

2017 Special 301 Report



Office of the United States Trade Representative

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EXECUTIVE SUMMARY

One of the top trade priorities for the Trump Administration is to use all possible sources of leverage to encourage other countries to open their markets to U.S. exports of goods and services, and provide adequate and effective protection and enforcement of U.S. intellectual property (IP) rights. Toward this end, a key objective for the Administration's trade policy will be ensuring that U.S. owners of IP have a full and fair opportunity to use and profit from their IP around the globe.

The Special 301 Report (Report) is the result of an annual review of the state of IP 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, the Uruguay Round Agreements Act, and the Trade Facilitation and Trade Enforcement Act of 2015 (19 U.S.C. § 2242).

The Report reflects the resolve of this Administration to call out foreign countries and expose the laws, policies, and practices that fail to provide adequate and effective IP protection and enforcement for U.S. inventors, creators, brands, manufacturers, and service providers. The identification of the countries and IP-related market access barriers in this Report and steps necessary to address those barriers are a critical component of the Administration's aggressive efforts to defend Americans from harmful IP-related trade barriers.

The Report identifies foreign trading partners where IP protection and enforcement has deteriorated or remained at unacceptable levels and where market access for Americans who rely on IP protection has been unfairly compromised. For example:

- USTR continues to place China on the Priority Watch List because longstanding and new IP concerns strongly merit attention. China is home to widespread infringing activity, including trade secret theft, rampant online piracy and counterfeiting, and high levels of physical pirated and counterfeit exports to markets around the globe. China imposes requirements that U.S. firms develop their IP in China or transfer their IP to Chinese entities as a condition to accessing the Chinese market. China also requires that mandatory adverse terms be applied to foreign IP licensors, and requires that U.S. firms localize research and development activities. Structural impediments to civil and criminal IPR enforcement are also problematic, as are impediments to pharmaceutical innovation.
- USTR identifies India on the Priority Watch List for lack of sufficient measurable improvements to its IP framework on longstanding and new challenges that have negatively affected U.S. right holders over the past year. Longstanding IP challenges facing U.S. business in India include those which make it difficult for innovators to receive and maintain patents in India, particularly for pharmaceuticals and software, enforcement action and policies that are insufficient to curb the problem, copyright policies that do not properly incentivize the creation and commercialization of content, and an outdated and insufficient trade secrets legal framework. New and growing concerns, including with respect to draft policies that negatively affect the commercialization of biotechnology, and the positions that India supports and voices in multilateral forum on IP issues, continue to generate skepticism about whether India is serious about pursuing pro-innovation and -

creativity growth policies.

- USTR identifies Indonesia on the Priority Watch List due to the lack of adequate and effective IP protection and enforcement. For example, revisions to Indonesia's patent law has raised serious concerns, including with respect to the patentability criteria for incremental innovations and computer implemented inventions and local manufacturing and use requirements.
- The Report highlights trading partners such as Chile and Colombia that have not delivered on IP commitments made to the United States.

The Report also identifies significant cross-cutting IP issues with regard to adequate and effective IP protection and enforcement worldwide. For example:

- In virtually all countries identified in this Report, IP enforcement is lacking. Many of the listed trading partners including Canada, Egypt, Indonesia, Mexico, Turkey, Turkmenistan, and Uzbekistan do not provide adequate or effective border enforcement against counterfeit and pirated goods; in addition, many listed countries' customs officials lack authority to take *ex officio* action to seize and destroy such goods at the border or to take such action for goods in-transit.
- Several countries including China, Mexico, Romania, Russia, Switzerland, Thailand, Ukraine and Vietnam have not addressed the continuing and emerging challenges of copyright¹ piracy. Countries such as Argentina, Greece, Tajikistan, Turkmenistan, Uzbekistan, and Venezuela do not have in place effective policies and procedures to ensure their own government agencies do not use unauthorized software.
- U.S. innovators face challenges including restrictive patentability criteria, that undermine opportunities for export growth in countries such as Argentina, Canada, India, and Indonesia. Innovators also face—for example in China, India, Indonesia, Thailand, and Russia—a lack of adequate and effective protection for regulatory test or other data submitted by pharmaceutical and agricultural chemical producers.
- Inadequate protection for trade secrets in a number of countries, notably in China and India, also puts U.S. trade secrets at unnecessary risk.
- The Report highlights negative market access effects of the European Union's approach to the protection of geographical indications in the EU and third-country markets on U.S. producers and traders, particularly those with prior trademark rights or who rely on the use of common food names.

USTR looks forward to working closely with the trading partners identified in this year's Report to address these and other priority concerns.

¹ As used in this report, the term "copyright" encompasses copyright and related rights.

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 IP protection, enforcement, or market access for persons relying on IP. Provisions of the Special 301 statute, as amended, direct USTR to develop action plans for each country identified as a Priority Watch List country that has been on the Priority Watch List for at least one year.

Public Engagement

USTR solicited broad public participation in the 2017 Special 301 review process to facilitate sound, well-balanced assessments of trading partners' IP protection and enforcement and related market access issues affecting IP-intensive industries, and to help ensure that the Special 301 review would be based on comprehensive information regarding IP issues in trading partner markets.

USTR requested written submissions from the public through a notice published in the *Federal Register* on December 28, 2016 (*Federal Register* notice). In addition, on March 8, 2017, USTR conducted a public hearing that provided the opportunity for interested persons to testify before the interagency 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, academics, and non-governmental organizations. USTR posted on its public website the testimony received 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.² The *Federal Register* notice and post-hearing comment opportunity drew submissions from 57 interested parties, including 16 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-2016-0026. The public can access the transcript of the hearing at WWW.USTR.GOV.

Country Placement

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

² Available at <https://ustr.gov/issue-areas/intellectual-property/special-301/2017-special-301-review>

interested parties.

USTR, together with the Special 301 Subcommittee, conducts a broad and balanced assessment of U.S. trading partners' IP protection and enforcement, as well as related market access issues affecting IP-intensive industries, in accordance with the statutory criteria. (See [ANNEX 1](#)). The Special 301 Subcommittee, through the TPSC, provides advice on country placement to 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 right 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 in [Section I](#). Each assessment is based upon the specific facts and circumstances that shape IP protection and enforcement in a particular trading partner.

In the year ahead, USTR will continue to engage trading partners on the issues 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 IP regimes;
- Encourage trading partners to engage fully, and with the greatest degree of transparency, with the full range of stakeholders on IP matters;
- Develop action plans with benchmarks for each country that has been on the Priority Watch List for at least one year to encourage progress on high-priority IP concerns; 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.

THE 2017 SPECIAL 301 LIST

The Special 301 Subcommittee received stakeholder input on more than 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, placed on the Priority Watch List, or Watch List, or not listed in the Report. Following extensive research and analysis, USTR has identified 34 trading partners as follows:

Priority Watch List

Watch List

-
- | | | |
|-------------|----------------------|----------------|
| • Algeria | • Barbados | • Jamaica |
| • Argentina | • Bolivia | • Lebanon |
| • Chile | • Brazil | • Mexico |
| • China | • Bulgaria | • Pakistan |
| • India | • Canada | • Peru |
| • Indonesia | • Colombia | • Romania |
| • Kuwait | • Costa Rica | • Switzerland |
| • Russia | • Dominican Republic | • Turkey |
| • Thailand | • Ecuador | • Turkmenistan |
| • Ukraine | • Egypt | • Uzbekistan |
| • Venezuela | • Greece | • Vietnam |
| | • Guatemala | |

OUT-OF-CYCLE REVIEWS

An Out-of-Cycle Review (OCR) is a tool that USTR uses to encourage progress on IP issues of concern. OCRs provide an opportunity to address and remedy such issues through heightened engagement and cooperation with trading partners and other stakeholders. OCRs focus on identified IP challenges in specific trading partner markets. Successful resolution of specific IP issues of concern can lead to a positive change in a trading partner's Special 301 status outside of the typical period for the annual review. Conversely, failure to address identified IP concerns, or further deterioration as to an IP-related concern within the specified OCR period, can lead to an adverse change in status.

USTR has closed two OCRs with no change in status since the 2016 Report. USTR has closed the OCR of **Pakistan**. While Pakistan maintained positive momentum on enhancing its IP regime, including through issuing IP legislation and regulations, engaging bilaterally, and committing to timelines for further actions, stakeholders continue to face a number of challenges in this market. USTR continues to identify Pakistan on the Watch List this year and USTR will seek enhanced engagement on the issues identified in this Report. Additionally, USTR has closed the OCR of **Spain**. USTR announced the OCR of Spain in 2013 to focus on concrete steps Spain could take to combat online piracy. USTR welcomes the significant and positive actions Spain has taken over the past four years, including with respect to the passage of amendments to legislation and to the issuance of a revised Attorney General's circular. The United States urges Spain to continue its work in this area, for example, by ensuring adequate resources for the Intellectual Property Commission, implementing its new legal authorities, and supporting its effective operation. Spain is not listed in the 2017 Report.

In the coming months, USTR will conduct three OCRs with **Colombia**, **Kuwait**, and **Tajikistan**:

- USTR will continue to conduct the OCR, announced in 2016, of **Colombia**, which remains on the Watch List this year. The OCR assesses Colombia's commitment to the IP

provisions of the United States-Colombia Trade Promotion Agreement and monitors the implementation of Colombia's National Development Plan.

- USTR will conduct an OCR of **Kuwait**, which will focus on improving Kuwait's copyright regime to meet international standards by fall 2017.
- The OCR of **Tajikistan** announced in 2015 will remain open through fall 2017. The United States takes note of recent engagement with the software industry and reiterates the importance of Tajikistan completing the benchmark set in the OCR by formalizing a presidential-level decree, law, or regulation mandating government use of licensed software by fall 2017.

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 annually 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. In 2016, USTR requested such comments on August 25, 2016 and published the *2016 Notorious Markets List* on December 21. USTR plans to conduct its next OCR of Notorious Markets in the fall of 2017.

STRUCTURE OF THE SPECIAL 301 REPORT

The 2017 Report contains the following Sections and Annexes:

[SECTION I: DEVELOPMENTS IN INTELLECTUAL PROPERTY RIGHTS PROTECTION AND ENFORCEMENT AND RELATED MARKET ACCESS](#) discusses global trends and issues in IP protection and enforcement and related market access 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: SPECIAL 301 STATUTORY BASIS](#) describes the statutory basis of the Special 301 Report; and

[ANNEX 2: UNITED STATES GOVERNMENT-SPONSORED TECHNICAL ASSISTANCE AND CAPACITY BUILDING](#) highlights U.S. Government-sponsored technical assistance and capacity building efforts.

April 2017

SECTION I: Developments in Intellectual Property Rights Protection, Enforcement, and Related Market Access

Intellectual Property (IP) infringement, including trademark counterfeiting and copyright piracy³, causes significant financial losses for right 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, IP 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. economic growth, competitiveness, and the support of an estimated 45 million U.S. jobs that directly or indirectly rely on IP-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 IP Protection and Enforcement Internationally

The United States notes the following important developments in 2016 and early 2017:

- In 2016, **China** expanded a pilot program for specialized IP courts to include four new IP tribunals. The specialized courts initiated positive steps to address concerns regarding evidentiary burdens, low damages, and other matters. Additionally, China's Supreme People's Court (SPC) launched a publically-searchable online database of judicial decisions. The SPC selected the Beijing IP court as its research base on case guidance and precedent.
- In 2017, **China** recognized trade secrets as the subject of civil IP protection, pursuant to amendments to its General Provisions of the Civil Law. Additionally, in 2016 and again in 2017, China published for comment draft amendments to the 1993 Anti-Unfair Competition Law, which is one of several measures important to trade secrets protection. Although the 2017 draft addresses a number of concerns raised in bilateral engagement, other critical changes are still required.
- Pursuant to a detailed IP Work Plan agreed in 2016, **Honduras** took steps to address the retransmission of unauthorized satellite signals and promote regulatory compliance by cable providers, resulting in active investigations into illegal retransmission and at least one major rogue cable provider entering into content licensing agreements with U.S. right holders.

³ The terms “trademark counterfeiting” and “copyright piracy” may appear below also as “counterfeiting” and “piracy,” respectively.

- **India** amended draft Patent Rules to eliminate administrative patent-related incentives in a manner that better aligns with international best practices.
- In the last year, **Brazil** took significant steps to reduce the patent and trademark application backlog, including by hiring 210 new patent and trademark examiners.
- In May 2016, the National Assembly of **Kuwait** passed a new Copyright and Related Rights Law that represents a significant improvement over Kuwait's previous copyright regime. Kuwait also commenced new IP enforcement actions that signal a positive shift in attitudes towards respecting IP rights.
- The **United Arab Emirates** adopted legislation in December 2016 that would significantly increase the fines available for criminal cases of IP infringement from current non-deterrent levels. The legislation will reportedly be put into effect during the first half of 2017.
- As of April 2017, there are 56 members of the 1991 Act of the International Union for the Protection of New Varieties of Plants Convention (UPOV 91). **Kenya** is the most recent member of UPOV 91. The Convention entered into force in Kenya in May 2016. The UPOV Convention requires member countries to grant IP protection to breeders of new plant varieties, known as breeder's rights. An effective plant variety protection (PVP) system incentivizes plant-breeding activities, which leads to increased numbers of new plant varieties with improved characteristics such as high-yield, tolerance to adverse environmental conditions, and better food quality. In addition, promoting strong plant variety protection and enforcement globally helps improve industry competitiveness in foreign markets, encourages the importation of foreign plant varieties, and enhances domestic breeding programs.
- As of May 2017, there will be 95 Parties to the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty (WPPT) and 95 Parties to the WIPO Copyright Treaty (WCT), collectively known as the WIPO Internet Treaties. These treaties, completed in 1996 and which entered into force in 2002, have raised the standard of copyright protection around the world, particularly with regard to online delivery of copyrighted content. The treaties, which include certain exclusive rights, require parties to provide adequate legal protection and effective legal remedies against the circumvention of technological protection measures (TPMs) as well as certain acts affecting rights management information. **Brunei Darussalam** will become a party to the WPPT and WCT in May 2017.
- With entry into force of the Patent Cooperation Treaty (PCT) in **Kuwait**, all members of the Gulf Cooperation Council are now PCT members, reducing time and expense for inventors seeking patent protection in the region.

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

Best IP Practices by Trading Partners

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

- Cooperation and coordination among national government agencies involved in IP issues is another example of a best practice. Several countries, including the United States, have introduced IP enforcement coordination mechanisms or agreements to enhance interagency cooperation. In this year's review, stakeholders continue to report positively on the efforts of the National Directorate for Intellectual Property (DINAPI) in **Paraguay** to increase interagency effectiveness and cooperation despite insufficient resources. Similarly, an interagency Special Anti-Piracy Task Force in **Malaysia** has made progress in deterring and preventing networks that distribute counterfeit and infringing goods. **Thailand** also has established an interagency National Committee on Intellectual Property and a subcommittee on enforcement against IP infringement, led by the Prime Minister and a Deputy Prime Minister, respectively, which have improved coordination among government entities. The United States encourages other trading partners to consider adopting cooperative IP arrangements.
- Specialized IP enforcement units also have proven to be important catalysts in the fight against counterfeiting and piracy. The specialized IP police unit in Rio de Janeiro, **Brazil**, could be a model for other cities in the country and around the world. Another example includes the Special Internet Forensics Unit in **Malaysia's** Ministry of Domestic Trade, Cooperatives, and Consumerism responsible for IP enforcement.
- Many trading partners conducted IP awareness and educational campaigns, including jointly with stakeholders, to develop support for domestic IP initiatives. The **United Kingdom** (UK) in collaboration with right holders and Internet service providers (ISPs) is conducting the "Get It Right From A Genuine Site" campaign, which highlights the value of the creative industries to the UK and includes educational emails by ISPs. In 2016-2017, the campaign significantly decreased piracy rates among those exposed to it.
- Several trading partners have participated, or supported participation, in innovative mechanisms that enable government and private sector right 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 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 IP 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.

- The use and procurement of licensed software by government agencies can set the right example for private enterprises. Government agencies in **Mexico**, including the Ministry of Economy, the Tax Administration, and the Mexico Institute of Industrial Property have obtained Verafirm Certification. Such certification confirms that the agencies’ software asset management procedures (SAM) are aligned with the SAM standard of the International Standards Organization.
- 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 Initiatives

The United States works to promote adequate and effective IP protection and enforcement through various mechanisms, one of which is the **World Trade Organization (WTO)**. The multilateral structure of the WTO provides opportunities for USTR to lead U.S. Government engagement with more than 160 trading partners on IP issues to raise the global standard on trade enforcement of IP rights, including through trade policy reviews, 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 co-sponsored discussions in the TRIPS Council on the positive and mutually-reinforcing relationship between innovation and the protection and enforcement of IP.

For example, in June 2016, the United States, the **EU, Japan, Switzerland, Canada, Singapore,** and **Chinese Taipei** co-sponsored an agenda item on “Intellectual Property and Innovation: Sustainable Resource and Low Emission Technology Strategies” that offered delegations the opportunity to share experiences and exchange best practices, including how IP can advance technological innovation focused on conserving natural resources.

