

2018 Special 301 Report



Office of the United States Trade Representative

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EXECUTIVE SUMMARY

A top trade priority for the 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 of the Administration's trade policy is 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 of 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 inadequate levels and where U.S. persons who rely on IP protection have difficulty with fair and equitable market access. For example:

- USTR continues to place China on the Priority Watch List (and, as before, Section 306 monitoring remains in effect). China's placement on the Priority Watch list reflects the urgent need to remediate a range of IP-related concerns, including as to trade secret theft, online piracy and counterfeiting, the high-volume manufacture and export of counterfeit goods, technology transfer requirements imposed as a condition to access the Chinese market, the mandatory application of adverse terms to foreign IP licensors, and IP-ownership and research and development localization requirements. Structural impediments to administrative, civil, and criminal IP 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. businesses in India include those which make it difficult for innovators to receive and maintain patents in India, particularly for pharmaceuticals, 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 reductions in transparency by India's pharmaceutical regulator through the removal of a requirement that applicants submit information about a product's patent status, as well as positions that India supports and voices in multilateral fora 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 have raised serious concerns, including with respect to patentability criteria and local manufacturing and use requirements.
- USTR identifies Colombia on the Priority Watch List with an Out-of-Cycle Review focused on certain provisions of the United States-Colombia Trade Promotion Agreement (CTPA) and monitoring the implementation of Colombia's National Development Plan. In 2017, USTR conducted an Out-of-Cycle Review of Colombia focused on certain provisions of the CTPA and monitoring the implementation of Colombia's National Development Plan. Colombia's lack of meaningful progress warrants its elevation to the Priority Watch List. In 2018, Colombia will be subject to an Out-of-Cycle Review on the same issues to determine whether a change in status to Watch List is warranted.
- The Report also highlights trading partners such as Chile 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:

- USTR has been engaging with trading partners, including Algeria, Argentina, Canada, China, Korea, India, Indonesia, Japan, Malaysia, Saudi Arabia, and the United Arab Emirates (UAE), to address concerns related to IP protection and enforcement and market access barriers with respect to pharmaceuticals and medical devices so that trading partners contribute their fair share to research and development of new treatments and cures.
- 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, UAE, 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, Russia, Ukraine and Vietnam, have not addressed the continuing and emerging challenges of copyright piracy.¹ 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 unlicensed software.
- Online piracy remains a challenging copyright enforcement issue in many trading partner markets, including Canada, China, India, the Netherlands, Romania, Russia, Switzerland,

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

Taiwan, Ukraine, and elsewhere.

- U.S. innovators face challenges including restrictive patentability criteria that undermine opportunities for export growth in countries such as Argentina, India, and Indonesia. Innovators also face—for example in Argentina, China, India, Indonesia, Saudi Arabia, 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 approach of the European Union (EU) to the protection of geographical indications (GIs) 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 names.

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

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 2018 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 27, 2017 (*Federal Register* notice). In addition, on March 8, 2018, 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, 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 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 39 non-government stakeholders and 23 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-2017-0024. The public can access the transcript and video 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 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

² Available at <https://ustr.gov/issue-areas/intellectual-property/special-301/2018-special-301-review>.

- 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 2018 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 36 trading partners as follows:

Priority Watch List

- Algeria
- Argentina
- Canada
- Chile
- China
- Colombia
- India
- Indonesia
- Kuwait
- Russia
- Ukraine
- Venezuela

Watch List

- Barbados
- Bolivia
- Brazil
- Costa Rica
- Dominican Republic
- Ecuador
- Egypt
- Greece
- Guatemala
- Jamaica
- Lebanon
- Mexico
- Pakistan
- Peru
- Romania
- Saudi Arabia
- Switzerland
- Tajikistan
- Thailand
- Turkey
- Turkmenistan
- UAE
- Uzbekistan
- Vietnam

OUT-OF-CYCLE REVIEWS

An Out-of-Cycle Review is a tool that USTR uses to encourage progress on IP issues of concern. Out-of-Cycle Reviews provide an opportunity to address and remedy such issues through heightened engagement and cooperation with trading partners and other stakeholders. Out-of-Cycle Reviews 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 Out-of-Cycle Review period, can lead to an adverse change in status.

In December 2017, the United States concluded an Out-of-Cycle Review of **Thailand** and moved Thailand from the Priority Watch List to the Watch List. Engagement on IP protection and enforcement as part of the bilateral U.S.-Thailand Trade and Investment Framework Agreement yielded results on resolving U.S. IP concerns across a range of issues, including on enforcement, patents and pharmaceuticals, trademarks, and copyright.

USTR also conducted an Out-of-Cycle Review of **Colombia** in 2017 focused on certain provisions of the CTPA and monitoring the implementation of Colombia's National Development Plan. Colombia's lack of meaningful progress warrants its elevation to the Priority Watch List. As explained below, in 2018, Colombia will be subject to an Out-of-Cycle Review on the same issues to determine whether a change in status to Watch List is warranted.

USTR closed Out-of-Cycle Reviews for **Kuwait** and **Tajikistan**. While an Out-of-Cycle Review was conducted so that Kuwait could bring its copyright regime in line with its international commitments, the implementing regulations to the 2016 Copyright and Related Rights Law fell short of addressing all of the outstanding issues. USTR removed Tajikistan from the Watch List in 2017 due to Tajikistan carrying out IP reforms and promising progress in addressing unlicensed software issues. However, due to Tajikistan's failure to successfully resolve the previously identified software issues during the period of the Out-of-Cycle Review, Tajikistan returns to the Watch List in 2018.

In the coming months, USTR will conduct Out-of-Cycle Reviews of **Colombia**, **Kuwait**, and **Malaysia**.

- USTR will conduct an Out-of-Cycle Review of **Colombia**, which has been placed on the Priority Watch List this year. The Out-of-Cycle Review will assess Colombia's commitment to the IP provisions of the CTPA and will continue to monitor the implementation of Colombia's National Development Plan.
- USTR will conduct an Out-of-Cycle Review of **Kuwait**, which will focus on improving Kuwait's copyright regime to meet its international commitments.
- USTR will conduct an Out-of-Cycle Review of **Malaysia**, which will consider the extent to which Malaysia is providing adequate and effective IP protection and enforcement, including with respect to patents.

USTR may conduct additional Out-of-Cycle Reviews 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 Out-of-Cycle Review separately from the annual Special 301 Report. The *Notorious Markets List* identifies illustrative

examples of online and physical markets that reportedly engage in, facilitate, turn a blind eye to, or benefit from substantial 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 2017, USTR requested such comments on August 16, 2017, and published the *2017 Notorious Markets List* on January 11, 2018. USTR plans to conduct its next Out-of-Cycle Review of Notorious Markets in the fall of 2018.

STRUCTURE OF THE SPECIAL 301 REPORT

The 2018 Report contains the following Sections and Annexes:

[SECTION I: DEVELOPMENTS IN INTELLECTUAL PROPERTY RIGHTS PROTECTION, 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: U.S. GOVERNMENT-SPONSORED TECHNICAL ASSISTANCE AND CAPACITY BUILDING](#) highlights U.S. Government-sponsored technical assistance and capacity building efforts.

April 2018

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

An important part of the mission of the Office of the United States Trade Representative (USTR) is to support and implement the Administration’s commitment to protect American jobs and workers and to advance the economic interests of the United States. Intellectual property (IP) infringement, including patent infringement, trademark counterfeiting, copyright piracy, and trade secret theft,³ causes significant financial losses for right holders and legitimate businesses around the world. IP infringement undermines U.S. competitive advantages in innovation and creativity, to the detriment of American businesses and workers. In its most pernicious forms, IP infringement endangers the public, such as through exposure to health and safety risks from counterfeit products like semiconductors, automobile parts, apparel and footwear, toys, and medicines. In addition, trade in counterfeit and pirated products often fuels cross-border organized criminal networks and hinders sustainable economic development in many countries. Fostering innovation and creativity is essential to U.S. economic growth, competitiveness, and an estimated 45 million American jobs that directly or indirectly rely on IP-intensive industries. USTR continues to work to protect American innovation and creativity in foreign markets with all the tools of U.S. trade policy, including through the annual Special 301 Report.

This Section highlights developments in 2017 and early 2018 in IP protection, enforcement, and related market access in foreign markets, including: examples of initiatives to strengthen IP protection and enforcement; illustrative best practices demonstrated by the United States and our trading partners; U.S.-led initiatives in multilateral organizations; and bilateral and regional developments. It identifies outstanding challenges and trends including as they relate to trade in counterfeits, online piracy, forced technology transfer, innovative pharmaceutical products and medical devices, and geographical indications (GIs). This Section also highlights the importance of IP to innovation in the environmental sector and considerations at the intersection of IP and health. Finally, this Section discusses the importance of full implementation of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and developments on the U.S. use of WTO dispute settlement procedures to resolve IP concerns.

A. IP Protection, Enforcement and Related Market Access Challenges

1. Pharmaceutical and Medical Device Innovation and Market Access

In order to promote affordable healthcare for American patients today and innovation to preserve access to the cutting edge treatments and cures that they deserve tomorrow, USTR has been

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

engaging with trading partners to ensure that U.S. owners of IP have a full and fair opportunity to use and profit from their IP, including by promoting transparent and fair pricing and reimbursement systems. USTR has sought to ensure robust IP systems; reduce market access barriers to pharmaceutical products 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; and has pressed trading partners to appropriately recognize the value of innovative medicines and medical devices so that trading partners contribute their fair share to research and development of new treatments and cures. Examples include USTR actions to:

- Seek strong IP provisions, which are important to incentivizing innovation, in the renegotiation and modernization of the North American Free Trade Agreement (NAFTA) with **Canada** and **Mexico**, as well as provisions to ensure that national-level government processes for the listing and reimbursement of pharmaceutical products and medical devices are transparent, provide procedural fairness, are nondiscriminatory, and provide full market access for U.S. products;
- Obtain, through negotiations to improve and better implement the U.S.-Korea Free Trade Agreement (KORUS FTA), **Korea's** commitment to reform a key measure to better implement its KORUS FTA commitments to provide fair and non-discriminatory treatment of pharmaceutical products, including imported products, under certain medical pricing and reimbursement programs;
- Engage with **Japan** in the context of the U.S.-Japan Economic Dialogue to ensure transparency and fairness and address other concerns with respect to pharmaceutical and medical devices pricing and reimbursement policies;
- Press **China** on a range of issues affecting the pharmaceutical sector, including providing for effective protection against unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical products, as well as expediting its implementation of an effective mechanism for the early resolution of potential patent disputes;
- Engage with **India** to secure meaningful IP reforms on longstanding issues, including patentability criteria, criteria for compulsory licensing, protection against unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical products;
- Press **Indonesia** to resolve concerns regarding revisions to Indonesia's patent law, such as its patentability criteria, local manufacturing and use requirements, and the grounds and procedures for issuing compulsory licenses;
- Raise concerns with **Argentina** regarding the scope of patentable subject matter and effective protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products, among other issues;

- Engage with **Saudi Arabia** regarding the protection and enforcement of patents and effective protection against commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products, among other issues; and
- Seek confirmation that the **United Arab Emirates (UAE)** will continue to protect pharmaceuticals through local procedures and the Gulf Cooperation Council (GCC) patent system.

This year's Report highlights concerns regarding IP protection and enforcement and market access barriers affecting U.S. entities that rely on IP protection, including those in the pharmaceutical and medical device industries.

For example, actions by trading partners to unfairly issue, threaten to issue, or encourage others to issue, compulsory licenses raise serious concerns. Such actions can undermine a patent holder's IP, reduce incentives to invest in research and development for new treatments and cures, unfairly shift the burden for funding such research and development to American patients and those in other markets that properly respect IP, and discourage the introduction of important new medicines into affected markets. To maintain the integrity and predictability of IP systems, governments should use compulsory licenses only in extremely limited circumstances and after making every effort to obtain authorization from the patent owner on reasonable commercial terms and conditions. Such licenses should not be used as a tool to implement industrial policy, including providing advantages to domestic companies, or as undue leverage in pricing negotiations between governments and right holders. It is also critical that foreign governments ensure transparency and due process in any actions related to compulsory licenses. The United States will continue to monitor developments and to engage, as appropriate, with trading partners, including **Chile, Colombia, El Salvador, India, and Malaysia.**

Also, measures that are discriminatory, nontransparent, or otherwise trade-restrictive, have the potential to hinder market access in the pharmaceutical and medical device sectors, and potentially result in higher product costs. Unreasonable regulatory approval delays and non-transparent reimbursement policies also 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. By contrast, a number of countries have policies in place that speed up regulatory approvals for pharmaceutical products and reduce the complexity and administrative cost of the approval process, which can increase market access. For example, "reliance" systems, such as the ones implemented by **Egypt and Mexico**, recognize and rely on regulatory approvals by stringent health regulatory authorities in other countries. 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.

In addition, pricing and reimbursement systems in foreign markets that are not market-based, or that do not otherwise appropriately recognize the value of innovative medicines and medical

devices, present significant concerns. Such systems undermine incentives for innovation in the health care sector. It is important that trading partners contribute fairly to research and development for innovative treatments and cures.

The IP-intensive U.S. pharmaceutical and medical device industries have expressed concerns regarding the policies of several trading partners, including **Algeria, Australia, Canada, China, Colombia, Ecuador, Japan, Korea, New Zealand,** and **Turkey**, on issues related to pharmaceutical innovation and market access. Examples of these concerns include the following:

- **Algeria's** ban 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.
- Under the U.S.-Australia Free Trade Agreement, **Australia** must provide that a pharmaceutical product patent owner be notified of a request for marketing approval by a third party for a product claimed by that patent and provide measures in its marketing approval process to prevent persons other than the patent owner from marketing a patented product during the patent term. U.S. and Australian pharmaceutical companies have expressed concerns about delays in this notification process. The U.S. Government also has raised concerns about provisions in Australian law that impose a potential significant, unjustifiable, and discriminatory burden on the enjoyment of patent rights, and specifically on the owners of pharmaceutical patents.
- **Canada** has drawn concern from stakeholders by proposing changes that would dramatically reshape how the Patented Medicine Prices Review Board evaluates patented pharmaceuticals and sets their ceiling prices. If implemented, the changes would significantly undermine the marketplace for innovative pharmaceutical products, delay or prevent the introduction of new medicines in Canada, and reduce investments in Canada's life sciences sector.
- The United States has urged **Japan** to implement predictable and stable pricing and reimbursement policies that reward innovation and provide incentives for companies to invest in the research and development of advanced medical devices and innovative pharmaceuticals. Reforms to Japan's reimbursement system in 2017 represent a retreat from previous progress made in this area. Current plans may weaken incentives previously offered under the Price Maintenance Premium (PMP), a mechanism designed to accelerate the introduction of innovative drugs to the Japanese market. They may also introduce significant uncertainty into pricing for patented pharmaceuticals, undermining investment planning for capital-intensive drug discovery research and clinical trials. U.S. stakeholders have expressed strong concerns regarding new rules that provide tiered access to the PMP based on certain criteria that might be easier for domestic firms to meet and that might limit the ability for small- and medium-sized enterprises (SMEs) to qualify for the full premium.

