

2022 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- and creativity-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. Combating 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- and creativity-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

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.”).

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

THE 2022 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 27 trading partners as follows:

Priority Watch List	Watch List	
<ul style="list-style-type: none">• Argentina• Chile• China• India• Indonesia• Russia• Venezuela	<ul style="list-style-type: none">• Algeria• Barbados• Bolivia• Brazil• Canada• Colombia• Dominican Republic• Ecuador• Egypt• Guatemala	<ul style="list-style-type: none">• Mexico• Pakistan• Paraguay• Peru• Thailand• Trinidad and Tobago• Turkey• Turkmenistan• Uzbekistan• Vietnam

The Special 301 review of Ukraine has been suspended due to Russia's premeditated and unprovoked further invasion of Ukraine in February 2022.

OUT-OF-CYCLE REVIEWS

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

In 2022, USTR will conduct an Out-of-Cycle Review of Bulgaria, which will consider the extent to which Bulgaria has addressed deficiencies in its investigation and prosecution of online piracy cases, particularly its failure to adopt evidence sampling in criminal cases. The Out-of-Cycle Review will assess whether Bulgaria has made any material progress on these issues.

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

REVIEW OF NOTORIOUS MARKETS FOR COUNTERFEITING AND PIRACY

In 2010, USTR began publishing annually the *Review of Notorious Markets for Counterfeiting and Piracy (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 2021, USTR requested such comments on August 30, 2021, and published the *2021 Notorious Markets List* on February 17, 2022. USTR plans to conduct its next Review of Notorious Markets for Counterfeiting and Piracy in the fall of 2022.

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 2022 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 13, 2021 (*Federal Register* notice). In addition, due to the COVID-19 pandemic, USTR fostered public participation via written submissions rather than an in-person hearing. The interagency Special 301 Subcommittee of the Trade Policy Staff Committee (TPSC) sent 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-2021-0021. The *Federal Register* notice drew submissions from 44 non-government stakeholders and 18 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-2021-0021.

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 2022 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 2022

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 63 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 41% of the U.S. gross domestic product (GDP).⁵ The 47.2 million workers that IP-intensive industries employed directly also enjoyed pay that was, on average, 60% higher than workers in non-IP-intensive industries.⁶

IP infringement, including patent infringement, trademark counterfeiting, copyright piracy,⁷ 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, increases the vulnerability of workers to exploitative labor practices,⁸ and hinders sustainable economic development in many countries.

This Section highlights developments in 2021 and early 2022 in IP protection, enforcement, and related market access in foreign markets, including: examples of initiatives to strengthen IP

³ USPTO, *Intellectual Property and the U.S. Economy: Third Edition* at 4 (Mar. 2022), <https://www.uspto.gov/sites/default/files/documents/uspto-ip-us-economy-third-edition.pdf>.

⁴ *See id.* at 15 (table listing IP-intensive industries).

⁵ *Id.* at 13.

⁶ *Id.* at 4 and 9.

⁷ The terms “trademark counterfeiting” and “copyright piracy” may appear below also as “counterfeiting” and “piracy,” respectively.

⁸ The Issue Focus of the 2021 Review of Notorious Markets for Counterfeiting and Piracy examines the adverse impact of counterfeiting on workers involved with the manufacture of counterfeit goods. The illicit nature of counterfeiting requires coordination between relevant actors, including IP right holders, labor organizations, workers’ rights associations, and government enforcement agencies in order to effectively uncover and combat labor violations in counterfeiting operations across the globe.

protection and enforcement; illustrative best practices demonstrated by the United States and our trading partners; U.S.-led initiatives in multilateral organizations; and bilateral and regional developments. 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 United States to resolve IP concerns.

A. Initiatives to Strengthen Intellectual Property Protection and Enforcement in Foreign Markets

The Office of the United States Trade Representative (USTR) notes the following important developments in 2021 and early 2022:

- **Kuwait** is removed from the Watch List this year for making continued and significant progress on concerns that stakeholders identified with intellectual property (IP) enforcement and transparency. For example, the Ministry of Commerce and Industry (MOCI) and the Copyright Office each created online portals for streamlining the submission of trademark and copyright violation reports, respectively. Kuwait also increased engagement and transparency through meetings of the United States-Kuwait Trade and Investment Framework Agreement (TIFA) Intellectual Property Working Group. Kuwait plans to continue improving its IP enforcement systems by providing specialized training for its investigators, prosecutors, and judiciary; by conducting IP-focused public awareness campaigns; and by linking information between the MOCI Trademarks and Patents Department and the Kuwait General Administration for Customs Intellectual Property Rights Unit.
- **Saudi Arabia** is removed from the Priority Watch List this year due to steps the Saudi Authority for Intellectual Property (SAIP) took to publish its IP enforcement procedures; increase enforcement against counterfeit and pirated goods and online pirated content; create specialized IP enforcement courts with trained judges and expedited timelines; conduct strong IP awareness, outreach, training, and support; set up a centralized committee to coordinate IP enforcement actions across multiple authorities; and train IP specialists in 76 different authorities to increase government compliance with IP laws. Stakeholders continue to raise concerns that the Saudi Arabia Food and Drug Authority (SFDA) has granted 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. The SFDA has not granted these concerning marketing approvals since October 2020, and the United States will continue to closely monitor SFDA's actions in this area.

- **Romania** is removed from the Watch List this year due to taking significant actions to improve IP protection and enforcement. In January 2022, Romania appointed its first-ever national IP enforcement coordinator, who has been charged with developing a national IP strategy and coordinating interagency efforts. Romania has also taken other actions to improve efforts to investigate and prosecute IP crime. For example, last year, the economic police established a new department dedicated to online piracy cases and also dedicated a minimum of two additional officers per county to IP investigations. Moreover, the General Prosecutor Office’s Intellectual Property Coordination Department resumed coordination of IP working group sessions, holding meetings last year with representatives of different ministries involved in IP as well as private sector representatives. The United States will continue to monitor Romania’s efforts to finalize a national IP strategy, to implement that strategy, and to take specific actions to prioritize IP protection and enforcement.
- **Lebanon** is removed from the Watch List this year. Stakeholders have not raised significant concerns about IP protection or enforcement during the Special 301 review. The United States will continue to monitor Lebanon’s IP protection and enforcement regime, including the ratification and implementation of international IP treaties.
- **Japan** amended its Trademark Act in May 2021 to address concerns over Japan’s personal use exemption for imported goods, which was used increasingly to send counterfeit items to individuals in Japan via postal and courier services. Pursuant to the amendment, items imported from “overseas vendors” for personal use fall within the scope of the Trademark Act, such that counterfeits imported in this manner are subject to seizure. The amendment is expected to come into force by November 2022.
- **Chile**’s amendment to its Industrial Property Law took effect in January 2022. Changes include criminalizing trademark falsification, recognizing non-traditional marks, introducing provisional applications for patents, incorporating a broader definition of trade secrets, and extending the term of protection for industrial designs to 15 years.
- After being removed from the Watch List in 2021, the **United Arab Emirates (UAE)** continued to advance IP protection and enforcement by enacting a series of major legal reforms to its Industrial Property, Trademark, Copyright, and Cyber Crime laws. Aided by these legal reforms, other non-legal reforms, and improved judicial review of IP cases, the IP enforcement authorities, especially those in Abu Dhabi, Dubai, and Ajman, increased investigations into online and offline IP infringing activities and continued to seize and destroy counterfeit goods. The UAE also established its first collective management organization (CMO) to license the physical and digital copying of printed material, although a CMO for music rights still has not been established.
- As of March 2022, there are 61 members of the 1991 Act of the International Union for the Protection of New Varieties of Plants Convention (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. **Ghana** joined UPOV 1991 as a new member in 2021.

- **Bahrain** enacted its Protection of New Plants Varieties Law in December 2021, which is a critical step in acceding to UPOV 1991 as part of its United States-Bahrain Free Trade Agreement obligations.
- As of March 2022, there are 110 parties to the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty and 112 parties to the WIPO Copyright Treaty, collectively known as the WIPO Internet Treaties. These treaties, which were completed in 1996 and 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 2021 Special 301 Report, **Kiribati**, **Uganda**, and **Vietnam** have acceded to the WIPO Internet Treaties.

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 Intellectual Property Practices by Trading Partners

The Office of the United States Trade Representative (USTR) highlights the following illustrative best practices by trading partners in the area of intellectual property (IP) protection and enforcement:

- Cooperation and coordination among national government agencies involved in IP issues are examples 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, have 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 (SAIP) recently created the permanent 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, and the private sector and works to discuss ongoing IP enforcement issues, propose public policy initiatives, and organize public awareness workshops. In October 2021, **Ukraine's** Council of Intellectual Property Issues tasked the

Ministry of Economy and Ministry for Digital Transformation with drafting software audit methodology for executive agencies and coordinating with the Ministry of Finance on a budget for software licenses. Also, **Indonesia** established a new Intellectual Property Enforcement Task Force to improve coordination on IP enforcement. The United States encourages other trading partners to consider adopting cooperative IP arrangements.

- Specialized IP enforcement units also have proven to be important catalysts in the fight against counterfeiting and piracy. The Special Internet Forensics Unit in **Malaysia's** Ministry of Domestic Trade and Consumer Affairs, which is responsible for IP enforcement, could be a model for others around the world.
- 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 the **United Arab Emirates** (UAE), the Emirates Intellectual Property Association's Dhahi Khalfan Center for Intellectual Property, established to keep pace with IP developments by providing IP academic courses and applied training, held 120 training courses conducted remotely with 5,300 local and international participants. In response to the pandemic, **India's** CIPAM reportedly organized over 400 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 the Go for Real campaign in conjunction with the U.S. Patent and Trademark Office (USPTO), to enhance awareness among high school and university students. In **Trinidad and Tobago**, the Intellectual Property Office developed two courses on IP administration and IP enforcement for law enforcement authorities and collaborated with the Ministry of Education to host workshops and clinics on IP for schoolteachers and a law school. In **Saudi Arabia**, the SAIP created a national initiative to include IP-related subjects and materials in public school curricula.
- Another best practice is the active participation of government officials in technical assistance and capacity building. **Romania's** law enforcement officers and prosecutors participated in several IP workshops and trainings organized by the regional International Computer Hacking and Intellectual Property (ICHIP) Advisor of the U.S. Department of Justice (DOJ) to promote U.S. best practices for IP rights enforcement, including collaborations with the United Nations Food and Agriculture Program, the European Commission, the European Anti-Fraud Office, the USPTO, and the DOJ. **Algeria's** prosecutors and General Directorate of National Security officers participated in a virtual IP enforcement "train the trainer" workshop hosted by the DOJ ICHIP office in Abuja, Nigeria. 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, and DPIIT and USPTO are in the process of entering into a biennial work plan to guide implementation of the Memorandum. The Intellectual Property Office of the **Philippines** signed a Memorandum of Understanding with the World Intellectual Property Organization (WIPO) to conduct a nationwide survey to measure the level of IP awareness in the Philippines, identify gaps, and determine priority areas. With the support of the European Union Intellectual Property Office, the Philippines

also conducted a workshop for law enforcement officers and public prosecutors with the objective to strengthen coordination and capacity on enforcement. **Brazil's** judiciary participated in a series of dialogues and exchanges with U.S. district court judges on rule of law, sentencing, and evidence in criminal IP cases. 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 **United Kingdom** provides IP audits to help potential high growth, innovative MSMEs with a tailored assessment of the IP within their business to help them develop IP management strategies. In **Saudi Arabia**, the SAIP launched a public awareness program to educate MSMEs on the importance of IP and established a communication channel that allows inventors and MSMEs to consult with IP experts. In January 2021, building on similar efforts in the past with respect to patents and trademarks, **India** notified Design (Amendment) Rules 2021 that reduce fees for startups seeking design protection. **Algeria's** National Institute of Industrial Property (INAPI) is working with WIPO to provide Algerian MSMEs access to WIPO's new IP Diagnostics tool to help MSMEs assess their needs.