In November 2016, the **United States, Australia, the EU, Japan, Switzerland,** and **Chinese Taipei** co-sponsored a discussion of “Intellectual Property and Innovation: Regional Innovation Models.” This discussion focused on regional IP treaties and institutions, regional innovation networks, and regional integration as a transformative feature of the innovation landscape.

In March 2017, the United States joined **Australia, the EU, Japan, Switzerland,** and **Chinese Taipei** in co-sponsoring a discussion of “Intellectual Property and Innovation: Inclusive Innovation and Micro-, Small-, and Medium-Sized Enterprises.” This discussion was the first of three scheduled topics in 2017 to address the importance of IP to micro-, small-, and medium-sized enterprises. Members shared experiences in developing policies to foster inclusive innovation and explored how micro-, small-, and medium-sized enterprises can contribute to the innovation ecosystem, including through collaborative efforts.

Bilateral and Regional Initiatives

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

The following are examples of bilateral coordination and cooperation:

- The October 20, 2016, U.S.-India Trade Policy Forum held in New Delhi, **India**, included a meeting of the High-Level IP Working Group, a side-event on trade secrets, and several notable consensus outcomes related to promoting IP. Both countries voiced support for IP policies that promote innovation and creativity. India announced important initiatives designed to further these goals, including the establishment of a Copyright Board, state-level initiatives to combat piracy, new steps designed to enhance trade secrets protection, and administrative improvements to the patent regime.
- Trade and Investment Framework Agreements (TIFAs) between the United States and more than 50 trading partners and regions around the world have facilitated discussions on enhancing IP protection and enforcement. For example, at the inaugural meeting of the United States-Argentina TIFA council in November 2016, the United States and **Argentina** agreed to establish an Innovation and Creativity Forum for Economic Development to discuss issues of mutual interest, including geographical indications, industrial designs, and the importance of IP protection for small- and medium-sized enterprises. The first meeting of the Forum took place in early December in Buenos Aires. In addition, **Thailand** is taking steps to address the backlogs for patent and trademark applications, including hiring additional examiners, which addresses a key issue discussed under the United States-Thailand TIFA discussions.

The following are examples of regional coordination and cooperation:

- In November 2016, USTR welcomed the endorsement of a set of “Best Practices in Trade Secret Protection and Enforcement Against Misappropriation” by Asia-Pacific Economic Cooperation (APEC) Leaders and Ministers in Lima, Peru. Establishing these best practices is essential to protecting and promoting the many innovative American businesses and workers. The document is the culmination of a multi-year initiative led by the United States, with the support of APEC Leaders and Ministers, which also resulted in a four-volume report on Trade Secrets Protection in APEC Economies. APEC economies identified eight best practices that are part of a toolkit for good policy development across the region, including:
 - Broad standing to assert claims for the protection of trade secrets and enforcement against trade secret theft;
 - Civil and criminal liability, as well as remedies and penalties, for trade secret theft;
 - Robust procedural measures in enforcement proceedings; and
 - Adoption of written measures that enhance protection against further disclosure when governments require the submission of trade secrets.

- Under its practice of conducting trade preference program reviews, USTR, in coordination with other U.S. Government agencies, reviews IP practices in connection with the implementation of Congressionally-authorized trade preference programs, such as the Generalized System of Preferences program, and regional programs, including the African Growth and Opportunity Act, Caribbean Basin Economic Recovery Act, and Caribbean Basin Trade Partnership Act, and works with trading partners to address any policies and practices that may adversely affect their eligibility.
- In 2016, the United States continued to engage with members of the Caribbean Community and Common Market and other governments in the region on concerns regarding inadequate and ineffective copyright protection and enforcement. Heightened engagement on this regional basis, led by the regional IP attaché, has resulted in tangible improvements in recent years.

In addition to the work described above, the United States anticipates engaging with its trading partners on IP-related initiatives in fora such as the G7, WIPO, the Organization of Economic Cooperation and Development (OECD), and the World Customs Organization. USTR, in coordination with other U.S. Government agencies, looks forward to continuing engagement with trading partners to improve the global IP environment.

IP Protection and Enforcement and Related Market Access Challenges

Border and Criminal Enforcement Against Counterfeiting

The problem of trademark counterfeiting continues on a global scale and involves the production and sale of a vast array of fake goods. Counterfeit goods, including 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, make their way from **China** and other source countries directly to purchasers around the world and indirectly through transit hubs, including **Indonesia** and the **United Arab Emirates**, to third country markets such as **Brazil**, **Nigeria**, and **Thailand** that are reported to have ineffective or inadequate IP enforcement systems.

Trademark counterfeiting harms consumers, legitimate producers, and governments. 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. Infringers often disregard product quality and performance for higher profit margins. Legitimate producers and their employees face diminished revenue and investment incentives, adverse employment impacts, and loss of reputation when consumers purchase fake products. Counterfeiting may also increase costs for firms to enforce their IP rights, which may be passed on to consumers. Governments lose the tax revenues generated by legitimate businesses and may find it more difficult to attract investment when illegal competitors undermine the market.

In particular, the manufacture and distribution of pharmaceutical and biopharmaceutical

(“pharmaceutical”) products and active pharmaceutical ingredients bearing counterfeit trademarks is a growing problem that has important consequences for consumer health and safety. Counterfeiting contributes to the proliferation of substandard (medicines that do not conform to established quality standards), unsafe medicines that do not conform to established quality standards. The United States notes its particular concern with the proliferation of counterfeit pharmaceuticals that are manufactured, sold, and/or distributed in numerous trading partners, including **China, Guatemala, India, Indonesia, Lebanon, Peru, and Russia**. 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 and other federal agencies, supports programs in sub-Saharan Africa, Asia, and elsewhere that assist trading partners in protecting the public against counterfeit and substandard medicines in their markets.

Ninety percent of all counterfeit pharmaceuticals seized at the U.S. border in Fiscal Year 2016 were shipped from or transshipped through four economies: **China, Hong Kong, India, and Singapore**. The United States welcomes reports that certain authorities have increased their vigilance against these dangerous products. Additionally, in August 2016, U.S. Customs and Border Protection (CBP) collaborated with Singapore Customs to conduct a joint enforcement operation that focused on addressing the issue of counterfeit pharmaceuticals.⁴

Many countries, however, do not provide penalties that deter criminal enterprises engaged in global trademark counterfeiting operations. Even when such enterprises are investigated and prosecuted, the penalties imposed often are low. Rather than deter further infringements, such penalties merely add to the cost of doing business.

Online sales of 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. Counterfeiters increasingly continue to use legitimate express mail, international courier, and postal services to ship counterfeit goods in small consignments rather than ocean-going cargo, to evade the efforts of enforcement officials to interdict these goods. Over 90 percent of U.S. seizures at the border were made in the express carrier and international mail environments. Counterfeiters also continue to ship products separately from counterfeit labels and packaging to evade enforcement efforts that target, or are limited by laws that require, the counterfeit item to be “completed” which may overlook the downstream application of counterfeit labels.⁵

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 counterfeit 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

⁴ CBP Intellectual Property Rights Enforcement Update, December 2016, *available at* <https://www.cbp.gov/sites/default/files/assets/documents/2017-Jan/IPR%20Enforcement%20Update%20-%20December%202016.pdf>

⁵ For more information on these trends and CBP’s and ICE/HSI’s IPR enforcement efforts, see Department of Homeland Security, Intellectual Property Rights Seizure Statistics, Fiscal Year 2016 (2016) available at <https://www.cbp.gov/sites/default/files/assets/documents/2017-Jan/FY%2016%20IPR%20Stats%20FINAL%201.25.pdf>

and meaningful sentences of imprisonment, are available and applied to deter counterfeiting. In addition, trading partners should ensure that competent authorities seize and destroy counterfeit goods, as well as the materials and implements used for their production, thereby removing such goods from the channels of commerce. Permitting counterfeit 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 goods in country and at the border during import or export, or in transit movement, *ex officio*, without the need for a formal complaint from a right holder. For example, the re-exportation and transshipment of infringing goods in and through free trade zones, particularly in Dubai, continues to undermine the **United Arab Emirates'** reputation for effective and proactive IP enforcement. The United States remains deeply concerned over the transshipment and manufacturing of counterfeit products within certain free trade zones in the United Arab Emirates, a lack of will within some Emirate-level customs authorities to enforce IP in free trade zones, and reluctance to engage bilaterally on these and other border enforcement issues.

The United States 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). For example, CBP is interested in exploring opportunities for tangible cooperation on, among other issues, the border enforcement issues highlighted above. These opportunities could include sharing best practices and customs-to-customs information exchange for use in risk management and enforcement actions, as well as conducting joint customs enforcement operations designed to interdict shipment of IP-infringing goods destined for the United States. In addition, CBP is interested in engaging with foreign government counterparts on the role of online and mobile technologies in the facilitation and proliferation of counterfeit and pirated goods.

Online Piracy and Broadcast Piracy

The increased availability of broadband Internet connections around the world, combined with increasingly accessible and sophisticated mobile technology, has been a boon to the U.S. economy and trade. One key area of economic growth for the United States has been the development of legitimate digital platforms for distribution of copyrighted content, so that consumers around the world can enjoy copyrighted content by U.S. artists. However, technological developments have also made the Internet an extremely efficient vehicle for disseminating infringing content, thus competing unfairly with legitimate e-commerce and distribution services that copyright holders and online platforms use to deliver licensed content. While optical disc piracy continues in many countries, including in **China, India, Paraguay, and Vietnam**, online piracy is the most challenging copyright enforcement issue in many trading partner markets. The U.S. Government's *2016 Out-of-Cycle Review of Notorious Markets* includes examples of online marketplaces reportedly engaging in commercial-scale online piracy, including sites hosted in, operated by, or directed toward parties located in **Canada, China, Cyprus, India, Poland, Russia, Switzerland, Ukraine**, and elsewhere.

The proliferation of "camcords" also is an increasingly urgent trade problem. Illicit camcording is the primary source of unauthorized copies of newly-released movies found online. The recordings made in movie theaters today are very different from the old image of camcording as

something done by a single person sitting in a theater with a bulky videotape recorder. The results are not shaky, inaudible recordings. It is now easy for a surreptitious recording in a movie theater to result in a clean digital copy of a movie with perfect audio that can be quickly distributed online. The pirated version of the new release movie may be available online while it is still in the theaters. The problem is magnified by the fact that movies may be released in different markets at different times. Thus, a camcord of a movie released in one market can be made available unlawfully in another market before the movie hits the theaters. In addition to theater owners who lose revenue, legitimate digital platforms, who often negotiate for a certain period of exclusivity after the theatrical run, cannot fairly compete in the market.

Stakeholders reported a significant increase in illegal camcords this year. For example, the identified number of pirated American films sourced from illicit camcords in **Mexico** almost doubled in 2016. In **India**, industry reported that instances of camcording of U.S. films sourced from Indian theaters nearly doubled from 17 in 2015 to 32 in 2016. This situation is particularly unfortunate as draft amendments to India's Cinematograph Act were intended to address this problem have stalled since 2013. An increased volume of unauthorized camcording has also been traced to **China**, despite a 2015 official notice calling on cinema owners to address camcording and requiring digital watermarking to aid in forensics. A 2016 criminal conviction for unauthorized camcording and the enactment of the Film Promotion Act in 2017 did not reverse the negative trend.

Countries also need to update legal frameworks to effectively deter unauthorized camcording. Legal systems must keep up with changing practices. For example, the requirement in some countries that a law enforcement officer must observe a person camcording and then prove that the person is circulating the unlawfully recorded movie before intervention, will not stop camcording in theaters. The United States urges countries to adopt laws and enforcement practices designed to prevent unauthorized camcording, such as laws that have been adopted in **Japan**, the **Philippines**, and **Canada**. APEC has also issued a report on "Effective Practices for Addressing Unauthorized Camcording." As the practice of camcording evolves, so too must methods for detecting and preventing camcording. One best practice (although not sufficient alone) is building public awareness. For example, in 2016 the Attorney General's Office in **Mexico** worked with right holders to deter camcording by screening warning notices before exhibiting films in theaters in Mexico. Another is for the private sector to work on capacity building to help theater managers and employees to detect camcording and assist law enforcement.

Other examples of online piracy found in virtually every country on the Special 301 lists include: "stream-ripping"; the unauthorized retransmission of live sports programming online; servers or "grey shards" that allow users to play unauthorized versions of cloud-based entertainment software; online distribution of software and devices that allow for the circumvention of TPMs, including "game copiers" and mod chips that allow users to play pirated games on physical consoles; and devices (including set-top boxes, media boxes, and illicit streaming devices) preloaded with large volumes of pirated content or configured with apps to facilitate access to websites that offer infringing content. Piracy facilitated by online services presents unique enforcement challenges for right holders in countries where copyright laws have not been able to adapt or keep pace with these innovations in piracy.

The availability of, as well as recourse by right 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 online. For example, while the United States acknowledges **Hong Kong**'s efforts to enforce against online piracy using existing authorities, this welcome activity is not an effective substitute for reform of Hong Kong's outdated copyright laws.

Copyright Administration and Payment of Royalties

Collective management organizations (CMO) for copyright can play an important role in ensuring compensation for right holders when their practices are fair, efficient, transparent and accountable. Unfortunately, CMO systems in several countries are reportedly flawed or non-operational. The collection and distribution of royalties to U.S. and other right holders should be carried out on a national treatment basis. For example, two CMOs in **Argentina** have reportedly refused to pay U.S. performers and directors their share of royalties collected for the public performances of U.S. motion picture and television programs. In the **United Arab Emirates**, the Ministry of Economy's failure to issue a license to a single entity that would allow copyright royalties to be collected represents a 15-year challenge that the United Arab Emirates should address without further delay so that right holders can receive compensation for their works. **India** has yet to establish a Copyright Royalty Board to implement the Copyright Amendment Act, 2012, although recent steps and high-level statements have made progress towards this goal.

Trademark Protection Issues

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 trademark is often one of the company's most valuable business assets.

However, in numerous countries, legal and procedural obstacles exist to securing trademark rights. Many countries need to establish or improve transparency and consistency in their administrative trademark registration procedures. For example, the trademark system in **China** suffers from a high level of formalities required to bring opposition actions, inflexibility in relation to descriptions of goods/services, disregard for affidavits and witness declarations in *inter partes* proceedings, unreasonably high standards for establishing "well-known" mark status, and a lack of transparency in all phases of trademark prosecution. Many other countries, including **Argentina, Brazil, India, Malaysia,** and the **Philippines**, reportedly have slow opposition proceedings while **Russia** and **Panama** have no administrative opposition proceedings.

Mandatory requirements to record trademark licenses are another concern, as they frequently impose unnecessary administrative and financial burdens on trademark owners and create difficulty in the enforcement and maintenance of trademark rights. The absence of adequate means for searching trademark applications and registrations, such as by online databases, makes obtaining trademark protection more complicated and unpredictable. Such systems lead to additional cost, both in terms of initial filing and in relation to docketing and maintenance of

multiple registrations.

Also, a number of countries 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.

Trademark Protection Challenges in Country Code Top-Level Domain Names

Trademark holders continue to face challenges in protecting their trademarks against unauthorized uses in country code top-level domain names (ccTLDs). U.S. right 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. Many ccTLDs have policies that prohibit cybersquatting; require that the domain name have a nexus to the relevant country (e.g., citizenship or residency, a registered office, or a bona fide presence); require the registrant to provide true and complete contact information; and make such registration information publicly available or cooperate with brand owners whose trademarks are being infringed. The ccTLDs of some countries have been identified by right holders as ineffective or uncooperative. A related and growing concern is that some ccTLDs lack transparent and predictable domain name dispute resolution policies. Effective policies should assist in the quick and efficient resolution of trademark infringement-related domain name 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 Unlicensed Software

According to a study by BSA | The Software Alliance, the commercial value of unlicensed software globally was at least \$52 billion in 2015. The United States has undertaken an initiative to work with other governments to address the unauthorized government use of software, particularly in countries that are modernizing their software systems or where there are infringement concerns. Considerable progress has been made under this initiative, leading to numerous trading partners mandating that their government agencies use only legitimate software. It is important for governments to legitimize their own activities in order to set an example of respecting IP for private enterprises. Further work on this issue remains with certain trading partners, including **China, Macedonia, Pakistan, Panama, Paraguay, South Korea, Taiwan, Tajikistan, Thailand, Turkmenistan, Ukraine, and Vietnam**. The United States urges trading partners to adopt and implement effective and transparent procedures to ensure legitimate governmental use of software.

Trade Secrets

This year's Report continues to reflect the growing need for trading partners to provide effective protection and enforcement of trade secrets. Companies in a wide variety of industry sectors,

including information and communications technologies, services, pharmaceuticals, manufacturing, and environmental technologies, rely on the ability to protect and enforce their trade secrets and rights in proprietary information. Indeed, trade secrets, such as business plans, internal market analyses, manufacturing methods, customer lists, and recipes, are often among a company's core business assets. A company's competitiveness may depend on its capacity to protect such assets. Trade secret theft threatens to diminish U.S. competitiveness around the globe, and puts U.S. 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 U.S. Office of the National Counterintelligence Executive (ON-CIX), have reported specific gaps in trade secret protection and enforcement, particularly in **China**. 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 **China** and **India**. Lack of legal certainty regarding trade secrets also dissuades companies from entering into partnerships or expanding their business activities in these and other countries. Many countries do not provide criminal penalties for trade secret theft sufficient to deter such behavior. Some foreign countries' practices and policies, including evidentiary requirements in trade secrets litigation and mandatory technology transfer, put valuable trade secrets at risk of exposure. For example, in **Brazil**, **Indonesia**, and **Nigeria**, government procurement regulations may require companies to disclose valuable source code.