- The United States has urged **Korea** to seriously consider stakeholders’ concerns and ensure that pharmaceutical reimbursement is conducted in a fair, transparent, and nondiscriminatory manner that recognizes the value of innovation, including during recently concluded negotiations for an improved KORUS FTA. In March 2018, those negotiations concluded with a commitment that before the end of 2018, Korea will amend its Premium Pricing Policy for Global Innovative New Drugs to make it consistent with Korea’s commitments under the KORUS FTA to ensure non-discriminatory and fair treatment for pharmaceutical products and medical devices, including imported products and devices. It is critical that Korea not only fully implement this commitment but also address other concerns regarding the lack of transparency and predictability, and the need to appropriately recognize the value of innovative pharmaceuticals and medical devices, in Korea’s pricing and reimbursement policies and their underlying methodology.
- **Turkey** lacks efficiency, transparency, and fairness in its pharmaceutical manufacturing inspection process.
- There are long-standing concerns about the policies and operation of **New Zealand’s** Pharmaceutical Management Agency (PHARMAC), including, among other things, the lack of transparency, fairness, and predictability of the PHARMAC pricing and reimbursement regime, as well as 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 and pricing 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 these sectors.

2. *Technology Transfer, Indigenous Innovation, and Localization*

Right holders operating in other countries report an increasing variety of government measures, policies, and practices that require or pressure technology transfer from U.S. companies. While these measures are sometimes styled as means to incentivize domestic “indigenous innovation,” in practice, they disadvantage U.S. companies, requiring them to give up their IP as the price of market entry. These actions serve as market access barriers and deny U.S. companies reciprocal opportunities to access foreign markets relative to foreign companies operating in the United States. This discourages foreign investment and hurts local manufacturers, distributors, and retailers. Such government-imposed conditions or incentives may introduce non-market distortions into licensing and other private business arrangements, resulting in commercially suboptimal outcomes for the firms involved and for innovation in general. 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 investment and 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, or discouraging the enforcement of, U.S.-owned 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 participation by foreign firms and 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 or transferred to China, or is owned by or licensed, in some cases exclusively, to a Chinese party.

In August 2017, USTR initiated an investigation under Section 301 of the Trade Act of 1974, as amended, into acts, policies, and practices of the government of China related to technology transfer, intellectual property and innovation. On March 22, 2018, USTR issued a report supporting findings that the four categories of acts, policies and practices covered in the investigation are unreasonable or discriminatory and burden and/or restrict U.S. commerce.

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. In addition, 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 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 require local production

or utilization of Nigerian material and labor across a broad range of information communications technology (ICT) goods and services. Requirements of particular concern include server localization mandates, requirements for all ICT hardware to contain at least 50 percent of local value-added content or to outsource production to domestic firms, cross-border data flow restrictions, mandates for all hardware to be assembled in Nigeria, 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. In **Turkey**, government authorities are in the process of delisting from reimbursement pharmaceutical products that are not produced domestically as a way to promote domestic pharmaceutical manufacturing. 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**, refrain from coercive technology transfer and local content policies, and take account of the importance of voluntary and mutually agreed commercial partnerships.

3. 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 and medical devices, environmental technologies, and other manufacturing, rely on the ability to protect and enforce their trade secrets and rights in proprietary information. 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. In some foreign countries, certain 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 **European Union** (EU), and **Taiwan**, although China's legal amendments failed to embrace certain critical steps. Action in international organizations is crucial. For instance, the United States strongly supports continued work in the Organisation for Economic Co-operation and Development (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.

4. *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 SMEs, to create value, promote their goods and services, and protect their brands, even 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. Trademarks also deliver high levels of consumer awareness, significant contributions to GDP and employment, and accepted international systems of protection.

Second, troubling aspects of the EU GI system and strategy impact access for U.S. and other producers in the EU market and other markets. The EU has granted GI protection to thousands of terms that now only certain EU producers can use in the EU market. Furthermore, in 2017, the EU granted GI protection to the cheese name danbo, a widely traded type of cheese that is covered by an international standard under the Codex Alimentarius. Uruguay, Argentina, and South Africa, among other countries, produce danbo. Several countries, including the United States, opposed GI protection of this common name but the European Commission granted the protection over that opposition without sufficient explanation or notice to interested parties.

As part of its trade agreement negotiations, the EU pressures trading partners to prevent all producers other than those EU producers in certain EU regions, from using certain product names,

such as fontina, 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 effectively blocked from those markets or are otherwise restricted. For example, in some markets non-EU producers may only sell their products as “fontina-like,” “gorgonzola-kind,” “asiago-style,” or “imitation feta,” and in other markets, non-EU producers may not even use such descriptors, which is costly, unnecessary, and can reduce consumer demand for the non-EU 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 U.S.-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 over \$900 million of cheese to the United States each year. The United States exports only about \$4 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 World Intellectual Property Organization (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 certain 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 Asia-Pacific Economic Cooperation (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 **Argentina, Brazil, Canada, Chile, China, Colombia, Costa Rica, Ecuador, Indonesia, Japan, Malaysia, Mexico, Morocco, Paraguay, the Philippines, South Africa, Tunisia, Uruguay, 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.

5. 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**, **Turkey**, and the **UAE**, to third country markets such as **Brazil**, **Nigeria**, **Paraguay**, 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 subject 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 reputational damage 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, and is exacerbated by rapid growth of illegitimate online sales. Counterfeiting contributes to the proliferation of substandard, 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 distributed in numerous trading partners, including **China**, **India**, **Indonesia**, and **Thailand**. Ninety percent of the value of all counterfeit pharmaceuticals seized at the U.S. border in Fiscal Year 2017 was shipped from or transshipped through four economies:

China, the Dominican Republic, Hong Kong, and India. In particular, China and India are reportedly leading sources of counterfeit medicines distributed globally. While it is impossible to determine an exact figure, studies have suggested that up to 20 percent of drugs sold in the Indian market are counterfeit and could represent a serious threat to patient health and safety. The U.S. Government, through the United States Agency for International Development (USAID) and other federal agencies, supports programs in sub-Saharan Africa, Asia, and elsewhere that assist trading partners in protecting the public against counterfeit and substandard medicines in their markets.

The annual Out-of-Cycle Review of Notorious Markets (*Notorious Markets List*) draws attention to markets, including online markets, that sell counterfeit pharmaceuticals, among other types of counterfeit products. In some cases, this public attention has helped result in concrete action, such as action taken against Nanjing Imperiosus, which reportedly provided domain name services to over 2,300 known illegal online pharmacies. The Internet Corporation of Assigned Names and Numbers (ICANN) terminated Nanjing Imperiosus Technology's Registrar Accreditation Agreement for continued breach of the terms of the Agreement, including failure to provide records to ICANN related to abuse reports. The 2017 *Notorious Markets List* called attention to sites that facilitate the online sale of counterfeit pharmaceuticals, including e-commerce platform Indiamart.com and domain registrar Rebel.

Enforcement authorities face difficulties in responding to the trend of increasing online sales of counterfeit goods. Counterfeiters increasingly 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. Nearly 90 percent of U.S. seizures at the border are 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 are limited by laws or practices that require counterfeit items to be "completed" which may overlook the downstream application of counterfeit labels.⁴

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 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 them from the channels of commerce. Permitting counterfeit goods and enabling materials to re-enter 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

⁴ For more information on these trends and Customs and Border Protection's and Immigration and Customs Enforcement/Homeland Security Investigation's IP enforcement efforts, see Department of Homeland Security, Intellectual Property Rights Seizure Statistics, Fiscal Year 2017 (2018) available at <https://www.cbp.gov/sites/default/files/assets/documents/2018-Feb/trade-fy2017-ipr-seizures.pdf>.

through free trade zones (FTZs), particularly in Dubai but also in other emirates such as Ajman and Sharjah, continue to undermine the UAE's reputation for effective and proactive IP enforcement. The United States remains deeply concerned over the transshipment and manufacturing of counterfeit products within certain FTZs in the UAE, a lack of will within some Emirate-level customs authorities to enforce IP in FTZs, and reluctance to engage bilaterally on these and other border enforcement issues. Stakeholders also continue to report a lack of enforcement in **Singapore's** FTZs, including courts' unwillingness to issue search warrants for illicit goods imported into Singapore's FTZs. 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).

In June 2017, the OECD and EU Intellectual Property Office (EUIPO) published the joint study "Mapping the Real Routes of Trade in Fake Goods."⁵ This study traced the complex trade routes employed by counterfeiters across ten product categories and noted the prevalence of international counterfeit sales through small shipments and parcels. This research determined that "**China** is the top producer of counterfeit goods in nine out of ten analyzed product categories, while **Hong Kong (China), UAE, and Singapore** are global hubs for trade in counterfeit goods." In those categories alone, the trade in fakes amounted to \$284 billion in 2013. In certain sectors, other countries were found to be major counterfeit producers, including **India** for counterfeit medicines exported to Africa, the EU, the United States, Canada, South America, and the Caribbean; **Turkey** for counterfeit leather goods, foodstuffs, and cosmetics; and **Indonesia** for counterfeit foodstuffs.

Modern supply chains offer many new opportunities for counterfeits to enter into the supply chain, including in the production process. This practice can taint the supply chain for goods in all countries, and countries must work together to detect and deter commerce in counterfeit goods. To this end, the United States strongly supports continued work in the OECD on countering illicit trade. We encourage the OECD and our trading partners to build off the illuminating OECD report released in March 2018, entitled "Governance Frameworks to Counter Illicit Trade." The report provided an overview of key enforcement challenges in BRICS economies (Brazil, China, India, Russia and South Africa), identified gaps in enforcement systems, and highlighted ways in which governments can better combat the trade in counterfeit goods that threatens to permeate modern supply chains, including through: (1) establishing deterrent sanctions and penalties; (2) addressing sharp growth in the use of postal and courier streams to transport illicit goods; (3) improving supervision and enforcement within FTZs; and (4) strengthening cooperation with stakeholders and other governments.

In another example of an integrated approach to combatting illicit trade, the International Chamber of Commerce (ICC) launched the "Know Your Customer" initiative in 2018 aimed at tackling the problem of counterfeit goods transported by international shipping companies.⁶ This initiative promotes a voluntary framework of best practices agreed upon by maritime companies and brands. It emphasizes specific steps that shipping operators can take to ensure they deal only with legitimate customers, including verifying customers' identities, performing due diligence, identifying possible counterfeit shipments, communicating policies against the shipment of

⁵ OECD/EUIPO (2017), *Mapping the Real Routes of Trade in Fake Goods*, available at <http://dx.doi.org/10.1787/978926478349-en>.

⁶ See <https://cdn.iccwbo.org/content/uploads/sites/3/2018/03/kyc-paper-doi-published.pdf>

counterfeit goods, and taking certain remedies. The United States commends this effort by the ICC and the international shipping community.

6. *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 the latest movies, television, music, books, and other copyrighted content from the United States. 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, Mexico, Peru, and Vietnam**, online piracy is the most challenging copyright enforcement issue in many foreign markets. Stakeholders report some positive developments on efforts to combat online piracy. For example, in China, right holders are encouraged by initial actions to curb online piracy, including National Copyright Administration of China action against unlicensed music platforms and Beijing Copyright Enforcement Department action against an unauthorized subscription service offering online e-books and journal articles. However, more needs to be done. The 2017 *Notorious Markets List* includes examples of online marketplaces reportedly engaging in commercial-scale online piracy, including sites hosted in or operated by parties located in **Canada, China, Cyprus, India, the Netherlands, Russia, Switzerland, Ukraine**, and elsewhere.

Stream-ripping, the unauthorized converting of a file from a licensed streaming site into an unauthorized copy, is now a dominant method of music piracy, causing substantial economic harm to music creators and undermining legitimate online services. Stream-ripping is reportedly popular in countries such as **Canada, Mexico, the Netherlands, Saudi Arabia, Sweden, and Switzerland**.

Furthermore, as discussed in the 2017 *Notorious Markets List*, illicit streaming devices (ISDs) continue to pose a direct threat to content creators, sports leagues, and live performances, as well as legitimate streaming, on-demand, and over-the-top media service providers. Stakeholders continue to report rampant piracy through ISDs, including in **Argentina, Brazil, Chile, China, Hong Kong, Indonesia, Mexico, Peru, Singapore, Taiwan, and Vietnam**.

The proliferation of “camcords” continues to be an 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 dated image of 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 economic damage is magnified because 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, in **Russia**, the total number of sourced camcords rose to 78 in 2017, up from 63 in 2016, and from 26 in 2015, representing a 300 percent increase in illegal camcords since 2015. According to stakeholder reports, **Mexico** is now the second largest foreign source of illegally recorded films. In **India**, while stakeholders report that instances of video camcording have been on a decline since 2015, there has been a significant shift to audio camcording in the last three years. This situation is particularly unfortunate as draft amendments to India's Cinematograph Act 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 intervening, often precludes effective enforcement. Economies like **Brazil, Ecuador, Peru, and Taiwan** do not effectively criminalize unauthorized 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 **Canada, Japan, and the Philippines**. 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 to supplement, but not replace, such effective legal measures is building public awareness. Another important practice is for the private sector to work on capacity building to help theater managers and employees to detect camcording and assist law enforcement.

In addition to the distribution of copies of newly released movies resulting from unauthorized camcording, other examples of online piracy that damage legitimate trade are found in virtually every country on the Special 301 lists and include: the unauthorized retransmission of live sports programming online; servers or "grey shards" that allow users to play unauthorized versions of cloud-based entertainment software; and online distribution of software and devices that allow for the circumvention of technological protection measures (TPMs), including "game copiers" and mod chips that allow users to play pirated games on physical consoles. 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. For all the above reasons, governments should avoid creating a domestic environment that offers a safe haven for piracy online.

7. Copyright Administration and Payment of Royalties

Collective management organizations (CMOs) 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. In some countries, like **India** and **Korea**, rulings by government agencies are attempting to extend the scope of mandatory collective management of rights and statutory license fees for certain types of digital music services. Also, the collection and distribution of royalties to U.S. and other right holders should be carried out on a national treatment basis. For example, one CMO in **Argentina** has reportedly refused to pay U.S. directors their share of royalties collected for public performances of U.S. motion picture and television programs. In the **UAE**, the Ministry of Economy's failure to issue the necessary operating licenses to allow copyright licensing and royalty payments represents a 15-year-plus challenge that the UAE should address without further delay so that right holders can receive compensation for their works. **India's** copyright royalty board is not fully functional, although recent steps and high-level statements have made progress toward this goal. While **Ukraine** is advancing CMO legislation, currently a number of rogue CMOs are operating freely in Ukraine and have done so for years. It is critical that Ukraine's new law provide for a transparent, fair, and predictable system for the collective management of royalties. As a result of Ukraine's continued lack of meaningful progress on this and other copyright-related issues, the United States has announced Ukraine's partial suspension of Generalized System of Preferences (GSP) benefits. On December 27, 2017, the United States provided 120 days' advance notice of the suspension to give Ukraine an opportunity to remedy the situation, in particular by adopting legislation to improve the current legal regime governing royalty collection CMOs.

