

2021 Special 301 Report



Office of the United States Trade Representative

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EXECUTIVE SUMMARY

The Special 301 Report (Report) is the result of an annual review of the state of intellectual property (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 put a spotlight on foreign countries and 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, which, in turn, harm American workers whose livelihoods are tied to America’s innovation-driven sectors. The Report identifies a wide range of concerns, including: (a) challenges with border and criminal enforcement against counterfeits, including in the online environment; (b) high levels of online and broadcast piracy, including through illicit streaming devices; (c) inadequacies in trade secret protection and enforcement in China, Russia, and elsewhere; (d) troubling “indigenous innovation” and forced technology transfer policies that may unfairly disadvantage U.S. right holders in markets abroad; and (e) other ongoing, systemic issues regarding IP protection and enforcement, as well as market access, in many trading partners around the world. Combatting such unfair trade policies will encourage domestic investment in the United States, foster American innovation and creativity, and increase economic security for American workers and families.

A priority of this Administration is to craft trade policy in service of America’s workers, including those in innovation-driven export industries. The Report serves a critical function by identifying opportunities and challenges facing U.S. innovative and creative industries in foreign markets and by promoting job creation, economic development, and many other benefits that effective IP protection and enforcement support. The Report informs the public and our trading partners and seeks to be a positive catalyst for change. In addition, given the importance of innovation and IP in developing the advances necessary for fighting the ongoing COVID-19 crisis, this Administration is committed to trade policies that seek to save lives in this pandemic and ensure preparedness for the next one. USTR looks forward to working closely with the governments of the trading partners that are identified in this year’s Report to address both emerging and

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.”).

continuing concerns, and to build on the positive results that many of these governments have achieved.

THE 2021 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 32 trading partners as follows:

Priority Watch List

- Argentina
- Chile
- China
- India
- Indonesia
- Russia
- Saudi Arabia
- Ukraine
- Venezuela

Watch List

- Algeria
- Barbados
- Bolivia
- Brazil
- Canada
- Colombia
- Dominican Republic
- Ecuador
- Egypt
- Guatemala
- Kuwait
- Lebanon
- Mexico
- Pakistan
- Paraguay
- Peru
- Romania
- Thailand
- Trinidad and Tobago
- Turkey
- Turkmenistan
- Uzbekistan
- Vietnam

OUT-OF-CYCLE REVIEWS

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

USTR may conduct Out-of-Cycle Reviews of trading partners as circumstances warrant or as requested by a trading partner.

REVIEW OF NOTORIOUS MARKETS FOR COUNTERFEITING AND PIRACY (*NOTORIOUS MARKETS LIST*)

In 2010, USTR began publishing annually the *Notorious Markets List* 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 2020, USTR requested such comments on October 1, 2020, and published the *2020 Notorious Markets List* on January 14, 2021. USTR plans to conduct its next Review of Notorious Markets for Counterfeiting and Piracy in the fall of 2021.

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 a 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 U.S. 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 also been on the Priority Watch List for at least one year.

Public Engagement

USTR solicited broad public participation in the 2021 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 15, 2020 (*Federal Register* notice). In addition, due to COVID-19, USTR fostered public participation via written submissions rather than an in-person hearing with the interagency Special 301 Subcommittee of the Trade Policy Staff Committee (TPSC) sending written questions about issues relevant to the review to those that submitted written comments, including to representatives of foreign governments, industry, and non-governmental organizations. USTR posted the written questions and the written responses online at www.regulations.gov, docket number USTR-2020-0041. The *Federal Register* notice drew submissions from 50 non-government stakeholders and 22 foreign governments. The submissions filed in response to the *Federal Register* notice are available to the public online at www.regulations.gov, docket number USTR-2020-0041.

Country Placement

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

USTR, together with the Special 301 Subcommittee, conducts a broad and balanced assessment of U.S. trading partners' IP protection and enforcement, as well as related market access issues affecting IP-intensive industries, in accordance with the statutory criteria. (See ANNEX 1.) The Special 301 Subcommittee, through the TPSC, provides advice on country placement to USTR based on this assessment. This assessment is 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 an action plan 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.

STRUCTURE OF THE SPECIAL 301 REPORT

The 2021 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 2021

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. USTR works to protect American innovation and creativity in foreign markets employing all the tools of U.S. trade policy, including the annual Special 301 Report (Report).

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 intellectual property (IP)-intensive industries.³ IP-intensive industries, defined by the U.S. Patent and Trademark Office (USPTO) as industries that rely most heavily on IP protections, are a diverse group that include, among others, manufacturers, technology developers, apparel makers, software publishers, agricultural producers, and creators of creative and cultural works.⁴ Together, these industries generated 38.2% of the U.S. gross domestic product (GDP).⁵ The 27.8 million workers that IP-intensive industries employed directly also enjoyed pay that was, on average, 46% higher than workers in non-IP-intensive industries.⁶ IP-intensive industries play a prominent role in U.S. trade, as evinced by the \$842 billion worth of merchandise exports produced by these industries, which accounted for 52% of total U.S. export of goods in 2014, in addition to \$81 billion of services exports.⁷

IP infringement, including patent infringement, trademark counterfeiting, copyright piracy,⁸ and trade secret theft, 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, including 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.

This Section highlights developments in 2020 and early 2021 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

³ Economics and Statistics Administration and USPTO, *Intellectual Property and the U.S. Economy: 2016 Update* at 12-13 (Sept. 2016), <https://www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf>.

⁴ *See id.* at 48-50 (listing the 81 IP-intensive industries).

⁵ *Id.* at 6.

⁶ *Id.* at 19.

⁷ *Id.* at 27-28.

⁸ The terms “trademark counterfeiting” and “copyright piracy” may appear below also as “counterfeiting” and “piracy,” respectively.

developments. This Section identifies outstanding challenges and trends, including as they relate to trade in counterfeit goods, forced technology transfer and preferences for indigenous IP, protection of trade secrets, geographical indications (GIs), innovative pharmaceutical products and medical devices, and online and broadcast piracy. 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 use of WTO dispute settlement procedures by the U.S. to resolve IP concerns.

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

USTR notes the following important developments in 2020 and early 2021:

- The **United Arab Emirates** (UAE) is removed from the Watch List this year due to the Ministry of Health and Prevention resolving concerns with IP protection of pharmaceutical products by issuing Decree 321 that, among other things, provides protection against unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval. The UAE also made progress on long-standing IP enforcement concerns, particularly with Dubai Customs which was a major cause of industry complaints given its role in the global movement of goods, including counterfeit goods. The UAE increased transparency this past year as many authorities published their IP enforcement procedures and Federal Customs began publishing annual IP enforcement statistics. Recently, the Ajman Department of Economic Development cleared the Ajman China Mall, a notorious market for the past several years,⁹ of a substantial number of counterfeit goods and are monitoring the Mall to ensure continued compliance.
- **Algeria** moves from the Priority Watch List to the Watch List due to steps the government has taken to engage and cooperate with stakeholders, improve enforcement efforts, and reduce IP-related market access barriers.
- **Brazil's** law enforcement, with support from the Department of Justice's (DOJ) International Computer Hacking and Intellectual Property (ICHIP) Advisor for Latin America & the Caribbean and Computer Crime & Intellectual Property Section (CCIPS), the U.S. Attorney's Office for the Eastern District of Virginia, Homeland Security Investigations (HSI), as well as United Kingdom (UK) counterparts, launched "Operation 404.2," which seized the domain names of multiple commercial websites engaged in the illegal reproduction and distribution of copyrighted works.
- In the most significant criminal case under **Taiwan's** recently amended Trade Secrets Act, a court ruled that a Taiwan semiconductor company and three former employees were guilty of stealing trade secrets from a U.S. company to enable the development of semiconductor chips by a Chinese state-owned enterprise. The court imposed a \$3.4

⁹ USTR, *2020 Review of Notorious Markets for Counterfeiting and Piracy* at 46 (Jan. 2021), [https://ustr.gov/sites/default/files/files/Press/Releases/2020 Review of Notorious Markets for Counterfeiting and Piracy \(final\).pdf](https://ustr.gov/sites/default/files/files/Press/Releases/2020%20Review%20of%20Notorious%20Markets%20for%20Counterfeiting%20and%20Piracy%20(final).pdf).

million fine on the Taiwan company and sentenced the former employees to 5-6 years in prison. The case involved substantial cooperation with U.S. investigators and prosecutors.

- **Peru** took enforcement actions directed at popular local websites America TVGo and Y2MATE.com offering unauthorized infringing music and film materials.
- As of March 2021, there are 60 members of the 1991 Act of the International Union for the Protection of New Varieties of Plants Convention (known as UPOV 1991). The treaty 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. A new member of UPOV 1991 this year was **Saint Vincent and the Grenadines**.
- **Ukraine** continued to take positive steps in 2020 toward a transparent, fair, and predictable system for the collective management of royalties. In particular, pursuant to 2018 legislation that fundamentally reformed its collective management organization (CMO) system, Ukraine held open competitions and made progress toward completing accreditation of two additional CMOs in 2020. This follows the accreditation in 2019 of six other CMOs under the 2018 law. Some of the accredited CMOs have completed royalty negotiations and are paying royalties to right holders. For other CMOs selected under the 2018 law, progress continues on accreditation and royalty negotiation.
- As of March 2021, there are 108 parties to the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty and 109 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 technological protection measures (TPMs), as well as certain acts affecting rights management information (RMI). Since the publication of the 2020 Special 301 Report, **Afghanistan**, **Comoros**, **San Marino**, and **Vanuatu** have acceded to the WIPO Internet Treaties. Additionally, **Nauru** acceded to the WIPO Copyright Treaty in 2020.

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

B. 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**'s 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, has significantly 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. In **Saudi Arabia**, the Saudi Authority for Intellectual Property recently created the National Committee for the Enforcement of Intellectual Property to coordinate IP enforcement, issue reports and case studies, and develop IP legislation and regulations. **Brazil**'s National Council on Combating Piracy and Intellectual Property Crimes is composed of representatives from executive branch ministries, the legislature, and the private sector and works together to discuss ongoing IP enforcement issues, propose public policy initiatives, and organize public awareness workshops. Also, in **Indonesia**, the Director General for Intellectual Property (DGIP), the Ministry of Communication and Informatics (Kominfo), and the Indonesia National Police (INP) Cybercrime unit coordinated to increase enforcement against online piracy. 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 and Consumer Affairs responsible for IP enforcement and the Maharashtra Cyber Digital Crimes Unit (MCDCU) in **India**.
- 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 Industry, Trade, and Tourism's Patent and Trademark Office carried out campaigns against IP theft. In response to the pandemic, **India**'s CIPAM reportedly organized over 200 webinars for a variety of stakeholders and maintained an active social media presence. In **Thailand**, the Department of Intellectual Property continued to carry out various IP awareness activities, including seminars for law enforcement officials, a marathon to raise awareness on piracy, and a campaign for high school and university students to raise awareness about harm caused by piracy and counterfeiting. In **Vietnam**, IP Vietnam and its partners carried out various trainings and capacity-building activities, including on patents, copyright-related issues, and enforcement.
- Another best practice is the active participation of government officials in technical assistance and capacity building. **Singapore** collects manifest data from 18 major shipping lines as part of its World Customs Organization (WCO) Cargo Targeting System and maintains a strong working relationship conducting joint investigations with U.S. Immigration and Customs Enforcement (ICE)/HSI. **Romania**'s law enforcement and

prosecutors participated in several IP workshops and trainings organized by the regional DOJ ICHIP Advisor to promote U.S. best practices for IP rights enforcement, including collaborations with Interpol, the USPTO, the U.S. Food and Drug Administration, and the U.S. Department of Homeland Security (DHS). **Taiwan** hosted a virtual training session with the American Institute of Taiwan on the topics of trade secrets protection and digital piracy prevention, which featured law enforcement experts and prosecutors from both the United States and Taiwan. **Algeria**'s National Institute of Industrial Property (INAPI) has signed a memorandum of understanding with WIPO to begin a government-wide "train-the-trainer" program on patent and IP issues for start-ups. In December 2020, the USPTO and **India**'s Department for Promotion of Industry and Internal Trade (DPIIT) signed a new Memorandum of Understanding related to IP technical cooperation mechanisms. In October 2020, the USPTO and **Cambodia**'s Ministry of Industry, Science, Technology, and Innovation (MISTI) signed a Memorandum of Understanding on patent recognition to expedite the process for granting of Cambodian patents based on the corresponding U.S. patents. 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.

- Micro, small, and medium-sized enterprises (MSMEs) play a positive role in the global economy as they contribute widely to innovation, trade, growth, investment, and competition, and many trading partners provide capacity building, technical assistance, or other resources to help MSMEs better understand IP and how to protect and enforce their IP. For example, **Hong Kong** is providing capacity building to support MSMEs, including through pro bono IP consultation services and in-house "IP Manager" and "IP Manager Plus" schemes to oversee compliance and IP monetization through comprehensive and in-depth training courses. Similarly, the **UK** provides IP audits to help potential high growth, innovative SMEs with a tailored assessment of the IP within their business to help them develop IP management strategies. In April 2021, the USMCA Committee on Intellectual Property Rights met to discuss resources, education, and programs that are available in **Canada, Mexico**, and the United States that help MSMEs address issues such as IP infringement.

C. 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 the protection of IP, innovation, and business development.

In 2020, 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 supporting innovation and competitiveness, titled *Making Micro, Small and Medium-Sized Enterprises (MSMEs) Competitive*. Over the course of three meetings, the United States and co-sponsors presented on the IP management issues that affect MSMEs' growth and development and

enable them to develop innovative products and services to address pressing global challenges affecting communities. This discussion created an opportunity for WTO Members to exchange experiences to build awareness of MSMEs to protect their IP rights and to aid them in their efforts to leverage IP to attract partnerships, particularly in the area of green technology.

D. 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:

- Trade and Investment Framework Agreements (TIFAs) between the United States and more than 50 trading partners and regions around the world have facilitated discussions on enhancing IP protection and enforcement. A June 2020 United States-**Pakistan** TIFA Intersessional meeting included engagement on governmental use of unauthorized software and, following the meeting, Pakistan procured software licenses and technical support from the U.S. company at issue. In November 2020, the United States-**Argentina** Innovation and Creativity Forum for Economic Development held its fifth meeting to discuss IP issues that are essential to the success of each country's innovation economy. At a United States-**Nepal** TIFA Council meeting in December 2020, the United States and Nepal discussed developments related to long-standing IP challenges in Nepal, such as counterfeiting of well-known trademarks and the status of draft IP legislation. In January 2021, the Intellectual Property Working Group under the United States-**Central Asia** TIFA met virtually for a workshop on Interagency Coordination of the Protection and Enforcement of Intellectual Property Rights. In February 2021, the United States and **Fiji** held the first meeting under the United States-Fiji TIFA and discussed a range of IP issues, including joining certain international IP treaties, addressing counterfeiting and piracy, and enhancing border enforcement. At a United States-**Central Asia** TIFA Council meeting held in late March and early April 2021, member countries discussed developments related to long-standing IP challenges in the region, including those related to the protection of foreign sound recordings, IP enforcement, and use of licensed software by government authorities.
- The United States engaged closely with **Canada** and **Mexico** on the implementation of provisions under the United States-Mexico-Canada Agreement (USMCA), which entered into force on July 1, 2020, securing strong improvements in the protection and enforcement of IP.
- The UK left the European Union (EU) Single Market and Customs Union in 2020, creating new opportunities for the United States to expand and deepen our existing relationship with the UK, including strengthening the protection of IP rights and addressing a range of barriers to U.S. trade and investment. The United States and the UK launched trade negotiations in May 2020 under the prior administration. After her confirmation in March 2021, United States Trade Representative Tai began a review of the status and objectives

of the United States-UK Free Trade Agreement (FTA) to inform our next steps with the UK.

- At the November 2020 Transatlantic IP Working Group meeting, the United States and the EU discussed enforcement, as well as cooperation in third countries and in multilateral fora.
- In July 2020, the United States and **Kenya** launched trade negotiations under the prior administration. Through two negotiating rounds, the United States and Kenya discussed a range of issues related to an IP chapter. USTR is reviewing the status and objectives of the negotiations before deciding next steps.

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

- The United States continued to use the **Asia-Pacific Economic Cooperation (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 industrial design protections, including the benefits of the Hague System. Industrial design protection is a critical component of any IP portfolio for competitive businesses in the modern innovation economy, particularly for small- and medium-sized businesses in the APEC region. The United States also led an initiative on illicit streaming, including by jointly publishing the *Report on Results of Survey Questionnaire on Domestic Treatment of Illicit Streaming Devices (ISDs) by APEC Economies* with APEC and hosting a virtual workshop focused on enforcement against illicit streaming in the APEC region. This initiative is an important step to inform future APEC work on addressing piracy through ISDs in the region.
- 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, in 2017, USTR announced the partial suspension of GSP benefits to **Ukraine** due to inadequate protection and enforcement of IP. The announcement specifically referenced the importance of improving Ukraine's system for CMOs. In 2019, USTR announced the partial restoration of GSP benefits due to tangible steps Ukraine is taking to reform its CMO regime. USTR is also currently reviewing IP practices in **Indonesia** and **South Africa**. 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 addition to the work described above, the United States anticipates engaging with its trading partners on IP-related initiatives in fora such as the **Group of Seven (G7)**, **WIPO**, the **Organisation for Economic Co-operation and Development (OECD)**, and **WCO**. USTR, in

coordination with other U.S. Government agencies, looks forward to continuing engagement with trading partners to improve the global IP environment.