The United States uses all trade tools available to ensure that its trading partners provide robust protection for trade secrets and enforce trade secrets laws. Given the global nature of trade secret theft, action by our trading partners is also essential. Several trading partners have recently strengthened or have been working toward strengthening their trade secret regimes, including **China**, the **EU**, **Kazakhstan**, and **Taiwan**. Action in international organizations is similarly critical. For instance, the United States strongly supports continued work in the OECD on trade secret protection, building off the two studies released by the OECD in 2014. The first study, entitled "Approaches to Protection of Undisclosed Information (Trade Secrets)" (January 30, 2014), surveyed legal protection for trade secrets available in a sample of countries. The second study, entitled "Uncovering Trade Secrets—An Empirical Assessment of Economic Implications of Protection for Undisclosed Data" (August 11, 2014), examined the protection of trade secrets for a sample of 37 countries, provided historical data for the period since 1985, and considered the relationship between the stringency of trade secret protection and relevant economic performance indicators.

Localization, Indigenous Innovation, and Forced Technology Transfer

Right holders operating in other countries report an increasing variety of government measures, policies, and practices that are touted as means to incentivize domestic "indigenous innovation," but that, in practice, can disadvantage U.S. companies, such as by requiring foreign companies to give up their IP as the price of market entry. 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 IP 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:

- 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 (SOEs) in innovative sectors to seek non-commercial terms from their foreign business partners, including with respect to the acquisition and use or licensing of IP;
- Providing national firms with an unfair competitive advantage by failing to effectively enforce foreign-held IP, including patents, trademarks, trade secrets, and copyright;
- Failing to take meaningful measures to prevent or deter cyber-intrusions and other unauthorized activities;
- Requiring use of, or providing preferences to, products or services that contain locally-developed or owned IP, including with respect to government procurements;
- Manipulating the standards development process to create unfair advantages for national firms, including with respect to the terms on which IP is licensed; and
- Requiring the submission of unnecessary or excessive confidential business information for regulatory approval purposes and failing to protect such information appropriately.

In **China**, market access, government procurement, and the receipt of certain preferences or benefits may be conditioned on a firm's ability to demonstrate that certain IP is developed in China, or is 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**, new amendments to its Patent Law appear to require that the manufacture of patented products and use of patented processes take place in Indonesia. Also, it is reported that foreign companies' approvals to market pharmaceuticals in Indonesia are conditioned upon the transfer of technology to Indonesian entities or upon partial manufacture in Indonesia. In **Nigeria**, localization policies in the form of local content requirements would protect and favor local companies at the expense of foreign firms and

investors. In particular, the 2013 Guidelines for Nigerian Content Development in Information and Communications Technology (ICT) require local production or utilization of Nigerian material and labor across a broad range of ICT goods and services. Requirements of particular concern include server localization mandates, cross-border data flow restrictions, programs to support only local data hosting firms, and provisions that impose burdens on foreign firms by requiring in-country research and development departments and the disclosure of source code and other proprietary information. Other country-specific examples of these measures are identified in Section II.

The United States urges that, in formulating policies to promote innovation, trading partners, including **China** and **India**, refrain from coercive local content and technology transfer policies, and take account of the increasingly cross-border nature of commercial research and development and technology supply chains, as well as the importance of voluntary and mutually agreed commercial partnerships.

Pharmaceutical and Medical Device Innovation and Market Access

In order to facilitate both affordable health care today and the innovation that assures improved health care tomorrow, USTR has sought to reduce market access barriers to pharmaceutical and medical devices, including measures that discriminate against U.S. companies, are not adequately transparent, or do not offer sufficient opportunity for meaningful stakeholder engagement. This year's Report highlights concerns regarding market access barriers affecting U.S. entities that rely on IP protection, including those in 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. By some estimates, federal and state taxes can add 38 percent to the cost of medicines in **Brazil**, and according to an October 2012 WTO report titled “More Trade for Better Health? International Trade and Tariffs on Health Products,” **India** maintains some of 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 government efforts to promote increased access to health-care products.

Moreover, unreasonable regulatory approval delays and non-transparent reimbursement policies can impede a company's ability to enter the market, 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. The United States 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.

The IP-intensive U.S. pharmaceutical and medical device industry has expressed concerns regarding the policies of several trading partners, including **Algeria, Austria, Belgium, China, Colombia, Czech Republic, Ecuador, Hungary, Italy, Lithuania, New Zealand, Portugal, Romania, South Korea, Taiwan, and Turkey**, on issues related to pharmaceutical innovation and market access. Examples of these concerns include the following:

- A ban in **Algeria** on a significant number of imported pharmaceutical products and medical devices in favor of local products is a trade matter of paramount concern 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.
- The lack of efficiency, transparency, and fairness in the pharmaceutical manufacturing inspection process in **Turkey**.
- A series of measures in several EU Member States, including **Austria, Belgium, Czech Republic, Finland, Hungary, Italy, Lithuania, Portugal, and Romania** that raise concerns with respect to transparency and the opportunity for meaningful stakeholder engagement in policies related to pricing and reimbursement, and reportedly create uncertainty and unpredictability that adversely impact market access and incentives for further innovation.
- Proposals in **Colombia** and **Ecuador** that could adversely affect market entry and investment and, in effect, limit access by consumers to the latest generation of medicines.
- Policies and the operation of **New Zealand**'s Pharmaceutical Management Agency (PHARMAC), which include, among other things, the lack of transparency, fairness, and predictability of the PHARMAC pricing and reimbursement regime, as well as 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, cost-effective, and 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 (GIs)

The United States is working intensively through bilateral and multilateral channels to advance U.S. market access interests in foreign markets and to ensure that GI-related trade initiatives of the EU, its Member States, like-minded countries, and international organizations, do not undercut such market access. GIs typically include place names (or words associated with a place) and identify products as having a particular quality, reputation, or other characteristic essentially attributable to the geographic origin of the product. The EU GI agenda remains highly concerning, especially because of the significant extent to which it undermines the scope of trademarks and other IP rights held by U.S. producers, and imposes barriers on market access for American-made goods and services that rely on the use of common names, such as parmesan or feta.

First, the EU GI system raises concerns regarding the extent to which it impairs the scope of trademark protection, including with respect to prior trademark rights. Trademarks are among the most effective ways for producers and companies, including small- and medium-sized enterprises, to create value, promote their goods and services, and protect their brands, particularly with respect to food and beverage products covered by the EU GI system. Many such products are already protected by trademarks in the United States, in the EU, and around the world. Trademark systems offer strong protections through procedures that are easy to use, cost-effective, and transparent and that provide due process safeguards as well as high consumer awareness, significant contributions to national GDPs and employment, and long-recognized international systems of protection.

Second, troubling aspects of the EU GI system impact access for U.S. and other producers in the EU market. The EU has identified hundreds of terms that it argues only certain EU producers should be able to use. For example, the EU asks trading partners to prevent all producers other than those EU producers in certain EU regions, from using certain product names, such as parmesan, gorgonzola, asiago, or feta, even though they are the common names for products, and the products are produced in countries around the world. In the EU and other markets that have adopted the EU GI system, American producers and traders either are blocked effectively from those markets or must sell their products as “parmesan-like,” “gorgonzola-kind,” “asiago-style,” or “imitation feta” – which is costly, unnecessary, and can reduce consumer demand for the products.

The United States runs a significant deficit in food and agricultural trade with the EU. The EU’s GI system contributes to this asymmetry in United States-EU trade in agricultural products for products subject to the EU’s GI regime. In the case of cheese, for example, where many EU products enjoy GI protection under the EU GI system, the EU exports nearly \$1 billion of cheese to the United States each year; the United States exports only about \$6 million to the EU. Conversely, EU agricultural producers exporting to the United States are doing quite well, benefiting considerably from effective trademark protection provided in the United States and, notably, in the absence of an EU-style GI system.

Despite these troubling aspects of its GI system, the EU continues to seek to expand its harmful GI system within its territory and beyond. Within its borders, the EU is enlarging its system beyond agricultural products and foodstuffs, to encompass non-agricultural products, including apparel, ceramics, glass, handicrafts, manufactured goods, minerals, salts, stones, and textiles.

Beyond its borders, the EU has sought to advance its agenda through bilateral trade agreements, which impose the negative impacts of the EU GI system on market access and trademark protection in third countries, including through exchanges of lists of terms that receive automatic protection as GIs without sufficient transparency or due process.

The EU has pursued its GI agenda in multilateral and plurilateral bodies as well. For example, in 2015, the EU, several of its Member States, and others expanded the WIPO Lisbon Agreement for the Protection of Appellations of Origin and their International Registration to include GIs, thereby enshrining several detrimental aspects of EU law in this Agreement. The Geneva Act of the Lisbon Agreement that emerged from these negotiations was the product of a decision led by the EU and Member States to break with the long-standing WIPO practice of consensus-based decision-making and to vote to deny the United States and 160 other WIPO countries meaningful participation rights in the negotiations.

In response to the EU's aggressive promotion of its exclusionary GI policies, the United States continues its intensive engagement in promoting and protecting access to foreign markets for U.S. exporters of products that are trademark protected or are identified by common names. The United States is advancing these objectives through its free trade agreements, as well as in international fora, including in APEC, WIPO, and the WTO. In addition to these negotiations, the United States is engaging bilaterally to address concerns resulting from the GI provisions in existing EU trade agreements, agreements under negotiation, and other initiatives, including with **Canada, China, Costa Rica, Ecuador, El Salvador, Indonesia, Japan, Malaysia, Morocco, the Philippines, South Africa, and Vietnam**, among others. U.S. goals in this regard include:

- Ensuring that the grant 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 common names, such as parmesan or feta;
- 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 common name components; and
- Opposing efforts to extend the protection given to GIs for wines and spirits to other products.

Other Issues

Some public comments received in response to the 2017 Special 301 *Federal Register* notice also identified developments in several countries that may have created market uncertainties for technology companies and online content providers such as laws that involve remuneration by news aggregation services providers. The United States is monitoring these developments and other related measures. (See Fact Sheet: Key Barriers to Digital Trade). USTR detailed this and

many other issues in the 2017 National Trade Estimate Report.

Intellectual Property and the Environment

Strong IP 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. IP provides incentives for research and development in this important sector, including through university research. Conversely, inadequate IP protection and enforcement in foreign markets discourages entry into technology transfer arrangements and broader investment in those markets. This may hinder regional economic growth, as well as 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 effect of undermining innovation needed to address serious environmental challenges. For example, **India's** National Manufacturing Policy promotes the compulsory licensing of patented technologies as a means of technology transfer with respect to green technologies. Such policies, which India has sought to multilateralize in United Nations (UN) negotiations, will discourage, rather than promote, investment in and dissemination of green technology innovation, including those technologies that contribute to climate change adaptation and mitigation.

Intellectual Property and Health

Numerous comments in the 2017 Special 301 review process highlighted concerns arising at the intersection of IP policy and health policy. IP protection plays an important role in providing the incentives necessary for the development and marketing of new medicines. An effective, transparent, and predictable IP system is necessary for both manufacturers of innovative medicines and manufacturers of generic medicines.

The 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health recognized the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics. As affirmed in the Doha Declaration on 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 IP protection in the development of new medicines, while being mindful of the effect of IP 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 IP 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. In January 2017, five WTO Members submitted ratification notifications to amend the TRIPS Agreement. These actions secured the necessary two-thirds of WTO Member support and resulted in the formal amendment to the TRIPS Agreement.

The U.S. 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 UN and related institutions such as WIPO and the WHO, are consistent with U.S. policies concerning IP 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 IP 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 IP protection and enforcement. The TRIPS Agreement is the first broadly-subscribed multilateral IP 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 IP enforcement mechanisms.

Recognizing the particular issues faced by WTO Members that are least-developed countries (LDC), the United States has worked closely with them and other WTO Members to extend the implementation date for these countries. Most recently, on November 6, 2015, the TRIPS Council reached consensus to extend the transition period for LDC Members to implement Sections 5 and 7 of the TRIPS Agreement with respect to pharmaceutical products until January 1, 2033, and reached consensus to recommend waiving Articles 70.8 and 70.9 of the TRIPS Agreement with respect to pharmaceuticals also until January 1, 2033, which the WTO General Council adopted on November 30, 2015.

On November 23, 2015, the TRIPS Council reached consensus to extend the moratorium on non-violation and situation complaints under the TRIPS Agreement until the next Ministerial in 2017. The moratorium was originally introduced in Article 64 of the TRIPS Agreement, for a period of five years following the entry into force of the WTO Agreement (i.e., until December 31, 1999).

The moratorium has been referred to and extended in several WTO Ministerial documents, most recently in 2013. In 2015, the TRIPS Council intensified its discussions on this issue, including on the basis of a communication by the United States to the Council outlining the U.S. position on non-violation and situation complaints. This communication (document number IP/C/W/599) addressed the relevant TRIPS Agreement provisions, WTO and GATT disputes, and provided responses to issues raised by other WTO Members.

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.

Dispute Settlement and Enforcement

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 enforcement tools including the WTO and other 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 copyright 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 understanding 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.

SECTION II: Country Reports

PRIORITY WATCH LIST

Significant IP concerns exist in the countries on the Priority Watch List. The summaries below describe the goals and benchmarks of the 2016–2017 Priority Watch List Action Plans as well as actions taken by the trading partner.

EAST ASIA AND THE PACIFIC

CHINA

China remains on the Priority Watch List and subject to Section 306 monitoring in 2017.

Ongoing Challenges and Concerns

Serious challenges in China continue to confront U.S. intellectual property (IP) right holders with respect to adequate and effective protection of IP, as well as fair and equitable market access for U.S. persons that rely upon IP protection. China must enact new measures and policies that provide stronger and more effective protection for IP; allow market access for IP-intensive products, services, and technologies; and enhance the effectiveness of civil enforcement in Chinese courts.

China's protection of trade secrets is an area of ongoing concern and engagement. A number of laws and other measures address trade secret protection, giving rise to confusion on jurisdiction, difficulties in obtaining evidence, and insufficient civil compensation, among other issues. The United States has suggested that unified, stand-alone legislation would promote better trade secret protection. In the absence of such a law, improvements can flow from amendments to the Anti-Unfair Competition Law, the issuance of guiding court cases, and improvements to Chinese administrative, civil, and criminal enforcement rules and practices.

The extent of manufacturing and sale in China, and export from China, of counterfeit goods also continues to be a major concern. These counterfeits include those sold in markets that are identified in the annual *Out-of-Cycle Review of Notorious Markets*, and those that pose health and safety risks. Counterfeiting and piracy problems extend to China's enormous e-commerce markets, estimated to account for 40 percent of global e-commerce sales. Difficulties in addressing bad faith trademark registrations in China contribute to this problem. In addition, China should ensure that its GI regime do not pose barriers to U.S. products, by fully implementing prior bilateral commitments and resolving ambiguities in the determination and revocation of GIs.

China's promotion of self-sufficient, indigenous innovation through policies on patents and in related areas, including standards and competition law, implicates a cross-cutting set of concerns. China must ensure that present and future Information and Communications Technology (ICT)

policies (and other policies) do not disadvantage foreign IP-intensive industries by, *inter alia*, conditioning market access on the disclosure of IP and proprietary information, the localization of research and development, or by invoking “secure and controllable” standards, risk criteria, product reviews, or similar requirements that are disadvantageous to foreign firms. Also critical is that China eliminate discriminatory requirements and incentives to transfer technology to, or develop technology in, China. These policies affect U.S. IP holders across a range of sectors including ICT, medical devices, biotechnology, semiconductors, new energy vehicles, aviation, and high-tech equipment.

Developments, Including Progress and Actions Taken

Ambitious Goals Tempered by Contradictions and Lagging Implementation

High-level government statements continue to convey China’s stated goals of becoming an innovative society, embracing strengthened IP laws, allowing markets a decisive role in resource allocation, and committing to a rules-based system. These guiding statements should exercise a positive effect on China’s ongoing IP legal reform, but contradictory signals, including other high-level statements, cast doubt on China’s commitment to open markets for foreign products and persons, as well as to a fully independent judiciary. U.S. right holders report incremental gains but also that longstanding problems remain unaddressed. New and existing measures offer inadequate protections for IP rights, and raise market access barriers to U.S. exporters’ IP-intensive goods and services, as well as to U.S. companies doing business in China.

Intellectual Property-Related Legal Reform and Civil Judicial Reform

China continued its IP and civil judicial reform efforts in 2016 and early 2017. While the commitment to reform is welcome, the substantive content and results of those efforts are mixed. The United States has provided formal comments and engaged closely with China on a wide range of measures, and welcomes China’s modifications to drafts of measures that appear to address a number of U.S. concerns. At the same time, other major U.S. concerns have gone unaddressed. While the particulars vary according to the measure in question, new legislation must promote IP protection and enforcement and must not create new, or tolerate existing, market access obstacles to foreign IP-intensive industries, including in the ICT, motion picture, television, music, software, video game, and book publishing sectors. Legal reforms are not an end themselves, but must result in improved conditions in China for U.S. IP right holders. One particularly concerning development is that progress toward amendment of the Copyright Law appears to have stalled, despite the pressing need to address major gaps in protection.