8. 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 a company's most valuable business assets.

However, in numerous countries, legal and procedural obstacles exist to securing trademark rights. For example, the **UAE** reportedly institutes the highest trademark registration fees in the world and brand protection is considered cost-prohibitive, especially for SMEs. 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 inflexibility in relation to descriptions of goods and services, insufficient legal weight ascribed to notarized and legalized witness declarations in China Trademark Office and Trademark Review and Adjudication Board 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 **Brazil**, **India**, **Malaysia**, and the **Philippines**, reportedly have slow opposition proceedings while **Panama** and **Russia** have no administrative opposition proceedings.

Other concerns include mandatory requirements to record trademark licenses, as they frequently impose unnecessary administrative and financial burdens on trademark owners and create difficulty in the enforcement and maintenance of trademark rights. Also, the absence of adequate

means for searching trademark applications and registrations, such as by online databases, makes obtaining trademark protection more complicated and unpredictable. The lack of such online systems leads to additional cost, both in terms of initial filing and in relation to docketing and maintenance of multiple registrations.

In addition, 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.

9. Trademark Protection Challenges in Country Code Top-Level Domain Names

Trademark holders continue to face challenges in protecting their trademarks against unauthorized domain name registration and trademark 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 cybersquatting, and it is important for countries to provide for appropriate remedies in their legal systems to address this issue. Many ccTLDs have helpful policies that prohibit cybersquatting; require the registrant to provide true and complete contact information; and make such registration information publicly available. The ccTLDs of some countries have been identified by right holders as lacking 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.

10. 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 continues to work with other governments to address government use of unlicensed 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. Additionally, unlicensed software exposes governments and enterprises to higher risks of security vulnerabilities. Further work on this issue remains with certain trading partners, including **Argentina, Chile, China, Costa Rica, Greece, Kazakhstan, Korea, Tajikistan, Thailand, Turkey, 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.

11. Other Issues

Some public comments received in response to the 2018 Special 301 *Federal Register* notice raised concerns with respect to laws and legislative proposals in the EU that may hinder the provision of some online services, such as laws that would require certain online service providers—platforms

providing short excerpts (“snippets”) of text and images from other sources—to remunerate or obtain authorization from the original sources. The United States is monitoring these developments and other related measures. USTR detailed this and many other issues in the *2018 National Trade Estimate Report* (see [Fact Sheet: Key Barriers to Digital Trade](#)).

B. Initiatives to Strengthen IP Protection and Enforcement in Foreign Markets

USTR notes the following important developments in 2017 and early 2018:

- This Administration is engaging closely with **Thailand** on improving IP protection and enforcement as part of the bilateral U.S.-Thailand Trade and Investment Framework Agreement (TIFA). This engagement has yielded results on resolving U.S. IP concerns across a range of issues, including on enforcement, patents and pharmaceuticals, trademarks, and copyright. In light of Thailand’s progress, in December 2017, USTR closed the Out-of-Cycle Review of Thailand and moved Thailand from the Priority Watch List to the Watch List.
- **Bulgaria** passed amendments to its copyright law in March 2018 to facilitate the collection of copyright royalties by CMOs and strengthen government oversight. Bulgaria also participated in a EUROPOL operation to take down one of the largest Internet Protocol TV piracy networks in the region. Enforcement concerns remain with respect to high levels of online piracy, inadequate prosecution efforts, judicial delays, and insufficiently deterrent criminal penalties. However, Bulgaria recently devoted additional resources to the Cyber Crime Unit to investigate online piracy, and Bulgaria, including the Office of the Prosecutor General, has committed to taking additional steps to improve enforcement in 2018 including implementing an updated Prosecutors’ Manual for prosecuting IP crimes and adopting the practice of evidence sampling in criminal cases. Bulgaria is not placed on the Watch List this year. The United States will monitor implementation of these commitments as well as other steps that Bulgaria may take to improve IP enforcement.
- **Taiwan** enacted a legislative amendment to the Pharmaceutical Affairs Act that provides a mechanism for notifying interested parties of marketing requests or approvals for follow-on pharmaceuticals in a manner that should allow for the early resolution of potential patent disputes, as well as a period of at least three years for the protection against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical for “approved supplements or amendments to pharmaceutical indications.”
- In **China**, the State Administration for Industry and Commerce announced actions intended to bolster trademark protection, including procedures on oral hearing practice in trademark review cases and steps to curb bad-faith trademark registrations. China should take steps, including these, to stem widespread infringement of U.S.-held trademarks.

- **India** amended patent examination guidelines to eliminate a novel hardware requirement that may have hindered computer-related invention innovations, made progress toward significantly reducing patent and trademark pendency, became a participant in the WIPO Centralized Access to Search and Examination (CASE) system to facilitate patent work-sharing, produced an IP enforcement toolkit for police, and established a state-level enforcement unit to help address online piracy and counterfeit challenges.
- **Greece** enacted legislation to provide another tool to address online piracy. The law adds online piracy to an existing list of other serious crimes and requires that a committee be established with the authority to order removal of infringing content or that access to infringing content be discontinued and to impose fines in cases of non-compliance.
- In September 2017, the **Kuwait** General Administration of Customs signed a Customs Mutual Assistance Agreement with U.S. Customs and Border Protection (CBP) committing to enhancing collaboration, information sharing, and coordination in enforcement actions, including on IP cases.
- Enforcement of the Cyber Crimes Law in the **UAE** has reportedly resulted in deterrent penalties for online piracy. Additionally, the UAE established an IP special unit in the Customs Department in 2017 to pursue copyright infringements at the border.
- As of April 2018, there are 57 members of the 1991 Act of the International Union for the Protection of New Varieties of Plants Convention (UPOV 91). **Bosnia and Herzegovina** is the most recent member of UPOV 91. The Convention entered into force in Bosnia and Herzegovina in November 2017. 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 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.
- In June 2017, the Patent Cooperation Treaty (PCT) came into force for **Jordan**, bringing the number of contracting states of the PCT to 152.
- As of April 2018, there are 96 Parties to the WIPO Performances and Phonograms Treaty (WPPT) and 96 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 provide for certain exclusive rights, require parties to provide adequate legal protection and effective legal remedies against the circumvention of TPMs, as well as certain acts affecting rights management information. **Nigeria** became a party to the WIPO Internet Treaties in January 2018.

- In April 2017, an IP Tribunal in Karachi, **Pakistan** became operational, joining dedicated IP tribunals in Lahore and Islamabad.

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

C. Illustrative Best IP Practices by Trading Partners

USTR highlights the following illustrative 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 an example for effective IP enforcement. Several countries, including the United States, have introduced IP enforcement coordination mechanisms or agreements to enhance interagency cooperation. **Thailand** 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 improved coordination among government entities. **India's** Cell for IPR Promotion and Management (CIPAM) organizes and spearheads the government's efforts to simplify and streamline IP processes, increase IP awareness, promote commercialization, and enhance enforcement. 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 **Jamaica** Intellectual Property Office facilitated trainings and workshops on IP issues throughout 2017, including conducting a sub-regional patent drafting workshop and collaborating with WIPO to establish a Technology Innovation Support Center (TISC) at the University of the West Indies and the University of Technology, Jamaica. In **Spain**, the Ministry of Education, Culture, and Sport (MECD) partnered with the Ministry of Interior to include messaging against IP theft in police presentations in public schools. **India's** CIPAM has reportedly undertaken 19 IP awareness roadshows in 18 Indian states and maintains an active social media presence.
- 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.

D. Multilateral Initiatives

The United States works to promote adequate and effective IP protection and enforcement through various multilateral institutions, notably the **WTO**. 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.

In 2017, the United States advanced its IP and Innovation agenda in the TRIPS Council through a series of initiatives designed to facilitate greater understanding of the critical role that IP plays in promoting inclusive innovation for micro-, small-, and medium-sized enterprises (MSMEs). The United States cosponsored this year-long theme with **Australia**, the **EU**, **Japan**, and **Switzerland**, and Members dedicated attention to agenda items under this theme, including MSME Collaboration, MSME Growth, and MSME Trade. During these exchanges, the United States, co-sponsors of the agenda item, and a number of other WTO Members shared perspectives and first-hand experiences that demonstrated the value that IP systems play in stimulating creativity and innovation by MSMEs, and highlighted the beneficial role that governments can play through programs targeted toward helping these enterprises. WTO Members also benefited from a U.S.-sponsored side-event in October 2017 that brought together innovative MSMEs and those in the government directly involved in helping MSMEs commercialize their IP.

In February 2017, with **Australia**, the **EU**, **Japan**, and **Switzerland**, the United States co-sponsored an agenda item that explored MSME collaboration under the theme of IP and Inclusive Innovation. During the sessions, Members discussed how MSMEs contribute to the global trading economy, including as entrepreneurs, start-ups, businesses, researchers, and investors. A diverse set of Members shared national experiences and examples of inclusive innovation and MSME collaboration in their countries, in particular demonstrating how IP frameworks and innovation policies and programs assist MSMEs to successfully build and maintain collaborations.

In June 2017, the United States cosponsored with **Australia**, **Canada**, the **EU**, **Japan**, **Singapore**, and **Switzerland** an agenda item on IP and Innovation: Inclusive Innovation and MSME Growth. During the session, Members recognized that underutilization by MSMEs of the IP system as a tool for growth and cooperation is an important challenge for all countries—developed, developing, and least-developed. Members discussed ways to foster IP awareness among MSMEs and exchanged best practices to encourage and assist MSMEs in the use of the IP system.

In October 2017, the United States cosponsored along with **Australia**, the **EU**, **Japan**, **Switzerland**, and **Chinese Taipei** an agenda item on IP and Innovation: Inclusive Innovation and MSME Trade. During this session, Members shared domestic experiences and examples of successful measures promoting inclusive innovation and MSME trade—in particular, how IP frameworks and innovation policy or programs have assisted MSMEs to help MSMEs integrate into global value chains. In addition, the United States sponsored a side event at the WTO on the margins of the October 2017 meeting that brought together MSME stakeholders from around the world, including from Indonesia, Israel, South Africa, and Colombia, to speak directly about the benefits of IP to promoting MSME development.

E. 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:

- 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, during the 2017 review of the implementation of **Taiwan's** IP-related commitments from the 2016 TIFA Council meetings, Taiwan recognized the need to take further steps to enhance protection for innovation, curb piracy and infringement (particularly those occurring in the digital environment), and deepen engagement on trade secrets protection and enforcement. In July 2017, the U.S.-**Argentina** Innovation and Creativity Forum for Economic Development held its second meeting to discuss IP issues that are essential to the success of each country's innovation economy.
- During the November 2017 and March 2018 IP meetings of the U.S.-**United Kingdom** (UK) Trade and Investment Working Group, the UK and United States recognized the importance of IP to their respective economies and to the bilateral trade relationship, developed joint educational tools and resources for SMEs to support the export of creative and innovative products and services between the two countries, and agreed to continue discussions on enforcement approaches, policy tools, and voluntary initiatives for addressing online piracy, including the emerging challenge of ISDs.

Regional coordination and cooperation also increase the effectiveness of engagement on IP protection and enforcement challenges that extend beyond individual jurisdictions:

- In 2017, the United States continued to use the **APEC** Intellectual Property Experts Group and other APEC sub-fora to build capacity and raise standards for the protection of IP rights in the Asia-Pacific region. This included U.S.-led initiatives on combating trademark-infringing and counterfeit goods, which often present threats to consumer health and safety, at the border. Also, through the APEC Subcommittee on Customs Procedures, the United States and other participating economies jointly created an APEC Compendium for IP Enforcement. The document identifies IP educational, engagement, and enforcement practices that can be used as a resource to deter counterfeits and to enhance IP collaboration among APEC economies.
- Under its trade preference program reviews, USTR, in coordination with other U.S. Government agencies, examines IP practices in connection with the implementation of Congressionally-authorized trade preference programs, such as the GSP program, and regional programs, including the African Growth and Opportunity Act, Caribbean Basin Economic Recovery Act, and Caribbean Basin Trade Partnership Act. Pursuant to such a review, USTR has announced partial suspension of GSP benefits to **Ukraine** due to inadequate protection and enforcement of IP. USTR is also currently reviewing IP

practices in **Indonesia** and **Uzbekistan**. USTR continues to work with trading partners to address policies and practices that may adversely affect their eligibility under the IP criteria of each preference program.

- In 2017, the United States continued to engage with members of the Caribbean Community and other governments in the region on concerns regarding inadequate and ineffective IP protection and enforcement, including ongoing broadcast television and satellite signal piracy. Heightened engagement on this regional basis, including conferences and trainings in the **Dominican Republic, Trinidad and Tobago, Barbados, and Jamaica**, with strong U.S. Government leadership and participation, has led to heightened expertise, awareness, and initial positive steps.

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 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.

F. 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 broader investment in those markets. This may hinder regional economic growth, as well as technological advances needed to meet environmental challenges.

G. Intellectual Property and Health

Numerous comments in the 2018 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. The United States urges its trading partners to consider ways to address their public health challenges while also maintaining IP systems that promote innovation.

The United States also 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, the necessary two-thirds of WTO Member support was secured, resulting in the formal amendment to the TRIPS Agreement. Additional notifications of Member acceptances of the Agreement have followed.

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.

H. 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.

At the WTO Ministerial Conference in December 2017, WTO Members reached consensus to extend the moratorium on non-violation and situation complaints under the TRIPS Agreement until the next Ministerial in 2019. 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. 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 (IP/C/W/599) addressed the relevant TRIPS Agreement provisions and WTO and General Agreement on Tariffs and Trade (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 uses the WTO's Trade Policy Review mechanism to pose questions and seek constructive engagement on issues related to TRIPS Agreement implementation.

I. Dispute Settlement and Enforcement

The United States continues to monitor the resolution of concerns and 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 those provided under U.S. law, the WTO and other dispute settlement procedures, as appropriate.