E. IP Protection, Enforcement, and Related Market Access Challenges

Border, Criminal, and Online Enforcement Against Counterfeiting

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.

The problem of trademark counterfeiting continues on a global scale and involves the production, transshipment, and sale of a vast array of fake goods. Counterfeit goods, including semiconductors and other electronics, chemicals, medicines, automotive and aircraft parts, food and beverages, household consumer products, personal care products, apparel and footwear, toys, and sporting goods, make their way from **China**¹⁰ and other source countries, such as **India** for counterfeit medicines and **Turkey** for counterfeit apparel and foodstuffs, directly to purchasers around the world. The counterfeits are shipped either directly to purchasers or indirectly through transit **hubs**, including **Hong Kong**, **Turkey**, and the **UAE**, to third country markets such as **Brazil**, **Nigeria**, and **Paraguay** that are reported to have ineffective or inadequate IP enforcement systems. According to an OECD and European Union Intellectual Property Office (EUIPO) 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% of the global trade in goods for that year.¹¹ According to that study, **China** was “by far the biggest origin” economy for counterfeit and pirated goods, accounting (together with **Hong Kong**) for 63.4% of the world exports of counterfeit goods in 2016 with a total value of \$322 billion, and the value of counterfeit and pirated goods exported from the **UAE**, primarily through its free trade zones (FTZs), reached \$16 billion in 2016.¹² Stakeholders also continue to report dissatisfaction with enforcement in **Singapore**, including concerns about the lack of coordination between Singapore’s Customs authorities and the Singapore Police Force’s IPR Branch.

¹⁰ In fiscal year 2019, China and Hong Kong accounted for 92% of all U.S. IP rights seizures. U.S. Customs and Border Protection Office of Trade, *Intellectual Property Rights Seizure Statistics: Fiscal Year 2019* at 12 (Aug. 2020), [https://www.cbp.gov/sites/default/files/assets/documents/2020-May/FY 2019 IPR Seizure Powerpoint FINAL PBRB APPROVED_0.pdf](https://www.cbp.gov/sites/default/files/assets/documents/2020-May/FY%2019%20IPR%20Seizure%20Powerpoint%20FINAL%20PBRB%20APPROVED_0.pdf).

¹¹ OECD/EUIPO, *Trends in Trade in Counterfeit and Pirated Goods* at 11 (Mar. 2019), <https://www.oecd-ilibrary.org/docserver/g2g9f533-en.pdf>.

¹² *Id.* at 12, 46; see also OECD/EUIPO, *Mapping the Real Routes of Trade in Fake Goods* (Jun. 2017), https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/Mapping_the_Real_Routes_of_Trade_in_Fake_Goods_en.pdf.

The manufacture and distribution of 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 the rapid growth of illegitimate online sales. Counterfeiting contributes to the proliferation of substandard, unsafe medicines that do not conform to established quality standards. The United States is particularly concerned with the proliferation of counterfeit pharmaceuticals that are manufactured, sold, and distributed in numerous trading partners. The majority, by value, of all counterfeit pharmaceuticals seized at the U.S. border in Fiscal Year 2020 was shipped from or transshipped through **China, Hong Kong, India, Canada,** and the **Dominican Republic**. A recent study by OECD and EUIPO found that **China, India, the Philippines, Vietnam, Indonesia,** and **Pakistan** are the leading sources of counterfeit medicines distributed globally.¹³ Industry has also identified **Bangladesh** and **Myanmar** as emerging sources of counterfeit oncology drugs. This past year, countries reported significant quantities of COVID-19 testing kits, personal protective equipment (PPE) such as N-95 and equivalent masks, and sanitizers, detergents, and disinfectants from **China** that were determined to be counterfeit. Border authorities have also seized record shipments of counterfeit PPE, including a seizure of approximately 950,000 counterfeit facemasks by the **Vietnam** Directorate of Market Surveillance. U.S. brands are the most popular targets for counterfeiters, and counterfeit U.S.-brand medicines account for 38% of global counterfeit medicine seizures.¹⁴ While it may not be possible to determine an exact figure, the World Health Organization (WHO) estimated that substandard or falsified medical products comprise 10% of total medical products in low- and middle-income countries.¹⁵ Furthermore, the increasing popularity of online pharmacies¹⁶ has aided the distribution of counterfeit medicines. A 2020 study by Pennsylvania State University found that illicit online pharmacies, which provide access to prescription drugs, controlled substances, and substandard or counterfeit drugs, represent between 67% to 75% of web-based drug merchants.¹⁷ 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.

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

¹³ OECD/EUIPO, *Trade in Counterfeit Pharmaceutical Products* at 35 (Mar. 2020), <http://www.oecd.org/gov/trade-in-counterfeit-pharmaceutical-products-a7c7e054-en.htm>.

¹⁴ *Id.* at 12.

¹⁵ WHO, *Substandard and falsified medical products* (Jan. 2018), <https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>.

¹⁶ See Alliance for Safe Online Pharmacies (ASOP Global) / Abacus Data, *2020 National Survey on American Perceptions of Online Pharmacies* (Oct. 2020), https://buysaferx.pharmacy/wp-content/uploads/2020/10/ASOP-Global-Survey-Key-Findings_October-2020-FINAL.pdf (based on a July 2020 poll of 1500 American consumers, “35% of Americans have now reported using an online pharmacy to buy medication for themselves or someone in their care” with “31% [doing] so for the first time this year because of the pandemic”).

¹⁷ Journal of Medical Internet Research, *Managing Illicit Online Pharmacies: Web Analytics and Predictive Models Study* (Aug. 2020), <https://www.jmir.org/2020/8/e17239/>; cf. ASOP Global / Abacus Data, *infra* (“At any given time, there are 35,000 active online pharmacies operating worldwide, 96% of which are operating illegally in violation of state and/or federal law and relevant pharmacy practice standards.”); FDA, *Internet Pharmacy Warning Letters* (Mar. 2021), <https://www.fda.gov/drugs/drug-supply-chain-integrity/internet-pharmacy-warning-letters> (listing illegally operating online pharmacies that have been sent warning letters by the FDA).

of enforcement officials to interdict these goods. Over 90% 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.¹⁸

Counterfeiters also increasingly sell counterfeit goods 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, vetting third-party sellers, engaging with right holders to quickly address complaints, and working with law enforcement to identify IP violators.

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 waste resources and compromise the global enforcement effort.

In addition, trading partners should also provide enforcement officials with *ex officio* authority to seize suspect goods and destroy counterfeit goods in-country as part of their criminal procedures and at the border during import, export, or in-transit movement, without the need for a formal complaint from a right holder. In **Colombia**, for example, the customs police reportedly do not have authority to enter primary inspection zones and lack *ex officio* authority to inspect, seize, and destroy counterfeit goods in those zones. Although **Indonesia** provides *ex officio* authority for its customs authorities and has a recordation system, right holders can only benefit from the system if they meet several stringent requirements, including local permanent establishment requirements and large deposit requirements. **Turkey** provides its National Police with *ex officio* authority only in relation to copyright violations and not for trademark counterfeiting violations.

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).

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.

¹⁸ For more information on these trends and U.S. Customs and Border Protection’s and ICE/HSI’s IP enforcement efforts, see DHS, Intellectual Property Rights Annual Seizure Statistics at <https://www.cbp.gov/trade/priority-issues/ipr/statistics>.

To this end, the United States strongly supports continued work in the OECD and elsewhere on countering illicit trade. For example, the OECD recently adopted recommendations for enhancing transparency and reducing opportunities for illicit trade in FTZs.¹⁹ The United States encourages the OECD and our trading partners to build off the *Governance Frameworks to Counter Illicit Trade* OECD report²⁰ and the International Chamber of Commerce (ICC) *Know Your Customer* initiative²¹ aimed at tackling the problem of counterfeit goods transported by international shipping companies. The United States commends these efforts by the OECD and the ICC.

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, Mexico, and Pakistan**, online piracy is the most challenging copyright enforcement issue in many foreign markets. For example, countries such as **Argentina, Canada, Chile, China, Colombia, the Dominican Republic, India, Mexico, the Netherlands, Romania, Russia, Switzerland, Thailand, Ukraine, and Vietnam** have high levels of online piracy and lack effective enforcement. A June 2019 report, titled *Impacts of Digital Video Piracy on the U.S. Economy*, estimated that global online video piracy costs the U.S. economy at least \$29.2 billion and as much as \$71 billion in lost revenue each year.²²

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, and Switzerland**.

¹⁹ OECD, *Recommendation of the Council on Countering Illicit Trade: Enhancing Transparency in Free Trade Zones* (Oct 2019), <https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0454>.

²⁰ OECD, *Governance Frameworks to Counter Illicit Trade* (Mar. 2018), https://www.oecd-ilibrary.org/governance/governance-frameworks-to-counter-illicit-trade_9789264291652-en.

²¹ International Chamber of Commerce, *Know Your Customer* (Mar. 2018), <https://cdn.iccwbo.org/content/uploads/sites/3/2018/03/kyc-paper-doi-published.pdf>.

²² Blackburn, David et al., *Impacts of Digital Video Piracy on the U.S. Economy* at Foreword, ii (Jun. 2019), <https://www.theglobalipcenter.com/wp-content/uploads/2019/06/Digital-Video-Piracy.pdf>. See also Danaher, Brett et al, *Piracy Landscape Study: Analysis of Existing and Emerging Research Relevant to Intellectual Property Rights (IPR) Enforcement of Commercial-Scale Piracy*, USPTO Economic Working Paper No. 2020-2 (Apr. 2020) (evaluating peer-reviewed studies addressing the scope and magnitude of economic harm from piracy, particularly via digital channels, across music and books as well as movies and television), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3577670.

Furthermore, as highlighted in the 2017 *Notorious Markets List* and called out in subsequent *Notorious Markets Lists*, 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. Similarly, illicit Internet Protocol Television (IPTV) services unlawfully retransmit telecommunications signals and channels containing copyrighted content through dedicated web portals and third-party applications that run on ISDs or legitimate devices. Today, there are many illegal IPTV services worldwide, many of which are subscription-based, for-profit services with vast and complex technical infrastructures. Stakeholders continue to report notable levels of piracy through ISDs and illicit IPTV apps, including in **Argentina, Brazil, Chile, China, Guatemala, Hong Kong, Indonesia, Iraq, Mexico, Saudi Arabia, Singapore, Switzerland, Taiwan, Thailand, Ukraine, and Vietnam.** **China**, in particular, is a manufacturing hub for these devices, and **Iraq** is reportedly a source of satellite receivers pre-loaded with pirate IPTV apps.

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 copyrighted content. For example, while **Egypt** has stepped up efforts to combat this type of infringement, enforcement authorities continue to find infringers providing unauthorized hardwired connections to cable channels. 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 copyrighted 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 serious concerns regarding illegal camcords. For example, in **Russia**, the number of sourced camcords was reportedly 245, along with an additional 185 audio-only recordings, during the four years before the 2020 closure of theaters due to the COVID-19 pandemic. 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 continues to await consideration and passage by India’s Parliament. Although the closure of theaters and delays in release of films in 2020 led to a decreased volume of unauthorized camcording, **China** remains a notable source of illegal camcords, including live

streams of theatrical broadcasts online. Notwithstanding several criminal convictions for illegal camcording in 2020, China still lacks a specific criminal law to address the issue.

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. Countries like **Argentina, Brazil, Ecuador, India, Peru, and Russia** 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 titled *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 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 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.

Trade Secrets

This year's Report continues to reflect the growing need for trading partners to provide effective protection and enforcement of trade secrets. Companies in a wide variety of industry sectors, including Information Communications Technology (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 and Security Center, have reported specific gaps in trade secret protection and enforcement, particularly in **China** and **Russia**.²³ 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.

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 **EU** and **Taiwan**. In addition, the USMCA, which entered into force in July 2020, has the most robust protection for trade secrets of any prior U.S. trade agreement. It includes a number of commitments addressing the misappropriation of trade secrets, including by state-owned enterprises: civil procedures and remedies, criminal procedures and penalties, prohibitions against impeding licensing of trade secrets, judicial procedures to prevent disclosure of trade secrets during the litigation process, and penalties for government officials for the unauthorized disclosure of trade secrets. The United States-China Economic and Trade Agreement (Phase One Agreement), signed in January 2020, also includes several trade secret commitments to address a number of long-standing concerns in **China**, including on expanding the scope of civil liability, covering acts such as electronic intrusions as trade secret theft, shifting the burden of producing evidence, making it easier to obtain preliminary injunctions to prevent use of stolen trade secrets, allowing criminal investigations without need to show actual losses, ensuring criminal enforcement for willful misappropriation, and prohibiting unauthorized disclosure of trade secrets and confidential business information by government personnel or third-party experts.

Action in international organizations is also crucial. For instance, the United States strongly supports continued work in the OECD on trade secret protection, building off two studies released by the OECD in 2014. The first study, titled *Approaches to Protection of Undisclosed Information (Trade Secrets)*,²⁴ 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*,²⁵ examined the protection of trade secrets for a sample of 37 countries, provided historical data for the period since 1985, and considered the

²³ National Counterintelligence and Security Center, *Foreign Economic Espionage in Cyberspace* at 5-9 (2018), <https://www.dni.gov/files/NCSC/documents/news/20180724-economic-espionage-pub.pdf>.

²⁴ Schultz, M. and D. Lippoldt, *Approaches to Protection of Undisclosed Information (Trade Secrets): Background Paper* (Jan. 2014), <https://doi.org/10.1787/5jz9z43w0jnw-en>.

²⁵ Lippoldt, D. and M. Schultz, *Uncovering Trade Secrets - An Empirical Assessment of Economic Implications of Protection for Undisclosed Data* (Aug. 2014), <https://doi.org/10.1787/5jxzl5w3j3s6-en>.

relationship between the stringency of trade secret protection and relevant economic performance indicators. Also, in November 2016, APEC endorsed a set of *Best Practices in Trade Secret Protection and Enforcement Against Misappropriation*,²⁶ 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.

Forced Technology Transfer, Indigenous Innovation, and Preferences for Indigenous IP

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, effectively 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 market access provided to foreign companies operating in the United States. Such government-imposed conditions or incentives for technology transfer to domestically owned companies may also 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. Furthermore, these measures discourage foreign investment in national economies, hurt local manufacturers, distributors, and retailers, and slow the pace of innovation and economic progress. This kind of 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 as a condition 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;

²⁶ *Best Practices in Trade Secret Protection and Enforcement Against Misappropriation*, <https://ustr.gov/sites/default/files/11202016-US-Best-Practices-Trade-Secrets.pdf>.

- Failing to take meaningful measures to prevent or to 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. China has made enforceable commitments to address forced technology transfer in the Phase One Agreement.

In **Indonesia**, it is reported that foreign companies' approvals to market pharmaceuticals are conditioned upon the transfer of technology to Indonesian entities or upon partial manufacture in Indonesia. Indonesia has removed localization provisions in its 2016 Patent Law that require the manufacture of patented products and use of patented processes in Indonesia.

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 preferences for indigenous IP and take account of the importance of voluntary and mutually agreed commercial partnerships or arrangements.

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 held by U.S. producers and imposes barriers on market access for U.S.-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 protection of a GI. Trademarks are among the most effective ways for producers and companies, including MSMEs, to create

value, to promote their goods and services, and to 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 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 and protection of GIs that are confusingly similar to 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 by granting protection to terms that are considered in those markets to be the common name for products. The EU has granted GI protection to thousands of terms that now only certain EU producers can use in the EU market, and many of these producers then block the use of any term that even “evokes” a GI. However, many EU member states, such as Denmark and France, still produce products that are GIs of other European countries, such as feta, and export these products outside of the EU using the common names. 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 (Codex). Argentina, South Africa, Uruguay, and other countries produce danbo. Similarly, in 2019, the EU granted GI protection to havarti, notwithstanding the long-standing and widespread use of this term by producers around the world. Australia, New Zealand, the United States, and other countries produce havarti. Like in the case of danbo, the Codex established an international standard for havarti in 2007, premised on the fact that havarti is produced and marketed in many countries throughout the world under that name. The EU’s approval of GIs for havarti and danbo undermine the Codex standards for these products, and WTO Members have repeatedly challenged the EU to explain its disregard for Codex cheese standards at the WTO, including in the Technical Barriers to Trade (TBT) Committee. Moreover, havarti is included in the EU’s most favored nation (MFN) tariff rate quota, indicating that havarti was expected to be produced outside of and imported into the EU. Several countries, including the United States, opposed GI protection of these common names, both during the EU’s opposition period and at the WTO, 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, parmesan, asiago, or feta. This is despite the fact that these terms are the common names for products produced in countries around the world. In the EU and other markets that have adopted the EU GI system, U.S. producers and traders either are effectively blocked from those markets or must adopt burdensome workarounds. They either cannot use the descriptors at all, or anything even evoking them, in the market or at best may sell their products only as “fontina-like,” “gorgonzola-kind,” “asiago-style,” or “imitation feta.” This is costly, unnecessary, and can reduce consumer demand for the non-EU products, as well as can reduce consumer choice and cause consumer confusion.