C. Multilateral Initiatives

The United States works to promote adequate and effective intellectual property (IP) protection and enforcement through various multilateral institutions, notably the **World Trade Organization** (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 WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) on the positive and mutually reinforcing relationship between the protection of IP, innovation, and business development.

In 2021, the United States advanced its Intellectual Property and Innovation agenda in the TRIPS Council through a series of different initiatives that cover often unexplored areas connected to IP and innovation. Over the course of three meetings, the United States and co-sponsors presented on the relationship between IP and investment, IP and green technology, and women and IP. The discussions were wide-ranging and spurred Members to consider the links between these areas.

Throughout 2021, the United States, together with other Members of the WTO, worked to orient Members' efforts towards a pandemic response and greater preparedness, and sought to identify priority steps that could be taken, including in the area of trade facilitation and IP protections. While some progress has been made, there is still no multilaterally agreed outcome. The Biden

Administration supports a waiver of intellectual property protections for COVID-19 vaccines under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), but the broader institution has not been able to reach consensus on an agreement to do so.

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 March 2022 United States-**Pakistan** TIFA Intersessional meeting included engagement on updates to Pakistan's IP laws, use of unauthorized software, and Pakistan's progress on joining IP treaties. In May 2021, the United States and **Kuwait** created a TIFA Intellectual Property Working Group that met in May, September, and December to discuss progress on Kuwait's IP enforcement activities and systems, including streamlined online procedures for reporting copyright and trademark infringement. In November 2021, the United States-**Argentina** Innovation and Creativity Forum for Economic Development held its sixth meeting to discuss IP issues that are essential to the success of each country's innovation economy. In September, November, and December 2021, the United States held technical meetings under the United States-**Indonesia** TIFA. In July 2021, the Intellectual Property Working Group under the United States-**Central Asia** TIFA met virtually to discuss and share ideas about recent innovations in IP protection and enforcement in each country. In June 2021, the United States and **Taiwan** held a TIFA Council meeting under the auspices of the American Institute in Taiwan (AIT) and the Taipei Economic and Cultural Representative Office in the United States (TECRO), and discussed developments related to the enforcement of trade secrets protections, copyright legislation, and digital piracy. At the tenth meeting of the United States-**Ukraine** Trade and Investment Council, held in November 2021, Ukraine agreed to pursue an Intellectual Property Work Plan identifying tangible steps Ukraine can take to demonstrate progress on key IP issues and to develop and implement a program to eliminate use of unlicensed software by government agencies. The Intellectual Property Working Group under the **India**-United States Trade Policy Forum (TPF), which met three times in 2021, exchanged ideas and discussed developments on patent, copyright, and trademark issues, among others. At the twelfth Ministerial-level meeting of the TPF held in November 2021, India clarified certain aspects of its patent and trademark systems and agreed to comply with the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty and WIPO Copyright Treaty, collectively known as the WIPO Internet Treaties.
- 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.

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 illicit streaming, which involved the joint publication of the *Report on Results of Survey Questionnaire on Domestic Treatment of Illicit Streaming Devices (ISDs) by APEC Economies* with APEC and discussions on effective practices for enforcement against illicit streaming. The United States also continues to lead an initiative on industrial design protection, 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.
- Under its trade preference program reviews, the Office of the United States Trade Representative (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. USTR has ongoing GSP reviews of 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 the **World Customs Organization**. USTR, in coordination with other U.S. Government agencies, looks forward to continuing engagement with trading partners to improve the global IP environment.

E. Intellectual Property 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,⁹ particularly medicines, automotive and airplane parts, and food and beverages that may not be subject to the

⁹ See OECD/EUIPO, *Dangerous Fakes: Trade in Counterfeit Goods that Pose Health, Safety and Environmental Risks* (March 2022), <https://www.oecd.org/publications/dangerous-fakes-117e352b-en.htm> (identifying types of potentially dangerous counterfeit products, associated health and safety risks, and global trade statistics from 2017 to 2019 for these products).

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 intellectual property (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, Kazakhstan, Kyrgyzstan,** and the **United Arab Emirates,** to third-country markets such as **Brazil, Nigeria, Russia,** and **Paraguay** that are reported to have ineffective or inadequate IP enforcement systems.

According to an Organisation for Economic Co-operation and Development (OECD) and European Union Intellectual Property Office (EUIPO) study released in June 2021, titled *Global Trade in Fakes: A Worrying Threat*, the global trade in counterfeit and pirated goods reached \$464 billion in 2019, accounting for 2.5% of the global trade in goods for that year.¹¹ **China** continues to be the largest origin economy for counterfeit and pirated goods, accounting (together with **Hong Kong**) for more than 85% of global seizures of counterfeit goods from 2017 to 2019.¹² Stakeholders also continue to report dissatisfaction with border enforcement in **Singapore**, including concerns about the lack of coordination between Singapore's Customs authorities and the Singapore Police Force's Intellectual Property Rights Branch.

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 by numerous trading partners. The majority, by value, of all counterfeit pharmaceuticals seized at the U.S. border in Fiscal Year 2021 was shipped from or transshipped through **India, China,** and the **Dominican Republic.** A recent study by OECD and EUIPO found that **China, India,** the

¹⁰ In fiscal year 2020, China and Hong Kong accounted for 83% of all U.S. IP rights seizures. U.S. Customs and Border Protection Office of Trade, *Intellectual Property Rights Seizure Statistics: Fiscal Year 2020* at 24 (Sep. 2021), <https://www.cbp.gov/document/report/fy-2020-ipr-seizure-statistics>.

¹¹ OECD/EUIPO, *Global Trade in Fakes: A Worrying Threat* at 9 (Jun. 2021), <https://www.oecd-ilibrary.org/sites/74c81154-en/index.html?itemId=/content/publication/74c81154-en>.

¹² *Id.* at 27.

Philippines, Vietnam, Indonesia, and Pakistan are the leading sources of counterfeit medicines distributed globally.¹³ This past year, countries continue to report significant quantities of counterfeit imports from China, including COVID-19 testing kits, personal protective equipment (PPE) such as those air-purifying particulate respirators meeting U.S. Department of Health certification standards (N95) and equivalent masks, sanitizers, detergents, and disinfectants. In the first year of the pandemic alone, U.S. Customs and Border Control (CBP) seized more than 30 million counterfeit face masks.¹⁴ U.S. brands are the most popular targets for counterfeiters, and counterfeit U.S.-brand medicines account for 38% of global counterfeit medicine seizures.¹⁵ 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.¹⁶ Furthermore, the increasing popularity of online pharmacies¹⁷ 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.¹⁸ 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 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.¹⁹

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 CBP, Trade News Snapshot, Volume 3, Issue 2 (2021), https://www.cbp.gov/sites/default/files/assets/documents/2021-Apr/Trade%20News%20Snapshot_V3_I2.pdf.

¹⁵ OECD/EUIPO, *Trade in Counterfeit Pharmaceutical Products* at 12 (Mar. 2020), <http://www.oecd.org/gov/trade-in-counterfeit-pharmaceutical-products-a7c7e054-en.htm>.

¹⁶ WHO, *Substandard and Falsified Medical Products* (Jan. 2018), <https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>.

¹⁷ 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”).

¹⁸ 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).

¹⁹ For more information on these trends and CBP’s and ICE/HSI’s IP enforcement efforts, see the Department of Homeland Security (DHS), Intellectual Property Rights Annual Seizure Statistics at <https://www.cbp.gov/trade/priority-issues/ipr/statistics>.

Counterfeiters also increasingly sell counterfeit goods on online marketplaces, particularly through platforms that permit consumer-to-consumer sales. The Office of the United States Trade Representative (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.²⁰

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, as well as materials and implements, to re-enter the channels of commerce after an enforcement action wastes resources and compromises 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. **Pakistan** has not provided criminal enforcement authorities *ex officio* authority to take action against counterfeit goods. **Uzbekistan** and **Turkmenistan** lack *ex officio* authority for border enforcement.

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. 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 free trade zones.²¹ The United States

²⁰ For more examples, see DHS, *Combating Trafficking in Counterfeit and Pirated Goods* (January 2020), https://www.dhs.gov/sites/default/files/publications/20_0124_ply_counterfeit-pirated-goods-report_01.pdf.

²¹ 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>.

encourages the OECD and our trading partners to build off the *Governance Frameworks to Counter Illicit Trade* OECD report²² and the International Chamber of Commerce (ICC) *Know Your Customer* initiative²³ 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 that competes 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 **China, India, Mexico, and Pakistan**, online piracy is the most challenging copyright enforcement issue in many foreign markets. For example, during the review period, countries such as **Argentina, Bulgaria, Canada, Chile, China, Colombia, the Dominican Republic, India, Mexico, the Netherlands, Romania, Russia, Switzerland, Thailand, Ukraine, and Vietnam** had high levels of online piracy and lacked effective enforcement. For example, Bulgaria was removed from the Watch List in 2018 after it committed to taking additional steps to improve enforcement, including adopting the practice of evidence sampling, but progress has stalled since then. The failure to adopt evidence sampling is a primary reason for the lack of significant, successful intellectual property (IP) prosecutions in Bulgaria and for weak enforcement efforts against online piracy. Bulgarian prosecutors did not charge anyone with copyright infringement last year and only filed one copyright indictment the year before. 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.²⁴

Stream-ripping software can be used to create infringing copies of copyrighted works from licensed streaming sites, and stream-ripping is now a dominant method of music piracy, causing substantial economic harm to music creators and undermining legitimate online services. During

²² OECD, *Governance Frameworks to Counter Illicit Trade* (Mar. 2018), https://www.oecd-ilibrary.org/governance/governance-frameworks-to-counter-illicit-trade_9789264291652-en.

²³ International Chamber of Commerce, *Know Your Customer* (Mar. 2018), <https://cdn.iccwbo.org/content/uploads/sites/3/2018/03/kyc-paper-doi-published.pdf>.

²⁴ 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.

the review period, stream-ripping was reportedly popular in countries such as **Canada, India, Mexico, Russia, Switzerland, and Ukraine.**

Furthermore, as highlighted in the 2017 *Notorious Markets List* and called out in subsequent *Notorious Markets Lists*, illicit streaming devices (ISDs), also referred to as piracy devices, continue to pose a direct threat to content creators, sports leagues, and live performances, as well as legitimate streaming, on-demand, and over-the-top media service providers. Similarly, illicit Internet Protocol Television (IPTV) services unlawfully retransmit telecommunications signals and channels containing copyrighted content through dedicated web portals and third-party applications. 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, Canada, Chile, China, Guatemala, Hong Kong, India, Indonesia, Iraq, Mexico, Singapore, Switzerland, Taiwan, Thailand, 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, in **Brazil**, signal theft is used as a source of premium live content. **Argentina's** law enforcement authorities do not prioritize theft of pay-tv signals. Prior to January 2022, many **Ukrainian** cable operators reportedly had continued to transmit audiovisual programming without licenses. 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. Unauthorized camcording is the primary source of infringing 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 showing in 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 there. In addition to theater owners who lose revenue, legitimate digital platforms, which often negotiate for a certain period of exclusivity after the theatrical run, cannot fairly compete in the market due to unauthorized camcording.