On August 14, 2017, the President of the United States issued a Memorandum instructing the Trade Representative to determine whether to investigate under section 301 of the Trade Act of 1974 (the Trade Act) (19 U.S.C. § 2411), laws, policies, practices, or actions of the government of China that may be unreasonable or discriminatory and that may be harming American intellectual property rights, innovation, or technology development. *See* 82 FR 39007. After consultation with the appropriate advisory committees and the inter-agency Section 301 Committee, on August 18, 2017, USTR initiated an investigation into certain acts, policies, and practices of China related to technology transfer, intellectual property, and innovation. *See* 82 FR 40213. On March 22, 2018, the Presidential Memorandum on the Actions by the United States Related to the Section 301 Investigation noted that the Trade Representative had advised that the investigation supports findings that acts, policies, and practices of the China related to technology transfer, intellectual property, and innovation covered in the investigation are unreasonable or discriminatory and burden or restrict U.S. commerce. The President directed the Trade Representative to take all appropriate action under Section 301, including considering increased tariffs on goods from China and pursuing dispute settlement proceedings in the WTO. On March 23, 2018, the United States requested consultations with China under the WTO Dispute Resolution Understanding (in matter DS542), and on April 3, 2018, USTR published a proposed list of products imported from China, worth approximately \$50 billion in imports, that could be subject to additional tariffs. Additional

detail on the investigation and other proceedings are found in the discussion of China in Section II below.

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

EAST ASIA AND THE PACIFIC

CHINA

China remains on the Priority Watch List in 2018, and is subject to continuing Section 306 monitoring.

Ongoing Challenges and Concerns

The state of intellectual property (IP) protection and enforcement in China, and market access for U.S. persons that rely on IP protection, reflect the country's failure to implement promises to strengthen IP protection, open China's market to foreign investment, allow the market a decisive role in allocating resources, and refrain from government interference in private sector technology transfer decisions. While some positive developments have emerged in this complex and fast-changing environment, right holders continue to identify the protection and enforcement of IP, and IP-related market access barriers, as leading challenges in what is already a very difficult business environment. Concerns extend not only to gaps in legal authorities and weak enforcement channels, but also to investment and other regulatory requirements that promote the acquisition of foreign technology by domestic firms at the expense of providing the reciprocity, a level playing field, the transparency, and the predictability upon which the United States and others rightly insist. Assertions by Chinese government officials that China's shortcomings should be excused in light of the country's stage of economic development appear to suggest an underlying lack of commitment to address longstanding problems and undermine any confidence stemming from positive developments and high-level statements in support of IP and innovation.

The United States, other countries, and the private sector have stressed the urgent need for China to embrace meaningful and deep reform as it proceeds with a years-long overhaul of its IP-related legal and regulatory framework. Yet, results to date have disappointed, as China enacts measures that fail to reflect priority recommendations of the United States and others. China's shortcomings in this respect suggest that China intends to continue business as usual. For these reasons, as elaborated below, China remains a hazardous and uncertain environment for U.S. right holders hoping to protect and enforce their IP rights.

Developments, Including Progress and Actions Taken

As discussed below, although we continue to see some signs of progress in China, significant missed opportunities and troubling steps backward cast long shadows on the IP landscape in China.

Initial Positive Developments

In 2017, China continued an overhaul of its IP-related legal and regulatory framework. While the stated commitment to reform is welcome, the results are mixed. The United States has provided China with detailed input on a wide range of draft measures and recognizes those instances in which China modified drafts to address some U.S. concerns. At the same time, major U.S. concerns have gone wholly unaddressed. While the particulars vary by the measure in question, new legislation should promote IP protection and enforcement, and must not create new, or accept existing, market access obstacles to U.S. persons reliant on IP protection, including in the information and communications technology (ICT), motion picture, television, music, software, video game, and book and journal publishing sectors. Legal reforms are not an end themselves, but must result in improved conditions in China for U.S. IP right holders.

Positive signals are found in China's judicial reforms. In 2017, China concluded a three-year pilot program for specialized IP courts in Beijing, Shanghai, and Guangzhou with a favorable assessment. China has continued the IP courts and added specialized IP tribunals, which enjoy cross-regional jurisdiction, sometimes including jurisdiction over criminal, civil, and administrative enforcement, in order to promote the quality, efficiency, and consistency of IP adjudications. Observers report that the IP courts generally demonstrate competence, expertise and transparency to a greater degree than seen in other Chinese courts. Continuing this trend of specialization, in August 2017, China opened the nation's first Internet Court in Hangzhou, with 40 judges and assistant judges. There are also reports that China is researching the creation of a national-level appellate IP court, which could lend consistency to outcomes. Notwithstanding these positive developments, interventions by local government officials, powerful local interests, and the Chinese Communist Party remain obstacles to the independence of the courts and rule of law. A truly independent judiciary is critical to promote rule of law in China. In addition to insufficient judicial independence in certain cases, stakeholders continue to report that onerous authentication requirements for evidence and documentation, lack of means to require evidence production, and insufficient damage awards all undermine the effectiveness of China's court system for addressing IP infringement.

Other signs of progress came in the form of China Food and Drug Administration notices for public comment setting out a conceptual framework to protect against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products and to promote the efficient resolution of patent disputes between right holders and the producers of generic pharmaceuticals. The notices and China's engagement with private sector stakeholders appeared to provide cause for cautious optimism, although the important work of reducing concepts to text remains, and it is not yet clear whether other elements of China's government will provide critical collaboration.

A development of potential significance is the government reorganization approved by the National People's Congress on March 17, 2018. According to the State Council Reorganization Plan, the reforms place several IP-related government functions under a new State Administration of Market Supervision and Management. While officials indicate that reforms were enacted to increase the efficiency of IP protection and enforcement, it remains too early to determine whether the reforms will accomplish those goals and improve market access for U.S. persons that rely on IP.

Although early positive developments are welcome, any potential for growing confidence is undermined by a series of failures to address major ongoing concerns.

Trade Secrets

China's 2017 amendment of the Anti-Unfair Competition Law (AUCL) represents a major missed opportunity to address critical concerns. Despite extensive U.S. engagement regarding the first amendment since 1993 to the AUCL, China did not address major flaws in the outdated legislation, including the overly narrow scope of covered actions and actors, the failure to address obstacles to injunctive relief, and the need to allow for evidentiary burden shifting in appropriate circumstances, in addition to other concerns.

More fundamentally, despite long-term engagement from the United States and others—including from within China—China chose not to establish a stand-alone trade secrets law, and instead continued to seat important trade secrets provisions in the AUCL, an arrangement which contributes to definitional, conceptual, and practical shortcomings relating to trade secrets protection.

China should not only address these shortcomings, but also issue guiding court decisions to improve consistency in judicial decisions on trade secrets. Finally, reforms should also prevent the disclosure of trade secrets and other confidential information submitted to government regulators, courts, and other authorities, and address obstacles to criminal enforcement.

Manufacturing, Domestic Sale, and Export of Counterfeit Goods

China also failed in 2017 to take decisive action to curb the widespread manufacture, domestic sale, and export of counterfeit goods. Together with Hong Kong, through which Chinese merchandise often transships, China accounted for 78 percent of the value (measured by manufacturer's suggested retail price) and 87 percent of the seizures by CBP in 2017.⁷ Other authorities such as the European Union and OECD report similar figures, and by one estimate, counterfeits may account for over 12 percent of Chinese merchandise exports.⁸ Nevertheless, CBP and U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI) report positive cooperation with the General Administration of China Customs (GACC) in joint operations and information sharing. In February 2017 CBP, ICE, and GACC officials met in Long

⁷ <https://www.cbp.gov/sites/default/files/assets/documents/2018-Feb/trade-fy2017-ipr-seizures.pdf>

⁸ *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>).

Beach, California for an IP working group meeting. CBP and the General Administration of China Customs (GACC) conducted two month-long joint operations in April and August 2017. During the operations, both CBP and GACC focused on stopping shipments of IPR-infringing goods from entering U.S. commerce, with CBP making seizures at the U.S. border and GACC interdicting exports of counterfeit goods destined to the United States. The two joint operations resulted in approximately 3,500 seizures. Right holders also praise the GACC's proactive seizure of suspected goods prior to export from China. Despite cooperation on this relatively limited scale, China still needs to take measures to address the widespread availability of counterfeit goods sold both online and in physical markets in China, including those mentioned in past Out-of-Cycle Reviews 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 has not shown significant progress in addressing the registration of trademarks in bad faith, despite a number of announcements by China's State Administration for Industry and Commerce (SAIC) in September 2017. 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. As a result, third parties are able to obtain trademarks in China in bad faith 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.

E-Commerce Piracy, Counterfeiting and Other Issues

Widespread online piracy and counterfeiting in China's e-commerce markets represent major additional unaddressed concerns. According to published reports, online retail sales in China topped \$1 trillion in 2017.⁹ While the proportion of counterfeit and pirated goods and services is difficult to assess precisely, in 2014, 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. Given the scale, IP infringement in China's massive online markets causes deep 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, and books and journals, including scientific, technical, and medical publications. Compounding these losses in China are the export of pirated works to foreign markets. One report indicates that pirated books printed and exported from China appear in markets throughout the world, including in Africa. 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, including those selling compromised log-in credentials online. A range of such concerns led to the re-listing of Alibaba online sales platform Taobao as a notorious market in the 2017 Out-of-Cycle Review of Notorious Markets (*Notorious Markets List*). Reports also indicate that the 2017 Film Industry Promotion Law does not include meaningful sanctions and has failed to address the ongoing problem of unauthorized camcording of movies in theaters, one of the primary sources for online audiovisual infringements.

⁹ <https://www.digitalcommerce360.com/2018/02/08/online-retail-sales-china-soar-past-1-trillion-2017>

Two drafts of the new E-Commerce Law failed to address major concerns, despite some improvements in the second draft. It is critical that the final version of this law not undermine the existing framework for Internet service provider (ISP) notices of infringement and cease-and-desist letters. In addition, the E-Commerce Law should implement a predictable legal environment that promotes effective cooperation among interested parties in deterring online copyright infringement. In a positive private-sector development, China's Capital Copyright Industry Alliance now comprises more than 400 organizations and individuals, and it has taken actions to curb advertising on infringing websites. The search engine Baidu has worked with the film industry to reduce infringing content on that company's cloud storage service. Still, many piracy websites remain. One indication of the scope of the problem is that although China has the largest population and second largest economy in the world, it remains just the twelfth largest music market.

In 2017, China again failed to reform measures that bar or limit the ability of foreign entities to engage in online publishing, broadcasting, and distribution of creative content. One missed opportunity occurred in July 2017, when revisions to China's Foreign Investment Catalogue continued to prohibit foreign investment in the production of audiovisual products and network publication services. Other measures or draft measures continue to discriminate against foreign content, interfere with the simultaneous release of foreign content in China and other markets, require SOEs 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.

China failed to take decisive 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 (ISDs) configured with apps to facilitate access to such websites. China should enact deterrent-level criminal sanctions to address the country's status as the global hub for the production and export of devices and methods that facilitate the circumvention of technological protection measures (TPMs), which enable the delivery of services via the cloud and protect video games and other licensed content. In a positive step, the 2017 National Copyright Administration of China's Sword Net campaign focused on film and television works, copyright in news reporting, pirated books, discs sold through e-commerce platforms, and mobile apps that facilitate piracy. Despite a focus on mobile apps in the previous year's Sword Net campaign as well, stakeholders continue to report that the piracy app problem continues to expand and that Chinese enforcement authorities appear reluctant to take action despite the filing of stakeholder complaints. It is still unclear whether a January 2017 requirement that app sellers register with the State Internet Information Office will promote effective government enforcement action against piracy apps.

Need to Promote Innovation through Sound Patent and Related Policies

The fourth amendment of the Patent Law is still pending. While successive drafts have addressed certain U.S. recommendations, remaining concerns include the presence of competition law

concepts that belong elsewhere; an undue emphasis on administrative enforcement; a one-size-fits-all disclosure obligation in standards setting processes; a failure to clarify that a patentee's right to exclude extends to manufacturing for export; and the need to harmonize China's patent grace period and statute of limitations with international practices.

China's enactment of amendments to China's Standardization Law represents yet another missed opportunity to address longstanding concerns. Despite strong recommendations by the United States and others, the final version of the amended law, effective January 1, 2018, failed to establish that China's standards setting processes are open to domestic and foreign participants on a non-discriminatory basis, and cast doubt on, or failed to clarify, whether standards-related copyright and patent protections would be respected.

In 2017, Chinese authorities published for comment draft guidelines for Anti-Monopoly Law (AML) enforcement as it relates to IP rights. 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, transparent, 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.

Effective April 1, 2017, China's revised patent examination guidelines appeared to address, among other issues, the treatment of supplemental data submitted in support of pharmaceutical patent applications. However, right holders report that examiners have not in practice applied the guidelines to all examination questions to which supplemental data is germane, too often leading to the denial of applications on alternative grounds, even though counterpart patents may be routinely granted by other major patenting offices. As noted in last year's Special 301 Report, clarifications on these and other matters are needed to better promote pharmaceutical innovation and bring China into closer alignment with the practices of other major patenting jurisdictions.

The United States was encouraged by the China Food and Drug Administration's draft Notices 52, 53, 54, and 55 issued in May 2017. In particular, draft Notice 55 indicated that China's regulatory authorities would define "new drug" as one that is new to China, including those first marketed outside of China. However, in November 2017, China issued its draft Drug Registration Regulations (DRR), which missed the opportunity to reinforce the notion set forward in draft Notice 55. Instead, the draft DRR would define a "new drug" as only one that is new to the world, meaning that if a drug has been marketed outside of China, but not yet launched in China, it would fail to qualify as a "new drug." Only a "new drug" can receive full protection of regulatory data in China. This regulation puts foreign pharmaceutical applicants at a competitive disadvantage with domestic counterparts and could have the indirect effect of forcing companies to file first in China, even when market demand or health needs are elsewhere.

Stalled Copyright Law Amendments

Progress toward amendment of the Copyright Law appears to have stalled, despite the pressing need to address major gaps in copyright protection. Reports of a possible intention to move forward with only uncontroversial changes underscore concern of a missed opportunity to address

major deficiencies in China's copyright framework. Also needed are changes to the Criminal Transfer Regulation, in particular the adoption of a "reasonable suspicion" threshold in order to facilitate the transfer of administrative cases to criminal investigation and prosecution.

China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

Notwithstanding years of bilateral negotiation and other engagement, China has repeatedly failed to address a range of measures and practices that force or pressure U.S. right holders to relinquish control of their valuable IP as a condition for accessing the large and growing Chinese market. On August 14, 2017, the President of the United States instructed the U.S. Trade Representative to consider whether to investigate under Section 301 of the 1974 Trade Act (19 U.S.C. § 2411) any Chinese acts, policies, or practices that may be unreasonable or discriminatory and that may be harming American intellectual property rights, innovation, or technology development. On August 18, 2017, the U.S. Trade Representative initiated a Section 301 investigation, which included a public hearing on October 10, 2017, and two rounds of public written comments from interested members of the public. Based on the investigation, the Trade Representative has made the following determination: the acts, policies, and practices covered in the investigation are unreasonable or discriminatory and burden or restrict U.S. commerce, and are thus actionable under section 301(b) of the 1974 Trade Act. In particular:

1. China uses foreign ownership restrictions, such as joint venture requirements and foreign equity limitations, and various administrative review and licensing processes, to require or pressure technology transfer from U.S. companies.
2. China's regime of technology regulations forces U.S. companies seeking to license technologies to Chinese entities to do so on non-market-based terms that favor Chinese recipients.
3. China directs and unfairly facilitates the systematic investment in, and acquisition of, U.S. companies and assets by Chinese companies to obtain cutting-edge technologies and intellectual property and generate the transfer of technology to Chinese companies.
4. China conducts and supports unauthorized intrusions into, and theft from, the computer networks of U.S. companies to access their sensitive commercial information and trade secrets.

