act (CBERA), and Caribbean Basin Trade Partnership Act (CBTPA), and works with trading partners to address any policies and practices that may adversely affect their eligibility.

USTR, in coordination with other U.S. Government agencies, looks forward to continuing engagement with trading partners in bilateral, regional, plurilateral, and multilateral fora to improve the global IPR environment. In addition to the work described above, the United States anticipates engaging with its trading partners on IPR-related initiatives in multilateral and regional fora such as the G-8, WIPO, the Organization for Economic Cooperation and Development (OECD), and the World Customs Organization (WCO). In addition, U.S. Customs and Border Protection (CBP) is interested in exploring opportunities for tangible cooperation on improving IPR border enforcement. These opportunities could include sharing best practices and customs-to-customs information exchange for use in risk management and enforcement actions, and conducting joint customs enforcement operations designed to interdict shipments of IPR-infringing goods destined for the United States.

Trends in Trademark Counterfeiting and Copyright Piracy

The problems of trademark counterfeiting and copyright piracy continue on a global scale and involve the mass production and sale of a vast array of fake goods and a range of copyright-protected content pirated in various forms. Counterfeited goods include semiconductors and other electronics, chemicals, automotive and aircraft parts, medicines, food and beverages, household consumer products, personal care products, apparel and footwear, toys, and sporting goods.

Consumers, legitimate producers, and governments are harmed by trademark counterfeiting and copyright piracy. Consumers may be harmed by fraudulent and potentially dangerous counterfeit products, particularly medicines, automotive and airplane parts, and food and beverages that may not be subjected to the rigorous “good manufacturing practices” used for legitimate products. Producers and their employees face diminished revenue and investment incentives, an adverse employment impact, and loss of reputation when consumers purchase fake

products. Governments may lose tax revenue and find it more difficult to attract investment because infringers generally do not pay taxes or appropriate duties, and often disregard product quality and performance.

An example which can serve to illustrate the extent of the economic harm arising from such trademark counterfeiting comes from India. In September 2013, the International Chamber of Commerce and the Federation of Indian Chambers of Commerce and Industry published a study which analyzed seven key industry sectors that are vulnerable to counterfeiting, piracy, and smuggling, *e.g.*, automotive parts, alcohol, computer hardware, mobile phones, packaged foods, personal goods, and tobacco products. The study concluded that, in 2012, rights holders suffered a 21.7 percent, or an approximately \$11.9 billion, loss in sales in India as a result of trademark counterfeiting issues. Collectively, according to the study, the Indian government's economic loss associated with these illicit activities totaled approximately \$4.26 billion.

Industry reports the following trends in counterfeiting and piracy:

- Many countries provide penalties that fail to deter criminal enterprises engaged in global copyright piracy and trademark counterfeiting operations. Even when such enterprises are investigated and prosecuted, the penalties imposed on them in many countries are low, and therefore, rather than deter further infringements, such penalties only add to the cost of doing business.
- Online sales of pirated and counterfeit goods have the potential to surpass the volume of sales through traditional channels such as street vendors and other physical markets. Enforcement authorities, unfortunately, face difficulties in responding to this trend. Online advertisements for the sale of illicit physical goods are ubiquitous.
- The continued increase in the use of legitimate express mail, international courier, and postal services to deliver counterfeit and pirated goods in small consignments, makes it more challenging for enforcement officials to interdict these goods.
- The practice of shipping products separately from counterfeit labels and packaging to evade enforcement efforts that target the completed counterfeit item continues.
- Media box-based piracy, whereby storage devices, often with capability to play high definition content, are loaded with large quantities of pirated works or are configured to facilitate the user's access to websites featuring unlicensed content, is growing in popularity, reportedly in **China, Hong Kong, Indonesia, Malaysia, Taiwan, Thailand, and Vietnam**. In 2014, Hong Kong Customs conducted a raid against a syndicate selling preloaded media

boxes, arresting nine people and seizing 41 boxes, but greater action and coordination will be needed in this region.

The United States continues to urge trading partners to undertake more effective criminal and border enforcement against the manufacture, import, export, transit, and distribution of pirated and counterfeited goods. USTR engages with its trading partners through bilateral consultations, trade agreements, and international organizations to help ensure that penalties, such as significant monetary fines and meaningful sentences of imprisonment, are available and applied so as to have a deterrent effect on counterfeiting and piracy. In addition, trading partners should ensure that both counterfeit goods, as well as the materials and implements used for their production, are seized and destroyed, and thereby removed from the channels of commerce. Permitting counterfeit and pirated goods and enabling materials to reenter the channels of commerce after an enforcement action wastes resources and compromises the global enforcement effort. Trading partners should also provide enforcement officials with the authority to seize suspect goods and destroy counterfeit and pirated goods during import or export, or in transit movement, *ex officio*, without the need for a formal complaint from a rights holder. The U.S. Government coordinates with, and supports, trading partners through technical assistance and sharing of best practices on criminal and border enforcement, including with respect to the destruction of seized goods. (*See Annex 2*).

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 a contributing dimension of the larger problem of the proliferation of substandard, unsafe medicines. The United States notes its particular concern with the proliferation of counterfeit pharmaceuticals that are manufactured, sold, and distributed in trading partners such as **Brazil, China, India, Indonesia, Lebanon, Peru, and Russia**. China and India are the sources of most of the counterfeit pharmaceuticals shipped to the United States. While it is impossible to determine an exact figure, studies have suggested that up to 20 percent of drugs sold in the Indian market are counterfeit and could represent a serious threat to patient health and safety. The U.S. Government, through the United States Agency for International Development (USAID) and other Federal agencies, supports programs in sub-Saharan Africa, Asia, and elsewhere that assist trading partners in protecting the public against counterfeit and also substandard medicines (medicines that do not conform to established quality standards) introduced into their markets. (*See discussion immediately below*).

In many cases, the bulk active pharmaceutical ingredients (API) that are used to manufacture pharmaceuticals bear counterfeit trademarks. Because such API are unlawfully produced or marketed, their manufacturers are unlikely to subject themselves to regulatory oversight or comply with good manufacturing practices. Hence, these products may contain substandard and potentially hazardous materials, and may threaten the health of American consumers. For

instance, in **China**, some domestic chemical manufacturers that produce API have avoided regulatory oversight by failing to declare that the chemicals are intended for use in pharmaceutical products. This practice serves as a contributing factor to China's status as a major source country for harmful APIs used in counterfeit pharmaceutical products. In a welcome initial step to address this shared concern, in 2014, China committed to develop amendments which provide enhanced regulatory control over manufacturers of bulk chemicals that can be used as API.

Trademark Counterfeiting in Sub-Saharan Africa

This year USTR heard from several stakeholders that noted increasing concerns regarding the large number of counterfeit goods entering sub-Saharan Africa from China and other source countries. Key ports in **Kenya**, **Nigeria**, and **South Africa** serve as entry points for counterfeit goods into the continent's distribution channels. These counterfeit goods can endanger lives, displace legitimate products, and adversely affect opportunities for legitimate economic growth. Counterfeit goods flooding sub-Saharan Africa's markets include, but are not limited to, medicines, automotive parts, and electronics. Such products pose serious health and safety dangers to individuals and communities. The lack of resources and other challenges make enforcement particularly difficult in this region.

Kenya and Nigeria are the largest markets in East Africa and West Africa, respectively, and face many serious enforcement challenges resulting from this trend. In Kenya, despite a robust legal framework supporting IPR enforcement, agencies with a positive track record of effectiveness, such as the Kenyan Anti-Counterfeiting Agency and Kenyan Revenue Authority, have experienced significant resource cuts. Minimum penalties for IPR infringement, clear sentencing guidelines, and adequate staffing and resources are critical tools for Kenyan authorities to operate effectively. Nigeria has some of the largest and most notorious markets for counterfeit goods in Africa, including several in Lagos State. (*See 2014 Notorious Markets List*, available at www.ustr.gov).

The United States lauds measures previously taken against counterfeit products and those underway throughout sub-Saharan Africa against trade in such goods. The United States supports measures taken in the region to address these issues. However, it is imperative that source-country governments enhance their enforcement against such exports in support of sub-Saharan African governments, such as Kenya and Nigeria, that are working to combat this serious challenge.

Trademark Issues and Domain Name Disputes

Trademarks help consumers distinguish providers of products and services from each other and thereby serve a critical source identification role. The goodwill represented in a company's trademarks is often one of the company's most valuable business assets.

However, in numerous countries, legal and procedural obstacles exist to securing and enforcing trademark rights. For example, many countries need to establish or improve transparency and consistency in their administrative trademark registration procedures. For example, the lack of opposition procedures or effective implementation of such procedures in countries such as **Mexico** and **Russia**, deprives legitimate brand owners of a key tool to challenge bad-faith registrations.

Of additional concern is a report that significant punitive damages were imposed on the owner of a trademark registered in **Panama** in connection with that owner's efforts to oppose the registration and use of a second mark which has been found to be confusing similar in other markets. While the decision in this dispute is not necessarily representative of a systemic concern in Panama, the damage award may discourage other legitimate trademark owners from entering the market out of concern that defending their marks will result in punitive action.

Mandatory requirements to record trademark licenses are another concern, as they frequently impose unnecessary burdens, both administrative and financial, on trademark owners and create difficulty in the enforcement and maintenance of trademark rights. The absence of adequate means for searching for trademark applications and registrations, such as by electronic information systems like online databases, makes obtaining trademark protection more complicated and unpredictable. The ability to research proposed new trademarks and determine whether there are any conflicting trademarks filed or registered in other countries is critical for launching products in foreign markets.

Also, in a number of countries, governments often do not provide the full range of internationally-recognized trademark protections. For example, dozens of countries do not offer a certification mark system for use by foreign or domestic industries. The lack of a certification mark system can make it more difficult to secure protection for products with a quality or characteristic that consumers associate with the product's geographic origin. Robust protection for well-known marks is also important for many U.S. producers and traders who have built up the reputation of their brands.

Another area of concern for trademark holders is the lack of protection of their trademarks against unauthorized uses under country code top level domain names (ccTLDs). U.S. rights holders face significant trademark infringement and loss of valuable Internet traffic because of

such uses, and it is important for countries to provide for appropriate remedies in their legal systems to address this issue. A related and growing concern is that ccTLDs lack transparent and predictable uniform domain name dispute resolution policies (UDRPs). Effective UDRPs should assist in the quick and efficient resolution of these disputes. The United States encourages its trading partners to provide procedures that allow for the protection of trademarks used in domain names and to ensure that dispute resolution procedures are available to prevent the misuse of trademarks.

Government Use of Licensed Software

Under Executive Order 13103 issued in September 1998, U.S. Government agencies maintain policies and procedures to ensure that they use only authorized business software. Pursuant to the same directive, USTR has undertaken an initiative to work with other governments, particularly in countries that are modernizing their software systems or where concerns have been raised, against unauthorized government use of software. Considerable progress has been made under this initiative, leading to numerous trading partners' mandating that only legitimate software be used by their government bodies. It is important for governments to legitimize their own activities in order to set an example for the public of respecting IPR. Further work on this issue remains with certain trading partners, such as **Algeria, China, Costa Rica, Morocco, Pakistan, Paraguay, Tajikistan, Thailand, Ukraine, and Vietnam**. The United States urges trading partners to adopt and implement effective and transparent procedures to ensure legitimate governmental use of software.

Digital Piracy, Piracy Online, and Broadcast Piracy

The increased availability of broadband Internet connections around the world, combined with increasingly accessible and sophisticated mobile technology, is generating significant benefits, ranging from economic activity based on new business models to greater access to information. However, these technological developments have also made the Internet an extremely efficient vehicle for disseminating infringing content, and for supplanting legitimate opportunities for copyright holders and online platforms that deliver licensed content. The U.S. Government's *2014 Notorious Markets List* (available at www.ustr.gov) includes examples of online marketplaces reportedly engaging in commercial-scale IPR counterfeiting and piracy, including sites hosted in, or operated by, parties located in **Brazil, Canada, China, Russia, Switzerland, Ukraine**, and elsewhere.

While optical disc piracy continues in many countries, including in **China, India, Paraguay, and Vietnam**, piracy over the Internet has become the priority copyright enforcement issue in many trading partner markets. For example, the unauthorized retransmission of live sports programming over the Internet continues to grow in a number of countries and regions,

particularly in **China**, and in Latin America, the Middle East, and the Caribbean region. Websites that link to infringing content are intensifying the problem. In addition, pirate servers or “grey shards” that allow users to play unauthorized versions of cloud-based entertainment software, and the development and online distribution of devices that allow for the circumvention of technological protection measures (TPMs), including “game copiers” and mod chips, allowing users to play pirated games on physical consoles, present unique enforcement challenges for rights holders.

“Camcorder” copies (*i.e.*, unauthorized recordings made in movie theaters) of first-run motion pictures that are distributed worldwide via the Internet result in economic harm not only in the market where the film was originally shown, but in other markets as well. The availability of, and recourse by rights holders to, enforcement procedures and remedies is a critical component of the online ecosystem. However, governments must also play a role, particularly in situations of online piracy that implicate multiple jurisdictions. Governments should avoid creating a domestic environment that offers a safe haven for piracy on the Internet.

For example, the United States also is increasingly concerned with **Switzerland’s** system of online copyright protection and enforcement. Several years have elapsed since the issuance of the judicial decision which gave rise to these concerns. Switzerland is reportedly attracting illicit sites formerly hosted in Eastern Europe, so the urgency for action by Swiss authorities has increased considerably. The United States strongly urges Switzerland to demonstrate its commitment to provide robust copyright protection and to combat online piracy by taking concrete steps to ensure that rights holders can protect their rights. The United States continues to welcome many aspects of the December 2013 report of the *Arbeitsgruppe zum Urheberrecht* (AGUR12 working group) on copyright, and continues to encourage the Swiss government to move forward expeditiously with measures that address copyright piracy in an appropriate and effective manner, including through administrative action and legislation. The United States looks forward to intensified engagement by, and cooperation with, Swiss authorities in their enhanced efforts with respect to this important issue.

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. The United States encourages trading partners to adopt measures to address these challenges, including by implementing the WIPO Internet Treaties. These treaties, agreed in 1996 and which entered into force in 2002, have raised the standard of copyright protection around the world, particularly with regard to Internet-based delivery of copyrighted content. The treaties, which included certain exclusive rights, require signatories to provide adequate legal protection and effective legal remedies against the circumvention of certain technological measures as well as certain acts affecting rights management information. A growing number of trading partners are implementing the provisions of the WIPO Internet Treaties to create a legal environment

conducive to investment and growth in legitimate Internet-related businesses, services, and technologies.

Copyright-Related Challenges in the Caribbean Region

The United States continues to express serious concerns regarding copyright protection and enforcement in the Caribbean region. (See Section II and the *2014 Special 301 Report* for a more detailed discussion). The United States has raised these issues at meetings of the Caribbean Community and Common Market (CARICOM) in 2013 and 2014, and looks forward to continuing to engage on these challenges with CARICOM and its member governments, and with other trading partners whose markets present these challenges. The following is a summary of U.S. concerns in CARICOM (and associated) markets:

U.S. musical works are being publicly performed by radio and TV broadcasting stations without obtaining licenses from the appropriate public performances rights organizations (PROs). This problem has been reported again this year in **Antigua and Barbuda, Barbados, Belize, Dominica, Grenada, Guyana, Jamaica, St. Lucia, and St. Vincent and the Grenadines**. In some cases, the alleged infringing broadcaster is licensed by the government or is government-owned, which makes such actions even more troubling.

Cable operators and television and radio broadcasters, some government-owned (*e.g.*, in **Barbados**), reportedly refuse to negotiate with the PROs for compensation for public performances of music. PROs also assert that they have struggled to advance their legal claims in the local courts and, even when successful, cannot obtain payments. These problems have been reported in **Barbados, Jamaica, and Trinidad and Tobago** as well as **Antigua and Barbuda, Belize, Dominica, Grenada, Guyana, St. Lucia, and St. Vincent and the Grenadines**.

With regard to cable and satellite broadcasting of copyrighted network programming, although **Antigua and Barbuda, Barbados, Belize, Dominica, Grenada, Jamaica, St. Kitts and Nevis, Saint Lucia, and St. Vincent and the Grenadines** currently maintain a statutory licensing regime that includes a requirement to pay royalties to rights holders, reportedly, royalties are not being paid. Other countries in the region, including **Anguilla, the Cayman Islands, Dominica, Montserrat, and the Turks and Caicos Islands**, do not maintain statutory licensing regimes and reportedly fail to intercede when unauthorized entities, many of them government-owned, intercept and retransmit copyrighted content without remuneration. Satellite signal theft remains a serious concern in these countries as well.

IPR Protection and Market Access Challenges Affecting Multiple Industry Sectors

Trade Secrets

This year's Report again reflects an increasingly urgent need for trading partners to effectively protect and enforce trade secrets. Trade secret theft, including industrial and economic espionage conducted by cyber means, appears to be escalating. Companies in a wide variety of industry sectors, including information and communication technologies, services, biopharmaceuticals, manufacturing, and environmental technologies, rely on the ability to protect and enforce their trade secrets and rights in other proprietary information. Indeed, trade secrets, such as business plans, internal market analysis, manufacturing methods, and recipes, are often among a company's core business assets; and a company's competitiveness may depend on its capacity to protect such assets.

If a company's trade secrets are stolen by a competitor or the agent of a competitor, it may be extremely difficult, if not impossible, to recoup past investments in R&D, and future innovation may be compromised. Moreover, trade secret theft threatens to diminish U.S. competitiveness around the globe, and puts American jobs at risk. The reach of trade secret theft into critical commercial and defense technologies poses threats to U.S. national security interests as well.