Stakeholders continue to report serious concerns regarding unauthorized camcords. For example, in **Russia**, the number of sourced camcords prior to the COVID-19 pandemic was reportedly 48 in 2018 and 45 in 2019. While COVID-19-related cinema closures suppressed this activity during the pandemic, camcords have reportedly reappeared as theaters have started to re-open. In early

2019, **India**, a source of video and audio camcords, proposed draft legislation to criminalize unauthorized camcording, although this legislation continues to await consideration and passage by India's Parliament. India's Ministry of Information and Broadcasting sought public comments in June 2021 on revised draft legislation that would further enhance penalties for camcording. Although the closure of theaters and delays in the release of films in 2021 continued to result in a decreased volume of unauthorized camcording, **China** remains a notable source of unauthorized camcords, including live streams of theatrical broadcasts online. Notwithstanding several criminal convictions for unauthorized 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 and India have 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, the Philippines, and Ukraine**. The Asia-Pacific Economic Cooperation (APEC) has also issued a report titled *Effective Practices for Addressing Unauthorized Camcording*.²⁵ 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 the online distribution of software and devices that allow for the circumvention of technological protection measures, 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 recourse to right holders, enforcement procedures, and remedies are critical components 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,

²⁵ APEC, *Effective Practices for Addressing Unauthorized Camcording* (November 11, 2011), https://www.apec.org/docs/default-source/groups/ip/11_amm_014app05.doc.

including information and communications technology, 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 National Counterintelligence and Security Center (NCSC), have reported specific gaps in trade secret protection and enforcement, particularly in **China** and **Russia**.²⁶ 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**, **India**, and **Russia**. 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. Certain data governance regimes (whether proposed or implemented) also raise concerns for intellectual property protection in general and trade secret protection of proprietary data in particular. The United States continues to monitor this trend and its impact on incentivizing innovation and market access. **India's** Personal Data Protection Bill and draft Non-Personal Data Governance Framework are examples of initiatives that potentially threaten innovation and economic growth.

The United States uses all trade tools available to ensure that its trading partners provide robust protection for trade secrets and enforce trade secrets laws. Given the global nature of trade secret theft, action by our trading partners is also essential. Several trading partners have recently strengthened or have been working toward strengthening their trade secret regimes, including the **European Union (EU)**, **Chile**, and **Taiwan**. In addition, the United States-Mexico-Canada Agreement (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,

²⁶ NCSC, *Foreign Economic Espionage in Cyberspace* at 5-9 (2018), <https://www.dni.gov/files/NCSC/documents/news/20180724-economic-espionage-pub.pdf>.

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 Organisation for Economic Co-operation and Development (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)*,²⁷ 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*,²⁸ examined the protection of trade secrets for a sample of 37 countries, provided historical data for the period since 1985, and considered the relationship between the stringency of trade secret protection and relevant economic performance indicators. Also, in November 2016, the Asia-Pacific Economic Cooperation endorsed a set of *Best Practices in Trade Secret Protection and Enforcement Against Misappropriation*,²⁹ which includes best practices such as: broad standing for claims for the protection of trade secrets and enforcement against trade secret theft; civil and criminal liability, as well as remedies and penalties, for trade secret theft; robust procedural measures in enforcement proceedings; and adoption of written measures that enhance protection against further disclosure when governments require the submission of trade secrets.

Forced Technology Transfer, Indigenous Innovation, and Preferences for Indigenous Intellectual Property

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 intellectual property (IP) is not consistent with international practice and may raise concerns regarding consistency with international obligations as well.

²⁷ Schultz, M. and D. Lippoldt, *Approaches to Protection of Undisclosed Information (Trade Secrets): Background Paper* (Jan. 2014), <https://doi.org/10.1787/5jz9z43w0jnw-en>.

²⁸ 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>.

²⁹ *Best Practices in Trade Secret Protection and Enforcement Against Misappropriation*, <https://ustr.gov/sites/default/files/11202016-US-Best-Practices-Trade-Secrets.pdf>.

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 domestically owned 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 domestically owned firms with an unfair competitive advantage by failing to effectively enforce, or discouraging the enforcement of, U.S.-owned IP, including patents, trademarks, trade secrets, and copyright;
- Failing to take meaningful measures to prevent or to deter cyber intrusions and other unauthorized activities;
- Requiring use of, or providing preferences to, products or services that contain domestically developed or owned IP, including with respect to government procurement;
- Manipulating the standards development process to create unfair advantages for domestically owned 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 United States-China Economic and Trade Agreement (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. Although Indonesia amended its 2016 Patent Law to remove localization provisions that require the manufacture of patented products and use of patented processes in Indonesia, the status of the amendments is unclear due to a ruling by the Indonesian Constitutional Court.

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 geographical indications (GI)-related trade initiatives of the **European Union (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 protection 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 exclusive rights in registered trademarks that pre-date the protection of a GI. Trademarks are among the most effective ways for producers and companies, including micro, small, and medium-sized enterprises (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 claimed as GIs of other European countries, such as feta, and export these products outside of the EU using the protected GIs as the common name of the products. 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 World Trade Organization (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 Committee.

Moreover, havarti is included in the EU's most favored nation 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 any producer, except from those 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 protected EU GIs within their own GI systems, 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 more than \$1 billion of cheese to the United States last year. Conversely, the United States exported only about \$3 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 the effective U.S. system of trademark protection of GIs, and despite 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 remain concerned about certain changes to the EU's Common Agricultural Policy, adopted in November 2021 and entering into force on January 1, 2023, which 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 World Intellectual Property Organization (WIPO) Lisbon Agreement for the Protection of Appellations of Origin and their International Registration to include GIs, thereby enshrining several detrimental aspects of EU law in that Agreement. The Geneva Act of the Lisbon Agreement that emerged from these negotiations was the product of a decision led by the EU and certain Member States to break with the long-

standing WIPO practice of consensus-based decision-making and 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 the Asia-Pacific Economic Cooperation, 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, Malaysia, Mexico, Moldova, Morocco, New Zealand, Paraguay, the Philippines, Singapore, Tunisia, Uruguay, and Vietnam**, among others. U.S. goals in this regard include:

- Ensuring that the grant of GI protection does not violate prior rights (for example, in cases in which a U.S. company has a trademark that includes a place name);
- Ensuring that the grant of GI protection does not deprive interested parties of the ability to use common names, such as parmesan or feta;
- Ensuring that interested persons have notice of, and opportunity to oppose or to seek cancellation of, any GI protection that is sought or granted;
- Ensuring that notices issued when granting a GI consisting of 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 innovations, as well as a lack of widespread, timely, and equitable global distribution of these innovations. While recognizing that certain extraordinary circumstances such as pandemics call for extraordinary measures, the Office of the United States Trade Representative (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 and nontransparent have the potential to hinder market access in the pharmaceutical and medical device sectors, and potentially result in higher costs. For example, taxes or tariffs may be levied, often in a non-transparent manner, on imported medicines. The increased expense associated with those levies may then be 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 an October 2021 Geneva Network report titled *How Tariffs Impact Access to Medicines*, low and middle-income countries maintain the highest tariffs on medicines and pharmaceutical inputs among the World Trade Organization (WTO) Members identified in the report, a trend that contributes to higher prices and decreased supply of medical goods in those countries.³⁰ The report notes that, in particular, large developing countries such as **Brazil, India, and Indonesia** have the highest tariffs for such products. These tariffs, combined with domestic charges or measures, particularly those that lack transparency or opportunities for meaningful stakeholder engagement or that appear to exempt domestically-developed and manufactured medicines, can hinder government efforts to promote increased access to health care products.

Moreover, unreasonable regulatory approval delays and non-transparent reimbursement policies can impede a company's ability to enter the market. The criteria, rationale, and operation of such measures are often non-transparent or not fully disclosed to patients or to pharmaceutical and medical device companies seeking to market their products. By contrast, various countries have implemented policies that significantly decrease regulatory timelines by "relying" on regulatory approvals by stringent health regulatory authorities in other countries, or relevant assessments by the World Health Organization. These policies are especially critical during health emergencies, where efficiencies are needed more than ever. 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:

- Monitored and enforced the implementation of **Canada** and **Mexico**'s IP commitments in the United States-Mexico-Canada Agreement (USMCA), which are important to incentivizing innovation, as well as the implementation of other 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;
- Monitored and enforced **China**'s commitments with respect to: (1) 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) patent term extensions to compensate for unreasonable patent office

³⁰ Geneva Network, *How Tariffs Impact Access to Medicines* (Oct. 2021), <https://geneva-network.com/research/how-tariffs-impact-access-to-medicines/>.

and marketing approval delays that cut into the effective patent term; and (3) the use of supplemental data to meet relevant patentability criteria for pharmaceutical patent applications;

- 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;
- Engaged with **India** on the administration of its patent regime, including on disclosure requirements, treatment of confidential information, patent application oppositions; 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, Brazil, Canada, China, Japan, Korea, New Zealand, Russia, 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 expressed concerns about **Japan's** shortcomings in terms of transparency, meaningful stakeholder input, and predictability regarding 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 concerns raised by stakeholders relate to a reported lack of meaningful stakeholder input in the development of a health technology assessment system, as well as a lack of transparency and predictability associated with Japan's implementation in April 2021 of annual repricing for drug reimbursement, which applies to a larger-than-expected range of products.
- Stakeholders continue to report concerns regarding a lack of transparency and predictability in **Korea's** pricing and reimbursement policies for pharmaceuticals and medical devices.
- Stakeholders have raised 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 Co-operation 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 United States-China Economic and Trade Agreement (Phase One Agreement) related to these concerns will improve the protection of IP.

Trademark holders also continue to face challenges in protecting their trademarks against unauthorized domain name registration and trademark uses in some country code top-level domain names.

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.

Another concern includes mandatory requirements to record trademark licenses, such as in **Brazil, Ecuador, Egypt, Spain, Turkmenistan, and Uzbekistan**, as they frequently impose unnecessary administrative and financial burdens on trademark owners and create difficulty in the enforcement and maintenance of trademark rights.

Travel restrictions and closures associated with the COVID-19 pandemic continue to limit options for obtaining traditional pen-and-ink signatures, notarized or legalized powers of attorney, and original documents to comply with formalities and documentation requirements. Numerous countries including **Algeria, China, Indonesia, Iraq, Jordan, and the United Arab Emirates** require burdensome formalities for filing documents such as intellectual property (IP) applications, registration maintenance, transfer of ownership submissions, and in opposition and cancellation proceedings.

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 the owners of the applications and registrations clearly have no interest in or intention of defending their claims to exclusive rights in such marks, 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 have an ongoing interest in their trademark in order to continue with a full proceeding before the relevant authorities.