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 exported approximately \$1 billion of cheese to the United States last year. Conversely, the United States exported only about \$5.5 million of cheese to the EU last year. Based on this evidence, 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. Unfortunately, U.S. producers, as evidenced by the deficit, are not afforded the same level of market access to the EU.

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. The United States continues to urge the EU to not implement certain proposed changes to the EU's Common Agricultural Policy, which, if adopted, would transfer much of the GI 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 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 denying the United States and 160 other WIPO countries meaningful participation rights in the negotiations. In 2020, the EU became party to the Geneva Act of the Lisbon Agreement. In other international organizations, such as the United Nations Food and Agriculture Organization, the EU has attempted to pursue its agenda by alleging a connection between GIs and unrelated issues, such as biodiversity, sustainability, and food safety.

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 identified by common names or otherwise marketed under previously registered trademarks. 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, Australia, Brazil, Canada, Chile, China, Ecuador, Indonesia, Japan, Kenya, Korea, Mexico, Morocco, New Zealand, Paraguay, the Philippines, Singapore, Tunisia, Ukraine, 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 multiple terms identify its common name components; and
- Opposing efforts to extend the protection given to GIs for wines and spirits to other products.

Pharmaceutical and Medical Device Innovation and Market Access

The COVID-19 pandemic has highlighted the importance of pharmaceutical, medical device, and other health-related innovation, as well as a lack of widespread, equitable distribution of these innovations. USTR continues to seek adequate and effective protection for pharmaceutical and other health-related IP around the world to ensure robust American innovation in these critical industries to fight not only the current, but also future pandemics. In addition, USTR has sought to level the playing field abroad by reducing market access barriers, including those that discriminate against U.S. companies, are not adequately transparent, or do not offer sufficient opportunity for meaningful stakeholder engagement. USTR continues to seek to address policies that harm American innovators and workers in health-related industries through unfair competition. Addressing these market access barriers will help to facilitate affordable and accessible health care today and encourage innovation for improved health care tomorrow.

Measures, including those 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 costs and less accessible health care for certain populations, particularly in developing countries. For example, taxes or tariffs may be levied, often in a non-transparent manner, on imported medicines; the increased expense associated with those levies is then passed directly to health care institutions and patients. By some estimates, federal and state taxes can add 31% to the cost of medicines in **Brazil**. According to a January 2017 Asian Development Bank report titled *Trade in Health Products: Reducing Trade Barriers for Better Health*, developing countries overall maintain the highest tariffs on medicines, pharmaceutical inputs, and medical devices among the WTO Members identified in the report.²⁷ The report notes that, in particular, large developing countries such as **India** and **Pakistan** have the highest tariffs for such products. For example, in **India**, the combination of import duties and domestic taxes on imported medicines reportedly amount to an effective tax that can exceed 20%. These tariffs, combined with domestic

²⁷ Asian Development Bank, *Trade in Health Products: Reducing Trade Barriers for Better Health* at 10 (Jan. 2017), <https://www.adb.org/sites/default/files/publication/224171/adbi-wp643.pdf>.

charges or measures, particularly those that lack transparency or opportunities for meaningful stakeholder engagement or that appear to exempt domestically-developed and manufactured medicines, can hinder government efforts to promote increased access to health care products.

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

Among other examples, USTR engagement in the past year included:

- Secured and implemented strong IP provisions with **Canada** and **Mexico**, which are important to incentivizing innovation, in the 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;
- Secured enforceable commitments from **China** to: (1) establish a mechanism for the early resolution of potential pharmaceutical patent disputes, including a cause of action to allow a patent holder to seek expeditious remedies before the marketing of an allegedly infringing product; (2) provide patent term extensions to compensate for unreasonable patent office and marketing approval delays that cut into the effective patent term; and (3) permit the use of supplemental data to meet relevant patentability criteria for pharmaceutical patent applications;
- Engaged with the **UAE**, which issued Decree 321 that provides effective protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products;
- Engaged with **Korea** to secure meaningful reforms on long-standing issues pertaining to Korea's commitments under the United States-Korea Free Trade Agreement (KORUS FTA) to ensure transparency and stakeholder engagement with respect to pricing and reimbursement policies and non-discriminatory treatment for U.S. pharmaceutical exports;
- Engaged with **Japan** to ensure transparency and fairness, including by providing meaningful opportunities for interested stakeholders to provide input regarding changes to pricing and reimbursement policies and regarding Japan's mechanism for the early resolution of potential pharmaceutical patent disputes; and
- Pressed **Indonesia** to fully resolve concerns regarding revisions to Indonesia's patent law, such as its patentability criteria, and disclosure requirements for inventions related to traditional knowledge and genetic resources.

The IP-intensive U.S. pharmaceutical and medical device industries have expressed concerns regarding the policies of several trading partners, including **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:

- Stakeholders have expressed concerns about delays by **Australia** in its implementation of the notification process as required, for example, under Article 17.10.4(b) of the United States-Australia Free Trade Agreement. In October 2020, the Ministry of Health announced planned reforms, but they require legislative changes, which have yet to be introduced in Parliament. The United States will continue to engage with Australia as it introduces legislation to increase transparency and to promote the early resolution of potential pharmaceutical patent disputes.
- Stakeholders have long urged **Japan** to implement predictable pricing and reimbursement policies for advanced medical devices and innovative pharmaceuticals. Recent policy changes to the Price Maintenance Premium (PMP) appear to make it easier for Japanese companies to qualify for the premium as compared to non-Japanese companies, particularly those that qualify as small- and medium-sized enterprises. Other causes for concern are a health technology assessment system reportedly developed without meaningful opportunities for stakeholder input, as well as a lack of transparency and predictability associated with Japan's implementation of annual repricing for drug reimbursement, which is scheduled to begin in April 2021 and applies to a larger-than-expected range of products.
- Stakeholders have urged **Korea** to ensure that pharmaceutical reimbursement is conducted in a fair, transparent, and nondiscriminatory manner. It is critical that Korea continues addressing U.S. concerns regarding the lack of transparency and predictability 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.
- Stakeholders continue to raise concerns regarding **Turkey's** pharmaceutical manufacturing inspection process. The United States urges Turkey to build upon its recent accession to the Pharmaceutical Inspection Convention and Cooperation Scheme (PIC/S) and to recognize Good Manufacturing Practices certificates issued by any of the PIC/S members to improve regulatory timelines.

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.

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, and trademark registration procedures lack transparency and consistency. For example, the trademark system in **China** lacks effective tools to combat widespread bad faith trademark applications, in part because it unnecessarily constrains examiners from considering marks for related goods or services in different classes when evaluating bad faith, likelihood of confusion, and other matters. The China National Intellectual Property Administration's Trademark Registration and Examination Department and the Trademark Review and Adjudication Department proceedings give insufficient legal weight to notarized and legalized witness declarations. Such proceedings also have unreasonably high standards for establishing well-known mark status and do not give full consideration to consent and coexistence agreements. Furthermore, China lacks transparency in all phases of trademark prosecution. It remains to be seen whether commitments made by China in the Phase One Agreement related to these concerns will improve the protection of IP.

In addition, many other countries, including **India, Malaysia,** and the **Philippines**, reportedly have slow opposition or cancellation proceedings, while **Panama** and **Russia** have no administrative opposition proceedings. Delays in obtaining registrations present a significant obstacle for protecting IP rights in foreign markets, with stakeholders identifying **Iraq** and **South Africa** as countries with extreme delays in processing trademark applications. A number of countries do not perform relative examination, which provides for *ex officio* rejection of trademark applications based on a likelihood of confusion with previously filed applications and registrations. Failure to employ relative examination places the onus on trademark holders, including MSMEs, to bring and litigate costly invalidation proceedings to protect their IP, and it risks the contemporaneous registration of multiple conflicting marks in a jurisdiction. Numerous countries including **Algeria, China, Indonesia, Iraq, Kuwait, Oman,** and the **UAE** require burdensome formalities such as pen-and-ink signatures, notarized or legalized powers of attorney, or certified copies of priority documents.

Another concern includes mandatory requirements to record trademark licenses, such as in **Brazil, Ecuador, Egypt,** and **Spain**, 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. Furthermore, strict use of the Nice Classification or a country's own sub-classification system that does not reflect the underlying goods or services introduces uncertainty into the registration process.

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 or impose burdens relating to ownership or assignment of certification marks. The lack of a certification mark system can make it more difficult for consumers to identify products with a certain quality or characteristic either of their manufacture or production, such as environmentally “green” products, or that consumers associate with the product’s geographic origin. Robust protection for well-known marks, another internationally recognized means of protecting marks outlined in the Paris Convention for Protection of Industrial Property, is also important for many U.S. producers and traders who have built up the reputation of their brands. Stakeholders report that some countries that do have well-known mark provisions, such as **China**, nevertheless impose significant burdens on brand owners that attempt to establish that their marks are well known.

The absence of default judgments in opposition and invalidation proceedings in certain countries, such as **China**, incurs significant costs to U.S. companies. Companies are forced to submit detailed arguments and evidence in proceedings when it is clear that the owners of the applications and registrations have no interest or intention in defending them, particularly in the case of bad faith trademark registrations and trademark squatters. Owners of challenged trademarks should be required to submit a written statement that they still have an interest in their trademark in order for a full proceeding to continue.

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 some 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.²⁸ 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.

²⁸ 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 .euo 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. *Press Release: EURid and IACC Team Up to Fight Cybercrime* (Jun. 2018), <https://www.iacc.org/media/press-release-eurid-and-iacc-team-up-to-fight-cybercrime>. 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. Danish Internet Forum, *Crime prevention on the internet: Report on the efforts of DK Hostmaster and DIFO to prevent internet crime pertaining to IPR violations* at 3, 5, 9 (undated), https://www.dk-hostmaster.dk/sites/default/files/2018-06/DIFOs_kriminalitetsbekaempelse_EN.pdf; *Press Release: Significantly fewer scam web shops in the .dk zone* (Apr. 2018), <https://www.dk-hostmaster.dk/en/news/significantly-fewer-scam-web-shops-dk-zone>.

Copyright Administration and Payment of Royalties

CMOs for copyright can play an important role in ensuring compensation for right holders when CMO practices are fair, efficient, transparent, and accountable. Also, the collection and distribution of royalties to U.S. and other right holders should be carried out on a national treatment basis. Unfortunately, CMO systems in several countries are reportedly flawed or non-operational. In some countries, like **India**, government agencies have attempted to extend the scope of mandatory collective management of rights and statutory license fees to certain online transmissions. In the **UAE**, the Ministry of Economy's failure to issue the necessary operating licenses to allow CMOs represents a 17-year-plus challenge that the UAE should address without further delay so that right holders can receive compensation for their works. While **Ukraine** passed legislation in 2018 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 continue pursuing amendments to the law to ensure that there is a transparent, fair, and predictable system for the collective management of royalties in Ukraine.

In addition, it is important for right holders of a work, performance, or phonogram to be able to freely and separately transfer their economic rights by contract and to fully enjoy the benefits derived from those rights. Limitations on the freedom to contract raise concerns because they reduce the ability of creators to earn a living from their works, performances, and phonograms. For example, proposed provisions in two pending bills in **South Africa** limiting certain assignments are vague, lack certainty for parties, and provide for the government to set standard and compulsory contractual terms for certain contracts governing the use of works, performances, and phonograms.

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 2018.²⁹ 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, China, Guatemala, Indonesia, Pakistan, Paraguay, Romania, Thailand, Turkey, Turkmenistan, Ukraine, Uzbekistan, and Vietnam**. The United States urges trading partners to adopt and implement effective and transparent procedures to ensure legitimate governmental use of software.

²⁹ BSA, 2018 Global Software Survey at 12 (Jun. 2018), https://gss.bsa.org/wp-2content/uploads/2018/05/2018_BSA_GSS_Report_en.pdf.

Other Issues

U.S. stakeholders have expressed views with respect to the EU Directive on Copyright in the Digital Single Market. The United States continues to monitor copyright issues in the EU and its member states as implementation progresses. Stakeholders have expressed concern with the inconsistencies in member states' approaches to implementation. 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. The United States will continue to engage with various EU and member state entities to address the equities of U.S. stakeholders.

The United States also will closely monitor the EU Commission's Digital Services Act proposal, another legislative initiative that would govern online services and how content is shared online.

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 economic growth, as well as technological advances needed to meet environmental challenges.

G. Intellectual Property and Health

The 2021 Special 301 review period has taken place during the COVID-19 pandemic, the largest global health crisis in more than a century. The top priority of the United States is saving lives and ending the pandemic in the United States and around the world. This includes investing in the COVAX Facility, sharing our surplus vaccine doses, and working with our international partners, such as the Quad Vaccine Partnership, to surge production and delivery, including through efforts to achieve greater regional and local manufacturing capacity, in recognition of the importance of widespread vaccination against COVID-19 to combat the pandemic and hasten economic recovery.

As part of rebuilding U.S. alliances, the United States is exploring every avenue to coordinate with the global community and is evaluating the efficacy of proposals in multilateral fora, including the WTO, by their true potential to save lives, end this pandemic, and respond to the next one.

Numerous comments in the 2021 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.

As affirmed in the Doha Declaration on the TRIPS Agreement and Public Health, the United States emphasizes trading partners' rights to protect public health and, in particular, to promote access to medicines for all. International obligations such as those in the TRIPS Agreement provide flexibility for trading partners to take measures to address serious public health emergencies and circumstances of extreme urgency within that trading partner's territory. The COVID-19 pandemic certainly qualifies as such. Consistent with this view, the United States respects its trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health.

Article 31 of the TRIPS Agreement establishes requirements that must be met with respect to compulsory licenses. Importantly, some of these requirements may be waived. For example, in cases of national emergency or extreme urgency or in cases of public non-commercial use, WTO Members may waive the requirement to seek prior authorization from the patent holder before issuing a compulsory license. In addition, under Article 31bis, the requirement that compulsory licenses must be authorized predominantly for the supply of the Member's domestic market may be waived in certain circumstances. Recognizing that Members with insufficient pharmaceutical manufacturing capacities could face difficulties in making effective use of compulsory licensing, Article 31bis and its related Annex set forth a system whereby such Members can import from another Member pharmaceutical products produced subject to a compulsory license. The United States respects the right of its trading partners to exercise the full range of existing flexibilities in the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health in order to scale up the production and distribution necessary to overcome the challenges of the ongoing COVID-19 pandemic.

The United States also strongly supports the WTO General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, concluded in August 2003. Under this decision, WTO Members are permitted, in accordance with specified procedures, to issue compulsory licenses to export pharmaceutical products to countries that cannot produce drugs for themselves. The WTO General Council adopted a Decision in December 2005 that incorporated this solution into Article 31bis, as described above, 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 WTO 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 (UN) and related institutions such as WIPO and the WHO, are consistent with U.S. policies concerning IP and health policy and do not impede its trading partners from taking measures necessary to protect public health. Accordingly, USTR will continue its close cooperation with relevant agencies to ensure that public health challenges are addressed and IP protection and enforcement are supported as one of various mechanisms to promote research and innovation.

H. Implementation of the WTO TRIPS Agreement

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

Developed country WTO Members were required to implement the TRIPS Agreement fully as of January 1, 1996. Developing country WTO Members were given a transition period for many obligations until January 1, 2000, and in some cases until January 1, 2005. Nevertheless, certain WTO 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 WTO Members to implement Sections 5 and 7 of Part II 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 for LDC Members also until January 1, 2033, which the WTO General Council adopted on November 30, 2015. Likewise, on June 11, 2013, the TRIPS Council reached consensus on a decision to again extend the transition period under Article 66.1 of the TRIPS Agreement for LDC WTO Members. Under this decision, LDC WTO Members are not required to apply the provisions of the TRIPS Agreement, other than Articles 3, 4, and 5 (provisions related to national treatment and most-favored nation treatment), until July 1, 2021, or until such a date on which they cease to be an LDC WTO Member, whichever date is earlier. The United States is engaging LDC WTO Members on an additional extension to the transition period.

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. On December 10, 2019, the General Council reached consensus to extend this moratorium until the 12th Ministerial Conference. 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 extended in several WTO Ministerial Decisions. 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 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.

Under Section 301 of the Trade Act of 1974, USTR is taking action to address a range of unfair and harmful Chinese acts, policies, and practices related to technology transfer, IP, and innovation. USTR also initiated dispute settlement proceedings at the WTO to address discriminatory licensing practices. Over the past year, the United States' engagement with China began to demonstrate progress with the signing of the Phase One agreement in January 2020. The agreement requires changes in China's acts, policies, and practices, including structural reforms and other changes to China's legal and regulatory regime to address numerous long-standing concerns of a wide range of U.S. industries.

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 Dispute Settlement Body (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 continues 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

ARGENTINA

Argentina remains on the Priority Watch List in 2021.