Various sources, including the Office of the National Counterintelligence Executive (ONCIX), have reported specific gaps in trade secret protection and enforcement, particularly in **China**. The ONCIX publication titled *Foreign Spies Stealing U.S. Economic Secrets in Cyberspace*, states that "Chinese actors are the world's most active and persistent perpetrators of economic espionage." Theft may arise in a variety of circumstances, including those involving departing employees taking portable storage devices containing trade secrets, failed joint ventures, cyber intrusion and hacking, and misuse of information submitted by trade secret owners to government entities for purposes of complying with regulatory obligations. In practice, effective remedies appear to be difficult to obtain in a number of countries, including in China. In addition, many countries do not provide criminal penalties for trade secret theft sufficient to deter such behavior.

Consequently, the United States uses all trade tools available to ensure that its trading partners provide robust protection for trade secrets and enforcement of trade secrets laws.

U.S. Government Strategy on Mitigating the Theft of U.S. Trade Secrets

On February 20, 2013, the U.S. Intellectual Property Enforcement Coordinator (IPEC) issued the *Administration Strategy on Mitigating the Theft of U.S. Trade Secrets*. The Strategy highlights

U.S. efforts to combat the theft of trade secrets that could be used by foreign governments or companies to gain an unfair commercial and economic advantage by harming U.S. innovation and creativity, including:

- Focusing diplomatic efforts regarding trade secret protection in other countries, which include, among others, sustained and coordinated engagement with trading partners, the use of trade policy tools (including through the use of this Report), cooperation, and training;
- Promoting voluntary best practices by private industry to protect trade secrets, including best practices regarding information security, physical security, and human resources policies;
- Enhancing domestic law enforcement operations, especially through the activities of the Departments of Justice and Defense, Federal Bureau of Investigation, and National IPR Coordination Center; and
- Conducting public awareness campaigns and outreach to educate stakeholders regarding trade secret theft.

Trade secret theft can result in illegitimate technology transfer to foreign actors and can undermine U.S. competitive advantage.

Given the global nature of trade secret theft, action by our trading partners also is essential. On May 26, 2014, the European Council adopted its position on the draft *Directive of the European Parliament and of the Council on the Protection of Undisclosed Know-How and Business Information (Trade Secrets) Against Their Unlawful Acquisition, Use and Disclosure*, which was introduced by the European Commission on November 28, 2013. The draft Directive is now before the Legal Affairs (JURI) Committee of the European Parliament (document number 2013/0402(COD)). This Directive would harmonize civil trade secret law throughout the EU. The United States welcomes these important steps and looks forward to continued progress on this draft measure specifically, and on EU efforts to protect trade secrets from theft and misappropriation generally.

Localization, Indigenous Innovation, and Forced Technology Transfer

Rights holders operating in other countries may face a variety of government measures, policies, and practices that are touted as means to incentivize domestic “indigenous innovation,” but that, in practice, often disadvantage foreign companies, including those holding IPR. Such initiatives serve as market access barriers, discouraging foreign investment and hurting local manufacturers, distributors, and retailers. Such government-imposed conditions or incentives may distort licensing and other private business arrangements, resulting in commercially

suboptimal outcomes for the firms involved and for innovation, generally. Further, these measures discourage foreign investment in national economies, slowing the pace of innovation and economic progress. Government intervention in the commercial decisions that enterprises make regarding the ownership, development, registration, or licensing of IPR is not consistent with international practice, and may raise concerns regarding consistency with international obligations as well.

These government measures often have the effect of distorting trade by forcing U.S. companies to transfer their technology or other valuable commercial information to national entities. Examples of these policies, include, but are not limited to:

- Requiring the transfer of technology as a condition for obtaining regulatory approvals or otherwise securing access to a market, or for allowing a company to continue to do business in the market;
- Directing state-owned enterprises in innovative sectors to seek non-commercial terms from their foreign business partners, including with respect to the acquisition and use or licensing of IPR;
- Providing national firms with a competitive advantage by failing to effectively enforce IPR, including patents, trademarks, trade secrets, and copyrights, thereby allowing those firms to misappropriate or infringe U.S. companies' IPR;
- Failing to take meaningful measures to prevent or deter cyber intrusions and other unauthorized activities;
- Requiring use of, or providing preferences to, including with respect to government procurement, products or services that contain locally-developed or owned IPR or that are produced by local manufactures or service providers;
- Manipulating the standards development process to create unfair advantages for national firms, including with respect to the terms on which IPR is licensed; and
- Requiring the submission of excessive (and often unnecessary) confidential business information for regulatory approval purposes and failing to protect such information appropriately.

Some country-specific examples of these measures are identified in Section II. In **China**, market access, government procurement, and the receipt of certain preferences or benefits are conditioned on a firm's ability to demonstrate that certain IPR is developed in China or are

owned by or licensed, in some cases exclusively, to a Chinese party. In **India**, in-country testing requirements and data- and server-localization requirements are frequently cited by U.S. industry as inhibiting market access and blunting innovation in the information and communications technology sector. In **Indonesia**, a foreign party's approval to market pharmaceuticals is conditioned on the transfer of technology to an Indonesian entity or partial manufacture in Indonesia. In **Nigeria**, the United States is concerned about a push toward localization aimed at protecting, favoring, or stimulating local companies at the expense of foreign exporters and investors. For example, some recent measures require the procurement and use of locally-produced hardware, software, and other technological products, including Subscriber Identity Module (SIM) cards, and require that all subscriber and consumer data be hosted locally.

The United States urges that, in formulating policies to promote innovation, trading partners, including India and China, take account of the increasingly cross-border nature of commercial R&D, and of the importance of voluntary and mutually agreed commercial partnerships.

Challenges Affecting the Copyright and the Information and Communications Technology Sectors

Leveraging the power of the Internet, U.S. stakeholders continue to develop innovative business models that deliver content and services directly to consumers and businesses, support innovative business processes, and allow businesses to collaborate via new and efficient mechanisms. Increasingly, however, trading partners are creating obstacles that threaten continued growth and innovation by U.S. and other participants in the global digital economy. Emerging market access barriers reported by IP-intensive industry stakeholders include: restrictions on cross-border data flows and storage; discriminatory practices in government procurement of Information and Communications Technology (ICT) products and services; local content quotas; obstacles to investment; and other restrictions. As trading partners look to increase their own participation in the growing digital economy, these barriers must be eliminated to support continued innovation and growth.

For example, in 2014 and early 2015, China issued several measures imposing certain trade-restrictive IPR, R&D, and encryption-related requirements on ICT products, services, and technologies used in certain sectors of China's economy. China subsequently suspended one of the measures, which appears to be a signal that China is reconsidering its approach to ICT regulations. The United States welcomes this suspension and calls on China to engage in close consultation with concerned foreign governments and industry.

Some public comments received in response to the 2015 Special 301 *Federal Register* notice also identified developments in several countries that may have created market uncertainties for both technology companies and online content providers. For example, laws have recently been

enacted in some European countries that involve required remuneration or authorization for certain online activities relating to publishing excerpts from others' websites. The United States is closely monitoring these developments.

Market Access and Pharmaceutical and Medical Device Innovation

Among other mechanisms to support pharmaceutical and medical device innovation, USTR has sought to reduce market access barriers, including those that discriminate against U.S. companies, are not adequately transparent, or do not offer sufficient opportunity for meaningful stakeholder engagement, in order to facilitate both affordable health care today and the innovation that assures improved health care tomorrow. This year's Report highlights concerns regarding market access barriers affecting U.S. persons that rely on intellectual property protection, including the pharmaceutical and medical device industries, particularly in **Algeria, India, and Indonesia.**

Measures, including those that are discriminatory, nontransparent or otherwise trade-restrictive, have the potential to hinder market access in the pharmaceutical and medical device sector, and potentially result in higher healthcare costs. For example, taxes or tariffs may be levied – often in a non-transparent manner – on imported medicines, and the increased expense associated with those levies is then passed directly to healthcare institutions and patients. According to an October 2012 WTO report titled *More Trade for Better Health? International Trade and Tariffs on Health Products*, India maintains the highest tariffs on medicines, pharmaceutical inputs, and medical devices among the WTO members identified in the report. These tariffs, combined with domestic charges or measures, particularly those that lack transparency or opportunities for meaningful stakeholder engagement or that appear to exempt domestically-developed and -manufactured medicines, can hinder the Indian government's efforts to promote increased access to healthcare products.

Moreover, unreasonable regulatory approval delays and non-transparent reimbursement policies can impede a company's ability to exercise its rights, and thereby discourage the development and marketing of new drugs and other medical products. The criteria, rationale, and operation of such measures are often nontransparent or not fully disclosed to patients or to pharmaceutical and medical device companies seeking to market their products. USTR encourages trading partners to provide appropriate mechanisms for transparency, procedural and due process protections, and opportunities for public engagement in the context of their relevant health care systems.

U.S. industry has expressed concerns regarding the policies of several trading partners, including **Algeria, Austria, Belgium, China, Colombia, Czech Republic, Ecuador, Hungary, Italy,**

Korea, Lithuania, New Zealand, Portugal, Romania, Spain, Taiwan, and Turkey, on issues related to pharmaceutical innovation and market access. Examples of these concerns include:

- In **Algeria**, a ban on a number of imported pharmaceutical products and medical devices in favor of local products is a trade matter of paramount concern in this market and is the primary reason why Algeria remains on the Priority Watch List. The United States urges Algeria to remove this market access barrier that is also reportedly adversely affecting access to legitimate medicines;
- With respect to **Turkey**, U.S. industry continues to express significant concerns regarding the lack of efficiency, transparency, and fairness in the pharmaceutical manufacturing inspection process;
- With respect to the **EU**, U.S. industry continues to identify a series of concerning measures in several Member States, including **Austria, Belgium, Czech Republic, Finland, Hungary, Italy, Lithuania, Portugal, Romania, and Spain**. Such measures raise concerns with respect to the transparency and the opportunity for meaningful stakeholder engagement in policies related to pricing and reimbursement, which reportedly create uncertainty and unpredictability that adversely impact market access and incentives for further innovation;
- In **Colombia and Ecuador**, proposals designed to enhance domestic manufacturing capacity for pharmaceuticals could adversely affect market entry and investment and, in effect, limit access by consumers to the latest generation of medicines. One of the Ecuadorian proposals appears to limit the use of trademarks on off-patent and other pharmaceutical products, which has the potential to adversely affect both generic and innovative manufacturers, and generate consumer confusion; and
- With respect to **New Zealand**, U.S. industry has expressed serious concerns about the policies and operation of New Zealand's Pharmaceutical Management Agency (PhARMAC), including, among other things, the lack of transparency, fairness, and predictability of the PhARMAC pricing and reimbursement regime, as well as the negative aspects of the overall climate for innovative medicines in New Zealand.

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

The United States, like many countries, faces healthcare challenges, including with respect to aging populations and rising health care costs. The United States shares the objectives of continuing improvement in the health and quality of life of its citizens, and of delivering efficient, responsive, and cost-effective, high-quality health care to its population. The United States looks forward to engaging with its trading partners on the concerns noted above.

Geographical Indications

The United States is working intensively through bilateral and multilateral channels to advance U.S. market access interests and to ensure that the trade initiatives of other countries and regions, including with respect to geographical indication (GI) protection, do not undercut U.S. industries' market access. GIs typically include place names (or words associated with a place) and they identify products or services as having a particular quality, reputation, or other characteristic essentially attributable to the geographic origin of the product or service.

The United States is actively involved in promoting and protecting access to foreign markets for U.S. exporters whose products are identified by common names or generic terms, like parmesan and mozzarella for cheese. The United States is pursuing these objectives in international fora, including in APEC, WIPO, and the WTO as well as in bilateral agreements. The United States is also engaging bilaterally to address GI-related concerns, including with **Canada, China, Costa Rica, El Salvador, the EU and its Member States, Jordan, Morocco, the Philippines, South Africa, and Vietnam**, among others. U.S. goals in this regard include:

- Ensuring that the grants of GI protection does not violate prior rights (for example, in cases in which a U.S. company has a trademark that includes a place name);
- Ensuring that the grant of GI protection does not deprive interested parties of the ability to use generic or common terms, such as parmesan or mozzarella;
- Ensuring that interested persons have notice of, and opportunity to oppose or to seek cancellation of, any GI protection that is sought or granted;
- Ensuring that notices issued when granting a GI consisting of compound terms identify its generic components; and
- Opposing efforts to extend the protection given to GIs for wines and spirits to other products.

The United States is particularly concerned with the EU system of GI protection, both within the EU and as extended through its trade agreements. These concerns include the scope of protection provided to GIs, including in relation to trademarks and generic or common names, as

well as with respect to the transparency and due process of the EU GI registration systems. These concerns have become increasingly pronounced in the context of EU trade agreements, where due process safeguards, such as GI opposition and cancellation, have been diminished.

Intellectual Property and the Environment

Strong IPR protection and enforcement are essential to promoting investment in innovation in the environmental sector. Such innovation not only promotes economic growth and supports jobs, but also is critical to responding to environmental challenges. IPR provides incentives for R&D in this important sector, including through university research. Conversely, inadequate IPR protection and enforcement in foreign markets discourages entry into technology transfer arrangements in those markets. This may hinder the realization of the technological advances needed to meet environmental challenges, including the mitigation of, and adaptation to, climate change.

Certain national policies and practices advanced domestically and in multilateral fora may have the unintended effect of undermining national and global efforts to address serious environmental challenges. For example, India's National Manufacturing Policy promotes the compulsory licensing of patented technologies as a means of effectuating technology transfer with respect to green technologies. India has pressed to multilateralize this approach through its proposals in the negotiations under the United Nations Framework Convention on Climate Change (UNFCCC). These actions will discourage, rather than promote, investment in and dissemination of green technologies, including those technologies that contribute to climate change adaptation and mitigation.

The United States continues to work to ensure robust IPR protection and enforcement, which gives inventors and creators the confidence to: engage in foreign direct investment, joint ventures, local partnerships, and licensing arrangements; collaborate with foreign counterparts; open research facilities in markets abroad; establish local operations and work with local manufacturers and suppliers; create jobs, including local worker training; and invest in infrastructure for the production, adoption, and delivery of green technology goods and services, without fear of misappropriation of their IPR. Strong IPR protection is, therefore, not only critical to the objective of addressing environmental challenges and developing a global response to climate change, but also to national economic growth. The United States promotes strong IPR protection and enforcement as an environmental as well as an economic imperative, providing critical development benefits for, in particular, developing and least-developed country (LDC) partners.

Intellectual Property and Health

Numerous comments in the 2015 Special 301 review process highlighted concerns arising at the intersection of IPR policy and health policy. IPR protection plays an important role in providing the incentives necessary for the development and marketing of new medicines. An effective, transparent, and predictable IPR system is necessary for both manufacturers of innovative medicines and manufacturers of generic medicines.

The 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health recognized the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics. As affirmed in the Doha Declaration on the TRIPS Agreement and Public Health, the United States respects a trading partner's right to protect public health and, in particular, to promote access to medicines for all. The United States also recognizes the role of IPR protection in the development of new medicines, while being mindful of the effect of IPR protection on prices. The assessments set forth in this Report are based on various critical factors, including, where relevant, the Doha Declaration on the TRIPS Agreement and Public Health.

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

The United States also strongly supports the WTO General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health concluded in August 2003. Under this decision, WTO 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 WTO General Council adopted a Decision in December 2005 that incorporated this solution into an amendment to the TRIPS Agreement, and the United States became the first WTO Member to formally accept this amendment. The United States encourages other WTO members to accept this amendment by the current deadline, December 31, 2015. If two-thirds of WTO members accept the amendment, it will go into effect for those Members. The August 2003 waiver will remain in place and be available until the amendment takes effect.

The United States Government works to ensure that the provisions of its bilateral and regional trade agreements, as well as U.S. engagement in international organizations, including the United Nations and related institutions such as WIPO and the WHO, are consistent with U.S. policies

concerning IPR and health policy and do not impede its trading partners from taking measures necessary to protect public health. Accordingly, USTR will continue its close cooperation with relevant agencies to ensure that public health challenges are addressed and IPR protection and enforcement are supported as one of various mechanisms to promote research and innovation.

Implementation of the WTO TRIPS Agreement

The TRIPS Agreement, one of the most significant achievements of the Uruguay Round (1986-1994), requires all WTO Members to provide certain minimum standards of IPR protection and enforcement. The TRIPS Agreement is the first broadly-subscribed multilateral IPR agreement that is subject to mandatory dispute settlement provisions.

Developed country WTO Members were required to implement the TRIPS Agreement fully as of January 1, 1996. Developing country Members were given a transition period for many obligations until January 1, 2000, and in some cases, until January 1, 2005. Nevertheless, certain Members are still in the process of finalizing implementing legislation, and many are still engaged in establishing adequate and effective IPR enforcement mechanisms.

Recognizing the particular challenges faced by LDC WTO Members, the United States has worked closely with them and other WTO Members to extend the implementation date for these countries. For example, on June 11, 2013, the TRIPS Council reached consensus on a decision to again extend the transition period under Article 66.1 of the TRIPS Agreement for LDC WTO Members. Under this decision, LDC WTO Members are not required to apply the provisions of the TRIPS Agreement, other than Articles 3, 4, and 5 (provisions related to national treatment and most-favored nation treatment), until July 1, 2021, or until such a date on which they cease to be an LDC WTO Member, whichever date is earlier.

The United States participates actively in the WTO TRIPS Council's scheduled reviews of WTO Members' implementation of the TRIPS Agreement, and also uses the WTO's Trade Policy Review mechanism to pose questions and seek constructive engagement on issues related to TRIPS Agreement implementation.

