



2019 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 (the Trade Act, 19 U.S.C. § 2242). Congress amended the Trade Act in 1988 specifically "to provide for the development of an overall strategy to ensure adequate and effective protection of intellectual property rights and fair and equitable market access for United States persons that rely on protection of intellectual property rights."¹ In particular, Congress expressed its concern that "the absence of adequate and effective protection of United States intellectual property rights, and the denial of equitable market access, seriously impede the ability of the United States persons that rely on protection of intellectual property rights to export and operate overseas, thereby harming the economic interests of the United States."²

This Report provides an opportunity 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 the 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.

Specifically, this Administration continues to closely monitor developments in and to engage with those countries that have been on the Priority Watch List for multiple years. Over the coming weeks, USTR will review the developments against the benchmarks established in the Special 301 action plans for those countries. For countries that fail to address U.S. concerns, USTR will take appropriate actions, such as enforcement actions under Section 301 of the Trade Act or pursuant to World Trade Organization or other trade agreement dispute settlement procedures, necessary to combat unfair trade practices and to ensure that trading partners follow through with their international commitments.

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:

¹ Omnibus Trade and Competitiveness Act of 1988, § 1303(a)(2), 102 Stat. 1179.

² *Id.* § 1303(a)(1)(B); *see also* S. Rep. 100-71 at 75 (1987) ("Improved protection and market access for U.S. intellectual property goes to the very essence of economic competitiveness for the United States. The problems of piracy, counterfeiting, and market access for U.S. intellectual property affect the U.S. economy as a whole. Effective action against these problems is important to sectors ranging from high technology to basic industries, and from manufacturers of goods to U.S. service businesses.").

- 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 for fundamental structural changes to strengthen IP protection and enforcement, including as to trade secret theft, online piracy and counterfeiting, the high-volume manufacture and export of counterfeit goods, and impediments to pharmaceutical innovation. Under Section 301 of the Trade Act of 1974, USTR has taken action to address a range of unfair and harmful conduct, including technology transfer requirements imposed as a condition to access the Chinese market. USTR also initiated dispute settlement proceedings at the World Trade Organization (WTO) to address discriminatory licensing practices. Structural impediments to administrative, civil, and criminal enforcement continue to undermine IP protections, as do certain information communications technology (ICT), IP-ownership, and research and development localization requirements.
- USTR identifies India on the Priority Watch List for lack of sufficient measurable improvements to its IP framework on long-standing and new challenges that have negatively affected U.S. right holders over the past year. Long-standing 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, insufficient enforcement actions, copyright policies that do not properly incentivize the creation and commercialization of content, and an outdated and insufficient trade secrets legal framework. In addition to these long-standing concerns, India also further restricted the transparency of information provided on state-issued pharmaceutical manufacturing licenses, expanded the application of patentability exceptions to reject pharmaceutical patents, and missed an opportunity to establish 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 certain agricultural chemical products.
- USTR identifies Indonesia on the Priority Watch List due to the reported lack of adequate and effective IP protection and enforcement. Indonesia's patent law continues to raise serious concerns, including with respect to patentability criteria, local manufacturing and use requirements, and compulsory licensing.
- USTR identifies Saudi Arabia on the Priority Watch List for failing to address long-standing IP concerns and further deteriorating IP protection and enforcement within its borders. Specifically, concerns remain regarding the lack of IP protection for innovative pharmaceutical products, including the lack of adequate and effective protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval. Further, Saudi Arabia has not taken action against the rampant satellite and online piracy made available by illicit pirate service BeoutQ.
- 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, Australia, Canada, China, Colombia, Ecuador, Egypt, India, Indonesia, Japan, Korea, Mexico, New Zealand, Saudi Arabia, Turkey, 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 trading partners, including Brazil, China, Colombia, Hong Kong, India, Indonesia, Nigeria, Paraguay, Singapore, Thailand, Turkey, the UAE, and Vietnam, 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.
- Online and broadcast piracy remains a challenging copyright enforcement issue in many countries, including Argentina, Bulgaria, Canada, Chile, China, Colombia, Greece, India, Mexico, the Netherlands, Romania, Russia, Saudi Arabia, Switzerland, Ukraine, and elsewhere.³
- Several countries, including Brazil, India, the UAE, and Ukraine, have not addressed the continuing and emerging challenges of copyright piracy. Countries such as Argentina, Brazil, China, Costa Rica, Egypt, Greece, Indonesia, Kenya, Mexico, Nigeria, the Philippines, Romania, Russia, Thailand, and Vietnam, do not have in place effective policies and procedures to ensure their own government agencies do not use unlicensed software.
- 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, and Saudi Arabia—a lack of effective protection against unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products.
- 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 the 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.

The Office of the U.S. Trade Representative looks forward to working closely with the trading partners identified in this year's Report to address these and other priority concerns.

³ As used in this report, the term "copyright" encompasses copyright and related rights.

THE SPECIAL 301 PROCESS

The Congressionally-mandated annual Special 301 Report is the result of an extensive multi-stakeholder process. Pursuant to the statute mandating the Report, the United States Trade Representative 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 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 the United States Trade Representative 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 2019 Special 301 review process to facilitate sound, well-balanced assessments of trading partners' IP protection and enforcement and related market access issues affecting IP-intensive industries, and to help ensure that the Special 301 review would be based on comprehensive information regarding IP issues in trading partner markets.

USTR requested written submissions from the public through a notice published in the *Federal Register* on December 28, 2018 (*Federal Register* notice). In addition, on February 27, 2019, 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.⁴ The *Federal Register* notice and post-hearing comment opportunity drew submissions from 48 non-government stakeholders and 25 foreign 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-2018-0037. 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.

⁴ Available at <https://ustr.gov/issue-areas/intellectual-property/special-301/2019-special-301-review>.

USTR, together with the Special 301 Subcommittee, conducts a broad and balanced assessment of U.S. trading partners' IP protection and enforcement, as well as related market access issues affecting IP-intensive industries, in accordance with the statutory criteria. (See ANNEX 1.) The Special 301 Subcommittee, through the TPSC, provides advice on country placement to USTR based on this assessment. This assessment is necessarily conducted on a case-by-case basis, taking into account diverse factors such as a trading partner's level of development, its international obligations and commitments, the concerns of right holders and other interested parties, and the trade and investment policies of the United States. It is informed by the various cross-cutting issues and trends identified in Section I. Each assessment is based upon the specific facts and circumstances that shape IP protection and enforcement in a particular trading partner.

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

- Engage with U.S. stakeholders, the U.S. Congress, and other interested parties to ensure that the U.S. Government's position is informed by the full range of views on the pertinent issues;
- Conduct extensive discussions with individual trading partners regarding their respective IP regimes;
- Encourage trading partners to engage fully, and with the greatest degree of transparency, with the full range of stakeholders on IP matters;
- Develop action plans with benchmarks for each country that has been on the Priority Watch List for at least one year to encourage progress on high-priority IP concerns; and
- Identify, where possible, appropriate ways in which the U.S. Government can be of assistance. (See ANNEX 2.)

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

THE 2019 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

Watch List

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

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 2018, USTR conducted an Out-of-Cycle Review of **Colombia** focused on certain provisions of the U.S.-Colombia Trade Promotion Agreement (CTPA) and the implementation of Colombia's 2014-2018 National Development Plan. As a result, Colombia was moved from the Priority Watch List to the Watch List. Colombia made meaningful progress in enacting copyright reform legislation to meet CTPA obligations and is actively engaging stakeholders on Internet service provider (ISP) liability to address another CTPA commitment.

USTR also conducted an Out-of-Cycle Review of **Kuwait** in 2018 focused on improving Kuwait's copyright regime to meet its international commitments. While Kuwait made some progress in its new draft copyright law, USTR has concluded the Out-of-Cycle Review process and determined that Kuwait has not yet resolved the issues raised in connection with the Out-of-Cycle Review.

USTR conducted an Out-of-Cycle Review of **Malaysia** in 2018 to consider the extent to which Malaysia is providing adequate and effective IP protection and enforcement, including with respect to patents. During this review, the United States and Malaysia have held numerous consultations with a view to resolving outstanding issues. In 2019, USTR will extend the Out-of-Cycle Review

of Malaysia and will press Malaysia to complete actions to fully resolve these concerns in the near term.

USTR may conduct additional Out-of-Cycle Reviews of other trading partners as circumstances warrant, or as requested by a 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 2018, USTR requested such comments on August 16, 2018, and published the *2018 Notorious Markets List* on April 25, 2019. USTR plans to conduct its next Out-of-Cycle Review of Notorious Markets in the fall of 2019.

STRUCTURE OF THE SPECIAL 301 REPORT

The 2019 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 2019

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,⁵ 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 such as semiconductors, automobile parts, apparel, 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 the estimated 45 million American jobs that directly or indirectly rely on IP-intensive industries.⁶ USTR continues to work to protect American innovation and creativity in foreign markets employing all the tools of U.S. trade policy, including the annual Special 301 Report.

This Section highlights developments in 2018 and early 2019 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 innovative pharmaceutical products and medical devices, forced technology transfer and localization policies, protection of trade secrets, geographical indications (GIs), online and broadcast piracy, and trade in counterfeit goods. 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

⁵ The terms “trademark counterfeiting” and “copyright piracy” may appear below also as “counterfeiting” and “piracy,” respectively.

⁶ Intellectual Property and the U.S. Economy: 2016 Update (USPTO), at 12-13, available at <https://www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf>.

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 enable 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. Among other examples, USTR, in the past year:

- Secured strong IP provisions with **Canada** and **Mexico**, which are important to incentivizing innovation, in the United States-Mexico-Canada Agreement (USMCA), 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;
- Obtained, through negotiations to improve and better implement the United States-Korea Free Trade Agreement (KORUS FTA), **Korea's** commitment to amend its Premium Pricing Policy for Global Innovative Drugs to make it consistent with Korea's commitments under the KORUS FTA to ensure non-discriminatory treatment for U.S. pharmaceutical exports;
- Engaged with **Japan** to ensure transparency and fairness and address other concerns with respect to pharmaceutical and medical devices pricing and reimbursement policies;
- Pressed **China** on a range of issues affecting the pharmaceutical sector, including on the need to implement an effective mechanism for the early resolution of potential patent disputes; provide effective protection against unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical products; and provide a reliable and effective means of extending the patent term to compensate for the marketing approval review period and for patent office delays;
- Engaged with **India** to secure meaningful IP reforms on long-standing issues, including patentability criteria, criteria for compulsory licensing, and protection against unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical products;
- Pressed **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;
- Raised concerns with **Argentina**, including 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;

- Engaged with **Saudi Arabia** regarding the protection and enforcement of patents 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 products; and
- Sought confirmation that the **United Arab Emirates (UAE)** will continue to protect innovative pharmaceuticals through local procedures and the Gulf Cooperation Council patent system.

This year's Report continues to highlight 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, Indonesia, Malaysia, Russia, Turkey, and Ukraine**.

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 depend 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, 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 that compete with products manufactured domestically is a 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 United States-Australia Free Trade Agreement, **Australia** must provide that a pharmaceutical 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, particularly for the owners of pharmaceutical patents.
- **Canada** has drawn significant 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 long 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 since 2017 represent a retreat from previous progress made in this area. The United States has serious concerns regarding recent policy changes to the Price Maintenance Premium (PMP), a mechanism designed to accelerate the introduction of innovative drugs to the Japanese market. Several factors taken into consideration in PMP calculations, such as the number of local clinical trials and product launches, appear to make it easier for Japanese companies to qualify for the premium. Reimbursement outcomes under the PMP system suggest that U.S. companies, especially small- and medium-sized enterprises, are at a disadvantage compared to Japanese companies. The PMP revisions may also introduce significant uncertainty into pricing for patented pharmaceuticals, undermining investment planning for capital-intensive drug discovery research and clinical trials. The implementation of

the Cost-Effectiveness Assessment, a health technology assessment system, may add uncertainty for companies selling highly innovative and high-impact drugs and medical devices in Japan. Any assessment of healthcare spending should fairly evaluate all areas contributing to costs in the long term, rather than targeting a particular sector. These concerns will remain a priority for the United States, and the United States will continue to closely monitor the situation as it develops.

- 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. In March 2018, negotiations to improve and better implement the KORUS FTA concluded with a commitment from Korea to amend its Premium Pricing Policy for Global Innovative New Drugs to ensure non-discriminatory and fair treatment for pharmaceutical products and medical devices, including imported products and devices. Korea's implementation of this commitment has resulted in amendments that appear to make it so that very few, if any, companies or products will qualify for premium pricing. It is critical that Korea implement this commitment fully and in good faith, while also addressing continuing U.S. 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.
- 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.
- **Turkey** lacks efficiency, transparency, and fairness in its pharmaceutical manufacturing inspection process. Additionally, localization requirements for innovative pharmaceutical products and ongoing reimbursement issues continue to act as market access barriers.

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. 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, hurt local manufacturers, distributors, and retailers, and slow 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 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 procurement;
- 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**, investment and regulatory approvals, market access, government procurement, and the receipt of certain preferences or benefits may be conditioned on a firm's ability to demonstrate that IP is developed in or transferred to China, or is owned by or licensed to a Chinese party.

In **Indonesia**, 2016 amendments to the 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. Although Indonesia took steps to address some localization concerns by issuing a regulation

allowing for postponement of the local working requirements for patents, the law itself remains problematic. Compounding these concerns, Indonesia issued compulsory licensing regulations in late 2018 that include troubling localization provisions.

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 ICT, services, pharmaceuticals and medical devices, environmental technologies, and other manufacturing sectors, 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, 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, Malaysia, 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 the **European Union (EU)**, and **Taiwan**. Action in international organizations is also 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, titled “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, titled “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. Also, in November 2016, the Asia-Pacific Economic Cooperation (APEC) endorsed a set of “Best Practices in Trade Secret Protection and Enforcement Against Misappropriation,” which includes best practices such as: (1) broad standing for claims for the protection of trade secrets and enforcement against trade secret theft; (2) civil and criminal liability, as well as remedies and penalties, for trade secret theft; (3) robust procedural measures in enforcement proceedings; and (4) adoption of written measures that enhance protection against further disclosure when governments require the submission of trade secrets.

4. Geographical Indications

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, because it significantly undermines the scope of trademarks and other IP rights held by U.S. producers and imposes barriers on market access for American-made goods 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 trademark rights that pre-date the issuance of a GI. Trademarks are among the most effective ways for producers and companies, including small and medium-sized enterprises (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, transparent, and provide due process safeguards. Trademarks also deliver high levels of consumer awareness, significant contributions to gross domestic product (GDP) and employment, and accepted international systems of protection. The EU GI system undermines trademark protection and may result in consumer confusion to the extent that it permits the registration of GIs that are confusingly similar with prior trademarks.