China’s reform efforts extend to its courts and measures relating to enforcement. China is nearing the end of a three-year pilot program for specialized IP courts in Beijing, Shanghai, and Guangzhou. Preliminary data suggest that U.S. parties account for a large percentage of foreign litigants, and that the IP Courts award higher damages compared with other courts in China. Further, the IP Courts have also been tasked with, and have already begun to take steps to address, problems with evidentiary burdens, low damages, and other concerns. Other developments in civil enforcement include the expansion of the pilot program to four new IP tribunals, the Supreme People’s Court’s (SPC) selection of the Beijing IP Court as the location for the SPC’s research

base on case guidance and precedent, a coordinated effort to increase compensation for infringement and the use of punitive damages, as well as the SPC's launch and continued maintenance of a publicly-searchable online database of judicial decisions and other official documents.

Draft measures have promoted a greater role for administrative enforcement, but this avenue appears ill-suited to patent or other complex disputes. Administrative enforcement reforms should include improvements to the system for coordinating and transferring administrative investigations to criminal authorities, including by clarifying standards for criminal investigations; ensuring that confidential information revealed or submitted during investigations is handled appropriately and not disclosed; and continuing to address strong local protectionism by enforcement officials in certain areas. China's civil enforcement should increase the availability of preliminary orders, facilitate greater production of critical evidence in the hands of adverse parties, continue efforts to calculate damages based on actual harm or profits, and continue existing reforms that increase the timely enforcement of judgements. Significant obstacles continue to thwart private parties' efforts to vindicate their rights in China's criminal enforcement system, including burdensome documentation requirements to establish copyright ownership, which have frustrated what appear to be sustained and determined enforcement efforts by affected right holders.

Trade Secrets

Industry continues to identify trade secret protection as one of their most pressing concerns in China. In March 2017, China amended its General Provisions of the Civil Law, which now recognizes that trade secrets are a subject of civil IP protection. In early 2016 and again in early 2017, China published for comment draft amendments to the 1993 Anti-Unfair Competition Law (AUCL), which is one of several measures important to trade secrets protection. The 2017 draft addresses a number of concerns raised in bilateral engagement, but other critical changes are still required. However, to date, China has not signaled an intention to develop the standalone legislation that would best remedy concerns. Additionally, China should issue guiding court decisions to improve consistency in judicial decisions on trade secrets. Legal reform should promote the availability of preliminary injunctions, and asset and evidence preservation orders. At the same time, China should ensure that groundless claims of trade secret misappropriation are resolved efficiently, and not wielded as leverage in unrelated disputes. Reforms should also address obstacles to criminal enforcement and prevent the disclosure of trade secrets and other confidential information submitted to government regulators, courts, and other authorities.

Manufacturing, Domestic Sale, and Export of Counterfeit Goods

The widespread manufacture, domestic sale, and export of counterfeit goods from China continues. An appreciable share of Chinese manufacturing may be dedicated to the production of counterfeit goods, as one estimate holds that counterfeits may account for over 12 percent of Chinese merchandise exports.⁶ U. S. Customs and Border Protection (CBP) and U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI) report positive cooperation

⁶ *Measuring the Magnitude of Global Counterfeiting: Creation of a Contemporary Global Measure of Physical Counterfeiting* at 3
(<https://www.uschamber.com/sites/default/files/documents/files/measuringthemagnitudeofglobalcounterfeiting.pdf>).

with the General Administration of China Customs (GACC) in joint operations and information sharing. In March 2016, ICE/HSI and GACC initiated a joint outbound enforcement operation targeting counterfeit items bearing trademarks of professional sporting leagues, which resulted in GACC seizures of more than 46,000 items. In April 2016, CBP and GACC conducted a joint IP enforcement operation resulting in over 1,400 combined seizures, and in September 2016, CBP, ICE, and GACC officials met in China for an IP working group meeting to plan additional joint enforcement activities.⁷ Right holders also praise the GACC's proactive seizure of suspected goods prior to export from China. Nevertheless, China should take measures to address the widespread availability of counterfeit goods sold in physical markets in China, including those mentioned in past *OCRs of Notorious Markets*. Special measures should address counterfeit products that present health and safety risks, including pharmaceuticals, medical devices, agricultural and other chemicals, auto parts, and semiconductors.

China should also take additional steps to address concerns regarding registration of trademarks in bad faith. For many years, U.S. brand owners have reported that third parties are registering large numbers of trademarks that are identical to, substantially indistinguishable from, or similar to, existing U.S. brands. Although China sought to address this issue with the revision to the Trademark Law that went into effect in 2014, current procedures for removal of these bad faith trademarks by legitimate owners remain inadequate. As a result, third parties are able to obtain trademarks in China even when the U.S. trademark is famous or well-known and the resulting registrations damage the goodwill or interests of U.S. right holders. The use of these trademarks is also likely to confuse Chinese consumers who may be unaware that a Chinese trademark is used for goods and services that are not connected with the U.S. right holder.

Piracy and Counterfeiting in China's E-Commerce Markets and Promoting New Markets for Legitimate Goods and Content

Widespread online piracy and counterfeiting in China's e-commerce markets cause great losses for U.S. right holders involved in the distribution of a wide array of trademarked products, as well as legitimate film and television programming, music, software, video games, books and journals, including scientific, technical, and medical publications. According to published reports, online retail sales in China reached nearly \$752 billion in 2016.⁸ While the proportion of counterfeit and pirated goods and services is difficult to assess precisely, in 2014, China's State Administration for Industry and Commerce (SAIC) reported that more than 40 percent of goods that SAIC purchased online during a survey were "not genuine," a classification that it described as including fakes. Although some leading online sales platforms claim to have streamlined procedures to remove offerings of infringing articles, right holders report that the procedures are still burdensome and that penalties do not deter repeat infringers. Reports indicate that unauthorized camcording of movies in theaters, one of the primary sources for online audiovisual infringements, remained a serious problem in 2016.

In late December 2016, China published a draft e-commerce law for comment. It is critical that

⁷ <https://www.cbp.gov/newsroom/national-media-release/us-%E2%80%93-china-joint-intellectual-property-rights-enforcement-1>

⁸ <https://www.forbes.com/sites/wadeshepard/2017/03/14/as-amazon-floods-with-chinese-sellers-western-brands-move-into-chinas-booming-e-commerce-market/>

the final version of this law not undermine Internet service providers (ISPs) notices of infringement and cease-and-desist letters, and that it promote a balanced and effective notice-and-takedown regime that addresses online piracy and counterfeiting while providing appropriate safeguards to ISPs. Furthermore, China should also take action on the long-delayed amendments to its Copyright Law this year, including to ensure that sports broadcasts are eligible for copyright protections.

In terms of promoting new markets for legitimate content, a range of measures continue to raise serious concerns. A number of measures bar or limit the ability of foreign entities to engage in online publishing, broadcasting, and distribution of creative content. Other measures or draft measures discriminate against foreign content, interfere with the simultaneous (day and date) release of foreign content in China and other markets, require state-owned entities to hold an ownership stake in online platforms for film and television content, and exclude or limit the participation of foreign entities. Collectively, these measures create conditions that result in greater piracy and a market that is less open than others in terms of foreign content and foreign entity participation. Additionally, it is critical that China fully implement the terms of the 2012 U.S.-China Memorandum of Understanding regarding films and abide by its commitment to negotiate additional meaningful compensation for the United States in 2017.

China must also take action on other fronts as well. China remains a leading source and exporter of systems that facilitate copyright piracy, including websites containing or facilitating access to unlicensed content, and illicit streaming devices configured with apps to facilitate access to such websites. These systems also include devices and methods that facilitate the circumvention of technological protection measures, which enable the delivery of services via the cloud and protect video games and other licensed content. The National Copyright Administration of China's Sword Net campaign focused on apps that facilitate piracy via mobile devices and television. Still, industry reports that the piracy app problem continues to expand and that Chinese enforcement authorities appear reluctant to take action despite the filing of industry complaints. Starting in January 2017, apps sellers were required to register with the State Internet Information Office, which could promote government enforcement action against piracy apps.

Need to Promote Innovation through Sound Patent and Related Policies

Despite encouraging high-level statements on the need to protect IP and China's intention to focus on innovation, industry stakeholders continue to report serious concerns about China's progress in implementing sound patent policies and other policies that affect U.S. patent holders.

Chinese authorities continue work toward the fourth amendment of the Patent Law. While successive drafts have addressed a number of U.S. concerns, the most recent draft presents troubling provisions, including the insertion of competition law concepts that should be addressed elsewhere; an undue emphasis on administrative enforcement; a one-size-fits-all imposition of disclosure obligations in standards setting processes; a lack of clarification that a patentee's right to exclude extends to manufacturing for export; and missed opportunities to harmonize China's patent grace period and statute of limitations with international practices.

Reform efforts continue in IP-related legal and policy areas. In early 2016, China published for

comment draft amendments to its Standardization Law. China should ensure that standards setting processes are open to domestic and foreign participants on a non-discriminatory basis and eliminate pressures on patentees to contribute proprietary technologies to standards and license them to implementers against their will. Chinese authorities have also published for comment draft guidelines for Anti-Monopoly Law (AML) enforcement as it relates to IP rights, most recently in March 2017. There is ongoing concern that China's competition authorities may target foreign patent holders for AML enforcement and use the threat of enforcement to pressure U.S. patent holders to license to Chinese parties at lower rates. The United States has stressed to China that it is critical that China's AML enforcement be fair and non-discriminatory, afford due process to parties, focus only on the legitimate goals of competition law and not be used to achieve industrial policy goals.

China's legislative and regulatory efforts extend to pharmaceutical innovations, including pending amendments to the Drug Administration Law and Drug Registration Regulation. In November 2016, China committed that drug registration review and approval shall not be linked to pricing commitments and shall not require specific pricing information. Subsequent reports from industry representatives, as well as the February 2017 State Council *Guiding Opinion on the Production and Circulation of Drug Use Policy*, call into question how China is implementing this commitment. In October 2016, China issued draft revised patent examination guidelines addressing, among other issues, the treatment of supplemental data submitted in support of pharmaceutical patent applications. China recently issued the final version of these guidelines, effective April 1, 2017. However, clarifications are needed to better promote pharmaceutical innovation and bring China into closer alignment with the practices of other major patenting jurisdictions.

Additional concerns in this area include the extent to which China provides, as set forth in China's World Trade Organization (WTO) Working Party Report commitments, effective protection against unfair commercial use of, unauthorized disclosure of, and reliance on, undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. The extent of protection has turned, in part, on the definition of terms such as "new chemical entity" and "new drugs" as they appear in a number of draft and final measures. In particular, in March 2016, China put into effect a *Work Plan for the Reform of Chemical Drug Registration Categories*, which limits the definition of "new drugs" to those for which initial marketing approval is first sought in China. In March 2017, CFDA issued the *Draft Decision of Import Drugs Registration Management Adjustment*, which also makes reference to China's problematic definition for new drugs. This definition is inconsistent with harmonized practice, reflected in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, and represents a failure to implement China's related commitment of the 2012 Joint Commission on Commerce and Trade (JCCT).

Other concerns include the lack of an effective mechanism for notifying interested parties of marketing requests or approvals for follow-on pharmaceuticals in a manner that would allow for the early resolution of potential patent disputes. China also needs to implement commitments to address regulatory approval backlogs, streamline procedures, and to close gaps in its regulation of active pharmaceutical ingredients to curb the production and export of substandard pharmaceuticals (including some counterfeits). It should be noted that in the draft decision on

import drugs registration management adjustment China reportedly no longer requires that manufacturers wait until a pharmaceutical product is in phase 2 or 3 clinical trials overseas before they may conduct multi-regional clinical trials in China.

China's "Secure & Controllable" Policies Should Not Disadvantage U.S. IP-Intensive Industries

Ensuring that China's "secure and controllable" measures do not disadvantage U.S. IP-intensive industries is a major ongoing concern to the United States and the private sector. China has continued to issue draft and final measures invoking security as a putative justification for mounting barriers to foreign products, services, and technologies. For example, as conditions for market access, China's Cybersecurity Law and related measures may require the disclosure of critical IP, and may require that IP rights be owned in China, that research and development be conducted in China, or both. The Cybersecurity Law would also curtail or prohibit cross border data flows, harming IP-intensive U.S. industries whose global service delivery models rely on cloud computing platforms.

The trend with respect to "secure and controllable" measures began to accelerate with regulations on ICT purchases by the banking sector in late 2014 and has continued to grow through both widely applicable and sector-specific measures. Many of the measures invoke the requirement that ICT products be "secure and controllable" or conform to other vaguely defined criteria. While China has suspended or postponed the implementation of some of these measures, others have gone into effect over the objections of the United States, other governments, and the U.S. and international private sector.

China adopted the Cybersecurity Law in 2016 over the objections of the United States, other governments, and the international business community. Also, President Xi Jinping confirmed in October 2016 that China is accelerating the pursuit of a foreign technology substitution program based on indigenous innovation. This stands in contrast to Xi's September 2015 commitment that "generally applicable measures to enhance ICT cybersecurity in commercial sectors (ICT cybersecurity regulations) should be consistent with WTO agreements, be narrowly tailored, take into account international norms, be nondiscriminatory, and not impose nationality-based conditions or restrictions, on the purchase, sale, or use of ICT products by commercial enterprises unnecessarily." China further clarified at the 2016 JCCT that these commitments cover China's "secure and controllable" policies. China explained that its secure and controllable policies generally applicable to the commercial sector are not to unnecessarily limit or prevent commercial sales opportunities for foreign suppliers, of ICT products, services, or technologies and will not impose nationality-based conditions and restrictions on the purchase, sale, and use of ICT by commercial enterprises unnecessarily. China also committed to notify its technical regulations to the WTO Committee on Technical Barriers to Trade.

Since the 2016 JCCT, China has published several draft implementing measures for the Cybersecurity Law, which raise serious concerns about China's adherence to these bilateral commitments. China's draft Regulation on Cybersecurity Review of Network Products and Services, was published for public comment in February 2017. The measure raises concerns, including on how China's Cybersecurity Review Commission will conduct cybersecurity reviews

under the Cybersecurity Law, and whether the reviews require disclosure of sensitive, proprietary IP for purposes unrelated to national security, or both. The Cybersecurity Law itself incorporates the Multi-Level Protection System requirements, which have numerous problematic aspects, one of which is a requirement for products to have indigenous Chinese IP, notwithstanding China's commitments in the United State-China Strategic and Economic Dialogue (S&ED) to treat IP owned or developed in foreign countries the same as domestically owned or developed IP, and China's JCCT commitment to bring these measures into conformity with China's commitments to the United States. China also issued numerous draft standards in support of the Cybersecurity Law, including draft standards published in November 2016 by the National Information Security Standardization Technical Committee (TC-260). These standards laid out an untested approach to assign a score to ICT products for cybersecurity using subjective and inappropriate benchmarks (e.g. the extent to which a party discloses sensitive IP; the extent to which a product is authentic, auditable, compliant, and complete; and the extent to which all the factors of product R&D and manufacturing, including core IP, is clear and undisputable). In conjunction with the Cybersecurity Law, China is also pursuing sector-specific implementing regulations in areas like aviation. Going forward, China must not invoke security concerns in order to erect market access barriers, require the disclosure of critical IP, or discriminate against foreign-owned or developed IP.

Technology Transfer Requirements and Incentives, and Obstacles to Foreign Participation

The United States is concerned that many of China's innovation-related and other industrial policies may have negative impacts on U.S. exports or U.S. investors and their investments or IP. Chinese measures frequently call for technology transfer and, in certain cases, appear to include criteria requiring that certain IP be developed in China, or be owned by or licensed to, in some cases exclusively, a Chinese party. Posing similar concerns are China's Technology Import Export Administration Regulations, which impose mandatory licensing terms only to foreign technology licensed or transferred to China, including mandating that Chinese parties own any improvements made from licensed foreign technology and requiring foreign technology owners to indemnify Chinese licensees against infringement. Additionally, China's efforts to limit the distribution of digital content by foreign wholly-owned companies and foreign joint ventures is an area in which recent Chinese regulations have presented challenges for U.S. IP-intensive industries. Such government intervention, including quotas on foreign online content, and prohibitions on foreign firms directly distributing content online, reflect imposed conditions or incentives, or overly burdensome regulation that may distort licensing and other private business arrangements, resulting in reduced innovation and a disincentive for relevant firms to participate in the Chinese market.

China continues to issue other troubling measures. For example, China's State Council issued the Made in China 2025 Plan and shortly thereafter the Chinese National Advisory Committee on Building a Manufacturing Power Strategy issued the related Technical Roadmap (sometimes referred to as the Greenbook). This Plan aims to turn China into an indigenously self-sufficient advanced manufacturing superpower with well-known Chinese brands across a wide range of high technology industries (e.g., semiconductors, industrial robots, smart sensors, and other advanced equipment, including aerospace/aviation, telecommunication, marine, rail, energy-saving vehicle

and electrical, medical, agricultural equipment), in many of which U.S. IP right holders have sizeable market shares globally. This drive may run counter to commitments China has made to the United States and be in tension with basic market economy principles. Other recent developments include amendments to China's *High and New Technology Enterprise* tax preference, which further restricted the IP-related requirements in a manner disproportionately impacting U.S. and other foreign enterprises, and a draft State Council opinion offering accelerated regulatory approval to firms that manufacture their pharmaceutical products in China.