A number of countries do not provide the full range of internationally recognized trademark protections. For example, many countries do not provide protection for certification marks that are used to show consumers that particular goods or services, or their providers, come from a specific geographic region, meet standards with respect to quality, materials, or manufacturing methods such as with environmentally “green” products, or that labor was performed by a union member or member of a specific organization. In other countries, the nature of the requirements imposed for registration of certification marks create burdens on certifying entities. As direct-to-consumer global e-commerce has flourished during the COVID-19 pandemic, certified products have been valued by an ever-growing marketplace of purchasers. Providing for registration of and mechanisms to enforce rights in certification marks are essential to ensure safe, compliant, and reputable products and services. The recently adopted Gulf Cooperation Council Trademark Law introduced certification marks to the laws of **Kuwait and Qatar**. In **Mexico**, reforms to the Law for the Protection of Industrial Property in 2020 provide for registration of certification marks.

Companies use letters of consent to resolve potential disputes and overcome refusals based on a likelihood of confusion when multiple trademark owners agree that their marks may coexist in the marketplace without confusion as to the source of the identified goods or services. Some countries refuse to recognize letters of consent. Some countries accept the letters yet view them as informational only. Other countries allow submission of the letters with the caveat that they may be ignored. When letters of consent are rejected, or given little or no effect, companies may be forced to employ alternative measures requiring detailed arguments and evidence, including litigation, that could be avoided. Some countries such as **Turkey** now accept letters of consent.

Strict use of the Nice Classification or a country's own sub-classification system to determine conflicts with prior marks does not reflect the realities of the relatedness of underlying goods or services in the current marketplace and introduces uncertainty into the registration process. Goods and services should be considered based on their commercial relationship and not solely in light of classification systems developed for administrative convenience.

Many 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 consider a likelihood of confusion with previously filed applications and registrations during examination, otherwise known as "relative grounds" refusals. The failure to make these rejections costs U.S. companies millions of dollars a year in unnecessary opposition proceedings. Some countries that do consider relative grounds provide a pre-examination opposition period to allow third parties to submit objections before the national office conducts its own examination, thus resulting in unnecessary expenses to oppose marks the national office would likely refuse during examination.

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.

Copyright Administration and Payment of Royalties

Collective management organizations (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 **United Arab Emirates (UAE)**, the Ministry of Economy established the UAE's first CMO to license the physical and digital copying of printed material, but the failure to issue the necessary operating licenses to allow CMOs for music rights 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, as of January 2022, stakeholders continued to report significant concerns with the law, including those pertaining to royalty rate calculations, and with the operation of the CMO regime.

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. In 2021, **Japan** amended its Copyright Act to create a presumption that when a right holder enters into a license agreement authorizing a broadcast or cablecast (linear broadcast rights) of a copyrighted work, the agreement will be presumed to also grant so-called “simulcast” rights to the broadcaster (allowing simultaneous transmissions of the broadcasted content for one week on other platforms, such as online streaming) unless a contrary intention is clearly indicated. This represented a departure from the previous practice in Japan and current practice of many other countries where express permission from the copyright owner for the additional transmission is not presumed, but required, and exceptions are confined to certain special cases.

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 2018.³¹ 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 intellectual property for private enterprises. Additionally, unlicensed software exposes governments and enterprises to higher risks of security vulnerabilities. Further work on this issue remains with certain trading partners, including **Argentina, Brazil, China, Guatemala, Indonesia, Pakistan, Paraguay, Romania, Saudi Arabia, Tajikistan, Turkey, Turkmenistan, Uzbekistan, and Vietnam**. The United States urges trading partners to adopt and implement effective and transparent procedures to ensure legitimate governmental use of software.

Other Issues

U.S. stakeholders have expressed views with respect to the **European Union (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.

³¹ BSA, *2018 Global Software Survey* at 12 (Jun. 2018), https://gss.bsa.org/wp-2content/uploads/2018/05/2018_BSA_GSS_Report_en.pdf.

The United States also is closely monitoring the European Commission’s Digital Services Act proposal, another legislative initiative that would govern online services and how content is shared online. U.S. stakeholders have raised concerns that the EU Council’s version of the DSA proposal could weaken the current liability regime and have a detrimental impact on the existing standards and practices for addressing illegal content and activities, including online infringement of copyright and related rights.

F. Intellectual Property and the Environment

Strong intellectual property (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 2022 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 acute phase of the pandemic in the United States and around the world. This includes continuing to donate vaccine doses to countries in need, investing in delivery and administration of vaccines globally, and engaging with our international partners and stakeholders to continue to increase equitable global access to safe and effective vaccines, tests, treatments, and other critical products to respond to COVID-19. The United States also encourages voluntary licensing and technology transfer agreements on mutually agreed terms to promote greater access to pandemic response products. For example, in 2021, stakeholders entered into voluntary licensing agreements with the Medicines Patent Pool (MPP) to help create broad access to COVID-19 therapeutics in all low-income countries and several middle-income countries.

The Biden-Harris Administration supports a waiver of intellectual property (IP) protections for COVID-19 vaccines under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The Office of the United States Trade Representative (USTR) has worked hard to facilitate an outcome on IP that can achieve consensus across the 164 Members of the WTO to help end the pandemic. The United States will continue to engage with WTO Members as part of the Biden-Harris Administration’s comprehensive effort to get as many safe and effective vaccines to as many people as fast as possible.

Numerous comments in the 2022 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.

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, a Member choosing to issue a compulsory license may waive some of these requirements in certain circumstances. 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 and related institutions such as the World Intellectual Property Organization (WIPO) and the World Health Organization (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. For example, in recent U.S. trade agreements, we have clarified that notwithstanding provisions on the protection of undisclosed test or other data, a Party may take measures to protect public health in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, or any waiver or amendment of the TRIPS Agreement to implement the Doha Declaration on the TRIPS Agreement and Public Health. 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 World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) requires all WTO Members to provide certain minimum standards of intellectual property (IP) protection and enforcement. The TRIPS Agreement is the first broadly-subscribed multilateral IP agreement that is subject to 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 least developed countries (LDCs), the United States has worked closely with them and other WTO Members to extend the implementation date for these countries. Most recently, on June 29, 2021, the WTO Council for the Trade-Related Aspects of Intellectual Property Rights (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, 2034, or until such a date on which they cease to be an LDC WTO Member, whichever date is earlier. Likewise, 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.

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. During 2021, the United States joined the consensus in the TRIPS Council to extend the moratorium on the initiation of non-violation and situation complaints under the TRIPS Agreement to the 13th Ministerial Conference.

The United States participates actively in the 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 World Trade Organization (WTO), and other dispute settlement procedures, as appropriate.

Under Section 301 of the Trade Act of 1974, as amended (19 U.S.C. § 2411) (Section 301), 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, intellectual property (IP), and innovation. USTR has also successfully pursued dispute settlement proceedings at the WTO to address discriminatory licensing practices. The United States and China signed the United States-China Economic and Trade Agreement (Phase One Agreement) in January 2020, which included commitments to address numerous long-standing concerns in the areas of trade secrets, patents, pharmaceutical-related IP, trademarks, copyrights, geographical indications, and technology transfer. The United States has been closely monitoring China's progress in implementing its commitments.

Following the 1999 Special 301 review process, the United States initiated dispute settlement consultations concerning the European Union (EU) regulation on food-related geographical indications (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 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 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

UKRAINE – REVIEW SUSPENDED

Ukraine was placed on the Priority Watch List in 2021. Over the past year, Ukraine has engaged meaningfully with the United States on longstanding areas of concern with Ukraine’s intellectual property regime, including: (1) the administration of the system for collective management organizations that are responsible for collecting and distributing copyright royalties to right holders; (2) the use of unlicensed software by government agencies; and (3) the implementation of effective means to combat widespread online copyright infringement. However, due to Russia’s premeditated and unprovoked further invasion of Ukraine in February 2022, the Special 301 review of Ukraine has been suspended.

PRIORITY WATCH LIST

ARGENTINA

Argentina remains on the Priority Watch List in 2022.

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. The National Institute of Industrial Property (INPI) continues to operate with a reduced number of patent examiners. INPI’s participation in the Patent Prosecution Highway with the U.S. Patent and Trademark Office expired in March 2020 and there are no plans for renewal.

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. The

physical market of La Salada in Buenos Aires has resumed operations after being closed due to the pandemic, and online orders of counterfeit goods continue 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 Barrio Once and Avellaneda Street markets 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-level 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 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 2021. Argentina's transition to an all-electronic patent and trademark filing system have allowed for increased efficiency in the processing of filings. There were a record number of 115,000 trademark filings in 2021 alone, and INPI granted 117,800 trademarks. 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. 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. During 2021, Argentina did not file or approve any new legislation to update IP laws. The United States encourages legislative proposals along the lines of prior bills introduced in Argentina's 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 has not met since 2019, 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 Argentina's 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 2021, Argentina and the United States held a bilateral meeting under the Innovation and Creativity Forum for Economic Development, which is 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 2022.

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 (TPMs). The United States continues to urge Chile to ratify and implement the 1991 Act of the International Union for the Protection of New Varieties of Plants Convention (UPOV 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 United States 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 also 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

There was notable progress by Chile in strengthening its legal framework for IP. In May 2021, Chile's Congress voted to join the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks. In January 2022, a new law modernizing many aspects of Chile's IP regime entered into force, with changes that include criminalizing trademark falsification, recognition of non-traditional marks, introducing provisional applications for patents, incorporating a broader definition of trade secrets, and extending the term of protection for industrial designs to 15 years. In February 2022, Chile enacted a new law that criminalizes aiding and abetting the trade of counterfeit, pirated, and other types of illicit goods and that authorizes more severe fines and penalties for these types of acts. In addition, in December 2021, the administration of former President Piñera introduced legislation that defines and outlines civil and criminal penalties for the circumvention of TPMs, although the draft remains under review in Chile's Congress. The United States also 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, particularly as Chile proceeds with the modernization of the European Union-Chile Association Agreement.

The United States appreciates Chile's engagement with the United States and the steps Chile has taken as an attempt to resolve ongoing issues pertaining to the Chile FTA, but it has been over eighteen years since the Chile FTA entered into force. It remains critical that Chile show tangible progress in addressing the long-standing Chile FTA implementation issues and other IP issues in 2022.

CHINA

China remains on the Priority Watch List in 2022 and is subject to continuing monitoring pursuant to Section 306 of the Trade Act of 1974, as amended (19 U.S.C. § 2416).

Ongoing Challenges and Concerns

In 2021, China enacted amendments to the Patent Law, Copyright Law, and Criminal Law, as well as other measures aimed at addressing intellectual property (IP) protection and enforcement. While right holders have welcomed these developments, they continue to raise concerns about the adequacy of these measures and their effective implementation, as well as about long-standing issues like bad faith trademarks, counterfeiting, and online piracy. China needs to complete the full range of fundamental changes that are required to improve the IP landscape in China. In particular, China needs to address weak enforcement channels and a lack of transparency and judicial independence.

Statements by Chinese officials that tie IP rights to Chinese market dominance continue to raise strong concerns. In a September 2021 outline on IP goals for the period 2021-2035, the Chinese Communist Party Central Committee and State Council emphasized that the IP system should serve the needs of domestic innovation-driven development and highlighted IP as a “strategic resource” for China’s international competitiveness. The outline also called for building China into an optimal location for international IP litigation. An October 2021 five-year plan emphasized that “indigenous” or “independent” “critical core technologies” were important to national security. In an essay published earlier that year, the president of the Supreme People’s Court wrote that the courts should serve the Chinese Communist Party and industrial policy goals. Taken together, such statements recall long-standing concerns about requiring and pressuring technology transfer from foreign individuals or companies to Chinese companies, as well as about whether IP protection and enforcement will apply fairly to foreign right holders in China. China must provide a level playing field for IP protection and enforcement, refrain from requiring or pressuring technology transfer to Chinese companies at all levels of government, open China’s market to foreign investment, and embrace open and market-oriented policies.