Second, the EU GI system and strategy adversely 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. Argentina, South Africa, Uruguay, and 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 and 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 in certain EU regions, from using certain product names, such as fontina, gorgonzola, asiago, or feta. This is despite the fact that these terms are the common names for products and 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 must adopt burdensome workarounds. For example, in some markets, non-EU producers may sell their products only as “fontina-like,” “gorgonzola-kind,” “asiago-style,” or “imitation feta.” In other markets, non-EU producers may not even use such descriptors. This 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 GI system contributes to this asymmetry, which is acute in trade in agricultural products subject to the EU GI system. In the case of cheese, for example, where many EU products enjoy protection under the EU GI system, the EU exports over \$1 billion of cheese to the United States each year. Conversely, the United States exports only about \$5 million of cheese to the EU. Clearly, EU agricultural producers exporting to the United States are doing quite well, benefiting considerably from effective trademark protection, 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. In 2018, the United States urged the EU not to implement certain proposed changes to the EU’s Common Agricultural Policy, which, if adopted, would transfer much of the application review process to interested EU Member States and sharply reduce the period for filing a reasoned basis in support of an opposition to register a GI. As noted above, the EU has also 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 EU 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 that 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 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, Ecuador, Indonesia, Japan, Malaysia, Mexico, Morocco, Paraguay, the Philippines, Singapore, 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. 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 pirated 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, Indonesia, Mexico, Peru, Ukraine,** and **Vietnam**, online piracy is the most challenging copyright enforcement issue in many foreign markets. For example, countries such as **Argentina, Bulgaria, Canada, Chile, China, Colombia, Greece, India, Mexico, the Netherlands, Romania, Russia, Saudi Arabia, Switzerland,** and **Ukraine** have high levels of online piracy and lack effective enforcement. Still, stakeholders report some positive developments on efforts to combat online piracy. For instance, in **Peru**, right holders are encouraged by examples of successful enforcement against online piracy, including the first criminal case against online copyright infringement, and a substantial drop in the audience for websites devoted to pirated music. While the United States commends such enforcement actions, more needs to be done.

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 Out-of-Cycle Review of Notorious Markets (*Notorious Markets List*), illicit streaming devices (ISDs), also referred to as piracy devices, 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, the Dominican Republic, Hong Kong, India, Indonesia, Mexico, Peru, Saudi Arabia, Singapore, Taiwan,** the **UAE,** and **Vietnam**. China, in particular, is a manufacturing hub for these devices.

ISDs are part of a greater online piracy ecosystem, which includes apps and add-ons that enable the devices to be used to access pirated content. An example of an illicit operation that spans such an ecosystem is BeoutQ, an illicit pirate service widely available in **Saudi Arabia** and throughout the Middle East and Europe. As highlighted in the 2018 *Notorious Markets List*, BeoutQ's activities include satellite and online piracy, as well as supporting piracy devices and related services, such as apps and ISDs that allow access to unlicensed movies and television productions, including sports events.

Similar to ISDs, illegal Internet Protocol Television (IPTV) is an emerging threat as it unlawfully retransmits telecommunication signals and channels via dedicated web portals, third-party applications, and piracy devices. Today, there are over a thousand illegal IPTV services worldwide, many of which are subscription-based, for-profit services with vast and complex technical infrastructure.

Signal theft by cable operators continues to be a problem. In most cases, infringers circumvent encryption systems or otherwise unlawfully access cable or satellite signals to access content. Unauthorized distributors may also steal "overspill" broadcast or satellite signals from

neighboring countries, access broadcast signals, or otherwise hack set-top boxes to allow consumers unauthorized access to content, including premium cable channels. Hotels remain common sites of this type of infringement as they may use their own, on-site facilities to intercept programming services and retransmit them throughout the hotel without paying right holders.

The proliferation of “camcords” continues to be a significant 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 those by a single person sitting in a theater with a bulky videotape recorder. The results are not shaky, inaudible recordings. It is now easy for a surreptitious recording in a movie theater to result in a clean digital copy of a movie with perfect audio that can be quickly distributed online. The pirated version of the newly-released 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 continue to report a high number of illegal camcords this year. For example, in **Russia**, the total number of sourced camcords was 48 in 2018, with an additional 34 audio-only recordings. According to stakeholder reports, **Mexico** is now the second largest foreign source of illegally recorded films. In early 2019, **India**, a source of video and audio camcords, took important steps to issue revised draft legislation to criminalize illicit camcording. This legislation awaits consideration and passage by India’s Parliament. An increased volume of unauthorized camcording, including live streams of theatrical broadcasts online, has 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, which allowed cinema personnel to stop camcording, did not reverse the negative trend.

Countries also need to update legal frameworks to effectively deter unauthorized camcording and 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 **Argentina, Brazil, Ecuador, Peru, and Taiwan** do not effectively criminalize unauthorized camcording in theaters, although Peru has submitted draft legislation to address the issue. 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 listed in the Special 301 Report and include: the unauthorized retransmission of live sports programming online; the unauthorized cloning of cloud-based entertainment software, through reverse engineering or hacking, onto servers that allow users to play pirated content online, including pirated online games; 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 online and broadcast piracy.

6. Border, Criminal, and Online 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. The counterfeits are shipped either directly to purchasers or 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. According to an OECD study released in March 2019, titled “Trends in Trade in Counterfeit and Pirated Goods,” the global trade in counterfeit and pirated goods reached \$509 billion in 2016, accounting for 3.3 percent of the global trade in goods for that year.⁷ According to that study, **China** was the top origin economy for counterfeit and pirated goods, accounting for 47 percent of the world exports of counterfeit goods in 2016 with a total value of \$239 billion.⁸

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.

⁷ OECD/EUIPO (2019), *Trends in Trade in Counterfeit and Pirated Goods*, available at <http://www.oecd.org/governance/risk/trends-in-trade-in-counterfeit-and-pirated-goods-g2g9f533-en.htm>.

⁸ *Id.* at 46.

In particular, 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. Over 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.⁹

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. The United States 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 *ex officio* authority to seize suspect goods and destroy counterfeit goods in-country and at the border during import, export, or in-transit movement, without the need for a formal complaint from a right holder. For example, the re-exportation and transshipment of infringing goods in and through free trade zones (FTZs), particularly in Dubai but also in other emirates such as Ajman, Ras Al-Khaimah, and Sharjah, continue to undermine the UAE’s reputation for effective and proactive IP enforcement. According to the March 2019 OECD study, the value of counterfeit and pirated goods exported from the UAE, primarily through its FTZs, reached \$16 billion in 2016.¹⁰ 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 dissatisfaction with enforcement in **Singapore**’s FTZs, including concerns about the process for obtaining 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 the European Union Intellectual Property Office (EUIPO) published the joint study titled “Mapping the Real Routes of Trade in Fake Goods.”¹¹ This study traced the complex trade routes employed by counterfeiters across ten product categories and noted the

⁹ 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 available at <https://www.cbp.gov/trade/priority-issues/ipr/statistics>.

¹⁰ OECD/EUIPO (2019), *Trends in Trade in Counterfeit and Pirated Goods*, at 46, available at <http://www.oecd.org/governance/risk/trends-in-trade-in-counterfeit-and-pirated-goods-g2g9f533-en.htm>.

¹¹ OECD/EUIPO (2017), *Mapping the Real Routes of Trade in Fake Goods*, available at https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/Mapping_the_Real_Routes_of_Trade_in_Fake_Goods_en.pdf.

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 counterfeit goods amounted to \$284 billion in 2013. By 2016, the value of exports of counterfeit goods in those same categories had reached about \$292 billion, and the value of the ten most heavily exported product categories of counterfeit goods was about \$320 billion.¹² Also, in **Colombia**, the customs police reportedly does not have authority to enter primary inspection zones and lacks *ex officio* authority to inspect, seize, and destroy counterfeit goods in those zones. In certain sectors, other countries were found to be major counterfeit producers, including **India** for counterfeit medicines exported to Africa, Canada, the Caribbean, the EU, South America, and the United States; **Turkey** for counterfeit leather goods, foodstuffs, and cosmetics; and **Indonesia** for counterfeit foodstuffs.

Modern supply chains offer many new opportunities for counterfeit goods 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 OECD report released in March 2018, titled “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.¹³ 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 counterfeit goods, and taking certain remedial actions. The United States commends this effort by the ICC and the international shipping community.

Also, 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

¹² OECD/EUIPO (2019), *Trends in Trade in Counterfeit and Pirated Goods*, at 47, available at <http://www.oecd.org/governance/risk/trends-in-trade-in-counterfeit-and-pirated-goods-g2g9f533-en.htm>.

¹³ See International Chamber of Commerce (2018), *Know Your Customer*, available at <https://cdn.iccwbo.org/content/uploads/sites/3/2018/03/kyc-paper-doi-published.pdf>.

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**. The majority of the value of all counterfeit pharmaceuticals seized at the U.S. border in Fiscal Year 2018 was shipped from or transshipped through **China, Hong Kong, India, and Vietnam**. In particular, China and India are reportedly leading sources of counterfeit medicines distributed globally. While it may not be possible to determine an exact figure, studies have suggested that up to 20 percent of drugs sold in the Indian market are counterfeit and could represent a serious threat to patient health and safety. The U.S. Government, through the United States Agency for International Development and other federal agencies, supports programs in sub-Saharan Africa, Asia, and elsewhere that assist trading partners in protecting the public against counterfeit and substandard medicines in their markets.

The annual *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 Technology Co., Ltd., which reportedly provided domain name services to over 2,300 known illicit 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. Following the termination of Nanjing Imperiosus Technology, other registrars, including those in Indonesia and Turkey, have reportedly taken action to disrupt illicit online pharmacy operators. The 2018 *Notorious Markets List* continues to call attention to domain registers that serve as havens for online sellers of counterfeit pharmaceuticals, this time highlighting Hosting Concepts B.V. and Regional Network Information Center.

USTR also notes the proliferation of counterfeit goods for sale on online marketplaces, particularly through platforms that permit consumer-to-consumer sales. USTR urges e-commerce platforms to take proactive and effective steps to reduce piracy and counterfeiting, for example, by establishing and adhering to strong quality control procedures in both direct-to-consumer and consumer-to-consumer sales, engaging with right holders to quickly address complaints, and working with law enforcement to identify IP violators.

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**, 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. In the **UAE**, the Ministry of Economy's failure to issue the necessary operating licenses to allow copyright licensing and royalty payments represents a 16-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 remains non-functional. While **Ukraine** passed legislation seeking to reform its CMO regime and combat the prevalence of rogue CMOs operating freely in Ukraine,

significant concerns remain with the law, including those pertaining to royalty rate calculations. It is critical that Ukraine pursue amendments to the law to ensure that there is a transparent, fair, and predictable system for the collective management of royalties in Ukraine.

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** lacks effective tools to combat widespread bad faith trademark applications, suffers from inflexibility in relation to descriptions of goods and services, gives insufficient legal weight to notarized and legalized witness declarations in China Trademark Office and Trademark Review and Adjudication Board proceedings, has unreasonably high standards for establishing well-known mark status, and lacks 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.

Another concern includes 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 costs, 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 ccTLD registrars have helpful policies that prohibit cybersquatting, require the registrant to provide true and complete contact

information, and make such registration information publicly available.¹⁴ However, the ccTLD registrars 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 \$46 billion in 2018.¹⁵ 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, Brazil, Chile, China, Costa Rica, Egypt, Greece, Indonesia, Kenya, Mexico, Nigeria, the Philippines, Romania, Russia, Thailand, Ukraine, and Vietnam**. The United States urges trading partners to adopt and implement effective and transparent procedures to ensure legitimate governmental use of software.

11. Other Issues

U.S. stakeholders have expressed views with respect to the EU Digital Single Market Directive on Copyright. The United States continues to monitor copyright issues in the EU and its Member States and will continue to engage with various EU and Member State entities to address the equities of U.S. stakeholders. The United States urges the European Commission to engage closely with stakeholders as it develops guidance on certain implementation issues. It is also critical that EU Member States ensure full transparency in the implementation process with meaningful opportunities for stakeholders to provide input.

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

USTR notes the following important developments in 2018 and early 2019:

- **Tajikistan** is not being placed on the Watch List this year due to concrete steps Tajikistan took to improve its IP regime. Specifically, mandating *ex officio* authority for customs officials and issuing a presidential-level decree to facilitate the use of licensed software in government agencies represented tangible progress towards addressing long-standing issues pertaining to IP protection and enforcement in the country.

¹⁴ For example, in June 2018, the European Registry of Internet Domains and the International AntiCounterfeiting Coalition announced a joint initiative to combat cybercrime on .eu and .europa domain names, with a focus on clearing the registration database of fraudulent domain names through the exchange of knowledge and support pertaining to cybercrime, specifically counterfeiting and piracy. Also, Denmark's ccTLD body, DK Hostmaster, created stricter identity checks at the end of 2017, which DK Hostmaster claims have helped combat IP infringement.

¹⁵ 2018 Global Software Survey (BSA), at 11, available at https://www.bsa.org/~media/Files/StudiesDownload/2018_BSA_GSS_Report_en.pdf.

- **Costa Rica** took important steps to address two long-standing obstacles to IP protection. It issued an amended decree that requires generic terms in compound names to be identified and another decree that clarifies that online service providers must expeditiously remove alleged infringing content to participate in the notice-and-takedown system.
- **Colombia** took necessary steps to update its copyright law and improve copyright protection through legislative amendments, which included the right to authorize the making available to the public of the original and copies of performances and phonograms, civil liability for circumvention of TPMs, statutory damages provisions, and the extension of the copyright term for sound recordings and corporate right holders.
- **Brazil** reinvigorated the dormant Council on Combatting Piracy and Intellectual Property Crimes, and the Brazil film agency created a Technical Working Group to Combat Piracy.
- **Chile** passed a satellite piracy law that criminalizes the commercialization of a device or system that decodes an encrypted program-carrying satellite signal without the authorization of the legal distributor of the signal. The United States looks forward to further engaging with Chile to ensure that this law fully implements its Free Trade Agreement obligations.
- In **Taiwan**, the Intellectual Property Office issued a public notice clarifying that the Copyright Act was applicable not only to prohibiting peer-to-peer infringement, but also infringement through all forms of technology used to publicly transmit or reproduce works.
- **India** issued revised draft legislation to criminalize illicit camcording that currently stands before Parliament. In early March 2019, India's Office of Controller General of Patents, Designs, and Trademarks issued a revised Manual of Patent Office Practice and Procedure that eliminated significant burdens on patent applicants by minimizing international patent reporting requirements.
- The United States and the **Philippines** issued a joint statement in October 2018 addressing several outstanding Trade and Investment Framework Agreement (TIFA) issues. As part of the joint statement, the Philippines committed to continue protecting GIs in a manner mutually beneficial to both countries by ensuring transparency, due process, and fairness in the laws, regulations, and practices that provide for the protection of GIs, respecting prior trademark rights, and not restricting the use of common names. The United States welcomes the commitment of the Philippines to further discuss ways to ensure that Philippine laws, regulations, and policies do not restrict or prohibit entry of U.S. products into the Philippine market. The Philippines also confirmed that it will not provide automatic GI protection, including pursuant to terms exchanged as part of a trade agreement.
- In September 2018, following the approval of the amended Copyright Act in 2017 and implementing decree, **Greece** established the Committee for Notification of Copyright and

Related Rights Infringement on the Internet. Since November 2018, the Committee has reportedly issued multiple decisions and has ordered Internet service providers (ISPs) to take action against several sites with pirated content.

- As of April 2019, there are 75 members of the 1991 Act of the International Union for the Protection of New Varieties of Plants Convention (UPOV 91). UPOV 91 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.
- As of April 2019, there are 100 parties to the WIPO Performances and Phonograms Treaty and 100 parties to the WIPO Copyright Treaty, 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.

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 of 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 Intellectual Property Rights 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. Other examples

include the Special Internet Forensics Unit in **Malaysia's** Ministry of Domestic Trade, Cooperatives, and Consumerism responsible for IP enforcement, and **Jamaica's** establishment of a specialized intellectual property vice-squad within the Jamaica Constabulary Force.