Ongoing Challenges and Concerns

Argentina continues to present long-standing and well-known challenges to intellectual property (IP)-intensive industries, including those from the United States. A key deficiency in the legal framework for patents is the unduly broad limitations on patent-eligible subject matter, including patent examination guidelines that automatically reject patent applications for categories of pharmaceutical inventions that are eligible for patentability in other jurisdictions and requirements that processes for the manufacture of active compounds disclosed in a specification be reproducible and applicable on an industrial scale. Stakeholders remain concerned about the limits on patentability for biotechnological innovations based on living matter and natural substances in Resolution 283/2015, which differ from the standard in many other countries. 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, although Argentina, through Resolution 56/2016, has allowed for a partial reduction of its patent backlog through reliance on favorable decisions from counterpart foreign patent applications, Argentina continues to struggle with a substantial backlog of patent applications for biotechnological and pharmaceutical inventions resulting in long delays for innovators in these fields seeking patent protection in the market. Government-wide hiring restrictions that remain in place, going back to a hiring freeze in 2018, have resulted in a limited number of patent examiners. However, new online-processing procedures implemented by the National Institute of Industrial Property (INPI) have allowed for increased numbers of filings and, according to industry, have improved efficiency in the processing of patents and trademarks in 2020. As for INPI's participation in the Patent Prosecution Highway with the U.S. Patent and Trademark Office, the project expired in March 2020.

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. Although the physical market of La Salada in Buenos Aires was closed during much of 2020, many of its activities involving the sale of counterfeit goods moved online through social media applications. Counterfeit sales in other physical locations also increased, with surges in the selling of counterfeit goods occurring in small markets, through illegal street vendors, and in activity in the Avellaneda Street market in Buenos Aires. In addition, 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, infringers rarely receive deterrent sentences. Hard goods counterfeiting and optical disc piracy are widespread, and online piracy continues to grow due to

nearly non-existent criminal enforcement against such piracy. As a result, IP enforcement online in Argentina consists mainly of right holders trying to convince Argentine Internet service providers to agree to take down specific infringing works, as well as attempting to seek injunctions in civil cases, both of which can be time-consuming and ineffective. Right holders also cite widespread use of unlicensed software by Argentine private enterprises and the government.

Developments, Including Progress and Actions Taken

Argentina made limited progress in IP protection and enforcement in 2020. INPI began accepting the electronic filing of patent, trademark, and industrial design applications in 2018 and completed its transition to an all-electronic filing system in 2020. Argentina continued to improve procedures for trademarks and saw record high trademark filings in 2020, with INPI reducing the time for trademark registrations and implementing a fast track for trademark renewals. The United States welcomes and continues to monitor these enhancements. 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. The United States urges Argentina to ensure transparency and procedural fairness in the protection of geographical indications (GIs) and to ensure that the grant of GI protection does not deprive interested parties of the ability to use common names, particularly as Argentina proceeds with the European Union-Mercosur Trade agreement.

Argentina's efforts to combat counterfeiting continue, but without systemic measures, illegal activity persists. As noted, reports show a resurgence of markets selling counterfeit and pirated goods. The United States encourages Argentina to create a national IP enforcement strategy to enhance interagency coordination in enforcement efforts and move to having a sustainable, long-lasting impact on IP infringements. 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 2017, Argentina formally created the Federal Committee to Fight Against Contraband, Falsification of Trademarks, and Designations, formalizing the work on trademark counterfeiting under the National Anti-Piracy Initiative. The Committee did not meet during 2020, but the United States encourages Argentina to continue this initiative and expand it to include online piracy. Revisions to the criminal code that had been submitted to Congress, including certain criminal sanctions for circumventing technological protection measures, have stalled. The creation of a federal specialized IP prosecutor's office and a well-trained enforcement unit could potentially help combat online piracy as well as prevent lengthy legal cases with contradictory rulings. In November 2020, Argentina and the United States held a bilateral meeting under the Innovation and Creativity Forum for Economic Development, part of the United States-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 2021.

Ongoing Challenges and Concerns

The United States continues to have serious concerns regarding long-standing implementation issues with a number of intellectual property (IP) provisions of the United States-Chile Free Trade Agreement (Chile FTA). Chile must establish protections against the unlawful circumvention of technological protection measures. 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 1991) and improve protection for plant varieties. Chile passed legislation establishing criminal penalties for the importation, commercialization, and distribution of decoding devices used for the theft of encrypted program-carrying satellite signals, but the U.S. Government urges 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. In addition, the United States urges Chile to improve its Internet service provider liability framework to permit effective and expeditious action against online piracy. Pharmaceutical stakeholders continue to raise concerns over the efficacy of Chile's system for resolving patent issues expeditiously in connection with applications to market pharmaceutical products and over the provision of 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. Stakeholders have expressed concerns over the vagueness of certain provisions of the "Medicines II" bill under consideration by the National Congress.

Developments, Including Progress and Actions Taken

Chile's National Institute of Industrial Property continued to make improvements to strengthen the climate for IP protection, further reducing the patent backlog by 7.7% as of December 2020 compared to the prior year. Separately, the United States encourages Chile to provide transparency and procedural fairness to all interested parties in connection with potential recognition or protection of geographical indications (GIs) and to ensure that the grant of GI protection or recognition does not deprive interested parties of the ability to use common names, including in connection with trade agreement negotiations.

It has now been over seventeen years since the Chile FTA entered into force. The United States appreciates Chile's engagement with the United States and the steps Chile has taken as an attempt to resolve these ongoing issues, but it remains critical that Chile show tangible progress in addressing the long-standing Chile FTA implementation issues and other IP issues in 2021.

CHINA

China remains on the Priority Watch List in 2021 and is subject to continuing Section 306 monitoring.

Ongoing Challenges and Concerns

China needs to deepen reforms strengthening intellectual property (IP) protection and enforcement, fully implement recent revisions to its IP measures, refrain from requiring or pressuring technology transfer to Chinese companies, open China's market to foreign investment, and allow the market a decisive role in allocating resources. For U.S. persons who rely on IP protection in what is already a very difficult business environment, severe challenges persist because of excessive regulatory requirements and informal pressure and coercion to transfer technology to Chinese companies, continued gaps in the scope of IP protection, incomplete legal reforms, weak enforcement channels, and lack of administrative and judicial transparency and independence.

Under Section 301 of the Trade Act of 1974, the Office of the United States Trade Representative (USTR) has been taking action to address a range of unfair and harmful Chinese acts, policies, and practices related to technology transfer, IP, and innovation. USTR has also successfully pursued dispute settlement proceedings at the World Trade Organization (WTO) to address discriminatory licensing practices. In addition, the United States' engagement with China has been demonstrating progress since the signing of the United States-China Economic and Trade Agreement (Phase One Agreement) in January 2020.

The Phase One Agreement contains separate chapters on IP and technology transfer. The chapters address numerous long-standing concerns of a wide range of U.S. industries, including in the areas of trade secrets, patents, pharmaceutical-related IP, trademarks, copyrights, and geographical indications. The United States has been closely monitoring China's progress in implementing its commitments.

In 2020, China published a large number of draft IP-related legal and regulatory measures and finalized over a dozen measures. Notably, China amended the Patent Law, Copyright Law, and Criminal Law in the past year. However, these steps toward reform require effective implementation and also fall short of the full range of fundamental changes needed to improve the IP landscape in China. As discussed further below, right holders report some improvements to IP enforcement but uncertainty about the effectiveness of certain law changes. Furthermore, long-standing problems such as bad faith trademarks and counterfeiting persist, and worrying developments such as broad anti-suit injunctions issued by Chinese courts have emerged.

Moreover, Chinese officials have made high-level statements suggesting that IP rights should be linked to national security and the "external transfer" of IP rights in certain technologies should be prevented and emphasizing the need to develop "indigenous" innovation. Chinese agencies have also proposed incentive measures for semiconductors and software that condition eligibility on "indigenous" IP. Other official statements indicate that the judiciary must uphold the absolute leadership of the Chinese Communist Party and do its part to ensure Chinese ownership of

technologies critical to China’s development. Such statements and measures raise concerns about requiring and pressuring technology transfer and about whether IP protection and enforcement will apply fairly to foreign right holders in China.

Developments, Including Progress and Actions Taken

In 2018, USTR reported that its investigation under Section 301 of the Trade Act of 1974 found that China pursues a range of unfair and harmful acts, policies, and practices related to technology transfer, IP, and innovation. These include investment and other regulatory requirements that require or pressure technology transfer, substantial restrictions on technology licensing terms, 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 into and theft from computer networks of U.S. companies to obtain unauthorized access to IP.

In March 2018, the United States initiated a WTO case challenging Chinese measures that deny foreign patent holders the ability to enforce their patent rights against a Chinese joint-venture partner after a technology transfer contract ends and that impose mandatory adverse contract terms that discriminate against and are less favorable for imported foreign technology as compared to Chinese technology. Consultations took place in August 2018, and a panel was established to hear the case at the United States’ request in November 2018. In March 2019, China announced the withdrawal of certain measures that the United States had challenged in its panel request. After China’s announcement, the WTO panel suspended its work in light of ongoing consultations between the United States and China to resolve their dispute.

As part of the Phase One Agreement, China agreed to provide effective access to Chinese markets without requiring or pressuring U.S. persons to transfer their technology to Chinese persons. China also agreed that any transfer or licensing of technology by U.S. persons to Chinese persons must be based on market terms that are voluntary and mutually agreed, and that China would not support or direct the outbound foreign direct investment activities of its persons aimed at acquiring foreign technology with respect to sectors and industries targeted by its industrial plans that create distortion. USTR is working with stakeholders to evaluate whether these commitments have resulted in changes in China’s ongoing conduct at the national, provincial, and local levels.

Legislative and Judicial Reforms

Recent amendments to IP-related laws, discussed further below, introduced several changes. These amendments increased the minimum and maximum levels of statutory damages in the Patent Law and Copyright Law, as well as the minimum and maximum criminal penalties for IP-related crimes under the Criminal Law. In addition, the Patent Law and Copyright Law amendments provided for punitive damages for “intentional infringement” that were “under serious circumstances.” The Patent Law and Copyright Law also provided a burden-shifting provision similar to that in the amended Trademark Law, where a court has the discretion to order a defendant to produce accounting records and other evidence relating to illegal sales and to rely on the plaintiff’s evidence of damages if the defendant fails to produce evidence or produces false evidence.

In addition, the Supreme People's Court (SPC) issued several new judicial interpretations on the treatment of evidence in IP trials, the handling of civil disputes on trade secret misappropriation, the handling of criminal cases for IP infringement, administrative cases involving the granting of patent rights, IP disputes that are Internet-related or involve e-commerce platforms, increasing punishment for IP infringement, and protection for copyright and related rights. The SPC also issued an implementation plan and guidelines for the enforcement of IP judgments. Also, the State Council issued a new regulation on the transfer of cases from administrative to criminal authorities when there is a reasonable suspicion of a criminal violation. The Supreme People's Procuratorate (SPP) and the Ministry of Public Security (MPS) issued new regulations revising the criminal prosecution standards for trade secret misappropriation cases.

However, it remains to be seen whether these measures sufficiently address existing challenges to right holders, such as obstacles to obtaining preliminary injunctive relief, a lack of means to require evidence production, onerous authentication and other evidentiary requirements, difficulties in establishing actual damages, insufficient damage awards based on low-level statutory minimums, burdensome thresholds for criminal enforcement, and lack of deterrent-level statutory damages and criminal penalties. At the early stages of implementation for all these changes, reports have been mixed. For example, the introduction of statutory minimums for copyright infringement and the reported increase in overall damage awards for civil IP cases have been positive developments. However, the minimum amount for statutory copyright damages (approximately \$75) and failure to raise minimum terms of imprisonment in criminal copyright cases may be insufficient to deter future infringement. As another example, while foreign right holders have been able to submit documentary evidence in some courts without any consularization or notarization of the documents, the Beijing IP Court reportedly continues to reject even consularized and notarized documentation on various dubious grounds.

Furthermore, Chinese judicial authorities continue to demonstrate a lack of transparency, such as by publishing only selected decisions rather than all preliminary injunctions and final decisions. U.S. right holders report that procedural obstacles to appealing decisions to the Beijing IP Court are sometimes insurmountable and may frustrate appeals altogether. Administrative enforcement authorities fail to provide right holders with information regarding the process or results of enforcement actions. Broader concerns include the continuing emphasis on administrative enforcement, as well as interventions by local government officials, party officials, and powerful local interests that undermine China's judicial system and rule of law. A truly independent judiciary is critical to promote rule of law in China and to protect IP rights.

Trade Secrets

The SPC's recent judicial interpretation on the handling of civil disputes on trade secret misappropriation includes provisions relating to the scope of civil liability for misappropriation beyond business operators, prohibited acts of trade secret theft, burden-shifting, and the availability of preliminary injunctive relief. In addition, the amended Criminal Law, the recent judicial interpretation on the handling of criminal cases of IP infringement, and the revised prosecution standards include changes to the thresholds for criminal investigation and prosecution and the scope of criminal acts of trade secret theft. Along with the April 2019 amendments to the Anti-Unfair Competition Law and Administrative Licensing Law, these changes represent positive

developments in China's trade secret regime. However, concerns remain about the implementation of these new measures and gaps persisting in the scope of protections. Right holders continue to face challenges such as the lack of means to require evidence production, as highlighted by a recent study suggesting that Chinese courts have not widely adopted the burden-shifting mechanism provided by the amended Anti-Unfair Competition Law.

Also, the recent judicial interpretation on criminal cases introduces new methods for calculating remedial costs and other losses to meet the criminal threshold for trade secret crimes, but right holders may encounter obstacles in demonstrating the extent of their losses under the definitions in the new interpretation.

In addition, reforms should provide procedural safeguards to prevent the unauthorized disclosure of trade secrets and other confidential information submitted to government regulators, courts, and other authorities, including related disclosures to third-party experts and advisors, an issue of serious concern to the United States as well as to U.S. stakeholders in industries such as software and cosmetics. Also, China should further address obstacles to criminal enforcement.

Bad Faith Trademarks and Other Trademark Examination Issues

Bad faith trademarks remain one of the most significant challenges for U.S. brand owners in China, despite Trademark Law amendments that allow trademark examiners to refuse bad faith trademark applications and invalidate existing bad faith registrations. Right holders report some improvements in the China National Intellectual Property Administration's (CNIPA) rejection at the examination stage of bad faith trademarks that lack an intention to use in commerce as well as reduced examination times. However, problems persist with the large number of inconsistent decisions and low rate of success for oppositions. With the elimination of appeals for opposition procedures, bad faith trademarks are immediately registered after a failed opposition, and bad actors have longer windows to use their marks or extort from the legitimate brand owner, before a decision is made in a cancellation proceeding. Furthermore, the bad actors behind knockoffs and "parasite brands," which make products similar enough to the genuine product to cause consumer confusion about the source, have shifted tactics to filing a small number of marks or filing marks for only one brand at a time, to avoid the examiners' focus on trademark "hoarding" through a large number of contemporaneous filings from an applicant. Such third parties have been 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 and interests of U.S. right holders.

Stakeholders continue to express concerns relating to trademark examination, such as unnecessary constraints on examiners' ability to consider applications and marks across classes of goods and services, as well as the lack of consideration of co-existence agreements and letters of consent in the registration processes. Trademark applicants also complain of onerous documentation requirements, the lack of transparency in opposition proceedings, and the unavailability of default judgments against applicants who fail to appear in opposition, cancellation, and invalidation proceedings. In addition, stakeholders urge the adoption of reforms to address legitimate right holders' difficulty in obtaining well-known trademark status.

Manufacturing, Domestic Sale, and Export of Counterfeit Goods

China continues to be the world's leading source of counterfeit and pirated goods, reflecting its failure to take decisive action to curb the widespread manufacture, domestic sale, and export of counterfeit goods.³⁰ As in prior years, China and Hong Kong account for over 80% of U.S. IP seizures.³¹ The massive problem affects not only 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.

In 2020, the Office of the National Leading Group on Fight Against IP Rights Infringement and Counterfeiting, the SPC, and several other agencies jointly issued detailed regulations for the destruction of counterfeit goods, as well as materials and tools mainly used for the manufacture and production of such goods. The SPC also issued two judicial interpretations relating to the destruction of counterfeit goods in civil and criminal proceedings. China has reported enforcement actions at the border and in physical markets, and right holders have indicated more proactive efforts by administrative and criminal authorities to conduct investigations.

The newly amended Criminal Law introduces criminal penalties for selling medicine without regulatory approval, providing false materials for regulatory applications, or falsifying production or testing records. Also, China amended its Drug Administration Law in 2019 to require that active pharmaceutical ingredients (APIs) used in drug production must comply with good manufacturing practice regulations but did not provide definitions under the amended law that would encompass all APIs. As the top manufacturer and a leading exporter of pharmaceutical ingredients, China still has not closed the gaps in regulatory oversight. In particular, China does not regulate manufacturers that do not declare an intent to manufacture APIs for medicinal use. It also does not subject exports to regulatory review, enabling many bulk chemical manufacturers to produce and export active pharmaceutical ingredients outside of regulatory controls. Furthermore, China lacks central coordination of enforcement against counterfeit pharmaceutical products or ingredients, resulting in ineffective enforcement at the provincial level and with respect to online sales.