WTO Dispute Settlement

The United States continues to monitor the resolution of disputes announced in previous Special 301 Reports. The most efficient and preferred manner of resolving concerns is through bilateral dialogue. Where these bilateral efforts are unsuccessful, the United States will use the WTO dispute settlement procedures, as appropriate.

In April 2007, the United States initiated dispute settlement procedures relating to deficiencies in China's legal regime for protecting and enforcing copyrights and trademarks on a wide range of products. In March 2009, the WTO Dispute Settlement Body (DSB) adopted a panel report that upheld two of the claims advanced by the United States, finding that: (1) China's denial of copyright protection to works that do not meet China's content review standards is impermissible under the TRIPS Agreement; and (2) China's customs rules cannot allow seized counterfeit goods to be publicly auctioned after only removing the spurious trademark. With respect to a third claim concerning China's thresholds for criminal prosecution and conviction of counterfeiting and piracy, while the United States prevailed on the interpretation of the important legal standards in Article 61 of the TRIPS Agreement, including the finding that criminal enforcement measures must reflect and respond to the realities of the commercial marketplace, the panel found that it needed additional evidence before it could uphold the overall U.S. claim that China's criminal thresholds are too high. On March 19, 2010, China announced that it had completed all the necessary domestic legislative procedures to implement the DSB recommendations and rulings. The United States continues to monitor China's implementation of the DSB recommendations and rulings in this dispute.

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

Following the 1999 Special 301 review process, the United States initiated dispute settlement consultations concerning the EU regulation on food-related GIs, which appeared to discriminate against foreign products and persons, notably by requiring that EU trading partners adopt an "EU-style" system of GI protection, and appeared to provide insufficient protections to trademark owners. On April 20, 2005, the DSB adopted a panel report finding in favor of the

United States that the EU GI regulation is inconsistent with the EU's obligations under the TRIPS Agreement and the General Agreement on Tariffs and Trade 1994. On March 31, 2006, the EU published a revised GI Regulation that is intended to comply with the DSB recommendations and rulings. There remain some concerns, however, with respect to this revised GI Regulation, which the United States has asked the EU to address. The United States intends to continue monitoring this situation. The United States is also working intensively bilaterally and in multilateral fora to advance U.S. market access interests, and to ensure that the trade initiatives of other countries, including with respect to GIs, do not undercut market access for U.S. companies.

The Interagency Trade Enforcement Center

In his State of the Union address on January 24, 2012, President Obama announced the creation of the Interagency Trade Enforcement Center (ITEC) to take a whole-of-government approach to monitoring and enforcing Americans' trade rights around the world. On February 28, 2012, the President issued an Executive Order that established ITEC. ITEC's role in coordinating international and domestic trade enforcement helps to ensure that America's trading partners abide by their obligations, including by maintaining open markets on a non-discriminatory basis, and by following rules-based procedures in a transparent way. ITEC leverages and mobilizes the Federal Government's resources and expertise to address unfair foreign trade practices and barriers, including those adversely affecting IPR. In particular, ITEC uses expertise from across the Federal Government to assist in asserting U.S. trade rights implicated by various international trade agreements.

SECTION II. COUNTRY REPORTS

PRIORITY WATCH LIST

East Asia and Pacific

CHINA

China remains on the Priority Watch List and subject to Section 306 monitoring in 2015.

China's leadership has acknowledged the critical role that IPR plays in spurring innovation and the need to improve China's protection and enforcement of IPR. Consistent with China's policy objectives, the country's judicial, legislative, administrative, and enforcement authorities continue to pursue wide-ranging legal reform efforts relating to the protection and enforcement of IPR in China. Individual rights holders report a greater ability to obtain relief, including temporary injunctive relief, against infringers in civil court actions. The United States also notes increased cooperation between U.S. and Chinese law enforcement agencies in an effort to stem cross-border flows of infringing products. The United States looks forward to strengthened cooperation, building on the increasing and positive cooperation between U.S. customs and investigative agencies and their Chinese counterparts, including the General Administration of China Customs (GACC) and the Ministry of Public Security (MPS).

Notwithstanding the generally positive effects of these reform efforts, several recent measures relating to ICT products, services, and technologies, have caused sharply adverse impacts on U.S. companies and raise serious concerns. Although one of the measures is in draft form and the other was recently suspended, the measures would impose certain trade-restrictive IPR-, R&D-, and encryption-related requirements on ICT products, services and technologies used in certain sectors of China's economy. The United States welcomes the recent suspension, but underscores that it is critical that China reconsider its approach to certain ICT issues and engage closely with governments and industry as it does so.

Independent of the new measures, a wide range of U.S. stakeholders in China continues to report serious obstacles to effective protection of IPR in all forms, including patents, copyrights, trademarks, trade secrets, and protection of pharmaceutical test data. As a result, sales of IPR-intensive goods and services in China remain disproportionately low when compared to sales in similar, or even less developed, markets that provide a stronger environment for IPR protection and market access. Despite laudable policy objectives and a welcome ongoing reform effort, foreign rights holders in China continue to face a complex and challenging IPR environment. Given the size of China's consumer marketplace and its global importance as a producer of a broad range of products, China's protection and enforcement of IPR continues to be a focus of U.S. trade policy.

The theft of trade secrets remains a particular concern. Such theft occurs inside and outside of China for the competitive advantage of Chinese state-owned and private companies. Conditions are unlikely to improve as long as those committing such theft, and those benefitting, continue to operate with relative impunity, often taking advantage of the theft in order to compete unfairly or to enter into business relationships that disadvantage their victims. The United States strongly urges the Chinese government to take serious steps to put an end to these activities and to deter any recurrence by rigorously investigating and prosecuting theft of trade secrets undertaken by cyber and conventional means.

Of longstanding concern are central, provincial, and local government measures and actions that appear to require or pressure rights holders to transfer IPR from foreign to domestic entities. Sometimes guided by government measures or policy statements intended to promote indigenous innovation and the development of strategic industries, government authorities may condition eligibility for certain benefits (*e.g.*, certain subsidies and tax preferences) or deny or delay access to certain markets (*e.g.*, government procurement or the ICT market) upon IPR being owned or developed in China, or licensed to a Chinese entity. The United States is concerned by the number of stakeholders reporting that Chinese government entities are using regulatory pressure to compel the licensing of important technologies or to dissuade the stakeholders from pursuing available legal avenues to enforce their IP. China has made commitments to the United States on certain of these matters, and the United States continues to press China to comply with those commitments.

Legal Reform

The United States generally welcomes China's ongoing legal reform efforts, despite serious reservations regarding certain recent legal changes. Since 2012, China has undertaken revisions to, and invited comments on, draft revisions to its existing laws on civil procedure, patents, copyrights, trademarks, drug administration, and scientific and technological achievements. In terms of procedure, effective January 1, 2013, China's amended Civil Procedure Law includes provisions that may help U.S. rights holders to obtain preliminary measures and other actions to enforce their rights in civil court actions. In early 2015, China's Supreme People's Court (SPC) invited comment on draft judicial *Interpretations of the Supreme People's Court on Issues Related to the Application of Laws in Reviewing Act Preservation Cases of Disputes over Intellectual Property Right and Competition*, which would provide additional guidance relative to provisions of the Civil Procedure Law. In addition to procedural reforms, on May 1, 2014, a revised Trademark Law and implementing regulations went into effect. China's State Council Legislative Affairs Office (SCLAO) is also reviewing and considering draft amendments to the Patent Law and Copyright Law. Very recent draft amendments to the Patent Law appear not to address concerns identified by the United States and industry, and the amendments may

introduce new provisions of substantial additional concern. The United States welcomes the opportunity to comment and engage with China on this important subject matter before the law takes final form. The United States believes that copyright reform in China is an urgent matter, but cautions that SCLAO must take the time to study carefully international developments and copyright industry practices to ensure that the new law provides adequate and effective protection and enforcement, including with respect to online piracy. A careful revision of the Copyright Law aligned with international best practices would put China on a stronger footing for the economic growth of its domestic cultural industries.

In particular, the United States and China share the goal of increased sales of legitimate copyright goods in China. From the view of the United States, the best way to achieve growth in sales of legitimate Chinese works is to ensure that authors and copyright owners, both Chinese and foreign, can license their rights in a manner consistent with international copyright industry business practices and can effectively enforce their rights. The United States believes that the deterrence provided by strong criminal remedies is essential to supporting an environment where rights holders can earn adequate revenue from their creations. To this end, the United States also welcomes the planned revision of the Criminal Code and encourages China to strengthen the provisions criminalizing commercial-scale piracy. Efforts to amendment of the Anti-Unfair Competition Law (AUCL), unrevised since first entering into force in 1993, are proceeding at a slower pace. While applauding China's consideration of U.S. Government and private sector perspectives and experiences, the United States notes the need to move forward expeditiously with remaining revisions to China's IPR-related laws. The United States underscores the urgent need to update and amend the AUCL and related trade secret laws, regulations, and judicial interpretations. China is currently conducting a legislative study on a revised law on trade secrets.

In 2013 and 2014, China invited comment on various judicial interpretations, regulations, and departmental rules on a range of subjects including the remuneration of inventors, administrative and judicial enforcement of patents, and other matters that impact Chinese market access for U.S. entities that rely upon IPR protection, such as provisions involving the administration of online foreign films and television dramas. The United States applauds China's openness to receiving comments and looks forward to continued engagement as future drafts are developed and evaluated, and as drafts move through the SCLAO and the National People's Congress, as required. Additional legal reforms require action, including amending the Criminal Law and other relevant measures to correct continuing deficiencies in China's criminal IPR enforcement.

Judicial Reform

In late 2014, China set in motion a three-year pilot program to study the merits of specialized intellectual property courts, currently including courts in Beijing, Shanghai, and Guangzhou.

Designated as intermediate courts in China’s judicial system, the intellectual property courts will have original jurisdiction over civil “technical cases,” or those involving patents, new plant varieties, integrated circuit layout designs, technical know-how, and computer software, as well as over determinations as to well-known trademarks. These courts will also hear appeals of administrative IPR decisions handed down by government authorities on IPR and unfair competition matters. The Beijing intellectual property court will have jurisdiction to hear appeals of patent and trademark validity determinations issued by the Patent Reexamination Board and Trademark Review and Adjudication Board. The new courts will likely provide a venue with greater IPR expertise and experience, but the success of the courts will be judged in large part by their impartial consideration of the facts and law, and their efficient operation.

National Leading Group

Following the completion of China’s 2010-2011 Special IPR Campaign, the State Council established a permanent office of the national leading group on combating IPR infringement (Leading Group) to better coordinate and improve China’s efforts to combat IPR infringement and the manufacture and sale of counterfeit and substandard goods. In 2014, the Leading Group continued to coordinate enforcement actions and undertake special campaigns, including concerning online markets and cross-border infringement cases. The United States encourages China to continue to work with foreign governments and rights holders to share information and demonstrate the constructive role the Leading Group can play to improve the protection and enforcement of IPR.

ICT Measures

Recent Chinese measures risk creating troubling barriers to the sale of ICT products, services, and technologies by non-Chinese firms. China’s counterterror law, still in draft form, would appear to require telecommunications business operators and Internet service providers to, among other things, disclose critical proprietary intellectual property to regulators. Of more immediate impact are the efforts to govern the use of ICT products, services, and technologies by financial institutions operating in China. On December 26, 2014, China issued the *Circular of the General Offices of China Banking Regulatory Commission (CBRC) and Ministry of Industry and Information Technology (MIIT) on Printing and Distributing the Guidelines for Promoting the Application of Secure and Controllable Information Technology in Banking Sector* along with the *Guidelines for Promoting the Application of Secure and Controllable Information Technology in Banking Sector*, with an accompanying annexing classification catalogue. This measure was a follow-up to the September 3, 2014, *Guidelines for Applying Secure and Controllable Information Technology to Enhance Banking Industry Cybersecurity and Informatization Development* (referred to collectively as the “ICT rules for banks”), issued by CBRC, MIIT, the National Development and Reform Commission, and the Ministry of Science

and Technology. The ICT rules for banks were not published in advance for public comment and were not published in their entirety in final form. These rules would regulate the use of ICT products, services, and technologies by financial institutions operating in China by requiring that an increasing percentage of these products, services and technologies be purchased from suppliers whose IPR is indigenously Chinese. In addition, the rules would require foreign firms to conduct ICT-related R&D in China and to divulge proprietary intellectual property as a condition for the sale of ICT products in China. On April 13, 2015, China issued an official notice to its banking sector, including to Chinese and foreign-owned banks, suspending its September 2014 ICT rules for banks. The United States welcomes this suspension and looks forward to receiving reports that conditions for U.S. ICT firms and market practices have returned to normal. The United States calls on China to engage with the United States and other governments and industry as it develops ICT policies in line with its international commitments and consistent with global standards and industry best practices. In discussions to follow, it is imperative to ensure that foreign and domestic IPR is treated the same and to ensure that product choice is decided by businesses independently and not as a pre-condition for market access.

Trade Secrets

Trade secret theft is a serious and growing problem in China. Misappropriation of a trade secret may arise in a variety of circumstances, including those involving departing employees, failed joint ventures, and cyber intrusion and hacking. Particularly troubling is misappropriation reportedly arising from the misuse of information submitted to government entities for purposes of complying with regulatory obligations. The misappropriation of trade secrets and their use by a competing enterprise can have a devastating impact on a company's business, making the company's recourse to adequate and effective legal remedies particularly important.

Under Chinese law, however, available remedies are difficult to obtain, given that civil, administrative, and criminal enforcement against misappropriation of trade secrets remains severely constrained. Enforcement obstacles include deficiencies in China's AUCL, constraints on gathering evidence for use in litigation, difficulties in meeting the criteria for establishing that information constitutes a trade secret, and criminal penalties that are not clearly deterrent. In addition, the AUCL's primary application is to "commercial undertakings" and not individual actors, and requires that a trade secret have "practical applicability," which may limit the scope of protection for early stage research. There are other important weaknesses in China's civil enforcement system, which relate to mechanisms for gathering evidence, and procedures for obtaining preliminary injunctions. Without changes to address these weaknesses, some of which are not specific to IPR but relate to China's civil process generally, effective enforcement against misappropriation of trade secrets in China will remain challenging.

The United States is encouraged by China's December 2013 Joint Commission on Commerce and Trade (JCCT) commitment to undertake an Action Program, which includes concrete actions to address enforcement, enhance public awareness, and require strict legal compliance with respect to trade secrets. The United States also welcomed China's December 2014 JCCT commitment to protect from improper disclosure trade secrets submitted to the government in administrative or regulatory proceedings. China also affirmed that it is conducting a legislative study of a new trade secrets law. The United States urges China to address past weaknesses in the law and to do so expeditiously. The United States continues to engage with China as it advances legal and regulatory reforms to better protect trade secrets.

Software Legalization by Government Entities, Online Copyright Piracy, and Other Concerns

Software Legalization

The United States continues to urge all levels of the Chinese government, as well as state-owned enterprises (SOEs), to use only legitimate, licensed copies of software. China reported that from 2011 to 2014, software legalization was completed at government offices of all levels. In 2014, inspection teams dispatched by the Inter-Ministerial Joint Conference on Promoting Use of Authorized Software Inspections identified problems among local governments, including the continued use of unauthorized software and incomplete implementation of software asset management tools. Despite China's attention to the concern, U.S. software companies have seen only a modest increase in sales to government agencies, and specific information about the procedures and tools used to ascertain budget or audit information remains unavailable.

Software legalization efforts have extended to China's SOE sector. Losses by software companies due to piracy at SOEs and other enterprises remain very high. To the extent that Chinese firms do not pay for the software that runs many of their operations, they reap a cost advantage relative to competitors who pay for legally acquired software. The United States remains committed to working with China to continue to address these challenges.

Online Piracy

Despite bilateral commitments to increase IPR enforcement, online piracy in China persists on a large scale. China has the largest Internet user base in the world, estimated at around 650 million, with nearly 560 million mobile web users. Despite national campaigns and the leadership of the Leading Group, widespread piracy affects industries involved in the distribution of legitimate music, motion pictures, books and journals, video games, and software. For example, industry reports that in 2013, the revenues from digital music sales in China were \$65.4 million, compared to potential sales of over \$1.2 billion if China's per capita spending were on par with that in Thailand, a country with a roughly equivalent per capita GDP and substantial

piracy problems of its own. Effects are also seen in the share of film revenues made up by box office receipts. For U.S. films released in China, box office receipts make up over 90 percent of total revenues generated, compared to only 25-30 percent in the United States. This difference is partly due to the widespread piracy of motion pictures over the Internet and on optical discs. Reports indicate that unauthorized camcording of movies in theaters, one of the primary sources for online audiovisual infringements, remains a serious problem in China, especially in the South. Online piracy extends to unauthorized access to, or unauthorized copies of, scientific, technical, and medical publications as well.

While these very substantial problems continue, a range of enforcement actions by China are welcome and could have increasingly beneficial impacts if sustained and expanded. In 2014, China carried out the 10th “Sword-Net” campaign focused on protecting digital copyright. Administrative authorities reportedly investigated 4,400 online piracy cases, issued substantial fines, made 66 referrals to criminal authorities, and took other actions against pirate websites. Chinese courts and agencies entered deterrent-level penalties against a number of large major online piracy services including those offered by *QVOD*, *Baidu*, *SiluHD*, *HDstar*, *DY161*, and *FunShion*. For instance, in June 2014, the Shenzhen Market Supervision Administration imposed a record \$42 million fine against *QVOD*, a video streaming website, for making available pirated movies and TV shows to its subscribers. In addition, National Copyright Administration of China (NCAC) entered administrative penalties against *Yyets* and *Shooter.cn*. Another welcome development was China’s first criminal conviction for illegal camcording.