It is imperative that China implement its bilateral commitments to the United States, including that:

- “Technology transfer and technological cooperation shall be decided by businesses independently and will not be used by the Chinese government as a pre-condition for market access”;
- China must “treat intellectual property rights owned or developed in other countries the same as domestically owned or developed intellectual property rights”;
- “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”; and
- “China is actively conducting research on the Technology Important and Export Administration Regulations (2002) to address U.S. concerns, to support China’s efforts to become an innovative economy, and to better address newly emerging areas of technology transfer.”

The United States calls for China’s full implementation of these and other commitments, and the revision of measures as needed to ensure that they are consistent with these commitments.

Other Concerns

Industry reports considerable concern that China’s rules and procedures enable parties to participate in opposition, cancellation, invalidation, and other processes to ensure GIs not impose market access barriers to U.S. exports. In 2014 and 2015, the United States welcomed important Chinese commitments on rules and procedures concerning the registration of GIs under China’s existing systems, as well as those registered pursuant to an international agreement. The United States has continued to work with China to ensure that U.S. products that rely on common names do not face displacement in the Chinese market due to GI registrations.

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 confirmed at government offices of all levels. Despite this effort, industry reports that government and SOE software legalization programs are still not being implemented comprehensively. China should provide specific information about the relevant procedures and tools used to ascertain budget and audit information, and to ensure accountability. While 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.

As China continues implementation of the 2013 amendments to the Trademark Law, industry has identified concerns relating to opposition examiners at the China Trademark Office (CTMO), who face very large dockets, may have limited training, and whose decisions may be unpredictable and too often focus narrowly on whether the respective goods or services in question are found in the same class or sub-class or on whether the marks in question are identical or substantially indistinguishable (without duly considering whether a likelihood of confusion exists based on practical or market considerations). Industry continues to report that trademark authorities do not give full consideration to co-existence agreements and letters of consent in registration processes, among other issues. Additional concerns include onerous documentation requirements for opposition, cancellation, and invalidation proceedings; and legitimate right holders' difficulty in obtaining well-known trademark status. Additionally, changes to trademark opposition procedures have eliminated appeals for oppositions and have resulted in longer windows for bad-faith trademark registrants to use their marks before a decision is made in an invalidation proceeding. In early 2017, the CTMO and Trademark Review and Adjudication Board issued amended Trademark Examination and Adjudication Standards, while the SPC issued a judicial interpretation entitled, "*Notice on Issuing the Opinions on Several Issues Concerning the Trial of Administrative Cases Involving the Authorization and Determination of Trademark Rights.*" The United States will monitor the impact of these new measures and urges China to address these and other issues affecting U.S. right holders.

INDONESIA

Indonesia remains on the Priority Watch List in 2017.

Ongoing Challenges and Concerns

U.S. right holders continue to face challenges with respect to adequate and effective IP protection and enforcement, as well as fair and equitable market access, in Indonesia. Concerns include widespread piracy and counterfeiting and, in particular, the lack of enforcement against dangerous counterfeit products. To address these issues, Indonesia would need to develop and fully fund a robust and coordinated IP enforcement effort that includes deterrent-level penalties for IP infringement in physical markets and online. Indonesia also lacks 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. In addition, the United States remains concerned about a range of market access barriers in Indonesia, including requirements for domestic manufacturing and technology transfer for pharmaceuticals and other sectors, as well as certain measures related to motion pictures.

Developments, Including Progress and Actions Taken

Indonesia has made progress in addressing some of these concerns, but has faltered or has taken steps backward in other areas. For example, U.S. stakeholders have noted positive developments related to Indonesia's efforts to address online piracy and with respect to collective management organizations. Indonesia removed film and recording studios from its negative investment list, allowing 100 percent foreign direct investment in the production of films and sound recordings, as well as in film distribution and exhibition, but Indonesia has been drafting implementing regulations to the 2009 Film Law that raise concerns that it will further restrict foreign participation in this sector. In addition, Indonesia enacted a revised Trademark Law in November 2016 that provides shortened timeframes for examination, allows for sound marks, and prepares Indonesia to join the Madrid Protocol. However, IP enforcement has been insufficient and Indonesia still has not issued long-awaited regulations confirming *ex officio* authority for border enforcement. The United States continues to urge Indonesia to improve enforcement cooperation among relevant agencies, including the National Inter-Ministerial IPR Task Force, Directorate General for Intellectual Property, Attorney General's Office, Creative Economy Agency, and National Agency for Drug and Food Control. The United States also encourages Indonesia to create a specialized IP unit under the Indonesia National Police to focus on investigating the Indonesian criminal syndicates behind counterfeiting and piracy and to initiate larger and more significant cases. In addition, revisions to Indonesia's Patent Law in July 2016 have raised concerns, including with respect to the patentability criteria for incremental innovations and computer implemented inventions; local manufacturing and use requirements; the grounds and procedures for issuing compulsory licenses; disclosure requirements for inventions related to traditional knowledge and genetic resources; and requirements to disclose the details of private licensing agreements. As Indonesia enacts implementing regulations for the revised Patent Law, the United States continues to urge Indonesia to address these concerns and to provide affected stakeholders with meaningful opportunities for input. Regarding GIs, revisions to Indonesia's law concerning GIs raise

questions about the effect of new GI registrations on pre-existing trademark rights and the ability to use common food names. The United States plans intensified engagement with Indonesia, including through the IPR Working Group of the United States-Indonesia Trade and Investment Framework Agreement, to address these important issues.

THAILAND

Thailand remains on the Priority Watch List in 2017. The United States is prepared to review that status if Thailand continues taking positive steps and makes substantial progress in addressing the concerns described below.

Ongoing Challenges and Concerns

U.S. right holders continue to face challenges with respect to adequate and effective IP protection and enforcement, as well as fair and equitable market access, in Thailand. U.S. concerns remain regarding the widespread availability of counterfeit and pirated goods, both in physical markets and online, as well as the lack of effective and deterrent enforcement measures. In addition, the United States remains concerned about a range of copyright-related issues. In particular, the 2014 Copyright Act amendments failed to address concerns expressed by the United States and other foreign governments and industry, including with respect to the absence of an effective landlord liability provision, the lack of adequate protections against the circumvention of technological protection measures and the unauthorized modification of rights management information, and procedural obstacles to enforcement against unauthorized camcording. Other U.S. concerns include a backlog in pending patent applications, widespread use of unlicensed software in both the public and private sectors, lengthy civil IP enforcement proceedings and low civil damages, and extensive cable and satellite signal theft. U.S. right holders have also expressed concerns regarding legislation that allows for content quota restrictions and regarding possible unintended effects of data and cyber security laws.

Developments, Including Progress and Actions Taken

The United States notes the initial steps that Thailand has taken to address ongoing concerns and urges Thailand to build on these efforts to achieve concrete, sustainable progress.

Thailand has expressed a strong political commitment to improving the environment for IP protection and enforcement, as reflected in public statements by the Prime Minister and the inclusion of effective enforcement and the timely grant of protection as pillars of its 20-Year Intellectual Property Roadmap. Thailand also has established an interagency National Committee on Intellectual Property Policy and a subcommittee on enforcement against intellectual property infringement, led by the Prime Minister and a Deputy Prime Minister, respectively, which have improved coordination among government entities. As a result, Thailand has increased its focus on investigations and raids, and the United States urges Thailand to further improve efforts throughout the country to investigate and successfully pursue IP cases in the judicial system that result in deterrent sentences, fines, or both, including with respect to online piracy and unauthorized camcording in movie theaters. In addition, U.S. stakeholders have reported progress relating to Thailand's efforts to effectively address online piracy, although there remains a lack of clarity in the operation of notice-and-takedown procedures. The United States recognizes steps that Thailand is taking to address the backlogs for patent and trademark applications, including hiring additional examiners. The United States also continues to encourage Thailand 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. In addition, the United States urges Thailand to engage in a meaningful and transparent manner with all relevant stakeholders, including IP owners, as it considers ways to address the country'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 through the United States-Thailand Trade and Investment Framework Agreement and other bilateral engagement.

SOUTH AND CENTRAL ASIA

INDIA

India remains on the Priority Watch List in 2017.

Ongoing Challenges and Concerns

India remains one of the world's most challenging major economies with respect to protection and enforcement of IP. Despite positive statements and initiatives upon which the Modi Administration has embarked, the pace of reform has not matched high-level calls to foster innovation and promote creativity. India has yet to take steps to address longstanding patent issues that are affecting innovative industries. These include the application of narrow patentability criteria, challenges faced by the pharmaceutical industry due to Section 3(d) of the India Patents Act, and the issuance of problematic guidelines that appear to restrict the patentability of computer implemented inventions. Innovative companies remain concerned about the potential threat posed to their IP through the possible use of compulsory licensing and patent revocation, as well as overly broad criteria for issuing such licenses and revocations under the India Patents Act. Across all industries, patent applicants face costly and time-consuming patent opposition hurdles, long timelines for receiving patents, and excessive reporting requirements. In the pharmaceutical and agricultural chemical sectors, India continues to lack an effective system for protecting against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for such products. In the pharmaceutical sector, India lacks an effective system for notifying interested parties of marketing approvals for follow-on pharmaceuticals in a manner that would allow for the early resolution of potential patent disputes. Innovative industries also face pressure to localize the manufacture of their products, including due to the Drug Price Control Order and to high customs duties directed to IP-intensive products, such as medical devices, pharmaceuticals, information and communications technology products, solar energy equipment, and capital goods.

Notwithstanding the positive developments on state-level enforcement described below, India's overall levels of IP enforcement remain deficient, and the lack of uniform progress across the country threatens to undercut the positive steps that certain states have taken. India has yet to take the final steps to enact anti-camcording legislation, formally establish a copyright royalty board, appoint a functional Intellectual Property Appellate Board, and ensure that collective management organizations are licensed promptly and able to operate effectively. Right holders continue to report high levels of piracy and counterfeit sales, including on the Internet, in physical markets (for recent examples, refer to the 2016 OCR of Notorious Markets), and through commercial broadcasts. Furthermore, illegal practices that contribute to high piracy rates include the underreporting of cable subscriptions, widespread use of illicit streaming devices, and circumvention of technological protection measures. Finally, the expansive granting of licenses under Chapter VI of the Indian Copyright Act and overly-broad exceptions for certain uses have raised concerns about the strength of copyright protection.

Although some administrative improvements have been made and others are in progress, overall levels of trademark counterfeiting remain high, and U.S. brand owners continue to report significant challenges and excessive delays in obtaining trademarks and efficiently utilizing opposition and cancellation proceedings, as well as quality of examination issues. Companies also continue to face uncertainty caused by insufficient legal means to protect trade secrets in India, although in recent years there have been encouraging signs that India is reviewing relevant laws and practices on this issue.

India has not yet joined important international treaties and agreements that could improve aspects of India's IP regime, such as the WIPO Internet Treaties and the Singapore Treaty on the Law of Trademarks. However, India has indicated that it may "examine accession" to some of these agreements in the context of its National IPR Policy. In addition, India's vocal encouragement and propagation of initiatives that promote the erosion of IP around the world, especially in the pharmaceutical sector, sends a concerning signal about India's commitment to strengthening its IP regime. This also contradicts positive statements made by Prime Minister Modi and high-level initiatives, including the National IPR Policy and Start-up India.

Developments, Including Progress and Actions Taken

While India made meaningful progress to promote IP protection and enforcement in some areas over the past year, it failed to resolve recent and longstanding challenges, and it created new concerns for right holders. India continues to pursue important administrative work to reduce the time for processing patent and trademark applications, while the Department of Industrial Policy and Promotion (DIPP) has increased the pace of administrative copyright reforms. The United States welcomed the initiative taken by the Indian Patent Office (IPO) to hire new examiners and to engage with stakeholders on a regular basis regarding the administrative progress IPO is making. There have been notable enforcement efforts carried out by state authorities, including the establishment of the Telangana IP Crime Unit (TIPCU) to coordinate IP enforcement activities across various state-level IP and enforcement agencies. The United States is interested in the Maharashtra Government's recent announcement that it is constituting an IPR Task Force. We encourage India to adopt a national-level enforcement task force for IP crimes. The state of Andhra Pradesh also carried out a significant campaign to dismantle a large film piracy group. In addition, the United States welcomed India's amendments to the Patents Rules in a manner that better aligns with international best practices. India's commitment to bilateral dialogue remained strong, with frequent government-to-government engagements and working- and high-level meetings, as well as broader workshops with stakeholders on copyright and trade secrets.

Another notable development was the finalization and issuance of the National IPR Policy, which put forward a number of broad objectives to achieve on several IP-related issues. The Policy largely avoids a discussion of specific legal and policy issues that the United States and other stakeholders had suggested that the Modi Government address to promote innovation and creativity, but it does devote resources to improving IP administration and promoting commercialization and public awareness. The Policy does not preclude India from taking up more concrete policy reforms. We encourage India to continue to engage with the United States and stakeholders to find ways to implement policies that achieve the Policy's objectives of "foster[ing] creativity and innovation and thereby, promot[ing] entrepreneurship and enhanc[ing] socio-

economic and cultural development”. To this end, the United States is encouraged by the creation of the Cell for IPR Promotion and Management (CIPAM) under DIPP to move forward implementation of the policy and hopes that CIPAM can harness enthusiasm for more robust IP protection into meaningful policy reforms.

In 2016, India offered promising action that may improve its trade secrets regime. Specifically, India announced the preparation of a toolkit for industry that will highlight existing applicable laws and policies that address the theft of trade secrets in India, the creation of a training module on trade secrets for judicial academies, and the initiation of a study on various legal approaches to protecting trade secrets.

The 2015 passage of the Commercial Courts Act, highlighted in last year’s Report, provided an opportunity to reduce delays and increase expertise in judicial IP matters. However, to date, India has established only two courts, and the results continue to be evaluated. If successful, these courts could significantly alleviate a major deficiency in India’s IP enforcement regime that right holders face.

In addition to unresolved concerns highlighted in last year’s Report, there are several new issues. The Ministry of Agriculture and Farmers Welfare’s “Licensing and Formats for Genetically-Modified Technology Agreement Guidelines, 2016” (2016 Guidelines) were issued in final form without an opportunity for the public to comment, raising serious concerns over India’s respect for innovation, IP, transparency, and the freedom of contract. Although the United States appreciates India’s swift action to convert the 2016 Guidelines into draft form and subsequently to accept public comments, India’s prolonged consideration of the Guidelines remains troubling. Given the chilling effect the 2016 Guidelines would likely have on agricultural innovation and the negative signal they would send to innovative and IP-intensive industries, the United States urges India to formally abandon the 2016 Guidelines.

As mentioned above, India’s copyright royalty regime remains problematic for a broad range of creative industry stakeholders. The United States was encouraged by India’s confirmation of the importance of a Copyright Board and its expression of hope that the Board could be functional by the second quarter of 2017. Such action, along with efficient licensing of collective management organizations and a narrow, predictable, and appropriately tailored statutory licensing regime, will help foster a healthy environment for creative content in India.

The United States intends to continue to engage with India on these and other IP matters through the primary channel of the Trade Policy Forum.

NEAR EAST, INCLUDING NORTH AFRICA

ALGERIA

Algeria remains on the Priority Watch List in 2017.

Ongoing Challenges and Concerns

Significant challenges continue with respect to fair and equitable market access for U.S. IP right holders in Algeria, notably for pharmaceutical and medical device manufacturers. Algeria's ban on a vast number of imported pharmaceutical products and medical devices in favor of local products is a trade matter of serious concern. Further, Algeria continues to struggle to provide adequate and effective IP protection and enforcement. Algeria fails to enforce its existing anti-piracy statutes, including those combating the use of unlicensed software, and to provide adequate judicial remedies in cases of patent infringement. Algeria does not 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.

Developments, Including Progress and Actions Taken

Algeria has taken steps to raise awareness of IP issues and has begun to engage with the United States; however, it did not take significant steps to improve IP enforcement or effectively address IP-related deficiencies in 2016. Algeria failed to address concerns with respect to IP enforcement and the ban on the importation of pharmaceutical products and medical devices. The United States strongly urges Algeria to remove these market access barriers and to continue engaging with the United States on a full range of important IP issues.

KUWAIT

Kuwait remains on the Priority Watch List in 2017 with an Out-of-Cycle Review focused on addressing gaps in Kuwait's copyright regime.

Ongoing Challenges and Concerns

The United States welcomes the 2016 passage of the Copyright and Related Rights Law, which represents a significant development towards a robust copyright regime. There are still steps that Kuwait needs to take for its copyright regime to meet international standards, including with respect to the term of protection; the scope of certain exceptions for reproduction; enforcement, remedies, and damages; and definitions.

The United States commends Kuwait's recent boost in enforcement efforts and encourage the government to build upon this progress and devote additional resources and political attention to curbing the manufacture and sale of counterfeit and pirated goods, including by targeting manufacturers and increasing fines and penalties to deterrent levels. While the United States applauds the referral of IP cases to Kuwaiti courts for prosecution in 2016, none of these cases has resulted in a successful prosecution to date.