- Many trading partners conducted IP awareness and educational campaigns, including jointly with stakeholders, to develop support for domestic IP initiatives. In **Spain**, the Ministry of Education and the Ministry of Culture and Sport 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. **Paraguay's** National Directorate of Intellectual Property has reportedly undertaken 45 IP workshops and trained over 7,485 people including students, private sector representatives, and government officials. The **Philippines** created an IP Academy to develop IP education programs that incorporate international aspects and adopt a multi-disciplinary approach to addressing IP issues. **Taiwan** worked with right holders to organize dozens of outreach campaigns for students and created training seminars to reach multiple sectors of the government to address IP rights, piracy, and camcording.
- Another best practice is the active participation of government officials in technical assistance and capacity building. **Mexico** engaged with trading partners in ongoing training programs. **Singapore** collects manifest data from 11 major shipping lines as part of its World Customs Organization Cargo Targeting System and maintains a strong working relationship conducting joint investigations with U.S. Immigration and Customs Enforcement/Homeland Security Investigations. **Romania's** economic police officers were involved in 57 international IP operations, working groups, and training programs, including Europol's IP Crime Coordinated Coalition working group. 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**. These efforts are critical, as stakeholders have raised concerns regarding the use of multilateral institutions to undermine IP rights by some member countries. 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 2018, 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 innovation, entitled "The Societal Value of Intellectual Property in the New Economy." The United States co-sponsored three submissions under this year-long theme with Members, including Australia, Canada, Chinese Taipei, the EU, Japan, the Republic of Korea, Singapore, and Switzerland, examining how IP protection and enforcement helps to create conditions that

encourage risk-taking and investments in innovation of all kinds, including in the development of new technologies, new solutions to business challenges, new cultural and artistic expressions, and the means to distribute such works to the public. The United States advanced discussion among member states at TRIPS Council meetings in 2018 on how IP protection and enforcement help to create new businesses and expand opportunities for individuals and societies.

During the IP and Innovation portion of three 2018 TRIPS Council meetings in February, June, and November, Members shared experiences of how IP-intensive industries have contributed to the development of their economies, relaying examples of inventions and creations made possible by IP systems that have improved and enriched lives, and examined the role that IP can play in stimulating and supporting new businesses. The United States contributed empirical data and studies that demonstrated the critical role that IP protection plays in the U.S. economy and employment throughout the life cycle of a business. The United States also contributed specific examples of cross-cultural exchanges facilitated by copyright protection, technological breakthroughs made possible by the U.S. patent system that have improved the lives of millions of visually-impaired individuals, and U.S.-sponsored programs dedicated to promoting international creative exchanges and innovative solutions to global challenges.

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. At the May 2018 U.S.-**Indonesia** TIFA meeting, the United States and Indonesia formally adopted an IP work plan that sets a roadmap for addressing concerns identified with respect to Indonesia in previous Special 301 Reports. At the May 2018 U.S.-**Saudi Arabia** TIFA meeting, the United States and Saudi Arabia discussed IP priorities in Saudi Arabia, including pharmaceutical IP protection, online and signal piracy, and enforcement. Engagement in 2018 under the U.S.-**Philippines** TIFA resulted in positive progress on GI issues (see Section B for more details). In May 2018, the U.S.-**Argentina** Innovation and Creativity Forum for Economic Development held its third meeting to discuss IP issues that are essential to the success of each country's innovation economy. A digital video conference was held between the United States and Argentina in November 2018 to follow-up on certain issues, including the progress on updates to Argentina's criminal code and copyright law.
- During the November 2018 meetings of the United States-**United Kingdom** (UK) Trade and Investment Working Group, the United States and the UK continued to recognize the importance of IP to their respective economies and to their bilateral trade relationship, and agreed to continue discussions on a range of IP concerns, including enforcement approaches and policy tools. At the October 2018 Transatlantic IP Working Group

meeting, the United States and the **EU** discussed enforcement cooperation in third-countries and in multilateral fora.

- In the October 2018 U.S.-**Algeria** TIFA meeting, the United States continued to emphasize that IP-related market access barriers, such as the prohibition on the importation of pharmaceutical products that compete with similar, domestically-produced goods, stifle investment in Algeria. Also, at the December 2018 U.S.-**Moldova** Joint Commercial Commission meeting, the United States stressed the need for effective enforcement of IP rights in order to support innovative and creative industries and encourage investment in Moldova. In addition, the October 2018 U.S.-**Ukraine** Trade and Investment Council meeting provided an opportunity for the United States to applaud the growing bilateral engagement on IP issues and voice concerns regarding online piracy, the use of unlicensed software by government agencies, and the shortcomings of the recently passed CMO law.

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

- In 2018, 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 a U.S.-led initiative on patent grace period harmonization that took the form of a multi-panel workshop consisting of government representatives and IP industry counsel. A consistent patent grace period helps to facilitate IP protection for SMEs, which are often strapped for resources, and research institutions, which are driven by international collaboration. Additionally, in 2018 within the APEC Subcommittee on Customs Procedures, the United States introduced and coordinated a joint IPR enforcement operation that built upon past joint operational work in APEC. The operation focused primarily on interdicting counterfeit consumer electronics with nine APEC economies participating (Australia, Chile, Chinese Taipei, Hong Kong, Mexico, Japan, Singapore, the United States, and Vietnam). The operation helped to raise awareness on successful cross-border enforcement practices and highlighted developments and trends related to consumer electronics in the Asia-Pacific region.
- At the October 2018 U.S.-Central Asia TIFA meeting, participants launched the Central Asia IP Working Group, which will provide a mechanism to improve the IP regime in the region. Specifically, the IP Working Group agreed to address long-standing IP issues in the region, including: (1) protecting foreign sound recordings, including accession to the Geneva Phonograms Treaty and WIPO Internet Treaties; (2) improving enforcement of IP rights for hard goods and in the digital environment by providing the necessary legal framework to stem the illicit trade in counterfeit goods and piracy; (3) enhancing the capacity of government efforts to implement international best practices for IP protection and enforcement; and (4) facilitating the use of licensed software by government authorities.
- 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 Generalized System of

Preferences (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 2018, 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 and unlicensed and uncompensated use of copyrighted music. Heightened engagement on a regional basis, including conferences and trainings in the **Dominican Republic, Jamaica**, and others, with strong U.S. Government leadership and participation, has led to increased expertise, awareness, and initial positive steps. The United States is looking forward to increased engagement on this topic in 2019.

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 2019 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 (LDCs), 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 United Nations and related institutions, such as WIPO and the World Health Organization, 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, the Office of the U.S. Trade Representative 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 LDCs, 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 United States will use all available means to resolve concerns, including bilateral dialogue and enforcement tools such as 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 United States 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 China that may be unreasonable or discriminatory and that may be harming U.S. IP rights, innovation, or technology development. *See* 82 FR 39007. After consultation with the appropriate advisory committees and the interagency Section 301 Committee, on August 18, 2017, the Office of the U.S. Trade Representative initiated an investigation into certain acts, policies, and practices of China related to technology transfer, IP, 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 United States Trade Representative had advised that the investigation supports findings that acts, policies, and practices of China related to technology transfer, IP, and innovation covered in the investigation are unreasonable or discriminatory and burden or restrict U.S. commerce. The President directed the United States Trade Representative to take all appropriate action under Section 301, including considering increased tariffs on goods from China. On March 23, 2018, the United States requested consultations with China under the WTO Dispute Settlement Understanding (in matter DS542), and on April 3, 2018, the Office of the U.S. Trade Representative published a proposed list of imports from China, worth approximately \$50 billion, that could be subject to additional tariffs. In November 2018, the Office of the U.S. Trade Representative issued an updated report that found that China had not fundamentally altered its

unfair, unreasonable, and market-distorting policies and practices. On the basis of the Office of the U.S. Trade Representative's investigation, the United States has imposed additional tariffs on \$250 billion worth of Chinese imports. 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 copyrights and trademarks on a wide range of products. In March 2009, the WTO Dispute Settlement Body (DSB) adopted a panel report that upheld two of the claims advanced by the United States, finding that: (1) China's denial of copyright protection to works that do not meet China's content review standards is impermissible under the TRIPS Agreement; and (2) China's customs rules cannot allow seized counterfeit goods to be publicly auctioned after only removing the spurious trademark. With respect to a third claim concerning China's thresholds for criminal prosecution and conviction of counterfeiting and piracy, while the United States prevailed on the interpretation of the important legal standards in Article 61 of the TRIPS Agreement, including the finding that criminal enforcement measures must reflect and respond to the realities of the commercial marketplace, the panel found that it needed additional evidence before it could uphold the overall U.S. claim that China's criminal thresholds are too high. On March 19, 2010, China announced that it had completed all the necessary domestic legislative procedures to implement the DSB recommendations and rulings. The United States continues to monitor China's implementation of the DSB recommendations and rulings in this dispute.

In addition, the United States requested WTO dispute settlement consultations with China concerning certain other Chinese measures affecting market access and distribution for imported publications, movies, music, and audio-visual home entertainment products, such as 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 a Memorandum of Understanding 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 that the United States has asked the EU to address. The United States intends to continue monitoring this situation. The United States is also working 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 2019, and is subject to continuing Section 306 monitoring.

Ongoing Challenges and Concerns

Despite a broad government reorganization, including of intellectual property (IP) responsibilities among government agencies, and proposed revisions to IP laws and regulations, China failed to make fundamental structural changes to strengthen IP protection and enforcement, 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. For U.S. persons who rely on IP protection in what is already a very difficult business environment, severe challenges persist because of gaps in the scope of IP protection, stalled legal reforms, and weak enforcement channels.

As part of an investigation under Section 301 of the Trade Act of 1974 on policies and practices related to technology transfer and IP, the United States found that China has engaged in a range of unfair and harmful conduct, including investment and other regulatory requirements that require or pressure technology transfer, discriminatory licensing restrictions, direction or facilitation of the acquisition of foreign companies and assets by domestic firms to obtain cutting-edge technologies, and conducting and supporting unauthorized intrusions and theft from computer networks of U.S. companies to obtain unauthorized access to IP. The Section 301 investigation and remedies have prompted numerous high-level discussions between the United States and China, which are ongoing.

High-profile statements in support of IP and innovation by Chinese government officials are no substitute for real structural changes to address shortcomings in China's IP system, which cannot be excused by the country's stage of economic development. The United States, other countries, and the private sector continue to urge China to embrace meaningful and deep reform to its IP-related legal and regulatory framework. The results to date have represented missed opportunities to address priority concerns of the United States and others, including where China's proposed revisions to legal and regulatory measures fail to adopt U.S. recommendations for reform. Necessary progress will not be achieved unless China can demonstrate its resolve to protect and enforce IP rights. For these reasons, as elaborated below, China remains a precarious and uncertain environment for U.S. right holders.

Developments, Including Progress and Actions Taken

As discussed below, although China has reorganized its IP protection and enforcement authorities and proposed draft amendments to certain IP-related legal and regulatory measures, these steps toward reform fall short of needed fundamental changes to the IP landscape in China.

In March 2018, China instituted broad changes to the organization of ministries and agencies responsible for the protection and enforcement of IP. China created a new State Administration for Market Regulation (SAMR), which centralized responsibilities for administrative enforcement of patents and trademarks, enforcement of the Anti-Monopoly Law, regulatory approval of pharmaceutical products, and standards setting, among other responsibilities. The China Trademark Office was moved under the State Intellectual Property Office (SIPO) and took on the administration of China's geographical indication (GI) system. SIPO moved under the newly created SAMR, and is now known as the China National Intellectual Property Administration (CNIPA). As a separate part of the reorganization, the National Copyright Administration moved from the State Administration of Press, Publication, Radio, Film, and Television to the Central Propaganda Department of the Communist Party of China. The drug and medical device related components of China's Food and Drug Administration became the National Medical Products Administration. Given their recent completion, it is too soon to determine whether these efforts to reorganize and centralize administration and enforcement of IP will be positive for right holders.

China has continued with judicial reforms in the past year. The most prominent change was the establishment of a new appellate tribunal within the Supreme People's Court (SPC), titled the "SPC IP Court," on January 1, 2019. The new SPC IP Court has jurisdiction over appeals of decisions from lower courts in technically-complex IP cases, as well as appeals of certain administrative enforcement decisions. As the three intermediate-level specialized IP Courts reportedly demonstrate competence, expertise, and transparency to a greater degree than other Chinese courts, the SPC IP Court is a promising step for improved consistency in outcomes. After the establishment of the Hangzhou Internet Court, which typically addressed disputes arising from Internet services in half the time as conventional courts, China created two new Internet courts in Beijing and Shanghai. Notwithstanding these positive developments, U.S. right holders report that procedural obstacles to appealing decisions of the CNIPA Trademark Adjudication Board to the Beijing IP Court are sometimes insurmountable and may discourage appeals altogether. A broader concern is intervention by local government officials, party officials, and powerful local interests, which undermines 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, right holders continue to report that burdensome thresholds for criminal enforcement, onerous authentication and other evidentiary requirements, lack of means to require evidence production, insufficient damage awards, and lack of deterrent-level statutory damages and criminal penalties all undermine the effectiveness of China's court system for addressing IP infringement.

Trade Secrets

China's 2017 amendment of the Anti-Unfair Competition Law (AUCL) went into effect on

January 1, 2018. The amended AUCL represented a major missed opportunity to address critical concerns, 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.

One particular area for continued monitoring is the availability of preliminary injunctions in trade secret and other IP disputes. A new judicial interpretation, titled the “Provisions of the Supreme People’s Court Regarding Certain Issues Concerning the Application of Law During the Examination of Act Preservation in Intellectual Property and Competition Disputes,” went into effect on January 1, 2019. It remains unclear whether, in practice, this judicial interpretation will enable right holders to obtain timely preliminary injunctions against all categories of trade secret misappropriation.

China should not only address these shortcomings, but also issue guiding court decisions to improve consistency in judicial decisions on trade secrets. Reforms also should 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 continued to be the world’s leading source of counterfeit goods, reflecting its failure to take decisive action to curb the widespread manufacture, domestic sale, and export of counterfeit goods. According to a 2019 Organisation for Economic Co-operation and Development (OECD) report, China together with Hong Kong, through which Chinese merchandise often transships, continued to account for over 80 percent of seizures of counterfeit and pirated goods worldwide.¹⁶ Applying a different methodology, another analysis from the 2019 OECD report analyzed 2016 data and estimated that China and Hong Kong were the source of \$322 billion in fake exports, around 63.4 percent of the global total.¹⁷ This massive problem impacts not only the interests of IP right holders, but also poses health and safety risks. Right holders report that the production, distribution, and sale of counterfeit medicines, fertilizers, pesticides, and under-regulated pharmaceutical ingredients remain widespread in China.

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. In February 2019, CNIPA issued for comment a new draft measure, titled “Provisions on Regulating the Registration of Trademark Applications,” to combat “abnormal” applications, including applications submitted in

¹⁶ *Trends in Trade in Counterfeit and Pirated Goods*, at 27-28, available at <https://euipo.europa.eu/ohimportal/en/web/observatory/trends-in-trade-in-counterfeit-and-pirated-goods>.

¹⁷ *Id.* at 46.

bad faith. The United States has provided China detailed comments on the draft, identifying the need to clarify key provisions and include additional actions if it is to help curb bad faith trademark registrations in China. Other critical reforms should be addressed by amendments to the Trademark Law and related implementing regulations.