Availability of Counterfeit Goods Online, Online Piracy, and Other Issues

Widespread counterfeiting in China's e-commerce markets, the largest in the world, has been exacerbated by the migration of infringing sales from physical to online markets, which accelerated during the COVID-19 pandemic. Counterfeiters have become adept at evading enforcement efforts, such as through the use of small parcels and minimal warehouse inventories, separating counterfeit labels and packaging from products prior to the final sale, and exploiting 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

³⁰ OECD/EUIPO, *Trends in Trade in Counterfeit and Pirated Goods* at 27-28 (Mar. 18, 2019), <https://www.oecd-ilibrary.org/docserver/g2g9f533-en.pdf>.

³¹ CBP, *Intellectual Property Rights: Fiscal Year 2019 Seizure Statistics* (Sept. 2020) [https://www.cbp.gov/sites/default/files/assets/documents/2020-Sep/FY 2019 IPR Statistics Book \(Final\).pdf](https://www.cbp.gov/sites/default/files/assets/documents/2020-Sep/FY%2019%20IPR%20Statistics%20Book%20(Final).pdf).

enforcement of IP, right holders continue to express concerns about ineffective takedown procedures, slowness to respond to small- and medium-sized enterprises, and insufficient measures to deter repeat infringers. In addition, right holders report difficulties meeting the threshold for criminal enforcement because of the way online platforms record sales, and law enforcement authorities often demand evidence of the manufacturer or distribution network before initiating investigations. Other right holders report a growing trend of counterfeit products being offered for sale through e-commerce features related to large online platforms, as well as the emergence of infringing sales through live-streaming features of such platforms. Sellers of counterfeit and pirated goods have also recently taken advantage of social media and messaging websites and mobile apps to subvert detection controls and trick consumers.

Widespread online piracy also remains a major concern. Right holders express concern over the growth of 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, or codes to access these protected materials. As a leading source and exporter of systems that facilitate copyright piracy, China should take sustained action against websites and online platforms containing or facilitating access to unlicensed content, illicit streaming devices (ISDs), and piracy apps that facilitate access to such websites.

The E-Commerce Law and the issuance in 2020 of the Tort Liability Chapter of the Civil Code have increased uncertainty about how online platforms handle counter-notifications submitted by users, including whether to review evidence contained in such counter-notifications. In 2020, the SPC issued two new judicial interpretations relating to liability for erroneous notices filed in good faith, the deadline by which right holders must file an administrative complaint or civil lawsuit after receipt of a counter-notification, and information required for counter-notifications. However, these new measures fall short of providing a predictable legal environment that promotes effective cooperation among interested parties in deterring online infringement.

In 2020, 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 enterprises (SOEs) hold an ownership stake in online platforms for film and television content. Right holders report that growing advance approval requirements and other barriers have severely limited the availability of foreign TV content and prevented the simultaneous release of foreign content in China and other markets. Also, recent reports indicate that China has extended its content review system to cover books printed in China but intended for distribution in other markets, imposing heavy burdens on foreign publishers. Collectively, these measures create conditions that result in greater piracy and a market that is less open than others to foreign content and foreign entity participation. Additionally, it is critical that China fully implement the terms of the 2012 United States-China Memorandum of Understanding (MOU) regarding films and abide by its commitment to negotiate additional meaningful compensation for U.S. content.

Copyright Law Amendments

The amended Copyright Law, which will take effect June 1, 2021, included broader definitions of protected works, new rights of public performance and broadcasting for producers of sound recordings, protections against circumvention of technological protection measures, increased statutory damages, destruction of pirated goods and materials or tools mainly used to produce infringing copies, and legal presumptions of ownership and subsistence. Right holders welcomed these developments but noted the need for effective implementation and new measures to address online piracy. Also, although some Chinese courts have issued decisions recognizing copyright protection against the unauthorized transmission of sports and other live broadcasts, and recent amendments to the Copyright Law may protect sports and other live broadcasts, further implementation and confirmation of these changes is needed.

Patent Examination

Since 2018, China has completed efforts to reorganize and centralize administration and enforcement of IP, through CNIPA under the State Administration for Market Regulation (SAMR). However, these efforts have not reduced the large quantities of poor-quality patents granted to applicants. This situation continues to undermine the integrity of the patent registry. Although CNIPA announced the elimination of patent subsidies by 2025, the actual implementation of that goal remains to be seen.

With respect to patent prosecution, reports indicate that patent applicants do not receive notice of third-party submissions or the opportunity to respond, despite the reliance of examiners on arguments from such submissions. Right holders express strong concerns about the lack of transparency and fairness in patent prosecution.

Patent and Related Policies

The amended Patent Law includes provisions relating to protections for partial designs, patent term extensions for patent office and marketing approval delays, and the statutory basis for a mechanism for early resolution of pharmaceutical patent disputes. A new judicial interpretation and the first set of amended Patent Examination Guidelines address circumstances that allow for the filing of supplemental data to support disclosure and patentability requirements. Right holders welcome these developments, while noting the need to monitor issues such as the examination of supplemental data. However, strong concerns remain about the implementation of these changes, obstacles to patent enforcement, the presence of competition law concepts in the Patent Law and related measures, an undue emphasis on administrative enforcement, and the absence of additional critical reforms.

China has issued draft measures in an effort to implement an effective mechanism for early resolution of potential patent disputes, but right holders express strong concerns about notice to the patent owners, the scope of patents and pharmaceuticals covered by the proposed mechanism, the length of the stay period, the availability of injunctive relief, and other uncertainties in the proposed system, which allows parallel civil judicial and administrative proceedings. Regarding administrative proceedings, the lack of technical expertise to make technical determinations of

patent infringement is also a concern, as is the lack of transparency and possibility of local bias toward Chinese companies. Right holders also express concern about the implementation of patent term extensions, including the definition of “new” drugs covered by the system, scope of patents eligible for extension of the patent term, the type of protection provided, and method of calculation for the extensions. Furthermore, existing obstacles to patent enforcement include lengthy delays in the court system, the reported unwillingness of courts to issue preliminary injunctions, and burdensome hurdles created by parallel administrative invalidity proceedings.

China 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. The United States and China agreed to address this issue in future negotiations.

The Human Genetic Resources Administrative Regulation, which went into effect in July 2019, mandated collaboration with a Chinese partner for any research generated by using human genetic resource materials in China, sharing of all records and data, and joint ownership of any patent rights resulting from the collaboration. In 2020, China enacted a Biosecurity Law that similarly required partnership with Chinese entities throughout the course of research. These and other requirements, such as the requirement to sign an undertaking letter to certify compliance with China’s regulations and to seek government approval before any transfer of research data outside of China, create significant hurdles for pharmaceutical innovators seeking to bring products to market in China, including by conducting research and clinical trials in China. 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, 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.

Implementation of the Standardization Law failed to require the use of international standards except when they would be ineffective or inappropriate or establish that standards-setting processes are open to domestic and foreign participants on a non-discriminatory basis and to provide sufficient protections for standards-related copyright and patent rights and protections from public disclosure for enterprise standards. Right holders have also expressed strong concerns about the emerging practice in Chinese courts of issuing anti-suit injunctions in standards essential patents (SEP) disputes, reportedly without notice or opportunity to participate in the injunction proceedings for all parties. Since the first issuance of such an anti-suit injunction in August 2020, Chinese courts have swiftly issued additional anti-suit injunctions in other SEP cases. Several of these anti-suit injunctions are not limited to enjoining enforcement of an order from a specific foreign proceeding but broadly prohibit right holders from asserting their patents anywhere else in the world. These anti-suit injunctions have imposed penalties for violation as high as 1 million RMB (approximately \$155,000 USD) per day. Recent high-level statements have raised concerns about whether the proliferation of such anti-suit injunctions has been purposeful, including

statements from President Xi about promoting the extraterritorial application of China's IP law and from China's IP appellate court about how issuance of China's first SEP-related anti-suit injunction accelerated global settlement in a SEP dispute and was an example of the court "serving" the "overall work" of the Chinese Communist Party and the Chinese state.

After various ministries issued a November 2018 MOU imposing "social credit system" penalties for certain categories of patent-related conduct, CNIPA issued in October 2019 the Trial Measures for Administering the List of Targets for Joint Punishment Due to Serious Dishonesty in the Patent Field. These measures lack critical procedural safeguards, such as notice to the targeted entity, clear factors for determinations, or opportunities for appeal. The United States objects to any attempt to expand the "social credit system" in the field of IP.

The pending draft of the Anti-Monopoly Law (AML) and the 2015 IP abuse rules raise 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. Also concerning are high level statements indicating that the AML should be used to address national security concerns and that CNIPA may develop a system to prevent IP rights "abuse" via a mechanism that is outside of existing AML enforcement mechanisms. 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 or other goals.

China's "Secure and Controllable" Policies

Since enacting its Cybersecurity Law in 2017, China has continued to build on its policies for "secure and controllable" Information Communications Technology (ICT) products, such as the issuance of the Cybersecurity Classified Protection Scheme in May 2020. Along with the adoption of the Cryptography Law in 2019 and the Cybersecurity Review Measures in 2020, these developments represent multiple steps backward through China's 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 restrict market access. Through draft and final measures, China has often applied the poorly defined concept of "secure and controllable" ICT products and services and associated "risk" factors as a putative justification for erecting barriers to sale and use in China.

Right holders continue to report strong concerns about other draft and final measures, particularly cybersecurity reviews by the Cyberspace Administration of China (CAC) and other measures that may require disclosure of source code, which risk disclosure of valuable trade secrets and other proprietary information and may be used to unfairly target foreign companies. Concerns also persist about the public disclosure of enterprise standards under the amended Standardization Law and the draft standards published by the National Information Security Standardization Technical Committee (TC-260).

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

Following the agreement between China and the European Union on geographical indications (GIs) in November 2019, CNIPA published a gazette of almost one hundred approved GIs under the agreement. The gazette specified which individual components of multi-component terms were not protected and identified transitional periods for several GIs, but with limited eligibility for the transitional periods. A number of these GIs had been unsuccessfully opposed by stakeholders, who report considerable concern that China's rules and procedures limit parties' abilities to challenge GIs via opposition, cancellation, invalidation, and other processes that would ensure GIs do not impose market access barriers to U.S. exports. It is critical that China 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.

Right holders have raised concerns about plant protection in China, including about the definition of novelty, exemptions from protection, and gaps in protection that exclude species outside a limited number of taxa. Certain plant-based inventions are excluded from protection under the patent law and under China's plant variety protection system.

The United States continues to urge all levels of the Chinese government, as well as SOEs, to use only legitimate, licensed copies of software. Right holders report that government and SOE software legalization programs are still not implemented comprehensively. The United States urges the use of third-party audits to ensure accountability, which China has committed to provide under the Phase One Agreement.

INDIA

India remains on the Priority Watch List in 2021.

Ongoing Challenges and Concerns

Over the past year, India has remained inconsistent in its progress on intellectual property (IP) protection and enforcement. While India's enforcement of IP in the online sphere has gradually improved, a lack of concrete benefits for innovators and creators persists, which continues to undermine their efforts. India remains one of the world's most challenging major economies with respect to protection and enforcement of IP.

Patent issues continue to be of particular concern in India as long-standing issues remain for innovative industries. The potential threat of patent revocations, lack of presumption of patent validity, and the narrow patentability criteria under the India Patents Act burden companies across different sectors. Moreover, patent applicants continue to confront costly and time-consuming pre- and post-grant oppositions, long waiting periods to receive patent approval, and excessive reporting requirements. Stakeholders continue to express concerns over vagueness in the interpretation of the India Patents Act.

Stakeholders continue to raise concerns with the lack of an effective system for protecting against the unfair commercial use, and unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. In the pharmaceutical sector, the United States continues to monitor the restriction on patent-eligible subject matter in Section 3(d) of the India Patents Act and its impact on incentivizing innovation that benefits Indian patients. Pharmaceutical stakeholders also express concerns over the lack of an effective system for notifying interested parties of marketing approvals for follow-on pharmaceuticals, which would allow for the early resolution of potential patent disputes, and view the further restricting in 2019 of transparency of information about manufacturing licenses issued by states as a step backward. Despite India's justifications of limiting IP protections as a way to promote access to technologies, India maintains high customs duties directed to IP-intensive products such as medical devices, pharmaceuticals, Information and Communications Technology (ICT) products, solar energy equipment, and capital goods.

India's overall IP enforcement, despite progress made online, remains inadequate. During the last year, India has continued to take steps against websites with pirated content. Nonetheless, weak enforcement of IP by the courts and police officers, a lack of familiarity with investigation techniques, and the continued absence of any centralized IP enforcement agency, combined with a failure to coordinate actions on both the national and state level, threaten to undercut any progress made. The status of India as one of the top five source-economies for fake goods, as noted in the OECD's *Trends in Trade in Counterfeit and Pirated Goods* (2019), highlights the serious nature of counterfeiting and the ineffective level of enforcement. India remains home to several markets that facilitate counterfeiting and piracy, as identified in the 2020 *Notorious Markets List*. While some of India's state authorities, such as Maharashtra, continue to operate dedicated crime enforcement units, other states have not followed suit or face organizational challenges. Given the

scale and nature of the problem, the United States continues to encourage the adoption of a national-level enforcement task force for IP crimes.

Overall, the levels of trademark counterfeiting continue to remain problematic. In addition, U.S. brand owners continue to report excessive delays in trademark opposition proceedings and a lack of quality in examination. For example, there is little clarity concerning whether trademark owners can apply directly for recognition of “well-known” trademark status without having to rely on Indian court decisions. 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. India’s 2016 National IPR Policy identified trade secrets as an “important area of study for future policy development.” However, as of 2021, no civil or criminal laws in India specifically address the protection of trade secrets. While India relies on contract law to provide some trade secret protection, this approach is effective only in situations where the trade secret owner and party accused of misappropriation have a contractual relationship. Criminal penalties are not available for trade secret misappropriation in India, and civil remedies reportedly are difficult to obtain and do not have a deterrent effect. U.S. and Indian companies have identified trade secret protection as a growing concern and expressed interest in India eliminating gaps in its trade secrets regime, such as through the adoption of trade secret legislation that comprehensively addresses these concerns.

Copyright holders continue to report high levels of piracy, particularly online. Court cases and government memoranda also raise concerns that a broad range of published works will not be afforded meaningful copyright protection. In 2019, the Department for Promotion of Industry and Internal Trade (DPIIT) proposed draft Copyright Amendment Rules that would broaden the scope of statutory licensing to encompass not only radio and television broadcasting but also online transmissions, despite a high court ruling earlier in 2019 that held that statutory broadcast licensing does not include online transmissions. If implemented to permit statutory licensing of interactive transmissions, the Amendment Rules would have severe implications for right holders who make their content available online, and the United States urges India to ensure consistency with international standards. The Amendment Rules, along with the 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. Furthermore, industry has reported continuing problems with unauthorized file sharing of videogames, signal theft by cable operators, commercial-scale photocopying and unauthorized reprints of academic books, and circumvention of technological protection measures.

The 2015 passage of the Commercial Courts Act, highlighted in previous Reports, provided an opportunity to reduce delays and increase expertise in judicial IP matters. However, to date only a limited number of courts have benefited under this Act, and right holders report that jurisdictional challenges have reduced their effectiveness and that inadequate resources for staffing and training continue. While India’s copyright royalty board became a functional part of the Intellectual Property Appellate Board (IPAB) in 2020, the United States is closely monitoring legislation proposed in early 2021 that seeks to abolish the IPAB and a temporary ordinance promulgated in

April 2021 that effectively disbands the IPAB. India also has yet to ensure that collective management organizations 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.

India's accession to the World Intellectual Property Organization (WIPO) Internet Treaties in 2018 and the Nice Agreement in 2019 were positive steps. However, amendments to the Copyright Act needed to bring India's domestic legislation into alignment with international best practices are absent. The United States is monitoring India's next steps, including DPIIT's December 2020 solicitation of public comments on amending the Copyright Act. The December 2018 draft Cinematograph Act (Amendment) Bill containing promising provisions to criminalize illicit camcording of films continues to await Parliament's approval.

India took steps to address stakeholder concerns over burdensome patent reporting requirements by issuing a revised Manual of Patent Office Practice and Procedure in November 2019 and revised Form 27 on patent working in October 2020. The Manual includes the requirement for patent examiners to look to the WIPO Centralized Access to Search and Examination (CASE) system and Digital Access Service (DAS) to find information filed by patent applicants in other jurisdictions, with the aim of eliminating the need for applicants to file redundant information with India. While some stakeholders have welcomed the revised version of Form 27, concerns remain with respect to whether Indian authorities will treat as confidential sensitive business information that parties are required to disclose on Form 27.

Among other positive developments, in September 2019, the Nice Agreement for the classification of goods and services for the purposes of registering trademarks came into force, and India continues to work on guidelines for its implementation. The Cell for IPR Promotion and Management (CIPAM) continues to promote IP awareness, commercialization, and enforcement throughout India. In December 2020, the United States Patent and Trademark Office and DPIIT signed a new Memorandum of Understanding relating to IP technical cooperation mechanisms.

In March 2021, the United States and India, along with Australia and Japan, announced the Quad Vaccine Partnership. They are taking shared action necessary to expand safe and effective COVID-19 vaccine manufacturing in 2021 and are working together to strengthen and assist countries in the Indo-Pacific with vaccination, in close coordination with the existing relevant multilateral mechanisms including the World Health Organization (WHO) and COVID-19 Vaccines Global Access (COVAX). In addition, Indian manufacturers have entered into voluntary licensing agreements with international partners to produce billions of COVID-19 vaccine doses.