Developments, Including Progress and Actions Taken

In a notable development, in May 2016, Kuwait's National Assembly passed the new Copyright and Related Rights Law. This law represents a significant improvement over previous legislation. Kuwait is now in the process of drafting implementing regulations and has the opportunity to bring its regime in line with international standards by clarifying and addressing ambiguities and deficiencies in the statute. Kuwait also significantly increased its level of IP enforcement over past years, and took action against online offerings of pirated materials, conducted raids and criminal trials on a range of pirated and counterfeit physical goods, and worked with right holders to enhance enforcement efforts. The United States also welcomed positive developments, including Kuwait's interest in further cooperation and increased public awareness activities.

EUROPE AND EURASIA

RUSSIA

Russia remains on the Priority Watch List in 2017.

Ongoing Challenges and Concerns

Challenges to IP protection and enforcement in Russia include copyright infringement, trademark counterfeiting, and non-transparent collective management organization procedures. In particular, the United States remains concerned about stakeholder reports that IP enforcement continued to decline overall in 2016, following similar declines in the prior four years including a reduction in resources for enforcement personnel. The volume of counterfeit goods trafficking originating from abroad is increasing and Russian enforcement agencies continue to lack sufficient staffing, expertise, and the political will to combat IP crimes.

Developments, Including Progress and Actions Taken

Russia took some positive steps in 2016 but overall the IP situation remains extremely challenging. The Moscow City Court granted more than 700 preliminary injunctions against IP infringers. However, despite this limited progress, the lack of enforcement of intellectual property crimes is a persistent problem, with the overall number of raids, criminal charges, and convictions continuing to decline. Burdensome procedural requirements hinder right holders' ability to bring civil actions, which are exacerbated for foreign right holders by strict documentation requirements such as verification of corporate status.

Inadequate and ineffective protection of copyright, including with regard to online piracy, continues to be a significant problem, damaging both the market for legitimate content in Russia as well as in other countries. Russia remains home to several sites that facilitate online piracy, as identified in the *2016 OCR of Notorious Markets*. Stakeholders report significant piracy of video games, music, movies, books, journal articles, and television programming. Russia has enacted legislation that enables right holders to seek court-ordered injunctions, but has not taken the steps to get at the root of the problem—namely, investigating and prosecuting the owners of the large commercial sites selling such pirated material, including software. Additionally, stakeholders report a 300 percent increase in 2016 of unauthorized camcords, exacerbating a sharp rise in 2015. Stakeholders further report that these problems negatively affect, in particular, independent producers and distributors, the majority of which are small and medium-sized enterprises.

Royalty collection in Russia continues to lack transparency and fails to meet international standards. The United States encourages collective management organizations (CMOs) to update and modernize their procedures, including enabling full representation of right holders in CMO governing bodies, regardless of whether right holders are individuals or legal entities.

Russia is a thriving market for counterfeit hard goods sourced from China, entering the country through Kazakhstan, Kyrgyzstan, and Azerbaijan. Stakeholders report nominal customs seizures

in 2016. Similarly, there is little enforcement against the trafficking in counterfeits online, including apparel, footwear, sporting goods, pharmaceutical products, and electronic devices.

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 unfair commercial use of, unauthorized disclosure of, and reliance on, undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. Stakeholders report that Russia is eroding protections for undisclosed data, and the United States urges Russia to adopt a system that meets international norms of transparency and fairness.

The United States urges Russia to develop a more comprehensive, transparent, and effective enforcement strategy to reduce IP infringement, particularly the sale of counterfeit goods and the piracy of copyright-protected content. The United States continues to monitor Russia's progress on these and other matters through appropriate channels.

UKRAINE

Ukraine remains on the Priority Watch List in 2017.

Ongoing Challenges and Concerns

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 collective management organizations, which are responsible for collecting and distributing royalties to U.S. and other right holders; (2) widespread (and admitted) use of unlicensed software by Ukrainian government agencies; and (3) failure to implement an effective means to combat the widespread online infringement of copyright in Ukraine. The United States recognizes that, since that time, Ukraine has taken some positive steps, but these problems are not resolved.

Developments, Including Progress and Actions Taken

In 2016, Ukraine passed legislation to create a specialized Intellectual Property High Court by September of 2017. The United States hopes this specialized court will have a positive impact on IP enforcement. The National Police of Ukraine cooperated with the Federal Bureau of Investigations (FBI) and INTERPOL on IP matters. Ukraine also closed the State Intellectual Property Service of Ukraine (SIPSU), which had long been criticized for nontransparent and unfair practices. However, it is not clear to right holders whether other government agencies are fulfilling all the responsibilities SIPSU previously handled.

With respect to unauthorized collective management organizations, little has changed. A number of rogue collective management organizations continue to operate freely in Ukraine, collecting royalties but not distributing those royalties to legitimate right holders. However, Ukraine appears to be making progress on finalizing a draft collective management society bill. It will be important to ensure that the final bill will be effective, both in law and in practice. The United States hopes that the fixes in this bill will result in a transparent, fair, and predictable system for collective management of royalties because the current state of the system is entirely inadequate.

Ukraine has taken preliminary steps to reduce the use of unlicensed software by some Ukrainian government agencies, but it has not made sufficient systemic progress. While individual pilot programs appear to have had some success in reducing the use of unlicensed software by specific government departments, there does not appear to be a centralized approach, or sufficient funds allocated to enable the government to transition to authorized software.

Online piracy remains a significant problem in Ukraine and fuels piracy in other markets. Pirated films generated from illegal camcording and made available online particularly damage the market for first-run movies. However, this year, the site ex.ua, repeatedly listed in USTR's OCRs of Notorious Markets shut down. Further, enforcement officials took down fs.to, one of the largest pirate sites in Ukraine, with an estimated number of users exceeding 20 million per month. Though other Notorious Markets continue to operate out of Ukraine, including extratorrent.cc and MP3VA.com, it is highly encouraging that the work of the new special Cybersecurity Police

Department has already resulted in several successful enforcement actions online. However, few offenders have been prosecuted for these serious crimes.

One development that reflects new political will to address the problem of online piracy is the signing into law of the bill “On State Support of Cinematography” which, among other things, establishes criminal penalties for illegal camcording and clarifies the availability of penalties for online piracy (not just hard copy piracy). Presently, many Ukrainian website operators with knowledge of infringing material on their sites do not respond to notice and takedown requests. The creation of a copyright safe harbor system in this law is an important step forward. However, aspects of the new law have engendered concern by many different stakeholder groups, who report that certain obligations and responsibilities are too ambiguous or too onerous to facilitate an efficient and effective response to online piracy. The United States’ concerns with respect to online piracy in Ukraine, which have been set forth in prior Special 301 Reports, would be ameliorated by a system similar to that in U.S. law. The United States urges Ukraine to actively engage with all affected stakeholders to ensure the statutory infrastructure for reducing online piracy is effective and efficient. The United States will continue to engage intensively on these issues with the Government of Ukraine, including through the U.S.-Ukraine Trade and Investment Council.

WESTERN HEMISPHERE

ARGENTINA

Argentina remains on the Priority Watch List in 2017.

Ongoing Challenges and Concerns

Argentina continues to present long standing and well-known deficiencies in IP protection and enforcement, and is a challenging market for IP-intensive industries. A key challenge in Argentina is the lack of effective IP enforcement by the national government. Argentine police do not take *ex officio* actions, prosecutions can stall, cases may languish in excessive formalities, and, even when a criminal investigation reaches final judgment, infringers do not receive deterrent sentences. In terms of physical counterfeiting and piracy, La Salada in Buenos Aires has been included in past OCRs of Notorious Markets and is one of the largest open-air markets in Latin America offering for sale high quantities of counterfeit and pirated goods, and it continues to thrive. While optical disc copyright piracy is widespread, online piracy continues to be a growing concern and criminal enforcement for online piracy is nearly nonexistent. As a result, IP enforcement online in Argentina consists mainly of right holders trying to convince cooperative Argentine ISPs to agree to take down specific infringing works, as well as attempting to seek injunctions in civil cases. Right holders also cite widespread use of unlicensed software by Argentine private enterprises and the government.

There are also a number of ongoing challenges to innovation in the agricultural chemical, biotechnology, and pharmaceutical sectors, including with respect to patent pendency, scope and term of patent protection, and meaningful enforcement options. There is a substantial backlog of patent applications resulting in long delays to obtain protection and register rights, and Argentina does not provide provisional protection for pending patents. Pursuant to a highly problematic 2012 Joint Resolution establishing guidelines for the examination of patents, Argentina summarily rejects patent applications for categories of pharmaceutical inventions that are eligible for patentability in other jurisdictions, including in the United States. Additionally, 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. Industry asserts that Resolution 283/2015, introduced in September 2015, also limits the ability to patent biotechnological innovations based on living matter and natural substances. These measures have interfered with the ability of companies investing in Argentina to protect their IP and may be inconsistent with international norms. The United States also remains concerned that Argentina does not appear to 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.

Developments, Including Progress and Actions Taken

Over the last year, Argentina took several noteworthy steps to improve IP protection and enforcement including legislative initiatives, enforcement operations, procedural enhancements for patent protection, and the creation of bilateral engagement mechanisms. Argentina introduced

a number of legislative proposals to improve the protection and enforcement of IP: a bill to provide for landlord liability and enhance enforcement in non-conventional, or informal, marketplaces such as La Salada; a bill to amend the trademark law to increase criminal penalties for counterfeiting carried out by criminal networks; and a bill to enhance protection for industrial designs. Other legislative initiatives including regulation of collective management organizations, criminal sanctions including for circumventing technological protection measures, and the creation of a federal specialized IP prosecutor's office are reportedly in the drafting stages. While these legislative initiatives are welcome, others raise questions and potential concerns. Although perhaps well-intentioned, elements of various legislative proposals to update the national seed law may negatively affect the ability to protect and enforce plant variety rights and other IP, and a bill regarding responsibilities of ISPs may not go far enough to encourage effective action against online piracy. With respect to enforcement operations, the city of Buenos Aires conducted operations to close illegal street vendors, but the lack of a national IP enforcement strategy limits successes to targeted neighborhoods in the capital.

The National Institute of Industrial Property (INPI) has taken steps to confront its lengthy patent examination backlog. In September 2016, INPI issued a regulation creating expedited procedures for patent applicants that have obtained patents in other jurisdictions. INPI is also hiring more patent examiners and is working toward digitization of internal procedures and a more efficient online application management system. In addition to collaborating with other foreign patent offices, INPI and the USPTO commenced in March 2017 a Patent Prosecution Highway (PPH) pilot program to increase efficiency and timeliness of patent examinations. In 2016, Argentina and the United States established a bilateral Innovation and Creativity Forum for Economic Development under the U.S.-Argentina Trade and Investment Framework Agreement and held productive first meetings in December. The United States is hopeful that the important steps Argentina has taken as well as its plans for future progress will bear tangible results, thereby creating a more attractive environment for investment and innovation.

CHILE

Chile remains on the Priority Watch List in 2017.

Ongoing Challenges and Concerns

The United States continues to have serious concerns regarding longstanding implementation issues with respect to IP provisions of the United States-Chile Free Trade Agreement. The United States continues to urge Chile to implement both protections against the unlawful circumvention of TPMs and protections for encrypted program-carrying satellite signals. Chile also needs to ensure that effective administrative and judicial procedures, as well as deterrent remedies, are made available to right holders and satellite and cable service providers, including measures to address ongoing concerns with decoder boxes. The United States continues to urge Chile to join UPOV 91 and improve protection for plant varieties. The United States also urges Chile to implement an effective system for addressing patent issues expeditiously in connection with applications to market pharmaceutical products and 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. Finally, the United States urges Chile to amend its ISP liability regime to permit effective and expeditious action against online piracy.

Developments, Including Progress and Actions Taken

Over the past year, Chile has taken some steps toward potential progress. The National Institute of Industrial Property entered into a PPH agreement with the Pacific Alliance (Colombia, Mexico, and Peru) which came into force in July 2016, and a PPH commenced in September 2016 with members of the PROSUR regional cooperation system on IP (Argentina, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru and Uruguay). These agreements may accelerate patent processing. A bill that would criminalize satellite signal theft and circumvention devices, as well as amendments to the industrial property law, are pending in Congress, and the government has stepped up its efforts to draft TPMs legislation. While the United States and Chile engaged in several bilateral discussions about IP issues, the Bachelet Administration has not prioritized pending and drafted legislation to address these issues. The United States will work closely with Chile, including in meetings of the bilateral Free Trade Commission, to address ongoing IP issues.

VENEZUELA

Venezuela remains on the Priority Watch List in 2017.

Ongoing Challenges and Concerns

Challenges continue with respect to adequate and effective IP protection and enforcement. These challenges range from a lack of enforcement against IP infringement that includes widespread piracy and counterfeiting, to substandard levels of IP protection. Venezuela's formal withdrawal from the Andean Community and the reinstatement of its 1956 Industrial Property Law, in conjunction with provisions in Venezuela's 1999 constitution and international treaty obligations still in effect, has created legal ambiguity for IP and has impeded the registration of patents for pharmaceutical products.

Developments, Including Progress and Actions Taken

In 2016, the National Assembly introduced a bill for a new IP law to address some of the concerns regarding Venezuela's 1956 Industrial Property Law, but there has been no further legislative progress. Additionally, Venezuela's Autonomous Intellectual Property Service (SAPI) has not issued a new patent since 2007, and has substantially increased patent filing and maintenance fees. Additionally, brand owners report that SAPI regularly approves and publishes applications for trademarks that are identical with, substantially indistinguishable from, or confusingly similar to registered marks and that trademark opposition procedures are slow and ineffective. 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. Piracy, including online piracy, remains a persistent challenge. Additionally, infringing copies of movies found to be contributing to online piracy were traced back to unauthorized camcording in Venezuelan theaters. Venezuela is also reported to have the highest level of unlicensed software use in Latin America. IP enforcement remains insufficient to address widespread counterfeiting and piracy, including online. Prosecutions of IP crimes are rare, adjudication of cases is slow, and penalties are insufficient to deter counterfeiting and piracy. While the Venezuelan tax and customs authority (SENIAT) reportedly has occasionally conducted some low-level raids against small vendors of counterfeit products, major vendors of such products continue to operate in the absence of deterrent penalties or effective enforcement actions. The World Economic Forum's 2016-2017 Global Competitiveness Report ranked Venezuela last, for the fourth straight year, out of 138 countries, in IP protection. The Property Rights Alliance's 2016 International Property Rights Index also ranked Venezuela last for the second time in three years in a metric that includes standards of IP protection.

WATCH LIST

EAST ASIA AND THE PACIFIC

VIETNAM

Vietnam remains on the Watch List in 2017. Enforcement continues to be a challenge for Vietnam. Piracy and sales of counterfeit goods online remain common. Unless Vietnam takes stronger enforcement action, online piracy and sales of counterfeit goods are likely to worsen as more Vietnamese people obtain broadband Internet access and smartphones. Counterfeit goods, including counterfeits of high-quality, remain widely available in physical markets, and, while still limited, domestic manufacturing of counterfeit goods is emerging as a concern. In addition, book piracy, software piracy, and cable and satellite signal theft persist. Capacity constraints related to enforcement continue, in part due to a lack of resources and IP expertise. Vietnam also continues to rely heavily on administrative enforcement actions, which have failed to deter widespread counterfeiting and piracy. The United States will closely monitor ongoing implementation of amendments to the Penal Code, which establish criminal liability for organizations and business owners with respect to certain IP violations. While Vietnamese agencies have engaged in public awareness campaigns, foreign companies continue to face various impediments to selling legitimate products in Vietnam. In addition, Vietnam's system for protecting against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products needs clarifications. Vietnam has committed to strengthen its IP regime in its international agreements and is in the process of drafting or revising circulars in a number of IP-related areas, including those addressing pharmaceutical issues and interagency cooperation on enforcement. The United States will continue to engage with Vietnam on these issues and encourages Vietnam to provide interested stakeholders with meaningful opportunities for input as it proceeds with these reforms. The United States will continue to address these and other IP issues with Vietnam through the United States-Vietnam Trade and Investment Framework and other bilateral engagement.

SOUTH AND CENTRAL ASIA

PAKISTAN

Pakistan remains on the Watch List in 2017. Over the past year, Pakistan has maintained momentum on IP reforms, including by revising and issuing laws and regulations. However, sales of counterfeit and pirated goods remain widespread, including with respect to pharmaceuticals, printed works, optical media, digital content, and software. Pakistan's establishment of IP Tribunals in Lahore, Islamabad, and Karachi was a positive development, but the effectiveness of these courts remains to be seen. The publication of an IP Judicial Benchbook, the application of deterrent penalties, and a sustained focus on judicial consistency and efficiency will be critical moving forward. Also, a strong and effective Intellectual Property Organization (IPO) will support Pakistan's reform efforts, and the government should provide sufficient human and financial resources to empower IPO's efforts. The United States encourages Pakistan to continue to work bilaterally and make further progress on IP reforms, with a particular focus on aligning its IP laws, regulations, and enforcement regime with international standards. The United States also welcomes Pakistan's interest in joining international treaties, such as the WIPO Internet Treaties, Madrid Protocol, and PCT.