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

Other Concerns

New regulations related to State Administration of Press, Publication, Radio, Film, and Television (SAPPRFT) review of foreign television content present a serious market access concern for the online distribution of imported films and television series. Legitimate video streaming websites such as those operated by Sohu, Tencent, and others represent an important gateway for U.S. and other foreign television content providers to reach consumers in China. The new regulations threaten legitimate commerce through the imposition of a number of onerous registration requirements, while doing little to curb infringing streaming sites. The

United States urges China to suspend the new regulations and to further consider the potential impacts of these far-reaching regulatory changes.

Counterfeit Goods

Despite increased enforcement efforts, USTR's *2014 Notorious Markets List* reported that many sources identify China as the source of counterfeit products sold illicitly in markets around the world. Counterfeit goods produced in China that are shipped to the United States include: food and beverages; apparel, footwear, and accessories; consumer electronics, computers and networking equipment; entertainment and business software; batteries; chemicals; appliances; pharmaceuticals; and auto parts. As described in Section I, the effects of these counterfeit goods go beyond lost sales volumes and harm to the reputations of U.S. trademark owners. Counterfeit pharmaceuticals potentially threaten the health of American consumers, and faulty or substandard goods that enter the supply chains of American manufacturers are dangerous as well. For example, higher defect and failure rates among counterfeit semiconductors may cause malfunctions in medical devices and vehicle safety and braking systems.

The United States and China have committed to strengthened cooperation on IPR border enforcement. In 2013, U.S. CBP and GACC conducted a successful joint customs IPR enforcement operation designed to interdict shipments of consumer electronics. However, during Fiscal Year 2014, products from China accounted for an estimated 63 percent of the total value³ of the IPR infringing products seized at U.S. ports. Products transshipped through, or designated as originating in, Hong Kong, many of which also were produced in China, accounted for 25 percent of the estimated total value of such seizures. The United States welcomes additional opportunities for enhanced bilateral engagement with China on IPR border enforcement issues. Such cooperation would include sharing best practices and customs-to-customs information exchange for use in risk management and enforcement actions, and conducting joint customs enforcement operations designed to deter and interdict shipments of counterfeit and pirated goods destined to the United States both as cargo and through international mail and international express carriers.

Although rights holders report increased enforcement activities, mostly but not exclusively on behalf of local brands, enforcement efforts have yet to slow the sale of counterfeit goods online. This is particularly concerning in light of the rapid growth of e-commerce in China and from China to overseas markets. Rights holders report that local Administrations for Industry and Commerce (AICs) typically confine their efforts to physical markets. While both the State Administration for Industry and Commerce (SAIC) and local AICs have called on online trading websites to improve procedures for removing listings of IPR-infringing goods, these measures

³ The value is based on the corresponding legitimate products' manufacturer's suggested retail price.

have not significantly deterred repeat and large-scale offenders who quickly place new postings offering infringing goods soon after complying with takedown notices.

In a welcome development, the SAIC published a report on IPR infringement and other concerns at the online sales platform Taobao. The report indicated that only about a third of products offered at the site were authentic. The United States commends SAIC's commitment to address this concern and urges Taobao to promptly address concerns identified in the report, consistent with the recommendations in the *2014 Notorious Markets List*.

In another welcome development, in July 2014 at the S&ED, China committed to develop regulatory amendments to assert better regulatory control over manufacturers of bulk chemicals that can be used as API in counterfeit drugs. China recognized the goal of fighting against the illegal manufacture, distribution, and export of counterfeit and substandard pharmaceutical products. The United States urges China to implement these reforms in short order.

In another positive note, over the past year, U.S. investigators and prosecutors have improved bilateral law enforcement cooperation with their Chinese counterparts on significant cross-border IPR cases. This has allowed U.S. authorities not only to prosecute and convict distributors of counterfeit goods in the United States, but to further investigations by exchanging information with Chinese authorities about the companies in China that manufacture or traffic in those goods. In one example last year, U.S. authorities convicted two individuals of trafficking in counterfeit airbags imported from China. As part of the U.S. investigation, U.S. authorities shared evidence with Chinese authorities regarding the entities and individuals supplying the U.S. defendants with the airbags and the Chinese opened their own investigation. Subsequently, Chinese police raided those sources, seizing counterfeit airbags and auto parts valued at about \$200,000 and arresting four individuals. According to Chinese authorities, based on business financial records, the operation made hundreds of thousands of dollars selling counterfeit auto parts primarily through e-commerce sites to customers in the United States, Canada, and elsewhere. The United States looks forward to working with MPS, GACC, and other enforcement authorities in China to pursue additional coordinated actions against traffickers of counterfeit goods and to seize fake products.

IPR and Technology Transfer Requirements

In addition to challenges with IPR protection and enforcement, rights holders in China must also contend with government measures, policies and practices, such as the recently-suspended ICT measures discussed above, that are purportedly intended to hasten China's development into an innovative economy, but that also disadvantage foreign rights holders. The United States is concerned about reports that many of China's innovation-related policies and other industrial policies, such as strategic emerging industry policies, may have negative impacts on U.S. exports

or U.S. investors and their investments or IPR. Chinese regulations, rules, and other measures frequently call for technology transfer and, in certain cases, appear to include criteria requiring that certain IPR is developed in China, or are owned by or licensed, in some cases exclusively, to a Chinese party. Such government intervention, including imposed conditions or incentives, may distort licensing and other private business arrangements, resulting in commercially suboptimal outcomes for the firms involved and for innovation.

Sustained U.S.-China engagement through the JCCT, the U.S.-China S&ED and high-level government engagement has resulted in important Chinese commitments, including now-President Xi Jinping's 2012 commitment "that technology transfer and technological cooperation shall be decided by businesses independently and will not be used by the Chinese government as a pre-condition for market access," and China's 2014 JCCT commitments that China must "treat intellectual property rights owned or developed in other countries the same as domestically owned or developed intellectual property rights," and that "enterprises are free to base technology transfer decisions on business and market considerations, and are free to independently negotiate and decide whether and under what circumstances to assign or license intellectual property rights to affiliated or unaffiliated enterprises." In addition, at the 2012 JCCT, China "reaffirmed that technology transfer and technology cooperation are the autonomous decisions of enterprises" and pledged further that "[i]f departmental or local documents contain language inconsistent with the above commitment, China will correct them in a timely manner." At the 2013 JCCT, China committed not to implement rules or finalize a draft catalogue containing indigenous innovation criteria for the procurement of vehicles for official use that are inconsistent with China's 2012 commitment. The United States looks forward to China's full implementation of its commitments, and the revision of measures as needed to ensure that they are consistent with such commitments, including with respect to ICT and elements of the High and New Technology Enterprise tax incentive, such as requirements that beneficiaries license core IPR exclusively to a party in China and make 60 percent of their global R&D expenditures in China.

Patent-Related and Other Policies

IPR and Technological Standards

The growing importance of IPR and technological standards in China heightens U.S. concerns regarding a range of Chinese government policies and practices. Whereas open, voluntary, and consensus-based standards best promote economic development, efficiency and innovation, standards development bodies in China reportedly often deny membership or participation rights to foreign parties based on opaque and exclusionary practices, and effectively prevent foreign parties from participating in the standard setting process. In some cases, a firm's ability to participate may be conditioned upon a requirement to act through a joint venture in which the

firm only has a minority ownership stake, license IPR on concessional terms, or transfer technology against its will. Based on a limited number of investigations conducted to date, there is also growing concern that Chinese competition authorities may target for investigation those foreign firms that hold IPR that may be essential to the implementation of certain technological standards. Reports of intimidating and non-transparent investigative conduct contribute to these concerns.

In the related realm of national standards, the Standardization Administration of China (SAC) and the State Intellectual Property Organization (SIPO) published *Regulatory Measures on National Standards Involving Patents (Interim)* that went into effect on January 1, 2014. Relative to prior drafts, the Measures appear to address a number of U.S. Government and industry concerns. However, the United States continues to have serious concerns about potential requirements for entities not participating in the development of the standards to disclose relevant patents and make licensing commitments. The United States recognizes that there is a lack of clarity as to whether the positions of standards setting bodies regarding voluntary disclosure and voluntary licensing of essential patents have been incorporated appropriately into the positions of the anti-monopoly law enforcement authorities. In particular, the recently issued *Regulation by the Administration for Industry and Commerce on the Prohibition of Conduct Eliminating or Restricting Competition by Abusing Intellectual Property Rights* appears to retain provisions that may unnecessarily inhibit a patent holder's exercise of discretion in making licensing commitments for standards essential patents, despite U.S. requests that such language be stricken from the final regulation. The provisions appear in tension with China's recognition at the 2014 JCCT that IPR protection and enforcement is important for companies that voluntarily agree to incorporate patents protecting technologies into a standard, and that concerns may exist relating to the licensing requirements of standard essential patents that are subject to licensing agreements.

IPR Protection for Pharmaceutical Products

The United States has engaged intensively with China to address troubling obstacles to obtaining and maintaining patents on pharmaceutical innovations. Although SIPO guidelines governing the review of patent applications were once generally consistent with those of the United States and leading patent offices in other countries, a revised interpretation of the guidelines has severely restricted a patent applicant's ability to provide supplemental data in support of an application. As a result, China has, in some cases, denied pharmaceutical patent applications and invalidated existing patents, while the United States and other jurisdictions have consistently granted patent protection in similar cases. This problem was the subject of great attention during Vice President Biden's visit to Beijing in November 2013 and the annual meeting of the JCCT the following month. These engagements resulted in China's revision of the policy on data supplementation in late 2013, and a commitment to work with the United States to follow up on

implementation, including the examination of individual cases. Industry generally reports progress as a result of the change, but implementation of the commitment has been inconsistent, resulting in patent invalidations that create uncertainty and potentially undermine incentives to innovate.

The United States continues to have concerns about the extent to which China provides effective protection against unfair commercial use of, as well as unauthorized disclosure of, and reliance on, undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. China has undertaken commitments to ensure that no subsequent applicant may rely on the undisclosed test or other data submitted in support of an application for marketing approval of new pharmaceutical products for a period of at least six years from the date of marketing approval in China. However, there are reports that generic manufacturers have, in fact, been granted marketing approvals by the China Food and Drug Administration (CFDA) prior to the expiration of this period, and in some cases, even before the originator's product has been approved. The United States was encouraged by China's 2012 JCCT commitment to define "new chemical entity," a term that is central to the application of data protection in the marketing approval process, in a manner consistent with international R&D practice. Given that more than two years have passed since that time, the United States urges China to implement its commitment without delay.

The United States has engaged closely with China to increase efficiency in regulatory approval processes for pharmaceuticals and medical devices to accelerate patient access and incentives to innovate and market new products in China. The United States welcomed China's commitment at the 2014 JCCT to reform its authorization processes and to add personnel and funding. The United States continues to engage with China in support of its reform agenda.

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

INDONESIA

Indonesia remains on the Priority Watch List in 2015. The United States welcomes the new Administration's recent focus on IPR, including with respect to Indonesia's copyright law and trademark legislation. The United States also applauds continued educational outreach to the Indonesian public to advance IPR awareness. Nevertheless, the United States remains concerned about gaps in Indonesia's laws relating to the protection and enforcement of IPR and urges Indonesia to address these issues.

The United States is concerned about rampant piracy and counterfeiting in Indonesia, particularly with respect to the lack of enforcement against dangerous products. In 2014, the

Indonesian National Police (INP) only investigated 97 criminal IPR cases and the Attorney General's Office (AGO) only brought twelve IPR cases to trial. It is essential that Indonesia fully fund and support a robust IPR enforcement effort. The United States encourages Indonesia to address this problem through greater coordination between the National Inter-Ministerial IPR Task Force and Creative Economy Agency to create a specialized IPR unit under the INP to focus on investigating the Indonesian criminal syndicates behind counterfeiting and piracy, and initiate larger and more significant cases. Enforcement cooperation among relevant agencies is essential, including with the Directorate General for Intellectual Property (DGIP) and Badan Pengawas Obat dan Makanan, the regulatory agency that focuses on fake and substandard food and drug products. Further, the United States suggests increased coordination between the INP and the AGO so that specialized IPR inspectors and prosecutors can enhance the effectiveness and efficiency of their investigations. Finally, the United States encourages deterrent-level penalties for IPR infringement in physical markets and on the Internet.

The United States continues to encourage Indonesia to provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. The United States also remains concerned about market access barriers in Indonesia, including measures that appear to condition permissions to import medicines on at least some local manufacturing or technology transfer requirements. Other measures that could restrict market access relate to the importation of motion pictures. The United States remains concerned about the lack of clarity surrounding legal procedures under the Indonesian patent law in connection with the grant of compulsory licenses. The United States encourages Indonesia to provide for judicial or other independent review of any compulsory license authorizations. The United States welcomes increased engagement with the Government of Indonesia, including through the IPR Working Group of the United States-Indonesia Trade and Investment Framework, to substantively resolve these important issues.

THAILAND

Thailand remains on the Priority Watch List in 2015. The United States notes Thailand's stated desire to improve IPR protection and enforcement. At the same time, IPR enforcement does not seem to be a top priority for Thai law enforcement and poor coordination among government entities has seen limited improvement despite the launch of the National IPR Center of Enforcement in 2013. The United States urges Thailand to do more to address longstanding organizational challenges to enforcement and to prioritize IPR enforcement. The Thai government took several legislative steps in 2014, including an amendment to the Customs Act that provides Thai Customs officers with *ex officio* authority to suspend and seize illegal goods in transit, as well as copyright law amendments to address unauthorized camcording. Unfortunately, the Thai government in drafting several of the amendments failed to give weight

to concerns expressed by foreign governments and industry on prior drafts of the law. As a result, the amendments omit a much-needed landlord liability provision, and do not provide adequate protections against the circumvention of technological protection measures and the unauthorized modification of rights management information, or address procedural obstacles to enforcement against illegal camcording. Another Copyright Act amendment, introducing an option for rights holders to obtain a court order to force online service providers to take down infringing content, has resulted in a lack of clarity in the operation of the notice-and-takedown procedures. Rights holders also express concerns regarding pending legislation imposing content quota restrictions and the unintended effects from data and cyber security laws. It will be critical for Thai authorities to engage closely with foreign governments and industry as this and other legislation takes shape. Other concerns include a backlog in pending patent applications, widespread use of unlicensed software in both the public and private sectors, growing Internet-based copyright piracy, rampant trademark counterfeiting, lengthy civil IPR proceedings and low civil damages, and extensive cable and satellite signal theft. The United States continues to encourage Thailand to provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. The United States urges Thailand to engage in a meaningful and transparent manner with all relevant stakeholders, including IPR owners, as it considers ways to address Thailand's public health challenges, while maintaining a patent system that promotes innovation. The United States looks forward to continuing to work with Thailand to address these and other issues.

South and Central Asia

INDIA

India remains on the Priority Watch List in 2015. The United States Government conducted an OCR of India in the autumn of 2014 to evaluate U.S.-India bilateral engagement on IPR areas of concern to the United States and U.S. stakeholders. In the course of the review, the United States concluded that the Government of India took steps that indicate that the Modi Administration is engaged and is examining key IPR issues. These steps include India's establishment of a domestic IPR-focused experts group, commitment to technical engagement on specific issues of concern, and the issuance of encouraging domestic policy pronouncements. India has continued its engagement with the United States on IPR issues of interest to both countries, including by establishing the High Level Working Group on Intellectual Property ("IPR Working Group"). The IPR Working Group, established by President Obama and Prime Minister Modi, operates under the auspices of the United States-India Trade Policy Forum, which exists to facilitate the enhancement of our overall bilateral trade relationship. In our bilateral dialogue, the United States is working with India to foster an environment that will enable India to achieve its important domestic policy goals of increasing investment and stimulating innovation through, not at the expense of, IPR protection and enforcement. Attention

to our IPR priorities and action to resolve concerns through bilateral fora can benefit both the United States and India. Ultimately, however, recent positive developments on engagement should translate into substantive and measurable action.

In many areas, IPR protection and enforcement challenges continue, and there are serious questions regarding the future of the innovative climate in India, across multiple sectors and disciplines. A wide array of stakeholders in this year's Special 301 review process welcomed recognition by the Government of India of areas where reform is needed. However, some stakeholders also continue to underscore the challenges that rights holders face in India. The United States urges India to take specific actions to address the concerns raised, including by means of constructive bilateral engagement directly with the U.S. Government and stakeholders. The United States also urges India to reconsider how to meet its domestic policy objectives through fostering a climate that incentivizes innovation. The United States continues to encourage India to strengthen civil IPR enforcement by increasing judicial efficiency and reducing court backlogs through electronic case management, instituting fast-track procedures for certain IPR matters, training and instituting a system of using specialized judges, and other judicial reform measures. In addition, the United States supports India's enforcement-related efforts, including efforts to: initiate criminal investigations and launch raids at counterfeit goods markets; combat the manufacture, sale, and distribution of counterfeit medicines; initiate investigations and judicial actions against Internet-based piracy; and seek deterrent sentences against persons or entities engaging in copyright piracy and trademark counterfeiting.