The United States intends to continue to engage with India on IP matters, including through the United States-India Trade Policy Forum's Intellectual Property Working Group.

INDONESIA

Indonesia remains on the Priority Watch List in 2021.

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 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 2016 Patent Law continues to raise concerns, including with respect to the patentability criteria for incremental innovations and the disclosure requirements for inventions related to traditional knowledge and genetic resources. 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. Stakeholders also raise concerns over certain procedures associated with the 2016 Patent Law and with the lack of an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. Piracy through piracy devices and applications is a concern, and illegal camcording and unlicensed use of software remain problematic. In addition, the United States remains concerned about a range of market access barriers in Indonesia, including certain measures related to motion pictures and requirements for domestic manufacturing and technology transfer for pharmaceuticals and other sectors.

Developments, Including Progress and Actions Taken

Indonesia has made progress in addressing some of these concerns, but significant concerns remain in other areas. In November 2020, Indonesia amended its 2016 Patent Law to remove local manufacturing and use requirements. The United States welcomes this progress but continues to urge Indonesia to undertake a more comprehensive amendment to the 2016 Patent Law to address remaining concerns. As Indonesia amends the Patent Law and other legislation and develops implementing regulations, the United States also urges Indonesia to provide affected stakeholders with meaningful opportunities for input. U.S. stakeholders continue to note positive developments related to Indonesia's efforts to address online piracy, including increased enforcement efforts and cooperation between the Ministry of Communications and Informatics and the Directorate General for Intellectual Property (DGIP). In 2018, the Ministry of Finance issued regulations clarifying its *ex officio* authority for border enforcement against pirated and counterfeit goods and instituted a recordation system, but concerns remain regarding the ability of foreign right holders to benefit from the system. Although Indonesia took steps in 2016 to allow 100% foreign direct investment in the production of films and sound recordings, as well as in film distribution and exhibition, Indonesia has issued implementing regulations to the 2009 Film Law that, if enforced, would further restrict foreign participation in this sector. Specifically, Ministry of Education and Culture Regulation 34/2019 includes screen quotas and a dubbing ban for foreign films.

To address insufficient IP enforcement, the United States continues to urge Indonesia to improve enforcement cooperation among relevant agencies, including the Coordinating Ministry for Politics, Law, and Security, DGIP, Attorney General's Office, Ministry of Tourism and Creative Economy, and National Agency for Drug and Food Control. In particular, the United States is concerned that the National IPR Task Force continues to be inactive. 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.

Indonesia also has imposed excessive and inappropriate penalties upon patent holders as an incentive to collect patent maintenance fees. Although DGIP has extended its deadline to collect the fees, the United States continues to monitor the issue. The United States also continues to urge Indonesia to fully implement the bilateral Intellectual Property Rights Work Plan and plans continued, intensified engagement with Indonesia under the United States-Indonesia Trade and Investment Framework Agreement to address these important issues.

RUSSIA

Russia remains on the Priority Watch List in 2021.

Ongoing Challenges and Concerns

Challenges to intellectual property (IP) protection and enforcement in Russia include continued copyright infringement, trademark counterfeiting, and the existence of nontransparent procedures governing the operation of collective management organizations (CMOs). In particular, the United States is concerned about stakeholder reports that IP enforcement remains inadequate and that Russian authorities continue to lack sufficient staffing, expertise, and the political will to effectively combat IP violations and criminal enterprises.

Developments, Including Progress and Actions Taken

The overall IP situation in Russia remains extremely challenging. The lack of robust enforcement of IP rights is a persistent problem, compounded by burdensome court procedures. For example, the requirement that plaintiffs notify defendants a month in advance of instituting a civil cause of action allows defendants to liquidate their assets and thereby avoid liability for their infringement. Additionally, requiring foreign right holders to abide by strict documentation requirements, such as verification of corporate status, hinders their ability to bring civil actions.

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. Although implementation of 2017 anti-piracy legislation has shown some promise, Russia remains home to several sites that facilitate online piracy, as identified in the 2020 *Notorious Markets List*. Stakeholders continue to report significant piracy of video games, music, movies, books, journal articles, and television programming. Mirror sites related to websites that offer infringing content and smartphone applications that facilitate illicit trade are also a concern. Russia needs to direct more action to rogue online platforms targeting audiences outside the country. In 2018, right holders and online platforms in Russia signed an anti-piracy memorandum to facilitate the removal of links to websites that offer infringing content. This memorandum, recently extended until November 31, 2021, may be implemented as legislation that would cover all copyrighted works and apply to all Russian platforms and search engines. Furthermore, although right holders are able to obtain court-ordered injunctions against websites that offer infringing content and, starting in 2020, smartphone applications, additional steps must be taken to target the root of the problem, namely, investigating and prosecuting the owners of the large commercial enterprises distributing pirated material, including software. Moreover, prominent Russian online platforms continue to provide access to thousands of pirated films and television shows. Stakeholders report that, in 2020, Russia remained among the most challenging countries in the world in terms of video game piracy.

Royalty collection by CMOs in Russia continues to lack transparency and does not correspond to international standards. Reports indicate that right holders are denied detailed accounting reports, making it difficult to verify how much money is being collected and distributed. Also, right holders are excluded from the selection and management of CMOs. The United States encourages

Russia to update and modernize its CMO regime and institute practices that are fair, transparent, efficient, and accountable.

Russia remains a thriving market for counterfeit goods sourced from China. Despite increased seizures by the Federal Customs Service, certain policies hamper IP enforcement efforts. For example, the “return to sender” policy for small consignments, which returns counterfeit goods to their producer, is problematic because it does not remove such goods from channels of commerce.

The United States is also concerned about Russia’s implementation of its World Trade Organization (WTO) 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 continue to express concerns regarding the application of Article 1360 and 1362 of the Russian Civil Code, including evidentiary standards applied by the judiciary.

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 works. The United States continues to monitor Russia’s progress on these and other matters through appropriate channels.

SAUDI ARABIA

Saudi Arabia remains on the Priority Watch List in 2021.

Ongoing Challenges and Concerns

Saudi Arabia was placed on the Priority Watch List in 2019 for failing to take action against the rampant satellite and online piracy made available by illicit pirate service beoutQ, continued lack of effective protection of intellectual property (IP) for pharmaceutical products, and long-standing concerns regarding enforcement against counterfeit and pirated goods within the country. BeoutQ ceased operations in August 2019. The Saudi Authority for Intellectual Property (SAIP) continued to take steps to improve IP protection, enforcement, and awareness throughout Saudi Arabia in 2020. However, concerns remain over actions by the Saudi Arabia Food and Drug Authority (SFDA), which the Minister of Health oversees, that are contrary to Saudi Arabia's public statements in paragraph 261 of the *Report of the Working Party on the Accession of the Kingdom of Saudi Arabia to the World Trade Organization*. Starting in 2016, SFDA has been granting marketing approval to domestic companies for subsequent versions of registered products, without requiring the submission of data that meets the same requirements applied to the initial applicant, despite the period of protection provided to the initial applicant by Saudi regulations. SFDA's continued actions and the lack of redress for affected companies have intensified concerns. Furthermore, the National Unified Procurement Company for Medical Supplies, also overseen by the Minister of Health, reportedly awarded national tenders to some of these domestic companies for the affected products.

The United States continues to remain concerned about reportedly high levels of online piracy in Saudi Arabia, particularly the streaming of live sports and other copyrighted content through illicit streaming devices (ISDs), which right holders report are widely available and generally unregulated in Saudi Arabia. The United States encourages Saudi Arabia to increase IP enforcement actions and IP awareness campaigns particularly targeted at reducing online piracy and to combat the perception spurred by beoutQ's activity that pirating copyrighted material is permissible.

Right holders have expressed further concerns regarding effective civil enforcement of IP, including the ability to file civil actions. The United States encourages Saudi Arabia to join and fully implement the World Intellectual Property Organization (WIPO) Internet Treaties to address some of these concerns.

Regarding the criminal enforcement of IP, right holders remain concerned that criminal sentences and financial penalties are not consistently imposed. Saudi Arabia recently established a specialized IP court, which the United States hopes will resolve the concerns expressed by right holders, but procedures for filing civil and criminal enforcement actions in this court are not yet finalized.

Developments, Including Progress and Actions Taken

In 2017, Saudi Arabia established SAIP to regulate, support, develop, sponsor, protect, enforce, and upgrade IP fields in accordance with the best international practices. Over the past three years, SAIP has worked to consolidate IP protection competence, coordinated and led online and in-market IP enforcement efforts, and promoted awareness of the importance of respecting IP and the consequences of violating another's IP rights. The United States recognizes SAIP's commitment to the highest standards for Saudi Arabia's IP environment and appreciates the positive cooperation with SAIP to achieve its goals.

In 2020, SAIP launched the Intellectual Property Respect Officer program with the participation of more than 70 government agencies with the goal of raising compliance with IP laws and regulations, and established the National IP Enforcement Committee. SAIP also published certain draft IP laws and regulations for public comment, which are now centralized through the website of the National Competitiveness Center, and organized industry workshops to discuss the development of the laws.

Regarding enforcement against counterfeit and pirated goods and pirated content, SAIP led an online inspection campaign that resulted in enforcement actions against 308 websites, conducted market raids to seize IP infringing goods and implements such as compact discs and ISDs, destroyed more than 3.5 million seized IP infringing goods in collaboration with the Ministry of Media, and destroyed more than 2 million seized counterfeit items in collaboration with the Saudi Arabia Customs Authority.

The United States has engaged Saudi Arabia on its new geographical indications (GI) law and is monitoring the development of implementing regulations, particularly with respect to transparency and due process related to GI protection and the impact on market access for U.S. products.

The United States welcomes continued progress on these areas but also underscores the need for Saudi Arabia to address the serious concerns regarding IP protection and enforcement identified above.

UKRAINE

Ukraine remains on the Priority Watch List in 2021.

Ongoing Challenges and Concerns

While Ukraine has made consistent progress since 2018 in the protection and enforcement of intellectual property (IP), its IP regime remains unsatisfactory in the three areas of long-standing concern: (1) administration of the system for collective management organizations (CMOs) that are responsible for collecting and distributing royalties to right holders; (2) continued use of unlicensed software by Ukrainian government agencies; and (3) ongoing failure to implement an effective means to combat widespread online copyright infringement. The United States will continue to closely monitor Ukraine's ongoing legislative and operational efforts to improve IP protection and enforcement.

Developments, Including Progress and Actions Taken

For many years, Ukraine's CMO regime has been non-transparent, unfair, and dominated by rogue CMOs that did not distribute the royalties they collected. 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 IP rights. The announcement specifically referenced the importance of Ukraine improving its CMO regime. In July 2018, Ukraine enacted legislation that fundamentally reformed its CMO system and, in 2019, the United States restored some of the suspended GSP benefits in recognition of the concrete steps Ukraine took on CMO reform. While Ukraine's CMO system remains a work in progress and a source of concern, Ukraine continues to build on the 2018 law and take positive steps toward a CMO system under which U.S. right holders can receive proper and adequate compensation for their creative works in Ukraine. Under the 2018 law, Ukraine has accredited six CMOs, some of which have completed royalty negotiations and are paying royalties to right holders. For other CMOs selected under the 2018 law, progress continues on accreditation and royalty negotiation. It is critical that Ukraine continue this progress, including through effective implementation and enforcement of the 2018 law, as well as further legislative reform addressing still-existing concerns with the law.

The use of unlicensed software by Ukrainian government agencies has abated slowly since 2016, as Ukraine has explored using its state procurement systems to require the purchase of legitimate software and started allocating funds for software licensing. However, use of unlicensed software by government agencies continues to raise serious concerns for the United States both in terms of agencies using software without licenses, particularly on legacy systems, and where agency usage exceeds the number of purchased licenses. The United States encourages Ukraine to continue to work with industry representatives to assess and remedy both forms of unlicensed software use.

Online piracy remains a significant problem in Ukraine and fuels piracy in other markets. Pirated films generated from illegal camcording, which are made available online and in some theaters, cause particular damage to the market for first-run movies. In addition, inadequate enforcement in Ukraine continues to raise concerns among IP stakeholders. 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). Although the Cyber Police launched a nationwide operation to target prominent websites that offer infringing content in 2019 and undertook investigations into advertising firms that finance those websites in 2020, effective enforcement with deterrent effect remains elusive in Ukraine. The United States urges Ukraine to engage actively with all affected stakeholders, including on provisions of its draft Law on Copyright and Related Rights, to ensure the statutory framework for reducing online piracy becomes more effective and efficient. Increasing the number of Cyber Police Officers and state IP inspectors to investigate copyright violations would likely help combat online piracy. Initiatives like the Cyber Police’s April 2019 anti-piracy operation, coupled with coordinated and effective prosecutions against operators of illicit websites, would also help fight online piracy in Ukraine.

Recently, Ukraine has adopted legislation concerning semiconductors, geographical indications, customs enforcement, patents, trademarks, and industrial designs. While the United States welcomes Ukraine’s efforts to align domestic IP laws with international best practices, the United States will continue to monitor implementation of the patent legislation’s restrictions on the scope of patentable subject matter directed to pharmaceutical inventions and its impact on incentivizing innovation that benefits Ukrainian patients. Progress continues, albeit slowly, to establish a fully functional specialized Intellectual Property High Court, legislatively enacted in 2017. In addition, in 2020, Ukraine passed legislation creating a National Intellectual Property Authority (NIPA) to replace the State Intellectual Property Service. The United States looks forward to working with NIPA to strengthen Ukraine’s system for IP protection and enforcement.

The United States appreciates the increased engagement with Ukraine, including the tangible steps Ukraine is taking to improve its IP regime. The United States will continue to work intensively with Ukraine, including through the United States-Ukraine Trade and Investment Council, with the goal of more sustained and concrete progress.

VENEZUELA

Venezuela remains on the Priority Watch List in 2021.

Ongoing Challenges and Concerns

Recognizing the significant challenges in Venezuela at this time, the United States has several ongoing concerns with respect to the country's 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 international standards and raises concerns about 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 *2019 Global Competitiveness Report* ranked Venezuela last in IP protection, out of 141 countries, for the seventh straight year. The Property Rights Alliance's *2020 International Property Rights Index* also ranked Venezuela 127th out of 129 countries in a metric that includes standards for IP protection.

Developments, Including Progress and Actions Taken

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

ALGERIA

Algeria moves from the Priority Watch List to the Watch List in 2021. Algeria has taken some positive steps to improve the environment for intellectual property (IP) protection and enforcement in recent years. Algerian authorities have increased efforts at IP enforcement, including by disbanding informal markets selling counterfeit merchandise, increasing coordination between customs authorities and law enforcement, and engaging in capacity-building and training efforts for law enforcement, customs officials, judges, and IP protection agencies. In addition, Algeria worked with the World Intellectual Property Organization (WIPO) to establish a WIPO external bureau in Algiers to help improve Algeria's IP framework. Moreover, there have been improvements on market access issues, including the resolution of IP-related concerns with respect to an import ban on certain products that was originally imposed in 2009; replacement of temporary import barriers, originally established in January 2018, with a set of tariffs; and development of regulations allowing companies to register their representative offices to do business in Algeria. However, challenges continue with respect to the adequate and effective protection and enforcement of IP in Algeria. Algeria still lacks an effective mechanism for the early resolution of potential pharmaceutical patent disputes. Stakeholders express concern that Algeria does not provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. Furthermore, Algeria needs to make more progress in other areas, including by providing adequate judicial remedies in cases of patent infringement; providing administrative opposition, as well as fewer formalities, in its trademark system; and increasing enforcement efforts against trademark counterfeiting and copyright piracy. The United States strongly urges Algeria to build upon these positive developments. The United States will continue to engage with Algeria to improve its IP system and enforcement of IP.

BARBADOS

Barbados remains on the Watch List in 2021. Barbados acceded to the World Intellectual Property Organization (WIPO) Internet Treaties in 2019. A government-led, public-private advisory committee has submitted proposed amendments to the Copyright Act to implement its treaty obligations to a parliamentary committee for review. Evidence of a strong commitment to enforce existing legislation remains incomplete. In the realm of copyright and related rights, the United States continues to have concerns about the unauthorized retransmission of U.S. broadcasts and cable programming by local cable operators in Barbados, particularly state-owned broadcasters, without adequate compensation to U.S. right holders. The United States also has continuing concerns about the refusal of Barbadian TV and radio broadcasters and cable and satellite operators to pay for public performances of music. The United States urges Barbados to take all actions necessary to address such cases to ensure that all composers and songwriters receive the royalties they are owed for the public performance of their musical works. Additional sources of concern include long-standing backlogs in the judicial system, failure to enforce judgments and other successful outcomes for right holders, and the resulting lack of deterrence of further violations. The United States looks forward to working with Barbados to resolve these and other important issues.