E-Commerce Piracy, Counterfeiting, and Other Issues

As China has become the largest e-commerce market in the world, widespread online piracy and counterfeiting in e-commerce markets represent critical concerns for U.S. right holders. According to published reports, online retail sales in China are expected to grow to \$1.9 trillion in 2019.¹⁸ OECD reports have noted that the growth of small parcels carrying counterfeit and pirated goods reflected the move from offline to online sales,¹⁹ and China together with Hong Kong have been the leading source of seized counterfeit goods shipped by mail or express couriers.²⁰ Right holders report that online sellers of counterfeit goods often advertise that orders will be fulfilled via China Post's express mail service and exploit the high volume of packages to the United States to escape enforcement. Furthermore, although some leading online sales platforms have reportedly streamlined procedures to remove offerings of infringing articles and enhanced cooperation with stakeholders to improve criminal and civil enforcement of IP, right holders continue to express concerns about ineffective takedown procedures, slowness to respond to small and medium-sized enterprises (SMEs), and insufficient measures to deter repeat infringers. Other right holders report growing online piracy in the form of thousands of "mini Video on Demand" (VOD) locations that show unauthorized audiovisual content and online platforms that disseminate unauthorized copies of scientific, technical, and medical journal articles and academic texts. A range of such concerns led to the re-listing of DHgate.com and Alibaba online sales platform Taobao as notorious markets in the 2018 Out-of-Cycle Review of Notorious Markets (*Notorious Markets List*), as well as the first-time listing of Pinduoduo.com.

The new E-Commerce Law took effect on January 1, 2019. Despite extensive U.S. engagement regarding drafts of the law, China failed to address major concerns regarding provisions that would impose burdensome requirements on right holders seeking to enforce their IP, while allowing infringing sellers to halt takedown procedures through submission of counter-notifications that lack sufficient information to ensure their validity and without penalties for submissions in bad faith. It is critical that the E-Commerce Law, as implemented, does not undermine the existing framework for Internet service provider notices of copyright infringement and cease-and-desist letters. A further negative signal was the issuance of a draft Tort Liability Chapter of the Civil Code that contained similar provisions to problematic portions of the E-Commerce Law. The final version of the Tort Liability Chapter should implement a predictable legal environment that promotes effective cooperation among interested parties in deterring online copyright infringement.

¹⁸ *Chinese Retail Sales Are Set to Dwarf U.S. Sales This Year* (Jan. 23, 2019), available at <https://www.washingtonpost.com/business/2019/01/23/chinese-retail-sales-are-set-dwarf-us-sales-this-year/>.

¹⁹ *Trends in Trade in Counterfeit and Pirated Goods*, at 19-20, available at <https://euipo.europa.eu/ohimportal/en/web/observatory/trends-in-trade-in-counterfeit-and-pirated-goods>.

²⁰ *Misuse of Small Parcels for Trade in Counterfeit Goods*, at 42-43, available at <https://euipo.europa.eu/ohimportal/en/web/observatory/trade-in-fakes-in-small-parcels>.

In 2018, 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, such as prohibitions in the Foreign Investment Catalogue and requirements that state-owned enterprise hold an ownership stake in online platforms for film and television content. Right holders report that growing advance approval requirements and other barriers have reduced the availability of foreign television content and prevented the simultaneous release of foreign content in China and other markets. 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.

As a leading source and exporter of systems that facilitate copyright piracy, China should take sustained action against websites containing or facilitating access to unlicensed content, illicit streaming devices, and piracy apps that facilitate access to such websites. Short-lived campaigns are no substitute for deterrent-level criminal sanctions to combat online piracy and the circumvention of technological protection measures used to protect licensed content.

Need to Promote Innovation through Sound Patent and Related Policies

On January 4, 2019, China released a new draft of amendments to the Patent Law. Promising provisions include extension of the design patent term, availability of increased punitive damages for willful patent infringement, and discretionary authority for a court to order production of damages-related evidence. However, strong concerns remain about the presence of competition law concepts in the draft law, an undue emphasis on administrative enforcement, and the absence of critical reforms, as described below.

Major challenges confront pharmaceutical innovators attempting to protect and enforce their IP rights in China. Despite revisions to China's patent examination guidelines in April 2017, pharmaceutical innovators report that they are not permitted to rely on supplemental data on a consistent basis to satisfy relevant requirements for patentability during patent examination proceedings, patent review proceedings, and judicial proceedings. This practice leads to application denials, or the invalidation of existing patents, even when counterpart patents are granted by other major patenting offices. China also continues to impose unfair and discriminatory conditions on the effective protection against unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical products. China provides such protection only if the drug in question has not previously received marketing authorization outside China, which is an unfair and discriminatory condition that is unrelated to the purpose of such protection. Despite issuing for comment draft opinions and amendments to measures, China also has failed to establish an effective mechanism for the early resolution of potential pharmaceutical patent disputes. China additionally has failed to provide patent term extensions to compensate for unreasonable delays that occur in granting a patent (a concern not limited to pharmaceutical patents) or in relation to marketing approvals. Draft amendments to the Patent Law to provide for such extensions in relation to marketing approvals were unsatisfactory in part because extensions would be available only to patent holders that file for marketing approval of a pharmaceutical simultaneously in China and another jurisdiction. The

draft amendments failed to provide extensions for patent office delays and granted extensions only on a discretionary basis without a clear elaboration of the factors governing such a determination. China should also address delays, a lack of transparency, and inadequate engagement with pharmaceutical suppliers in government pricing and reimbursement processes.

China must address each of these concerns to better promote pharmaceutical innovation and bring China into closer alignment with the practices of other major patenting jurisdictions. In addition, China should address continuing problems with the difficulty in obtaining evidence of infringement, the disclosure obligations in standards-setting processes, the 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.

On November 21, 2018, three dozen Chinese ministries and authorities issued a memorandum of understanding imposing "social credit system" penalties for certain categories of patent-related conduct, including repeated infringement of an adjudicated patent and misconduct in the course of patent prosecution. The United States objects to any attempt to expand the "social credit system" in the field of intellectual property.

The Standardization Law took effect on January 1, 2018, and China subsequently issued draft administrative measures for the management of mandatory standards and final administrative measures for management of association standards. These measures nonetheless failed to establish that standards-setting processes are open to domestic and foreign participants on a non-discriminatory basis and provide sufficient protections for standards-related copyright and patent rights.

In 2018, Chinese authorities indicated that draft guidelines for Anti-Monopoly Law (AML) enforcement, as it relates to IP rights, have been approved for issuance. In January 2019, China published for public comment draft Rules for the Prohibition of Abuse of Market Dominance Conduct, specifying that the ownership of IP and refusal to enter transactions are factors to examine. These draft provisions heighten concerns that China's competition authorities may continue to 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, despite the United States repeatedly expressing strong concerns regarding this practice. 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.

Pending Copyright Law Amendments

Chinese authorities have indicated that they made progress toward draft amendments of the Copyright Law, but no draft has been published. It is critical to address major deficiencies in China's copyright framework, such as the failure to provide deterrent-level remedies and penalties, protection against unauthorized transmission of sports and other live broadcasts, and effective criminal enforcement, including amendments to the Regulations on the Transfer of Alleged Criminal Cases by Administrative Enforcement Organs to adopt a "reasonable suspicion" threshold for the transfer of administrative cases to criminal investigation and prosecution.

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

On March 22, 2018, based on an investigation in response to a Presidential memorandum, the United States Trade Representative issued a detailed report that supports a finding that China's acts, policies, and practices that force or pressure U.S. right holders to transfer technology and IP 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 IP 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 directed the United States 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 direction from the President, and after the submission of written comments by interested parties and public hearings, the United States Trade Representative imposed increased tariffs on certain goods of Chinese origin in several tranches. 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. In November 2018, the United States Trade Representative issued another detailed report, explaining that China had not fundamentally altered the unfair, unreasonable, and market-distorting policies and practices that were the subject of the March 2018 report. In December 2018, at a meeting between the President and China's President Xi Jinping in Buenos Aires, the United States agreed to hold off on raising the duty rate on certain goods while the two sides engaged in intensive negotiations for 90 days on the structural changes needed in China's trade regime. On February 24, 2019, in light of progress in discussions with China, the President directed the United States Trade Representative to postpone the increase in tariffs scheduled for March 2, 2019.

In March 2018, 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. Consultations took place in July 2018, a panel was established to hear the case in November 2018, and the United States filed its first written submission in March 2019.

China's "Secure and Controllable" Policies

Since enacting its Cybersecurity Law (CSL) in 2017, China has taken multiple steps backward through its efforts to invoke 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. Through draft and final measures, China has often applied the poorly-defined concept of "secure and controllable" information communications technology (ICT) products and services and associated "risk" factors as a putative justification for erecting barriers to sale and use in China.

On June 27, 2018, China released draft Cybersecurity Classified Protection Regulations (CCPR), which represent a continuation of the Multi-Level Protection Scheme requirements that, among other restrictions, limit procurement of software and other ICT products for purportedly sensitive systems to those containing indigenous Chinese IP. The CCPR imposed restrictions on networks operating within China, such as requiring that certain systems be connected with the Public Security Bureau system and that technical maintenance be performed within China. In September 2018, the Ministry of Public Security released the Internet Security Supervision and Inspection Provisions by Public Security Organs, which authorized public security authorities to enforce the CSL. As previously reported, pursuant to the CSL, China may require disclosure of critical source code and IP to government authorities, require IP rights be owned in China, require associated research and development be conducted in China, and curtail or prohibit cross border data flows in sectors such as cloud services.

Right holders continue to report strong concerns about other draft and final measures, particularly requirements for public disclosure of enterprise standards under the amended Standardization Law. The draft standards published by the National Information Security Standardization Technical Committee (TC-260) would assign scores to ICT products based on inappropriate benchmarks (*e.g.*, the extent to which a party discloses sensitive IP). The draft Encryption Law would impose severe restrictions on foreign businesses to keep them from competing in the commercial cryptography market.

U.S. right holders should not be forced to choose between protecting their IP against unwarranted disclosure and competing for sales in China. 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 limit parties' abilities to challenge GI's via 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. In late February 2019, CNIPA issued for comment draft revisions to the Measure on Protection of Foreign Geographical Indication Products. In detailed comments on the draft, the United States explained that it is critical that the final version of the revisions ensure full transparency and procedural fairness with respect to the protection of GIs, including safeguards for generic terms, respect for prior trademark rights, clear procedures to allow for opposition and cancellation, and fair market access for U.S. exports to China relying on trademarks or the use of generic terms.

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. Right holders report that government and SOE software legalization programs still are not implemented comprehensively and urge the use of external audits to ensure accountability. Though it reflects a slight decline from past years, the reported 66 percent rate of unlicensed software use in China represents \$6.8 billion in lost commercial value, far above regional and global rates.

Finally, stakeholders have identified concerns relating to opposition examiners at the China Trademark Office, who face very large dockets and whose decisions on likelihood of confusion are often narrowly focused on goods or services in the same sub-class rather than also taking into account goods and services in other classes and other market realities. 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, lack of transparency in opposition proceedings, absence of default judgments against applicants who fail to appear, and legitimate right holders' difficulty in obtaining well-known trademark status. Moreover, changes to trademark opposition procedures eliminated appeals for opposers, which resulted in longer windows for bad-faith trademark registrants to use their marks—or blackmail the legitimate brand owner—before a decision is made in an invalidation proceeding.

INDONESIA

Indonesia remains on the Priority Watch List in 2019.

Ongoing Challenges and Concerns

U.S. right holders continue to face challenges in Indonesia with respect to adequate and effective intellectual property (IP) protection and enforcement, as well as fair and equitable market access. Concerns include widespread piracy and counterfeiting and, in particular, the lack of enforcement against dangerous counterfeit products. To address these issues, Indonesia would need to develop and fully fund a robust and coordinated IP enforcement effort that includes deterrent-level penalties for IP infringement in physical markets and online. Indonesia's law concerning geographical indications (GIs) raises questions about the effect of new GI registrations on pre-existing trademark rights and the ability to use common food names. Indonesia's Patent Law continues to raise 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. 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. After acceding to the Madrid Protocol for the international registration of trademarks in 2018, Indonesia issued implementing regulations. 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 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 develop 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 2018, the Ministry of Law and Human Rights (MLHR) issued Regulation 15/2018, which provides welcome allowances for patent holders to request postponement of the Patent Law's problematic local working requirement, but the United States continues to encourage Indonesia to amend the 2016 Patent Law to eliminate this requirement entirely. In late 2018, MLHR issued, without an opportunity for public comment, Regulation 39/2018, which establishes procedures for compulsory licenses that raise serious concerns from the perspective of IP rights and trade policy, transparency and due process, and global innovation. Indonesia also has imposed excessive and inappropriate penalties upon patent holders as an incentive to collect patent maintenance fees. As Indonesia continues to develop implementing regulations for the Patent Law, the United States urges Indonesia to address these concerns and to provide affected stakeholders with meaningful opportunities for input. The United States welcomes Indonesia's agreement to a bilateral Intellectual Property Rights Work Plan under the U.S.-Indonesia Trade and Investment Framework Agreement and plans continued, intensified engagement with Indonesia to address these important issues.

SOUTH AND CENTRAL ASIA

INDIA

India remains on the Priority Watch List in 2019.

Ongoing Challenges and Concerns

Over the past year, India took steps to address intellectual property (IP) challenges and promote IP protection and enforcement. However, many of the actions have not yet translated into concrete benefits for innovators and creators, and long-standing deficiencies persist. 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 long-standing 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. Furthermore, patent applicants face costly and time-consuming patent opposition hurdles, long timelines for receiving patents, and excessive reporting requirements.

In the pharmaceutical and agricultural chemical sectors, India continues to lack an effective system for protecting against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for such products. In the pharmaceutical sector, Section 3(d) of the India Patents Act restricts patent-eligible subject matter in a way that fails to properly incentivize innovation that would lead to the development of improvements with benefits for Indian patients. 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. Despite India's justifications of limiting IP protections as a way to promote access to technologies, India maintains extremely high customs duties directed to IP-intensive products, such as medical devices, pharmaceuticals, information communications technology (ICT) products, solar energy equipment, and capital goods. India still maintains the draft Ministry of Agriculture and Farmers Welfare's "Licensing and Formats for Genetically-Modified Technology Agreement Guidelines, 2016" that contain overly prescriptive terms and imposes mandatory licensing requirements that, if implemented, would undermine market incentives critical to the agricultural biotechnology and other innovative sectors.

India's overall IP enforcement remains inadequate, and the lack of uniform progress across the country threatens to undercut the positive steps that certain states have taken. A 2019 publication produced by the Organisation for Economic Co-operation and Development (OECD), "Trends in Trade in Counterfeit and Pirated Goods," finds that India is among the top five provenance economies for counterfeit goods. A 2017 report from the OECD and the European Union Intellectual Property Office, "Mapping the Real Routes of Trade in Fake Goods," revealed India to be a key producer and exporter of counterfeit foodstuffs, pharmaceuticals, perfumes and cosmetics, textiles, footwear, electronics and electrical equipment, toys, games, and sporting equipment. The 2017 report also found that 55 percent of global seizures of counterfeit pharmaceuticals, by total value, originated in India—making it by far the largest producer. The

report noted that these counterfeit pharmaceuticals are shipped “around the globe, with a special focus on African economies, Europe, and the United States.”