Draft National IPR Policy

The Government of India has embarked on a thorough and holistic review of its IPR regime to “nurture the IP culture and address all facets of the IP system including legal, administrative and enforcement infrastructure, human resources, institutional support system and international dimensions.” The stated outcome of this review is to produce a National IPR Policy, a first draft of which was presented by a body of government-selected experts (IPR Think Tank) for public comment in December 2014. The United States submitted comments to the Government of India on the First Draft of India's National IPR Policy in January 2015. The United States commends India for undertaking this task, and will continue to engage with India on this policy, noting, in particular, those areas identified by the IPR Think Tank as target issues for Indian policymakers: transparency and stakeholder consultation; coordination among national and state authorities; public awareness; legal and legislative reforms; administration; commercialization; and enforcement. The United States understands that the Government of India received many informative inputs following the publication of the First Draft of India's National IPR Policy. Thus, the United States requests that India solicit another round of inputs, and conduct another round of stakeholder consultations on the next iteration of this draft policy.⁴

⁴ India's Draft National IPR Policy, December 19, 2014, available at: http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/IPR_Policy_24December2014.pdf

Copyright and Piracy

The United States continues to seek changes to India's copyright protection and enforcement regime that would protect both Indian and U.S. rights holders in the vibrant and promising Indian market. In particular, the United States urges India to: enact anti-camcording legislation; model its statutory license provisions relating to copyrighted works on the standards of the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention); ensure that collecting societies are licensed promptly and able to operate effectively; and provide additional protections against signal theft, circumvention of technological protection measures, and online copyright piracy. This is an area of substantial common interest between the United States and India, as two countries with vibrant content producers.

The United States also notes its interest in engaging with the Government of India on its policy reforms and initiatives that aim to increase investment in the Indian market and enhance the policy environment supporting innovation, notably through the "Make in India" and "Digital India" campaigns. As noted in the *2014 Special 301 Report*, while U.S. stakeholders eagerly anticipate India's growth in its Internet user base, projected to be, by the end of 2015, the second largest in the world with up to 370 million users, they also fear increased piracy as a negative corollary to this growth. This trend makes it all the more imperative that India incorporate into its legal system more effective measures to counter online piracy. The United States encourages the Government of India to adopt effective measures to counter online piracy, including appropriate notice-and-takedown procedures and other efficient mechanisms for rights holders to seek removal of infringing content from websites, consistent with international best practices. The United States also encourages the Government of India to undertake a review of its applicable statutory damages provisions for copyright piracy to ensure that they are appropriately calibrated to have a deterrent effect.

The high incidence of camcording in India underscores the importance of developing an effective legal framework to address this problem. India has one of the highest rates of video piracy in the world, according to a 2013 study conducted by the Motion Pictures Distributors Association of India (MPDA). This study found that incidents originating in India accounted for approximately half of all such incidents in the Asia-Pacific region in that year. Though the United States has welcomed past statements made by the Ministry of Information and Broadcasting about the desire to include specific anti-camcording provisions in the draft Cinematographic Bill, this bill has not yet been considered by the Indian Parliament. The United States notes that, in the First Draft of the National IPR Policy, the Government of India recognized the efforts of Indian state authorities in Tamil Nadu, Kerala, Andhra Pradesh, and Maharashtra to include video piracy as a legal offense. A positive next step would be the introduction of national anti-camcording legislation.

The United States notes some limited improvements with respect to copyright enforcement, including reports that enforcement officials cooperate with music industry rights holders in

conducting complaint-based raids, and of an increase in use of judicial orders that have strengthened enforcement against pirated movies and music online. The United States encourages India to take additional steps to improve coordination with enforcement officials of Indian state governments. To strengthen engagement on these and other copyright issues, and to build upon the strengths of the vibrant Indian and U.S. copyright-intensive industries, including in movies, music, and software, the United States would welcome closer bilateral cooperation with India to address the challenges of copyright piracy of U.S. and Indian content globally, including, for example, through cooperation and exchanges at the technical level between copyright protection and enforcement experts in each government.

Patents & Regulatory Data Protection

The United States continues to encourage India to promote an efficient, transparent, and predictable patent system that nurtures and incentivizes innovation. As leading economies with strong traditions of innovation, India and the United States can and should ensure supportive, enabling environments for innovators at all stages of the innovation lifecycle to achieve success and contribute significantly to economic growth. The United States commends India on actions taken in recent years to improve the operations of its Patent Office, which included digitizing records, upgrading online search and e-filing capabilities, and hiring additional patent examiners. The United States understands that, per the recommendation under the First Draft of India's National IPR Policy, India will continue to focus on patent administration issues that aim to increase human resource development, training, use of technology, and address other capacity issues. India's demonstrated commitment to address these issues will help promote efficiency, transparency, and predictability in patent administration in India, to the benefit of domestic and foreign innovators, and to India overall. The United States also welcomes April 2015 statements made by Prime Minister Modi recommending that India align its patent laws with international standards and encourages India expeditiously undertake this initiative.

With respect to patents, the United States continues to have serious concerns about the innovation climate for the biopharmaceutical and other sectors, such as agricultural chemical and green technology. Innovators in these sectors face serious challenges in securing and enforcing patents in India. This is not only detrimental to these commercial interests, but also to India's effort to address pressing domestic policy challenges, as it may discourage companies from entering the Indian market, or engaging in the kinds of voluntary and mutually agreed technology development and transfer that India is seeking domestically and in multilateral fora. The United States urges India to reject policies and practices that amount to barriers that will adversely affect not only American companies, but Indian companies as well. The United States encourages India to instead adopt policies that both address domestic challenges and support the cutting-edge innovation that can be critical to meeting legitimate domestic policy goals.

For example, a patent system should encourage the development of inventions that meet the well-established international criteria, enshrined in the TRIPS Agreement, of being new, involving an inventive step, and being capable of industrial application. Consistent with this,

Section 2(j) of India’s Patents Act sets forth the criteria for patentability. An “invention” under the Act is any product or process that is novel, has an inventive step, and is capable of industrial application. Section 3(d) of India’s Patents Act states, in relevant part, that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance” is not considered to be an “invention” under Indian law.⁵ As noted in the *2014 Special 301 Report*, the Indian Supreme Court explained, in the case of patent applications for pharmaceuticals and other chemicals:

“The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions [O]n reading [section 2] with section 3(d) it would appear that the Act sets different standards for qualifying as ‘inventions’ things belonging to different classes, and for medicines and drugs and other chemical substances, the Act sets the invention threshold higher, by virtue of [section 3(d)]. ... [I]n case of chemicals and especially pharmaceuticals if the product for which patent protection is claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of section 2(1), the test of enhanced efficacy as provided in section 3(d) read with its explanation.”⁶

The United States continues to have concerns that Section 3(d) of India’s Patents Act, as interpreted, may have the effect of limiting the patentability of potentially beneficial innovations. Such innovations could include drugs with fewer side effects, decreased toxicity, improved delivery systems, or temperature or storage stability. In practice, India has already applied this standard to deny patent protections to potentially beneficial innovations, some of which enjoy patent protection in multiple other jurisdictions. In addition, the United States supports patent systems that incorporate efficient patent procedures and foster high-quality patents; as such, the United States urges India to improve and streamline its patent opposition procedures as it adopts and implements the Draft IPR Policy. Specifically, under India’s patent regime, the same interested person may, at minimal cost, challenge a patent through *both* pre-grant and post-grant opposition proceedings on any of eleven enumerated grounds, including by citing the same grounds in both pre and post-grant challenges. As a result, applications can be tied up in costly challenge proceedings for years, all the while running the potential term of the patent, which begins from the application filing date. This has the ensuing effect of impeding an applicant’s ability to make investments and conduct business in India.

Second, while emphasizing our continued commitment to the Doha Declaration on the TRIPS Agreement and Public Health, as discussed in the Intellectual Property and Health section of this

⁵ Section 3(d) contains a further Explanation stating that “[f]or the purposes of this clause [3(d)], salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”

⁶ *Novartis AG v. Union of India & Others*, Civ. App. Nos. 2706-2716 (Supreme Court, April 1, 2013), paragraphs 103, 104, and 192 (*emphasis added*).

Report (*See* Section I), the United States also continues to monitor India's application of its compulsory licensing law. The United States requests clarity from the Government of India regarding the compulsory license decision-making process as it affects U.S. stakeholders. Although the government has issued only one compulsory license under Section 84 of India's Patents Act, India has made clear in other policy statements that it views compulsory licensing as an important tool of industrial policy for green technologies, with the potential to be applied more regularly across economic sectors. Specifically, India has, in the past, promoted compulsory licensing in its National Manufacturing Policy as a mechanism available for government entities to effectuate technology transfer in the clean energy sector.

In the UNFCCC negotiations, India continues to identify patents as obstacles to the dissemination of climate change technologies, pressing for outcomes that would potentially undermine incentives for innovation, such as patent protection and competitiveness conditions that are critical parts of the response to climate change and other environmental challenges. Despite India's claims, there is significant empirical evidence demonstrating that green technology patents promote innovation and technology transfer. Supported by its patent system, India has become a leading global manufacturer in several green technology sectors, with Indian companies leading global R&D efforts in this sector. India need only create a truly enabling environment in its market, with the features of openness, predictability, consistency, and fairness, and the investment, technology transfer, and innovation on which India's further development depends, will follow.

The United States also notes with concern the continuing challenges involved with the enforcement of patent rights in India, including challenges that some patent holders reportedly face in securing injunctions against firms that manufacture patented inventions without authorization from the patent holder. In addition, when approving such marketing without authorization, Indian state governmental authorities reportedly do not have a mechanism to confirm whether the item to be manufactured is under patent. Recent cases such as *Merck v. Glenmark* and *Cipla v. Roche* illustrate this problem and underscore the need for greater regulatory coordination between officials in state and central governments.

Finally, the United States continues to urge India to provide an effective system for protecting against unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. Without these types of protections, companies in India reportedly are able to copy certain pharmaceutical products and seek immediate government approval for marketing based on the original developer's data. The United States notes the potential to address this issue as part of the First Draft of India's National IPR Policy, which describes protection of undisclosed information as an "important area of study and research for future policy development." The United States understands that the issue of agricultural chemical data protection may be considered by the Indian Parliament under the Pesticides (Amendment) Bill.

Trade Secrets

The United States continues to note its concern regarding trade secret protection in India, particularly the reported difficulty in obtaining remedies and damages. India appears to rely primarily upon contract law to provide trade secret protection. Although India's approach may address the theft of trade secrets where a contract has been breached, India's approach may be less effective in covering situations in which there is no contractual relationship, such as in cases of theft by a business competitor. Although Indian law does provide for some remedies, including injunctive relief, in practice, damages can be very difficult to obtain. Finally, because India's court system reportedly lacks sufficient procedural safeguards to protect trade secrets or other confidential information divulged through discovery in civil or criminal litigation, there is a risk that such information may be disclosed publicly in the course of judicial proceedings, deterring victims of trade secret theft from using the court system to enforce their rights. The United States notes positive statements in the First Draft of India's National IPR Policy that seek to address gaps in its legal framework with respect to adequately protecting trade secrets in India, and the United States welcomes the opportunity to work closely with India on this issue.

Trademarks and Counterfeiting

The United States continues to receive stakeholder complaints regarding significant delays associated with cancellation and opposition proceedings at the administrative level of the Trademark Registry. Trademark owners' ability to enforce their rights against subsequent applicants for, or users of, potentially-infringing marks is hindered further by delays in India's judicial processes.

In addition, the level of production, sale, distribution, importation, and exportation of counterfeit goods affecting India's market remains very troubling. (*See* Section I). The First Draft of India's National IPR Policy notes that the Government of India should have an interest in strongly combating copyright piracy and trademark counterfeiting, as these illicit activities harm consumers and legitimate producers in India. As described in Section I of this Report, U.S. consumers may be harmed by fraudulent and potentially dangerous counterfeit products, particularly medicines, originating in India. Producers face the risk of diminished profits and loss of reputation when consumers purchase fake products, and governments lose tax revenue and find it more difficult to attract investment. Infringers generally pay no taxes or duties and often disregard basic standards for worker health and safety and product quality and performance.

U.S. enforcement authorities continue to express concerns about counterfeit and pirated goods produced in India and shipped to the United States. Some of these products (*e.g.*, counterfeit pharmaceuticals) pose serious risks to American consumers. The United States welcomes opportunities for enhanced bilateral engagement with India on IPR-related border enforcement issues. Such cooperation could include sharing best practices, customs-to-customs information exchange for use in risk management and enforcement actions, and conducting joint customs

enforcement operations designed to deter and interdict shipments of IPR-infringing goods destined for the United States.

Localization Trends

The United States remains concerned about actions and policies in India that appear to favor local manufacturing or Indian IPR owners in a manner that distorts the competitive landscape needed to ensure the development of globally-successful and innovative industries. For example, under India's Drug Price Control Order (DPCO), the National Pharmaceutical Pricing Authority implemented pricing restrictions on 509 drug formulations, effective April 1, 2015. However, exemptions from those restrictions allow certain medicines that are manufactured in India and "developed using indigenous R&D," to be priced higher, providing an advantage to Indian companies. In addition, the Indian Intellectual Property Appellate Board's interpretation of Section 84 of India's Patents Act suggests that a patent could be subject to a compulsory license if the patented product is not manufactured in India. Further, despite a Central Drug Standard Control Organization Office Order on waiver of local clinical trial requirements, industry still faces inconsistent application of requirements for local clinical trial data for approval of new drugs. In the information and communications technology sector, U.S. industry cites in-country testing requirements and data- and server-localization requirements as inhibiting market access in India.

The United States continues to press India in our bilateral dialogues, including through the IPR Working Group, to address the concerns identified in this Report. The United States will prioritize the achievement of substantive and measurable results that benefit both the United States and India.

PAKISTAN

Pakistan remains on the Priority Watch List in 2015 as there have not been significant improvements in its overall IPR protection. Most critically, Pakistan has not yet fully implemented key provisions of the Intellectual Property Organization of Pakistan Act of 2012 (IPO Act). In particular, Pakistan has yet to establish fully the specialized intellectual property tribunals provided for under the IPO Act. Pakistan should ensure that its enforcement officials can exercise *ex officio* authority without the need for a formal complaint by a rights holder and should provide for deterrent-level penalties for criminal IPR infringement. Due, in part, to a lack of effective enforcement, widespread counterfeiting and piracy of pharmaceuticals, printed materials, optical media, digital content, and software continue to present serious concerns for U.S. industry. Pakistan should also take the necessary steps to reform its copyright law to address the piracy challenges of the digital age and to reform its trademark legislation to meet international standards and to streamline the registration process. The United States continues to encourage Pakistan to provide an effective system for protecting against unfair commercial use,

as well as the unauthorized disclosure of tests and other data generated to obtain marketing approval for pharmaceutical products.

The United States appreciates Pakistan's interest in improving its IPR environment as evidenced by meetings Pakistan has convened with business associations and private companies to discuss IPR concerns and to increase public awareness on the importance of IPR. The United States looks forward to working with Pakistan to address these and other issues, including with respect to the full implementation of the IPO Act.

Near East, including North Africa

ALGERIA

Algeria remains on the Priority Watch List in 2015. The United States welcomes Algeria's increased work on promoting awareness of the importance of intellectual property in Algeria as well as its ongoing efforts that seek to root out the use of unlicensed software in government computers. The United States notes, however, that despite these efforts, much more remains to be done in the area of enforcement against piracy and counterfeiting, particularly, enforcement of existing anti-piracy statutes, and the provision of judicial remedies in the event of patent infringement. The United States encourages Algeria to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure of test or other data generated to obtain marketing approval for pharmaceutical products. Algeria's ban on a number of imported pharmaceutical products and medical devices in favor of local products is a trade matter of paramount concern in Algeria and the primary reason that Algeria remains on the Priority Watch List. The United States urges Algeria to remove this market access barrier, and looks forward to continuing its engagement with Algeria, including in the context of Algeria's efforts to accede to the WTO.

KUWAIT

Kuwait remains on the Priority Watch List in 2015, having been elevated from the Watch List in November 2014 as the result of an OCR. The *2014 Special 301 Report* stated that if, by the time the OCR was completed, Kuwait did not introduce to the National Assembly legislation resulting in a copyright law consistent with international standards, and resume effective enforcement against copyright and trademark infringement, then Kuwait would be moved to the Priority Watch List. These developments did not occur, and Kuwait was moved to the Priority Watch List in November 2014. The United States commends the Government of Kuwait's enforcement efforts taken since the OCR announcement and encourages Kuwait to maintain these efforts. However, the United States awaits the introduction to Kuwait's National Assembly of long-overdue copyright legislation that is consistent with Kuwait's international commitments. The United States stands ready to work with Kuwait towards resolving these important issues.

RUSSIA

Russia remains on the Priority Watch List in 2015 as a result of continued and significant challenges to IPR protection and enforcement, notably in the areas of copyright infringement and trademark counterfeiting. In particular, the United States remains concerned over stakeholder reports that IPR enforcement continues to decline overall in 2014, following similar declines in the prior two years, including a reduction in resources for enforcement personnel.

Copyright infringement is a persistent problem in Russia, including, but not limited to, online piracy. Although Russia's antipiracy legislation continues to evolve, its impact is unclear, as is whether further, needed modifications will occur. Russia remains home to many sites facilitating online piracy, which damage both the market for legitimate content in Russia as well as in other countries. While Russian courts issued the first two criminal convictions for online piracy this year, both resulted in suspended sentences, undermining the deterrent effect of the convictions. Enforcement against copyright infringement that does not take place online is also a notably low priority for law enforcement, particularly in major cities. Enforcement actions combating end-user piracy have declined sharply, as have the overall number of raids, criminal charges, and convictions. The United States urges Russia to ensure that ongoing legislative and enforcement efforts will result in copyright enforcement mechanisms that are fair, effective, and transparent.