The President instructed the Trade Representative to take all appropriate actions under Section 301 to address the referenced acts, policies, and practices of China that are unreasonable or discriminatory and that burden or restrict U.S. commerce.

Pursuant to sections 301(b) and (c) and instructions from the President, the Trade Representative proposed that appropriate action would include increased tariffs on certain goods of Chinese origin and provided notice of a public hearing and opportunity to submit comments on the proposed action. The USTR also initiated dispute settlement proceedings at the World Trade Organization (WTO) to address China's discriminatory licensing practices, a concern highlighted repeatedly in

past Special 301 Reports. The President also directed the Secretary of the Treasury to address concerns about investment in the United States directed or facilitated by China in industries or technologies deemed important to the United States.

China's "Secure & Controllable" Policies

China has taken additional steps backward by its repeated invoking of cybersecurity as a pretext to force U.S. IP-intensive industries to disclose sensitive IP to the government, transfer it to a Chinese entity, or both, in order to address purported security concerns. China has continued to issue draft and final measures invoking cybersecurity—often in relation to the poorly-defined concept of “secure and controllable” products and services and associated “risk” factors—as a putative justification for erecting barriers to the sale and use of foreign ICT and other products, services, and technologies in China.

A leading example is China's Cybersecurity Law, which took effect on June 1, 2017, and is expected to serve as the foundation for future legislation on telecommunications, encryption, personal information protection, and a range of new measures and technical standards. Critically, this and related measures may require that the sellers of products and services in various sectors of China's economy disclose critical IP to government authorities, and may additionally require that IP rights be owned in China, that associated research and development be conducted in China, or both. Such requirements may effectively force U.S. right holders to choose between protecting their IP against unwarranted disclosure and competing for sales in major portions of China's economy. 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.

Related measures of concern include China's draft Regulation on Cybersecurity Review of Network Products and Services, published for public comment in February 2017. The measure raises concerns, including as to 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. The Cybersecurity Law itself incorporates the Multi-Level Protection Scheme requirements, which have numerous problematic aspects, one of which is a requirement for products to have indigenous Chinese IP, notwithstanding China's prior commitments to the United States to treat IP owned or developed in foreign countries the same as domestically owned or developed IP. 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 draft standards lay 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, are 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.

Other Concerns

Stakeholders report considerable concern that China's rules and procedures do not enable parties to participate in opposition, cancellation, invalidation, and other processes that would ensure GIs do 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, stakeholders report that government and SOE software legalization programs are still not 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 enjoy a cost advantage relative to competitors who pay for legally acquired software.

Finally, as China continues implementation of the 2013 amendments to the Trademark Law, stakeholders have identified concerns relating to opposition examiners at the China Trademark Office, who face very large dockets, may have limited training, and whose decisions are often too narrowly focused on whether the goods or services are in the same sub-class rather than market realities when determining likelihood of confusion. Stakeholders continue 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. Moreover, 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.

INDONESIA

Indonesia remains on the Priority Watch List in 2018.

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. Regarding GIs, Indonesia's law concerning GIs raises questions about the effect of new GI registrations on pre-existing trademark rights and the ability to use common food names. 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, such as its support of industry-led efforts to develop an Infringing Website List to help advertising brokers and networks avoid placing advertisements on such websites. In addition, in January 2018, Indonesia became a party to the Madrid Protocol for the international registration of trademarks. Although Indonesia took steps to allow 100 percent foreign direct investment in the production of films and sound recordings, as well as in film distribution and exhibition, 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 August 2017, regulations came into force clarifying *ex officio* authority for border enforcement against pirated and counterfeit goods, although concerns remain regarding the ability of foreign right holders to benefit from the system. Overall, IP enforcement has been insufficient, and 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 2016 have raised concerns, including with respect to the patentability criteria for incremental innovations; local manufacturing and use requirements; the grounds and procedures for issuing compulsory licenses; and disclosure requirements for inventions related to traditional knowledge and genetic resources. As Indonesia enacts implementing regulations for the revised Patent Law, the United States continues to urge Indonesia to address these concerns and to continue to provide affected stakeholders with

meaningful opportunities for input. The United States plans intensified engagement with Indonesia, including through the IP Working Group of the United States-Indonesia Trade and Investment Framework Agreement, to address these important issues.

SOUTH AND CENTRAL ASIA

INDIA

India remains on the Priority Watch List in 2018.

Ongoing Challenges and Concerns

In 2017, India continued to carry out high-level initiatives involving IP, including the 2016 National IP Policy and Startup India. While these and other Modi Administration initiatives have acknowledged the important role innovation and creativity play in India's development, they have failed to draw a direct link to specific IP reforms that would best help achieve these goals. Over the past year, despite administrative actions aimed at improving India's IP system, India has yet to address key longstanding deficiencies in its IP regime. India remains one of the world's most challenging major economies with respect to protection and enforcement of IP.

In particular, India has yet to take steps to address longstanding patent issues that affect innovative industries. Companies across different sectors remain concerned about narrow patentability standards, the potential threat of compulsory licensing and patent revocations, as well as overly broad criteria for issuing such licenses and revocations under the India Patents Act. Further, patent applicants face costly and time-consuming patent opposition hurdles, long timelines for receiving patents, and excessive reporting requirements. The U.S. Government and right holders welcomed the steps that India took in 2017 to better integrate its patent office into the World Intellectual Property Organization (WIPO) Centralized Access to Search and Examination (CASE) system and hope that India will take further steps to streamline and clarify 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, Section 3(d) of the India Patents Act restricts patent eligible subject matter in a way that poses a major obstacle to innovators seeking timely entry into the Indian market and India still 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. In 2017, the Ministry of Health and Family Welfare created further uncertainty in the pharmaceutical market when it issued a notification that eliminated a requirement from Form 44, which asked applicants seeking approval of a drug to declare the patent status of that drug to the regulator. Innovative industries also face pressure to localize the development and manufacture of their products, including under provisions of the Drug Price Control Order and also due to high customs duties directed to IP-intensive products, such as medical devices, pharmaceuticals, ICT products, solar energy equipment, and capital goods. The Ministry of Agriculture and Farmers Welfare's "Licensing and Formats for Genetically-Modified Technology Agreement Guidelines, 2016" (2016 Guidelines) contained overly prescriptive terms that, if implemented, would undermine market incentives critical to the agricultural biotechnology and other innovative sectors. The United States continues to urge India to formally rescind the 2016 Guidelines.

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. A 2017 publication produced by the OECD and EU Intellectual Property Office, "Mapping the Real Routes of Trade in Fake Goods," revealed India to be a key producer and exporter of counterfeit foodstuff, pharmaceuticals, perfumes and cosmetics, textiles, footwear, electronics and electrical equipment, toys, games, and sporting equipment. With respect to counterfeit pharmaceuticals, the report found that India was the origin for 55 percent of the total value of global counterfeit pharmaceutical seizures—by far the largest and noted that these counterfeit pharmaceuticals are shipped "around the globe, with a special focus on African economies, Europe, and the United States."

Although India has made some administrative improvements 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.

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 2017 *Notorious Markets List*), and through commercial broadcasts. In specific sectors, certain stakeholder reports are especially troubling. For example, counterfeit pesticides may account for 30 percent of sales by volume, the rate of unlicensed software use stands at around 58 percent, stakeholders have identified specific incidents of camcording that originate in Indian cinemas, and Indian products bear the mark of forged accreditation certificates. Recent court cases also raise concerns that a broad range of published works will not be afforded meaningful copyright protection. Furthermore, illegal practices that contribute to high piracy rates include the underreporting of cable subscriptions, widespread use of ISDs, and circumvention of TPMs. 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 and complicated the functioning in the market for music licensing.

India has yet to take the final steps to enact anti-camcording legislation, and the copyright royalty board, which has been folded into the Intellectual Property Appellate Board, is not fully functional as technical members still need to be appointed. India also has yet to ensure that CMOs are licensed promptly and able to operate effectively. The United States continues to urge India to join 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. 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 Startup 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, as described above. India continues to pursue important administrative work to reduce the time for processing patent applications and has already achieved significant progress in reducing pendency for trademark applications, while the Department of Industrial Policy and Promotion (DIPP) has continued to undertake administrative copyright reforms. The United States welcomed the June 2017 issuance of Computer-Related Invention Patent Examination Guidelines that eliminated the “novel hardware” requirement. The United States hopes that India’s patent office implements the new guidelines in a manner that fully recognizes the important innovations in this sector.

The amended Trademark Rules also reflected progress, including by reducing certain fees, eliminating paperwork, clarifying well-known mark criteria, and allowing the submission of sound mark applications. There have been notable enforcement efforts conducted by state authorities, including the establishment of the Maharashtra Intellectual Property Crime Unit, modeled on the Telangana IP Crime Unit, to coordinate IP enforcement activities across various state-level IP and enforcement agencies. A joint effort between India’s central government and industry helped launch the IPR Enforcement Toolkit for Police, which has become a useful tool to guide enforcement efforts throughout the country, and India has carried out important enforcement-related training and capacity building activities. Nonetheless, given the scale of the problem, we continue to encourage India to adopt a national-level enforcement task force for IP crimes. Notable raids on IP crimes occurred in Delhi and Mumbai. India’s commitment to bilateral dialogue remained strong, with frequent government-to-government engagements and working- and high-level meetings.

The Cell for IPR Promotion and Management, established under DIPP to move forward implementation of the National IPR Policy, has successfully spearheaded efforts to promote IP awareness, commercialization, and enforcement throughout India.

The 2015 passage of the Commercial Courts Act, highlighted in previous Reports, 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.

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 2018.

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. The United States continues to have serious concerns regarding the adequate and effective enforcement of existing anti-piracy statutes, including those combating the use of unlicensed software, and the provision of 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 and build capacity on IP issues and has improved engagement with the United States. However, Algeria failed to address longstanding concerns with respect to IP enforcement and other IP-related deficiencies. Also, Algeria moved backward with respect to the ban on the importation of pharmaceutical products and medical devices by increasing the number of pharmaceutical products and medical devices covered by the ban. 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 2018 with an Out-of-Cycle Review focused on addressing gaps in Kuwait's copyright regime.

Ongoing Challenges and Concerns

The United States welcomed the 2016 passage of the Copyright and Related Rights Law, which represents a significant development toward a robust copyright regime. However, there are still steps that need to be taken for Kuwait's copyright regime to meet Kuwait's international commitments, including with respect to the term of protection; limitations on the amount of work reproduced; enforcement, remedies, and damages; and definitions. The United States acknowledges Kuwait's willingness to work with U.S. Government agencies to draft amendments to the Law to bring its regime in line with its international commitments.

While the United States commends Kuwait's recent boost in enforcement efforts, the United States continues to encourage the government to devote additional resources and take action that would have the effect of curbing the manufacture and sale of counterfeit and pirated goods, including by targeting manufacturers and increasing fines and penalties to deterrent levels. Also, while the United States applauds the referral of IP cases to Kuwaiti courts for prosecution in 2017, the United States strongly urges Kuwait to prioritize the successful prosecution of such cases.

Developments, including Progress and Actions Taken

In June 2017, Kuwait promulgated implementing regulations following the passage of a new Copyright and Related Rights Law in May 2016. Although this law represented a significant improvement over previous legislation, did not resolve questions related to Kuwait's international commitments, and an Out-of-Cycle Review was conducted so that Kuwait could clarify and address ambiguities and deficiencies in the statute. The implementing regulations, however, fell short of addressing all of the steps that need to be taken. Kuwait is in the process of drafting amendments to the Law. The United States encourages Kuwait to continue to work with U.S. Government agencies throughout the remaining legislative process.

Kuwait has continued to make significant progress on its level of IP enforcement over past years, including border enforcement. Kuwait took action against online offerings of pirated materials, conducted raids and criminal trials on a range of pirated and counterfeit physical goods, and no longer allows counterfeit shipments to be exported. Kuwait also worked with right holders to enhance enforcement efforts. In particular, the United States commends the close collaboration between Kuwaiti customs officials and the U.S. Customs and Border Protection (CBP) in-country advisory program, and the signing of a bilateral Customs Mutual Assistance Agreement in September 2017 committing to collaboration, information sharing, and coordination in enforcement activities.

EUROPE AND EURASIA

RUSSIA

Russia remains on the Priority Watch List in 2018.

Ongoing Challenges and Concerns

Challenges to IP protection and enforcement in Russia include continued copyright infringement, trademark counterfeiting, and the existence of non-transparent CMO procedures. In particular, the United States remains concerned about stakeholder reports that IP enforcement continued to decline overall in 2017, following similar declines in prior years. The volume of counterfeit goods imported 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 2017, but the overall IP situation remains extremely challenging. The lack of enforcement against 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 2017 *Notorious Markets List*. 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 unauthorized camcords since 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 (SMEs).

Royalty collection in Russia continues to lack transparency and fails to meet international standards. The United States encourages 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 goods sourced from China that enter the country through Kazakhstan, Kyrgyzstan, and Azerbaijan. Similarly, there is little enforcement against counterfeits trafficked 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 2018.

Ongoing Challenges and Concerns

Ukraine was designated a Priority Foreign Country (PFC) in the 2013 Special 301 Report on three identified grounds. Although Ukraine made some progress in 2017 in addressing those issues, concerns remain. The three grounds for Ukraine's PFC designation were: (1) the unfair, nontransparent administration of the system for CMOs, which are responsible for collecting and distributing royalties to U.S. and other right holders; (2) widespread 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. As a result of Ukraine's continued lack of meaningful progress on these issues, the United States announced Ukraine's partial suspension of Generalized System of Preferences (GSP) benefits. On December 27, 2017, the United States provided notice 120 days prior to the suspension to give Ukraine an opportunity to remedy the situation, in particular, by adopting legislation to improve the current legal regime governing royalty reimbursement to right holders' organizations.

Developments, Including Progress and Actions Taken

In 2016 and 2017, Ukraine was active in developing draft legislation relating to patents, copyright and related rights, trademarks, geographical indications (GIs), integrated circuit topographies, and collective management organizations, although this legislation was not enacted during that timeframe. Ukraine also developed draft legislation to increase deterrent criminal penalties for IP infringement, and to improve customs enforcement. In 2017, Ukraine passed legislation to create a specialized Intellectual Property High Court, which is scheduled to become operational in September 2018.