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. The United States continues to urge India to join the Singapore Treaty on the Law of Trademarks. 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 2018 *Notorious Markets List*), and through commercial broadcasts. Court cases and government memoranda also raise concerns that a broad range of published works will not be afforded meaningful copyright protection. Furthermore, industry has reported that continuing problems include widespread Internet piracy, unauthorized file sharing of videogames, signal theft by cable operators, commercial scale photocopying and infringing reprints of academic books, and circumvention of technological protection measures. Finally, the expansive granting of licenses under Chapter VI of the Indian Copyright Act and overly-broad exceptions for certain uses have raised concerns about the strength of copyright protection and complicated the functioning of the market for music licensing.

The 2015 passage of the Commercial Courts Act, highlighted in previous Special 301 Reports, provided an opportunity to reduce delays and increase expertise in judicial IP matters. However, to date, India has established only five courts, and right holders report that jurisdictional challenges have reduced their effectiveness. Furthermore, India’s 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 collective management organizations (CMOs) are licensed promptly and able to operate effectively.

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 long-standing challenges, and it created new concerns for right holders.

In early 2019, India acceded to the World Intellectual Property Organization (WIPO) Internet Treaties and the Nice Agreement. Additional amendments to the Copyright Act are needed to bring India’s domestic legislation into conformity with international best practices. The December 2018 draft Cinematograph Act (Amendment) Bill contains promising provisions to criminalize illicit camcording of films. This legislation now awaits Parliament’s approval. In early 2019, India followed through on resolving burdensome patent reporting requirements by issuing a revised Manual of Patent Office Practice and Procedure that includes the requirement for patent examiners to look to the WIPO Centralized Access to Search and Examination system and Digital Access Service to find information filed by patent applicants in other jurisdictions, which should eliminate the need for applicants to file redundant information with India. In 2018, an important judgment in a trademark infringement case resulted in a significant damage award. The Cell for Intellectual Property Rights Promotion and Management, established under the Department of

Industrial Policy and Promotion to move forward implementation of the National Intellectual Property Rights Policy, continues to spearhead efforts successfully to promote IP awareness, commercialization, and enforcement throughout India and undertook new and collaborative efforts in 2018. India continues to pursue important administrative work to reduce the time for processing patent and trademark applications and digitize the process for registering a copyright.

In January 2019, the Ministry of Health and Family Welfare issued a notice that placed further restrictions on the transparency of information about manufacturing licenses issued by states, which represented a step backward toward providing 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. Right holders also reported growing concerns over the expansive application of patentability exceptions to reject pharmaceutical patents. In 2018, India also missed an opportunity to establish 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 agricultural chemical products. Although a small number of India's state authorities, including in Maharashtra and Telangana, continue to operate dedicated crime enforcement units to coordinate IP enforcement activities across various state-level IP and enforcement agencies, other states have not followed suit or face organizational challenges. Given the scale and nature of the problem, we continue to encourage India to adopt a national-level enforcement task force for IP crimes.

India's commitment to bilateral dialogue remains strong, and the United States intends to continue to engage with India on IP matters, including through the U.S.-India Trade Policy Forum.

NEAR EAST, INCLUDING NORTH AFRICA

ALGERIA

Algeria remains on the Priority Watch List in 2019.

Ongoing Challenges and Concerns

Significant challenges continue with respect to fair and equitable market access for U.S. intellectual property (IP) right holders in Algeria, notably for pharmaceutical and medical device manufacturers. Algeria's ban on the import of a vast number of pharmaceutical products and medical devices in favor of local products remains a trade matter of serious concern. Furthermore, Algeria continues to struggle to provide adequate and effective IP protection and enforcement overall. The United States continues to have serious concerns regarding the adequate and effective enforcement of existing anti-piracy statutes, including those prohibiting the use of unlicensed software and the provision of adequate judicial remedies in cases of patent infringement. Algeria also 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 took some steps to improve the environment for IP protection and enforcement in 2018. Customs authorities successfully seized counterfeit items through increased coordination with law enforcement. A court, for the first time, issued an injunction that stopped the marketing approval of an allegedly infringing pharmaceutical product. Algeria also supported capacity building and training efforts for law enforcement, customs officials, and judges, and has filed briefs in court proceedings supporting companies who have turned to the judiciary for assistance in combatting infringing activity. In addition, Algeria worked with the World Intellectual Property Organization (WIPO) and established a WIPO external bureau in Algiers to facilitate the training of African nations on IP protection and enforcement. The United States strongly urges Algeria to build upon these positive developments, remove IP-related market access barriers, and continue engaging with the United States on a full range of important IP issues.

KUWAIT

Kuwait remains on the Priority Watch List in 2019.

Ongoing Challenges and Concerns

The United States conducted an Out-of-Cycle Review (OCR) in 2018 and early 2019 that was primarily focused on addressing gaps in Kuwait's copyright regime. While the United States welcomed the 2016 passage of the Copyright and Related Rights Law, which represented a significant improvement over previous legislation, necessary steps still remain for Kuwait's copyright regime in light of international commitments, including with respect to the term of protection; limitations on the amount of work reproduced; enforcement, remedies and damages; and definitions. Although efforts were devoted to remedy some of the concerns related to Kuwait's copyright regime, the United States concluded the OCR process and determined that Kuwait has not yet resolved the issues raised in connection with the OCR.

The United States continues to highlight counterfeiting and piracy problems in Kuwait. Right holders continue to raise systemic concerns regarding the difficulty in having the Ministry of Commerce and Industry's Consumer Protection Department remove illicit physical goods from the market, as well as the lack of transparency with administrative and criminal enforcement proceedings. While the Ministry of Commerce and Industry continued to work with the United States this year, a clear and predictable intellectual property (IP) enforcement procedure remains elusive. The United States encourages Kuwait to devote additional resources and to take action that would curb the sale of counterfeit merchandise, including the relabeling and repackaging of pirated goods by increasing administrative and criminal fines and penalties to deterrent levels. The United States strongly urges Kuwait to prioritize the successful prosecution of any criminal behavior in such cases and minimize undue delays in the judicial process.

Developments, including Progress and Actions Taken

The United States acknowledges the National Library of Kuwait's willingness to work with the United States in an effort to address existing gaps in Kuwait's copyright regime, and encourages Kuwait to continue to work with the United States throughout the legislative and implementation processes.

The Kuwait General Administration for Customs Intellectual Property Rights Unit (Unit) continues to increase efforts, with over three hundred reported seizures of counterfeit or pirated goods in the past year, by enhancing outreach and communication with trademark and copyright owners, and no longer allowing shipments of counterfeit goods under seizure to be exported. The Unit could improve further with additional resources and personnel, as well as increased automation and targeting capacity. Kuwait also took action against online offerings of counterfeit and pirated materials and is working closely with copyright owners on improving enforcement actions against services that provide pirated content. Also, the Kuwait Ministry of Interior's Police and Criminal Investigation Department conducted raids and initiated criminal proceedings on a range of activities involving pirated and counterfeit physical goods. In particular, the United States commends the continued collaboration between Kuwaiti customs officials and the U.S. Customs

and Border Protection in-country advisory program. The United States also recognizes the modernization of the Kuwait Patent and Trademark Office throughout 2018, including its acceptance of Patent Cooperation Treaty national phase applications and instituting a trademark e-filing and e-publication system.

SAUDI ARABIA

Saudi Arabia is placed on the Priority Watch List in 2019.

Ongoing Challenges and Concerns

Saudi Arabia was placed on the Watch List in 2018 in response to deterioration in intellectual property (IP) protection for innovative pharmaceutical products, as well as long outstanding concerns regarding enforcement against counterfeit and pirated goods within the country. Despite extensive engagement by the U.S. Government and private sector stakeholders, the IP environment in Saudi Arabia has continued to deteriorate in the past year.

In recent years, the Saudi Arabia Food and Drug Authority (SFDA), which the Minister of Health oversees, has authorized domestic companies to produce generic versions of pharmaceutical products that are under patent protection either in Saudi Arabia or the Gulf Cooperation Council (GCC), or that are still covered by 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. After granting marketing approval in 2016 and 2017 to produce generic versions of two pharmaceutical products protected by Saudi Arabian or GCC IP rights, the SFDA again granted marketing approvals to produce generic versions of additional innovative pharmaceutical products this past year. These approvals reportedly relied on data from innovators that is subject to Saudi Arabia's system for protection against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval. Furthermore, in 2018, the National Unified Procurement Company for Medical Supplies, also overseen by the Minister of Health, reportedly awarded a national tender, in part, to a generic manufacturer while the innovative product covered by the tender was still under patent protection in the GCC.

Rampant satellite and online piracy is a rising concern in Saudi Arabia. BeoutQ, an illicit service for pirated content whose signal is reportedly carried by Saudi Arabia-based satellite provider Arabsat, continues to be widely available in Saudi Arabia and throughout the Middle East and Europe. BeoutQ's activities include satellite and online piracy, as well as support for devices and related services, such as apps and illicit streaming devices, that facilitate this piracy and allow access to unlicensed movies and television productions, including sports events. While Saudi officials have confirmed the illegal nature of BeoutQ's activities and claim to be addressing this issue by seizing BeoutQ set-top boxes, such devices nevertheless continue to be widely available and are generally unregulated in Saudi Arabia. Saudi Arabia also has not taken sufficient steps to address the purported role of Arabsat in facilitating BeoutQ's piracy activities.

Additionally, there are ongoing concerns regarding IP enforcement, including difficulty for stakeholders to obtain information on the status of enforcement actions and investigations, the lack of seizure and destruction of counterfeit and pirated goods in markets, and limits on the ability to enter facilities suspected to be involved in the sale or manufacture of counterfeit goods, including facilities located in residential areas.

Developments, including Progress and Actions Taken

In 2017, Saudi Arabia established the Saudi Authority for Intellectual Property (SAIP), which when fully operational will reportedly be responsible for all IP policymaking functions, including IP enforcement policy, as well as the registration of all copyrights, trademarks, industrial designs, and patents. While the United States commends the creation of SAIP, its impact on addressing outstanding IP concerns is unclear, particularly with respect to ongoing pharmaceutical and satellite piracy concerns and IP enforcement generally. The United States notes the positive cooperation between SAIP and the U.S. Patent and Trademark Office over the past year, including the signing of a Memorandum of Understanding in September 2018. In particular, the United States notes SAIP's efforts to increase transparency, join international treaties, improve stakeholder involvement in policymaking, and continue legislative development. The United States also recognizes the efforts by the Saudi Arabia Customs Authority to significantly enhance its IP enforcement efforts and capacity, including partnering closely with trademark and copyright owners and to systematically notify right holders of suspected illicit shipments.

EUROPE AND EURASIA

RUSSIA

Russia remains on the Priority Watch List in 2019.

Ongoing Challenges and Concerns

Challenges to intellectual property (IP) protection and enforcement in Russia include continued copyright infringement, trademark counterfeiting, and the existence of non-transparent procedures governing the operation of collective management organizations (CMO). In particular, the United States is concerned about stakeholder reports that IP enforcement overall is down from where it was a decade ago, and that Russian enforcement agencies continue to lack sufficient staffing, expertise, and the political will to combat IP violations and criminal enterprises.

Developments, Including Progress and Actions Taken

Russia took some positive steps in 2018, but the overall IP situation remains extremely challenging. The lack of robust enforcement of IP rights is a persistent problem, which has been compounded by long delays regarding criminal action and prosecutions. Additionally, burdensome procedural requirements continue to hinder right holders' ability to bring civil actions, which are exacerbated for foreign right holders by strict documentation requirements such as verification of their 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. While recent implementation of anti-piracy legislation holds some promise, Russia remains home to several sites that facilitate online piracy, as identified in the 2018 *Notorious Markets List*. Stakeholders continue to report significant piracy of video games, music, movies, books, journal articles, and television programming. Mirror sites related to infringing websites are playing a role in the surge of the number of pirate websites in Russia. Russia needs to direct more action to rogue web platforms targeting audiences outside the country. Recently, right holders and Internet platforms in Russia signed an anti-piracy memorandum to facilitate the removal of links to infringing websites. However, this memorandum is set to expire in September 2019, and compliance is unlikely if legislation is not adopted by this deadline. Furthermore, Russia has enacted legislation that enables right holders to obtain court-ordered injunctions against pirate websites, but additional steps must be taken to target the root of the problem—namely, investigating and prosecuting the owners of the large commercial websites distributing pirated material, including software. Moreover, stakeholders report a 200 percent increase since 2015 in unauthorized camcords that often appear on the Internet within a few days of a movie's theatrical release. Stakeholders further report that these problems negatively affect, in particular, independent producers and distributors, the majority of which are small and medium-sized enterprises.

Royalty collection by CMOs in Russia continues to lack transparency and fails to meet international standards. The United States encourages CMOs to update and modernize their

procedures, including the full representation of right holders in CMO governing bodies, regardless of whether right holders are individuals or legal entities.

Russia remains a thriving market for counterfeit goods sourced from China. Similarly, there is little enforcement against counterfeits trafficked online, including apparel, footwear, sporting goods, pharmaceutical products, and electronic devices.

The United States is also concerned about Russia's implementation of its World Trade Organization commitments related to the protection 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. 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. Stakeholders are also concerned about recent regulatory initiatives that reportedly may inappropriately expand the use of compulsory licensing.

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 2019.

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 2018 in addressing those issues, concerns remain. The three grounds for Ukraine's PFC designation were: (1) the unfair, nontransparent administration of the system for collective management organizations (CMOs), which are responsible for collecting and distributing royalties to right holders; (2) widespread use of unlicensed software by Ukrainian government agencies; and (3) failure to implement an effective means to combat widespread online copyright infringement in Ukraine. In December 2017, the United States announced Ukraine's partial suspension as a beneficiary country under the Generalized System of Preferences (GSP) due to Ukraine's failure to provide adequate and effective protection of intellectual property (IP) rights. The announcement of the partial suspension of Ukraine's GSP benefits specifically referenced the importance of improving its CMO regime. While Ukraine made some progress in addressing the above referenced matters, significant concerns remain. The United States will also continue to monitor recent legislative and operational efforts to improve IP protection and enforcement in Ukraine.

Developments, Including Progress and Actions Taken

A number of rogue CMOs have operated freely in Ukraine for years, collecting royalties but not distributing those royalties to legitimate right holders, contributing to an unfair and nontransparent CMO regime. In July 2018, Ukrainian President Petro Poroshenko signed into law legislation that fundamentally reforms Ukraine's CMO system. While the law is not perfect, it creates a framework in which U.S. right holders can receive proper and adequate compensation for their creative works in Ukraine. It is critical that Ukraine continue its work to establish a transparent, fair, and predictable system for the collective management of royalties, including through further legislative work, as well as faithful implementation, because the new system requires improvement.

The use of unlicensed software by Ukrainian government agencies continues to raise concerns for the United States. Recently, the Cabinet of Ministers passed a resolution that requires an audit of the software used by each ministry, directs ministries to remove unlicensed software programs by the end of 2019, and facilitates the purchase of legitimate software. Importantly, Ukraine continues to work with industry representatives to remedy this issue. While this resolution holds some promise, it is still being implemented, and the use of unlicensed software by Ukrainian government agencies persists.