Under Section 301 of the Trade Act of 1974, as amended (19 U.S.C. § 2411) (Section 301), 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. The United States and China signed the United States-China Economic and Trade Agreement (Phase One Agreement) in January 2020, which included commitments to address numerous long-standing concerns in the areas of trade secrets, patents, pharmaceutical-related IP, trademarks, copyrights, geographical indications (GIs), and technology transfer. The United States has been closely monitoring China’s progress in implementing its commitments.

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

In 2018, USTR reported that its investigation under Section 301 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. In addition, China committed to ensuring that any enforcement of laws and regulations with respect to U.S. persons is impartial, fair, transparent, and non-discriminatory. USTR continues to work with stakeholders to evaluate whether these commitments have resulted in changes in China's ongoing conduct at the national, provincial, and local levels.

Trade Secrets

Stakeholders reported that the amendment of the Criminal Law and the continuing implementation of previously issued judicial interpretations are positive developments. In particular, stakeholders noted stronger procedural protections for right holders and broader definitions of misappropriation. Further implementation of these measures is still needed. For example, the Supreme People's Court (SPC) should issue new judicial interpretations to apply changes to the thresholds for triggering criminal investigations and the scope of criminal acts in the amended Criminal Law, as well as to address other obstacles to criminal enforcement. With respect to the burden-shifting mechanism provided by the amended Anti-Unfair Competition Law, the Jiangsu High People's Court and the Beijing IP Court issued new guidelines in 2021. However, it is unclear whether this burden-shifting mechanism has been widely adopted in civil litigation.

Furthermore, draft *Guiding Opinions on Strengthening the Protection of Trade Secrets and Confidential Business Information in Administrative Licensing* were published for public comment in August 2020 by the Ministry of Justice but have not been finalized. The draft guiding opinions and other reforms are needed to limit government requests for trade secrets and confidential business information and prevent the unauthorized disclosure of such information submitted to government authorities, including unauthorized disclosure by third-party experts and advisors. Such unauthorized disclosures continue to be a serious concern for the United States and U.S. stakeholders in industries such as software and cosmetics.

U.S. stakeholders have also raised concerns about administrative trade secret enforcement, for which the State Administration of Market Regulation (SAMR) issued draft rules in 2020 that have not been finalized. In particular, stakeholders express reservations about the potential for discriminatory treatment and unauthorized disclosure of their information by local authorities under the proposed expansion of the administrative enforcement system.

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 recent Trademark Law amendments, the limited success brand owners have had in challenging bad faith registrations is insufficient when compared to the overwhelming number of bad faith trademark applications filed and registrations granted. While some right holders welcomed the reported reduction in filing fees, review times, and examination times, these changes also make it easier for bad faith trademarks to be registered and gain approval. Right holders also report some improvements in the China National Intellectual Property Administration's (CNIPA) rejection at the examination stage of bad faith trademarks filed without an intention to use the marks in commerce, such as marks filed in volume by "hoarders." 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 in 2013, bad faith trademarks are immediately registered after a failed opposition, and bad actors have longer windows in which to use their marks or extort from the legitimate brand owner before a decision is made in a cancellation proceeding.

Authorities have not yet addressed the targeting of specific brands by bad faith actors, which involves filing only a small quantity of marks to avoid the examiners' focus on trademark "hoarding" through a large number of contemporaneous filings from an applicant. This tactic allows many knockoffs and "parasite brands" to avoid immediate scrutiny by CNIPA and to obtain trademarks in China in bad faith, even when the U.S. trademark is famous or well known. Right holders report that even if one bad faith trademark is successfully challenged, there is little consistency with respect to other applications by the same or related entities. The resulting registrations damage the goodwill and interests of U.S. right holders, including by preventing them from marketing their legitimate products in China.

Right holders seek more active support from CNIPA to combat bad faith trademarks before the marks are published for opposition, to address stylization of letters or numbers, to clarify *ex officio* authority to address bad faith applications, to apply consistent examination standards, and to impose deterrent penalties. CNIPA released an Action Plan in March 2021, introducing new mechanisms to address bad faith trademarks. However, right holders report a lack of measurable

progress, largely due to authorities' focus on bad faith trademark registrations that "offend socialist morality" as opposed to those that seek to capitalize on the reputations of existing brands.

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 continue to 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. For example, a recent report identified China and Hong Kong as the largest exporters of counterfeit foodstuffs and cosmetics, accounting for approximately 60% of counterfeit foodstuffs customs seizures and 83% of counterfeit cosmetics customs seizures.³² As in prior years, China and Hong Kong account for over 83% of U.S. IP seizures.³³ The failure to curb the widespread manufacture, domestic sale, and export of counterfeit goods affects not only right holders, but also the health and safety of consumers. The production, distribution, and sale of counterfeit medicines, fertilizers, pesticides, and under-regulated pharmaceutical ingredients remain widespread in China.

Right holders point to national plans to crack down on counterfeit medicines and new criminal penalties under the amended Criminal Law as positive developments. However, right holders expressed concerns regarding reported deprioritization of prosecution of IP-related crimes and the reduction in use of criminal penalties. Furthermore, as the top manufacturer and a leading exporter of pharmaceutical ingredients, China still lacks effective regulatory oversight. In particular, China does not regulate manufacturers that do not declare an intent to manufacture active pharmaceutical ingredients (APIs) for medicinal use. It also does not subject exports to regulatory review, enabling many bulk chemical manufacturers to produce and export APIs outside of regulatory controls. Furthermore, China lacks central coordination of enforcement against counterfeit pharmaceutical products and 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

China's e-commerce markets, the largest in the world, remain the source of widespread counterfeits as infringing sales have migrated from physical to online markets. Some sellers have shifted tactics by maintaining less inventory on site in physical markets and offering a larger range of counterfeit products online. Counterfeiters exploit the use of small parcels and minimal warehouse inventories, the separation of counterfeit labels and packaging from products prior to

³² OECD/EUIPO, *Dangerous Fakes: Trade in Counterfeit Goods that Pose Health, Safety, and Environmental Risks* at 68, 70 (Mar. 9, 2022), <https://www.oecd.org/social/dangerous-fakes-117e352b-en.htm>.

³³ CBP Office of Trade, *Intellectual Property Rights Seizure Statistics: Fiscal Year 2020* at 24 (Sep. 2021), <https://www.cbp.gov/document/report/fy-2020-ipr-seizure-statistics>.

the final sale, and the high volume of packages to the United States to escape enforcement. Although some leading online sales platforms have streamlined procedures and improved monitoring, concerns remain about ineffective, inefficient, and duplicative takedown procedures, unresponsiveness to requests from small- and medium-sized enterprises, and insufficient measures to deter repeat infringers. Obstacles to criminal enforcement include the method by which online platforms record sales, difficulties in obtaining records to pursue investigations, and strict evidentiary requirements before the initiation of investigations. Counterfeit products are increasingly offered for sale through non-traditional online e-commerce conduits, including through e-commerce features related to large online platforms, as well as through live-streaming features of such platforms. Counterfeiters have also taken advantage of social media and messaging websites and mobile apps to subvert detection controls and trick consumers on traditional e-commerce platforms.

Widespread online piracy also remains a major concern, including in the form of “mini Video on Demand (VOD)” locations and online platforms with unauthorized copies of or access codes to scientific, technical, and medical journal articles and academic texts. 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, and piracy apps that facilitate access to such websites.

On August 31, 2021, SAMR issued a new draft E-Commerce Law for public comment. The draft amendments to the E-Commerce Law include changes that extend the deadline for right holders to respond to a counter-notification of non-infringement, penalties for fraudulent counter-notifications, and penalties that restrict the business activities of platforms for serious circumstances of infringement. Although noting improvements under the draft amendments, right holders raised concerns about the failure to codify the elimination of liability for erroneous notices submitted in good faith, as well as proposed changes that would allow reinstatement of listings upon posting a guarantee.

The 2020 Foreign Investment Negative List continues to maintain restrictions on foreign investment in online publishing, broadcasting, and distribution of creative content. The revised Foreign Investment Negative List allowed foreign investment in online music services, which right holders regard as a positive step. China continues to maintain requirements for state-owned enterprises (SOEs) to hold an ownership stake in online platforms for film and television content.

Right holders also report significant obstacles to releasing content in China, including limited windows to submit content for review, a non-transparent content review system, and significantly slowed processing and licensing of content for online streaming platforms. Another challenge has been burdensome requirements for legalized documentation of chain of title and ownership information. These barriers have severely limited the availability of foreign content, prevented the simultaneous release of foreign content in China and other markets, and created conditions for greater piracy. Right holders also report that a draft bill published in March 2021 could restrict participation of foreign companies in radio and television, including online. Also, China’s extension of its content review system to cover books intended for distribution in other markets has imposed heavy burdens on foreign publishers.

Additionally, it is critical that China fully implement the terms of the 2012 United States-China Memorandum of Understanding regarding films and abide by its commitment to negotiate additional meaningful compensation for U.S. content.

Developments, Including Progress and Actions Taken

Legislative and Judicial Reforms

Amendments to the Copyright Law and Patent Law went into effect on June 1, 2021. The amended Criminal Law, including changes to the trade secret provisions, went into effect on March 1, 2021. These amendments, discussed further below, introduced changes to some minimum and maximum levels of statutory damages and criminal penalties, provided for punitive damages, and introduced burden-shifting mechanisms.

On March 3, 2021, the SPC issued a new judicial interpretation on the application of punitive damages in civil cases of IP infringement. The new judicial interpretation clarified when plaintiffs may request punitive damages, how courts determine punitive damages, and the criteria for damage awards.

Right holders have noted these legislative and judicial reforms as positive developments. However, these changes have introduced new concerns. For example, according to right holders, the replacement of “income” with “gains” for purposes of establishing thresholds for criminal prosecution under the amended Criminal Law could allow counterfeiters to contend that they did not make substantial profits because of their expenses. Right holders urge a return to income-based standards for such thresholds to avoid legal ambiguities that may decrease the likelihood of criminal charges. As another example, right holders report that the transfer of administrative IP cases for criminal enforcement remains uneven even under the new and less stringent standard. Law enforcement authorities reportedly lack the budget for warehousing counterfeits and investigations, and administrative authorities may be reluctant to transfer cases where they can collect large fines.

Existing challenges also persist with respect to preliminary injunctive relief, evidence production, authentication and other evidentiary requirements, establishing actual damages, insufficient damage awards, burdensome thresholds for criminal enforcement, and lack of deterrent-level damages and penalties. For example, right holders continue to raise concerns about their ability to meet consularization and notarization requirements for documents submitted to the Beijing IP Court and in other IP-related proceedings.

Transparency remains a key concern with Chinese courts, which publish only selected decisions rather than all preliminary injunctions and final decisions. Likewise, right holders express concerns about the increased emphasis on administrative enforcement, as authorities often fail to provide right holders with information regarding the process or results of enforcement actions. Additional concerns include interventions in judicial proceedings by local government officials, party officials, and powerful local interests that undermine the authority of China’s judiciary and rule of law. A truly independent judiciary is critical to promote rule of law in China and to protect and enforce IP rights.