In 2017, Ukraine's parliament enacted the law "On State Support of Cinematography," which contains provisions to address online piracy. The law establishes criminal penalties for illegal camcording and clarifies the availability of penalties for online piracy (not just hardcopy piracy). The creation of a limitation on liability in this law is another important step forward. Notwithstanding these improvements, some aspects of the new law have engendered concerns by different stakeholder groups, who report that certain obligations and responsibilities that the law imposes are too ambiguous or too onerous to facilitate an efficient and effective response to online piracy. The United States urges Ukraine to engage actively with all affected stakeholders to ensure the statutory infrastructure for reducing online piracy is effective and efficient.

With respect to Ukraine's collective management regime, a number of rogue CMOs have operated freely in Ukraine for years, collecting royalties but not distributing those royalties to legitimate right holders. In fact, the announcement of the suspension of some of Ukraine's GSP benefits specifically referenced the importance of improving the current legal regime governing royalty reimbursement to right holders' organizations. In response, Ukraine advanced several bills aimed at revising its CMO regime. At least one draft received positive support from right holders and foreign governments. It is critical that the final law adopted by Ukraine's parliament result in a

transparent, fair, and predictable system for the collective management of royalties because the current state of the system is entirely inadequate.

Although Ukraine has taken preliminary steps to reduce the use of unlicensed software by some Ukrainian government agencies, 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, Ukraine has not yet carried out a centralized work plan or allocated sufficient funds 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. In addition, inadequate enforcement continues to raise concerns among IP stakeholders in Ukraine.

Following closure of the State Intellectual Property Service of Ukraine, an entity that had been criticized for nontransparent and unfair practices, Ukraine has announced its intention to establish a new National IP Office. The United States looks forward to the new National IP Office as a new independent body that can become a strong voice for IP in Ukraine.

The United States will continue to engage intensively on these issues with Ukraine, including through the U.S.-Ukraine Trade and Investment Council.

WESTERN HEMISPHERE

ARGENTINA

Argentina remains on the Priority Watch List in 2018.

Ongoing Challenges and Concerns

Argentina continues to present longstanding and well-known challenges to IP-intensive industries, including from the United States. A key deficiency in the legal framework for patents is the unduly broad limitations on patent eligible subject matter. 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. Stakeholders assert 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. Another ongoing challenge to the innovative agricultural chemical and pharmaceutical sectors is inadequate 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. Finally, Argentina struggles with a substantial backlog of patent applications resulting in long delays for innovators seeking patent protection in the market.

Enforcement of IP rights in Argentina continues to be a challenge and stakeholders report widespread unfair competition from sellers of counterfeit and pirated goods and services. Argentine police do not take enough *ex officio* actions, prosecutions can stall, cases may languish in excessive formalities, and, when a criminal investigation reaches final judgment, criminal infringers rarely receive sentences that deter recidivists or other potential infringers. In terms of physical counterfeiting and piracy, USTR has included La Salada in Buenos Aires in past Out-of-Cycle Reviews of Notorious Markets as one of the largest markets in Latin America known for high quantities of counterfeit and pirated goods. 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.

Developments, Including Progress and Actions Taken

Over the last year, Argentina continued the positive trajectory noted in the 2017 Special 301 Report to improve IP protection and enforcement, including enforcement operations, procedural enhancements for patent protection, legislative initiatives, and the creation of bilateral engagement

mechanisms. Most significantly, Argentina took decisive action in 2017 against operators of the notorious market La Salada. The United States encourages Argentina to create a national IP enforcement strategy to transition these successes to a sustainable, long-lasting initiative. In November 2017, Argentina entered into an agreement with the Chamber of Medium-Sized Enterprises and the Argentine Anti-Piracy Association to create a National Anti-Piracy Initiative focusing initially on trademark counterfeiting. The United States encourages Argentina to expand this initiative to online piracy. Several legislative proposals that the United States welcomed in last year's Special 301 Report remain pending, including 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 CMOs, criminal sanctions including for circumventing TPMs, and the creation of a federal specialized IP prosecutor's office, are reportedly in a more advanced drafting stage but have not yet been submitted to Congress.

Over the past year, the National Institute of Industrial Property (INPI) continued to take steps to reduce the lengthy patent examination backlog. Under the 2016 INPI resolution establishing expedited patent examination procedures for applicants who have obtained a patent application at a foreign office, INPI received nearly 800 fast-track applications and approved 84 percent. To further improve patent protection in Argentina, including for SMEs, the United States urges Argentina to ratify the Patent Cooperation Treaty (PCT). INPI is also working toward digitization of internal procedures and a more efficient online application management system by the end of 2018. Argentina also issued a Presidential decree in January 2018, which includes procedural improvements for the registration of patents, trademarks, and designs. Specifically, the decree creates simplified opposition procedures for trademark owners to monitor their rights and establishes a use requirement to maintain a trademark registration, thereby improving the accuracy of the trademark register. Additionally, in July 2017, Argentina and the United States met under the bilateral Innovation and Creativity Forum for Economic Development, part of the U.S.-Argentina Trade and Investment Framework Agreement (TIFA), to continue discussions and collaboration on IP topics of mutual interest. 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.

CANADA

Canada is placed on the Priority Watch List in 2018.

Ongoing Challenges and Concerns

Canada remains the only G7 country identified in the Special 301 Report and the downgrade to the Priority Watch List this year reflects a failure to resolve key longstanding deficiencies in protection and enforcement of IP. Because inadequate and ineffective IP protection and enforcement constitute a barrier to U.S. exports and investment, these issues are a continuing priority in bilateral trade relations with Canada. Significant concerns include poor border and law enforcement with respect to counterfeit or pirated goods, weak patent and pricing environment for innovative pharmaceuticals, deficient copyright protection, and inadequate transparency and due process regarding GIs. The United States remains deeply concerned that Canada does not provide customs officials with the ability to inspect, detain, seize, and destroy in-transit counterfeit and pirated goods entering Canada destined for the United States. As the United States has emphasized, this failure permits counterfeit and pirated goods to enter our highly integrated supply chains. Additionally, there were no known criminal prosecutions for counterfeiting in Canada in 2017, which makes Canada a striking outlier among OECD countries. With respect to pharmaceuticals, the United States has serious concerns about the fairness of Canada's Patented Medicines (Notice of Compliance) proceedings as amended in September 2017. Canada's long-anticipated proposal to provide for patent term restoration for delays in obtaining marketing approval appears to be disappointingly limited in duration, eligibility, and scope of protection. The United States also has serious concerns about the breadth of the Minister of Health's discretion in disclosing confidential business information. The United States also remains deeply troubled by the ambiguous education-related exception to copyright that has significantly damaged the market for educational publishers and authors. While Canadian courts have worked to clarify this exception, confusion remains. Additionally, Canada does not provide full and fair national treatment with respect to copyright and related rights, and has specifically denied U.S. creators and performers remuneration to a greater extent than other countries. The United States urges Canada to reform these aspects of its copyright regime to compensate creators for their works fully and fairly. The United States also has concerns about lack of due process and transparency relating to the GI system in Canada, including commitments Canada made without public notification or opposition procedures to protect certain GIs under the Comprehensive Economic and Trade Agreement with the EU, which came into force provisionally on September 21, 2017. These measures negatively affect market access for U.S. agricultural producers. The United States urges Canada to ensure transparency and due process with respect to the protection or recognition of GIs, including with respect to existing trademarks, safeguards for the use of common names, and meaningful opposition and cancellation procedures. These current policies and practices are the basis for Canada's downgrade to Priority Watch List.

The United States also has significant concerns about proposed changes to Canada's Patented Medicine Prices Review Board. If finalized in their current form, these policies would fail to appropriately recognize the value of innovative medicines in both the private and public markets, and would make Canada's pricing policies an outlier among similarly situated countries. The United States encourages Canada to reassess the proposed changes and to meaningfully engage

with all interested stakeholders before releasing a final policy to ensure its system is transparent and contributes fairly to research and development for innovative treatments and cures.

Developments, Including Progress and Action Taken

The United States welcomes the Supreme Court of Canada’s decision in June 2017 rejecting the application of a restrictive patent utility standard, known as the “promise doctrine” that resulted in the invalidation of patents held by U.S. pharmaceutical companies. Additionally, the Federal Court of Canada in July 2017 ruled in favor of an educational content company, which may help circumscribe the overly broad fair dealing copyright exception for educational purposes. The United States will monitor developments concerning remaining issues and looks forward to working closely with Canada in the coming year to address priority IP issues.

CHILE

Chile remains on the Priority Watch List in 2018.

Ongoing Challenges and Concerns

The United States continues to have serious concerns regarding a number of longstanding implementation issues with the IP provisions of the United States-Chile Free Trade Agreement (Chile FTA). Chile did not deliver any tangible progress on outstanding IP commitments in recent years, and Chile failed to adequately prioritize these important shortcomings. The United States urges Chile to pass legislation establishing criminal and civil penalties for theft of satellite signals and trafficking in decoder devices. Chile must also establish protections against the unlawful circumvention of TPMs used to control access to and copying of protected works. Effective administrative and judicial procedures, as well as deterrent remedies, must be in place and available to right holders and satellite and cable service providers. The United States continues to urge Chile to ratify and implement the 1991 Act of the International Union for the Protection of New Varieties of Plants Convention (UPOV 91) and improve protection for plant varieties. The United States also urges Chile to make effective its 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 correct its ISP liability framework to permit effective and expeditious action against online piracy.

Developments, Including Progress and Actions Taken

Over the past year, the National Institute of Industrial Property (INAPI) made operational improvements to patent and trademark registration processes, such as implementing an electronic signature program, strengthening security measures to safeguard information, taking steps toward becoming a paperless organization, and inaugurating a technology and innovation support center. INAPI also performed an important role for the region as an International Search Authority under the PCT, receiving a 20 percent increase in 2017 of PCT applications and expanding its competency to include search and examination reports in both Spanish and English to better serve PCT users from the Caribbean. Chile's specialized IP crime unit, the Investigative Brigade of IP Crimes (BRIDEPI), celebrated its tenth anniversary in 2017. One of BRIDEPI's recent achievements was a targeted enforcement campaign against counterfeit toys, during which 300,000 counterfeit toys were seized, some of which contained lead paint and other toxic materials unsafe for children. With respect to the outstanding FTA implementation concerns noted, Chile took insufficient steps toward potential progress. A bill that would criminalize satellite and cable signal theft and related decoder devices, as well as amendments to the industrial property law, are pending in Congress. The United States will continue to work closely with Chile to address IP issues, but it has been fourteen years since the Chile FTA entered into force, and the United States expects to see tangible progress in these areas in 2018.

COLOMBIA

Colombia is placed on the Priority Watch List in 2018 with an Out-of-Cycle Review focused on certain provisions of the United States-Colombia Trade Promotion Agreement (CTPA) and monitoring the implementation of Colombia's National Development Plan (NDP).

Ongoing Challenges and Concerns

In 2017, USTR conducted an Out-of-Cycle Review of Colombia focused on certain provisions of the CTPA and monitoring the implementation of Colombia's NDP. Colombia's lack of meaningful progress, particularly in relation to its CTPA obligations, warrants its elevation to the Priority Watch List. In 2018, Colombia will be subject to an Out-of-Cycle Review on the same issues to determine whether a change in status to Watch List would be appropriate.

In 2017, Colombia took steps toward completing implementation of certain provisions of the CTPA, including by introducing into the legislature copyright law amendments that would address certain provisions of the CTPA. The United States urges Colombia to move quickly to enact the recently introduced copyright law amendments. Colombia also still needs to make other improvements with respect to implementation of significant IP-related commitments under the CTPA, including commitments to address the challenges of online piracy and accession to UPOV 91. The United States urges Colombia to begin working on necessary provisions regarding 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 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 goods crossing the border or being sold at Bogota's San Andresitos markets, on the street, and at other distribution hubs around the country. 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 (FTZ) areas. Finally, the United States continues to monitor Colombia's implementation of certain provisions of the NDP that could undermine innovation and IP systems, particularly those that would condition pharmaceutical regulatory approvals on factors other than safety or efficacy. In March 2018, Colombia issued Decree 433 to partially implement NDP Article 72, although questions remain as to whether the decree would condition regulatory approvals on factors other than safety and 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.

Developments, Including Progress and Actions Taken

Noteworthy developments from 2017 and early 2018 include the introduction of the copyright amendments noted above, as well as Colombia's inclusion of new IP-related provisions in a revised police code that was introduced in January 2017. That code tightened requirements for public performances, requiring event organizers to submit proof of authorization for works to be performed before a permit can be approved.

VENEZUELA

Venezuela remains on the Priority Watch List in 2018.

Ongoing Challenges and Concerns

Recognizing the significant challenges faced by Venezuela at this time, the United States recites the following ongoing concerns with respect to the lack of adequate and effective IP protection and enforcement. Venezuela's reinstatement several years ago of its 1955 Industrial Property Law, which falls below the standards in international trade agreements and treaties that Venezuela subsequently ratified, has created significant uncertainty and deterred investments in innovation and IP in recent years. Additionally, Venezuela's Autonomous Intellectual Property Service (SAPI) has not issued a new patent since 2007, and patent applications have dropped by over 50 percent between 2015 and 2017. Similarly, trademark applications have dropped by over 33 percent between 2005 and 2016. Piracy, including online piracy, as well as unauthorized camcording and widespread use of unlicensed software, remain a persistent challenge. Counterfeit goods are also widely available, and IP enforcement remains ineffective. The World Economic Forum's 2017-2018 Global Competitiveness Report ranked Venezuela last, for the fifth straight year, out of 137 countries, in IP protection. The Property Rights Alliance's 2017 International Property Rights Index also ranked Venezuela 126th out of 127 countries in a metric that includes standards of IP protection.

Developments, Including Progress and Actions Taken

Due to limited opportunities for engagement with Venezuela on IP issues, the United States is unaware of significant progress or actions taken by Venezuela to address IP protection and enforcement deficiencies over the past year.