Online piracy remains a significant problem in Ukraine and fuels piracy in other markets. Pirated films generated from illegal camcording and made available online cause particular damage to the market for first-run movies. In addition, inadequate enforcement continues to raise concerns among IP stakeholders in Ukraine. 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 United States urges Ukraine to engage actively with all affected stakeholders to ensure the statutory framework for reducing online piracy is effective and efficient. Reinstating an empowered group of state inspectors to investigate copyright violations may also help combat online piracy.

Recently, Ukraine has been active in developing draft legislation relating to patents, trademarks, geographical indications, and industrial designs. Ukraine also developed draft legislation to increase deterrent criminal penalties for IP infringement and to improve customs enforcement. Progress continues, albeit slowly, to establish a specialized Intellectual Property High Court, legislatively enacted in 2017. In addition, Ukraine announced its intention to create a new National IP Office to replace the State Intellectual Property Service. 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 appreciates the increased engagement with Ukraine, including the tangible steps Ukraine is taking to improve its IP regime, and will continue to work intensively with Ukraine, including through the U.S.-Ukraine Trade and Investment Council.

WESTERN HEMISPHERE

ARGENTINA

Argentina remains on the Priority Watch List in 2019.

Ongoing Challenges and Concerns

Argentina continues to present long-standing and well-known challenges to intellectual property (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 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 products in those sectors. Finally, Argentina struggles with a substantial backlog of patent applications resulting in long delays for innovators seeking patent protection in the market. This problem is compounded by a reduction in the number of patent examiners in 2018, primarily due to a government-wide hiring freeze.

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. La Salada in Buenos Aires remains the largest counterfeit market in Latin America. Argentine police generally do not take *ex officio* actions, prosecutions can stall and languish in excessive formalities, and, when a criminal case does reach final judgment, criminal infringers rarely receive deterrent sentences. Hard goods counterfeiting and optical disc piracy is widespread, and online piracy continues to grow as criminal enforcement against online piracy is nearly nonexistent. As a result, IP enforcement online in Argentina consists mainly of right holders trying to convince cooperative Argentine Internet service providers (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 made limited progress in IP protection and enforcement. Beset with economic challenges, Argentina's government agencies were strapped by a reduction of funding and a government-wide hiring freeze, and many of Argentina's IP-related initiatives that had gained momentum last year did not gain further traction due to a lack of resources. Despite these circumstances, the National Institute of Industrial Property (INPI) revamped its procedures and

began accepting electronic filing of patent, trademark, and industrial designs applications as of October 1, 2018. Argentina also improved registration procedures for trademarks and industrial designs. On trademarks, the law now provides for a fast track option that reduces the time to register a trademark to four months. The United States continues to monitor this change as INPI works on the implementing regulation. For industrial designs, INPI now accepts multiple applications in a single filing, and applicants may substitute digital photographs for formal drawings. To further improve patent protection in Argentina, including for small and medium-sized enterprises, the United States urges Argentina to ratify the Patent Cooperation Treaty.

Argentina's efforts to combat counterfeiting continue, but without systemic measures, illegal activity persists. Argentine authorities arrested the alleged operators of the market La Salada as well as numerous associates in 2017, but vendors continue to sell counterfeit and pirated goods at the market and throughout Buenos Aires. The United States encourages Argentina to create a national IP enforcement strategy to build on these successes and move to a sustainable, long-lasting initiative. The United States also encourages legislative proposals to this effect, along the lines of prior bills introduced in Congress to provide for landlord liability and stronger enforcement on the sale of infringing goods at outdoor marketplaces such as La Salada, and to amend the trademark law to increase criminal penalties for counterfeiting carried out by criminal networks. 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. In March, revisions to the criminal code, including certain criminal sanctions for circumventing technological protection measures, were submitted to Congress. While Argentina has moved forward with the creation of a federal specialized IP prosecutor's office, the office is not yet operational. In November 2018, following a constructive bilateral meeting earlier in the year, Argentina and the United States held a digital video conference under the bilateral Innovation and Creativity Forum for Economic Development, part of the U.S.-Argentina Trade and Investment Framework Agreement, to continue discussions and collaboration on IP topics of mutual interest. The United States intends to monitor all the outstanding issues for progress and urges Argentina to continue its efforts to create a more attractive environment for investment and innovation.

CHILE

Chile remains on the Priority Watch List in 2019.

Ongoing Challenges and Concerns

Although there was positive movement this year by Chile with regard to the implementation of certain intellectual property (IP) obligations under the United States-Chile Free Trade Agreement (Chile FTA), the United States continues to have serious concerns regarding long-standing implementation issues with a number of other IP provisions of the Chile FTA. Chile took a step forward in passing legislation establishing criminal penalties for the importation, commercialization, and distribution of decoding devices used for the theft of encrypted program-carrying satellite signals. We urge Chile to clarify the full scope of activities criminalized in the implementation of the law. The United States also urges Chile to provide remedies or penalties for willfully receiving or further distributing illegally-decoded encrypted program-carrying satellite signals, as well as the ability for parties with an interest in stolen satellite signals to initiate a civil action. Concerns remain regarding the availability of effective administrative and judicial procedures, as well as deterrent-level remedies, to right holders and satellite service providers. Chile also must establish protections against the unlawful circumvention of technological protection measures (TPMs). 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 resolving 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. The United States urges Chile to improve its Internet service provider liability framework to permit effective and expeditious action against online piracy.

In addition, in 2018, Chile's Ministry of Health issued Resolution 399, which declared that there are public health reasons that justify issuing compulsory licenses on certain patent-protected drugs used to treat hepatitis C. While Chile has not issued a compulsory license, the resolution satisfies an initial legal requirement after which a third party may then make the request. The United States urges Chile to ensure transparency and due process in any actions related to compulsory licenses. To maintain the integrity and predictability of IP systems, Chile 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.

Developments, Including Progress and Actions Taken

In the past year, Chile carried out strong enforcement efforts to combat counterfeits. The National Customs Service reported that it had seized more than 7 million counterfeit products in 2018, worth a total of nearly \$103 million. Chile's specialized IP crime unit, the Investigative Brigade of IP Crimes, reported strong enforcement actions, with seizures totaling 379,429 counterfeit products. The National Institute of Industrial Property continued to make improvements to strengthen the climate for IP protection, reducing the average time of patent application processing to 3.8 years

in 2018. With respect to the outstanding FTA implementation concerns noted above, the United States is closely monitoring potential legislation on TPMs, an effective mechanism for the early resolution of potential patent disputes, and the implementation of UPOV 91.

The United States will continue to work closely with Chile to address IP issues. This year marks the fifteenth anniversary since the Chile FTA entered into force, and the United States expects to see additional tangible progress in these areas in 2019.

VENEZUELA

Venezuela remains on the Priority Watch List in 2019.

Ongoing Challenges and Concerns

Recognizing the significant challenges in Venezuela at this time, the United States recites the following ongoing concerns with respect to the lack of adequate and effective intellectual property (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 related to innovation and IP protection in recent years. Additionally, Venezuela's Autonomous Intellectual Property Service has not issued a new patent since 2007. Piracy, including online piracy, as well as unauthorized camcording and widespread use of unlicensed software, remains a persistent challenge. Counterfeit goods are also widely available, and IP enforcement remains ineffective. The World Economic Forum's 2018 Global Competitiveness Report ranked Venezuela last in IP protection for the sixth straight year, out of 140 countries. The Property Rights Alliance's 2018 International Property Rights Index also ranked Venezuela 123rd out of 125 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 2019. Thailand continues to make progress to implement the 2016 Work Plan and address concerns raised as part of the bilateral U.S.-Thailand Trade and Investment Framework Agreement (TIFA), and a subcommittee on enforcement against intellectual property (IP) infringement, led by a Deputy Prime Minister, continues to convene. This strong interest from the highest levels of the government has led to improved coordination among government entities, as well as enhanced and sustained enforcement efforts to combat counterfeit and pirated goods throughout the country. One particular focus of Thailand's enforcement efforts has been physical markets previously listed on the Office of the U.S. Trade Representative's *Notorious Markets List*. Thailand also continues to take steps to address backlogs for patent and trademark applications, including significantly increasing the number of examiners and preparing legislative amendments to streamline the patent registration process and reduce patent backlog and pendency. Thailand has been building capacity and awareness since joining the Madrid Protocol, making it easier for U.S. companies to apply for trademarks, and taking steps to address concerns regarding online piracy affecting the U.S. content industry. In addition, Thailand also is considering draft amendments to the Patent Act to help prepare for accession to the Hague Agreement. With respect to copyright legislation, Thailand amended the Copyright Act to accede to the Marrakesh Treaty and is in the process of further amending this act to prepare for accession to the World Intellectual Property Organization Internet Treaties. 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 United States urges Thailand to address through amendments to the 2014 Copyright Act concerns expressed by the United States and other foreign governments and stakeholders, including overly broad technological protection measure exceptions 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 (particularly for pharmaceutical 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 2019. 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. While Vietnamese agencies have engaged in public awareness campaigns, foreign companies continue to face various impediments to selling legitimate products in Vietnam. 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 intellectual property (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 2015 Penal Code with respect to criminal enforcement of IP violations, as well as implementation of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, which the National Assembly ratified in November 2018. 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 in its international agreements to strengthen its IP regime 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 Trade and Investment Framework Agreement 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 2019. In 2018, Pakistan maintained positive dialogue with the United States on intellectual property (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. In May 2018, the Ministry of National Food Security and Research moved forward to establish a registry to protect plant breeders' rights and is taking steps to recruit staff and operationalize the registry. Despite progress, 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, along with plans to create new tribunals in Peshawar and Quetta, have been welcome developments. However, litigants with experience in these courts raise concerns over the lack of capacity, consistency, and insufficient penalties. In addition, many of the injunctive orders issued by these courts have been ignored by criminal enterprises. Although Pakistan reconstituted the IP policy board established by the IPO Act following the expiration of its mandate in late 2017, the new board has not yet met. IPO continues to face challenges in coordinating enforcement among different government agencies and operates at levels well below approved staffing. 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 U.S. Patent and Trademark Office capacity-building programs, Commercial Law Development Program programs, and the U.S.-Pakistan Trade and Investment Framework Agreement, and to make further progress on IP reforms with a particular focus on aligning its IP laws, regulations, and enforcement regime with international standards. As Pakistan amends its IP laws, the United States encourages Pakistan to undertake a transparent process that provides stakeholders with an opportunity to comment on draft laws. The United States also welcomes Pakistan's interest in joining international treaties, such as the World Intellectual Property Organization Internet Treaties, Madrid Protocol, and Patent Cooperation Treaty, and urges Pakistan to convene meetings of the IP policy board.

TURKMENISTAN

Turkmenistan remains on the Watch List in 2019. The United States is concerned by the lack of observable progress made by Turkmenistan in raising its intellectual property (IP) protections to international standards since its accession to the Berne Convention in 2016. Turkmenistan has yet to issue a presidential-level decree, law, or regulation mandating the use of licensed software by government ministries and agencies and has yet to provide adequate copyright protection for foreign sound recordings, including through accession and implementation of the Geneva Phonograms Convention and the World Intellectual Property Organization Internet Treaties. The United States continues to be concerned with current levels of protection and enforcement of IP rights and Turkmenistan's failure to fully implement and enforce its IP laws. 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 to improve its enforcement procedures in accordance with current IP laws. The United States stands ready to assist Turkmenistan through enhanced engagement facilitated by the Central Asia IP Working Group.

UZBEKISTAN

Uzbekistan remains on the Watch List in 2019. Uzbekistan took important steps in 2018 to address long-standing issues pertaining to intellectual property (IP) protection and enforcement. In particular, Uzbekistan's accession to the Geneva Phonograms Convention and passing legislation that authorized accession to the WIPO Internet Treaties represent progress toward adequate copyright protection for foreign sound recordings. The United States also recognizes the increased high-level political attention to IP, including Uzbekistan's support for and facilitation of the launch of the Central Asia IP Working Group at the October 2018 Council Meeting of the U.S.-Central Asia Trade and Investment Framework Agreement. In addition, the United States notes the progress toward developing a new national strategy for IP and incremental advances in enforcement. The United States encourages Uzbekistan to continue improving its copyright statutory framework, including through providing adequate protection for foreign sound recordings, completing the accession process for the World Intellectual Property Organization Internet Treaties, and developing implementing legislation for the above referenced international treaties. Also, Uzbekistan needs to make progress to address other concerns raised in previous Special 301 Reports, including with regard to *ex officio* authority for enhanced border enforcement, allocating resources to administrative and enforcement IP agencies, and mandating government use of licensed software via presidential decree, law, or regulation.

NEAR EAST, INCLUDING NORTH AFRICA

EGYPT

Egypt remains on the Watch List in 2019. While stakeholders generally acknowledge increased engagement with Egypt on intellectual property (IP) matters, concerns with respect to copyright and trademark enforcement, patentability criteria, and pharmaceutical-related IP issues continue to impede progress towards adequate and effective IP protection and enforcement. The United States welcomes Egypt's efforts to strengthen the enforcement of IP. However, copyright piracy remains widespread in Egypt, and IP enforcement continues to be hampered by unnecessary administrative hurdles. Problems continue with the number of unlicensed satellite channels offering pirated broadcasts of U.S. works, unlawful decryption of encrypted signals, and illegal camcording. Also, counterfeit products remain widely available, enforcement efforts are hindered because offenders are often allowed to retain custody of seized counterfeit goods, and prosecution takes many months, even years, to conclude. 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 increased training for enforcement officials. Additionally, while Egypt successfully reduced its patent application backlog from ten years to five years, it continues to lack a transparent and reliable patent registration system. Egypt also 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. In addition, the exclusion from patentability of certain biotechnology inventions remains a concern for innovative stakeholders. 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 2019. The United States welcomes Lebanon's continued work to promote intellectual property (IP) protection and enforcement in 2018, as well as its attempts to revive stalled IP-related legislation. The United States commends the Ministry of Economy and Trade, in cooperation with the World Intellectual Property Organization (WIPO), for beginning the development of a national IP strategy. However, the United States continues to raise long-standing concerns, including those regarding progress on pending IP legislative reforms, including draft laws concerning trademarks and amendments to existing copyright and patent laws, and inadequate protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval. The United States encourages Lebanon to ratify and implement several IP treaties, including Articles 1-12 of the Paris Convention, the Singapore Treaty on the Law of Trademarks, and the latest acts of the Nice Agreement. In addition, the United States encourages Lebanon to ratify and implement the Berne Convention for the Protection of Literary and Artistic Works and the WIPO Copyright Treaty. The United States also encourages Lebanon to join the Patent Cooperation Treaty, the Madrid Protocol, and the WIPO Performances and Phonograms Treaty. While enforcement efforts have

been improving slowly, additional training for enforcement officials is needed to enhance investigative skills. The United States urges Lebanon to allocate sufficient resources for IP protection and enforcement. The United States looks forward to continuing to work with Lebanon to address these and other issues.