The lack of enforcement of trademarks has resulted in the continued problem of counterfeit goods in Russia. Stakeholders express concern that counterfeit goods continue to be manufactured, transshipped and sold in Russia, including counterfeit agricultural chemicals, electronics, information technology, auto parts, consumer goods, machinery, and other products. The smuggling of Chinese-origin counterfeit products also continued unabated over the Kazakhstan-China border and through Kyrgyzstan, continuing on into Russia. Counterfeit pharmaceuticals are also manufactured in Russia and made available through online pharmacies. However, the United States welcomes the fact that in 2014 Russia's State Duma adopted new legislation aimed at criminalizing pharmaceutical counterfeiting as well as the distribution of fake and adulterated medicines.

The United States also is concerned about Russia's implementation of the commitments it made in the WTO Working Party Report related to the protection against unauthorized disclosure of, or reliance on, undisclosed test or other data generated to obtain marketing approval for pharmaceutical products.

The United States urges Russia to develop a more comprehensive, transparent and effective legal framework and enforcement strategy to reduce IPR infringement, particularly the sale of

counterfeit goods, and the piracy of copyright-protected content. Although the U.S. Government has curtailed bilateral engagement with Russia on a myriad of issues in response to Russia's actions in Ukraine, the United States continues to monitor Russia's progress on these and other matters through appropriate channels.

UKRAINE

Ukraine is on the Priority Watch List in 2015. Ukraine was designated a Priority Foreign Country (PFC) in the *2013 Special 301 Report*. As described in that report, the three grounds for Ukraine's PFC designation were: (1) the unfair, nontransparent administration of the system for collecting societies, which are responsible for collecting and distributing royalties to U.S. and other rights holders; (2) widespread (and admitted) use of illegal software by the Ukrainian government agencies; and (3) failure to implement an effective means to combat the widespread online infringement of copyright and related rights in Ukraine, including the lack of transparent and predictable provisions on intermediary liability and liability for third parties that facilitate piracy, limitations on such liability for Internet Service Providers and enforcement of takedown notices for infringing online content. Following Ukraine's designation and pursuant to statute, the Office of the U.S. Trade Representative conducted an investigation under Section 301 of Ukraine's IPR acts, policies, and practices, which concluded in March 2014. The U.S. Trade Representative determined that while IPR problems persisted, no adverse actions would be taken against Ukraine because of the political situation in Ukraine at that time. (*See Notice of Determination in Section 301 Investigation of Ukraine*, 79 FR 14326 (March 13, 2014)). The *2014 Special 301 Report*, published a few weeks later, reiterated the severe deficiencies in Ukraine's IPR protection and enforcement.

The three problems identified in the *2013 Special 301 Report* have not been resolved. However, in contrast to the period of time leading up to the PFC designation, in the past year the Government of Ukraine has invested additional effort in tackling these problems, in conjunction with other economic reforms. With respect to improving the administration of collecting societies, there is active engagement on legislative reform. No legislation has been passed, however, and the government still accredits "rogue" collecting societies, *i.e.*, societies which do not actually represent rights holders.

With respect to the use of unlicensed software by Ukrainian government agencies, the government reports that some agencies have transitioned to authorized software, but it has not institutionalized any mechanisms to ensure a uniform and permanent transition to use of authorized software.

With respect to improving the government's response to online infringement, Ukrainian officials have participated in law enforcement training, engaged in at least one enforcement action, and

worked on draft legislation. However, the legislation has not yet been adopted and investigations and prosecutions remain sporadic. As highlighted in the *2014 Notorious Markets List*, Ukraine continues to host some of the largest pirate sites in the world. The United States appreciates that the Ministry of Internal Affairs' Cybercrime Division and Economic Crimes Division have both been willing to work closely with the U.S. Department of Justice on online piracy and that Ukrainian enforcement personnel have participated in training and engagement on this issue, including a workshop on Combating Digital Piracy by the Commercial Law Development Program of the United States Department of Commerce.

The Government of Ukraine has stated that it seeks to improve these and other IPR-related deficiencies to advance its own agenda for economic improvement, particularly in promoting foreign direct investment, ensuring that legitimate Ukrainian creators and innovators can build successful businesses, and fulfilling its obligations under the EU-Ukraine Association Agreement. The United States welcomes Ukraine's recent outreach and ongoing engagement on these important issues and looks forward to these efforts resulting in tangible and lasting improvement, both in legislative reform and in practice.

Western Hemisphere

ARGENTINA

Argentina remains on the 2015 Priority Watch List, as it continues to present a number of very long-standing and well-known deficiencies in IPR protection and enforcement, and has become an extremely challenging market for IPR-intensive industries.

A major challenge in Argentina is the lack of effective IPR enforcement by the national government. Argentine police do not take *ex officio* actions, prosecutions stall, cases wallow in excessive formalities and, even if a criminal investigation reaches final judgment, infringers do not receive deterrent sentences. In terms of physical piracy, the Notorious Market La Salada is one of the biggest open-air markets in Latin America offering counterfeit and pirated goods, and it continues to grow. Open twice a week, La Salada attracts over one million people a day who browse and buy literally millions of illegal goods each year. Recent efforts by the City of Buenos Aires to combat increasing lawlessness in the market received little assistance from the national government. In fact, Argentina has thousands of smaller markets known as "Saladitas" that offer pirated and counterfeit goods, and vendors can be seen on the streets of Buenos Aires and other big cities selling illicit works with impunity.

While optical disc copyright piracy is widespread, Internet piracy is a growing concern. Internet piracy rates approach 100 percent in several content areas. For example, Argentine-run Notorious Market cuevana.tv—offering pirated movies and TV shows—is the 75th most popular website in the country, with an estimated 150,000 visitors each day. As a result, IPR

enforcement in Argentina consists mainly of rights holders trying to convince cooperative Argentine online providers to agree to take down specific infringing works, and attempting to seek injunctions in civil cases. Criminal enforcement is nearly nonexistent.

Argentina does not provide adequate protection against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical or agricultural chemical products, nor does Argentina provide an appealing environment to patent owners in terms of pendency, scope and term of protection, or meaningful enforcement options. Rather than providing protection for pending patents, Argentina only provides patent protection from the date of the grant of the patent. There is a substantial backlog of patent applications which results in long delays in registering rights. Argentina rejects patent applications with claims for common pharmaceutical products. To be patentable, Argentina requires that processes for the manufacture of active compounds disclosed in a specification be reproducible and applicable on an industrial scale. It is unclear whether these restrictive guidelines also apply to biotechnology products. These restrictions limit the ability of companies investing in Argentina to protect their IPR, and are inconsistent with international practice.

Finally, rights holders complain of widespread use of unlicensed software by Argentine private enterprises and the government. The Argentine government's imposition of currency exchange restrictions and the prohibition on payment of dividends and royalties to foreign parties make it difficult for Argentine companies seeking proper software licenses to obtain the currency needed to pay for such licenses. This presents yet another significant market access barrier for IPR-intensive companies who consider investing in Argentina.

CHILE

Chile remains on the Priority Watch List in 2015. The United States continues to have serious concerns regarding longstanding IPR issues under the United States-Chile Free Trade Agreement. The United States continues to urge Chile to implement an effective system for addressing patent issues expeditiously in connection with applications to market pharmaceutical products. The United States also urges Chile to provide adequate protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. The United States continues to urge Chile to implement both protections against the unlawful circumvention of technological protection measures and protections for encrypted program-carrying satellite signals. Chile must also ensure that effective administrative and judicial procedures, as well as deterrent remedies, are made available to rights holders and satellite and cable service providers, including measures to address ongoing concerns with decoder boxes. Finally, the United States urges Chile to amend its Internet Service Provider liability regime to permit effective action against piracy over the Internet, and also urges Chile to improve protection for plant varieties. The United States

looks forward to continuing to work with Chile to resolve these and other issues, including through the TPP negotiations.

ECUADOR

Ecuador is elevated from the Watch List to the Priority Watch List in 2015. This decision is based on Ecuador's 2014 repeal of its criminal IPR provisions. The United States urges Ecuador to complete its work in reversing the repeal, or to achieve this effect through other means. The current lack of criminal procedures and penalties invites transnational organized crime groups that engage in copyright piracy and trademark counterfeiting to view Ecuador as a safe haven. If Ecuador reinstates the repealed provisions or adopts new acceptable procedures and penalties by December 30, 2015, USTR will promptly conduct an OCR to determine whether to return Ecuador to the Watch List.

Ecuador is strongly encouraged to conduct an open, transparent, and inclusive process before advancing the draft knowledge and innovation economy law that, as currently drafted, would represent a departure from international practice and could threaten foreign investment in and further development of Ecuador's innovative and creative industries. Ecuador is also encouraged to bring patent maintenance fees back into alignment with international practice. With respect to the pharmaceutical and agricultural chemical industries, Ecuador does not adequately protect against the unfair commercial use, or the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. Ecuador must also ensure that its implementation of recently-adopted Decree 522 regarding the use of registered trademarks on off-patent medications and generics does not prejudice the legitimate interests of affected trademark holders. Finally, the United States encourages Ecuador to provide clarification on its processes related to the compulsory licensing of pharmaceuticals.

VENEZUELA

Venezuela remains on the Priority Watch List in 2015, as there was no attempt to reverse the downward trajectory of Venezuela's IPR system in 2014. Following Venezuela's formal withdrawal from the Andean Community, the reinstatement of its 1955 Industrial Property Law in conjunction with provisions in Venezuela's 1999 constitution and international treaty obligations has created legal ambiguity and impeded the registration of patents for pharmaceutical products. Venezuela's Autonomous Intellectual Property Service (SAPI) has not issued a new patent since 2007. Venezuela also fails to provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. IPR enforcement remains insufficient to address widespread counterfeiting and piracy, including

online. Consistent with this deteriorating IPR picture, the World Economic Forum's 2014-2015 Competitiveness Report ranked Venezuela last for intellectual property protection of all 144 countries evaluated.

WATCH LIST

East Asia and Pacific

Vietnam

Vietnam remains on the Watch List in 2015. Online piracy and sales of counterfeit goods over the Internet are common, and, as more Vietnamese obtain broadband and purchase smartphones, the United States expects that conditions will continue to worsen unless the Government of Vietnam takes action. Counterfeit goods—including high-quality knockoffs—remain widely available in physical markets, and while still limited, manufacturing of counterfeit goods is emerging as an issue. In addition, book piracy, software piracy, and cable and satellite signal theft persist. Enforcement continues to be a challenge for Vietnam. Capacity constraints remain due, in part, to a lack of resources and IPR expertise. Vietnam continues to rely heavily on administrative enforcement actions, which have failed to deter counterfeiting and piracy. While there are laws in place for IPR crimes, Vietnam has yet to draft the implementing guidelines to the 2009 amendments to the 1999 Criminal Code, which would allow law enforcement agencies and courts to levy deterrent criminal penalties against IPR violators. Vietnam's system for protecting against the unfair commercial use, as well as unauthorized disclosure of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products also needs clarifications. The Government of Vietnam is in the process of drafting or revising circulars in a number of IPR-related areas, including on guidelines for interagency cooperation on enforcement issues, as well as criminal code reform, and various agencies continue to engage in public awareness campaigns. Meanwhile, various other impediments to doing business have complicated efforts by foreign companies to sell legitimate products in the Vietnam's market. The United States looks forward to continuing to work with Vietnam to address these and other issues, including in the TPP negotiations.

South and Central Asia

Tajikistan

Tajikistan remains on the Watch List in 2015, with an OCR to evaluate the possibility of removing Tajikistan from the Special 301 Watch List. During its WTO accession process, the Government of Tajikistan committed to providing *ex officio* authority to its enforcement agencies. However, the existing legislation does not establish conditions for the customs authorities to act *ex officio*, or for public officials to be held liable when acting in bad faith. The United States encourages Tajikistan to address this deficiency and amend its laws to comport

fully with the commitments it made on this issue during the WTO accession process. The United States continues to recommend that Tajikistan increase prosecutions of criminal IPR infringement, enforce laws against widespread optical disc piracy, and address a report alleging endemic government use of unlicensed software. An industry survey from 2007-08 estimated that up to 90 percent of software operating on the government's computers is unlicensed. The United States notes that the Government of Tajikistan also developed its 2014-2020 National Strategy for the Development of Intellectual Property, but has not allocated money to implement it. The OCR will evaluate whether Tajikistan adopts a presidential-level decree, law, or regulation mandating government use of licensed software and implements its WTO accession-related commitment to provide *ex officio* enforcement authority for enforcement officials. The United States stands ready to assist through enhanced engagement or technical assistance, if requested.

Turkmenistan

Turkmenistan remains on the Watch List in 2015. The United States will conduct an OCR in 2015 to evaluate the possibility of removing Turkmenistan from the Special 301 Watch List as noted below. In 2012, Turkmenistan adopted a Law on Copyright and Allied Rights and amended its Civil Code to enhance IPR protection. However, Turkmenistan reportedly has yet to provide for effective administrative, civil or criminal procedures or penalties for enforcement of these rights. The United States urges Turkmenistan to provide these enforcement procedures, including *ex officio* authority for its customs officials. In addition, the United States continues to strongly encourage Turkmenistan to join the Berne Convention and other international IPR treaties. The United States is also concerned about reports of widespread usage of unlicensed software on government computers. The United States seeks an affirmative response from the Government of Turkmenistan mandating that government agencies use only licensed software and comply with international agreements regarding copyright protection as a signal of Turkmenistan's commitment to protect and enforce IPR. The OCR will evaluate whether Turkmenistan addresses existing gaps in its IPR legal framework, including by joining the Berne Convention, and issuing a presidential-level decree, law, or regulation mandating government use of licensed software. The United States stands ready to assist through enhanced engagement or technical assistance, if requested.

Uzbekistan

Uzbekistan remains on the Watch List in 2015. While Uzbekistan made some progress towards better IPR protection in past years, there was little progress last year. The United States urges the Uzbek Parliament to take several critical legislative steps to address longstanding deficiencies in IPR protection: (1) approve Uzbekistan joining the Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of their Phonographs (Geneva Phonograms Convention); (2) approve Uzbekistan's accession to the WIPO Internet Treaties; and (3) take legislative action to provide adequate copyright protection for foreign sound

recordings. Additionally, Uzbekistan should provide additional resources to the Agency for Intellectual Property and other enforcement agencies in addition to granting *ex officio* authority to customs and criminal law enforcement officials in order to initiate investigations and enforcement actions, including at the border. Uzbekistan also lacks deterrent-level penalties for IPR infringement. The United States will continue to engage with Uzbekistan on these matters.

Near East

Egypt

Egypt remains on the Watch List in 2015. Although Egypt continues to improve its border and customs controls, continuing IPR enforcement challenges remain, including the failure to issue deterrent-level sentences for IPR violations and the need for additional training for enforcement officials. Egypt has not issued regulations to clarify border procedures for the destruction of counterfeit and pirated products and to provide customs officials with the authority to take *ex officio* action. Egypt is continuing to upgrade its trademark database system for use in detecting and preventing the import, export, and transshipment of counterfeit goods. However, rights holders have expressed concerns about the registration of trademarks filed in bad faith. The United States urges Egypt to clarify its protection against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval of pharmaceutical products. The United States appreciates Egypt's recent engagement on many of these and other IPR issues and stands ready to work with Egypt to improve its IPR regime.

Lebanon

Lebanon remains on the Watch List in 2015. The United States encourages Lebanon to continue its progress on pending IPR legislative reforms, including with respect to new draft laws (concerning trademark, geographical indications, and industrial designs) as well as amendments to Lebanon's copyright and patent laws. The United States notes that the enactment of revisions in 2015 to the copyright law would pave the way for ratification of the two WIPO Internet Treaties. The United States also encourages ratification and implementation of the latest acts of several IPR framework treaties, including the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, the Nice Agreement, and the Madrid Agreement on False or Deceptive Indications of Source on Goods. In addition, the United States encourages Lebanon to ratify and implement the Singapore Treaty on the Law of Trademarks, and join the Patent Cooperation Treaty and the Madrid Protocol. The United States continues to stress the importance of Lebanon providing its Cyber Crime and Intellectual Property Rights Bureau and Customs with *ex officio* enforcement authority and its enforcement authorities with adequate resources to carry out their enforcement functions. The United States welcomes the continued efforts of the Ministry of Economy and Trade's Intellectual Property Protection Office to bolster its administration and enforcement capacity for intellectual property rights protection, and urges the commitment of additional resources to

support its work. Intellectual property enforcement through the Lebanese judiciary remains weak. The United States urges imposition of deterrent-level penalties for infringers. The United States looks forward to continuing to work with Lebanon to address these and other issues.

Europe and Eurasia

Belarus

Belarus remains on the Watch List in 2015. Levels of piracy and counterfeiting remain high in Belarus, and enforcement is weak. Despite passing laws in 2014 to make it easier for notaries to collect and preserve evidence of online IPR infringement for later court proceedings and to provide legal protection for plant varieties, Belarus' criminal law, criminal procedure, civil, and administrative codes—as well as its copyright and customs laws—remain inadequate to deal with IPR infringement. For example, copyright infringement is not a violation of criminal law in Belarus unless it occurs within a year after imposition of an administrative penalty for the same offense or is associated with the receipt of “large-scale” income. Similarly, trademark counterfeiting is not a criminal offense unless it happens within a year after imposition of an administrative penalty for the same offense. Moreover, Belarusian law does not explicitly give police officers *ex officio* authority to initiate IPR criminal cases or provide customs officials *ex officio* power to seize counterfeit and pirated goods and begin their own investigations. In 2014, Belarus also failed to follow through on plans to expand administrative liability for traffickers in counterfeit goods and to increase minimum administrative penalties for IPR infringement. The United States recognizes Belarus' participation in two recent INTERPOL-organized law enforcement operations targeting counterfeit goods—Operation Black Poseidon III and Operation Opson IV—and urges Belarus to participate in more joint enforcement exercises with its neighbors and other countries. Last year, Belarus signed the Treaty establishing the Eurasian Economic Union (EAEU), which includes Part XXIII “Intellectual Property” and Annex 26 on protecting IPR. Given the free movement of goods within the EAEU, the United States looks forward to seeing how Belarus will implement the Treaty through related measures, at both the EAEU and national levels as well as through additional enforcement. The United States appreciates its discussions with Belarus on IPR issues and looks forward to further cooperation on them.