WATCH LIST

EAST ASIA AND THE PACIFIC

THAILAND

Thailand remains on the Watch List in 2018, after an Out-of-Cycle Review between September and December 2017 resulted in moving Thailand from the Priority Watch List to the Watch List. Engagement on IP protection and enforcement as part of the bilateral U.S.-Thailand TIFA yielded significant progress on addressing U.S. IP concerns across a range of issues, including enforcement, patents and pharmaceuticals, trademarks, and copyright. For example, Thailand established an interagency National Committee on Intellectual Property Policy and a subcommittee on enforcement against IP infringement, led by the Prime Minister and a Deputy Prime Minister, respectively. This strong interest from the highest levels of the government led to improved coordination among government entities, as well as enhanced and sustained enforcement efforts to combat counterfeit and pirated goods throughout the country. Thailand also has been taking steps to address backlogs for patent and trademark applications, including significantly increasing the number of examiners and streamlining regulations. In addition, Thailand joined the Madrid Protocol, making it easier for U.S. companies to apply for trademarks, and took steps to address concerns regarding online piracy affecting the U.S. content industry. However, concerns remain regarding the availability of counterfeit and pirated goods, both in physical markets and online, and the United States urges Thailand to continue to improve on its provision 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 a number of concerns expressed by the United States and other foreign governments and stakeholders, including on ISP liability, TPMs, rights management information, and procedural obstacles to enforcement against unauthorized camcording. The United States urges Thailand to address these issues in upcoming amendments to its Copyright Act. Other U.S. concerns include a backlog in pending patent applications, widespread use of unlicensed software in both the public and private sectors, unauthorized collective management organizations, 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. 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 TIFA and other bilateral engagement.

VIETNAM

Vietnam remains on the Watch List in 2018. 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, and cable and satellite signal theft persist, while both private and public sector software piracy remains a concern. 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 continues to closely monitor ongoing implementation of amendments to the Penal Code with respect to criminal enforcement of 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 clarification. 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. The United States looks to Vietnam to engage on and address 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 press on these and other IP issues with Vietnam through the U.S.-Vietnam TIFA and other bilateral engagement, and it is imperative that Vietnam fully engage and work toward resolving these issues over the next year.

SOUTH AND CENTRAL ASIA

PAKISTAN

Pakistan remains on the Watch List in 2018. In 2017, Pakistan maintained positive dialogue with the United States on IP and conducted meaningful public awareness, capacity building, and training programs to promote IP protection and enforcement in Pakistan. Pakistan's Intellectual Property Organization (IPO) also continues to make efforts to coordinate the various government bodies involved in IP. 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 has been a welcome development, but the effectiveness of these courts remains to be seen. Pakistan has not reconstituted the IP policy board established by the IPO Act following the expiration of its mandate in late 2017. 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 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, including through the Commercial Law Development Program (CLDP) program, 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, and urges Pakistan to reconstitute the IP policy board.

TAJIKISTAN

Tajikistan returns to the Watch List in 2018. Tajikistan had been taken off the Watch List in 2017 due to concrete steps Tajikistan took to improve its IP regime. An Out-of-Cycle Review was extended through the fall of 2017 to allow time for Tajikistan to formalize a presidential-level decree, law or regulation mandating government use of licensed software. Tajikistan failed to undertake this reform. In addition to widespread use of unlicensed software, Tajikistan's IP enforcement efforts remain insufficient and the government has not published IP enforcement statistics since 2013. Current enforcement actions are hampered by routine government reshuffling, weak bureaucratic capacity, and inadequate public education on the importance of IP. The United States stands ready to assist Tajikistan through enhanced engagement or technical assistance, if requested.

TURKMENISTAN

Turkmenistan remains on the Watch List in 2018. The United States is concerned by the lack of observable progress made by Turkmenistan in bringing its IP protections up to international standards since its accession to the Berne Convention in 2016. The United States also remains

concerned with current levels of protection and enforcement of IP rights and Turkmenistan's failure to fully implement its IP laws. The State Agency for Intellectual Property hears few cases of infringement, even though counterfeit and pirated goods reportedly remain widely available in major cities in Turkmenistan. The United States continues to encourage Turkmenistan to undertake legislative IP reforms, including to provide *ex officio* authority for its customs officials and improve its enforcement procedures in accordance with current IP laws. Further, the United States remains concerned about reports of widespread use of unlicensed software by government agencies. The United States continues to urge 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 2018. The United States continues to raise long-standing concerns to Uzbekistan, including those regarding the lack of copyright protection for foreign sound recordings, a key issue related to the current review of Uzbekistan's eligibility for the GSP program. The United States strongly encourages Uzbekistan to take several critical steps, including: (1) joining the Geneva Phonograms Convention; (2) accede to the WIPO Internet Treaties; and (3) take legislative action to provide adequate copyright protection for foreign sound recordings. At the same time, the United States recognizes the positive steps taken by Uzbekistan to improve IP protection and enforcement over the past year, including increased high-level political attention to IP, progress toward developing a new national strategy for IP, and incremental advances in enforcement. The United States encourages Uzbekistan to address concerns raised in previous Special 301 Reports, including in the areas of border enforcement, resourcing administrative and enforcement IP agencies, and addressing software piracy.

NEAR EAST, INCLUDING NORTH AFRICA

EGYPT

Egypt remains on the Watch List in 2018. The United States notes Egypt's effort to strengthen enforcement of IP, including steps to initiate cases regarding unauthorized broadcasts and infringement of satellite content and to reduce regulatory approval delays for pharmaceuticals. 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 2018. The United States welcomes Lebanon's continued work to promote IP protection and enforcement in 2017, as well as its stated interest in reviving efforts to pass IP-related legislation when its parliament is able to resume normal functioning. The United States also commends the Ministry of Economy and Trade, in cooperation with WIPO, for agreeing to begin the development of a national IP strategy. While the United States commends these efforts, more is needed to consider removing Lebanon from the Watch List. In particular, 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 IP framework treaties, including Articles 1-12 of the Paris Convention and the Nice Agreement. In addition, the United States encourages Lebanon to ratify and implement the Berne Convention, the Singapore Treaty on the Law of Trademarks and to join the PCT and the Madrid Protocol. While enforcement efforts have been improving slowly, additional training for enforcement officials is needed to enhance investigative skills. The United States also urges Lebanon to allocate sufficient resources for IP protection and enforcement. Specifically, Lebanon should allocate resources to provide customs officials with facilities to store seized counterfeit or pirated goods, as well as with the authority to establish procedures for the destruction of such seized goods. The United States looks forward to continuing to work with Lebanon to address these and other issues.

SAUDI ARABIA

Saudi Arabia is included in the Watch List in 2018 in response to recent deteriorations in IP protection for pharmaceutical products, in addition to outstanding concerns on enforcement and the continued use of unlicensed software by the government. Saudi Arabia was removed from the Watch List in February 2010 in recognition of the progress to improve its IP regime. However, in recent years, Saudi Arabia has granted marketing approvals to domestic companies to produce generic versions of pharmaceutical products that are under patent protection either in Saudi Arabia or in the GCC. Additionally, these approvals have been granted based on innovators' data that is still covered under Saudi Arabia'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. These approvals, which may conflict with Saudi Arabia's domestic law, raise significant questions about the transparency of marketing approvals and predictability of patent protection in Saudi Arabia. Additionally, concerns regarding IP enforcement are increasing, including related to difficulty in obtaining information on the status of enforcement actions and investigations, and the lack of seizure and destruction of counterfeit goods. Furthermore, the continued use of unlicensed software by the government, along with the limited number of and training for copyright inspectors, are outstanding concerns. The United States looks forward to continuing to work with Saudi Arabia to address these and other issues.

UNITED ARAB EMIRATES

The United Arab Emirates (UAE) is placed on the Watch List in 2018 in light of longstanding concerns about combatting the sale and transshipment of counterfeit goods and the establishment of collecting management organizations, as well as recent policy changes that may weaken IP protection for pharmaceutical products. While some UAE enforcement authorities seize and destroy counterfeit goods, significant copyright piracy and trademark infringement concerns remain. The 2017 *Notorious Markets List* included two physical marketplaces in the UAE for hosting over 5,000 stores selling a broad range of counterfeit goods, including appliances, communication and acoustic equipment, building materials, machinery, footwear, and designer handbags. In addition to serving purchasers in the UAE, these marketplaces also operate as gateways to distribute counterfeit goods to other markets in the region, North Africa, and Europe. Additionally, the lack of IP enforcement actions within FTZs is a concern. For instance, rather than seizing and destroying counterfeit goods in FTZs, UAE officials reportedly allow the re-export and transshipment of such products, despite having the authority for the destruction of counterfeit goods. U.S. right holders also continue to raise concerns over the lack of IP prosecutions; a lack of permanent staff solely dedicated to counterfeit enforcement; a lack of enforcement action without specific, written complaints from right holders; and a lack of transparency and available information related to raids and seizures of pirated and counterfeit goods. Moreover, despite repeated requests by the United States and right holders and the existence of implementing regulations, the UAE has yet to grant the necessary operating licenses to establish CMOs to allow copyright licensing and royalty payments. Stakeholders also raise concerns over the high trademark filing fees in UAE, which are the highest in the world and considered cost-prohibitive to protecting trademarks in the UAE. Furthermore, in April 2017, UAE officials allowed domestic manufacture of generic versions of pharmaceutical products still under patent protection in the United States. The UAE claimed that previous measures providing

country of origin patent protection for pharmaceutical products – the Decree 404 system – were no longer valid. The Decree 404 system provides important protections for innovative products that are not otherwise available through other mechanisms in the UAE’s intellectual property and regulatory systems. It is also unclear whether the UAE intends to continue to recognize patents granted by the GCC Patent Office. These actions demonstrate a lack of predictability and transparency that has created a sense of instability and confusion amongst stakeholders in the innovative pharmaceutical industry. The United States looks forward to continuing to work with UAE to address these and other issues.

EUROPE AND EURASIA

GREECE

Greece remains on the Watch List in 2018. Greece made progress on improving IP protection and enforcement in 2017 but widespread piracy continues and IP enforcement challenges remain. The United States welcomes the enactment in 2017 of amendments to the Copyright Law to address online piracy. The United States encourages Greece to fully implement the new law, including establishing expeditiously the committee that will administer enforcement requests. However, outstanding IP challenges remain, including related to unlicensed software use and inadequate IP enforcement against counterfeiting and piracy. According to U.S. stakeholders, Greece has one of the highest rates of unlicensed software use in the European Union. Greece has acknowledged that unlicensed software use by government agencies is a problem, but swift and effective action—such as establishing proper procurement requirements, implementing management policies, and conducting awareness campaigns for Greek officials—is needed to begin to ensure the public sector uses legitimate software and sets a positive example for the private sector. The United States is also concerned that enforcement agencies do not adequately prioritize IP infringement. IP-related criminal investigations, prosecutions, and sentences, as well as customs seizures, were often inadequate or ineffective over the past year. The United States urges Greece to address persistent problems with criminal enforcement delays and non-deterrent sentences and penalties, including for large-scale infringers. 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. The United States looks forward to working with Greece including through an IP work plan to address these and other issues.

ROMANIA

Romania remains on the Watch List in 2018. While the United States welcomes working-level cooperation in Romania between stakeholders 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 remains concerned that amendments to the Criminal Code in 2014 effectively decreased penalties for copyright crimes and that amendments to the Criminal Procedure Code in 2016 failed to grant authority to the Economic Police to carry out computer searches for copyright infringements. 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 IP 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 and instruct relevant enforcement authorities to prioritize IP cases. The United States also encourages Romania to continue its consultations with interested

stakeholders as Romania considers amendments to its Copyright Law. 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 2018. Generally, Switzerland 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. 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. A 2010 decision by the Swiss Federal Supreme Court 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. 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 Out-of-Cycle Reviews of Notorious Markets from recent years. The United States welcomes the steps Switzerland has taken to respond to this serious concern, including the draft amendments to the Swiss Copyright Act as submitted to the Parliament in November 2017, following robust public consultations and stakeholder roundtables to develop recommendations. The draft revisions seek to address the problematic Supreme Court decision from 2010. This legislative process, which began in 2012, is expected to come to a resolution in early 2019. The United States also encourages Switzerland to deter end-users from consuming pirated content through consumer awareness campaigns, public education, and voluntary stakeholder initiatives. The United States looks forward to cooperating with Switzerland to address these and other IP-related challenges.

TURKEY

Turkey remains on the Watch List in 2018. In 2017, Turkey continued to implement the 2016 Industrial Property Law and prepared draft legislation on a new Copyright Law. According to the latest Turkish Government data, domestic seizures by Turkey's law enforcement officials increased by 35 percent from 2015 to 2016. Despite these positive developments, concerns over IP protection and enforcement continue to grow. The United States views with particular concern Turkey's recent implementation of policies that require localized production of pharmaceutical products and strongly urges Turkey to rescind these problematic policies. U.S. pharmaceutical companies continue to complain that Turkey does not adequately protect against the unfair commercial use of pharmaceutical test data and has not done enough to reduce regulatory and administrative delays to granting marketing approvals for products. Additionally, U.S. companies report that Turkey's national pricing and reimbursement policies for pharmaceutical products suffer from a lack of transparency and procedural fairness. 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. Turkey remains a major source and transshipment point of counterfeit goods across a number of sectors. Levels of pirated products in Turkey remain high, such as unlicensed software, which is reportedly used by government agencies. The Turkish

National Police should be given the *ex officio* authority they currently lack and other tools to help them enhance their enforcement, particularly in obvious infringement cases. Enforcement processes are currently hampered by to procedural delays and insufficient personnel. Copyright infringement in Turkey proliferates largely due to insufficient penalties and resources, which has resulted in a backlog of cases. As Turkey prepares new copyright legislation, the United States continues to encourage Turkey to provide an effective mechanism to address online piracy, 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.

WESTERN HEMISPHERE

MEXICO

Mexico remains on the Watch List in 2018. Long-awaited updates to Mexico's copyright and enforcement laws, as well as ineffective IP enforcement, particularly with respect to counterfeit goods and online piracy, remain significant challenges. Piracy and counterfeit goods are widespread in Mexico, including online and at notorious physical marketplaces, such as Tepito in Mexico City and San Juan de Dios in Guadalajara. U.S. brand owners face bad-faith trademark registrations, and Mexico's enforcement against suspected infringing goods at the border remains hampered by overly restrictive policies. The Attorney General's Office has determined it will not take action against in-transit shipments of suspected infringing goods unless there is a determination of economic impact on the Mexican economy, which is virtually impossible to establish given the nature of in-transit movements. In addition, unauthorized camcording in Mexico is a serious concern and continued unabated in 2017. Mexico is now reportedly the second largest foreign source of unauthorized camcords in the world, fueling unlawful availability of first-run movies online, which damages the market for new releases. Similarly, Mexico is reportedly among the top countries for online sharing of infringing video game files and music piracy online, including via unauthorized stream-ripping. Although Mexico ratified the WIPO Internet Treaties in 2002, Mexico has not enacted legislation to protect against the circumvention of TPMs and RMI. Investigation and prosecution of IP crimes, particularly with regard to online IP crimes, continues to be inadequate, due in part to continued government-wide budget cuts. Patent infringement proceedings are lengthy, and stakeholders report concerns about insufficient protection against damages while proceedings take place. In administrative procedures on infringement, preliminary measures can be lifted without any burden of proof on the alleged infringer if the alleged infringer posts a counter-bond, which renders injunctions against continued infringement ineffective.