UNITED ARAB EMIRATES

The United Arab Emirates (UAE) remains on the Watch List in 2019. Although the UAE made progress in addressing some intellectual property (IP) concerns, many long-standing concerns remain. In April 2017, UAE officials allowed domestic manufacture of generic versions of a pharmaceutical product 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) are 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 IP and regulatory systems. It is also unclear whether the UAE intends to continue to recognize patents granted by the Gulf Cooperation Council (GCC) Patent Office. These actions demonstrate a lack of predictability and transparency that has created a sense of instability and confusion among stakeholders in the innovative pharmaceutical industry. Additionally, despite some recent progress to enhance the transparency of the process for the destruction of counterfeit goods, IP enforcement across most emirates remains a concern, especially by emirate-level customs authorities. While some UAE enforcement authorities periodically seize and destroy counterfeit goods within the UAE, in particular the Dubai Police and Dubai Department of Economic Development, significant copyright piracy and trademark infringement remain prevalent. The 2018 *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. Right holders continue to report the lack of IP enforcement actions within free trade zones (FTZs). 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. This contributes to the spread of counterfeit and pirated goods to other markets in the region, including the Gulf, North Africa, and Europe. U.S. right holders also continue to raise the following concerns: the lack of IP prosecutions; inconsistent and non-deterrent sentencing; 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 collective management organizations to allow copyright licensing and royalty payments. Stakeholders also raise concerns over the UAE's trademark examination and registration practice. Despite charging the highest, cost-prohibitive filing fees in the world, right holders report that registering a trademark is unduly time-consuming, and while efforts have been made to reduce the significant backlog in opposition proceedings, significant delays remain. The United States looks forward to a dialogue over the next year with UAE officials to address these and other issues.

EUROPE AND EURASIA

GREECE

Greece remains on the Watch List in 2019. Greece made progress on improving intellectual property (IP) protection and enforcement in 2018, but widespread piracy continues and IP enforcement challenges remain. The United States welcomes the 2018 enactment of amendments to the Copyright Law to address online piracy and updates to the Code of Civil Procedure that have helped to improve the efficiency and timeliness of civil infringement suits. However, outstanding IP challenges remain unresolved, including the use of unlicensed software, inadequate enforcement against counterfeiting and piracy, and deficiencies in the criminal justice system. According to U.S. stakeholders, Greece has one of the highest rates of unlicensed software use in the European Union (EU). Greece has acknowledged unlicensed software use by government agencies and has taken steps to assess the extent of the problem in the public sector. However, swift and effective action—such as establishing proper procurement requirements, implementing management policies, and moving forward with public tenders that require licensed software—is needed to begin to ensure the public sector uses legitimate software and set a positive example for the private sector. 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 insufficient sentences and penalties, including for large-scale infringers. The United States also encourages Greece to continue its consultations with interested stakeholders as it implements the EU Directive on Copyright in the Digital Single Market. The United States further encourages Greece to consult with interested stakeholders regarding implementation of the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No. 469/2009 concerning the supplementary protection certificate for medicinal products (SPC Waiver Proposal), if enacted. The United States looks forward to working with Greece, including through the recently launched U.S.-Greece Strategic Dialogue, to address these and other issues.

ROMANIA

Romania remains on the Watch List in 2019. The United States welcomes the participation of Romanian government experts and personnel in intellectual property (IP)-related technical trainings and the continued working-level cooperation in Romania between stakeholders and law enforcement authorities, including prosecutors and police. Also welcome are 2018 amendments to Romania's laws on collective management of copyrights and neighboring rights and on the right of public communication for musical works. An additional positive development is Romania's 2018 entry into a Memorandum of Understanding with the World Intellectual Property Organization (WIPO) establishing a single procedure for addressing issues in international IP litigation. Despite these positive developments, online piracy, the use of unlicensed software, and a drop in customs seizures of counterfeit goods present unresolved challenges for U.S. IP-intensive industries in Romania. Trademark concerns include obstacles to the assignment of certification marks, the unavailability of default judgments in opposition and invalidation proceedings, inadequate transparency in opposition proceedings, and the lack of administrative cancellation proceedings. The United States remains concerned that penalties for copyright crimes under

Romanian law are reportedly so low as to reduce any deterrent effect from criminal prosecutions. The United States continues to encourage Romania to develop 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 the Economic Crimes Investigation Directorate, and encourage the Department to prioritize its investigation and prosecution of significant IP cases, with a special focus on cases involving online piracy and criminal networks importing, distributing, or selling counterfeit products. Romania should also provide its specialized police, border polices, 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 it implements the European Union Directive on Copyright in the Digital Single Market. The United States further encourages Romania to consult with interested stakeholders regarding implementation of the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No. 469/2009 concerning the supplementary protection certificate for medicinal products, if enacted. 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 2019. Generally, Switzerland provides high levels of intellectual property (IP) protection and enforcement. The United States recognizes the important contributions Switzerland makes to promote strong 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. Implementation of a 2010 decision by the Swiss Federal Supreme Court has been interpreted to prevent copyright holders and prosecutors from collecting and using certain data in anti-piracy actions, making it difficult to enforce Swiss copyright law online. Enforcement is a critical element of providing meaningful IP protection. Some reports indicate that websites offering infringing content and the services that support them have moved operations away from Switzerland, while others indicate that several infringing websites maintain links to Switzerland. The United States welcomes steps that Switzerland is considering to strengthen online copyright protection. These actions should address outstanding protection and enforcement concerns and ensure compliance with international standards, as informed by public consultations and stakeholder engagements. The United States also encourages Switzerland to use consumer awareness campaigns, public education, and voluntary stakeholder initiatives to deter Swiss Internet users from consuming and further distributing pirated content. 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 2019. In 2018, Turkey made progress in improving its protection of intellectual property (IP) rights. The government continued to implement the 2016 Industrial Property Law that, among other things, increased criminal sanctions for importing and exporting counterfeit goods and enhanced authorities' ability to destroy counterfeit goods. The government also continued to prepare draft legislation on a new Copyright Law and initiated work

on an inter-ministerial 2019-2023 IP strategy. According to the latest Turkish government data, domestic seizures by Turkey's law enforcement officials increased by 18 percent from 2016 to 2017. Despite these positive developments, concerns among right holders regarding overall IP protection and enforcement in Turkey continue. The United States views with particular concern Turkey's implementation since 2017 of policies that require localized production of pharmaceutical products in order to remain on the reimbursement list and remains concerned about certain compulsory licensing provisions in the Industrial Property Law. U.S. pharmaceutical companies continue to complain that Turkey does not adequately protect against the unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical products, and has not done enough to reduce regulatory and administrative delays in granting marketing approvals for products. Turkey should encourage early resolution of patent disputes prior to the marketing of follow-on pharmaceuticals and rescind its problematic policies that act to discourage imports in favor of domestic production of pharmaceutical products and medical devices. Additionally, U.S. companies report that Turkey's national pricing and reimbursement policies for pharmaceutical products and medical devices suffer from a lack of transparency and procedural fairness. With respect to copyright matters, Turkey continues to work on amending its copyright legislation. The United States encourages Turkey to fully implement its obligations under the World Intellectual Property Organization Internet Treaties and develop effective mechanisms to address online piracy. The United States continues to encourage Turkey to require that collective management organizations adhere to fair, transparent, and non-discriminatory procedures. Turkey remains a major source and transshipment point for counterfeit goods across a number of industry sectors. Levels of pirated products in Turkey remain high. Further, unlicensed software, including use by some government agencies, is reported, as are increasing levels of satellite television channel piracy. Enforcement processes are hampered by procedural delays and insufficient personnel, as well as laws that contain insufficient penalties and inadequate procedures. The Turkish National Police should be given *ex officio* authority and other tools they currently lack to help them enhance their enforcement of trademark violations, particularly in obvious infringement cases. Some, but not all, sectors report that recent increased sanctions for importing and exporting counterfeit products in the 2016 law have had a positive impact on customs seizures, although seizures remain uneven. The United States looks forward to engaging with Turkey to address these and other issues.

WESTERN HEMISPHERE

BARBADOS

Barbados remains on the Watch List in 2019. While Barbados has established a basic legal framework for intellectual property (IP) protection and enforcement, the country's failure to accede to the World Intellectual Property Organization Internet Treaties to protect 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 legislation reportedly met only infrequently in 2018. Evidence of a strong commitment to enforce existing legislation also appears incomplete. 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 television 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 another source of concern. The United States looks forward to working with Barbados to resolve these and other important issues.

BOLIVIA

Bolivia remains on the Watch List in 2019. Challenges continue with respect to adequate and effective intellectual property (IP) protection in Bolivia. The United States is aware of the sudden and significant reduction of personnel employed by Bolivia's Servicio Nacional de Propiedad Intelectual (SENAPI) with material responsibilities involving IP protection. Right holders have expressed concern about the resulting long processing times for IP right registrations. The United States is also concerned about the absence of trade secret and industrial design protections and the breadth of exceptions and limitations relating to certain IP rights under Bolivian law. Significant challenges also persist with respect to adequate and effective IP enforcement. Video, music, literature, and software piracy rates are among the highest in Latin America, and rampant counterfeiting persists, including counterfeit medicine that reportedly represents 21 percent of the Bolivian market. Criminal charges and prosecutions remain rare, and customs authorities lack personnel and budgetary resources to act upon applications from right holders. The United States will monitor the effectiveness of the newly-created Vice-Ministry of Fight Against Contraband in its inter-institutional coordination among Bolivian enforcement authorities and in its coordination with Bolivia's neighbors to combat contraband activities. The United States encourages Bolivian Customs to use its new authority under the recently enacted Cinema and Audiovisual Arts Law to pursue criminal prosecutions for IP violations of foreign and domestic visual works. SENAPI's arbitration process to resolve IP disputes outside the judicial system continues to show promising results, although it does not compensate for the overall weakness of Bolivia's criminal and civil IP enforcement system. Finally, 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, and cooperating with right holders on enforcement.

BRAZIL

Brazil remains on the Watch List in 2019. The United States has long-standing concerns about Brazil's intellectual property (IP) enforcement activities, although the country took steps in 2018 to address several of them. After a period of dormancy, the National Council to Combat Piracy and Crimes Against Intellectual Property has approved a three-year National Plan to Combat Piracy and coordinated activities among multiple government and private sector organizations. The Brazil Film Agency established a Technical Working Group to Combat Piracy, which focused on educating the public and developing policies to address IP protection. Notable successes include a record level of seizures of counterfeit and pirated goods, as well as enforcement against illegal telecommunication products, set-top boxes, and piracy websites. The United States also commends the cooperation of Brazilian law enforcement with counterparts in its neighboring countries and in the United States. Nevertheless, levels of counterfeiting and piracy in Brazil, including online piracy, use of unlicensed software, and illicit camcording, remain unacceptably high. The dedication of additional resources at the federal, state, and local levels for IP enforcement, IP awareness campaigns, and stakeholder partnerships would help address these challenges, as would the enactment of legislation to increase deterrent penalties for IP crimes and to criminalize unauthorized camcording. The United States also recognizes positive developments at Brazil's National Institute of Industrial Property (INPI), which streamlined procedures for certain review processes and implemented measures to increase examiner productivity for patent and trademark decisions. The United States welcomes the next phase of INPI's Patent Prosecution Highway pilot program with the U.S. Patent and Trademark Office. The United States 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 long pendency of patent applications, as well as INPI's actions to invalidate or shorten the term of a significant number of "mailbox" patents for pharmaceutical and agricultural chemical products. The United States encourages Brazil to continue to undertake necessary reforms to address these concerns, and will continue to monitor progress in these and related areas. The United States welcomes the agreement that limits the role of Brazil's National Sanitary Regulatory Agency (ANVISA) on issues relating to the patentability of new biopharmaceutical inventions, but continues to monitor the situation in light of long-standing concerns about duplicative reviews by ANVISA of pharmaceutical applications. Also, although Brazilian law and regulations provide for protection against unfair commercial use, as well as unauthorized disclosure, 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. Right holders are also concerned about the protection of patent rights during Brazil's process for establishing Productive Development Partnerships 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 geographical indications including in connection with trade agreement negotiations with other trading partners. 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.

CANADA

Canada is placed on the Watch List in 2019. The most significant step forward taken by Canada is its agreement to important intellectual property (IP) provisions in the U.S.-Mexico-Canada Agreement (USMCA). Once implemented, these commitments will substantially improve the IP environment in Canada, including with respect to areas where there have been long-standing concerns, including enforcement against counterfeits, inspection of goods in transit, transparency with respect to new geographical indications (GIs), national treatment, and copyright term. In addition, the United States welcomes Canada's commitment to high IP standards through the seizure of suspected counterfeit items from the Pacific Mall in Ontario, which was listed in the 2017 *Notorious Markets List*. Right holders also report that Canadian courts have established meaningful penalties against circumvention devices and services. Canada also has made positive progress in reforming proceedings before the Copyright Board related to tariff-setting procedures for the use of copyrighted works. Despite this progress, various challenges to adequate and effective protection of IP rights in Canada remain. Significant issues include poor enforcement with respect to counterfeit or pirated goods at the border and within Canada, weak patent and pricing environments for innovative pharmaceuticals, deficient copyright protection, and inadequate transparency and due process regarding GIs protected through free trade agreements. The United States remains highly concerned about countries negotiating product-specific IP outcomes as a condition of market access from the European Union, and reiterates the importance of each IP right being independently evaluated on its individual merit. 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 is also closely monitoring proposed changes to Canada's Patented Medicine Prices Review Board. The United States urges Canada to appropriately recognize the value of innovative medicines in both the private and public markets, to ensure its decisions are made transparently, and to contribute fairly to research and development for innovative treatments and cures. The United States remains deeply troubled by the ambiguous education-related exception added to the copyright law in 2012, which has significantly damaged the market for educational publishers and authors. While Canadian courts have worked to clarify this exception, confusion remains and the educational publishing sector reports lost revenue from licensing. The United States continues to monitor the ongoing parliamentary review of the Copyright Act and the recent reforms to the Copyright Board. The United States also will monitor Canada's implementation of the USMCA's IP provisions as well as other developments on outstanding issues and looks forward to working closely with Canada in the coming year to address priority IP issues.

COLOMBIA

Colombia is placed on the Watch List in 2019, after an Out-of-Cycle Review in 2018 focused on certain provisions of the United States-Colombia Trade Promotion Agreement (CTPA) and monitoring the implementation of Colombia's 2014-2018 National Development Plan (NDP). Colombia's meaningful progress, particularly its enactment in July 2018 of copyright reform legislation to meet CTPA obligations, and Colombia's steps to clarify and resolve concerns about Articles 70 and 72 of the NDP, warrant the change in designation from the Priority Watch List to the Watch List. As noted above, in July 2018, Colombia enacted copyright law amendments to extend the term of copyright protection, impose civil liability for circumvention of technological protection measures, and strengthen enforcement of copyright and related rights. Colombia is also actively engaging with the United States on implementing notice-and-takedown and safe harbor provisions for Internet service providers, an additional CTPA commitment. With respect to Article 72 of the NDP, Colombia issued Decree 433 in March 2018, as amended by Decree 710 of April 2018, to clarify that Colombia would not condition regulatory approvals on factors other than the safety and efficacy of the underlying compound. With respect to Article 70 of the NDP, Colombia provided clarification to the Organisation for Economic Co-operation and Development Trade Committee that the Minister of Health would not be given any greater deference than other third parties in opposing a patent application, would not have any formal institutional role to oppose or interfere with patent applications that is distinct from those available to third parties, and would not take any other steps to delay a patent application. The United States commends Colombia on these accomplishments but notes that Colombia still needs to make additional progress on remaining intellectual property (IP)-related commitments under the CTPA, particularly provisions regarding copyright liability for ISPs and accession to the 1991 Act of the International Union for the Protection of New Varieties of Plants (UPOV 91). The United States expects Colombia to make substantial progress on a draft bill that will address online piracy through expeditious removal or disabling of access to pirated content by introducing the bill to the Colombian Congress as early as possible. The United States also expects Colombia to make progress toward accession to UPOV 91. The United States urges Colombia to increase its IP enforcement efforts. High levels of digital piracy persist year after year, and Colombia has not curtailed the number of free-to-air devices, community antennas, and unlicensed Internet Protocol Television services that permit otherwise-licensed content to be retransmitted to a large number of non-subscribers. Colombia has also not been able to reduce significantly the large number of pirated and counterfeit goods crossing the border or being sold at 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 zones. The United States encourages Colombia to provide key agencies with the requisite authority and resources to investigate and seize counterfeit goods, such as expanding the jurisdiction of the customs police. Finally, the United States continues to engage Colombia on patent-related matters and encourages it to incentivize innovation through strong IP systems.