China has continued to develop and implement “social credit systems” for IP filers and agents. In July 2021, SAMR finalized measures stating that regulators would add to the blacklist those entities that intentionally infringed IP, misappropriated trade secrets, engaged in unfair competition, filed abnormal patent applications, or maliciously submitted trademark applications. Punishments would include more stringent licensing review and more frequent inspections. These measures lack critical procedural safeguards, such as notice to the targeted entity, clear factors for determinations, and opportunities for appeal. The United States continues to object to any attempt to expand the “social credit system” in the field of IP.

Copyright Law Amendments

Right holders welcomed positive changes in the amended Copyright Law, such as new rights of public performance and broadcasting for producers of sound recordings, protections against circumvention of technological protection measures, and the destruction of materials or tools mainly used to produce infringing copies. However, right holders also highlighted the need for effective implementation and clarification of criminal liability for the manufacture, distribution, and exportation of circumvention devices, as well as new measures to address online piracy. Right holders also report continuing uncertainty about whether recent amendments to the Copyright Law protect sports and other live broadcasts and recommend clarification in the copyright regulations.

Patent Examination

In 2021, CNIPA issued measures aimed at improving the quality of patents and fined unqualified patent agencies. However, large quantities of poor-quality patents continue to be granted. Although CNIPA in January 2021 announced the elimination of patent subsidies by 2025, at least one local city government has continued to grant subsidies for new patents, patent agents, and patented technology developed into standards. On January 25, 2022, CNIPA issued a Notice on Continuing and Strictly Regulating Patent Application Behavior, requiring provincial and local IP offices to reduce patent subsidies by 25% per year towards the total elimination by 2025.

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

Right holders welcomed amendments to the Patent Law, which included protections for partial designs, patent term extensions for patent office and marketing approval delays, and the statutory basis for a mechanism for the early resolution of potential pharmaceutical patent disputes. Although the Patent Examination Guidelines allow for the filing of supplemental data to support disclosure and patentability requirements, right holders raise concerns about consistency in the specific practices of individual patent examiners. Strong concerns remain about obstacles to patent enforcement, such as lengthy delays in courts, lack of preliminary injunctions, competition law concepts in the Patent Law, and undue emphasis on administrative enforcement.

In 2021, China implemented a mechanism for the early resolution of potential patent disputes. Right holders have expressed concerns about the scope of patents and pharmaceuticals covered by the proposed mechanism, the length of the stay period, the availability of injunctive relief, the lack of clarity about what could trigger a dispute under the mechanism, and uncertainties with respect to parallel civil judicial and administrative proceedings. The lack of transparency and technical expertise in administrative proceedings is also a concern, as well as the possibility of bias in favor of Chinese companies. Right holders have also expressed concern about the implementation of patent term extensions for unreasonable marketing approval delays, including the definition of “new” drugs covered by the system, scope of eligible patents, and type of protection provided. 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.

Stakeholders continue to express concern regarding the 2019 Human Genetic Resources Administrative Regulation and the 2020 Biosecurity Law. In particular, these measures mandate collaboration with a Chinese partner, which would include shared ownership of patent rights arising out of any research generated by using human genetic resource materials in China. These measures also impose non-transparent requirements for government approval before any transfer of data outside of China. Lack of transparency in government pricing and reimbursement processes for pharmaceutical products also needs to be addressed by China.

In addition, China should address outstanding patent-related concerns, including regarding the onerous evidentiary requirements for proving patent infringement, ambiguity regarding whether a patentee’s right to exclude extends to manufacturing for export, and lack of harmonization between China’s patent grace period and statute of limitations and international practices. With respect to standards, China should require the use of international standards, establish that standards-setting processes are open to domestic and foreign participants on a non-discriminatory basis, eliminate unreasonable public disclosure obligations in standards-setting processes, and provide sufficient protections for standards-related copyrights and patent rights.

The issuance of anti-suit injunctions by Chinese courts in standards essential patents (SEP) disputes continues to raise due process and transparency concerns for right holders. Right holders are also concerned about how such rulings may favor domestic companies over foreign patent holders, which places pressure on royalty rate negotiations. Right holders have raised concerns that Chinese courts appear to use the issuance of anti-suit injunctions in support of their attempts to assert jurisdiction over global SEP disputes. High-level political and judicial authorities have called for extending the jurisdiction of China’s courts over global IP litigation and have cited the

issuance of an anti-suit injunction as an example of the court “serving” the “overall work” of the Chinese Communist Party and the Chinese State.³⁴

In October 2021, the National People’s Congress published draft revisions to the Anti-Monopoly Law (AML). SAMR expanded and elevated its anti-monopoly bureau in November 2021.

In 2021, a local intermediate court issued the first instance of a decision declaring certain IP developed by foreign company to be an “essential facility” and finding the company’s failure to license its IP to a Chinese plaintiff – notwithstanding existing licenses to other Chinese parties – to be an abuse of dominance. This decision raises concerns that China’s competition authorities may apply this approach to foreign patent holders for AML enforcement. The case is currently awaiting decision on appeal to the Supreme People’s Court. 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

In December 2021, the Cyberspace Administration of China (CAC) finalized Cybersecurity Review Measures that broadened the scope of the review to data-handling activities that may influence national security. China continues to build on its policies for “secure and controllable” information and communications technology products under the Cybersecurity Law and the Cryptography Law. Right holders raise concerns about the invocation of cybersecurity as a pretext to require disclosure of trade secrets and other types of IP, including in source code, and restrict market access. Furthermore, encryption laws, which impose mandatory approval requirements with unclear exemptions, create an uncertain business environment for foreign companies.

U.S. right holders should not be forced to choose between protecting their IP against unwarranted disclosure and competing for sales in China. 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

The agreement between China and the European Union on GIs entered into force in 2021. CNIPA issued a new guiding opinion on GIs in May 2021, but two other draft CNIPA measures on GIs have not been finalized. Right holders have also raised concerns about certain trademark examination cases that involve the use of common names (generic terms). It is critical that China ensure full transparency and procedural fairness with respect to the protection of GIs, including safeguards for common names, 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 common names.

³⁴ See, e.g., Supreme People’s Court Intellectual Property Tribunal, *Provide a Judicial Guarantee for Innovation-driven Development* (Feb. 2021), http://www.xinhuanet.com/politics/2021-02/05/c_1127068693.htm.

Amendments to the Seed Law became effective on March 1, 2022. The amended Seed Law introduced protections for essentially derived varieties of plants and increased maximum statutory damages. On July 7, 2021, a judicial interpretation of the SPC went into effect, which provided guidance on infringement cases involving plant variety rights. Right holders continue to raise concerns about gaps in plant protection with respect to genera and species outside a limited number of categories.

The United States continues to urge all levels of the Chinese government, as well as SOEs, to use only legitimate, licensed copies of software. The United States also urges the use of third-party audits to ensure accountability, as China committed to provide under the Phase One Agreement.

INDIA

India remains on the Priority Watch List in 2022.

Ongoing Challenges and Concerns

Over the past year, India has remained inconsistent in its progress on intellectual property (IP) protection and enforcement. Although India's enforcement of IP in the online sphere has gradually improved, increased IP examination staffing has reduced some patent and trademark examination times, and engagement with the United States on IP issues has accelerated, there continues to be a lack of progress on long-standing IP concerns raised in prior Special 301 Reports. 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. The potential threat of patent revocations, lack of presumption of patent validity, and the narrow patentability criteria under the Indian Patents Act impact 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 grants, and excessive reporting requirements. Stakeholders continue to express concerns over vagueness in the interpretation of the Indian Patents Act.

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 products, solar energy equipment, and capital goods. In the pharmaceutical sector, the United States continues to monitor the restriction on patent-eligible subject matter in Section 3(d) of the Indian Patents Act and its impacts. Pharmaceutical stakeholders also express concerns as to whether India has an effective mechanism for the early resolution of potential pharmaceutical patent disputes, particularly shortcomings in notifying interested parties of marketing approvals for follow-on pharmaceuticals, and view the further restricting in 2019 of transparency of information about manufacturing licenses issued by states as a step backward. Stakeholders also continue to raise concerns as to whether India has 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.

India's overall IP enforcement, despite some 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 Organisation for Economic Co-operation and Development'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 2021 *Notorious Markets List*. While some of India's state authorities continue to

operate dedicated crime enforcement units, 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, it remains unclear whether trademark owners can apply directly for recognition of “well-known” trademark status without having to rely on previous Indian court or trademark office decisions. The United States continues to urge India to join the Singapore Treaty on the Law of Trademarks.

Companies also continue to face uncertainty due to insufficient legal means to protect trade secrets in India. India’s 2016 National Intellectual Property Rights Policy, which is past-due for its 5-year review, identified trade secrets as an “important area of study for future policy development.” However, as of 2022, 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 expressly available for trade secret misappropriation in India, and civil remedies reportedly are difficult to obtain and do not have a deterrent-level 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 August 2021, the Department for Promotion of Industry and Internal Trade (DPIIT) issued a notice requesting comments on the recommendation of a Parliamentary committee to extend statutory licensing under Section 31D of the Indian Copyright Act to “internet or digital broadcasters.” Amending Section 31D to permit statutory licensing of interactive transmissions 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 lack of predictability around this issue, 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 in India. Furthermore, stakeholders have 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 Special 301 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. India’s April 2021 decision to abolish the Intellectual Property Appellate Board (IPAB) and redirect matters previously handled by the IPAB to courts has created uncertainty around adjudication of IP cases and copyright royalty rate setting.

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) Performances and Phonograms Treaty and WIPO Copyright Treaty, collectively known as the WIPO Internet Treaties, in 2018 and the Nice Agreement in 2019 were positive steps, as was India's commitment at the United States-India Trade Policy Forum (TPF) in November 2021 to comply with the WIPO Internet Treaties. However, amendments to the Indian 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 any actions taken following DPIIT's October 2020 solicitation of public comments on amending the Indian Copyright Act. The 2019 Cinematograph (Amendment) Bill containing promising provisions to criminalize unauthorized camcording of films continues to await Parliament's approval. However, in June 2021, the Ministry of Information and Broadcasting sought public comments on a proposed Cinematograph (Amendment) Bill, 2021, which incorporates revisions to the 2019 Bill. The United States is monitoring this proposed bill.

In December 2021, a Joint Parliamentary Committee released a report recommending changes to the Personal Data Protection Bill, 2019 (PDPB) that could undermine important IP protections in India. Among these recommendations was enlargement of the Bill's scope to include further regulation of non-personal data instead of addressing that issue under separate legislation. The United States on several occasions and in various fora has raised IP concerns regarding the potential implementation of India's data governance regime. These concerns are particularly acute given India's outdated and insufficient legal framework for protecting trade secrets. On this and other potential legislation affecting IP, the United States encourages India to undertake a transparent process that provides stakeholders with sufficient opportunity to comment.