Mexico made some progress over the past year to better protect and enforce IP rights. Mexico's customs authorities developed an improved trademark recordation system and launched a system to provide seizure information and automated notifications to right holders. The Specialized IP Unit also increased seizures and arrests, including apprehending a popular unauthorized movie streaming site "peliculasmas.com." With respect to legislative efforts, Mexico passed amendments to the Industrial Property Law in March 2018 to strengthen the trademark opposition system and provide protection for non-traditional marks. Mexico also made some progress toward much-needed legislative initiatives to enhance seizure authorities and improve customs procedures, and to amend the Criminal Code to include camcording as an offense without the need to prove commercial profit. The United States looks forward to the passage and effective implementation of these initiatives.

The United States urges Mexico to pass, enact, and fully implement in a timely manner the anti-camcording amendments, as well as other amendments to modernize its copyright regime. The

United States also urges Mexico to provide its customs officials with full *ex officio* authority to take action against in-transit or transshipped counterfeit or pirated goods. With respect to GIs, Mexico has agreed to protect a list of 340 EU GIs in its free trade agreement with the EU. Protection must only be granted after a fair and transparent examination independent of the trade negotiations, and the outcome must adequately respect existing trademark rights and continue to allow for the use of common names. Finally, to combat growing levels of IP infringement in Mexico, the United States also encourages Mexico 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 looks forward to working with Mexico to address these and other IP concerns.

COSTA RICA

Costa Rica remains on the Watch List in 2018. Despite a number of important unresolved concerns, the United States welcomes positive steps taken by Costa Rica, including the 2016 release of an online patent database, an increase in patent registrations, participation in a Patent Prosecution Highway pilot program with the U.S. Patent and Trademark Office, as well as other ongoing engagement with the United States. Also, positive were reports of increased intra-government coordination on IP matters, and a significant increase in the number of criminal investigations and prosecutions. The United States welcomes Costa Rica's decision to publish, starting in November 2017, official IP criminal enforcement statistics, and the January 2018 announcement of an official website to host such information. In terms of unresolved concerns, Costa Rica has made less progress on ensuring that government entities use only licensed software. The United States welcomes updates from Costa Rica in this respect, but notes that despite Costa Rica's efforts over the last several years, the problem appears to remain significant. In order to address other concerns, the United States urges Costa Rica to take effective action against all 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 up to 45 days to forward infringement notices to subscribers. The United States continues to call upon Costa Rica to provide greater transparency and clarity as to the scope of protections for GIs to alleviate market access uncertainty. To improve border enforcement, Costa Rica should create a formal customs recordation system for trademarks to allow customs officers to make full use of their *ex officio* authority to inspect and detain goods. The United States strongly encourages Costa Rica to build upon initial positive momentum to strengthen IP protection and enforcement, and to continue to draw on bilateral discussions to develop clear plans to demonstrate progress to tackle longstanding problems.

DOMINICAN REPUBLIC

The Dominican Republic remains on the Watch List in 2018. The United States notes actions by the Dominican Republic to address the existing patent application backlog, including an increase in the number of applications that have undergone review, the institution of priority review for long-pending applications, hiring additional examiners in 2016 and 2017, and a recently signed cooperation agreement with a foreign patent office. Nevertheless, a significant backlog remains, underscoring the need for patent term adjustment, as required by the Dominican Republic-Central

America Free Trade Agreement (CAFTA-DR), for unreasonable administrative delays. Aggravating this concern is the patent office's assertion that patent term adjustments do not apply to applications submitted before March 2008 (the effective date of CAFTA-DR). The denial of applications for adjustment continues at the administrative level based on this incorrect view, despite contrary rulings after judicial challenges. Other substantial IP concerns include government use of unlicensed software and the widespread availability of pirated and counterfeit products. Stakeholders estimate that 12 percent of pharmaceuticals and 30 percent of cigarettes available in the Dominican Republic bear counterfeit marks. In an initial positive step on a different front, the Dominican government convened an anti-piracy roundtable in June 2017 and began enforcement actions against unauthorized cable operators. It does not yet appear, however, that administrative enforcement actions have resolved ongoing concerns regarding unauthorized cable operators, retransmission piracy by hotels, or sales of satellite decoders intended for use in the United States or elsewhere that provide users in the Dominican Republic with unauthorized access to U.S. signals and copyrighted works. In general, a lack of political will, resources, and expertise hamper enforcement efforts. The United States recommends that the Dominican Republic improve coordination among enforcement agencies and build the technical capacity of its law enforcement officials, prosecutors, and judges, especially outside of Santo Domingo. 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 encourages the Dominican Republic to take clear actions in 2018 to improve its IP protection and enforcement.

GUATEMALA

Guatemala remains on the Watch List in 2018. Despite a generally strong legal framework in place, resource constraints, a lack of political will, and poor coordination among law enforcement agencies have resulted in IP enforcement that appears inadequate in relation to the scope of the problem in Guatemala. After an increase in enforcement activity in 2016, the number of enforcement raids and convictions declined significantly in 2017. The United States urges Guatemala to continue strengthening enforcement, including criminal prosecution, administrative and border measures, as well as intergovernmental coordination to address widespread copyright piracy and commercial-scale sales of counterfeit goods. Moreover, Guatemala has reportedly become a source country for counterfeit pharmaceutical products. Trademark squatting is also a significant concern, affecting the ability of legitimate businesses to use their trademarks, as both administrative remedies and relief through the courts are slow and expensive, and outcomes are unpredictable. Government use of unlicensed software and cable signal piracy are also serious problems, with stakeholders reporting both significant estimated losses and that administrative actions have not worked in practice. 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 2018 to improve the protection and enforcement of IP in Guatemala.

BARBADOS

Barbados remains on the Watch List in 2018. While Barbados has implemented a basic legal framework for IP protection and enforcement, the country's failure to adopt modern copyright legislation that protects works in both physical and online environments is a major concern. It does not appear that Barbadian authorities have made this or any other IP-related issue a priority, as the government committee authorized to propose IP-based legislation reportedly met only infrequently in 2017. Also, Barbados has not acceded to the WIPO Internet Treaties, a second major gap in protection. Evidence of a strong commitment to enforcement of existing legislation appears lacking. In a dispute involving apparel bearing the trademark of a high-profile individual, Barbados reportedly secured its first criminal trademark counterfeiting conviction in early 2018, which is a positive step, but much more needs to be done to provide effective deterrence. In the realm of copyright and related rights, the United States continues to have concerns about the 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. Reports that judgments and other successful outcomes for right holders in civil litigation have gone unenforced or not had the intended effect are yet another source of concern. The United States looks forward to working with Barbados to resolve these and other important issues.

JAMAICA

Jamaica remains on the Watch List in 2018. 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 the update is consistent with Jamaica's international obligations. 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 2018, the Broadcasting Commission of Jamaica initiated a periodic audit of cable operators to ensure they provide only licensed content to subscribers. Similar efforts in prior years reportedly led to improving compliance by major operators but left unaddressed problems at dozens of smaller ones. Effective enforcement against violations will be the measure of success in the effort to curb widespread signal theft. Also encouraging are reports of operations and arrests targeting transnational criminal organizations operating in Jamaica and engaging in IP violations. 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 2018. Challenges continue with respect to adequate and effective IP protection and enforcement. Concerns remain about IP protection in Bolivia, including in relation to the absence of trade secret protections and the breadth of exceptions and limitations relating to certain IP rights. With regard to enforcement, significant challenges persist to curbing widespread piracy and counterfeiting, including the counterfeiting of pharmaceuticals. Video, music, and software piracy rates are among the highest in Latin America, and rampant counterfeiting persists. In 2017, Bolivia's *Servicio Nacional de Propiedad Intelectual* (SENAPI) established an arbitration process to resolve IP disputes outside the judicial system. Although there have been some promising results under that new process, it does not compensate for the overall weakness of Bolivia's criminal and civil IP enforcement system. Criminal charges and prosecutions remain rare. While the number of private stakeholder requests for border measures has reportedly increased, customs authorities lack personnel and budgetary resources to act. There is an urgent need for public awareness regarding IP protection and enforcement beyond the government's 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 2018. The United States recognizes efforts by Brazilian officials at the federal, state, and local levels to improve enforcement of IP rights, despite severe resource constraints. Notable successes include the closure (albeit temporary) of São Paulo's Shopping 25 de Março notorious market, the launch by Brazilian authorities of the "Legality Movement" (Movimento Legalidade), and similar IP enforcement initiatives that have resulted in seizures of over \$150 million of counterfeit goods. The United States welcomes the cooperation of Brazilian law enforcement with counterparts in the United States and neighboring countries. Nevertheless, levels of counterfeiting and piracy in Brazil, including online piracy and camcording, remain unacceptably high. 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, although in 2017 the CNCP did not deliver accomplishments as in previous years. The dedication of additional resources to IP enforcement would help address these challenges, as would the enactment of pending legislation to increase deterrent penalties for IP crimes and criminalize unauthorized camcording. The United States also recognizes positive developments at Brazil's National Institute of Industrial Property (INPI), which hired new examiners, received additional funding, reduced patent and trademark backlogs, and adopted streamlined procedures for certain review processes. The United States also notes that proposals to allow INPI to retain patent and trademark filing fees would help address

budgetary constraints. Despite this positive progress, the United States remains concerned about the pendency of patent and trademark applications. The United States encourages Brazil to continue to undertake necessary reforms to address this concern. Regarding longstanding concerns about duplicative reviews by Brazil's National Sanitary Regulatory Agency (ANVISA) of pharmaceutical applications, the United States welcomes the April 2017 agreement between INPI and ANVISA that should help expedite the processing of such applications. The United States 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 encourages Brazil to provide transparency and procedural fairness to all interested parties in connection with potential recognition or protection of GIs including in connection with trade agreement negotiations with other countries. Finally, 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, 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.

ECUADOR

Ecuador remains on the Watch List in 2018. Ecuador entered into a Memorandum of Understanding (MOU) with the United States in 2017. The MOU is expected to serve as a basis for cooperative activities between the two entities on matters related to the acquisition, utilization, protection, and enforcement of IP rights. Additionally, as part of efforts to update the IP regime in Ecuador, a Presidential Decree changing the Ecuadorian Institute of Intellectual Property into the National Service for Intellectual Rights is pending signature. It is hoped that this change will provide IP authorities with increased resources and staffing. However, concerns remain in other areas. Enforcement of IP against widespread counterfeiting and piracy remains weak, including online and in physical marketplaces, and Ecuador has also reportedly become a major source of unauthorized camcords. Ecuador also lacks effective measures to deter online piracy, and has not yet established a system of limited liability for ISPs upon satisfaction of certain core conditions. Regarding the Organic Code on Social Economy of Knowledge, Creativity, and Innovation (Ingenuity Code), Ecuador is reportedly in the process of developing implementing regulations. Stakeholders have raised concerns about how those regulations will address issues, such as the scope of certain copyright exceptions and limitations and certain exceptions to patentable subject matter. Ecuador has also not yet followed through on a commitment to rescind Decree 522 governing generic medicines, a measure that some stakeholders fear prejudices their legitimate interests. 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 the 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, to provide for customs enforcement on an *ex officio* basis, and to promote more effective means of securing *ex parte* seizures. The United States looks forward to working with Ecuador to address these and other issues.

PERU

Peru remains on the Watch List in 2018. Peru took a number of positive steps relating to IP protection and enforcement in 2017. Peru successfully seized and shuttered several Spanish-language websites known to host large volumes of pirated content. Peru has improved inter-agency coordination with respect to IP enforcement. Peru also established new specialized IP prosecutors in both the Ventanilla and Tumbes regions in 2017, although there are still many areas of the country where this expertise is unavailable. The United States remains concerned about the widespread availability of counterfeit and pirated products in Peru. Right holders continue to 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 of pirated content and counterfeit goods, although Peru has begun to suspend the domains of some of these sites. The United States urges Peru to devote additional resources for IP enforcement, enhance its border controls, and build the technical IP-related capacity of its law enforcement officials, prosecutors, and judges. The United States also encourages Peru to undertake appropriate legislative reforms, such as by criminalizing camcording in a manner that allows for effective enforcement; 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 and establishing limited liability for ISPs within the parameters of the PTPA. Stakeholders have raised concerns about two recent Indecopi decisions that limit the right to collect royalties for the public performance of musical works contained in audiovisual works. The United States looks forward to continuing to work with Peru to address outstanding issues in 2018.

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 intellectual property (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 (FY) 2017, GIPA developed and provided capacity building programs that addressed a full range of IP protection and enforcement matters, including enforcement of IP rights at national borders, online piracy, express mail shipments, trade secrets, copyright policy, and patent and trademark examination. During the last year, the programs cumulatively included over 4,000 government officials, judges and prosecutors, from 120 countries.

- 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 71,000 times at WWW.USPTO.GOV. GIPA also produced a microlearning video on the protection of trade secrets, which is available on GIPA's YouTube channel, which has been viewed over 3,000 times since distribution in March 2017.
- 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 the World Intellectual Property Organization (WIPO). These partnerships help establish a framework for joint development of informational and educational IP 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 IP 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 FY 2017, U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI), through the National IPR Coordination Center (IPR Center), conducted law enforcement training in Argentina, Jamaica, the Philippines, Romania, Senegal, Ukraine, and Uruguay. The IPR Center also participated in three USPTO-led workshops; two of which were held at the Global Intellectual Property Academy, Alexandria, Virginia for Pakistani Customs officials and members of parliament, in cooperation with the U.S. Embassy in Islamabad. An additional workshop was held in Dubai, United Arab Emirates (UAE) for Customs officials, Police, and Ministry of Interior officials from the Kingdom of Bahrain, State of Qatar, Kingdom of Saudi Arabia, and the UAE, in cooperation with Consulate General of the United States. The IPR Center provided support to the Department of Justice-Intellectual Property Law Enforcement Coordinator

training in Brazil, Bangkok, Guatemala, Hong Kong, and the UAE. Additionally, the IPR Center participated in INTERPOL's Operation Chain training in Singapore and co-hosted the annual INTERPOL IP Crime Conference in New York City.

- In FY 2017, U.S. Customs and Border Protection provided IP training sessions to foreign customs officials in Dubai, UAE; Dushanbe, Tajikistan; Guatemala City, Guatemala; and Belo Horizonte, Brazil.
- 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, Customs and Border Protection (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 the World Intellectual Property Organization (WIPO) and INTERPOL.
- IP protection is a priority of the government-to-government technical assistance provided by the Department of Commerce'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 online 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.

Copyright Office staff participate 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 is being planned for summer 2018.

The United States reports to the World Trade Organization on its IP capacity-building efforts, including most recently in September 2017 (see Technical Cooperation Activities: Information from Members—United States of America, IP/C/W/632/Add.2). The United States also reports annually on international IP capacity building and training in the annual report 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 as the “Annual Intellectual Property Report to Congress,” in March 2018.