Bulgaria

Bulgaria is on the Watch List in 2015. Despite some incremental progress on IPR protection and enforcement, the United States continues to have serious concerns regarding Bulgaria's actions to enforce its IPR laws and to significantly reduce Internet piracy. Bulgaria's Cybercrime Division has done outstanding work on IPR enforcement over the years, but its effectiveness was drastically reduced after the Division was transferred to the State Agency for National Security in October 2013. The United States understands that the current government plans to return the Division to the Ministry of Interior, and urges that this be done as soon as possible. The United States also encourages Bulgaria to devote the necessary resources to improving the prosecution of IPR cases. The United States supports the Prosecutor General's 2012 appointment of a new

management team to the Supreme Cassation Prosecutor's Office and introduction of standard practices for investigating and prosecuting IPR crimes. The United States encourages the Prosecutor General to establish specialized IPR prosecutorial units in Sofia and other large cities, appoint a sufficient number of lawyers to these units, provide detailed guidance and training, and closely monitor and analyze their work. The United States also encourages Bulgaria to take steps to improve the efficiency of its judicial system in dealing with IPR cases and providing deterrent sentences. IPR cases often persist for years, and deterrent-level sentencing remains rare. For example, in the first nine months of 2014, Bulgarian courts resolved around 100 IPR cases, but in the 30 instances where judges imposed prison sentences, each of those sentences was suspended. Internet piracy remains rampant as well. In addition, Bulgaria is one of the few European countries that refuses to use "sampling" in IPR cases. As a result, if the police seize multiple servers loaded with many gigabytes of infringing material, experts at the Copyright Office must examine each work and prepare a detailed report. Prosecutors must include every infringing work that police seized in the indictment, and judges must examine every work individually. This unnecessarily delays and complicates every large Internet piracy case. As Bulgaria continues efforts to draft a new Criminal Code, the United States urges the Council for Intellectual Protection and the Prosecutor General to address Internet piracy to resolve the numerous enforcement difficulties in this area. In addition, the United States remains concerned that administrative enforcement actions are sporadic and ineffective, especially with regard to Internet piracy. For example, in 2013, the Ministry of Culture conducted 743 checks for copyright infringement on the Internet, but carried out only 13 in 2014, and only issued three penalties. The United States recognizes that the two biggest Bulgarian collecting societies have licensing agreements in place with radio and TV broadcasters, but recommends that the government also work to ensure compliance by cable operators and that it take action to address unlawful fee collection by smaller rogue societies. The United States looks forward to continuing to work with Bulgaria to address these and other issues.

Greece

Greece remains on the Watch List in 2015. In 2014, Greece continued to make progress in IPR protection and enforcement. Notably, with respect to trademark protection and combating trade in counterfeit goods, the Hellenic Police and Greek Customs Authority increased seizures and investigations. Moreover, last year Greece passed a law authorizing authorities to impose criminal as well as administrative sanctions on individuals caught trafficking in counterfeit goods. The United States encourages Greek officials to use this new authority to better fight the street sales of counterfeit and pirated goods present in Greece's largest cities and tourist areas. Recent changes to the Greek Code of Civil Procedure have improved the efficiency and timeliness of civil infringement suits. While the Government of Greece has made progress, several issues remain to be addressed. The United States urges Greece to enact official storage time limits for goods detained at Greek ports and to ensure the timely destruction of these goods, as well as to consider joining most EU member states in adopting a policy that allows for the

inspection and detention of counterfeit goods in transit. And while Greece remains vigilant against counterfeit pharmaceuticals entering its market, market access issues remain for the innovative pharmaceutical industry. In addition, the government has not followed through on efforts to address public- and private-sector use of unlicensed software. The United States encourages Greece to implement an official software registry system for government software end users and also continue and expand upon the outstanding 2012-2013 work of the Tax Police (SDOE) to audit, raid, and fine businesses for using unlicensed software. Internet piracy also remains a significant problem. The United States encourages Greece to bolster its system for combating piracy over the Internet including by strengthening its legal regime and enhancing enforcement. The United States also supports current efforts of rights holders to work with ISPs and others to adopt voluntary measures to reduce Internet piracy. Finally, the United States encourages Greece to continue to implement the 2009 IPR Action Plan to address priority issues, and continues to urge Greece to address persistent problems with criminal enforcement delays and judges' reluctance to impose deterrent sentences and penalties on large-scale infringers. The United States looks forward to continuing to work with Greece to address these and other issues.

Romania

Romania remains on the Watch List in 2015. Despite numerous improvements in IPR protection and enforcement in Romania, some systemic concerns remain. For example, the 2010 transfer of copyright jurisdiction from the tribunal courts to first-instance, or lower level, courts has had a negative effect on enforcement, and has made training and capacity building for prosecutors and judges more difficult. In addition, the requirement established in 2005 that police identify every computer and digital media device in order to obtain a search warrant for a specific location, and then acquire additional warrants for each of these devices, could be significantly streamlined in order to encourage the investigation and prosecution of Internet piracy cases, while maintaining a fair process. Additionally, because of ambiguity regarding who can conduct computer searches under the new Criminal Procedure Code, the United States encourages the Government of Romania to clarify that police certified as experts can conduct such searches. Moreover, since the 2012 Data Retention Law was found unconstitutional by the Romanian court in 2014, following the European Court of Justice (ECJ) decision striking down the EU Data Retention Directive, there has been no legal basis to retain or preserve electronic data for investigations and prosecutions. Police and prosecutors maintain good cooperation with rights holders. For example, in 2014 the police and software industry launched a national campaign against unlicensed software, sending out more than 30,000 letters to companies and holding public awareness events attended by over 800 businesses. The Romanian National Customs Authority also has done impressive work, more than doubling the number of counterfeit goods it seized in 2014 from the previous year. However, the United States encourages Romania to do more with respect to IPR enforcement. For instance, the government should fully staff and fund the IPR Coordination Department in the General Prosecutor's Office (GPO), and encourage its efforts to investigate and prosecute significant IPR cases around the country as well as to coordinate

government IPR enforcement efforts through the inter-ministerial Intellectual Property Working Group. Romania's specialized police and prosecutors should continue and expand their recent efforts to focus on longer-term, higher-priority IPR crimes, rather than opening criminal investigations of minor violations that are then typically dismissed subsequently for lack of "social harm." Because larger IPR cases often involve related crimes such as fraud, tax evasion, and money laundering, prosecutors should consider bringing multiple charges, rather than limiting themselves to copyright and trademark infringement. In fact, Romanian prosecutors only indict a small fraction of criminal IPR cases filed, and obtain relatively few convictions or sentences. In 2014, for example, the GPO filed new 7,310 IPR cases, but obtained only 60 indictments. While industry has had some success with respect to its own initiatives to address online piracy in Romania, and the GPO took over numerous Internet piracy investigations, there have very few recent successful prosecutions involving significant pirate sites. The United States looks forward to continuing to work with Romania to address these and other issues.

Turkey

Turkey remains on the Watch List in 2015. Turkey made little to no progress on IPR issues in 2014, and enforcement of existing IPR laws, particularly by the judiciary, remains weak. U.S. rights holders continue to raise serious concerns regarding the export from, and transshipment through, Turkey of counterfeit and pirated products. In each of the last three years, a significant and increasing amount of counterfeit goods shipped to the United States from Turkey was interdicted at the U.S. border. In addition, Turkey remains one of the leading points of entry for counterfeit products into the EU, ranking fourth in the number of items seized and third in terms of the value of infringing goods. Turkey appears as one of the three most prominent sources of counterfeit goods in a number of categories, including cosmetics and fragrances, a category in which Turkey was the country of provenance for a full majority (51.25 percent) of the goods seized at EU borders. Given Turkey's prominent role as a source and transshipment point of counterfeit goods, the government must make fundamental improvements in the country's IPR and enforcement regimes, including enhancing Turkey's border control measures. Currently, the Government of Turkey does not have an effective mechanism for ensuring the use of licensed software. The most recent available data indicate that the rate of unlicensed software use in Turkey is 60 percent, representing a commercial value of unlicensed software of \$504 million. Stakeholders report, however, that enforcement against unauthorized use of software by enterprises was slightly improved in 2014, but noted that the system could be further improved by encouraging judges to issue deterrent sentences and damage awards in criminal and civil cases, respectively. Turkey currently shows little inclination to act on many promised IPR legislative reforms that have been discussed for the past several years. Legislation would be appropriate to improve several deficiencies in the system: the copyright law should be amended to provide an effective mechanism to address piracy in the digital environment, including full implementation of the WIPO Internet Treaties; royalty collecting societies should be required to have fair and transparent procedures; and police should be given the *ex officio* authority they

currently lack, which impedes them from acting on obvious infringement cases. The United States continues to encourage Turkey to clarify how it protects against the unfair commercial use, as well as unauthorized disclosure, of test and other data generated to obtain marketing approval for pharmaceutical products. The United States is also concerned that Turkey appears to shorten the term of data protection if the patent term ends first. The United States urges Turkey to be consistent with its own legislation on its regulatory approval timeline (currently 210 days for pharmaceuticals approved by any EU member state) and, in particular, to eliminate regulatory delays that stem from nontransparent procedures or practices. Finally, as mentioned above in Section I, U.S. industry continues to express significant concerns regarding the lack of efficiency, transparency, and fairness in the pharmaceutical manufacturing inspection process.

Western Hemisphere

North America

Canada

Canada remains on the Watch List in 2015, as a number of IPR and related issues remain. Regarding Canada's implementation of its 2012 Copyright Modernization Act, provisions aimed at addressing copyright piracy over the Internet came into force in January 2015, and Canada completed its ratification of the WIPO Internet Treaties in August 2014. The United States continues to urge Canada to fully implement its WIPO Internet Treaties commitments and to continue to address the challenges of copyright piracy in the digital age. Regarding border enforcement issues, the Combating Counterfeit Products Act became law in December 2014. The new law provides authority to Canadian customs officials to detain pirated and counterfeit goods being imported and exported at the border. The United States is disappointed that the new law does not apply to pirated and counterfeit goods in customs transit control or customs transshipment control in Canada. The United States urges Canada to provide its customs officials with full *ex officio* authority to improve its ability to address the serious problem of pirated and counterfeit goods entering our highly integrated supply chains. With respect to pharmaceuticals, the United States continues to have serious concerns about the availability of rights of appeal in Canada's administrative process for reviewing regulatory approval of pharmaceutical products. The United States also continues to have serious concerns about the lack of clarity and the impact of the heightened utility requirements for patents that Canadian courts have applied recently. In these cases, courts have invalidated several valuable patents held by U.S. pharmaceutical companies on utility grounds, by interpreting the "promise" of the patent and finding that insufficient information was provided in the application to substantiate that promise. These recent decisions, which have affected products that have been in the market and benefiting patients for years, have led to uncertainty for patent holders and applicants, including with respect to how to effectively meet this standard. This unpredictability also undermines incentives for investments in the pharmaceutical sector. The United States closely

monitors developments on these issues and looks forward to continuing to work with Canada to address these and other IPR issues, including through the TPP negotiations.

Mexico

Mexico remains on the Watch List in 2015. Positive developments in Mexico in 2014 included progress in law enforcement operations, including at the Notorious Markets Tepito and San Juan de Dios, and the seizure and destruction of pirated and counterfeit goods as well as materials and implements used for their production. However, serious concerns remain, particularly with respect to the widespread availability of pirated and counterfeit goods in Mexico and increased Internet piracy made possible, in part, by higher broadband penetration. To combat these high levels of IPR infringements, Mexico needs to improve coordination among federal and sub-federal officials, devote additional resources to enforcement, bring more IPR-related prosecutions, and impose deterrent penalties against infringers. The United States continues to urge Mexico to enact legislation to strengthen its copyright regime, including by fully implementing the WIPO Internet Treaties and providing stronger protection against the unauthorized camcording of motion pictures in theaters. Prior to 2011, Mexican customs authorities and the Attorney General's Office worked jointly to intercept and prosecute transshipments of counterfeit and pirated goods. Following a shift in policy, however, Mexican authorities now only take action against transshipments of suspected infringing goods if there is evidence of "intent for commercial gain" in Mexican territory, which is very difficult to prove. The United States strongly urges Mexico to provide its customs officials with *ex officio* authority and to revert to the previous policy that allowed for the interception of potentially dangerous goods bearing counterfeit trademarks in transit to the United States and other countries. The United States looks forward to continuing to work with Mexico to address these and other issues, including through the TPP negotiations.

Central America and the Caribbean

Costa Rica

Costa Rica remains on the Watch List in 2015, although there is growing concern that several promised reforms have yet to yield tangible results. In 2010, the Government of Costa Rica announced a plan to ensure that the government would use only licensed software, but inaction and a series of postponements followed until January of 2015, when the Government of Costa Rica issued a decree requiring government institutions to report in writing the status of their software licenses by June 30, 2015. It is critical that the government both complete scheduled audits and close the unlicensed software gap in the coming year. In 2011, the United States applauded an announcement that the Government of Costa Rica would create a specialized IPR prosecution unit; however, four years later, the government appears not to have followed through with that effort. Nevertheless, a newly appointed Economic Crimes Prosecutor has reportedly instilled new purpose into IPR enforcement efforts, although the number of cases initiated has fallen slightly. It also remains unclear whether the Government of Costa Rica has committed the

necessary resources to effectuate lasting improvements. To better evaluate the effectiveness of IPR prosecutions in Costa Rica, the government should provide detailed information, by type of IPR involved, on the number of cases that are opened, that result in charges, that are resolved, and any resulting sentences. In addition, the Ministry of Justice should call more meetings of the inter-institutional commission on IPR. Other concerns focus on various laws and regulations. Costa Rican law still allows online service providers 45 days to forward infringement notices to subscribers. However, action at such a glacial pace may be of little help to rights holders, given the speed at which infringing content can be posted to and downloaded, streamed, or shared through the Internet, as well as the fact that content may be of relatively short-term interest to the public. Pharmaceutical patent holders report various concerns, including poorly defined exceptions to Costa Rica's data exclusivity regime. Further, certain rulings on applications to register GIs present serious market access concerns, as administrative determinations at both the initial and review levels appeared to reject evidence vital in determining whether elements of a compound GI are generic. It is critical that Costa Rican authorities consider all relevant facts and arguments and provide clear notice to the public as to generic terms, including any that are elements of a compound GI. Moreover, while giving rise to optimism in last year's report, Costa Rica's new electronic trademark database is reportedly unsearchable, resulting in the need for time-consuming paper searches. In addition, the government has acknowledged that its customs procedures could be improved significantly; for example, Costa Rica should create a formal customs recordal system for trademarks to give customs officers the technical and contact information they need to make full use of their *ex officio* authority to detain and examine goods and should speed up resolution of customs cases. The United States urges Costa Rica to develop clear plans to tackle longstanding problems and to demonstrate tangible progress in implementing those plans prior to the next Special 301 Report.

Dominican Republic

The Dominican Republic remains on the Watch List in 2015. While there has been some positive enforcement action over the past year to promote public safety against threats from potentially unsafe products, substantial IPR concerns remain, including the widespread availability of pirated and counterfeit products, satellite signal piracy, and a longstanding patent application backlog. In an encouraging development in 2014, the Government of the Dominican Republic created in the Public Ministry an office responsible for prosecuting makers and sellers of counterfeit drugs and food products and is working with the National Police to execute raids, close illegitimate pharmacies and food retailers, and make arrests. In other areas, however, IPR enforcement has not improved. One Embassy contact estimated that only 10 of 150 cable providers operating in the Dominican Republic are licensed to provide cable services, yet the Government of the Dominican Republic has not taken enforcement actions. Although the Dominican patent office (ONAPI) granted more patents in 2014 than in 2013, the large backlog of pending patent applications continues to grow, standing at 1,379 pending applications as of June 2014. ONAPI is in the process of digitizing patents and creating an online application and retrieval system, but these efforts will take several years to complete. The United States Patent and Trademark Office continues to offer technical assistance to complete this modernization effort. The large patent application backlog underscores the need for patent term adjustment for

unreasonable administrative delays, however applications for adjustment continue to be denied at the administrative level. Additionally, the United States urges the Government of the Dominican Republic to increase transparency and predictability in protecting undisclosed test or other data generated to obtain marketing approval for pharmaceutical products against unfair commercial use and unauthorized disclosure by issuing regulations governing the process. The United States looks forward to continuing to work with the Dominican Republic to address these and other issues.

Guatemala

Guatemala remains on the Watch List in 2015, as a number of problems persist. Rulings in Guatemala on applications to register geographical indications appear sound and well-reasoned for compound GI names. However, due to a ruling by administrative authorities in April 2014 on GI protection for single name cheeses, concerns arose that new U.S. exporters may not be able to export certain types of cheeses and other products to Guatemala. The United States continues to engage with the Ministry of Economy and the Intellectual Property Registry on this important issue. Despite a generally sound IPR legal framework, enforcement activities in Guatemala remain ineffective due to resource constraints and lack of coordination among law enforcement agencies. Pirated and counterfeit goods continue to be widely available, and Guatemala has become a source of counterfeit pharmaceutical products. Trademark squatting is a significant concern, impacting the ability of legitimate business to use their marks, as administrative remedies are inadequate and relief through the courts is slow and expensive. Government use of unlicensed software is another serious problem that remains largely unaddressed. The United States continues to work with Guatemala to improve IPR protection and enforcement issues.