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, although stakeholders report that this practice is not always followed and uncertainty persists over the scope of reporting requirements and consequences of non-compliance. 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 the wake of India's abolition of the IPAB, the Delhi High Court created an IP Division in July 2021 and released finalized draft rules for that Division in December 2021 for comment. The Cell for Intellectual Property Rights Promotion and Management (CIPAM) continues to promote IP awareness, commercialization, and enforcement

throughout India. In December 2020, the United States Patent and Trademark Office (USPTO) and DPIIT signed a new Memorandum of Understanding (MOU) relating to IP technical cooperation mechanisms, and DPIIT and USPTO are in the process of entering into a biennial work plan to guide implementation of the MOU.

The United States intends to continue to engage with India on IP matters, including through the TPF's Intellectual Property Working Group, building upon several meetings of the Group that took place in 2021.

INDONESIA

Indonesia remains on the Priority Watch List in 2022.

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. In 2021, Indonesia established a new IP Enforcement Task Force, which aims to improve intra-government coordination on enforcement. However, the Task Force's activities have been limited so far, and concerns regarding IP enforcement remain, including with respect to the lack of deterrent-level penalties for IP infringement in physical markets and online and ineffective border enforcement. Indonesia's 2016 Patent Law continues to raise concerns, including with respect to patentability criteria 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 have also raised concerns over Indonesia's Copyright Law, including with respect to the circumvention of technological protection measures. Stakeholders have also expressed concern about 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 unauthorized 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 certain 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. However, due to a ruling by the Indonesia Constitutional Court, the status of the amendments is uncertain. The United States continues to urge Indonesia to undertake a more comprehensive amendment to the 2016 Patent Law to address remaining concerns. As Indonesia amends the 2016 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 urges Indonesia to use the new IP Enforcement Task Force to improve enforcement cooperation among relevant law enforcement agencies and ministries. 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 engagement with Indonesia under the United States-Indonesia Trade and Investment Framework Agreement to address these issues.

RUSSIA

Russia remains on the Priority Watch List in 2022.

Ongoing Challenges and Concerns

In response to Russia's premeditated and unprovoked further invasion of Ukraine in 2022, the United States, in conjunction with its allies and partners, has taken or plans to take additional steps to isolate Russia from the global economy and hold President Putin accountable for his war against Ukraine. Consequently, the ability of the Office of the U.S. Trade Representative to raise and resolve intellectual property (IP) protection and enforcement issues in Russia is severely limited.

Challenges to 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. The United States is also closely monitoring recent proposals by Russia to counter international sanctions by allowing uncompensated use of IP held by right holders based in countries that have sanctioned Russia.

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 2021 *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 against rogue online platforms targeting audiences outside the country. In 2018, right holders and online platforms in Russia signed an anti-piracy memorandum, which was extended until February 2022, to facilitate the removal of links to websites that offer infringing content. Stakeholders had expected that in 2022 this memorandum would be implemented as legislation covering all copyrighted works and applying to all Russian platforms and search engines. Stakeholders also reported that in December 2021, right holders and online platforms agreed to update the original memorandum to include new measures on search engines. However, although right holders are able to obtain court-ordered injunctions against websites and smartphone applications that offer infringing content, Russia must

take additional steps 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 2021, Russia remained among the most challenging countries in the world in terms of video game piracy. While an August 2021 government decree on rules for showing films in theaters allows exhibitors to remove viewers attempting to record films illicitly, the decree does not remedy the existing lack of legal liability under Russian law for unauthorized camcording.

Royalty collection and distribution by CMOs in Russia continue to lack transparency and do 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.

Stakeholders also report that, in practice, Russia’s trade secret regime places an undue burden on right holders in terms of requiring specific prerequisites for protection that do not reflect the commercial realities of most businesses. Examples include keeping an inventory of trade secret-protected information and marking trade secrets with the names and addresses of owners. In terms of trade secret enforcement, stakeholders report that, despite their availability, deterrent-level penalties and preliminary measures are rarely imposed by courts for trade secret misappropriation.

The United States is also concerned about Russia’s implementation of its World Trade Organization commitments related to the protection against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. Stakeholders report that Russia is eroding protections for undisclosed data, and the United States urges Russia to adopt a system that meets international norms of transparency and fairness. Stakeholders also report that Russia lacks an effective mechanism for the early resolution of potential pharmaceutical patent disputes, and continue to express concerns regarding certain 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.

VENEZUELA

Venezuela remains on the Priority Watch List in 2022.

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. 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 *2021 International Property Rights Index* also ranked Venezuela 128th out of 129 countries in a metric that includes standards for IP protection.

Developments, Including Progress and Actions Taken

Venezuela's Autonomous Intellectual Property Service (SAPI) announced grants of several new patents in May 2021. In 2021, SAPI also waived various filing fees for small and medium enterprises to encourage use of the IP system.

WATCH LIST

ALGERIA

Algeria remains on the Watch List in 2022. Algeria continues to take steps to improve intellectual property (IP) protection and enforcement, including by seizing counterfeit goods, improving border enforcement, improving intra-government coordination on enforcement, and engaging in capacity-building and training efforts for law enforcement, customs officials, judges, and IP protection agencies. Algeria is also contemplating legislative amendments to address outstanding concerns, including by creating dedicated IP courts and addressing counterfeiting. As Algeria plans to amend its IP-related laws, the United States encourages Algeria to provide interested stakeholders with meaningful opportunities for input. Furthermore, Algeria has continued to make improvements on market access issues, including by replacing temporary import barriers with a set of tariffs and by developing regulations to allow companies to register their representative offices to do business in Algeria. However, concerns remain. Algeria needs to increase enforcement efforts against trademark counterfeiting and copyright piracy, including online and Internet Protocol Television (IPTV) piracy. Algeria also needs to provide adequate judicial remedies in cases of patent infringement and provide administrative opposition, as well as fewer formalities, in its trademark system. Algeria still lacks an effective mechanism for the early resolution of potential pharmaceutical patent disputes. Stakeholders have also expressed 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. The United States will continue to engage with Algeria to improve Algeria's IP protection and enforcement environment.

BARBADOS

Barbados remains on the Watch List in 2022. Barbados acceded to the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty and WIPO Copyright Treaty, collectively known as the WIPO Internet Treaties, in 2019. A government-led, public-private advisory committee has confirmed that proposed amendments to the Copyright Act to implement its treaty obligations are undergoing secondary review by the intellectual property office and will be resubmitted to a parliamentary counsel office 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 2022. Challenges continue with respect to adequate and effective intellectual property (IP) protection and enforcement in Bolivia. The IP laws in Bolivia are outdated, and constitutional restrictions limit effective IP protection. Bolivia has not acceded to the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty and WIPO Copyright Treaty, collectively known as the 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. Bolivia continues to express its intention to protect IP. 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 2022. The United States has long-standing concerns about Brazil's intellectual property (IP) enforcement regime, although the country took significant steps in 2021. Brazil continued to address IP infringement, particularly counterfeit goods often destined for online sale, with coordinated efforts between Brazilian law enforcement and U.S. counterparts. Law enforcement engaged in landmark campaigns, including a seizure of counterfeit perfume and cologne products valued at over \$100 million. Nevertheless, levels of counterfeiting and piracy in Brazil, including through online piracy, use of illicit streaming devices (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-level 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. Brazil continued to implement the country's first National Strategy on Intellectual Property, streamlined trademark processes as required under the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol), and reduced the backlog of pending patent applications by 76.8%. The United States also recognizes the continued implementation of the technology-neutral Patent Prosecution Highway Program. The United States remains concerned, however, about the pendency of patent applications and the impact on the effective patent term. In August 2021, Brazil took the positive step of eliminating the requirement for the National Sanitary Regulatory Agency (ANVISA) to review certain patent 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 (EU)-Mercosur Trade Agreement. The United States is also concerned about the additional market access impact of Brazil's revocation of the previous determination of entities that qualified as prior users for certain GIs under the EU-Mercosur Trade Agreement and the institution of a new qualification process with much more stringent criteria. The United States encourages Brazil to join the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty and WIPO Copyright Treaty, collectively known as the 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 2022. Canada made significant progress in intellectual property (IP) protection and enforcement with the implementation of important IP provisions in the United States-Mexico-Canada Agreement (USMCA), particularly 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, but piracy through these means persists. In 2019, Canada made positive reforms to the Copyright Board related to tariff-setting procedures for the use of copyrighted works. Despite this progress, various challenges to adequate and effective protection of IP rights in Canada remain. Significant concerns regarding 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. 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 2022. In 2021, Colombia made limited progress on the outstanding provisions related to its obligations under Chapter 16 of the United States-Colombia Trade Promotion Agreement (CTPA), including on draft legal provisions on notice-and-takedown and safe harbor provisions for Internet service providers. In addition, Colombia's accession to the 1991 Act of the International Union for the Protection of New Varieties of Plants Convention (UPOV 1991) remains outstanding. With respect to concerns raised about Article 72 of the National Development Plan, 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 success in combating counterfeiting and other intellectual property (IP) violations remains limited. High levels of digital piracy persist, 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. While seizures of illegal merchandise increased in 2021, 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. The United States looks forward to continuing to work with Colombia to address outstanding issues, particularly with respect to full implementation of the CTPA, in 2022.

DOMINICAN REPUBLIC

The Dominican Republic remains on the Watch List in 2022. Although the Dominican government appears to demonstrate political will to improve intellectual property (IP) protection and enforcement, including by taking steps to create the National Advisory Board for Intellectual Property to improve coordination on IP enforcement, concerns remain. In particular, the United States remains concerned with online and signal piracy, including a lack of IP prosecutions by the Special Prosecutor's Office for High-Tech Crimes and the National Copyright Office. While border enforcement and enforcement against counterfeit goods by the Special Office of the Attorney General for Matters of Health appear to be improving incrementally, the sale of counterfeit goods is still prevalent. 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 will monitor the effectiveness of the National Advisory Board for Intellectual Property in addressing these and other concerns.

ECUADOR

Ecuador remains on the Watch List in 2022. Ecuador continues to lack effective laws and regulations covering intellectual property (IP) protection and enforcement. Ecuador's Organic Code on Social Economy of Knowledge, Creativity, and Innovation (Ingenuity Code) governs the protection, exercise, and enforcement of IP rights. The Ingenuity Code's implementing regulations, issued in December 2020, do not address concerns raised by the U.S. Government and various stakeholders on issues related to overly broad or vaguely defined 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. While Ecuador still plans additional revisions to the Ingenuity Code, little tangible progress has been made. The United States remains open to any engagement on this process. Enforcement of 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 copyrighted works. The United States will continue working with Ecuador to address these and other issues.

EGYPT

Egypt remains on the Watch List in 2022. Although Egypt has made some efforts to strengthen intellectual property (IP) protection and enforcement, including on enforcement against piracy and counterfeiting and on reducing patent backlogs, concerns remain. On enforcement, 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. Stakeholders raise concerns regarding the lack of an effective mechanism for the early resolution of potential patent disputes. Egypt should also complete its plans to update and publish its patent and trademark examination guides online. Although Egypt has made some progress to address illegal streaming services that offer pirated broadcasts of U.S. works, the United States encourages Egypt to continue to strengthen efforts to address the number of unlicensed satellite channels offering pirated broadcasts of U.S. works and unlawful decryption of encrypted signals. Additionally, the United States encourages Egypt to join and fully implement the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty and WIPO Copyright Treaty, collectively known as the WIPO Internet Treaties. The United States looks forward to continuing to work with Egypt to address these and other issues.