TURKMENISTAN

Turkmenistan remains on the Watch List in 2017. Developments over the past year include the entry into force of the Berne Convention for the Protection of Literary and Artistic Works in May 2016 and the Hague System for the International Registration of Industrial Designs in December 2015. However, the United States remains concerned with the protection and enforcement of IP rights in Turkmenistan and its failure to fully implement and enforce its IP laws. Turkmenistan reportedly has yet to provide for effective civil or criminal procedures or penalties for enforcement of these rights. The United States encourages Turkmenistan to provide these enforcement procedures, including *ex officio* authority for its customs officials. Further, the United States remains concerned about reports of widespread usage of unlicensed software on government computers. The United States urges Turkmenistan to issue a presidential-level decree, law, or regulation mandating government use of licensed software. The United States also encourages Turkmenistan to take legislative action to provide adequate copyright protection for foreign sound recordings, including through implementation of the WPPT or the Geneva Phonograms Convention. The United States stands ready to assist Turkmenistan through enhanced engagement or technical assistance, if requested.

UZBEKISTAN

Uzbekistan remains on the Watch List in 2017. Uzbekistan made little progress toward demonstrating a political commitment to improve its IP regime or significantly enhancing its enforcement efforts. An example of a positive effort undertaken over the past year was the establishment of a platform for the electronic filing of patent applications and a public database of

patent information. The Lower House of Parliament also approved a bill reportedly intended to strengthen IP protection, and it awaits action in the Upper House. The United States continues to urge Uzbekistan to take several critical legislative steps to address longstanding deficiencies in IP protection, including: (1) approve Uzbekistan's accession to the 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. Further, Uzbekistan should provide additional resources to the Agency for Intellectual Property and other enforcement agencies, as well as grant *ex officio* authority to customs and criminal law enforcement officials in order to initiate investigations and enforcement actions, including at the border; as well as issue a presidential-level decree, law, or regulation mandating government use of licensed software. Uzbekistan also continues to lack deterrent-level penalties for IP rights infringement. The United States welcomes the opportunity to engage with Uzbekistan on these matters, particularly as Uzbekistan considers adopting IP legislation.

NEAR EAST, INCLUDING NORTH AFRICA

EGYPT

Egypt remains on the Watch List in 2017. The United States notes Egypt's effort to strengthen enforcement of IP, including some success shutting down satellite channels showing pirated movies. However, although Egypt has taken steps to improve IP enforcement, challenges and concerns remain, including Egypt's failure to combat reportedly widespread pirated and counterfeit goods, including software, music, and videos. The United States urges Egypt to provide deterrent-level penalties for IP violations, *ex officio* authority for customs officials to seize counterfeit and pirated goods at the border, and necessary additional training for enforcement officials. Egypt also fails to provide a transparent and reliable patent registration system and lacks an effective system for notifying interested parties of applications for marketing approval of follow-on pharmaceuticals in a manner that would allow for the early resolution of potential patent disputes. 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 for pharmaceutical products. The United States appreciates Egypt's recent engagement on IP issues with stakeholders and stands ready to work with Egypt to improve its IP regime.

LEBANON

Lebanon remains on the Watch List in 2017. The United States welcomes the continued efforts of the Ministry of Economy and Trade's Intellectual Property Protection Office and law enforcement agencies to strengthen Lebanon's administrative and enforcement capacity for IP protection, and urges the commitment of additional resources to support this work. In particular, Lebanon should allocate resources to update the electronic system for trademark registrations to facilitate use of the system by right holders who are not in the country. Lebanon should also allocate financial and human resources to law enforcement institutions, including to ministry inspectors, police officers, and customs officials, as well as to facilities to store seized counterfeit goods and the mechanisms to destroy such seized goods. The United States notes the ongoing collaboration between private sector right holders and Lebanese enforcement agencies to identify counterfeit goods in the local market and assist authorities in IP enforcement. The United States encourages Lebanon to make progress on pending IP legislative reforms, including draft laws concerning trademark, GIs, and industrial designs, and amendments to existing copyright and patent laws. The United States also encourages Lebanon to ratify and implement the latest acts of several international IP framework treaties, including the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, and the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks. In addition, the United States encourages Lebanon to ratify and implement the Singapore Treaty on the Law of Trademarks and to join the Patent Cooperation Treaty and the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks. The United States looks forward to continuing to work with Lebanon to address these and other issues.

EUROPE AND EURASIA

BULGARIA

Bulgaria remains on the Watch List in 2017. The United States welcomes Bulgaria's efforts in 2016 to continue to address cable piracy, increase cooperation with stakeholders, cooperate in international law enforcement operations, and develop plans to establish specialized IP prosecutorial units. However, the United States continues to have serious concerns regarding Bulgaria's protection and enforcement of IP. Online and cable television piracy in Bulgaria remain particularly troubling. This is due in part to gaps in Bulgaria's law with respect to the exclusive rights granted to right holders, including with respect to copyright enforcement online. The United States recognizes Bulgaria's attempts to amend its Penal Code and Copyright Law. However, Bulgaria has not yet passed or implemented those legislative proposals, and enforcement of IP remains a concern. For example, the 2007 case against the torrent tracker site – zamunda.net – is still pending in the court system. The United States therefore encourages Bulgaria to make the legal reforms necessary to protect IP adequately and effectively, as well as to enhance its enforcement efforts under existing law, which did not improve in 2016. The United States encourages Bulgaria to enhance the role of the enforcement division responsible for online piracy and to devote the necessary resources to improving the prosecution of IP cases. With respect to the planned specialized IP prosecutorial units, the United States encourages the Prosecutor General to 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 IP cases, and to impose deterrent penalties for those who are convicted of IP crimes. 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 2017. Outstanding concerns center on aspects of copyright protection and IP enforcement. IP-related criminal investigations, prosecutions, and sentences, as well as customs seizures, were often inadequate or ineffective over the past year. The United States is concerned that Greece's prioritization of IP protection and enforcement appears to be diminishing. The United States welcomes some recent developments, such as the introduction of draft legislation to the parliament to address online piracy and various efforts to combat software piracy in the public sector. However, the parliament has yet to pass the draft legislation, and use of unlicensed software within the public and private sectors is reportedly on the rise. The United States encourages Greece to pass the copyright legislation and implement measures to combat public and private uses of infringing software. The United States also encourages Greece to bolster its system for combating online piracy, including by strengthening its legal regime and enhancing enforcement efforts. With regard to customs enforcement, the United States urges Greece to enact official storage time limits for goods detained at its ports and to ensure the timely destruction of counterfeit and pirated goods, as well as to consider joining most EU Member States in adopting a policy that allows for the inspection and detention of these goods in transit. Finally, the United States urges Greece to address persistent problems with criminal enforcement delays and non-

deterrent sentences and penalties, including for 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 2017. While the United States welcomes the continued working-level cooperation in Romania between industry and law enforcement authorities, including prosecutors and police, concerns remain that Romania does not sufficiently prioritize IP enforcement. Online piracy, unlicensed software use, and distribution of counterfeit goods are key challenges for U.S. IP-intensive industries in Romania. The United States encourages Romania to continue to enhance its IP enforcement activities, including by developing a national IP enforcement strategy, which could include the appointment of a high-level intellectual property enforcement coordinator, responsible for directing the development and implementation of the national strategy. Romania should fully staff and fund the IP Coordination Department in the General Prosecutor's Office, and encourage the Department to prioritize its investigation and prosecution of significant IP cases, with special focus on cases involving online piracy and criminal networks importing, distributing, or selling counterfeit products. Romania should also provide its specialized police, customs, and local law enforcement with adequate resources (including necessary training), high-priority support, and instructions to prioritize IP cases. The United States looks forward to continuing to work with Romania to address these and other issues.

SWITZERLAND

Switzerland remains on the Watch List in 2017. Generally, Switzerland broadly provides high levels of IP protection and enforcement. The United States welcomes the important contributions Switzerland makes to promoting high levels of IP protection and enforcement internationally, including in bilateral and multilateral contexts. However, Switzerland remains on the Watch List this year due to U.S. concerns regarding specific difficulties in Switzerland's system of online copyright protection and enforcement. Seven years have elapsed since the issuance of a decision by the Swiss Federal Supreme Court, which has been implemented to essentially deprive copyright holders in Switzerland of the means to enforce their rights against online infringers. Enforcement is a critical element of providing meaningful IP protection. Since 2010, right holders report that Switzerland has become an increasingly popular host country for websites offering infringing content and the services that support them, as indicated in the OCRs of Notorious Markets from recent years. The United States welcomes the steps taken by Switzerland in response to this serious concern, including the creation of stakeholder roundtables to develop recommendations to address these concerns, the introduction of draft copyright legislation, and related public consultations. However, more remains to be done and the United States continues to encourage Switzerland to move forward expeditiously with concrete and effective measures that address copyright piracy in an appropriate and effective manner, including through legislation, administrative action, consumer awareness, public education, and voluntary stakeholder initiatives. The United States looks forward to cooperating with Switzerland to address these and other intellectual property-related challenges.

TURKEY

Turkey remains on the Watch List in 2017. Turkey's December 2016 passage of a wide-ranging new law to consolidate and update former IP decrees into a single, enforceable piece of legislation represents an important step forward in the country's approach to IP protection, but implementation will be key. In particular, the Industrial Property Law No. 6769 includes provisions relating to increasing the efficiency of administrative processes, improving transparency, and providing new enforcement tools for right holders. However, the law also introduces new challenges, including in the area of compulsory licensing, while failing to resolve some longstanding issues that would significantly improve its IP regime.

Despite these positive developments, Turkey remains a major source and transshipment point of counterfeit goods, especially to the EU, and stakeholders continue to report delays and challenges in effectively obtaining recourse in Turkey's courts. Levels of unlicensed software and pirated textbooks remain high. The Turkish National Police should be given the *ex officio* authority they currently lack and other tools to help them enhance their enforcement, particularly on obvious infringement cases. Enforcement processes are currently subject to procedural delays and insufficient personnel. Copyright infringement in Turkey proliferates largely due to insufficient penalties and a backlog of cases. The United States continues to encourage Turkey to amend its copyright law to provide an effective mechanism to address piracy in the digital environment, including full implementation of the WIPO Internet Treaties. The United States also continues to encourage Turkey to require that collective management organizations adhere to fair and transparent procedures. Concerns over IP protection and market access for pharmaceutical products continue to grow, including with respect to protection against the unfair commercial use of pharmaceutical test data and regulatory and administrative delays. The United States is increasingly concerned about Turkey's initiatives to localize the production of pharmaceutical products through pricing and reimbursement listings. Turkey should also consider adopting new procedures to promote transparency and encourage early resolution of patent disputes prior to the marketing of follow-on pharmaceuticals.

WESTERN HEMISPHERE

CANADA

Canada remains on the Watch List in 2017. The United States remains deeply concerned that Canada does not provide customs officials with the ability to detain, seize, and destroy pirated and counterfeit goods that are moving in transit or are transshipped through Canada. As a result, the United States strongly urges Canada to provide its customs officials with full *ex officio* authority to address the serious problem of pirated and counterfeit goods entering our highly integrated supply chains. The United States also remains deeply troubled by the broad interpretation of an ambiguous education-related exception to copyright that has significantly damaged the market for educational publishers and authors. The United States urges Canada to reform this aspect of its copyright regime, during the Copyright Modernization Act review this year, to ensure that creators are fully compensated for their works. Regarding GIs, the United States urges Canada to ensure transparency and due process with respect to the protection or recognition of GIs, including aspects related to the protection of existing trademarks, safeguards for the use of common food names, and effective opposition and cancellation procedures. 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 has serious concerns about the breadth of the Minister of Health's discretion in disclosing confidential business information. In addition, the United States continues to have serious concerns about the lack of clarity in, and the impact of, utility requirements for patents imposed by Canadian courts. In these cases, courts have invalidated valuable patents held by U.S. pharmaceutical companies on utility grounds by interpreting the "promise" of the patent and finding that insufficient information has been provided in the application to substantiate that promise. These 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 understands that the Supreme Court of Canada has the opportunity to clarify this doctrine in the near future. The United States urges Canada to engage meaningfully with affected stakeholders and the United States on patent utility issues. The United States also looks forward to working closely with Canada in the coming year to explore ways to address each country's IP priority issues.

MEXICO

Mexico remains on the Watch List in 2017. One significant positive development in 2016 was the passage of legislation establishing opposition procedures for trademark applications, which is expected to increase due process and transparency in the trademark registration process, helping to address the issue of bad-faith trademarks. However, serious concerns remain, particularly with respect to the reduction in the number of prosecutors previously dedicated to the investigation and prosecution of online IP crimes, as well as a troubling decline in 2016 of seizures, investigations and prosecutions and the United States strongly urges Mexico to reverse this decline. Additionally, government-wide budget cuts have negatively affected IP enforcement, with even more widespread availability of pirated and counterfeit goods throughout Mexico than

in the past year. Another troubling development is the recent surge in unauthorized camcords in Mexico. To combat the growing level of IP infringement, Mexico needs to improve coordination among federal and sub-federal officials, devote additional resources to enforcement, bring more IP-related prosecutions, and impose deterrent penalties against infringers. The United States continues to urge Mexico to enact legislation to modernize its copyright regime, including by fully implementing the WIPO Internet Treaties as well as by providing deterrent enforcement against the unauthorized camcording of motion pictures in theaters. While a new agreement between the Attorney General's Office and right holders has resulted in anti-camcording warnings being shown in theaters, the legal system needs to adapt to enable law enforcement officials to effectively stop those who are camcording in theaters and deter future camcording. Finally, Mexico's enforcement against suspected infringing goods at the border remains hampered by overly restrictive policies. Mexican authorities are unable to take action against in-transit shipments of suspected infringing goods unless there is evidence of "intent for commercial gain" in the Mexican territory, which can be very difficult to establish. The United States strongly urges Mexico to revert to its policy prior to 2011, and provide its customs officials with full *ex officio* authority to take action against in-transit or transshipped counterfeit or pirated goods. The United States looks forward to working with Mexico to address these and other IP concerns.

COSTA RICA

Costa Rica remains on the Watch List in 2017. The United States welcomes Costa Rica's ongoing commitment to engage with the United States to strengthen its IP regime. The United States also applauds the increased intra-government coordination on IP and the increase in the number of ongoing criminal investigations. While the Economic Crimes Prosecutor has taken on responsibilities for IP, it remains unclear whether Costa Rica has committed the necessary resources to effectuate lasting improvements in IP enforcement. To allow more transparency regarding the effectiveness of IP prosecutions, Costa Rica should publish annually detailed information by type of IP right involved on the number of cases opened, cases resulting in charges, case resolution, and any resulting sentences. The United States also welcomes reports that Costa Rican ministries recently purchased additional licensed software and urges Costa Rica to continue to address the use of unlicensed software by government entities until the issue is rectified. The United States urges Costa Rica to take effective action against any notorious online markets within its jurisdiction that specialize in unlicensed works and to address the concern that Costa Rican law still allows online service providers 45 days to forward infringement notices to subscribers. Costa Rica has recently issued an executive decree related to registration of agrochemical products and the United States will monitor its implementation. However, pharmaceutical and agricultural chemical companies report various concerns, including extensive delays in regulatory approvals and the lack of 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. Further, the United States calls upon Costa Rica to provide greater transparency and clarity as to the scope of protections for GIs to alleviate market access uncertainty. Specifically, the United States urges Costa Rica to provide clarity as to the opposition procedures of proposed GIs and treatment of common food names. In order to improve border enforcement, Costa Rica should create a formal customs recordal system for trademarks to allow customs officers to make full use of their *ex officio* authority to detain and examine goods. The United States strongly encourages Costa Rica to build on initial positive steps

and draw on bilateral discussions of these issues, to develop clear plans and to demonstrate progress to tackle longstanding problems.

DOMINICAN REPUBLIC

The Dominican Republic remains on the Watch List in 2017. The United States notes the commitment made by the Dominican Republic to address the existing patent application backlog, including by instituting a priority review of long-pending outstanding patent applications and hiring new examiners in 2016. Nevertheless, substantial IP concerns remain, including with respect to government and private sector use of unlicensed software and the widespread availability of pirated and counterfeit products, including counterfeit tobacco, alcohol, fuel, and pharmaceutical products. The unauthorized retransmission of satellite signals also is a significant problem that government authorities have not sufficiently addressed. In general, a lack of resources, expertise, and political will hamper enforcement efforts. The lengthy patent application backlog underscores the need for patent term adjustment for unreasonable administrative delays; however, the patent office maintains that patent term adjustments do not apply to applications submitted before March 2008, and applications for adjustment continue to be denied at the administrative level. The United States urges the Dominican Republic to improve coordination among enforcement agencies and to build the technical capacity of its law enforcement officials, prosecutors, and judges. Additionally, the United States urges 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. The United States urges the Dominican Republic to take clear actions in 2017 to improve IP protection and enforcement.