Barbados

Barbados remains on the Watch List in 2015. The United States continues to have concerns about the interception and retransmission of U.S. cable programming by local cable operators in Barbados and throughout the Caribbean region without the consent of, and without adequately compensating, U.S. rights holders. The United States also has continuing concerns about the refusal of Barbadian TV and radio broadcasters and cable and satellite operators to pay for public performances of music. (*See* Section I). The United States urges the Government of Barbados to take all administrative actions necessary, without undue delay, to ensure that all composers and songwriters receive the royalties they are owed for the public performance of their musical works. In one case, the local PRO won a case before the Supreme Court regarding the appropriate tariff to be paid for broadcasts of its members' music, and six years after that decision the PRO still has not received its monies because the requisite hearing at the administrative level has not yet been conducted. In addition, the United States urges the Government of Barbados to adopt modern copyright legislation that protects works in both physical and online environments and to take steps to prevent the unauthorized and uncompensated retransmission of copyrighted musical and audiovisual content. The United States looks forward to working with Barbados to resolve these issues.

Jamaica

Jamaica remains on the Watch List in 2015. The United States is watching the progress of proposed amendments to the Broadcasting and Radio Re-diffusion Act that would appear to permit advertising from local entities on the channels of foreign cable operators with the permission of content providers, which may lead to regulatory challenges and be difficult to enforce. In the area of copyright, Jamaica is one of several Caribbean countries with deficiencies related to protection and enforcement. (*See* Section I). For several years, Jamaica has been identified by rights holders as one of the region's most problematic markets with respect to the unlicensed and uncompensated cablecasting and broadcasting of copyrighted music. Jamaica maintains a statutory licensing regime for the retransmission of copyrighted television programming but has not consistently enforced the payment of statutory royalties to rights holders. Jamaica has, however, taken some steps to ensure that its regulatory agencies are monitoring broadcasting entities. The United States also continues to encourage Jamaica to adopt the long-awaited Patent and Designs Act, which has been under review for nearly a decade, and notes the recent developments with respect to copyright law amendments. The United States looks forward to working with Jamaica to address these issues.

Trinidad and Tobago

Trinidad and Tobago remains on the Watch List in 2015. The United States continues to urge the Government of Trinidad and Tobago to enforce the copyright provisions of its cable license agreements against cable operators who refuse to negotiate with the Copyright Music Organization of Trinidad and Tobago (COTT), the local performing rights organization, for compensation for public performance of music, including for music written by American composers. In one case involving a cable operator, the judicial authorities have not completed the appeal hearing nor assessed royalties owed to COTT four years after the court decision in COTT's favor. The United States urges the Government of Trinidad and Tobago to take all necessary actions to ensure that the terms of such licenses be fulfilled or that those licenses be terminated. These issues affect not only American artists but Caribbean artists as well. The United States looks forward to working with Trinidad and Tobago to address these issues.

South America

Bolivia

Bolivia remains on the Watch List in 2015. While Bolivia's legal framework addresses IPR, the lack of adequate enforcement has been a consistent problem. Stakeholders report that prosecutors rarely file criminal charges, civil suits face long delays, and customs authorities lack personnel and budgetary resources. Video, music, and software piracy rates are among the highest in Latin America, and rampant counterfeiting persists. On a positive note, governmental institutions reportedly have increased their acquisition of legal software, leading to a slight

decline in overall software piracy rates. Additionally, the Servicio Nacional de Propiedad Intelectual (SENAPI), Bolivia's IPR agency, has undertaken public awareness efforts, which have resulted in a significant increase in copyright, trademark, and patent registrations by Bolivians. Despite these positive developments, there were no reports of concrete enforcement operations against counterfeit goods in 2014. The United States encourages Bolivia to take the necessary steps to improve its poor enforcement of IPR, including by improving coordination among Bolivian enforcement authorities and with the authorities of its neighboring countries.

Brazil

Brazil remains on the Watch List in 2015. Brazil continued to improve its domestic IPR regime in 2014, working to expand IPR awareness and enforcement. This is evident, for example, in the work of the National Council on Combating Piracy and Intellectual Property Crime (CNCP), whose "Piracy-Free City" program provided training in eleven cities to help consumers identify counterfeit goods associated with the 2014 World Cup. CNCP also conducted several anti-piracy operations to target the importation of counterfeit goods. Brazilian customs and other enforcement authorities cooperated constructively with U.S. law enforcement agencies to target counterfeit goods entering the Brazilian market. Despite these very positive developments, significant concerns remain with respect to the high levels of counterfeiting and piracy in Brazil, including Internet piracy. Increased emphasis on enforcement at the tri-border region, as well as stronger deterrent penalties, are needed to make sustained progress on these IPR concerns. The National Industrial Property Institute (INPI) has taken steps to address a backlog of pending patent and trademark applications, including hiring new examiners; however, long delays still exist and additional examiners are needed. Concerns also persist with respect to Brazil's inadequate protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. The National Sanitary Regulatory Agency's (ANVISA) duplicative review of pharmaceutical patent applications for patentability requirements still lacks transparency and delays patent registration for innovative medicines. The United States remains concerned about multiple lawsuits filed by INPI seeking to invalidate or shorten the term of certain "mailbox" patents for pharmaceutical and agricultural chemical products. Strong IPR protection, available to both domestic and foreign rights holders alike, provides a critical incentive for businesses to invest in future innovation in Brazil. The United States looks forward to engaging constructively with Brazil in support of its work to build a strong IPR environment and to address remaining concerns.

Colombia

Colombia remains on the Watch List in 2015. In 2014, the Government of Colombia made progress on implementing the United States-Colombia Trade Promotion Agreement (CTPA), including by establishing patent term adjustment for unreasonable patent office delays and pre-established damages for trademark infringement. It also appears that Colombia has, thus far, implemented its geographical indications obligations to the EU in a manner that also is consistent

with CTPA obligations. Colombia also reduced patent application backlogs and continued to train judges and law enforcement officials on IPR. However, improvements are still needed with respect to implementation of significant IPR-related commitments made under the CTPA, including commitments to address the challenges of copyright piracy in the digital age. Online piracy, particularly via mobile devices, has grown significantly in Colombia in the last few years; Columbia is currently the third biggest smartphone market in Latin America, with over one-third of Colombians owning one, and more than two-thirds of Colombians having access to the Internet. Colombian law enforcement authorities with relevant jurisdiction, including the National Police and the specialized national-level IPR unit in the Attorney General's Office, have yet to engage in meaningful and sustained investigations and prosecutions against the operators of significant large pirate websites and mobile applications based in Colombia. And, despite dedicating more resources toward enforcement in 2014, the government has also not been able to reduce significantly the large number of pirate and counterfeit hard goods being sold at Bogota's San Andresitos markets, on the street, and at other distribution hubs around the country. Besides tackling online and mobile piracy, the United States urges Colombia to focus enforcement efforts on disrupting organized trafficking in illicit goods, including in the border and free trade zone areas. The United States looks forward to continuing constructive engagement with Colombia on these and other matters.

Paraguay

Paraguay remains on the Watch List in 2015. In addition, the United States continues to monitor Paraguay under Section 306. In 2014, promising negotiations occurred with the Cartes Administration to renew the bilateral IPR MOU that expired in April 2012. The United States encourages Paraguay to conclude the MOU by June 30, 2015. If this occurs, USTR will recommend an OCR to consider whether to remove Paraguay from the Watch List. Currently, USTR is identifying alternative options for enhanced engagement under the statute in the event that an MOU does not successfully conclude by the end of June. The United States recognizes that, even without the MOU, Paraguay has continued to take positive steps toward strengthening IPR. In 2014, for example, Paraguayan authorities, especially the National Directorate of Intellectual Property (DINAPI), took additional aggressive enforcement actions, including conducting raids and seizing merchandise from vendors and interdicting cargo at the international airport in Ciudad del Este. Authorities are beginning to work together to investigate cases and pursue legal actions, indicating a recognition by Paraguayan officials of the need for interagency coordination in order to have a significant impact on the availability of counterfeit and pirated merchandise in the marketplace. DINAPI has also continued its outreach to the public, signed inter-institutional cooperative agreements to improve IPR protection and enforcement, and has stepped up enforcement operations, including at the border. Nevertheless, Paraguay remains a major transshipment point for counterfeit and pirated goods, and the re-export trade on the black market is reportedly a source of significant foreign currency for the country. The United States encourages Paraguay to further improve enforcement efforts within

and at Paraguay's borders, including focusing on large-scale trafficking in counterfeit and pirated goods, reportedly by regional organized crime groups, in the Tri-Border Area and strengthening law enforcement cooperation with Brazil and Argentina. Paraguay also must find some way to address challenges in the prosecution and adjudication of IPR cases, as IPR violators are seldom charged and rarely receive deterrent sentences. In addition, many of the factors that resulted in Paraguay's designation as a Priority Foreign Country in 1998 remain. While DINAPI has begun issuing patents, ending a nearly nine year drought, Paraguay still does not adequately protect against the unfair commercial use, or the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. Paraguay also has yet to issue a government software legalization decree, although the United States understands that progress is underway to address the underlying concerns. While Paraguay's efforts over the past two years certainly merit acknowledgement, significant challenges remain, including many that could be addressed through a renewed MOU. The United States looks forward to working constructively with Paraguay to address enforcement and other IPR challenges, and to successfully conclude the MOU.

Peru

Peru remains on the Watch List in 2015. While Peru made some progress in 2014 to promote IPR and raise public awareness, including on counterfeit medicines, the United States remains concerned about the widespread availability of counterfeit and pirated products in Peru. The United States continues to urge Peru to devote additional resources for IPR enforcement, improve coordination among enforcement agencies, enhance its border controls, and build the technical IPR-related capacity of its law enforcement officials, prosecutors, and judges. The United States also encourages Peru to coordinate enforcement and pursue prosecutions under the law that criminalizes the sale of counterfeit medicines. In addition, the United States urges Peru to ensure that it implements its obligations under the United States-Peru Trade Promotion Agreement (PTPA) regarding the prevention of government use of unlicensed software, and its obligations under PTPA and other agreements to combat piracy over the Internet. Peru also needs to clarify its protections for biotechnologically-derived pharmaceutical products. The United States looks forward to continuing to work with Peru to address these and other issues, including through the TPP negotiations.

ANNEX 1. SPECIAL 301 STATUTORY BASIS

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 of 1994 (19 U.S.C. § 2242), USTR is required to identify “those foreign countries that deny adequate and effective protection of intellectual property rights, or deny fair and equitable market access to United States persons that rely upon intellectual property protection.”

The USTR shall only designate countries that have the most onerous or egregious acts, policies, or practices and whose acts, policies, or practices have the greatest adverse impact (actual or potential) on the relevant U.S. products as Priority Foreign Countries. Priority Foreign Countries are potentially subject to an investigation under the Section 301 provisions of the Trade Act of 1974. USTR may not designate a country as a Priority Foreign Country if it is entering into good faith negotiations or making significant progress in bilateral or multilateral negotiations to provide adequate and effective protection of IPR. USTR is required to decide whether to identify countries within 30 days after issuance of the annual National Trade Estimate Report. In addition, USTR may identify a trading partner as a Priority Foreign Country or re-designate the trading partner whenever the available facts indicate that such action is appropriate.

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

Additionally, under Section 306 of the Trade Act of 1974, USTR monitors a trading partner’s compliance with measures that are the basis for resolving an IPR-based investigation under Section 301. USTR may apply sanctions if a country fails to satisfactorily implement such measures.

The TPSC, in particular the Special 301 Subcommittee, in advising the USTR on the implementation of Special 301, obtains information from and holds consultations with the private sector, civil society and academia, U.S. embassies, foreign governments, and the U.S. Congress, among other sources.

ANNEX 2. UNITED STATES GOVERNMENT-SPONSORED TECHNICAL ASSISTANCE AND CAPACITY BUILDING

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

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

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

Other U.S. Government agencies bring foreign government and private sector representatives to the United States on study tours to meet with IPR professionals and to visit the institutions and businesses responsible for developing, protecting, and promoting IPR in the United States. One such program is the Department of State's International Visitors Leadership Program, which brings groups from around the world to cities across the United States to learn more about IPR and related trade and business issues.

Internationally, the U.S. Government is also active in partnering to provide training, technical assistance, capacity building, exchange of best practices, and other collaborative activities to improve IPR protection and enforcement. The following are examples of these programs.

- In 2014, GIPA provided training to 5,805 foreign IPR officials and college students and faculty in IPR-related programs of study, from 99 countries, through 113 separate programs. Attendees included IPR policy makers, judges, prosecutors, customs officers, examiners, and

college students as well as faculty in programs of study and training topics that covered the entire spectrum of IPR.

- GIPA also has produced seven free distance-learning modules, available on its website in multiple languages (English, Spanish, French, Arabic, and Russian); and several more are being prepared in areas such as copyright (advanced topics) and trade secrets. There have been about 42,000 hits on those modules since posted at www.USPTO.gov in early 2010.
- In addition, the USPTO's Office of Policy and International Affairs provides capacity building in countries around the world and has formed partnerships with 20 national, regional, and international IPR organizations, such as the United Kingdom Intellectual Property Office (UKIPO), Japan Patent Office (JPO), European Patent Office (EPO), German Patent and Trademark Office (DPMA), Government Agencies of the People's Republic of China, Mexican Institute of Industrial Property (IMPI), the Korean Intellectual Property Office (KIPO), and WIPO. These partnerships help establish a framework for joint development of informational, educational intellectual property content, technical cooperation, and classification activities.
- The Department of Commerce's International Trade Administration (ITA) collaborates with the private sector to develop programs to heighten the awareness of the dangers of counterfeit products and of the economic value of IPR to national economies. Additionally, ITA develops and shares small business tools to help domestic and foreign businesses understand IPR. ITA, working closely with other U.S. Government agencies and foreign partners, developed and made available IPR training materials in English, Spanish, and French. Under the auspices of the Transatlantic IPR Working Group, ITA worked closely with the EU's Directorate General for Enterprise and Industry to establish a Transatlantic IPR Portal so the resources of our respective governments are quickly and easily accessible to the public. All of the ITA-developed resources, including the Transatlantic IPR Portal, as well as information and links to the other programs identified in this Annex, are accessible via www.STOPfakes.gov.
- In Fiscal Year 2014, U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI), through the National IPR Coordination Center (IPR Center), and in conjunction with INTERPOL, conducted law enforcement training programs in France, Qatar, and China. ICE-HSI trained officials and police officers from Korea, China, Greece, Spain, Morocco, Algeria, France, Qatar, Ghana, Botswana, Gambia, Liberia, Nigeria, Rwanda, El Salvador, Colombia, Chile, Paraguay, Peru, Uruguay, Romania, Bulgaria, Ukraine, Thailand, Brazil, Honduras, Costa Rica, Venezuela, Benin, Guinea, Senegal, Togo, Curacao, Pakistan, Sri Lanka, Laos, and Turkey. The IPR Center also conducted advanced

training programs at the International Law Enforcement Academies (ILEAs) in Botswana, El Salvador, Ghana, Hungary and Peru for participants from 19 countries.

- In Fiscal Year 2014, U.S. Customs and Border Protection (CBP) supported U.S. Government sponsored IPR training sessions by providing instructors to train foreign customs officials in Kazakhstan, Armenia, Azerbaijan, Belarus, Georgia, Moldova, Kyrgyz Republic, Uzbekistan, Tajikistan, India, Ghana, Morocco, Kuwait, Vietnam, Laos, El Salvador, Hungary, Chile, and Togo.
- The Department of State provides training funds each year to U.S. Government agencies that provide IPR enforcement training and technical assistance to foreign governments. The agencies that provide such training include the U.S. Department of Justice (DOJ), USPTO, CBP, and ICE. In 2013-2014, the Department of State provided funds for 18 training programs for customs, police, and judicial officials from various trading partners, including Pakistan, Mexico, Indonesia, and the Philippines as well as regional trainings in Central America, Southeast Asia, and the Middle East. 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 INTERPOL.
- IPR protection is a main focus of the government-to-government technical assistance provided by the Commerce Department's Commercial Law Development Program (CLDP). CLDP programs address enforcement and adjudication of disputes, as well as IPR protection and its impact on the economy, IPR law compliance with the WTO TRIPS Agreement, IPR curricula in law schools, and public awareness campaigns. CLDP supports capacity building in innovation and technology licensing as well as in patent examination and copyright management in many countries worldwide. CLDP also works with the judiciary in various trading partners to improve the skills to effectively adjudicate IPR cases, and conducts interagency coordination programs to highlight the value of a whole-of-government approach to IPR protection and enforcement.
- The Department of Justice Criminal Division, using funding provided by and in cooperation with the Department of State, and in cooperation with other U.S. agencies, provides IPR enforcement training to foreign officials. Topics covered in these programs include: investigating and prosecuting cases under intellectual property, economic/financial and organized crime statutes; combating Internet piracy; intra-governmental and international cooperation and information sharing; obtaining and using electronic evidence; and the general importance of reducing trademark counterfeiting and copyright piracy. Major ongoing initiatives include multiple programs in Central and Eastern Europe, Asia, the Americas, and Africa.

- The U.S. Copyright Office, often in conjunction with various international visitor programs, hosts international visitors, including foreign government officials, to discuss and exchange information on the U.S. copyright system, including law, policy and the registration and recordation functions, as well as various international copyright issues. Staff also participates in a limited number of conferences in the United States and abroad to discuss current copyright issues and inform the public about the activities of the Copyright Office.

The United States reports annually to the WTO on its IPR capacity building efforts, including most recently in October 2014. (*See Technical Cooperation Activities: Information from Members – United States, IP/C/W/601/Add.6*).