BOLIVIA

Bolivia remains on the Watch List in 2021. Challenges continue with respect to adequate and effective intellectual property (IP) protection and enforcement in Bolivia. The IP laws in Bolivia are dated, and constitutional restrictions limit effective IP protection. Bolivia has not acceded to the World Intellectual Property Organization (WIPO) Internet Treaties. In addition, Bolivia relies on a century-old industrial privileges law, rather than any specific law governing industrial property. Bolivia underfunds the protection of IP. The Servicio Nacional de Propiedad Intelectual (SENAPI) has the primary responsibility involving IP protection but continues to suffer from inadequate resources. Similarly, Bolivian Customs lacks *ex officio* authority necessary to stop potentially infringing goods without an application from the right holder. Additionally, the customs authority does not have the human and financial resources needed to effectively address shipments containing counterfeit goods at its international borders. Significant challenges also persist with respect to adequate and effective IP enforcement and communication between SENAPI and Customs. Video, music, literature, and software piracy rates are among the highest in Latin America, and rampant counterfeiting persists. Criminal charges and prosecutions remain rare. Bolivian Customs has authority under the Cinema and Audiovisual Arts Law of 2018 to pursue criminal prosecutions for IP violations of foreign and domestic visual works, but Bolivia has not promulgated implementing regulations that are necessary to exercise this authority. A new government took office in Bolivia at the end of 2020 and expressed its intention to engage with the United States on IP issues. The United States will work with Bolivia on the necessary steps to improve its IP system and enforcement of IP.

BRAZIL

Brazil remains on the Watch List in 2021. The United States has long-standing concerns about Brazil's intellectual property (IP) enforcement regime, although the country took significant steps in 2020. Brazil continued to take actions to address online piracy with coordinated campaigns between Brazilian law enforcement and counterparts in the United States, as well as the importation of illicit streaming devices (ISDs), as it seized more than 300,000 devices. Nevertheless, levels of counterfeiting and piracy in Brazil, including online piracy, use of ISDs, and use of unlicensed software, remain excessively high, and the number of criminal prosecutions has been insufficient to confront the scale of the problem. The enactment of legislation for criminal enforcement to increase deterrent penalties, provide police with *ex officio* authority to open criminal investigations of suspected offenses of trademark counterfeiting and copyright piracy on a commercial scale, and criminalize unauthorized camcording would help to address these challenges, as would the dedication of additional resources at the federal, state, and local levels for IP enforcement, IP awareness campaigns for both public officials and the general public, and stakeholder partnerships. The United States looks forward to Brazil's implementation of the country's first National Strategy on Intellectual Property, which was released in December 2020. The United States also recognizes positive developments at Brazil's National Institute of Industrial Property (INPI), including the continued implementation of the technology-neutral Patent Prosecution Highway Program and streamlining procedures for certain patent review processes, which resulted in a backlog decrease of over 50% since 2019. The United States remains concerned, however, about the pendency of patent applications and the impact on the effective patent term. The United States welcomes limits on the role of Brazil's National Sanitary Regulatory Agency (ANVISA) on issues relating to the patentability of new pharmaceutical inventions but continues to monitor the situation in light of long-standing concerns about duplicative reviews by ANVISA of pharmaceutical applications. Also, pharmaceutical stakeholders remain concerned that Brazilian law and regulations do not provide for a similar level of protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products as that for veterinary and agricultural chemical 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 urges Brazil to ensure transparency and procedural fairness in the protection of geographical indications (GIs) and to ensure that the grant of GI protection does not deprive interested parties of the ability to use common names, particularly as Brazil proceeds with the European Union-Mercosur Trade Agreement. Following Brazil joining the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol) in 2019, the United States encourages Brazil to join the World Intellectual Property Organization (WIPO) Internet Treaties as soon as possible. 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 will engage constructively with Brazil to build a strong IP environment and to address remaining concerns.

CANADA

Canada remains on the Watch List in 2021. The most significant step forward taken by Canada was the implementation of important intellectual property (IP) provisions in the United States-Mexico-Canada Agreement (USMCA), in areas where there have been long-standing concerns, including with full national treatment for copyright protections, transparency and due process with respect to new geographical indications (GIs), and more expansive trade secret protection, including criminal penalties for willful misappropriation. The United States continues to monitor Canada's outstanding USMCA commitments with transition periods, including on the Brussels Satellites Convention, copyright term, and patent term extensions for unreasonable patent office delays. Right holders also report that Canadian courts have established meaningful penalties against circumvention devices and services. In 2019, Canada made positive reforms to the Copyright Board related to tariff-setting procedures for the use of copyrighted works, and efforts remain ongoing to implement those measures. Despite this progress, various challenges to adequate and effective protection of IP rights in Canada remain. Significant concerns of Canada's IP environment include poor enforcement with respect to counterfeit or pirated goods at the border and within Canada, high levels of online piracy, and inadequate transparency and due process regarding GIs protected through free trade agreements. In particular, reports of enforcement levels suggest that Canadian authorities have yet to take full advantage of expanded *ex officio* powers. Canada's system to provide for patent term restoration for delays in obtaining marketing approval is limited in duration, eligibility, and scope of protection. With respect to pharmaceuticals, the United States will continue to monitor the implementation and effects of recent changes to the Patented Medicine Prices Review Board's pricing regulations. The United States remains deeply troubled by the ambiguous education-related exception added to the copyright law in 2012, which reportedly has significantly damaged the market for educational publishers and authors.

COLOMBIA

Colombia remains on the Watch List in 2021. In 2019, Colombia was placed on the Watch List 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). In 2020, Colombia made limited progress on the outstanding provisions related to its obligations under Chapter 16 of the CTPA, including on draft legal provisions on notice-and-takedown and safe harbor provisions for Internet service providers. 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. Due to an action challenging these decrees, the Council of State provisionally suspended them in September 2019. Colombia is still considering how it will resolve this issue. Colombia's accession to the 1991 Act of the International Union for the Protection of New Varieties of Plants (UPOV 1991) remains outstanding. Colombia's success in combating counterfeiting and other intellectual property (IP) violations remains limited. 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 (IPTV) services that permit the retransmission of otherwise-licensed content to a large number of non-subscribers. Colombia continues to face a large number of pirated and counterfeit goods crossing the border or sold at 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.

DOMINICAN REPUBLIC

The Dominican Republic remains on the Watch List in 2021. Although customs enforcement and enforcement against counterfeit goods by the Special Office of the Attorney General for Matters of Health have improved incrementally, intellectual property (IP) protection and enforcement concerns remain. In particular, the United States remains concerned with the Dominican Republic's lack of political will to address long-standing IP issues, particularly against online and signal piracy, including the continued deprioritization of IP prosecutions and investigations by the Special Office of the Attorney General for High-Tech Crimes and the National Copyright Office. As a positive development, the Office of the Attorney General created a new IP unit to revive the anti-piracy technical working group and also convened an interagency working group to enhance coordination on IP enforcement. The United States continues to urge the Dominican Republic to improve coordination among enforcement agencies and to ensure that such agencies are adequately funded and staffed. The United States encourages the Dominican Republic to take clear actions in 2021 to improve its IP protection and enforcement.

ECUADOR

Ecuador remains on the Watch List in 2021. In December 2020, Ecuador published the final regulations implementing the Organic Code on Social Economy of Knowledge, Creativity, and Innovation (Ingenuity Code). The regulations do not address concerns raised by the U.S. Government and various stakeholders on 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. Ecuador plans additional revisions to the Ingenuity Code, and the United States remains open to any engagement on this process. Enforcement of intellectual property (IP) rights against widespread counterfeiting and piracy remains weak, including online and in physical marketplaces. Ecuador is also reportedly a source of unauthorized camcording. Online piracy continues to be a problem despite some increased enforcement activity, and Ecuador has not yet established notice-and-takedown and safe harbor provisions for Internet service providers. The United States urges Ecuador to continue to improve its IP enforcement efforts and to provide for customs enforcement on an *ex officio* basis, including actions against goods in-transit. The United States also encourages 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 will continue working with Ecuador to address these and other issues.

EGYPT

Egypt remains on the Watch List in 2021. The United States welcomes Egypt's recent efforts to strengthen the protection and enforcement of intellectual property (IP) and urges Egypt to continue addressing concerns that have been raised with respect to copyright and trademark enforcement, patentability criteria, patent and trademark examination criteria, and pharmaceutical-related IP issues. Egypt should provide deterrent-level penalties for IP violations, grant *ex officio* authority for customs officials to seize counterfeit and pirated goods at the border, and increase training for enforcement officials. Egypt successfully reduced its patent application backlog from ten years to five years, and would benefit from continued development of a transparent and reliable patent registration system. Egypt has made no progress on developing 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. Egypt should also take steps to clarify and formalize its biotechnology patent guidelines under its Intellectual Property Law. While Egypt has made progress toward establishing 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, it should clarify and formalize this protection. The United States will closely monitor its implementation. Egypt should also complete its plans to update and publish its patent and trademark examination guides online. Egypt has made some progress in resolving concerns with respect to illegal streaming services that offer pirated broadcasts of U.S. works. In recent years, Egypt has taken action against a number of major infringing streaming sites, enacted legislation criminalizing piracy online, and provided more emphasis on enforcement of the Intellectual Property Law of 2002. However, Egypt should strengthen efforts to address the number of unlicensed satellite channels offering pirated broadcasts of U.S. works, unlawful decryption of encrypted signals, and unauthorized camcording. Additionally, the United States encourages Egypt to join and fully implement the World Intellectual Property Organization (WIPO) Internet Treaties. The United States appreciates Egypt's recent enhanced engagement on IP issues with stakeholders and stands ready to work with Egypt to improve its IP regime, including by developing a work plan outlining necessary steps to resolve the concerns described above.

GUATEMALA

Guatemala remains on the Watch List in 2021. Despite a generally strong legal framework in place, resource constraints, inconsistent enforcement actions against counterfeiting of apparel and other products, as well as poor coordination among law enforcement agencies have resulted in insufficient intellectual property (IP) enforcement. The United States continues to urge Guatemala to ensure that its IP enforcement agencies receive sufficient resources and to strengthen enforcement, including criminal prosecution, administrative and border measures, and intergovernmental coordination to address widespread copyright piracy and commercial-scale sales of counterfeit goods. The production of counterfeit apparel in Guatemala, with little interference by law enforcement, is a significant concern, and the sale of counterfeit pharmaceuticals remains problematic. Additionally, government use of unlicensed software remains widespread. Although cable signal piracy continues to be a problem, some major cable providers have discontinued contracts with distributors that illicitly rebroadcast U.S. television programming, and U.S.-based content providers have subsequently entered into contracts with those cable providers. The United States urges Guatemala to take clear and effective actions in 2021 to improve the protection and enforcement of IP in Guatemala.

KUWAIT

Kuwait remains on the Watch List in 2021. Although Kuwait took steps to reform its copyright regime by passing the 2019 Copyright and Related Rights Law and the Implementing Regulations, concerns remain with provisions of the law that are unclear, such as ambiguities with certain definitions, the scope of protection, and the scope of certain limitations and exceptions. Regarding intellectual property (IP) enforcement, the Copyright Department of the Kuwait National Library now has inspectors with the authority to submit cases directly to the courts. The United States acknowledges increased IP enforcement by the Consumer Protection Department of the Ministry of Commerce & Industry and the Kuwait General Administration for Customs Intellectual Property Rights Unit. However, concerns remain with the lack of publicly available IP enforcement procedures, the lack of transparency regarding the fate of seized counterfeit and pirated goods, and the lack of legal consequences for vendors and importers of counterfeit and pirated goods due to long-pending court cases, inconsistent judicial decisions, and inconsistent penalties that do not seem to deter recidivism. The United States encourages Kuwait to continue to increase IP enforcement efforts, to enhance outreach and communication with trademark and copyright owners, to implement a modern customs trademark recordation system, and to coordinate IP investigations and enforcement actions between enforcement authorities.

LEBANON

Lebanon remains on the Watch List in 2021. The United States welcomes Lebanon's continued work to promote intellectual property (IP) protection and enforcement in 2020. The United States commends the Ministry of Economy and Trade for drafting a national IP strategy in 2019, which is awaiting approval by the Council of Ministers. The United States encourages Lebanon to ratify and implement Articles 1 through 12 of the Paris Convention, the Singapore Treaty on the Law of Trademarks, the latest acts of the Nice Agreement, and the Berne Convention. The United States also encourages Lebanon to join the Patent Cooperation Treaty, the Madrid Protocol, and the World Intellectual Property Organization (WIPO) Internet Treaties.

MEXICO

Mexico remains on the Watch List in 2021. During 2020, Mexico undertook significant legislative reforms to implement its intellectual property (IP) commitments under the United States-Mexico-Canada Agreement (USMCA), with changes to its Copyright Law, Criminal Code, and the passage of a new Industrial Property Act. These reforms included improvements in laws addressing protection against the circumvention of technological protection measures and rights management information, Internet-service provider liability, satellite and cable signal theft and penalties for aiding or abetting these activities, unauthorized camcording of movies, and transparency with respect to new geographical indications (GIs). The United States continues to monitor Mexico's actions to address long-standing concerns, including with respect to enforcement against counterfeiting and piracy, protection of pharmaceutical-related IP, pre-established damages for copyright infringement and trademark counterfeiting, and enforcement of IP rights in the digital environment. Mexico continues to operate on reduced resources for numerous government agencies. The failure to provide sufficient resources for IP protection will continue to hamper Mexico's efforts to improve the environment for IP. To combat growing levels of IP infringement in Mexico, the United States encourages Mexico to increase funding for enforcement, including for the specialized IP unit within the Attorney General's office, to improve coordination among federal and sub-federal officials, to bring more IP-related prosecutions, and to impose deterrent penalties against infringers. Piracy and counterfeit goods continue to be widespread in Mexico. As broadband access increases, online piracy has been increasing. The prevalence of counterfeit goods at notorious physical marketplaces also remains a significant problem, exacerbated by the involvement of transnational criminal organizations. Regarding IP enforcement at the border, Mexico's customs authority, the Tax Administration Service (SAT), initiated 642 cases, up from 541 cases in 2019, with seizures totaling 8.82 million articles in 2020, up from 3.45 million in 2019. U.S. brand owners continue to address ongoing issues pertaining to bad faith trademark registrations. Right holders also express concern about the length of administrative and judicial patent and trademark infringement proceedings and the persistence of continuing infringement while cases remain pending. In administrative procedures on infringement, preliminary measures still can be lifted without any burden of proof if the alleged infringer posts a counter-bond. On pharmaceutical-related issues, the United States has concerns that since May 2019, Mexico's health regulator COFEPRIS has all but paused on marketing approvals of new pharmaceutical products, with very few approvals granted during this period. The United States continues to monitor potential patent issues related to Mexico's pharmaceutical procurement processes, which were overhauled in 2020. With respect to GIs, Mexico must ensure that any protection of GIs, including those negotiated through free trade agreements, is only granted after a fair and transparent examination and opposition process. 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. The United States will continue to work with Mexico on these and other IP concerns.

PAKISTAN

Pakistan remains on the Watch List in 2021. Pakistan has maintained a positive dialogue with the United States on intellectual property (IP) matters and has 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. Nonetheless, serious concerns remain, particularly in the area of IP enforcement. Sales of counterfeit and pirated goods remain widespread, including with respect to pharmaceuticals, printed works, digital content, and software. Reports of numerous cable operators providing pirated content are also prevalent. While Pakistan's establishment of IP Tribunals in Lahore, Islamabad, and Karachi was a welcome development, plans to create new tribunals in other cities have not moved forward. Moreover, litigants with experience in these tribunals have raised concerns over the lack of capacity, inconsistency of rulings, nominal fines, and a general lack of expertise among tribunal judges. In addition, many of the injunctive orders issued by these courts for civil violations have been ignored by criminal enterprises. Effective trademark enforcement continues to be a challenge due to the lack of *ex officio* authority to take criminal enforcement actions without a right holder's complaint. Nonetheless, the Competition Commission of Pakistan has made some progress in cases involving counterfeit trademarks and other trademark-related anti-competitive violations. The reconstituted IP Policy Board, established by the IPO Act, did not meet in 2020. The IPO continues to face challenges in coordinating enforcement among different government agencies and operates at levels well below approved staffing. On IP enforcement, addressing the lack of deterrent-level penalties and a sustained focus on judicial consistency and efficiency are critical to moving forward. A strong and effective IPO will support Pakistan's reform efforts, and Pakistan should provide sufficient human and financial resources to empower IPO's efforts. On a positive note, in early 2021, Pakistan acceded to the Madrid Protocol. The Office of the United States Trade Representative, in conjunction with the U.S. Patent and Trademark Office (USPTO) and the Commercial Law Development Program (CLDP), provided technical advice on the drafts of the Patent, Trademark, and Copyright Ordinances. Although the IPO states that its Policy Board approved the most recent amendments to these ordinances, the amendments remain under review. The United States encourages Pakistan to continue to work bilaterally, including through USPTO capacity-building programs, CLDP programs, and Trade and Investment Framework Agreement meetings, and 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 sufficient opportunity to comment on draft laws. As Pakistan implements its 2020 law and rules on geographical indications (GIs), it is important that Pakistan ensures transparency and procedural fairness in the protection of GIs, including ensuring that the grant of GI protection does not deprive interested parties of the ability to use common names. The United States also welcomes Pakistan's interest in joining international treaties, such as the World Intellectual Property Organization (WIPO) Internet Treaties and the Patent Cooperation Treaty, and urges Pakistan to convene regular meetings of the IP Policy Board.