GUATEMALA

Guatemala remains on the Watch List in 2022. Despite a generally strong legal framework in place, resource constraints, inconsistent enforcement actions against counterfeiting of apparel and other products, as well as a lack of 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, continues to be a significant concern. While cable television providers and content distributors agreed to discontinue contracts due to signal piracy of U.S. broadcast networks throughout the region, signal piracy continues to be an issue, and online piracy through Internet Protocol Television (IPTV) services is also a concern. Furthermore, the sale of counterfeit pharmaceuticals and government use of unlicensed software remain unaddressed. The United States urges Guatemala to take clear and effective actions in 2022 to improve the protection and enforcement of IP in Guatemala.

MEXICO

Mexico remains on the Watch List in 2022. As part of its intellectual property (IP) commitments under the United States-Mexico-Canada Agreement (USMCA), Mexico undertook significant legislative reforms, 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 and the absence of prioritization on IP enforcement continues 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, improve coordination among federal and sub-federal officials, bring more IP-related prosecutions, and impose deterrent-level 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, the National Customs Agency (ANAM) initiated 493 cases, down from 642 cases in 2020, with seizures totaling 4.23 million articles in 2021, down from 8.82 million in 2020. Mexico's initiative to redistribute approximately three million seized goods through welfare markets under the Tianguis del Bienestar program has raised concerns regarding transparency and possible counterfeiting. 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. Stakeholders express concern that in administrative procedures on infringement, preliminary measures still can be lifted if the alleged infringer posts a counter-bond. 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 European Union 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 2022. Pakistan has maintained a positive dialogue with the United States on intellectual property (IP) matters and engaged in meaningful 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 various government bodies involved in IP. Nonetheless, serious concerns remain, particularly in the area of IP enforcement. Counterfeiting and piracy 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 three cities in 2016 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, a general lack of expertise among tribunal judges, and confusion over standards by which courts review tribunal decisions. In addition, judicial bodies in Pakistan have limited jurisdiction to adjudicate criminal complaints for IP violations. Effective trademark enforcement also 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 and met once in 2021. The United States urges Pakistan to appoint a new IP Policy Board given that the term of the previous Board expired in 2021, and to conduct regular meetings of the Board. 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 the IPO's efforts. Although 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 in 2019 on draft amendments to the Patent, Trademark, and Copyright Ordinances, the amendments remain under government review and the timeline for their enactment is unclear. 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) Performances and Phonograms Treaty and WIPO Copyright Treaty, collectively known as the WIPO Internet Treaties, and the Patent Cooperation Treaty, and encourages Pakistan to fully implement the Plant Breeders Rights Act.

PARAGUAY

Paraguay remains on the Watch List in 2022. The United States and Paraguay signed a Memorandum of Understanding (MOU) on Intellectual Property (IP) Rights in June 2015. Under the MOU, Paraguay committed to take specific steps to improve its IP protection and enforcement environment. 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 Ciudad del Este serves as 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 2022. 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 2021. Key enforcement initiatives include significant seizures of counterfeit medicines and beauty products. Peru has also taken many administrative enforcement actions. Peru's National Institute for the Defense of Competition and the Protection of Intellectual Property (INDECOPI) has increasingly taken action to fine individuals and legal entities that violated Peru's copyright laws. In addition, INDECOPI significantly increased processing of trademark infringement complaints in 2021. The United States recognizes Peru's efforts to increase the number of prosecutions against piracy and counterfeiting, particularly its efforts with respect to the sale of counterfeit medicines. The United States urges Peru to continue these efforts 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 also continues to encourage 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 2022.

THAILAND

Thailand remains on the Watch List in 2022. Thailand continues to make progress on improving intellectual property (IP) protection and enforcement. A subcommittee on enforcement against IP infringement, led by a Deputy Prime Minister, continues to convene. Thailand continues to seize counterfeit and pirated goods and to publish enforcement statistics online. Thailand also increased efforts to combat the sale of counterfeit goods online. Thailand has also increased efforts against online piracy, particularly through enhanced intra-agency coordination, though concerns remain. In February 2022, Thailand published amendments to its Copyright Act, which, among other things, would allow Thailand to accede to the World Intellectual Property Organization (WIPO) Copyright Treaty. The United States continues to urge Thailand to complete the amendment process to accede to the WIPO Performances and Phonograms Treaty. 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. Thailand has also increased the number of examiners to reduce the patent backlog. Furthermore, to address the use of unlicensed software in the public sector, Thailand adopted guidelines on the government acquisition of legitimate software. While Thailand continues to make progress in these areas, concerns remain. Counterfeit and pirated goods continue to be readily available, particularly 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 procedural obstacles to enforcement against unauthorized camcording, unauthorized collective management organizations, and amendments that will go into effect in August 2022 establishing a process that may lead to overly broad exceptions to the circumvention of technological protection measures. 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 the private sector, 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 United States-Thailand Trade and Investment Framework Agreement and other bilateral engagement.

TRINIDAD AND TOBAGO

Trinidad and Tobago remains on the Watch List for 2022. In 2021, the Telecommunications Authority of Trinidad and Tobago (TATT) conducted an audit of compliance with 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. Although there is reportedly a high level of compliance among broadcasters, TATT has not taken any enforcement action against the non-compliant broadcasters. 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, nonpayment of copyright royalties, and online piracy, as well as 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 2022. 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, 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. Furthermore, 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) Performances and Phonograms Treaty and WIPO Copyright Treaty, collectively known as the 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 and pirated goods across a variety of industry sectors. This has continued throughout 2021 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 staffing, as well as laws that contain lax penalties and inadequate procedures. Stakeholders also report that a lack of IP training for the judiciary, the paucity of interagency coordination, and burdensome evidence requirements for search warrants 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 seek to engage with Turkey to address these and other issues.

TURKMENISTAN

Turkmenistan remains on the Watch List in 2022. While the recent adoption of a Programme of Development of the Intellectual Property System of Turkmenistan for 2021-2025, issuance of a Presidential resolution on the establishment of an interdepartmental commission for the protection of intellectual property (IP), and participation at meetings of the Intellectual Property Working Group under the United States-Central Asia Trade and Investment Framework Agreement (TIFA) are positive steps, Turkmenistan's lack of tangible progress in recent years in raising its IP protections to international standards remains concerning. Several long-standing IP concerns raised in previous Special 301 Reports remain unaddressed. Turkmenistan has yet to issue a presidential-level decree, law, or regulation mandating the use of licensed software by government ministries and agencies. Additionally, Turkmenistan has yet to modernize its copyright protection for foreign sound recordings, including through accession to and implementation of the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty and WIPO Copyright Treaty, collectively known as the WIPO Internet Treaties. 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. The United States also continues to have concerns with Turkmenistan's reported failure to enforce its IP laws. Counterfeit and pirated goods reportedly remain widely available in major cities in Turkmenistan. Publishing the activities of the State Service of Intellectual Property and providing data pertaining to the seizures facilitated by the State Customs Service would provide transparency that may help inform and enhance IP enforcement in Turkmenistan. The United States stands ready to assist Turkmenistan in improving its IP regime through engagement facilitated by the Intellectual Property Working Group under the United States-Central Asia TIFA.

UZBEKISTAN

Uzbekistan remains on the Watch List in 2022. In recent years, Uzbekistan has taken important steps to address certain long-standing issues pertaining to intellectual property (IP) protection and enforcement. In particular, accession to the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty and WIPO Copyright Treaty, collectively known as the WIPO Internet Treaties, in 2019 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), the issuance of a January 2021 Presidential resolution on enhancing the IP system, and the establishment of regional IP Protection Centers. However, these steps have fallen short in terms of delivering concrete benefits for innovators and creators, and several concerns raised in the 2021 Special 301 Report remain unaddressed. 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 long-standing concerns, including by providing *ex officio* authority for border enforcement, allocating more 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 2022. Although Vietnam took steps to improve intellectual property (IP) protection and enforcement, including by continuing to amend its IP Law to comply with trade agreement commitments and by acceding to the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty and WIPO Copyright Treaty, collectively known as the WIPO Internet Treaties, IP enforcement continues to be a serious challenge. While Vietnamese authorities initiated a criminal investigation against the operators of Phimmoi.net, online piracy, including the use of piracy devices and applications to access unauthorized audiovisual content, remains a significant concern. Lack of coordination among ministries and agencies responsible for enforcement also remains concerning, and capacity constraints related to enforcement persist, along with a lack of political will to prioritize IP enforcement. Although Vietnam issued a decree to address the online sale of counterfeit goods, the online sale of pirated and counterfeit goods remains a serious problem. Also, counterfeit goods remain widely available in physical markets. 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. 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 pursuant to Vietnam's commitments under trade agreements with third parties. The European Union-Vietnam Free Trade Agreement (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. 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), the Office of the United States Trade Representative (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 through its Global Intellectual Property Academy (GIPA) 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-designed GIPA 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 Visitor 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) 2021, USPTO 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 were very limited during this time, training efforts continued as USPTO continued to provide live online training by leveraging various technologies. This included piloting the technological capability to run virtual international programs with simultaneous interpretation. During FY 2021, USPTO provided 250 programs, serving over 17,800 individuals, including over 10,000 government officials representing 131 countries and intergovernmental organizations. More information is available at www.uspto.gov/GIPA.
- In addition, the USPTO's OPIA provides capacity building in countries around the world and has formed partnerships with 31 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), the African Regional Intellectual Property Organization (ARIPO), the Organisation Africaine de la Propriété Intellectuelle (OAPI) 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 80 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 Intellectual Property 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 2021, U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI) led a regional IP enforcement training program in the Dominican Republic, which included representatives from the Dominican Republic, Haiti, Jamaica, St. Kitts and Nevis, Guadeloupe, Aruba, Bahamas, Curacao, Trinidad and Tobago, Barbados, Turks and Caicos, Sint Maarten, the Cayman Islands, and the U.S. Virgin Islands. This program was supported by U.S. Customs and Border Protection (CBP), USPTO, the Department of Justice (DOJ) International Computer Hacking and Intellectual Property Advisors (ICHIPs), and other U.S. agencies. HSI also sponsored a virtual IP and Global Trade Enforcement program for Canada. Additionally, the National Intellectual Property Rights Coordination Center (IPR Center), with support from the Department of State, participated in 11 IP-related programs sponsored by the USPTO and the ICHIPs for audiences from Botswana, Brunei, Cambodia, Cook Islands, the Dominican Republic, Fiji, the Gambia, Ghana, Hong Kong, Honiara, Indonesia, Kenya, Liberia, Malawi, Malaysia, Micronesia, Moldova, Myanmar, Namibia, Nigeria, Northern Mariana Islands, Panama, the Philippines, Rwanda, Sierra Leone, Singapore, South Africa, Tanzania, Thailand, Timor-Leste, Uganda, Vanuatu, Vietnam, and Zambia. Due to the ongoing COVID-19 pandemic, these programs were held on virtual platforms.

- 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 2021, despite pandemic related slow-downs, CBP participated in one meeting with a global toy company, and two international delegations. 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 2021, 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 Aruba, Bahamas, Barbados, Cayman Islands, Curacao, the Dominican Republic, Guadeloupe, Haiti, Jamaica, Sint Maarten, St. Kitts and Nevis, Trinidad and Tobago, Turks and Caicos, and the U.S. Virgin Islands.
- 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 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. In particular, 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 2021 (see Technical Cooperation Activities: Information from Members—United States of America, IP/C/R/TC/USA/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 April 2022.