GUATEMALA

Guatemala remains on the Watch List in 2017. The United States acknowledges the significant increase in IP prosecutions by the National Police and the Attorney General's Office in 2016. However, due to resource constraints and lack of coordination among law enforcement agencies, IP enforcement activities remain limited and inadequate in relation to the scope of the problem. The United States urges Guatemala to continue strengthening enforcement, including criminal prosecution, and administrative and customs border measures. Pirated and counterfeit goods continue to be widely available and Guatemala has reportedly become a source of counterfeit pharmaceutical products. Trademark squatting is of significant concern, affecting the ability of legitimate businesses to use their trademarks, as administrative remedies are inadequate and relief through the courts is slow and expensive. Cable signal piracy and government use of unlicensed software are also serious problems that remain largely unaddressed. Additionally, the United States urges Guatemala to provide greater clarity in the scope of protection for GIs, including by ensuring that all producers are able to use common food names, including any that are elements of a compound GI. The United States urges Guatemala to take clear and effective actions in 2017 to improve the protection and enforcement of IP in Guatemala.

BARBADOS

Barbados remains on the Watch List in 2017. While the legal framework in Barbados largely addresses IP, the United States continues to have concerns about the interception and retransmission of U.S. broadcast and cable programming by local cable operators in Barbados and throughout the Caribbean region without the consent of, and without adequately compensating, U.S. right 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. The United States urges 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 performance rights organization (PRO) won a case before the Supreme Court regarding the appropriate tariff to be paid for broadcasts of its members' music in 2007, and the PRO still has not received its monies more than nine years later. While the Copyright Tribunal set a rate in June 2015, that ruling remains unenforceable until it is issued in writing. Moreover, the ruling reportedly recommended a waiver of tariffs owed over the past decade. In addition, the United States urges 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. Lastly, the United States encourages Barbados to accede to the WIPO Internet Treaties. The United States looks forward to working with Barbados to resolve these and other important issues.

JAMAICA

Jamaica remains on the Watch List in 2017. The United States continues to urge Jamaica to provide adequate and effective protection for patents by expeditiously updating its Patent and Designs Act, which has been under review for over a decade, and ensuring that it is consistent with Jamaica's international obligations. The Jamaica Intellectual Property Office reportedly spent 2016 working with the Ministry of Industry, Commerce, Agriculture, and Fisheries to update the draft Patent and Designs Act to be voted on in 2017. In the area of copyright protection, the United States is encouraged by Jamaica's continued effort to ensure that its regulatory broadcasting agency is monitoring compliance with broadcast licensing requirements. In 2015, the Broadcasting Commission of Jamaica enforced a directive to cable licensees to cease the illegal transmission of 19 channels, serving as an example to encourage other Caribbean countries to take similar actions. The Commission in 2016 continued to enforce broadcasting rights, which resulted in improvements in compliance amongst the country's top providers. While the United States recognizes the Commission's efforts to facilitate licensing of content and its recommendation of financial sanctions to expand its enforcement toolkit, dozens of local operators continue to illegally broadcast content. In addition, although Jamaica maintains a statutory licensing regime for the retransmission of copyrighted television programming, it has not consistently enforced the payment of statutory royalties to right holders. Jamaica also remains one of several Caribbean countries with problems related to unlicensed public performances of copyrighted music via cable and broadcast television. The United States looks forward to working with Jamaica to address these and other important issues.

BOLIVIA

Bolivia remains on the Watch List in 2017. Challenges continue with respect to adequate and effective IP protection and enforcement. While certain Bolivian laws provide for the protection of copyrights, patents, and trademarks, significant concerns remain about trade secret protection. With regards to enforcement, significant challenges persist with respect to widespread piracy and counterfeiting in Bolivia. Legislative developments include steps taken in 2015 by the National Intellectual Property Service (SENAPI) to put forward a bill to modernize industrial property legislation, but the legislature has not yet approved that bill. Additionally, the National Movie Council (CONACINE) is reportedly working on draft legislation to update Bolivia's film and video law. Video, music, and software piracy rates are among the highest in Latin America, and rampant counterfeiting persists. Criminal charges and prosecutions remain rare, although the number of criminal indictments has gradually increased in recent years. While the number of private stakeholder requests for border measures has also reportedly increased, customs authorities continue to lack personnel and budgetary resources. There continues to be an urgent need for public awareness regarding IP protection and enforcement, although Bolivia has stepped up public awareness campaigns through radio spots and dissemination of printed materials. The United States encourages Bolivia to take the necessary steps to improve its weak enforcement of IP, including by continuing to expand its public awareness efforts, increasing training of government technical experts, cooperating with right holders on enforcement, and improving coordination among Bolivian enforcement authorities, including between Bolivian customs authorities and SENAPI. The United States also encourages Bolivia to enhance cooperation with the customs and other enforcement authorities of its neighboring countries.

BRAZIL

Brazil remains on the Watch List in 2017. The United States recognizes Brazil's efforts to protect IP during the 2016 Olympic and Paralympic Games and its continued progress on addressing online piracy. However, significant concerns remain with respect to the high levels of counterfeiting and piracy in Brazil, including online piracy. Increased emphasis on enforcement at the tri-border region and stronger deterrent penalties are critical to make sustained progress on these IP concerns. The National Council on Combating Piracy and Intellectual Property Crimes (CNCP) was identified in the past as an effective entity for carrying out public awareness and enforcement campaigns, but this year the CNCP appeared non-operational and did not deliver accomplishments as in recent years. Although there was some progress reducing the trademark application backlog, the United States remains concerned that long delays persist in the examination of both patent and trademark applications, with a reported average pendency of nearly two and a half years for trademarks and almost 11 years for patents. Brazil took a step to address the patent backlog in early 2016 when the United States and Brazil agreed on a Patent Prosecution Highway pilot program to expedite the patent examination process for inventions related to the oil and gas sector in Brazil and for any invention in the United States. However, the National Sanitary Regulatory Agency's (ANVISA) duplicative review of pharmaceutical patent applications has been a longstanding concern because it lacks transparency, exacerbates delays of patent registrations for innovative medicines, and has prevented patent examination by National Institute of Industrial Property

(INPI). In April 2017, Brazil announced an agreement between INPI and ANVISA, which is intended to expedite the examination of pharmaceutical patent applications and redefines ANVISA's role in that process. The United States looks forward to reviewing the agreement and will closely monitor the impact of ANVISA's new role as they implement the agreement. While Brazilian law and regulations provide for protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for veterinary and agricultural chemical products, they do not provide similar protection for pharmaceutical products. The United States also remains concerned about INPI's actions to invalidate or shorten the term of a significant number of "mailbox" patents for pharmaceutical and agricultural chemical products. Strong IP protection, available to both domestic and foreign right holders alike, provides a critical incentive for businesses to invest in future innovation in Brazil, and the United States looks forward to engaging constructively with Brazil to build a strong IP environment and to address remaining concerns.

COLOMBIA

Colombia remains on the Watch List in 2017 with an Out-of-Cycle Review focused on certain provisions of the United States-Colombia Trade Promotion Agreement and monitoring the implementation of Colombia's National Development Plan. In 2016, Colombia took steps toward completing implementation of certain provisions of the United States-Colombia Trade Promotion Agreement (CTPA), including by completing the public comment process for copyright law amendments and completing accession to the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure. Colombia still needs to make other improvements with respect to implementation of significant IP-related commitments made under the CTPA, including commitments to address the challenges of online piracy and accession to UPOV 91. The United States urges Colombia to move quickly to introduce into the legislature and enact the copyright law amendments, and urges Colombia to begin working on necessary provisions regarding Internet service providers (ISPs). The United States also urges Colombia to increase its IP enforcement efforts. As online piracy, particularly via mobile devices, continues to grow, Colombian law enforcement authorities with relevant jurisdiction, including the National Police and the Attorney General, have yet to conduct meaningful and sustained investigations and prosecutions against the operators of significant large pirate websites and mobile applications based in Colombia. Colombia has also not been able to reduce significantly the large number of pirated and counterfeit hard goods crossing the border or being sold at Bogota's San Andresitos markets, on the street, and at other distribution hubs around the country. A number of bus companies are also reportedly playing copyrighted works without a license. The United States recommends that Colombia increase efforts to address online and mobile piracy, and to focus on disrupting organized trafficking in illicit goods, including at the border and in free trade zone areas. Finally, while certain provisions of the National Development Plan (NDP) may be helpful, such as a requirement to develop an IP enforcement policy to help guide, coordinate, and raise awareness of IP enforcement, concerns remain regarding other provisions that could, in implementation, undermine innovation and IP systems (*e.g.*, establishing a role for the health ministry in the examination of pharmaceutical patent applications, or conditioning pharmaceutical regulatory approvals on factors other than safety or efficacy). The United States urges Colombia to take necessary steps to clarify such provisions and implement them in such a way as to ensure that they do not undermine innovation and IP systems.

ECUADOR

Ecuador remains on the Watch List in 2017. While enforcement of IP against widespread counterfeiting and piracy remains weak (including online and in marketplaces such as La Bahia Market in Guayaquil), Ecuador took a number of positive actions in 2016, including lowering patent fees and conducting an inclusive process during the drafting of the Code of Knowledge, Creativity, and Innovation Social Economy (Ingenuity Code). Some stakeholders have welcomed some provisions of the Ingenuity Code, while other stakeholders raise concerns, including with respect to the scope of certain copyright exceptions and limitations and certain exceptions to patentable subject matter. The Ingenuity Code reportedly specifies a term of five years 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. Ecuador also issued an amendment to Decree 522, clarifying which pharmaceutical products may be identified as reference products, and the United States encourages Ecuador to ensure that any future implementation of Decree 522 does not prejudice the legitimate interests of affected stakeholders. The United States urges Ecuador to provide greater transparency and clarity as to the scope of protection for GIs, including by clarifying the opposition procedures of proposed GIs and treatment of common food names, including any that are elements of a compound GI. Finally, given continuing reports of widespread counterfeiting and piracy, the United States urges Ecuador to continue to improve its IP enforcement efforts. The United States looks forward to continuing to work with Ecuador to address these and other issues.

PERU

Peru remains on the Watch List in 2017. Peru made progress in enhancing IP protections in 2016. INDECOPI continues to be responsive, if under-resourced, in engaging with the United States, the private sector, and civil society. In 2016, Peru launched special criminal IP courts and joined two Patent Prosecution Highways (PPH) – the PROSUR PPH and the Pacific Alliance PPH. At the same time, the United States remains concerned about the widespread availability of counterfeit and pirated products in Peru, and right holders report that Peru is a major source of unauthorized camcords and is the base of administrators of Spanish-language websites that offer or facilitate the use or sale pirated content and counterfeit goods. The United States continues to urge Peru to devote additional resources for IP enforcement, improve coordination among enforcement agencies, enhance its border controls, and build the technical IP-related capacity of its law enforcement officials, prosecutors, and judges. The United States encourages Peru to pursue prosecutions under the law that criminalizes the sale of counterfeit medicines, and to increase the imposition of deterrent-level fines and penalties for counterfeiting more broadly. In addition, the United States urges Peru to fully implement its obligations under the United States-Peru Trade Promotion Agreement (PTPA), including by providing statutory damages; protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for agricultural chemical products; establishing

limited liability for ISPs within the parameters of the PTPA; and clarifying protections for biotechnologically-derived pharmaceutical products. The United States looks forward to continuing to work with Peru to address these and other issues.

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, the Uruguay Round Agreements Act of 1994, and the Trade Facilitation and Trade Enforcement Act of 2015 (19 U.S.C. § 2242), USTR is required to identify “those foreign countries that deny adequate and effective protection of intellectual property (IP) rights, or deny fair and equitable market access to United States persons that rely upon intellectual property protection.”

The USTR shall only designate 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. 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 IP. 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 IP protection, enforcement, or market access for persons relying on IP rights. Countries placed on the Priority Watch List are the focus of increased bilateral attention concerning the specific problem areas.

The Trade Facilitation and Trade Enforcement Act of 2015 requires USTR to develop “action plans” for each foreign country that USTR has identified for placement on the Priority Watch List and that has remained on the list for at least one year. The action plans shall include benchmarks to assist the foreign country to achieve, or make significant progress toward achieving, adequate and effective IP protection and fair and equitable market access for U.S. persons relying on IP protection. USTR must provide to the Senate Finance Committee and to the House Ways and Means Committee a description of the action plans developed for Priority Watch List Countries and any actions taken by foreign countries under such plans. For those Priority Watch List countries for which an action plan has been developed, the President may take appropriate action if the country has not substantially complied with the benchmarks set forth in the action plan.

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

The Trade Policy Staff Committee, 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: U.S. Government-Sponsored Technical Assistance and Capacity Building

In addition to identifying IP 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 IP-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 IP.

Although many trading partners have enacted IP legislation, a lack of criminal prosecutions and deterrent sentencing has reduced the effectiveness of IP enforcement in many regions. These problems result from several factors, including a lack of knowledge of IP 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 IP 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 IP 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. right holders.

Other U.S. Government agencies bring foreign government and private sector representatives to the United States on study tours to meet with IP professionals and to visit the institutions and businesses responsible for developing, protecting, and promoting IP 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 about IP 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 IP protection and enforcement. The following are examples of these programs.

- In Fiscal Year 2016, GIPA provided training to 4,975 foreign IP officials and college students and faculty in IP-related programs of study from 114 countries through 112 separate programs. Attendees included IP 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 IP.

- GIPA has produced 31 free distance-learning modules available to the public. These modules cover six different areas of intellectual property law and are available in five different languages (English, Spanish, French, Arabic, and Russian). Since 2010, the modules have been visited over 63,300 times at WWW.USPTO.GOV. In 2016, GIPA also produced a video on the protection of trade secrets, which is available on GIPA's YouTube channel.
- 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 IP organizations, such as the United Kingdom Intellectual Property Office, Japan Patent Office, European Patent Office, German Patent and Trademark Office, government agencies of the People's Republic of China, Mexican Institute of Industrial Property, the Korean Intellectual Property Office, 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 IP to national economies. Additionally, ITA develops and shares small business tools to help domestic and foreign businesses understand IP and initiate protective strategies. U.S. companies can also find specific intellectual property information on the STOPfakes.gov website, including valuable resources on how to protect patents, copyright, trademarks, and trade secrets. Additionally, U.S. companies can find webinars focusing on best practices to protect and enforce IP in China. ITA, working closely with other U.S. Government agencies and foreign partners, developed and made available IP 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 Internal Market, Industry, Entrepreneurship and SMEs (DG-GROW) to establish a Transatlantic IPR Portal that makes the resources of our respective governments 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 2016, U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI), through the National IPR Coordination Center (IPR Center), conducted law enforcement training programs in the Philippines and Brazil, as well as in the Department of Defense-operated George C. Marshall European Security Center in Garmisch-Partenkirchen, Germany for 30 police and customs officials from the Ivory Coast, Morocco, Nigeria, Senegal, and Togo. The IPR Center also conducted two advanced training programs at the International Law Enforcement Academy (ILEA) in Budapest, Hungary for customs, law enforcement, and judicial officials from Bosnia-Herzegovina, Bulgaria, Kosovo Albania, Montenegro, Romania, Serbia, and Ukraine. ICE/HSI trained officials and police officers from Japan, South Korea, Taiwan, Morocco, Singapore, Hong Kong, Kazakhstan, Uzbekistan, Mongolia, Russia, Mexico, Dubai, Pakistan, Dominican Republic, and China.

- In 2016, U.S. Customs and Border Protection (CBP) provided IP training sessions to foreign customs officials in Kazakhstan and Mexico.
- The Department of State provides training funds each year to U.S. Government agencies that provide IP enforcement training and technical assistance to foreign governments. The agencies that provide such training include the U.S. Department of Justice, USPTO, CBP, and ICE. 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.
- IP protection is a priority of the government-to-government technical assistance provided by the Commerce Department's Commercial Law Development Program (CLDP). CLDP programs address numerous areas related to IP including legislative reform, enforcement and adjudication of disputes, IP protection and its impact on the economy, IP curricula in universities and law schools, as well as public awareness campaigns and continuing legal education for lawyers. CLDP supports capacity building in creating and maintaining an innovation ecosystem, including technology commercialization as well as in patent, trademark, and copyright examination and management in many countries worldwide. CLDP also works with the judiciary in various trading partners to improve the skills to effectively adjudicate IP cases, and conducts interagency coordination programs to highlight the value of a whole-of-government approach to IP protection and enforcement.
- Every year, the Department of Justice—with funding from and in cooperation with the Department of State and other U.S. agencies—provides technical assistance and training on IP enforcement issues to thousands of foreign officials around the globe. Topics covered in these programs include investigating and prosecuting IP cases under various criminal law and criminal procedure statutes; disrupting and dismantling organized crime networks involved in trafficking in pirated and counterfeit goods; fighting infringing goods that represent a threat to health and safety; combating Internet piracy; improving officials' capacity to detain, seize, and destroy illegal items at the border and elsewhere; increasing intra-governmental and international cooperation and information sharing; working with right holders on IP enforcement; and obtaining and using electronic evidence. Major ongoing initiatives include 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 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 Copyright Office also conducts the bi-annual International Copyright Institute (ICI) in conjunction with WIPO, providing weeklong training to foreign copyright officials. The 2016 program hosted officials from 22 countries. The next ICI program will be held in 2018.

The United States reports to the World Trade Organization on its IP capacity-building efforts, including most recently in October 2016. (See Technical Cooperation Activities: Information from Members—United States of America, IP/C/W/616/Add.5). The United States also reports annually on international IP capacity building and training in the *Annual Report on Intellectual Property Enforcement* issued by the U.S. Intellectual Property Enforcement Coordinator pursuant to Section 304 of the PRO IP Act of 2008 (15 U.S.C. § 8114), issued most recently in January 2017.