PARAGUAY

Paraguay remains on the Watch List in 2021. The United States and Paraguay signed a Memorandum of Understanding (MOU) on Intellectual Property (IP) Rights in June 2015, under which Paraguay committed to take specific steps to improve its IP protection and enforcement environment. In December 2019, Paraguay established an interagency coordination center to provide a unified government response to IP violations. Nevertheless, Paraguay failed to meet key commitments in the MOU, including adopting and enforcing penalties such as imprisonment and monetary fines sufficient to deter future acts of infringement and ensuring that government institutions use computer software with a corresponding license. Paraguay also remains a major transshipment point for counterfeit and pirated goods and has taken little action against IP infringement in Ciudad del Este, one of the main destinations for illicit goods in the region. The United States urges Paraguay to ensure transparency and procedural fairness in the protection of geographical indications (GIs) and to ensure that the grant of GI protection does not deprive interested parties of the ability to use common names, particularly as Paraguay proceeds with the European Union-Mercosur Trade Agreement. Although the MOU expired at the end of 2020, the United States urges Paraguay to make progress on its commitments to strengthen IP protection and enforcement. The United States looks forward to continuing to work with Paraguay to address outstanding IP issues through bilateral engagement, including through an IP work plan.

PERU

Peru remains on the Watch List in 2021. The primary reasons are the long-standing implementation issues with the intellectual property (IP) provisions of the United States-Peru Trade Promotion Agreement (PTPA), particularly with respect to Articles 16.11.8 and 16.11.29(b)(ix). The United States urges Peru to implement fully its PTPA obligations and recognizes the steps that Peru has begun to take on establishing statutory damages. With respect to IP enforcement, Peru continues to be a leader in the region over the past few years and took a number of positive steps in 2020. Peru conducted more than 1,604 operations to seize more than \$91 million in counterfeit goods in 2020. Key enforcement activities include a January 2020 raid on Peru's notorious Polvos Azules market with a seizure of more than \$2 million in pirated and counterfeit goods and raids on the Gamarra Market, known for apparel counterfeits, in February and October 2020. Peru has also taken many administrative enforcement actions. Peru's National Institute for the Defense of Competition and the Protection of Intellectual Property (INDECOPI) granted 332 precautionary measures on trademark matters. In the area of online enforcement, Peru took enforcement actions directed at local websites offering unauthorized infringing music and film materials. The United States urges Peru to increase the number of prosecutions against counterfeiting and piracy, to continue prosecuting individuals involved in the sale of counterfeit medicines, and to expand 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 protection and enforcement. The United States further encourages Peru to enhance its border enforcement measures and to continue to build the technical IP-related capacity of its agencies, law enforcement officials, prosecutors, and judges. The United States looks forward to continuing to work with Peru to address outstanding issues, particularly with respect to full implementation of the PTPA, in 2021.

ROMANIA

Romania remains on the Watch List in 2021. The United States continues to welcome the participation of the Romanian government in intellectual property (IP)-related trainings and in international enforcement operations, as well as the continued working-level cooperation in Romania between stakeholders and law enforcement authorities, including prosecutors and police. Positive steps over the past year include the passing in July 2020 of legislation to implement the European Union (EU) Trademark Directive and corresponding amendments to the national trademark law, as well as engagement with the United States on a proposed work plan on IP. Romanian IP enforcement authorities also made progress by increasing IP investigations and indictments and customs officials increased the total value of seized counterfeit goods in 2020. However, despite these steps forward, online piracy and the use of unlicensed software continue to present challenges for U.S. IP-intensive industries in Romania. Trademark concerns also remain, specifically regarding the lack of providing a copy of the applicant's response in trademark opposition proceedings. The United States continues to be concerned that penalties for copyright crimes under Romanian law are reportedly so low that they reduce any deterrent effect of criminal prosecutions. It is important that Romania appoints a high-level IP enforcement coordinator who would be responsible for directing the development and implementation of its national IP enforcement strategy and would aid in coordinating enforcement efforts on a national scale. The United States also encourages Romania to ensure sufficient staffing and funding of the IP Coordination Department in the General Prosecutor's Office and the Economic Crimes Investigation Directorate and encourages the Department to prioritize its investigation and prosecution of significant IP cases, with a special focus on online piracy and cases involving criminal networks importing, distributing, or selling counterfeit products. Romania should also provide its specialized police, border police, customs, and local law enforcement with adequate resources, including necessary training in technical expertise for managing IP cases and in online IP enforcement. The United States also encourages Romania to continue its consultations with interested stakeholders as it implements the EU Directive on Copyright in the Digital Single Market and to engage with interested stakeholders as Romania moves forward with fulfilling the requirements of Regulation (EU) 2019/933 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate waiver for medicinal products. The United States will continue to work with Romania to address these and other issues.

THAILAND

Thailand remains on the Watch List in 2021. Thailand continues to make progress and address concerns raised as part of the bilateral United States-Thailand Trade and Investment Framework Agreement (TIFA). A subcommittee on enforcement against intellectual property (IP) infringement, led by a Deputy Prime Minister, continues to convene. Thailand continues to seize counterfeit and pirated goods and increased efforts to combat the sale of counterfeit goods online and to publish enforcement statistics online. Thailand has also increased efforts against online piracy, particularly through enhanced intra-agency coordination, though concerns remain. To address the use of unlicensed software in the public sector, Thailand adopted guidelines on the government acquisition of legitimate software. Thailand is in the process of amending its Patent Act to streamline the patent registration process, to reduce patent backlog and pendency, and to help prepare for accession to the Hague Agreement. Furthermore, Thailand has increased the number of examiners to reduce the patent backlog. Thailand is also amending its Copyright Act to prepare for accession to the World Intellectual Property Organization (WIPO) Internet Treaties. While Thailand continues to make progress in these areas, concerns remain. Counterfeit and pirated goods continue to be readily available, 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 urges Thailand to ensure that amendments to its Copyright Act address concerns expressed by the United States and other foreign governments and stakeholders, including regarding overly broad technological protection measure exceptions, procedural obstacles to enforcement against unauthorized camcording, and unauthorized collective management organizations. The United States also continues to encourage Thailand to address the issue of online piracy by devices and applications that allow users to stream and download unauthorized content. Other U.S. concerns include a backlog in pending pharmaceutical patent applications, continued use of unlicensed software in both the public and private sectors, lengthy civil IP enforcement proceedings, and low civil damages. U.S. right holders have also expressed concerns regarding legislation that allows for content quota restrictions for films. Stakeholders also continue 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. The United States looks forward to continuing to work with Thailand to address these and other issues through the TIFA and other bilateral engagement, including by agreeing to a revised IP work plan.

TRINIDAD AND TOBAGO

Trinidad and Tobago remains on the Watch List for 2021. Despite pledges to take enforcement action, the Telecommunications Authority of Trinidad and Tobago (TATT) continues to extend the forbearance period of its enforcement of the concessions agreement it requires of domestic broadcasters, which mandates respect for intellectual property (IP). The concession agreement prohibits broadcasters from transmitting any program, information, or other material without first obtaining all required permissions from relevant IP right holders. The United States remains concerned about the lack of enforcement action against companies in Trinidad and Tobago that violate the agreement, particularly the two state-owned telecommunications networks, both of which broadcast unlicensed U.S. content. Other concerns include optical disc music and video piracy and nonpayment of copyright royalties, as well as online piracy and counterfeit pharmaceuticals and other goods. The United States will monitor TATT's enforcement of the concessions agreement with broadcasters and will seek progress on other IP issues.

TURKEY

Turkey remains on the Watch List in 2021. Over the last few years, Turkey has worked to strengthen its intellectual property (IP) regime, including through continued implementation of the 2016 Industrial Property Law that, among other things, increases criminal sanctions for importing and exporting counterfeit goods and enhances authorities' ability to destroy counterfeit goods. An updated copyright law has also been under review, as has a five-year, government-wide IP strategy. In addition, the Turkish patent and trademark office increased its number of patent and trademark examiners. Despite these positive developments, however, right holders continue to have concerns regarding overall IP protection and enforcement in Turkey. 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. Stakeholders continue to express concerns over vagueness in the interpretation of Industrial Property Law No. 6769. Stakeholders also continue to raise concerns 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. In addition, stakeholders have reported concerns with Turkey's implementation of policies that require localized production of certain pharmaceutical products in order to remain on the government reimbursement list. In addition, the United States urges Turkey to establish an effective mechanism for the early resolution of potential pharmaceutical patent disputes. The United States encourages Turkey to fully implement its obligations under the World Intellectual Property Organization (WIPO) 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 significant source of and transshipment point for counterfeit goods across a number of industry sectors. This has continued throughout 2020 with stakeholders reporting even higher levels of counterfeit good production and purchasing. Levels of pirated products in Turkey also remain high. Furthermore, right holders continue to report the use of unlicensed software by some government agencies, as well as high levels of satellite television channel piracy. Turkey's enforcement processes are hampered by procedural delays and insufficient personnel, as well as laws that contain lax penalties and inadequate procedures. Stakeholders also report that a lack of IP training for the judiciary and the paucity of interagency coordination continue to hamper enforcement efforts. The Turkish National Police should be given *ex officio* authority over trademark violations, as well as other tools they currently lack, to help enhance IP enforcement capabilities. The United States will engage with Turkey to address these and other issues.

TURKMENISTAN

Turkmenistan remains on the Watch List in 2021. Turkmenistan's lack of progress in raising its intellectual property (IP) protections to international standards since its accession to the Berne Convention in 2016 remains concerning. 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 modernize its copyright protection for foreign sound recordings, including through accession to and implementation of the World Intellectual Property Organization (WIPO) Internet Treaties. The United States continues to be concerned with the level of protection and enforcement provided for under Turkmenistan's IP laws, as well as Turkmenistan's reported failure to enforce those 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. Publishing the activities of the State Service of Intellectual Property, and providing data pertaining to the seizures facilitated by the State Customs Service, will provide transparency that may help inform and enhance IP enforcement in Turkmenistan. The United States stands ready to assist Turkmenistan through engagement facilitated by the Intellectual Property Working Group under the United States-Central Asia Trade and Investment Framework Agreement (TIFA).

UZBEKISTAN

Uzbekistan remains on the Watch List in 2021. In recent years, Uzbekistan has taken important steps to address long-standing issues pertaining to intellectual property (IP) protection and enforcement. In particular, accession to the World Intellectual Property Organization (WIPO) Internet Treaties represents progress toward improving the copyright regime in Uzbekistan. The United States also recognizes the continued high-level political attention to IP, including Uzbekistan's support for and participation in the Intellectual Property Working Group under the United States-Central Asia Trade and Investment Framework Agreement (TIFA) and the recent tasking of the Intellectual Property Agency to develop a three-year plan to improve the IP system. In addition, the United States notes more progress toward developing a new national strategy for IP. The United States encourages Uzbekistan to continue improving its copyright statutory framework, including through providing adequate protection for foreign sound recordings and implementing the WIPO Internet 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 IP protection and enforcement agencies, and mandating government use of licensed software via presidential decree, law, or regulation.

VIETNAM

Vietnam remains on the Watch List in 2021. Although Vietnam took steps to improve intellectual property (IP) protection and enforcement, including by publishing draft amendments to its IP Law to comply with trade agreement commitments and by continuing public awareness campaigns and training activities, IP enforcement continues to be a challenge. The online sale of pirated and counterfeit goods remains a serious problem. Lack of coordination among ministries and agencies responsible for enforcement remains concerning, and capacity constraints related to enforcement persist, along with a lack of political will to prioritize IP enforcement. Vietnam continues to rely heavily on administrative enforcement actions, which have consistently failed to deter widespread counterfeiting and piracy. The United States is closely monitoring and engaging with Vietnam on the ongoing implementation of amendments to the 2015 Penal Code with respect to criminal enforcement of IP violations. Counterfeit goods remain widely available in physical markets. In addition, online piracy, including the use of piracy devices and applications to access unauthorized audiovisual content, remains a significant concern, along with the use of unlicensed software in both the public and private sectors. Furthermore, 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. The United States is monitoring the implementation of IP provisions of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, which came into force in January 2019 for Vietnam; the European Union-Vietnam Free Trade Agreement (EVFTA), which came into force in August 2020; and the United Kingdom-Vietnam Free Trade Agreement, which came into force in January 2021. The EVFTA grandfathered prior users of certain cheese terms from the restrictions in the geographical indications provisions of the EVFTA, and it is important that Vietnam ensure market access for prior users of those terms who were in the Vietnamese market before the grandfathering date of January 1, 2017. Vietnam has also committed to accede to the World Intellectual Property Organization (WIPO) Internet Treaties by 2023. The United States urges Vietnam to engage on and address these issues and to provide interested stakeholders with meaningful opportunities for input as it proceeds with these reforms. The United States also encourages continued bilateral cooperation through the implementation of the Customs Mutual Assistance Agreement, which came into force in May 2020. The United States will continue to press on these and other IP issues with Vietnam through the United States-Vietnam Trade and Investment Framework Agreement and other bilateral engagement.

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 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 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 intellectual property (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 take trade action 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.

The Office of Policy and International Affairs (OPIA) of the U.S. Patent and Trademark Office (USPTO) conducts 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. OPIA programs are frequently conducted in collaboration with Intellectual Property Attaches and other U.S. Government agencies.

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) 2020, USPTO's OPIA developed and delivered 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. Although face-to-face training programs did not take place from mid-March through September 2020, training efforts continued as OPIA was able to pivot to all-remote delivery of its programs in mid-2020. This included piloting the technological capability to run virtual international programs with simultaneous interpretation. Overall, OPIA hosted 100 programs with a distance learning component, up 525% from previous years. In FY 2020, the programs cumulatively included over 4,800 government officials, including examiners, policymakers, police, customs, parliamentarians, judges, and prosecutors, from 120 countries.
- In addition, the USPTO's OPIA provides capacity building in countries around the world and has formed partnerships with 29 national, regional, and international IP organizations,

such as the 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, the Association of Southeast Asian Nations (ASEAN), the Oceania Customs Organisation (OCO), 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 program and helps U.S. companies navigate IP across the globe. STOPfakes presents Roadshows across the country with 12 partner agencies from across the U.S. Government. These Roadshows are day-long, in-depth seminars for U.S. companies on protecting IP at home and abroad. 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 70 global markets. The website also includes IP highlights on industry- and policy-specific IP topics. Consumers can also find webinars focusing on best practices to protect and enforce IP in China. In addition to STOPfakes, ITA develops and shares small business tools to help domestic and foreign businesses understand IP and initiate protective strategies. Under the auspices of the Transatlantic IP Rights Working Group, ITA collaborates with the European Union's 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 United States-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 2019, U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI), through the National IPR Coordination Center (IPR Center), conducted HSI-led regional IP enforcement training programs in Austria, Brazil, the Cayman Islands, Kenya, and Thailand. These programs were supported by U.S. Customs and Border Protection (CBP), USPTO, the Department of Justice International Computer Hacking and Intellectual Property Advisors (DOJ ICHIPs), and other U.S. agencies. Additionally, the IPR Center, with support from the Department of State, participated in 12 IP-related programs sponsored by the USPTO and DOJ ICHIPs in Argentina, Botswana, Colombia, Paraguay, Romania, Senegal, Singapore, Taiwan, Thailand, and Vietnam.
- CBP officials assigned to the IPR Center participate in many engagements with public, private and international stakeholders hosted by any of the IPR Center's 27 partner agencies. In FY 2020, CBP participated in three such meetings with IP right holders, three public groups, and three international delegations. In addition, CBP staff sponsored two special events at the IPR Center for foreign stakeholders: a delegation of customs and police attachés assigned to embassies in Washington, D.C., and a meeting and discussion with the Secretary of State of Poland. All of these engagements promoted U.S. leadership

in customs matters, illuminated current trends and issues in global IP protection, and developed trade intelligence for further review.

- CBP routinely joins HSI training programs and engagements overseas. In FY 2020, this integrated support included providing training, titled, *Customs Enforcement of Intellectual Property Rights at the Border*, to foreign officials in the Dominican Republic. The audience included representatives from Anguilla, Bermuda, Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, Jamaica, Panama, St. Lucia, and Trinidad.
- The Department of State provides foreign assistance anti-crime funds each year to U.S. Government agencies that provide cybercrime and 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. Department programs feature deployment of a global network of ICHIPs, experienced DOJ attorneys dedicated to building international cooperation and delivering training. Additionally, the State Department leads the U.S. delegation to the Organization for Economic Co-operation and Development's Task Force on Countering Illicit Trade, working to establish best practices in free trade zones and addressing the challenges that illicit trade poses. 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. As noted, such assistance is being increased using the new ICHIPs. 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 public 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. Additionally, through its Office of Policy and International Affairs (PIA), the U.S. Copyright Office co-hosts with WIPO a bi-annual International Copyright Institute, where government officials from developing countries and countries in transition gather in Washington, D.C. to listen to expert copyright panels and exchange information on copyright best practices.

The United States reports to the World Trade Organization (WTO) on its IP capacity-building efforts, including most recently in September 2019 (see Technical Cooperation Activities: Information from Members—United States of America, IP/C/W/655/Add.2). The United States also reports annually on international IP capacity building and training in the annual report issued by the U.S. Intellectual Property Enforcement Coordinator pursuant to Section 304 of the PRO IP Act of 2008 (15 U.S.C. § 8114), issued most recently as the *Annual Intellectual Property Report to Congress* in January 2021.