COSTA RICA

Costa Rica remains on the Watch List in 2019, but the United States recognizes substantial progress made by Costa Rica this past year. The Ministry of Foreign Trade advanced issues raised

in bilateral discussions for an action plan on intellectual property (IP) rights that resulted in two important developments. First, Costa Rica issued a decree to address a long-standing concern that Internet service providers were not required to expeditiously take down infringing content in order to benefit from a safe harbor. Second, Costa Rica also issued a decree requiring any geographical indication issued to include the identification of generic terms in compound names. If successfully implemented, these two changes could substantially improve the efficacy of IP protection and enforcement in Costa Rica. Also, positive steps included reports of increased intra-government coordination on IP matters, active IP investigations by the Economic Crimes Prosecutor, and the development of new tools for the IP Office to enhance its trademark, industrial design, and patent functions. The effectiveness of these positive developments remains to be demonstrated through enforcement and results on the ground. However, 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. Additionally, the United States urges Costa Rica to 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.

DOMINICAN REPUBLIC

The Dominican Republic remains on the Watch List in 2019. The United States notes some progress in reducing the patent backlog and prioritizing prosecution related to counterfeit pharmaceuticals, cigarettes, and alcohol. However, the government did not make meaningful progress on many of the issues for which it was designated a Watch List country in 2018. In particular, the United States is concerned with the government's lack of political will to address intellectual property (IP) issues. Little progress was made in improving coordination among enforcement agencies, and some enforcement agencies remain severely understaffed and under-resourced. Long-standing issues, such as signal piracy by unauthorized cable operators, retransmission piracy by hotels, and widespread availability of gray market satellite decoders that provide users with unauthorized access to copyrighted audiovisual works, remain unaddressed. The anti-piracy technical working group established in 2017 to address these issues has thus far failed to produce meaningful changes in policy or enforcement. Furthermore, the use of unlicensed software remains widespread, including within the government. Stakeholders have reported that the Customs Authority lacks adequate storage space for seized counterfeit goods. Moreover, some stakeholders have also recounted that the Customs Authority requests that right holders pay to destroy seized counterfeit goods, and returns the seized goods to importers if payment is not received. The United States urges the Dominican Republic to provide more resources to enforcement agencies, and to improve coordination among government agencies handling IP enforcement. The United States encourages the Dominican Republic to take clear actions in 2019 to improve its IP protection and enforcement.

ECUADOR

Ecuador remains on the Watch List in 2019. In July 2018, Ecuador published for public comment draft regulations implementing the Organic Code on Social Economy of Knowledge, Creativity, and Innovation (Ingenuity Code) and engaged with the U.S. Government and stakeholders. However, concerns remain about how the final regulations will address issues related to copyright

exceptions and limitations, patentable subject matter, and geographical indications (GIs), including opposition procedures for proposed GIs, the treatment of common food names, and the protection of prior trademark rights. As a positive development, in May 2018, Ecuador issued a presidential decree that clarified that medicines could continue to be labeled with trademarked brand names after expiration of their patents, replacing a decree requiring them to be labeled as “generic medicine” that raised concerns among right holders. However, enforcement of intellectual property (IP) rights against widespread counterfeiting and piracy remains weak, including online and in physical marketplaces, and Ecuador is also reportedly a source of unauthorized camcords. Ecuador also lacks effective measures to deter online piracy and has not yet established notice-and-takedown and safe harbor provisions for Internet service providers (ISPs) with corresponding liability for ISPs that receive notice of infringing content on their servers and do not take appropriate action. 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 also urges Ecuador to make meaningful progress with respect to ensuring that all right holders receive the royalties they are owed for their works. The United States looks forward to working with Ecuador to address these and other issues.

GUATEMALA

Guatemala remains on the Watch List in 2019. 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 intellectual property (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 and 2018. The United States urges Guatemala to strengthen 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 remains widespread. Although cable signal piracy is also a serious problem, with stakeholders reporting that administrative actions have not worked in practice, major cable providers took a positive step in 2018 by discontinuing contracts with distributors that illicitly rebroadcast U.S. television programming. Additionally, the United States urges Guatemala to provide greater clarity in the scope of protection for geographical indications (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 2019 to improve the protection and enforcement of IP in Guatemala.

JAMAICA

Jamaica remains on the Watch List in 2019 due to its outdated patent and industrial designs regime. At the same time, Jamaica has continued to make substantial improvements in its intellectual property (IP) system both in terms of the legal framework and enforcement, including the

establishment of a stand-alone specialized IP investigation unit to combat IP violations. The unit has increased counterfeit seizures and held a number of special training programs. 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 (BCJ) initiated a periodic audit of cable operators to ensure they provide only licensed content to subscribers and it anticipates completing that process shortly. A recent court case in Jamaica resulted in damages for copyright infringement by a local cable broadcaster, which is a positive step forward. BCJ reported increased compliance with music copyrights for television and radio in 2018. Jamaica also developed draft copyright amendments to implement the Beijing Treaty on Audiovisual Performances and the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled. The United States applauds this progress and looks forward to working with Jamaica to further improve its IP regime.

MEXICO

Mexico remains on the Watch List in 2019 because there has not been a significant change in the level of intellectual property (IP) protection and enforcement since last year. However, Mexico agreed to important IP provisions in the U.S.-Mexico-Canada Agreement (USMCA). When the USMCA is ratified and fully implemented by Mexico, these commitments will substantially improve the IP environment in Mexico, including with respect to enforcement against counterfeiting and piracy, protection of pharmaceutical-related IP, camcording of movies, satellite and cable signal theft, damages, transparency with respect to new geographical indications (GIs), copyright protection, and enforcement of IP rights in the digital environment. 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 also continue to be confronted with bad-faith trademark registrations, although the 2018 amendments to the Industrial Property Law that provide grounds for refusal, opposition, and cancellation of bad-faith applications and registrations should be a useful tool for all brand owners. Regarding IP enforcement at the border, Mexican customs (Servicio de Administración Tributaria) initiated 327 cases, down from 495 in 2017, with seizures totaling 4.8 million articles in 2018, down from 11.95 million in 2017. In addition, unauthorized camcording in Mexico remains a serious concern. Mexico is still 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 for online music piracy, including via unauthorized stream-ripping. Although Mexico ratified the World Intellectual Property Organization (WIPO) Internet Treaties in 2002, it has not enacted legislation to protect against the circumvention of technological protection measures and rights management information. Investigation and prosecution of IP crimes, particularly with regard to online IP crimes, continue to be inadequate, due in part to continued government-wide budget cuts. Right holders express concern about the length of administrative and judicial patent infringement proceedings and the persistence of continuing infringement while cases remain pending. 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, including amendments

to its Copyright Law to provide for preliminary injunctions in civil cases and *ex parte* preliminary injunctions. In addition, Mexico instituted amendments to its Industrial Property Law to strengthen the oppositions system and protect non-traditional marks. The United States urges Mexico to fully modernize its copyright, trademark, patent, and IP enforcement systems. With respect to GIs, Mexico must ensure that any protection of GIs, including those negotiated through free trade agreements, may only be granted after a fair and transparent examination. The United States remains highly concerned about countries negotiating product-specific IP outcomes as a condition of market access from the EU and reiterates the importance of each individual IP right being independently evaluated on its individual merit. 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 including the specialized IP unit within the Attorney General’s office, 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.

PARAGUAY

Paraguay returns to the Watch List in 2019. Paraguay was removed from the Watch List in 2015 pursuant to an Out-of-Cycle Review, and the United States and Paraguay signed a Memorandum of Understanding (MOU) on Intellectual Property (IP) Rights in June 2015. Under the MOU, Paraguay committed to take specific steps to improve its IP protection and enforcement environment. Although Paraguay has made minor progress in the face of structural challenges and resource constraints, it has failed to meet key commitments, including adopting and enforcing penalties such as imprisonment and monetary fines sufficient to deter future acts of infringement, establishing an interagency “Coordination Center” to provide a unified government response to IP violations, and ensuring that government institutions use computer software with a corresponding license. Paraguay also remains a major transshipment point for counterfeit and pirated goods. With the MOU due to expire in 2020, the United States urges Paraguay to make progress on its commitments to strengthen IP protection and enforcement. The United States stands ready to assist Paraguay through enhanced engagement or technical assistance, as appropriate.

PERU

Peru remains on the Watch List in 2019. Peru continued to take substantial positive steps relating to intellectual property (IP) enforcement in 2018. Peru more than doubled the number of seizures of counterfeit goods from 2017, significantly decreased the number of pirated television signals over the past two years, and reported a 38 percent decrease in visits to websites devoted to pirated music last year. Other promising developments were the application of deterrent-level criminal and administrative penalties for violations of IP rights in a number of cases and the improvement of interagency coordination with respect to IP enforcement. Peru also took positive steps in 2018 by joining the Singapore Treaty on the Law of Trademarks and the Global Patent Prosecution Highway, passing a law to impose secondary liability on third parties for trademark infringement, and partially overturning two decisions by the National Institute for the Defense of Competition and the Protection of Intellectual Property that limited the right to collect royalties for the public performance of musical works contained in audiovisual works. The United States encourages Peru to continue prosecuting individuals involved in the sale of counterfeit medicines and to continue

increasing the imposition of deterrent-level fines and penalties for counterfeiting and piracy more broadly. The United States further encourages Peru to continue its public awareness activities about the importance of IP rights. As an important priority for strengthening protection of IP, the United States urges Peru to fully implement its obligations under the United States-Peru Trade Promotion Agreement (PTPA) by providing statutory damages for copyright infringement and trademark counterfeiting. The United States also encourages Peru to establish notice-and-takedown and safe harbor provisions for ISPs within the parameters of the PTPA. The United States further encourages Peru to increase the number of prosecutions against counterfeiting and piracy, enhance its border enforcement measures, resolve jurisdictional issues over counterfeit medicines and specialized IP prosecutors, and continue to build the technical IP-related capacity of its agencies, law enforcement officials, prosecutors, and judges. The United States also strongly urges Peru to enact legislation to criminalize unauthorized camcording in movie theaters in a manner that allows for effective enforcement. The United States looks forward to continuing to work with Peru to address outstanding issues in 2019.

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 United States Trade Representative 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. The United States Trade Representative 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. The United States Trade Representative 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 have 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 judicial 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)'s Office of Policy and International Affairs, through its Global Intellectual Property Academy (GIPA), offers programs in the United States, around the world, and through distance learning to provide education, training, and capacity building on IP protection, commercialization, and enforcement. These programs, conducted for the benefit of U.S. stakeholders, 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, exchanges of best practices, and other collaborative activities to improve IP protection and enforcement. The following are examples of these programs:

- In Fiscal Year (FY) 2018, 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 just under 4,000 government officials, including examiners, policymakers, police, customs, parliamentarians, judges, and prosecutors, from 83 countries. This international capacity building comprised about 55 percent of GIPA

activity in FY 2018, with additional significant efforts to inform U.S. stakeholders and policymakers about IP protection and enforcement worldwide.

- GIPA has produced 31 free distance learning modules available to the public. These modules cover six different areas of IP law and are available in five different languages (English, Spanish, French, Arabic, and Russian). By the second quarter of FY 2019, the e-learning products had received over 76,000 hits by viewers all over the world since publication in FY 2010. In the fourth quarter of FY 2018, GIPA produced and published an updated [patents video](#), which by Q2 FY 2019 had received over 3,100 views. GIPA's Q2 FY 2017 trade secrets micro-learning video has received over 9,800 views (see also USPTO GIPA's YouTube Playlist at <http://bit.ly/USPTOGIPA>).
- In addition, the USPTO's Office of Policy and International Affairs provides capacity building in countries around the world and has formed partnerships with 21 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 China, the 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) leads the STOPfakes Roadshows, which are day-long, in-depth seminars on protecting IP at home and abroad. Roadshows are presented around the country and include 12 partner agencies from across the U.S. Government. 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 as well as targeted information about protecting IP in more than 50 global markets. Additionally, U.S. companies can find webinars focusing on best practices to protect and enforce IP in China. Under the auspices of the Transatlantic IP Rights Working Group, ITA collaborates with the European Union's (EU) Directorate-General for Trade to identify areas of cooperation to help protect IP in third countries as well as in the United States and the EU. All of the ITA-developed resources, including the U.S.-EU TransAtlantic Portal, as well as information and links to the other programs identified in this Annex, are accessible via WWW.STOPFAKES.GOV. ITA also manages the STOPfakes Twitter account, @STOPfakesGov, which publicizes the release of new resources, live-tweets the STOPfakes Roadshows, and supports IP posts from other agencies.
- In FY 2018, U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI), through the National IPR Coordination Center (IPR Center), conducted HSI-led IP enforcement training programs in Colombia, Morocco, and Romania. Additionally, the IPR Center, with support from the Department of State, participated in 14 IP programs sponsored by the USPTO and the Department of Justice –

Intellectual Property Law Enforcement Coordinator (DOJ IPLEC) in Armenia, El Salvador, Ghana, Guatemala, Hong Kong, Indonesia, Mexico, Papua New Guinea, Thailand, and Vietnam.

- In FY 2018, U.S. Customs and Border Protection (CBP) provided IP training sessions to foreign customs officials in Azerbaijan, the Dominican Republic, El Salvador, Georgia, Indonesia, Mexico, Morocco, Romania, and Sri Lanka.
- 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 DOJ, USPTO, CBP, and ICE. The U.S. Government works collaboratively on many of these training programs with the private sector and with various international entities, such as WIPO and the International Criminal Police Organization. Additionally, the State Department leads the U.S. delegation to the Organisation for Economic Co-operation and Development's Task Force on Countering Illicit Trade, working to establish best practices in areas such as free trade zones and small parcel deliveries. The Department of State combined an International Arts Envoy Program with IP outreach to highlight the importance of copyright to creative industries, launching the first program in Bucharest, Romania in 2018.
- 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, adjudication of disputes, IP protection and its impact on the economy, and 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 DOJ, with funding from and in cooperation with the Department of State and other U.S. Government 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; combatting 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 Africa, the Americas, Asia, and Central and Eastern Europe.

- 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 registration and recordation functions, as well as various international copyright issues. The Copyright Office conducts a bi-annual International Copyright Institute (ICI) in conjunction with WIPO, providing week-long training on copyright matters for foreign copyright officials. The June 2018 program hosted officials from 17 countries. The next ICI program will be held in 2020. In October 2018, the Copyright Office, working with WIPO, hosted an experts’ meeting on copyright registration and infrastructure that brought together senior officials from 10 national copyright offices and one regional organization.

The United States reports to the World Trade Organization on its IP capacity-building efforts, including most recently in October 2018 (see Technical Cooperation Activities: Information from Members—United States of America, IP/C/W/647). 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 February 2019.